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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, 2019
or
o **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: (**441) 295-5950**

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 o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o 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 o

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 o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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	o
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o 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, 2018 was approximately $755.2 million based on the last reported sale price of the registrant's common shares as reported on the New York Stock Exchange on September 28, 2018 of $26.55 per common share. Common shares held by Roivant Sciences Ltd., our majority stockholder, and each officer and director have been excluded in that such persons may be 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 21, 2019, was 72,198,383.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2019 Annual General Meeting of Shareholders, or the 2019 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, 2019

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PART I.

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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 on Form 10-K include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- the success and anticipated timing of our clinical trials for relugolix 40 mg in combination with low-dose estradiol and a progestin, relugolix 120 mg as a monotherapy and MVT-602;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical studies and clinical trials;
- the anticipated designs of our future clinical trials;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for relugolix 40 mg in combination with low-dose estradiol and a progestin, relugolix 120 mg as a monotherapy, MVT-602 and any future product candidates;
- our plans to commercialize relugolix, if approved;
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain coverage and adequate reimbursement 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;
- our ability to quickly and efficiently identify and develop product candidates;
- our ability to hire and retain our key scientific or management personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our 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 and cash equivalents currently on hand;
- our ability to raise additional capital;
- 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 on Form 10-K, and in our other filings with the United States, or U.S., Securities and Exchange Commission, or 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 on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially

available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners. Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its wholly-owned subsidiaries.

Item 1. Business

Overview

We are a clinical-stage healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer. Our lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist that is currently being evaluated in multiple Phase 3 clinical trials across three distinct indications. We are advancing relugolix 40 mg in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, and relugolix 120 mg as a monotherapy for advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as part of assisted reproduction. Both relugolix and MVT-602 were licensed to us by Takeda Pharmaceuticals International AG, or Takeda, in April 2016.

Since our inception, we have devoted substantially all of our efforts to identifying and in-licensing our product candidates, organizing and staffing our company, raising capital, preparing for and advancing the clinical development of our product candidates and preparing for potential future regulatory approvals and commercialization of relugolix.

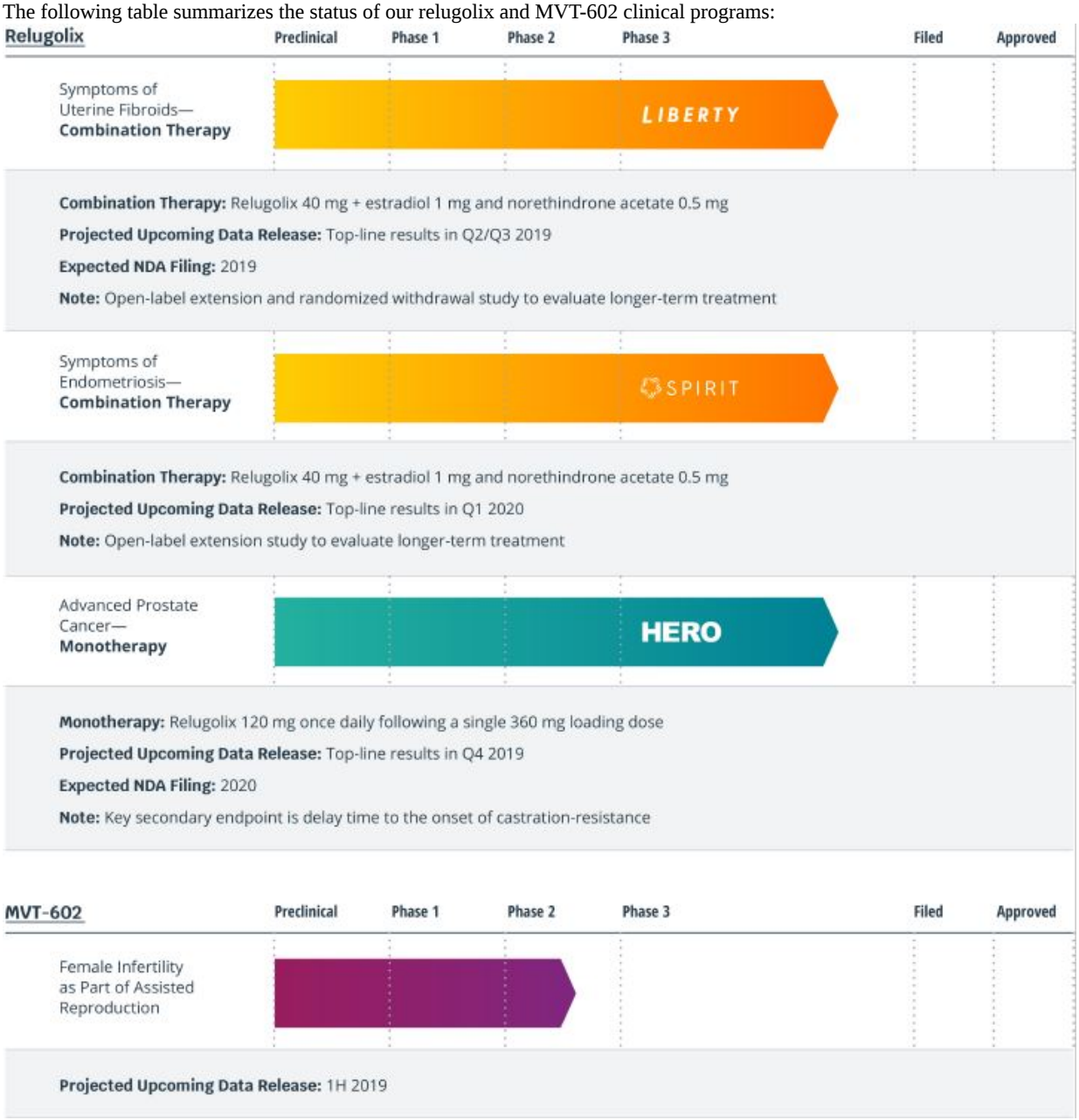
On May 14, 2019, we announced that LIBERTY 1, the first of two Phase 3 studies of once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and six key secondary endpoints. Relugolix combination therapy maintained bone mineral density at levels comparable to placebo over 24 weeks and was generally well tolerated.

In the primary endpoint analysis, 73.4% of women receiving once daily oral relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50 percent or greater reduction from baseline in menstrual blood loss volume during the last 35 days of the 24-week treatment period measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline, a clinically relevant secondary endpoint.

These data represent a top-line analysis of the results of the LIBERTY 1 study. Further review of the underlying data by Myovant is ongoing and may result in additional observations with respect to the study. We expect to submit data from LIBERTY 1 for presentation and publication in 2019.

We further expect to announce top-line results from four additional Phase 3 clinical trials over the next three quarters.

The following table summarizes the status of our relugolix and MVT-602 clinical programs:



Our Strategy

Our goal is to be the leading healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer. The key elements of our strategy to achieve this goal include the following:

- rapidly advance clinical development and prepare for regulatory filing and potential commercialization of relugolix 40 mg in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis;
- rapidly advance clinical development and prepare for regulatory filing and potential commercialization of relugolix 120 mg as a monotherapy for advanced prostate cancer;
- advance clinical development of MVT-602 for the treatment of female infertility as part of assisted reproduction;
- expand clinical development of relugolix for additional indications;

- acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of women's health or prostate cancer in a capital-efficient manner; and
- maximize the commercial potential of our product candidates.

Relugolix

We are currently developing relugolix in three target indications: heavy menstrual bleeding associated with uterine fibroids; pain associated with endometriosis; and advanced prostate cancer. Relugolix is an oral, once-daily, small molecule that acts as a 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 and follicle-stimulating hormone), 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 three target indications. Lowering estrogen and progesterone levels has previously been demonstrated to effectively decrease heavy menstrual bleeding in women with uterine fibroids and to reduce the pelvic pain associated with endometriosis. We are developing relugolix, 40 mg in combination with estradiol (1.0 mg) and a progestin (norethindrone acetate, 0.5 mg) administered orally once a day, with the goal of optimizing estradiol levels to maximize the benefit of relugolix on symptoms of uterine fibroids and endometriosis, while maintaining bone health and mitigating side effects from a low-estrogen state such as vasomotor symptoms. We expect to launch in our women's health indications with a single-tablet regimen of relugolix, 40 mg in combination with estradiol (1.0 mg) and a progestin (norethindrone acetate, 0.5 mg) administered orally once day. We believe our combination approach with relugolix has the potential to have a better safety and tolerability profile than the currently approved GnRH agonist therapies and has the potential to be used longer-term. The goal of this longer-term treatment is to provide women with uterine fibroids and endometriosis a medical alternative to hysterectomy and other invasive procedures often recommended to treat these conditions. If we are unsuccessful in our attempts to formulate a fixed-dose combination in time for the initial application for marketing authorization in the United States, or U.S., we expect to seek approval for relugolix tablets co-packaged with a commercially available tablet containing both the low-dose estradiol and norethindrone acetate.

Decreasing testosterone slows the growth and progression of advanced prostate cancer, such as when the disease recurs or the prostate-specific antigen, or PSA, is rising following prostatectomy or radiation therapy. Relugolix monotherapy is in Phase 3 clinical evaluation as a once daily oral treatment to lower testosterone. It is being evaluated at a three-times higher dose in men with advanced prostate cancer than the women's health indications (120 mg orally once daily following a single 360 mg loading dose compared to 40 mg). We are developing our women's health relugolix combination and our advanced prostate cancer relugolix monotherapy treatments with the potential of bringing to market two distinct branded products.

Myovant Sciences GmbH, our wholly-owned subsidiary, holds global commercial rights to relugolix, excluding Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam, including the territories and possessions of each of the foregoing. In May 2018, Takeda announced that it had entered into a license agreement granting ASKA Pharmaceutical Co., Ltd. exclusive commercialization rights to relugolix for uterine fibroids and exclusive development and commercialization rights to relugolix for endometriosis, in each indication in Japan, and in January 2019 Takeda and ASKA Pharmaceutical Co., Ltd. announced that Takeda obtained marketing authorization in Japan 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.

Uterine Fibroids

Uterine fibroids are noncancerous tumors that develop in or on the muscular walls 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 can cause debilitating symptoms such as abnormal uterine 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.

We estimate approximately 19 million women in the U.S. have uterine fibroids. Of those, approximately five million women are estimated to suffer from symptoms of uterine fibroids, approximately three million of whom are inadequately treated by current medical therapy and require further treatment.

The current approach to treating uterine fibroids includes both medical 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, tranexamic acid, and GnRH agonists. The current standard of care for the treatment of patients with mild symptoms includes the use of oral contraceptives or nonsteroidal anti-inflammatory drugs, or 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. GnRH 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 GnRH agonists. 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 even 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.

Our Phase 3 Program for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids

We initiated a Phase 3 clinical program in January 2017, evaluating relugolix in women with heavy menstrual bleeding associated with uterine fibroids. The program consists of two multinational, replicate pivotal clinical trials, which we refer to as LIBERTY 1 and LIBERTY 2. Each trial randomized women 1:1:1 to one of three treatment arms: relugolix 40 mg once daily co-administered in combination with commercially available low-dose hormonal therapy including 1.0 mg estradiol and 0.5 mg norethindrone acetate for 24 weeks; relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered in combination with low-dose hormonal therapy for an additional 12 weeks; or placebo once daily for a period of 24 weeks. We have completed enrollment in the two replicate LIBERTY 1 (N = 388) and LIBERTY 2 (N = 382) trials. Eligible women completing the initial 24-week period are offered an active treatment extension with relugolix 40 mg once daily co-administered in combination with low-dose hormonal therapy for an additional 28-week period, or a total treatment period of 52 weeks, to evaluate the safety of longer-term treatment. Women completing the open-label extension study will be offered the opportunity to participate in a randomized withdrawal study to provide up to two years of safety and efficacy data for relugolix combination therapy and information about the need for maintenance therapy. We are also conducting a one-year observational study of bone mineral density in women with uterine fibroids or endometriosis to provide additional context for our Phase 3 clinical programs.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 is the proportion of all women enrolled who achieve 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 as measured by the alkaline hematin method, a quantitative measurement of menstrual blood loss. The secondary endpoints include the proportion of women who achieve amenorrhea 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 from baseline 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, is also being assessed. We will conduct a bridging study intended to support approval of the single-tablet fixed-dose combination including relugolix, 40 mg, estradiol, 1.0 mg, and norethindrone acetate, 0.5 mg. We are conducting additional clinical trials to further support the commercial potential of relugolix in uterine fibroids in the U.S. and other major markets.

On May 14, 2019, we announced that LIBERTY 1, the first of two Phase 3 studies of once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and six key secondary endpoints. Relugolix combination therapy maintained bone mineral density at levels comparable to placebo over 24 weeks and was generally well tolerated.

In the primary endpoint analysis, 73.4% of women receiving once daily oral relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50 percent or greater reduction from baseline in menstrual blood loss volume during the last 35 days of the 24-week treatment period measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline, a clinically relevant secondary endpoint.

Bone mineral density was comparable between the relugolix combination and placebo groups. The distribution of the change in bone mineral density, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by dual energy x-ray absorptiometry (DXA).

The 24-week study achieved 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 secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination and placebo groups was comparable (62% vs. 66%). In the relugolix combination therapy group 5% of women discontinued treatment early due to adverse events compared with 4% in the placebo group. The only adverse event in the relugolix combination arm occurring in at least 10% of women and more frequently than in the placebo arm was hot flush (11% versus 8%). There were no pregnancies in the relugolix combination group and one in the placebo group. There were two serious adverse events related to study drug: one fibroid expulsion and one for pelvic pain.

These data represent a top-line analysis of the results of the LIBERTY 1 study. Further review of the underlying data by Myovant is ongoing and may result in additional observations with respect to the study. We expect to submit data from LIBERTY 1 for presentation and publication in 2019.

We currently expect data from LIBERTY 2, the replicate Phase 3 study evaluating relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, in the third quarter of calendar 2019, and, provided the LIBERTY 2 study is successful, we plan to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in the fourth quarter of calendar 2019.

Takeda's Phase 3 Program for Uterine Fibroids

In October 2017, Takeda reported positive top-line results from its Phase 3 trial in Japan evaluating the efficacy and safety of relugolix monotherapy compared with leuprorelin for the treatment of heavy menstrual bleeding associated with uterine fibroids. In this trial, approximately 280 patients were randomized 1:1 to receive either relugolix, 40 mg, administered orally once daily or leuprorelin acetate administered by injection once every four weeks. Relugolix achieved an 82.2% response rate, meeting the primary endpoint, which was the proportion of patients achieving a pre-defined reduction in menstrual bleeding (Pictorial Blood Loss Assessment Chart, or PBAC, score of <10), and was observed to be statistically non-inferior to leuprorelin alone ($p = 0.0013$). Additionally, in November 2017, Takeda reported positive top-line results from its Phase 3 trial in Japan evaluating the efficacy and safety of relugolix for the treatment of pain associated with uterine fibroids. In this trial, 65 patients were randomized 1:1 to receive either relugolix, 40 mg, or placebo administered orally once daily. Relugolix met the primary endpoint demonstrating a marked improvement in pain in 57.6% of women compared to 3.1% of women receiving placebo ($p < 0.0001$). A marked improvement was defined as decline from a maximum Numerical Rating Scale, or NRS, score of at least 4 on the 11-point scale during the baseline period (last menstrual cycle before the initiation of treatment) to a maximum NRS score of 1 or less over the last 28 days of treatment, representing a decline from moderate to severe pain to minimal or no pain. Adverse events in both studies were consistent with the mechanism of action of relugolix and adverse events observed in previous clinical trials. In February 2018, Takeda announced that it had submitted the data from both trials to the Ministry of Health, Labor and Welfare in Japan for marketing authorization of relugolix in Japan for the treatment of uterine fibroids. On January 8, 2019, Takeda and ASKA Pharmaceutical Co., Ltd. announced that Takeda obtained marketing authorization in Japan 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. The Phase 3 data from each of the trials described above will be available to us, and may be used to support our anticipated NDA submission to the FDA. Although we will be solely responsible for obtaining FDA approval for relugolix in the U.S., the FDA can accept the results of clinical trials conducted outside the U.S. that were not conducted under an investigational new drug application in support of an NDA under certain conditions. At a minimum, the trials must have been conducted in accordance with FDA's good clinical practice requirements, and the FDA may also require that the foreign data be applicable to the U.S. population and U.S. medical practice.

These studies were based on Takeda's placebo-controlled dose-finding study evaluating relugolix in Japanese women with uterine fibroids and heavy menstrual bleeding. The study met its primary endpoint, with relugolix decreasing menstrual blood loss in a dose-dependent manner with the highest proportion of responses (84%, 95% confidence interval (74% to 93%) vs. 0% placebo) in the relugolix 40 mg group ($p < 0.0003$ vs. placebo). The most commonly observed adverse events (occurring in at least 10% of patients and more frequently in treatment groups vs. placebo) were mild or moderate in severity and included headache, metrorrhagia, menorrhagia and hot flush. Bone mineral density decreased from baseline in a dose-dependent fashion with the greatest loss (-2.3%) observed in the relugolix 40 mg group.

Endometriosis

Endometriosis is a disease in which tissue that normally lines 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. The symptoms associated with endometriosis can include painful periods and chronic pelvic pain, painful ovulation, pain during or after sexual intercourse, heavy bleeding, fatigue, and even infertility. Endometriosis can also impact general physical, mental, and social well-being.

According to the Endometriosis Foundation, endometriosis affects an estimated 1-in-10 women during their reproductive years and, in the U.S., can take an average of 10 years from the onset of symptoms to accurately diagnose, often leading to unnecessary or inappropriate treatment. We estimate that approximately 6 million women in the U.S. suffer from symptomatic endometriosis, 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment.

Similar to uterine fibroids, lowering estrogen levels has been shown to reduce pain associated with endometriosis, and there are a variety of medical and surgical treatments available. Initial treatment usually involves over-the-counter pain medications, including NSAIDs, because pain is the primary symptom. In more severe cases, GnRH agonists such as leuprolide are used for short-term treatment and may involve hormonal combination therapy. The FDA has approved Lupaneta Pack, or 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. For many patients, surgical intervention, typically laparoscopy with ablation 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. 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.

Our Phase 3 Program for the Treatment of Pain Associated with Endometriosis

We initiated a Phase 3 clinical program in June 2017, evaluating relugolix in women with pain associated with endometriosis. The program consists of two multinational replicate pivotal clinical trials, which we refer to as SPIRIT 1 and SPIRIT 2. Each trial randomizes women 1:1:1 to one of three treatment arms: relugolix 40 mg once daily co-administered in combination with low-dose hormonal therapy for 24 weeks (1.0 mg estradiol and 0.5 mg norethindrone acetate); relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered in combination with commercially available low-dose hormonal therapy for an additional 12 weeks; or placebo once daily for a period of 24 weeks. We expect to enroll approximately 600 women in each of the two replicate SPIRIT 1 and SPIRIT 2 trials. Eligible women completing the initial 24-week period are offered an active treatment extension with relugolix 40 mg once daily co-administered in combination with low-dose hormonal therapy for an additional 80-week period, or a total treatment period of 104 weeks, to evaluate the safety of longer-term treatment.

The co-primary efficacy endpoints for the SPIRIT 1 and SPIRIT 2 trials are the proportion of all women enrolled with reductions in both dysmenorrhea, or menstrual pelvic pain, and nonmenstrual pelvic pain, as assessed by an endometriosis-specific patient questionnaire administered daily, with no increase in background pain medication. Secondary endpoints will include additional questionnaires assessing functional changes associated with endometriosis-specific pain and quality of life, and the use of pain medications to treat endometriosis. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, will be assessed.

We currently expect to complete enrollment for the SPIRIT 1 and SPIRIT 2 trials in calendar 2019 with top-line results expected in the first quarter of calendar 2020. If the results of SPIRIT 1 and SPIRIT 2 are favorable, we intend to submit an NDA to the FDA.

Takeda's Phase 2 Clinical Trial of Women with Endometriosis

In a randomized, placebo-controlled, Phase 2 clinical trial of women with endometriosis conducted by Takeda from 2012 to 2014, 487 women were randomized to relugolix at doses of 10 mg, 20 mg or 40 mg administered orally once daily for 12 weeks, to placebo for 12 weeks, or to leuprolide, 3.75 mg administered subcutaneously every four weeks for 12 weeks. The trial demonstrated dose-dependent decreases from baseline in pelvic pain. Pelvic pain, including both non-menstrual pelvic pain and dysmenorrhea, was assessed by visual analog scale, or VAS, score. The primary endpoint was the change from baseline in mean VAS score for pelvic pain from week 8 through week 12. The mean pelvic pain VAS scores at baseline for the four groups ranged between 14.6 mm to 15.6 mm. All doses were significantly better than placebo, with the greatest benefit observed at the highest dose evaluated, 40 mg once daily. The mean change from baseline in the VAS score was -10.4 mm in the relugolix 40 mg arm versus -3.8 mm in the placebo arm ($p < 0.0001$). The mean changes from baseline in the VAS score were -8.1 and -6.2, respectively, for the relugolix 20 mg and 10 mg arms. The mean change from baseline in the VAS score for the leuprolide arm was -10.5 mm, which was similar to that of the relugolix 40 mg arm. Secondary efficacy endpoints also

demonstrated clinical benefit. Secondary efficacy endpoints included individual VAS scores for non-menstrual pelvic pain, menstrual pain and painful intercourse during the treatment period; the modified Biberoglu and Behrman score for pelvic pain, a commonly used endometriosis-specific patient questionnaire; use of analgesics to treat pelvic pain; proportion of women achieving amenorrhea, or the absence of menstrual blood loss; and quality of life using the endometriosis health profile-30 questionnaire. Clinical improvement was observed on all pain endpoints, including dose-dependent responses in mean VAS score for dysmenorrhea, mean modified Biberoglu and Behrman score for pelvic pain and mean modified Biberoglu and Berhman score for dysmenorrhea. In the 40 mg once-daily treatment arm, mean changes on these endpoints were -29.7, -0.325, and -1.16, respectively, compared to -5.21, -0.178, and -0.172 for patients receiving placebo. The changes from baseline in mean VAS score for dysmenorrhea were -19.9 and -14.2, respectively, in the relugolix 20 mg and 10 mg arms. The change from baseline in mean VAS score for dysmenorrhea for the leuprolide arm was -26.9. The mean percent changes from baseline in VAS score for dysmenorrhea were -97.1%, -60.1%, -31.8%, -11.7% and -98.5%, respectively, in the relugolix 40 mg, relugolix 20 mg, relugolix 10 mg, placebo and leuprolide arms. The proportion of days in which the women used analgesics and the amount of menstrual bleeding both decreased, while the proportion of women who achieved amenorrhea increased in a time-dependent manner depending on relugolix dose level. The effects of relugolix on pelvic pain were generally maintained and estradiol levels suppressed for the duration of the study in the 397 women who enrolled in an extension study and received an additional 12 weeks of treatment, or a total of 24 weeks of treatment.

Advanced Prostate Cancer

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. According to the National Cancer Institute, approximately 3.1 million men are currently living with prostate cancer in the U.S., and approximately 175,000 men are newly diagnosed each year. Men with prostate cancer are often asymptomatic at the earliest stages of disease and prostate cancer is generally understood to be slow to progress, leading to a median age at diagnosis of 66 years and a five-year survival rate of 98.2%.

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, or 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: prostate-specific antigen, or 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. The cure rate following surgery, depending on the stage of the cancer, is about 70% overall and, following radiation, about 50% to 60%. Approximately 25% to 30% of men will, therefore, progress to advanced disease, excluding those with metastatic disease at the time of diagnosis.

First-line treatment for advanced prostate cancer typically involves treatment with androgen deprivation therapies, or 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, or removal of the testes which produce testosterone, can be successful in delaying prostate cancer progression. More than 80% of patients with advanced prostate cancer initially respond to ADT with varying degrees of tumor regression or stabilization. The duration and depth of response to ADT is presumably dependent on the underlying tumor biology and burden. Thus, patients with metastatic prostate cancer, or prostate cancer that has spread to other parts of the body, respond for an average of two years before any biochemical evidence of castration resistance occurs. By contrast, patients with biochemical-only evidence of progressive disease may respond to ADT for five years or more. As prostate cancer progresses, men remain on ADT while other therapies are added, typically until death.

The most commonly prescribed ADTs are GnRH agonists, such as long-acting leuprolide depot injections. GnRH agonists initially stimulate testosterone production, but with chronic stimulation of the GnRH 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 clinical flare. GnRH agonists are often given as depot formulations, requiring injections every month, three months or six months, and testosterone remains suppressed for weeks and months after cessation of therapy.

Our Phase 3 Program for the Treatment of Advanced Prostate Cancer

We initiated a Phase 3 clinical trial in March of 2017, evaluating the safety and efficacy of relugolix in men with advanced prostate cancer, which we refer to as the HERO trial. We believe the HERO trial, if successful, will be sufficient to support the submission of an NDA based on an End-of-Phase 2 meeting held with the FDA. The European Scientific Advice procedure and an End-of-Phase 2 meeting with the Japanese health authority have also been completed supporting the design of the HERO trial for approval in those regions should it be successful.

The HERO trial has completed enrollment after randomizing 934 men with advanced prostate cancer who require ADT in a 2:1 ratio to treatment with either oral relugolix 120 mg once daily (after a single oral loading dose of 360 mg) or a depot injection of leuprolide (per national or regional product label) for a period of at least 48 weeks. Based on FDA discussions, we believe that we will be required to conduct only one Phase 3 trial with a single relugolix arm to gain approval for relugolix in men with advanced prostate cancer in the U.S. Nonetheless, we have designed the trial to include a second arm with leuprolide to demonstrate that treatment with relugolix is noninferior to leuprolide in achieving sustained suppression of testosterone to castrate levels over 48 weeks, an outcome expected to be required for approval in other major markets such as Europe and Japan.

The primary efficacy endpoint accepted by the FDA is testosterone suppression (≤ 50 ng/dL) from week 5, day 1 through week 48, day 7. Relugolix must demonstrate that the lower bound of the 2-sided 95% confidence interval for the percent of patients achieving testosterone suppression through 48 weeks is at least 90%. The secondary efficacy endpoint is PSA reduction as a percentage change from baseline. Testosterone suppression is an approvable endpoint in the U.S. and several hormonal therapies have been approved based on this endpoint. If the results of this trial are favorable, we intend to submit an NDA to the FDA. We may conduct additional clinical trials to further support the commercial potential of relugolix in prostate cancer in the U.S. and other major markets. We currently expect to present top-line results from the HERO trial in the fourth quarter of calendar 2019 and to submit an NDA in early calendar 2020.

In addition, we filed an amendment to the HERO protocol to continue to enroll approximately 120 additional men with metastatic prostate cancer with the objective of prospectively demonstrating that relugolix can delay the time to progression to the lethal state of the disease, castration-resistant prostate cancer, as compared to leuprolide. We believe that relugolix, a direct GnRH receptor antagonist, has the potential to delay the time to castration-resistant disease as compared with leuprolide, a GnRH agonist, because relugolix more rapidly suppresses testosterone and PSA and more fully suppresses follicle-stimulating hormone than leuprolide.

Takeda's Phase 2 Clinical Trials of Men with Advanced Prostate Cancer

In 2014, Takeda initiated two Phase 2 clinical trials of relugolix in men with advanced prostate cancer requiring androgen deprivation therapy, or ADT, to demonstrate the ability of relugolix to achieve sustained castration (testosterone 50 ng/dL or less) over 24 weeks. Study C27002 enrolled 134 patients with advanced prostate cancer. In this open-label, parallel group study, men were enrolled to receive oral relugolix at a daily dose of 80 mg or 120 mg (after a single oral loading dose of 320 mg) or to receive GnRH agonist therapy (leuprolide 22.5 mg administered subcutaneously every 12 weeks) for up to 48 weeks. Study C27003 enrolled 103 men requiring six months ADT as neoadjuvant and adjuvant therapy to external beam radiation therapy. Patients were randomized to relugolix 120 mg once daily (after a single oral loading dose of 320 mg) or to degarelix 80 mg intramuscularly every four weeks for 24 weeks (after a single loading dose of 240 mg). In study C27002, 91% of men taking either relugolix 80 mg or relugolix 120 mg and 96% of men on leuprolide achieved sustained castration for 24 weeks. In study C27003, 95% of men taking relugolix and 89% of men taking degarelix achieved sustained castration for 24 weeks. The safety profile of relugolix in both trials was consistent with the known class effects of other GnRH analogs, and relugolix resulted in rapid suppression of testosterone levels and was not observed to cause a clinical flare of symptoms after initiation of treatment. In study C27002, relugolix demonstrated a more rapid reduction in prostate specific antigen, or PSA, compared to leuprolide. The percent of patients with at least a 50% reduction in PSA at Week 5 was 83%, 75% and 17%, respectively, in the relugolix 120 mg, relugolix 80 mg and leuprolide arms. The median time to PSA nadir was 12.3 weeks, 16.1 weeks and 20.5 weeks, respectively, in the relugolix 120 mg, relugolix 80 mg and leuprolide arms. No statistical comparisons were made between the relugolix and leuprolide arms. Study C27003 demonstrated rapid and sustained suppression of testosterone levels to below the castration threshold for the 24-week treatment duration. In study C27003, the testosterone recovery following the last dose of treatment was more rapid in the relugolix arm than in the degarelix arm. Baseline testosterone levels were similar between the two arms (405 ng/dL and 420 ng/dL in the relugolix and degarelix groups, respectively), but at 12 weeks after discontinuing therapy, the median testosterone levels were 285 ng/dL and 35 ng/dL, respectively. No statistical comparisons were made between the two arms.

MVT-602

As part of our license agreement with Takeda, or the Takeda License Agreement, we acquired the worldwide rights to MVT-602, our second product candidate, which previously has 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, or 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.

In October 2018, we presented data from a Phase 1 trial of MVT-602 at the American Society of Reproductive Medicine (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 luteinizing hormone concentrations and expected effects on follicle-stimulating hormone 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 dose of MVT-602 demonstrated dose-related increases in luteinizing hormone concentrations and expected post-dose increases in follicle-stimulating hormone 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 approximately 70 fertile women undergoing controlled ovarian stimulation. This study has been completed and we currently expect to present top-line results at the European Society of Human Reproduction in Vienna, Austria in June 2019. This study is intended to provide information for dose selection for a study of MVT-602 in infertile women seeking pregnancy.

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, or 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. 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.

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 trial 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.

Our Key Agreements

License Agreement with Takeda

In April 2016, we entered into the Takeda License Agreement. Pursuant to the Takeda License Agreement, Takeda 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 right 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 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.

We will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in our territory, subject to certain agreed reductions. Takeda will pay us a royalty at the same rate as ours 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.

During the period commencing on the effective date of the Takeda License Agreement and ending two years after the first commercial sale of product containing relugolix in a major market country, we and our controlling shareholder, Roivant Sciences Ltd., or RSL, have both agreed that we will not, directly or indirectly, and will cause all of our respective affiliates (other than any affiliate that is a public company) not to, alone or with others, research (or fund any research), develop, make, use, sell, offer for sale, or import any competing product in our territory or the Takeda Territory or enter into any agreement with any third party with respect to a license or other acquisition of rights relating to any competing product in our territory or the Takeda Territory. For these purposes, a competing product is (1) any small molecule oral GnRH receptor antagonist (other than a product containing relugolix) for uterine fibroids, endometriosis, or prostate cancer, and (2) any product containing MVT-602 for prostate cancer in the Takeda Territory. If, during such period, we or any of our nonpublic affiliates is acquired by a third party that is developing or commercializing a competing product, then we must divest our interest or terminate the development or commercialization of the competing product or cause our affiliate to do so.

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 trials 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.

In connection with the Takeda License Agreement, we issued 5,077,001 of our common shares, then equal to 12% of our outstanding share capital, to Takeda pursuant to a subscription agreement, and also issued Takeda a warrant to enable it to maintain its 12% ownership of us through the one-year anniversary of the warrant, unless earlier terminated as a result of our change in control. We issued a total of 2,343,624 of our common shares to Takeda under this warrant prior to its expiration on April 30, 2017. We also entered into an investor rights agreement with Takeda, pursuant to which Takeda and RSL, the other shareholder party thereto, are entitled to certain rights with respect to the registration of their common shares under the Securities Act.

Manufacture and Supply Agreements with Takeda

In June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited is supplying us, and we are obtaining from Takeda Limited, all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. Takeda Limited is also assisting us with a technical transfer of the manufacturing process for relugolix to us and our designee and we are paying the expenses related to such transfer.

On May 30, 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement, pursuant to which Takeda will manufacture and supply us with relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. Takeda has agreed to assist with the transfer of technology and manufacturing know-how to a second contract manufacturing organization of our subsidiary, Myovant Sciences GmbH. We will pay the expenses related to such transfers.

Right of First Negotiation and Board Observer Agreement with Pfizer

In October 2016, we and an entity affiliated with Pfizer Inc., or the Pfizer Affiliate, entered into a right of first negotiation and board observer agreement, or the Pfizer Agreement. Pursuant to the Pfizer Agreement, we granted to the Pfizer Affiliate, upon the closing of the sale of at least $30.0 million of our common shares to the Pfizer Affiliate in our initial public offering, or the IPO, a right of first negotiation with respect to any transaction that we would propose to a third party involving (A) the license or sale of rights to develop and commercialize relugolix or MVT-602 for the treatment of heavy menstrual bleeding associated with uterine fibroids, pain associated with endometriosis, advanced prostate cancer, or female infertility as part of assisted reproduction, in each case, in a major market country, or (B) a change of control of Myovant or the sale or disposition of all or substantially all of our assets. The right of first negotiation will terminate upon the earliest of (1) November 1, 2019 (the third anniversary of the IPO), (2) such time as the Pfizer Affiliate, together with its affiliates, owns less than 51% of the common shares purchased by the Pfizer Affiliate in the IPO, (3) a change of control of Myovant, (4) the sale or disposition of all or substantially all of our assets and (5) the liquidation or other dissolution of Myovant. In addition, during such period that the Pfizer Affiliate holds a right of first negotiation, one representative of the Pfizer Affiliate may attend any meetings of our board of directors in a non-voting observer capacity, subject to standard exceptions, such as conflict of interest. Such observer right will also terminate at such time as we file an NDA with the FDA for relugolix. The Pfizer Agreement will terminate upon the earliest of (1) November 1, 2021 (the fifth anniversary of the closing of the IPO), (2) such time as the Pfizer Affiliate, together with its affiliates, owns less than 51% of the common shares purchased by the Pfizer Affiliate in the IPO, (3) a change of control of Myovant, (4) the sale or disposition of all or substantially all of our assets, (5) the liquidation or other dissolution of Myovant, and (6) such time as we file an NDA with the FDA for relugolix.

Option Agreement with Roivant Sciences Limited

In June 2016, we entered into an option agreement with RSL pursuant to which RSL granted to us an option to acquire the rights to products to which RSL or any non-public affiliate of RSL acquires the rights (other than a relugolix product or a competing product, as described under the section titled "—License Agreement with Takeda" above) for uterine fibroids or endometriosis, or for which the primary target indication is hormone-sensitive prostate cancer. Our option is exercisable at any time during the period commencing on November 1, 2016 (the date we closed the IPO) and ending two years following the date of first commercial sale of a relugolix product in a major market country. If we elect to exercise our option for a product, we will be required to reimburse RSL for 110% of any payments made by RSL or its affiliate for such product, and will receive an assignment of the agreement through which RSL or its affiliate acquired the rights to such product.

Information Sharing and Cooperation Agreement

In July 2016, we entered into an information sharing and cooperation agreement, or the Cooperation Agreement, with RSL. The Cooperation Agreement, among other things: (1) obligates us to deliver periodic financial statements and other financial information to RSL and to comply with other specified financial reporting requirements; and (2) requires us to supply certain material information to RSL to assist it in preparing any future U.S. Securities and Exchange Commission, or SEC, filings. On May 24, 2019, we entered into Amendment No. 1 to the Cooperation Agreement, pursuant to which RSL has agreed, in connection with each of our next three public offerings of our common shares, that RSL will (1) provide to us and the underwriter(s) engaged by us in connection with such public offering an indication of interest for RSL to participate as a purchaser in such public offerings, and (2) enter into a customary lock-up agreement with the underwriters in connection with such public offerings.

Subject to specified exceptions, the Cooperation Agreement will terminate upon the earlier of the mutual written consent of the parties or when RSL is no longer required by U.S. generally accepted accounting principles, or U.S. GAAP, to consolidate our results of operations and financial position, account for its investment in us under the equity method of accounting or, by any rule of the SEC, include our separate financial statements in any filings it may make with the SEC.

Services Agreements with Roivant Sciences, Inc. and Roivant Sciences GmbH

In July 2016, we and our wholly-owned subsidiary Myovant Sciences, Inc., or MSI, entered into a services agreement, or the RSI Services Agreement, with Roivant Sciences, Inc., or RSI, a wholly owned subsidiary of RSL, effective April 29, 2016, under which RSI agreed to provide certain administrative and research and development, or R&D, services to us. Under the RSI Services Agreement, we pay or reimburse RSI for expenses it, or third parties acting on its behalf, incurs for us. For any general and administrative, or G&A, and R&D activities performed by RSI employees, RSI charges us based upon the relative percentage of time utilized on our matters by the respective employee. All other third-party pass thru costs are billed to us at cost.

In February 2017, we and MSI amended and restated the RSI Services Agreement, effective November 11, 2016, to include our wholly owned subsidiary, Myovant Sciences GmbH, or MSG, as a services recipient. In addition, in February 2017, MSG entered into a separate services agreement, or the RSG Services Agreement, with Roivant Sciences GmbH, or RSG, a wholly owned subsidiary of RSL, effective November 11, 2016, for the provisioning of services by RSG to MSG in relation to services related to clinical development, administrative and finance and accounting activities. We refer to the amended and restated services agreement with RSI and the RSG Services Agreement, collectively, as the Services Agreements.

We have replaced most of the services previously provided by RSI and RSG with our own internally developed capabilities or external professional service providers. Consequently, the level of support we receive from RSI and RSG has decreased substantially and is expected to continue to decrease as we further decentralize our activities from RSL.

Sales and Marketing

We are currently building our sales and marketing infrastructure; however, we currently do not have established marketing, sales, or distribution capabilities. In order to commercialize our product candidates, if approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third-parties that have sales and marketing experience. We plan to directly commercialize our product candidates in the U.S. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

Manufacturing

We do not own or operate, nor do we expect to own or operate, facilities for manufacturing, storage and distribution, or testing of our product candidates. In June 2016, we and Takeda Limited entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited is supplying us, and we are obtaining from Takeda Limited, all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. We also rely on a limited number of third-party contract manufacturers for packaging and distribution of finished drug products for our clinical trials, sourcing of comparator products, and development of new products. Takeda Limited is also assisting us with a technical transfer of the manufacturing process for relugolix drug substance and drug product to us and our designee and we are paying the expenses related to such transfer.

We expect that the manufacturing support provided by Takeda to us under the Takeda License Agreement will be sufficient for us to complete our planned Phase 3 programs for relugolix. If relugolix is approved by the FDA, we also plan to rely on Takeda and other third-party manufacturers to supply us with sufficient commercial quantities of relugolix. On May 30, 2018, we entered into the Takeda Commercial Supply Agreement pursuant to which Takeda will manufacture and supply us with relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. Takeda has agreed to assist with the transfer of technology and manufacturing know-how to a second contract manufacturing organization of our subsidiary, Myovant Sciences GmbH. We will pay the expense related to such transfers. In anticipation of receiving marketing approval by a regulatory agency for any one of our products, we intend to and have entered into additional agreements with Takeda and/or other third-party contract manufacturers for the commercial production of those products.

We expect that the MVT-602 drug substance transferred from Takeda to us under the Takeda License Agreement will be sufficient for our near-term development plans; however, additional process development and manufacturing would be required in order for us to complete Phase 2 and Phase 3 clinical studies for MVT-602. We intend to contract with third-party contract manufacturers to complete the additional development and manufacturing activities for our current MVT-602 programs and to fill, finish, supply, store, and distribute drug product for these programs.

If there are delays in initiating new relationships with one or more other third-party manufacturers for relugolix and/or MVT-602, or a delay in completing technology transfer to any of these manufacturers, we could experience delays in our development and commercialization efforts.

Manufacturing of any 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, or cGMP, conditions, which set forth the regulatory standards for the production of pharmaceuticals to be used in humans.

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 product candidates, knowledge, experience, and scientific resources provide us with competitive advantages, we face competition from 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 will significantly depend upon our ability to effectively complete necessary clinical trials and regulatory approval processes, and effectively commercialize, market, and promote approved products. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, acceptance by physicians, ease of patient compliance, dosing convenience, price, insurance and other reimbursement coverage, patent position, distribution, and marketing. Our competitors also 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 or potential future competitors have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Our current and certain 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 trial sites and patient enrollment and retention for clinical trials. 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 uterine fibroids, endometriosis or prostate cancer 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.

We consider relugolix's most direct competitor for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis to be ORILISSA™ (elagolix), an oral GnRH receptor antagonist for the management of moderate to severe pain associated with endometriosis, which has been approved as monotherapy (150 mg once a day or 200 mg twice a day) by the FDA and launched by AbbVie in August 2018. Abbvie also commenced two Phase 3b trials of elagolix in combination with hormonal therapy in women with pain associated with endometriosis in 2017, which are ongoing. In 2018, AbbVie announced that each of its two pivotal Phase 3 trials evaluating elagolix 300 mg twice a day with and without hormonal add-back therapy in women with heavy menstrual bleeding associated with uterine fibroids, met their primary endpoint. In addition, ObsEva SA, a Swiss-based clinical-stage biopharmaceutical company, reported the commencement of two Phase 3 clinical trials of linzagolix (OBE2109), also an oral GnRH receptor antagonist, in women with heavy menstrual bleeding associated with uterine fibroids in the first half of 2017. We expect ObsEva to initiate a Phase 3 program evaluating linzagolix in women with endometriosis-associated pain in 2019. 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 January 2017, Allergan and Gedeon Richter announced positive results from the second of two pivotal Phase 3 clinical trials evaluating the efficacy and safety of ulipristal acetate, a selective progesterone receptor modulator, in women with abnormal bleeding due to uterine fibroids. The FDA accepted the filing of their NDA submission for this indication in October 2017. On May 18, 2018, the European Medicines Agency Pharmacovigilance Risk Assessment Committee, or PRAC, completed its review of Esmya (ulipristal acetate) following reports of serious liver injury. The PRAC concluded that Esmya may have contributed to the development of some cases of serious liver injury. The PRAC has recommended that Esmya must not be used in women with known liver problems and should be used for more than one treatment course only in women who are not eligible for surgery. Liver function testing should be performed at the start of each treatment course and once a month and for two to four weeks after stopping treatment for the first two treatment courses. In February 2018, Allergan announced that the U.S. FDA had extended the Prescription Drug User Fee Act date by three months to the third quarter of 2018 to provide time for a full review of the file. In August 2018, the FDA issued a complete response letter to Allergan indicating it could not approve ulipristal acetate in its current form due to safety concerns related to post-marketing reports outside the U.S. The launch of Esmya in the U.S. is on hold. Other selective progesterone receptor modulators are also in development, including vilaprisan, a selective steroidal progesterone receptor modulator, for which Bayer was conducting a head-to-head study of vilaprisan compared with ulipristal acetate in women with heavy menstrual bleeding due to uterine fibroids and a long-term safety study of vilaprisan compared with standard of care. In December 2018, Bayer put clinical development of its ongoing vilaprisan trials on hold following safety findings in long-term toxicology studies.

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 part on our ability to obtain and maintain proprietary protection for relugolix, MVT-602 and any of our future 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 term 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, or PTA) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension, or PTE), or both. In addition, 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.

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 the use of relugolix to treat sex-hormone dependent prostate cancer and hysteromyoma (uterine fibroids); methods of manufacturing; and certain formulations. The patent family directed to the relugolix molecule and its use expires in 2024, subject to any extension of patent term that may be available in a particular country. We intend to apply for PTE for a patent covering relugolix. If granted, the patent term covering relugolix as a composition of matter may be extended for up to five years, or 2029. The patents and patent applications directed to methods of manufacturing and formulations, if issued, expire in 2033 and 2036, respectively, subject to any adjustment or extension of patent term that may be available in a particular country. We have also 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, and to the use of relugolix as a monotherapy to treat advanced prostate cancer. These applications are co-owned with Takeda under the Takeda License Agreement. These patent applications, if issued, would expire in 2037 subject to any adjustment or extension of patent term that may be available in a particular country.

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 molecule 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 and patent applications 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 patent applications directed to uses of MVT-602 in treating infertility. These applications, if issued, would expire in 2037 subject to any adjustment or extension of patent term that may be available in a particular country.

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.

Government Regulation

FDA Drug Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, 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, civil penalties, and criminal prosecution.

We cannot market a drug product candidate in the U.S. until the drug has received FDA approval. The steps required before a drug may be marketed in the U.S. generally include the following:

- completion of extensive nonclinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, requirements to establish the safety and efficacy of the drug for each proposed indication;

- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with Good Manufacturing Practice, or GMP, requirements; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the U.S.

Satisfaction of FDA pre-marketing approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations and requirements, including GLP regulations. 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 trial protocol. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. If the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

Clinical trials involve the administration of an investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, including GCP requirements, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval at each site at which the clinical trial will be conducted. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Other Phase 1 studies are usually conducted to understand the absorption, distribution, and metabolism of the drug in special populations and to characterize potential for drug-drug interaction or food effects. Phase 2 usually involves trials in a limited patient population to determine metabolism, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials, also called pivotal or registration trials, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial 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 trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial 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 trial would be practically or ethically impossible.

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 cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally 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. These fees are typically increased annually.

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 begins an in-depth review. The FDA has established internal substantive review goals of ten months for most NDAs once they have been accepted for filing and 6 months for most applications for priority review once they have been accepted for filing. Priority review can be applied to drugs to treat serious conditions that the FDA determines offer significant improvement in safety or effectiveness. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. 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 requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with GMP requirements is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. 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. 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. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy, or 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. The requirement for a REMS can materially affect the potential market and profitability 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 indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement 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 NDA supplements as it does in reviewing NDAs. Such supplements are typically reviewed within 10 months of receipt.

Post-Approval Requirements

Once an NDA is approved, a product is subject to post-approval requirements. 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. 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. 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 manufacture of the product, complete withdrawal of the product from the market, or product recalls;

- fines, warning letters, or holds on post-approval clinical trials;
- 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.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Foreign Regulation

In order to market any product outside of the U.S., we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of our products. 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 trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the U.S. apply similarly in the context of the European Union, 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 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

Although we currently do not have any products on the market, our current and future business operations may be subject to additional healthcare 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. Some of our pre-commercial activities are subject to some of these laws.

Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we are in the process of developing a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. 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 laws are interpreted broadly and enforced aggressively by various federal agencies, including the Centers for Medicare & Medicaid Services, or CMS, the Department of Justice, and the Office of the Inspector General for the United States Department of Health and Human Services, or HHS, and various state agencies. These anti-kickback laws, 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, improper discounts, and free or reduced-price items and services. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, beneficiaries, and others on the other hand. 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. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated.

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, or ACA, to a stricter standard 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. 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.

Federal and State Prohibitions on False Claims

The federal civil False Claims Act prohibits, 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. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, certain of our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party payor reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. 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 payors. Given the significant size of actual and potential settlements, it is expected that the government authorities will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

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

The federal Health Insurance Portability and Accountability Act of 1996, or 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 payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. Like the federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA 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

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical, and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which includes certain healthcare providers, health plans, and healthcare clearinghouses, that create, receive, or obtain protected health information in connection with providing a service for or on behalf of a covered entity. At present, it is unclear if we would be considered a business associate subject to HIPAA based on our business activities and service offerings upon the commercialization of a product. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. 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.

Outside the U.S., our clinical trial programs and research collaborations may implicate international data protection laws, including the General Data Protection Regulation, or GDPR, in the European Union. The GDPR became effective on May 25, 2018, increasing our responsibility and liability in relation to the processing of personal data of individuals in the EU. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the disclosures provided to the individuals, the transfer of personal data out of the EU, security breach notifications, security and confidentiality of the personal data. In addition, violations of the GDPR carry fines of up to the greater of 20 million Euros or 4% of annual global revenue. 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.

Additionally, California recently enacted legislation that has been referred to as the first "GDPR-like" law in the U.S. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for California residents and places increased privacy obligations on entities handling personal data of California residents or households. When it goes into effect on January 1, 2020, the CCPA will give 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 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 trials 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 wave 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

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 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 payor, 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 and medical 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, or FCPA. The FCPA prohibits U.S. companies and their representatives from processing, offering, or making payments of money or anything of value to foreign officials with the intent to obtain or retain business or seek a business advantage. In certain countries, the health care professionals we regularly interact with may meet the definition of a foreign government official for the purposes of the FCPA. Our international activities create the risk of unauthorized payments or offers of payments by our employees, consultants and agents, even though they may not always be subject to our control. We discourage these practices by our employees, consultants, and agents. However, our existing safeguards may prove to be less than effective, and our employees, consultants, and agents may engage in conduct for which we might be held responsible. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement activity by both the Department of Justice and the SEC. 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.

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 or our vendors must comply.

Health Reform

The U.S. and certain foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our future results of operations and our ability to sell our product candidates profitably, even if approved for sale. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In particular, the ACA has had, and is expected to continue to have, a significant impact on the healthcare industry. The ACA was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA- mandated fees including the so called "Cadillac" tax on certain higher cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," and increased, effective January 1, 2019, from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in the Medicare Part D program. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. The Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision.

Further, there has been heightened government scrutiny over the manner in which manufacturers set prices for their marketed pharmaceutical products. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to pharmaceutical product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs and contains additional proposals to increase manufacturing competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. There may be additional challenges and amendments to the ACA in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Moreover, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, which is being phased in over several years beginning in 2015. Among the requirements of this new legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Coverage and Reimbursement

Sales of our products, if and when approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government healthcare programs, private health insurers, and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the U.S., private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, if and when approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our product candidates, and those of any future product candidate, will therefore depend substantially on the extent to which the costs of our product candidates, and those of any future product candidate, will be paid by third-party payors. Additionally, the market for our product candidates, and those of any future product candidate, will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors 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 payor separately and will likely be a time-consuming process.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and challenging the prices charged for medical products and services. 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. Adoption of price controls and 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 payors 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 products once approved or a decision by a third-party payor 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 products once approved or additional pricing pressures.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the United Kingdom, or UK, held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." This referendum has created political and economic uncertainty, particularly in the UK and the EU, and this uncertainty may persist for years. Since the regulatory framework for pharmaceutical products in the UK covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. In addition, withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the UK and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. This is particularly the case if the UK and the EU do not reach agreement on how the UK will exit the EU, commonly referred to as "hard Brexit." The UK's vote to exit the EU could also result in similar referendums or votes in other European countries in which we do business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us.

Financial History

We have incurred, and expect to continue to incur, significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix. To date, we have not generated any revenue, and we do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for at least one of our product candidates. We have funded our operations primarily from the issuance and sale of our common shares, from the issuance of notes to NovaQuest Capital Management, or NovaQuest, and the funds received from the Term Loans with Hercules Capital, Inc., or Hercules.

A significant portion of our operating expense is related to R&D activities. Our R&D activities primarily include activities related to the Phase 3 development of our lead product candidate, relugolix, for the treatment of heavy menstrual bleeding associated with uterine fibroids, pain associated with endometriosis, and advanced prostate cancer, as well as activities related to the development of MVT-602 for the treatment of female infertility as part of assisted reproduction.

Employees

As of March 31, 2019, we had 167 employees. Our employees are not represented by labor unions or covered by collective bargaining agreements, and we believe our relations with our employees are good.

Corporate Information

We are an exempted company limited by shares incorporated under the laws of Bermuda on February 2, 2016 under the name Roivant Endocrinology Ltd. We changed our name to Myovant Sciences Ltd. in May 2016. Our common shares are currently listed on the New York Stock Exchange under the symbol “MYOV.”

Available Information

Our website is www.myovant.com. The contents of our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the SEC, including our Annual Report 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.

Investors and other interested parties should note that we also use our media and investor relations website (www.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 media and investor relations website and social media channels, in addition to our SEC filings.

The information contained on our websites and social media channels is not included as part of, or incorporated by reference, into this Annual Report on Form 10-K.

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, including the section of this Annual Report on Form 10-K titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our 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 on Form 10-K 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. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K. See the section of this Annual Report on Form 10-K titled "Forward-Looking Statements."

Risks Related to Our Business, Financial Position and Capital Requirements

We believe our current cash and cash equivalents will be sufficient to fund our business only for a limited amount of time, and if we are not able to raise additional funds, we may be unable to continue as a going concern.

As of March 31, 2019, we had approximately $156.1 million of cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the first quarter of our fiscal year ending March 31, 2020. 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. These funds will not be sufficient to enable us to complete all necessary development activities and commercially launch relugolix. We anticipate that we will continue to incur net losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period following the filing of this Annual Report on Form 10-K. We may be forced to delay or reduce the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. Management's plans in this regard are described in Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

We will require substantial additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development of, seek regulatory approval for, and commercialize relugolix or MVT-602.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize relugolix and MVT-602. These expenditures will include costs associated with the Takeda License Agreement, pursuant to which we are obligated to cover substantial development costs of relugolix and MVT-602 and make royalty payments in connection with the net sales of resulting products, if any. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned and ongoing clinical trials for relugolix and MVT-602;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, and comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our products or any future product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for our products in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

Our current funds will not be sufficient for us to compete all necessary development activities and commercially launch relugolix. Accordingly, we will need to obtain substantial further funding through other public or private offerings of our capital shares, debt financing, collaboration or licensing arrangements, or other sources. We cannot be certain that additional capital will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, when needed, we may have to significantly delay, scale back, or discontinue the development or

commercialization of our product candidates or potentially discontinue operations. 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 efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and anticipated product development programs.

Raising additional funds by issuing equity securities may cause dilution to existing shareholders; raising additional funds through debt financings may involve additional restrictive covenants; and raising funds through collaboration or licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our operations through a combination of cash and cash equivalents on hand, equity offerings, debt financings, structured transactions such as royalty financings, collaboration or license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership 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. Our existing agreements with NovaQuest and Hercules involve, 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, making capital expenditures, or declaring dividends.

In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We have a limited operating history and no history of commercializing products, which may make it difficult to evaluate our business and prospects.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in February 2016, and our operations to date have been limited to identifying and in-licensing our product candidates, organizing and staffing our company, raising capital, preparing for and advancing our product candidates through clinical development, conducting global clinical trials, and preparing for potential future regulatory approvals and commercialization of relugolix. Many of our Phase 3 clinical trials are still ongoing and we have not yet demonstrated an ability to obtain marketing approval, manufacture a commercial scale product, or conduct sales and marketing activities necessary for successful product commercialization. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown difficulties in achieving our business objectives. If our product candidates are approved by the FDA, we will need to expand our capabilities to support commercial activities and we may not be successful in adding such capabilities. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses and negative cash flows; and we have not generated any revenue from any commercial products and 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 will fail to gain regulatory approval or fail to become commercially viable. Since inception, we have focused most of our efforts on research and development with the goal of achieving regulatory approval and have incurred significant operating losses. Our net loss was $273.6 million, $143.3 million and $83.4 million for the years ended March 31, 2019, 2018 and 2017, respectively, and, as of March 31, 2019, we had an accumulated deficit of $502.0 million.

We expect to continue to incur significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix. Past operating losses, combined with expected future operating losses, have had and will continue to have an adverse effect on our results of operations, financial position and working capital. If we obtain regulatory approval for relugolix or MVT-602, we expect to incur increased sales, marketing and manufacturing expenses.

We have not obtained marketing approval for relugolix or MVT-602 anywhere in the world, and we may never receive such approval. As a result, we have never generated any product revenue. We are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of relugolix and MVT-602, obtain necessary regulatory approvals, and have relugolix and MVT-602 manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize relugolix or MVT-602. Even if we successfully obtain regulatory approvals to market relugolix or MVT-602, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for

which we gain regulatory approval, the number of competitors in such markets, the accepted price for relugolix and MVT-602 and whether we own the commercial rights for those territories. For example, ORILISSA™ (elagolix), an oral GnRH receptor antagonist for the management of moderate to severe pain associated with endometriosis, has been approved as monotherapy (150 mg once a day or 200 mg twice a day) by the FDA and launched by AbbVie in August 2018. The launch and commercialization of ORILISSA™ or other competing drugs may limit the revenue from relugolix. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, or if we are unable to obtain a favorable price for relugolix or MVT-602, we may not generate significant revenue from sales of relugolix or MVT-602, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common shares and our ability to raise capital and continue operations.

We are heavily dependent on the success of relugolix in combination with low-dose estradiol and a progestin for our women's health indications of uterine fibroids and endometriosis, relugolix monotherapy for men with advanced prostate cancer, and MVT-602, which are still under clinical development. If either relugolix or MVT-602 does not receive regulatory approval or is not successfully commercialized, our business will be harmed.

We are a clinical-stage biopharmaceutical company with no products approved for commercial sale. 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, relugolix in combination with low-dose estradiol and a progestin, relugolix monotherapy, and MVT-602. Our business and our ability to generate revenue depends heavily on the successful clinical development, regulatory approval and commercialization of these product candidates, which may never occur. We currently generate no revenue from sales of any product. We may never receive regulatory approval for any indication for relugolix or MVT-602 and may never be able to develop or commercialize a marketable product. 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 are not permitted to market relugolix or MVT-602 in the U.S. until we receive approval of New Drug Applications, or NDAs, or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries.

Obtaining approval of an NDA or similar 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 relugolix or MVT-602. See the Risk Factor titled "The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable, and 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 full market potential." We have not submitted an NDA to the FDA, or any comparable application to any other regulatory authority.

Even if we receive regulatory approval for one or both formulations of relugolix or MVT-602, our ability to generate revenues from relugolix or MVT-602 will depend on our ability to:

- set an acceptable price for relugolix or MVT-602 and obtain coverage and adequate reimbursement from third-party payors;
- establish effective sales, marketing, and distribution systems in jurisdictions around the world for relugolix (excluding Japan and certain other Asian countries) or MVT-602;
- initiate and continue relationships with Takeda and/or other third-party manufacturers and have adequate commercial quantities of relugolix or MVT-602 manufactured at acceptable cost and quality levels;
- attract and retain experienced management and advisory teams;
- achieve broad market acceptance of our products in the medical community and with third-party payors and consumers;
- launch commercial sales of our products, whether alone or in collaboration with others;
- establish the safety and efficacy of relugolix and MVT-602 in comparison to competing products; and
- maintain, expand, and protect our intellectual property rights.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment in us may be adversely affected.

If we are unable to formulate a fixed-dose combination version of relugolix with low-dose estradiol and a progestin for our women's health indications, its potential commercial opportunity and competitive advantage could be limited.

GnRH receptor antagonists, like relugolix, may cause loss of bone mineral density due to the induced hypoestrogenic state that may limit duration of use. This risk, and a related risk of hot flush or vasomotor symptoms, may be mitigated by the co-

administration of relugolix in combination with low-dose estradiol and a progestin. A key part of our relugolix clinical development strategy is to formulate a fixed-dose combination of relugolix with low-dose estradiol and a progestin to maintain bone health and mitigate side effects of a low-estrogen state such as vasomotor symptoms, and to facilitate patient convenience and compliance. If we are unsuccessful in our attempts to formulate a fixed-dose combination in time for the initial application for market authorization in the U.S., we expect to seek approval for relugolix tablets co-packaged with a commercially available tablet containing both the low-dose estradiol and norethindrone acetate. This would potentially decrease our advantages relative to our competition by requiring patients to take two pills once daily instead of one pill once daily until the fixed-dose combination can be developed and approved. If our competitors develop a fixed-dose combination with hormonal therapy before we do, or if we are unable to do so, then we would be at a competitive disadvantage and this could limit our commercial opportunity. We are not aware of any barriers preventing competitors from developing or achieving regulatory approval of a fixed-dose combination.

We are conducting our Phase 3 clinical trials of relugolix in our target women's health indications with co-administration of a relugolix tablet and a commercially-available tablet containing low-dose estradiol and a progestin product. We are conducting bridging studies and supplying information to support the submission of NDAs or comparable foreign applications for the proposed fixed-dose combination and the relugolix tablet co-packaged with a commercially available tablet containing both the low-dose estradiol and norethindrone acetate for each of our target women's health indications. Such bridging studies may be unsuccessful or the information provided may be insufficient to support approval of the fixed-dose combination formulation or the relugolix tablet co-packaged with a commercially available tablet containing both the low-dose estradiol and norethindrone acetate, which may delay or increase the expenses associated with our development program and could limit our commercial opportunities.

In addition, in order to support the bridging between the US and EU sourced commercially available tablets of the low-dose estradiol and norethindrone acetate that were used in our clinical trials, we need to demonstrate the comparability of the drug product obtained from the different sources. If the information provided is insufficient to support approval of either formulation, we may be required to conduct further studies, we could face delays and increased expenses associated with our development program and our commercial opportunity could be limited.

The terms of the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement place restrictions on our operating and financial flexibility.

In October 2017, we and our subsidiaries entered into the Hercules Loan Agreement and the NovaQuest Securities Purchase Agreement. Our obligations under the Hercules Loan Agreement are secured by a first lien security interest in substantially all of our and our subsidiaries' respective assets, other than intellectual property, and our obligations under the notes issued pursuant to the NovaQuest Securities Purchase Agreement are secured by a second lien security interest in substantially all of our and our subsidiaries' respective assets, other than intellectual property.

Each of these agreements include customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant. Under the NovaQuest Securities Purchase Agreement, a minimum cash covenant applies commencing on November 1, 2020 (or November 1, 2021 if extended pursuant to the terms of the NovaQuest Securities Purchase Agreement) and under the Hercules Loan Agreement, a minimum cash covenant applies until such time as Myovant achieves both the clinical development and financing milestones as set forth in the Hercules Loan Agreement. Other restrictive covenants include limitations on additional indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), transfers, mergers or acquisitions, taxes, corporate changes and deposit accounts. 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 NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement each also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, cross acceleration to certain debt, certain events relating to bankruptcy or insolvency and certain events relating to United Kingdom or Irish pension plans. Upon the occurrence of an event of default under the NovaQuest Securities Purchase Agreement, a default interest rate of an additional 5.0% will apply to the outstanding obligations under the NovaQuest Securities Purchase Agreement, and NovaQuest, as the agent for the holders of the notes, may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the NovaQuest Securities Purchase Agreement. Upon the occurrence of an event of default under the Hercules Loan Agreement, a default interest rate of an additional 5.0% may be applied to the outstanding obligations under the Hercules Loan Agreement, and Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Hercules Loan Agreement. In addition, upon the occurrence of certain bankruptcy and insolvency events, our obligations under the notes issued pursuant to the NovaQuest Securities Purchase Agreement and our obligations under the Hercules Loan Agreement would automatically become due and payable. We may not have enough available cash 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. NovaQuest and Hercules could also exercise their rights to take possession and dispose of the collateral securing our obligations, which collateral includes all of our and our subsidiaries' respective assets other than intellectual property. 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.

Part of our strategy involves diversifying our product development risk by 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 product candidates may not be effective in treating their targeted diseases.

In addition, we may choose to focus our efforts and resources on potential product candidates that ultimately prove to be unsuccessful. Further, 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 because the risk of failure of any particular development program in the pharmaceutical field is high.

We rely on agreements with Takeda to provide rights to the core intellectual property relating to our existing product candidates and to supply us with clinical and commercial trial material to support development and potential commercialization of relugolix and MVT-602. Any termination or loss of significant rights under those agreements would adversely affect our development or commercialization of relugolix and MVT-602.

In June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and clinical supply of relugolix. Under this agreement, Takeda Limited is supplying us, and we are obtaining from Takeda Limited, all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. Takeda Limited is also assisting us with a technical transfer of the manufacturing process for relugolix to us and our designee and we are paying the expenses related to such transfer. On May 30, 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement, pursuant to which Takeda will manufacture and supply us with relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. Takeda has also agreed to assist with the transfer of technology and manufacturing know-how to a second contract manufacturing organization. We are paying for the expenses related to such transfer. If Takeda fails to fulfill its obligations to manufacture and supply clinical and/or commercial quantities of relugolix or fails to enable the transfer of the manufacturing process for relugolix to us or our designee, our development plans and commercialization of relugolix, if approved, could be significantly delayed or otherwise adversely affected.

We currently rely in part on services provided by Roivant Sciences, Inc. and Roivant Sciences GmbH.

We previously entered into Services Agreements with Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG, wholly owned subsidiaries of Roivant Sciences Ltd., or RSL, pursuant to which RSI and RSG provide certain services to us. The RSI or RSG personnel and support staff who provide services to us under these Services Agreements are not required to treat management and administration of our business as their primary responsibility or act exclusively for us, and we do not expect them to do so. Under the Services Agreements, RSI and RSG have the discretion to determine who, among their employees, will perform services for us. RSI and RSG have limited resources. If either RSI or RSG fails to perform its obligations in accordance with the terms of the Services Agreements or to effectively manage services provided to us, the operations of our business may be adversely affected. During the past year, we have replaced most of the services previously provided by RSI and RSG with our own internally developed capabilities or external professional service providers. Consequently, the level of support we receive from RSI and RSG has decreased substantially and is expected to continue to decrease as we further decentralize our activities from RSL. If we are unable to fully integrate the internal capabilities or further develop capabilities to replace the services currently provided by RSI or RSG, or fail to do so in a timely and effective manner, the operations of our business would be adversely affected.

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

We expect to hire additional employees for our managerial team and other teams supporting G&A, commercial, clinical, medical affairs, operations and other functions. The market for talent in our industry is very competitive. Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, more favorable risk profiles and a longer operating history in the 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 and consultants than what we have to offer. Due to these reasons, we may not be able to attract or retain qualified personnel.

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. In addition, we do not maintain “key person” insurance for any of our executives or other employees. If we lose one or more members of our senior management team or key employees, our ability to successfully implement our business strategies could be seriously harmed. Replacing these individuals may be difficult, cause disruption, and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize products successfully. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital, our ability to commercialize relugolix or MVT-602 if we obtain regulatory approvals, and our ability to implement our business strategies.

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

We expect 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 require significant capital expenditures and 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 revenue could be adversely affected, and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to complete clinical development, obtain regulatory approval, and commercialize relugolix, MVT-602 or any potential future product candidate may be adversely affected.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers, and other vendors, or those of our affiliates, 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, contractors, advisers, including principal investigators, consultants, commercial collaborators, 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 current Good Manufacturing Practice, or 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 payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties,” “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.,” and “If we obtain approval to market any products outside of the U.S., a variety of risks associated with international operations could materially adversely affect our business.” These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. 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. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. If our employees, independent contractors, principal investigators,

consultants, commercial collaborators, service providers or other vendors, or those of our affiliates, are found to be in violation of any such regulatory or legal standards or requirements, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, suspension or delay in our clinical trials, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished future earnings and profits, additional reporting requirements, and regulatory oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our 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.

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the U.S. and establishing and maintaining relationships with health care providers, payors, government officials, distributors and manufacturers globally. Conducting business internationally involves a number of risks, including:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- possible failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- business interruptions resulting from geopolitical actions, economic instability, or natural disasters, including, but not limited to, wars and terrorism, political unrest, outbreak of disease, earthquakes, boycotts, curtailment of trade, and other business restrictions;
- 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 European Union General Data Protection Regulation, or the GDPR, which introduced strict requirements for processing personal data of individuals within the European Union, or the EU; and
- 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.

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

Our internal computer systems, as well as those of RSI and RSG, and 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 RSI, RSG and our contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other contractors, consultants, and law and accounting firms, may sustain damage or data leakage from computer viruses, unauthorized access or disclosure, data breaches, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, and telecommunication and electrical failures. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our information systems or unauthorized persons, could cause interruptions in our operations and result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned clinical trials could result in delays in our 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 or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of relugolix or MVT-602 or any future product candidate could be delayed.

The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers'

systems, portable media or storage devises. We could also experience a business interruption, theft of confidential information, intellectual property or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our information system infrastructure or lead to data leakage, either internally or at our third-party providers, and could result in liabilities that adversely affect our financial performance. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent services interruptions or security breaches.

The results of the United Kingdom's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, the United Kingdom, or UK, held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." This referendum has created political and economic uncertainty, particularly in the UK and the EU, and this uncertainty may persist for years. A withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the UK and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. This is particularly the case if the UK and the EU do not reach agreement on how the UK will exit the EU, commonly referred to as a "hard Brexit." The UK's vote to exit the EU could also result in similar referendums or votes in other European countries in which we do business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us.

For example, Brexit could result in the UK or the EU significantly altering its regulations affecting the clearance or approval of our product candidates that are developed in the UK. Brexit could also affect the clearance or timing of the release of our clinical trial materials into the UK or the EU. Any such delays could result in our clinical study sites not having sufficient clinical trial materials and could adversely affect the timing and completion of our clinical trials. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the UK, the EU and elsewhere. In addition, the announcement of Brexit and the withdrawal of the UK from the EU have had and may continue to have, particularly in the case of a hard Brexit, a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity and financial condition.

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, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes effect 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 trials data, and 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 trials 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 introduces 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 UK. In particular, it is unclear whether, post Brexit, the UK will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom 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.

Use of social media platforms presents new risks.

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 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 or our product candidates on any social networking website. 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.

The failure to successfully implement an enterprise resource planning system could adversely impact our business and results of operations.

We are implementing a company-wide enterprise resource planning, or ERP, system to upgrade certain existing business, operational, and financial processes, upon which we rely. ERP implementations are complex and time-consuming projects that require transformations of business and finance processes to reap the benefits of the ERP system. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations. Additionally, if the ERP system is not effectively implemented as planned, or the system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess those controls adequately could be delayed. Significant delays in documenting, reviewing and testing our internal control over financial reporting could cause us to fail to comply with the U.S. Securities and Exchange Commission, or the SEC, reporting obligations related to our management's assessment of our internal control over financial reporting, or result in the issuance of an adverse opinion on the effectiveness of internal control over financial reporting by our independent registered public accounting firm. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business during or following the implementation of the ERP system, our business and results of operations could be harmed.

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

The use of relugolix and MVT-602 in clinical trials 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, health care providers, other pharmaceutical companies or others taking or otherwise coming into contact with our products. On occasion, large monetary judgments have been awarded in class action lawsuits where drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

The product liability and clinical trial insurance we currently carry, and any additional product liability and clinical trial insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer.

Moreover, insurance coverage is becoming increasingly expensive and in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for relugolix or MVT-602, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. 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.

Legislation enacted in Bermuda in response to the European Union's review of harmful tax competition could be harmful to our business.

During 2017, the European Union Economic and Financial Affairs Council, or ECOFIN, released a list of noncooperative jurisdictions for tax purposes. The stated aim of this list, and accompanying report, was to promote good governance worldwide in order to maximize efforts to prevent tax fraud and tax evasion. In an effort to remain off this list, Bermuda committed to address concerns relating to economic substance by December 31, 2018. In accordance with that commitment, Bermuda has enacted legislation that requires certain entities in Bermuda engaged in "relevant activities" to maintain a substantial economic presence in Bermuda and to satisfy economic substance requirements. The list of "relevant activities" includes carrying on as a business any one or more of: banking, insurance, fund management, financing, leasing, headquarters, shipping, distribution and service center, intellectual property and holding entities. At present, it is unclear what (if anything) we would be required to do in order to satisfy economic substance requirements in Bermuda, but to the extent we are required to increase our substance in Bermuda to satisfy such requirements, it could result in additional costs that could adversely affect our financial condition or results of operations. If we were required to satisfy economic substance requirements in Bermuda but failed to do so, we could face automatic disclosure to competent authorities in the EU of the information filed by the entity with the Bermuda Registrar of Companies in connection with the economic substance requirements and may also face financial penalties, restriction or regulation of its business activities and/or may be struck off as a registered entity in Bermuda.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes. The results of previous clinical trials may not be predictive of future results, and interim or top-line data may be subject to change or qualification based the complete analysis of data.

Our product candidates are still in development and 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. We cannot predict with certainty if or when we might submit an NDA for regulatory approval for relugolix or MVT-602 in any indication or whether any such application will be approved by the relevant regulatory authorities. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or other regulatory authorities may not agree with our proposed plans for any clinical trials of relugolix or MVT-602, which may delay the approval of an NDA or similar application. The clinical trial process is also very time-consuming.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of an NDA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. For example, Takeda's Phase 2 trial for relugolix in men with advanced prostate cancer, C27002, did not meet the criteria for success for its 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 trial. A number of companies in the biopharmaceutical industry have suffered significant setbacks in or the discontinuation of advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, 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 of the data related to the particular study or trial. For example, on May 14, 2019, we announced top-line data for LIBERTY 1 trial, the first of two Phase 3 studies of once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding. 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. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Positive results from any of our clinical trials of relugolix and MVT-602 may not be predictive of the results of any of our other ongoing and potential future clinical trials, 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. Product candidates in clinical trials, including Phase 3 clinical trials, often fail to show the desired safety and efficacy outcomes despite having progressed successfully through prior stages of preclinical and

clinical testing. Even where we achieve positive results in clinical trials, subsequent clinical trials may fail, even if those subsequent trials are designed similarly to their predecessors.

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

- failure to obtain regulatory approval to commence a trial;
- unforeseen safety issues;
- lack of effectiveness during clinical trials;
- identification of dosing issues;
- inability to reach agreement on acceptable terms with prospective CROs and/or clinical trial sites, the terms of which can be subject to extensive negotiations and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment and enrollment or failure to recruit suitable patients to participate in a trial;
- failure to open a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to clinical trial design;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols;
- premature discontinuation of study participants from clinical trials 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 trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of study results.

Further, we, the FDA or an institutional review board, or IRB, or other regulatory authority may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a clinical trial in accordance with regulatory requirements, including, the FDA's current Good Clinical Practice, or 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 IND, or other submissions or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the timing for commencement or completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of relugolix or MVT-602 could be harmed, and our ability to generate product revenue from relugolix or MVT-602 may be delayed. In addition, any delays in our clinical trials 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 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 trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

In addition, 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 either 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 trials 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 trials and other research, and having supplied us with complete information, data sets, and reports required to adequately demonstrate the results reported through the date of our acquisition of these assets. Problems

related to any of such non-clinical 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 trials 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 trials on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our clinical trials. Enrollment in our clinical trials may be slower than we anticipated, leading to delays in our development timelines. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the study and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical trials will drop out of the trials before completion. Furthermore, any negative results we or Takeda may report in clinical trials of our product candidates may make it difficult or impossible to recruit, enroll, and retain patients in other clinical trials of that same product candidate. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment, enrollment, or retention in our clinical trials. 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 trials, delaying or potentially preventing us from completing clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop relugolix and MVT-602, or could render further development impossible.

The results of our clinical trials may not support our proposed claims for relugolix or MVT-602.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the efficacy or safety of relugolix or MVT-602. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical testing. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. In addition, the FDA may not agree that clinical trial results are sufficient for approval for any product candidate. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after 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. The results of nonclinical and early clinical studies of our product candidates may not be predictive of the results of later-stage nonclinical studies or clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical and initial clinical trials. A future failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDAs to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize relugolix and MVT-602 and generate product revenue.

Reported data or other clinical development announcements by Takeda may adversely affect our clinical development plan.

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 trials in Japan in women with uterine fibroids and announced that it had 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. Favorable announcements by Takeda do not guarantee that the results of our clinical trials will also be favorable as the designs of our Phase 3 clinical trials differ from those of Takeda. Further, if post marketing adverse events regarding Relumina® are reported, or subsequent announcements by Takeda regarding relugolix are unfavorable, it could negatively impact our clinical development plans for or opinions of the FDA or other regulatory authorities with respect to relugolix. Additionally, the Phase 3 data from the Takeda trials of Relumina® will be available to us, and may be used to support our anticipated NDA submission to the FDA. We cannot provide assurance that the FDA will allow us to use the data from Takeda's clinical trials in support of any NDA that we may submit, and such data may be interpreted differently by the FDA and provide contradictory evidence in support of FDA's evaluation. If it does not, we may be required to perform additional clinical trials.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Drug development is highly competitive and subject to rapid and significant technological advancements. As a significant unmet medical need exists for the treatment of each of uterine fibroids, endometriosis, and advanced prostate cancer, as well as infertility in women, there are several large and small pharmaceutical companies focused on delivering therapeutics for the treatment of these indications. For example, ORILISSA™, an oral GnRH receptor antagonist, has been approved by the FDA for the management of moderate to severe pain associated with endometriosis and was launched by AbbVie in August 2018. Further, it is likely that additional drugs will become available in the future for the treatment of each of our target indications.

We are aware of several companies that are developing and commercializing drugs that would compete against relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, pain associated with endometriosis, and/or advanced prostate cancer and against MVT-602 for the treatment of female infertility as part of assisted reproduction. Many of our current and potential future competitors have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or opt to take an approved product.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of uterine fibroids, endometriosis, or advanced prostate cancer, as well as infertility in females. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize medicines that are superior in safety and efficacy to other products in the market;
- demonstrate through our clinical trials that relugolix or MVT-602 are differentiated from existing and future therapies;
- attract qualified scientific, clinical, product development, and commercial personnel;
- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain market access, coverage and adequate reimbursement from third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development, and commercialization of new medicines.

The availability and pricing of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make relugolix or MVT-602 less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety to overcome price competition and to be commercially successful. Accordingly, 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.

In addition, if the competing drugs that are mechanistically similar to our product candidates do not meet the expectations of the marketplace or have safety or efficacy issues, the market perception of our product candidates may be negatively affected, and the commercial performance of our product candidates may suffer.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize relugolix or MVT-602, and our ability to generate product revenue will be materially impaired.

Relugolix and MVT-602 and the activities associated with their development and commercialization, including their design, research, testing, manufacture, formulations, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by similar regulatory authorities outside the U.S. Failure to obtain marketing approval for relugolix and MVT-602 will prevent us from commercializing them.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither relugolix in combination with low-dose estradiol and a progestin, relugolix monotherapy, MVT-602 nor any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Neither we nor Takeda, nor any future collaborator is permitted to market any of our product

candidates in the U.S. or any other jurisdiction until regulatory approval of an NDA from the FDA or similar regulatory authorities outside of the U.S. is received.

The time required to obtain approval of an NDA by the FDA or similar regulatory authorities outside of the U.S. is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authority. Prior to submitting an NDA to the FDA or any comparable application to any other foreign regulatory authorities for approval of relugolix, we will need to complete our ongoing Phase 3 programs for relugolix, and for approval of MVT-602, we will need to complete Phase 2 and Phase 3 clinical trials. 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.

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 relugolix and MVT-602 for the specified indication. Further, because we are exploring the use of relugolix in combination with low-dose estradiol and a progestin as a longer-term therapy (i.e., greater than 6 months) for the treatment of heavy menstrual bleeding associated with uterine fibroids and for the treatment of pain associated with endometriosis, we expect to be required to submit data on a patient population followed for at least one year. We expect to rely on third-party CROs and consultants to assist us in filing 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 approval 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 product revenue.

Relugolix and MVT-602 may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events associated with relugolix or MVT-602 could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay, request modification of, or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for relugolix or MVT-602 or any future 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 trial 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.

Furthermore, the FDA has raised concern about a potential increase in the risk of diabetes and certain cardiovascular diseases in men with prostate cancer treated with GnRH receptor agonists. Further, on May 18, 2018, the European Medicines Agency, or the EMA, Pharmacovigilance Risk Assessment Committee, or PRAC, completed its review of Esmya (ulipristal acetate) following reports of serious liver injury. The PRAC concluded that Esmya may have contributed to the development of some cases of serious liver injury. The PRAC has recommended that Esmya must not be used in women with known liver problems and should be used for more than one treatment course only in women who are not eligible for surgery. Liver function testing should be performed at the start of each treatment course and once a month and for two to four weeks after stopping treatment for the first two treatment courses. In August 2018, Allergan, Inc. announced that it received a Complete Response letter from the FDA in which the FDA cited safety concerns regarding Esmya post-marketing reports outside the U.S., indicated that Esmya could not be approved in its current form, and requested additional information. Although Esmya is in a different class of drugs from relugolix, the review of post-marketing events of liver toxicity for Esmya by regulatory bodies may lead to increased scrutiny regarding liver function for GnRH antagonists. Further, if post marketing adverse events related to Relumina® are reported, it could negatively impact our clinical development plans for relugolix.

If 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, or 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 trials;
- 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 trials;
- we may be required to repeat a nonclinical study or clinical trial or terminate a program, even if other studies or trials 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 relugolix or MVT-602.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable, and 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 full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. 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 by the FDA in the U.S. does not ensure approval by regulatory authorities in any other country or jurisdiction. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future development risks and regulatory difficulties.

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, 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 trials 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. If relugolix or MVT-602 receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

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. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, 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:

- restrictions on the manufacture of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- requirement of a REMS (or equivalent outside the U.S.);
- Warning or Untitled Letters;
- withdrawal of the products from the market;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of relugolix or MVT-602 or any future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Even if one of our product candidates receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if one of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue or become profitable. The degree of market acceptance of a product candidate, if approved for commercial sale, will depend 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 content of the approved product label and our ability to make compelling product claims;
- the effectiveness of sales and marketing efforts;
- the patient out-of-pocket costs in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the willingness of the potential patient population to try new therapies and of physicians to prescribe these therapies;
- the breadth and cost of distribution support;
- the availability of third-party payor coverage and adequate reimbursement;
- whether diagnosis and treatment rates increase for the diseases our products treat; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of relugolix and MVT-602, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of these product candidates to obtain market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, if approved.

To market any product that may be approved, we must build our sales, distribution, marketing, managerial, and other nontechnical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization. We are currently building our sales and marketing infrastructure; however, we currently do not have an established infrastructure for the sales, marketing, or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so.

We expect to build a focused sales, distribution, and marketing infrastructure to market our product candidates in the U.S., if approved. There are significant expenses and risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, generate sufficient sales, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing access teams. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities could delay any product launch, which would adversely impact its commercialization. For example, if the commercial launch of relugolix or MVT-602, if approved, for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train, and retain adequate numbers of qualified and effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain access to adequate numbers of physicians to prescribe any drugs;
- the inability to negotiate with payors regarding reimbursement and formulary access for our products; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

We may not have the resources in the foreseeable future to allocate to the sales, marketing and distribution of our product candidates in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in our products, and such collaborator's ability to successfully market and sell the products. We intend to pursue collaborative arrangements regarding the sales, marketing and distribution of our product candidates, if approved, for certain markets overseas; however, it might be difficult for us to find third parties that are willing to enter into such transactions on acceptable economic terms or at all. We also will be competing with many other companies as we seek sales partners for our product candidates and we may not be able to compete successfully against those other firms. We cannot assure you that we will be able to establish or maintain such collaborative arrangements on terms favorable to us, or even if we are able to do so, that they will have effective sales forces. To the extent that we depend on third parties for sales, marketing and distribution, the financial returns to us will depend on our future collaborators' capabilities. If any such future collaborator terminates its collaboration with us or fails to perform or satisfy its obligations to us, the sales, marketing and distribution of our product candidates would be delayed or may not occur and our business and prospects could be materially and adversely affected.

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

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may not become profitable. We will be competing with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to market any products outside of the U.S., a variety of risks associated with international operations could materially adversely affect our business.

If either relugolix or MVT-602 is approved for marketing outside of the U.S., we may enter into agreements with third parties to market these products in certain jurisdictions. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced or no protection over intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing, and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the United Kingdom Bribery Act 2010, or similar antibribery and anticorruption laws in other jurisdictions as well as various regulations pertaining to data privacy, such as the GDPR;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, and fires.

Also, see the Risk Factor titled “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.” We have no prior experience in these countries, and many biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, 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 payors, patient support channels, 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, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal Civil False Claims Act;
- the federal false claims and civil monetary penalties laws, including the Federal Civil False Claims Act which can be enforced by individuals, on behalf of the government, through civil whistleblower or qui tam actions, prohibits, among other things, individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and

their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses, and certain healthcare providers, known as covered entities, and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;

- a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of health or other personal data that are applicable to or affect our operations;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, as well as state and local laws that require the registration of pharmaceutical sales and medical representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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, individual imprisonment, possible exclusion from participation in Medicare, 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize relugolix or MVT-602 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 relugolix or MVT-602, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in the U.S. in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, or ACA, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the healthcare industry, and impose additional healthcare policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs.

The financial impact of the ACA over the next few years will depend on a number of factors including, but not limited to, the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. The tax legislation enacted on December 22, 2017, titled "an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," or the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment on certain individuals who fail to maintain qualifying health coverage, commonly known as the individual mandate. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated under the ACA. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans. In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent 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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has already begun the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other potential proposals may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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 regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, 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.

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

Market acceptance and sales of any approved product that we develop will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop through approval will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed, and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the U.S. and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, if approved.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on Takeda and its affiliates and other third parties to produce clinical and commercial supplies of relugolix and MVT-602 and any future product candidate.

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While relugolix and MVT-602 were being developed by Takeda, they were also being manufactured by Takeda and third-party CMOs. Takeda has retained rights to further develop and commercialize relugolix in Japan and certain other Asian countries and has announced that it has entered into a licensing agreement granting ASKA Pharmaceutical Co., Ltd. exclusive commercialization rights to relugolix for uterine fibroids and exclusive development and commercialization rights to relugolix for endometriosis, in each indication in Japan. We expect that manufacturing support provided by Takeda will be sufficient for us to complete our ongoing Phase 3 programs for relugolix. Takeda is no longer developing MVT-602. We expect that the MVT-602 drug substance transferred from Takeda to us under the terms of the Takeda License Agreement will be sufficient for our near-term development plans. However, additional process development and manufacturing would be required for us to complete further Phase 2 and 3 clinical studies for MVT-602, which we have not secured. Further, the drug substance transferred from Takeda may not meet our quality standards and may be disqualified from use in our planned clinical programs. Third-party vendors may be difficult to identify for MVT-602 process and formulation development and manufacturing due to special capabilities required and they may not be able to meet our quality standards. Further, we are dependent on third parties to help formulate and manufacture a fixed-dose combination product or a co-packaged product containing relugolix and low-dose estradiol and a progestin. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

Both relugolix and MVT-602 are potent hormonal therapies 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.

We also will rely on Takeda and other third-party manufacturers to supply us with sufficient quantities of relugolix and MVT-602 to be used, if approved, for the commercialization of each product. The facilities used by Takeda and our other contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for the manufacture of drug products. 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 will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- delay or inability to develop a fixed-dose combination of relugolix and low-dose estradiol and a progestin;
- failure of the drug substance transferred from Takeda or our other CMOs to meet our product specifications and quality requirements;
- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations, and standards, including GMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell relugolix monotherapy, a fixed-dose combination product or co-packaging of relugolix and low-dose estradiol and a progestin, or MVT-602, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the 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 trial 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 FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production.

We may not be able to obtain materials or supplies necessary to conduct clinical trials 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 trial needs and to manufacture commercial inventories of our product candidates, if approved. 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 the qualification of a new supplier is required. 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 GMP. Manufacturers are subject to regular, periodic inspections by the regulatory authorities 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. If the manufacturing operations of any single suppliers for any of our products are 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 trials. 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, 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, supervise, and monitor our clinical trials, 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, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. We rely substantially on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, 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 trial sponsors, principal investigators, and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with current GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical trials 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 trials, 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 trials, 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 trials 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 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 patents and 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 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, or 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 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.

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 and commercialization of relugolix, MVT-602, 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 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 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 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 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 product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. 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 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 product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our 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 drugs 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, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the 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 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 or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We 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.

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 expect to rely on third parties to manufacture relugolix, MVT-602, 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 R&D programs that may require us to share trade secrets under the terms of our R&D partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. 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.

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.

Risks Related to Our Common Shares

An active trading market for our common shares may not be sustained.

Although our common shares are listed on the New York Stock Exchange, or NYSE, we cannot assure you that an active trading market for our common shares will continue to be sustained. In addition, as a result of a large proportion of our common shares being held by passive investors (for example, RSL beneficially owning approximately 53.1% of our outstanding common shares as of May 21, 2019, trading in our common shares has been less liquid than the shares of companies with broader public active institutional investor ownership. If an active market for our common shares is not sustained, your ability to trade our shares may be limited. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration.

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 wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment, and ultimate completion of our clinical trials;
- actual or anticipated results of clinical trials of relugolix, MVT-602 or those of our competitors;
- any delay in filing an NDA or similar application for relugolix or MVT-602 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 relugolix, MVT-602 or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to relugolix, MVT-602, or any future product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for relugolix in combination with low-dose estradiol and a progestin, relugolix monotherapy, MVT-602 or any future product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to maintain effective internal control over financial reporting;
- failure to meet or exceed the estimates and projections of the investment 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;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- 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 key scientific or management personnel;
- short sales of our common shares;
- sales of a substantial number of our common shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares;
- sales or purchases of our common shares by our executive officers;
- issuance of additional shares of our common shares, or the perception that such issuances may occur, including through our "at-the-market" offering program;
- negative coverage in the media or analyst reports, whether accurate or not;
- 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 and our business;
- general political, economic, industry, and market conditions;

- effects of natural or man-made catastrophic events; and
- the other factors described in this “Risk Factors” section.

In addition, the 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.

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

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

We are a “controlled company” within the meaning of the applicable rules of the NYSE and, as a result, qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, you will not have the same protections afforded to shareholders of companies that are subject to such requirements.

RSL controls a majority of the voting power of our outstanding common shares. As a result, we are a “controlled company” within the meaning of the NYSE corporate governance requirements. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a “controlled company” and 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.

RSL owns a significant percentage of our common shares and is able to exert significant control over matters subject to shareholder approval.

Based on our common shares outstanding as of May 21, 2019, RSL beneficially owns approximately 53.1% of the voting power of our outstanding common shares and has the ability to substantially influence us through this ownership position. In addition, our board of directors and RSL have approved an amendment and restatement of our Bye-Laws that provides that at anytime that RSL owns between 35% and 50% of our common shares, RSL will have the right to appoint directors constituting a simple majority of our board of directors, which we expect to become effective in late June or early July 2019. As a result, until RSL owns less than 35% of our outstanding common shares. RSL and its shareholders will be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL’s interests may not always coincide with our corporate interests or the interests of other shareholders, and it may act in a manner with which you may not agree or that may not be in the best interests of our other shareholders. Further, RSL is a privately-held company whose ownership and governance structure is not transparent to our other shareholders. There may be changes to the management or ownership of RSL that could impact RSL’s interests in a way that may not coincide with our corporate interests or the interests of other shareholders. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence or effectively control our decisions.

Our organizational and ownership structure may create significant conflicts of interests.

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and minority holders of our common shares, on the one hand, and RSL and its shareholders, on the other hand. Certain of our directors and employees have equity interests in RSL and, accordingly, their interests may be aligned with RSL’s interests, which may not always coincide with our corporate interests or the interests of our other shareholders. Further, our other shareholders may not have visibility into the RSL ownership of any of our directors or officers, which may change at any time through acquisition, disposition, dilution, or otherwise. Any change in our directors’ or officers’ RSL ownership could impact the interests of those holders.

In addition, we are party to certain related party agreements with RSL, RSI, and RSG. These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the minority holders of our common shares. For example, we are party to an option agreement with RSL pursuant to which RSL granted to us an option to acquire the rights to products to which RSL or any nonpublic affiliate of RSL acquires the rights (other than a relugolix product or a competing product) for uterine fibroids or endometriosis, or for which the primary target indication is advanced prostate cancer. It is possible that we could fail to exercise our option with respect to a product candidate under this agreement and that product candidate is then successfully developed and commercialized by RSL or one of its other subsidiaries or affiliates. Any material transaction between us and RSL, RSI, or RSG is subject to our related party transaction

policy, which requires prior approval of such transaction by our Audit Committee. 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.

If securities or industry analysts cease to publish research or reports about our business, or publish negative reports about our business, our share price could decline.

The trading market for our common shares depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates, or one or more of the analysts who covers us downgrades their investment recommendation on our common shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price to decline.

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 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 NovaQuest Securities Purchase Agreement and the Hercules 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.

Future sales of our common shares, or the perception that such sales may occur, including through our "at-the-market" equity offering program, could depress our common share price, even if our business is doing well.

Sales of a substantial number of our common shares in the public market, or the perception by investors that our shareholders intend to sell substantial amounts of our common shares in the public market, could depress the market price of our common shares even if our business is doing well. Such a decrease in our share price could in turn impair our ability to raise capital through the sale of additional equity securities.

All of the common shares sold in our IPO, through our "at-the market" equity offering program and in our 2018 public offering, as well as shares issued upon the exercise of options granted to persons other than our officers and directors and other shares held by our non-affiliated shareholders, are freely transferable without restrictions or further registration under the Securities Act. If our major shareholders, including RSL and Takeda, or any of our executive officers or directors were to sell a substantial portion of our common shares, or if the market perceived that RSL, Takeda or any of our executive officers or directors intends to sell our common shares, it could negatively affect our common share price.

We have filed a registration statement on Form S-8 under the Securities Act to register the common shares that may be issued under our equity incentive plan. In addition, we have filed a registration statement on Form S-3 under the Securities Act to register the offer and sale of up to an aggregate of $300.0 million of our securities, including $100.0 million of our common shares under our "at-the market" equity offering program described below, as well as the resale of up to 49,800 common shares held by Hercules, and in 2018 sold 3,533,399 common shares under this registration statement. Sales of these common shares or the issuance of such securities may have an adverse effect on the trading price of our common shares. In addition, in the future we may issue additional common shares or other securities if we need to raise additional capital. The number of our new common shares issued in connection with raising additional capital could constitute a material portion of our then outstanding common shares and result in dilution to the market price of our common shares.

In April 2018, we entered into an "at-the-market" sales agreement with Cowen and Company, LLC, or Cowen pursuant to which we may sell from time to time, common shares having an aggregate offering price of up to $100.0 million through Cowen, acting as our agent. Through March 31, 2019, we have sold an aggregate of 3,970,129 shares for aggregate net proceeds of $84.1 million pursuant to this "at-the-market" equity offering program. Whether we choose to affect future sales under the "at-the-market" equity offering program will depend on a number of factors, including, among others, market conditions and the trading price of our common shares relative to other sources of capital. The issuance from time to time of common shares through our "at-the-market" equity offering program or in any other equity offering, or the perception that such sales may occur, could have the effect of depressing the market price of our common shares.

We have incurred and will continue to incur substantial and increasing costs as a result of operating as a public company, and our management has been and will be required to continue to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we have incurred and will continue to incur significant legal, accounting, and other expenses and these expenses will continue to increase further as we are no longer considered to be an "emerging growth company" as defined in the Jumpstart Our Business Startup Act of 2012, or the JOBS Act. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE, and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel devote a substantial amount of time to compliance with these requirements. Moreover, changing rules and regulations may increase our legal and accounting compliance costs and make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations, and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. In addition, as a result of the loss of our status as an "emerging growth company," we are now required to include in our annual report an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, which has increased the fees charged by our independent registered public accounting firm.

If we are unable to develop and 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, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of the end of each fiscal year. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, since we are no longer considered to be an "emerging growth company," we are also required to include in our 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, which could negatively impact the value of our common shares. We are also required to disclose significant changes in our internal control over financial reporting on a quarterly basis.

During the evaluation and testing process of our internal control over financial reporting, if we or our independent registered public accounting firm identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective and our independent registered public accounting firm will be required to provide an adverse opinion on the effectiveness of our internal control over financial reporting. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. 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.

We are a Bermuda exempted limited company and it may be difficult for you to enforce judgments against us or our directors and executive officers.

We are a Bermuda exempted limited company. 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, or the Companies Act, which differs in some material respects from laws typically applicable to U.S.

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

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our bye-laws and as permitted by Bermuda law, each shareholder 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 with the need for prior approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on the NYSE or another appointed stock exchange.

Our bye-laws enable our board of directors to issue preference shares, which may discourage a change of control.

Our bye-laws contain provisions that enable our board of directors to determine the powers, preferences, and rights of our preference shares and to issue the preference shares without shareholder approval.

This could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of this provision may adversely affect the prevailing market price of our common shares if it is viewed as discouraging takeover attempts in the future.

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 United Kingdom, and under current U.K. tax law, a company which is centrally managed and controlled in the United Kingdom is regarded as resident in the United Kingdom for taxation purposes. Accordingly, we expect to be subject to U.K. taxation on our income and gains, except where an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the United Kingdom 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 and RSL are incorporated under the laws of Bermuda. We currently have subsidiaries in the United Kingdom, 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 us, RSL, our controlling shareholder, and our subsidiaries. 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 and the availability of any tax holidays could be affected by any reduction of RSL's ownership and control of our company. 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. For example, the Tax Act was enacted in the U.S., which introduced a comprehensive set of tax reforms. Certain impacts of this legislation have been taken into account, including the reduction of the U.S. corporate income tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent. Also, there have been developments in the tax laws of other jurisdictions that are relevant to our operations. 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 the Tax Act, in conjunction with 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 United Kingdom and Switzerland), the U.S., Bermuda, and other jurisdictions, as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation was to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties, and reputational damage, which could adversely affect our business, results of our operations, and our financial condition.

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

U.S. holders that own 10 percent or more of the vote or value of our common shares may suffer adverse tax consequences because we and/or any of our non-U.S. subsidiaries are expected to be characterized as a "controlled foreign corporation," or a CFC, under Section 957(a) of the U.S. Internal Revenue Code of 1986, as amended, or the Code.

A non-U.S. corporation is considered a CFC if more than 50 percent of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by U.S. shareholders (U.S. persons who own stock representing 10% or more of the 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.

As a result of certain changes in the U.S. tax law introduced by the Tax Act, we believe that we and our non-U.S. subsidiaries are classified as CFCs in the current taxable year. For U.S. holders who hold 10% or more of the vote or value of our common shares, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income 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. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the 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 and the impact of the Tax Act, especially the changes to the rules relating to CFCs.

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, or 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.

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. Our status may also depend, in part, on how quickly we utilize the cash proceeds from our IPO and subsequent financings in our business. With respect to the taxable year that ended on March 31, 2019, we believe that we were not a PFIC; however, with respect to the current and 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, we cannot predict whether we will or will not be classified as a PFIC. Our status as a PFIC is a fact-intensive determination made on an annual basis and 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 in the current and future taxable years.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal 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 office space located in Brisbane, California, pursuant to a lease agreement that expires in May of 2026. We have the option to extend the lease term for an additional seven years. 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

In November 2016, we completed our initial public offering, or IPO, and our common shares began trading on the New York Stock Exchange, or NYSE, under the symbol "MYOV" on October 27, 2016. Prior to that date, there was no established public trading market for our common shares.

Shareholders

American Stock Transfer & Trust Company is the transfer agent and registrar for our common shares. As of the close of business on May 21, 2019, we had eight shareholders of record. The actual number of shareholders is greater than this number of record shareholders and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of shareholders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividend Policy

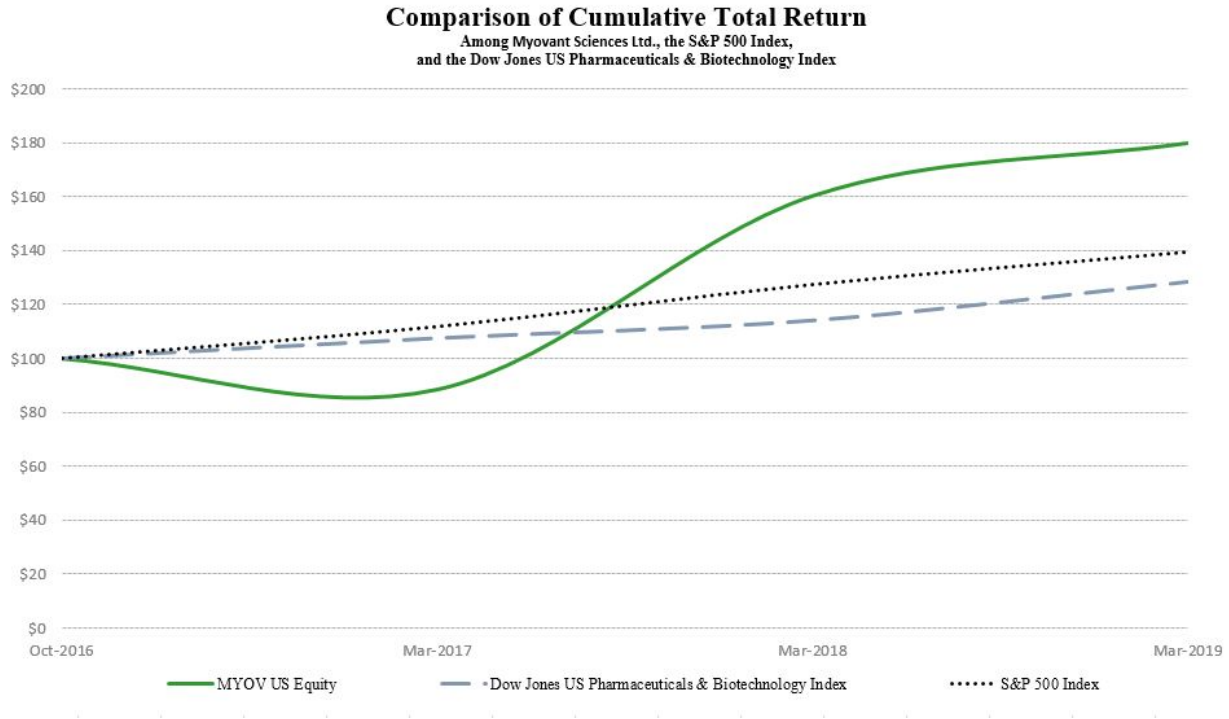
We have never declared or paid cash dividends on our common shares. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Any decision to declare and pay dividends 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. Under our amended and restated bye-laws, each common share is entitled to dividends if, as and when dividends are declared by our board of directors, subject to any preferred dividend right of the holders of any preference shares. Furthermore, our ability to pay cash dividends is currently restricted by the terms of the NovaQuest Capital Management Securities Purchase Agreement and the Hercules Capital, Inc. Loan Agreement.

Share Price Performance Graph

The following graph illustrates a comparison of the total cumulative shareholder return for our common shares since market close on October 27, 2016, the date our common shares began trading on the NYSE, with the cumulative total returns of the Standard & Poor's 500 Index and the Dow Jones U.S. Pharmaceuticals & Biotechnology Index.

The graph assumes an initial investment of $100 in our common shares at the closing price of $13.26 on October 27, 2016 (our initial listing date), and in each of the indexes with relative performance tracked through March 31, 2019, assuming reinvestment of the full amount of all dividends, if any.

Historical shareholder return is not necessarily indicative of the performance to be expected for any future periods.



This performance graph shall not be deemed "soliciting material" or "filed" with the United States Securities and Exchange Commission for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Recent Sales of Unregistered Equity Securities

Not applicable.

Purchases of Equity Securities by the Issuer

None.

Item 6. Selected Financial Data

You should read the following selected consolidated financial data in conjunction with our audited consolidated financial statements and related notes and Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the years ended March 31, 2019, 2018, and 2017 and the selected consolidated balance sheet data as of March 31, 2019 and 2018 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the period from February 2, 2016 (Date of Inception) to March 31, 2016 and the selected consolidated balance sheet data as of March 31, 2017 and 2016 has been derived from our audited consolidated financial statements not included herein. The selected consolidated financial data in this section are not intended to replace our audited consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

	Years Ended March 31,			Period from February 2, 2016 (Date of Inception) to March 31,
	2019	2018	2017	2016
Consolidated Statements of Operations Data	(In thousands, except share and per share data)			
Operating expenses:				
Research and development[(1)]	$ 222,607	$ 116,832	$ 43,500	$ —
General and administrative[(1)]	42,219	24,231	12,357	1,657
Total operating expenses	264,826	141,063	55,857	1,657
Changes in the fair value of the Takeda warrant liability	—	—	27,518	—
Interest expense	8,821	2,046	—	—
Interest income	(881)	—	—	—
Other expense (income), net	309	(67)	139	—
Loss before income taxes	(273,075)	(143,042)	(83,514)	(1,657)
Income tax expense (benefit)	476	213	(74)	—
Net loss	$ (273,551)	$ (143,255)	$ (83,440)	$ (1,657)
Net loss per common share — basic and diluted	$ (4.09)	$ (2.41)	$ (1.70)	$ (0.04)
Weighted average common shares outstanding — basic and diluted	66,910,060	59,520,747	49,184,668	37,231,342

[(1)]Includes the following share-based compensation expenses (in thousands):

Research and development	$ 7,161	$ 3,674	$ 3,893	$ —
General and administrative	$ 11,535	$ 7,909	$ 4,824	$ 987

	March 31,			
	2019	2018	2017	2016
Consolidated Balance Sheet Data	(In thousands)			
Cash and cash equivalents	$ 156,074	$ 108,624	$ 180,838	$ —
Working capital	$ 94,819	$ 77,678	$ 165,827	$ (223)
Total assets	$ 172,977	$ 119,101	$ 185,278	$ —
Long-term liabilities	$ 96,670	$ 44,287	$ 165	$ —
Accumulated deficit	$ (502,025)	$ (228,474)	$ (85,097)	$ (1,657)
Total shareholders' equity (deficit)	$ 4,334	$ 37,729	$ 166,776	$ (223)

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

The following discussion and analysis of our financial condition, results of operations, and cash flows should be read in conjunction with the audited consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K.

Business Overview

We are a clinical-stage healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer. Our lead product candidate is relugolix, an oral once-daily small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist that is currently being evaluated in multiple Phase 3 clinical trials across three distinct indications. We are advancing relugolix 40 mg in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, and relugolix 120 mg as a monotherapy for advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as a part of assisted reproduction. Both relugolix and MVT-602 were licensed to us by Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016. Additional information regarding our business and product candidates is included in Part I. Item 1. "Business" of this Annual Report on Form 10-K.

Since our inception, we have devoted substantially all of our efforts to identifying and in-licensing our product candidates, organizing and staffing our company, raising capital, preparing for and advancing the clinical development of our product candidates and preparing for potential future regulatory approvals and commercialization of relugolix.

On May 14, 2019, we announced that LIBERTY 1, the first of two Phase 3 studies of once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and six key secondary endpoints. We further expect to announce top-line results from four additional Phase 3 clinical trials over the next three quarters.

Fiscal Year Ended March 31, 2019 and Recent Clinical and Business Highlights

The following summarizes our fiscal year ended March 31, 2019 and recent clinical and business highlights:

Relugolix Phase 3 Clinical Programs

- We announced that LIBERTY 1, the first of two Phase 3 studies of once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and six key secondary endpoints. In the primary endpoint analysis, 73.4% of women receiving once daily oral relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). The 24-week study achieved 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. We currently expect data from LIBERTY 2, the replicate Phase 3 study evaluating relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, in the third quarter of calendar 2019, and, provided the LIBERTY 2 study is successful, we plan to submit the New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in the fourth quarter of calendar 2019. We expect to submit data from LIBERTY 1 for presentation and publication in 2019. Refer to Part 1. Item. 1 "Business" for additional information.
- We expect top-line data from the HERO Phase 3 trial evaluating the safety and efficacy of relugolix 120 mg as a monotherapy in men with advanced prostate cancer in the fourth quarter of calendar 2019, and assuming positive data, we expect to submit the NDA to the FDA in early calendar 2020.
- We continue to enroll patients in the two replicate SPIRIT 1 and SPIRIT 2 Phase 3 trials evaluating the safety and efficacy of relugolix combination therapy (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in women with pain associated with endometriosis. We expect to complete enrollment in the SPIRIT 1 and SPIRIT 2 Phase 3 trials later this calendar year, with top-line data expected in the first quarter of calendar 2020.
- In January 2019 Takeda and ASKA Pharmaceutical Co., Ltd. announced that Takeda obtained marketing authorization in Japan 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.

MVT-602 Clinical Program

- We completed our dose-finding pharmacokinetic/pharmacodynamic Phase 2a study of MVT-602, a kisspeptin-1 receptor agonist, in healthy women undergoing a controlled ovarian stimulation protocol. Top-line results are expected to be presented at the European Society of Human Reproduction in Vienna, Austria in June 2019.

Corporate

- We raised aggregate net proceeds of $272.9 million from equity offerings and financing transactions during the year ended March 31, 2019.

Financial History

We have incurred, and expect to continue to incur, significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix. To date, we have not generated any revenue, and we do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for at least one of our product candidates.

We have funded our operations primarily from the issuance and sale of our common shares, from the issuance of notes to NovaQuest Capital Management, or NovaQuest, and from the Term Loans we have with Hercules Capital, Inc., or Hercules. Our sources of funding have primarily consisted of:

- In November 2016, we completed our initial public offering, or IPO, in which we sold 14,500,000 common shares at a price of $15.00 per common share. The net proceeds to us were approximately $200.0 million, after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering costs paid by us.
- In October 2017, we and our subsidiaries, entered into financing arrangements with NovaQuest and Hercules under which we obtained financing commitments of up to $140.0 million. In October 2017, March 2018, and December 2018, we received gross proceeds of $33.0 million, $15.0 million, and $92.0 million, respectively, from these financing arrangements. As of March 31, 2019, these financing arrangements have been fully drawn. Additional information is included in Note 5, “Financing Arrangements,” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.
- In April 2018, we sold to Roivant Sciences Ltd., or RSL, our controlling shareholder, 1,110,015 of our common shares at a purchase price of $20.27 per common share, for gross proceeds of $22.5 million, in a private placement, or the Private Placement.
- In April 2018, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell our 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 acts as our agent. During the fiscal year ended March 31, 2019, we issued and sold 3,970,129 of our common shares under the Sales Agreement. The common shares were sold at a weighted-average-price of $21.91 per common share for aggregate net proceeds to us of approximately $84.1 million, after deducting underwriting commissions and offering costs paid by us. As of March 31, 2019, we had approximately $13.0 million of capacity available to us under our “at-the-market” equity offering program. In April 2019, we issued and sold an additional 106,494 common shares for aggregate net proceeds of $2.5 million pursuant to this program.
- In July and August 2018, we completed an underwritten public equity offering of 3,533,399 of our common shares, which includes 200,065 common shares issued and sold upon the partial exercise of the underwriters’ option to purchase additional shares, at a public offering price of $22.50 per common share. After deducting underwriting discounts and commissions and offering costs paid by us, the net proceeds to us in connection with the underwritten public equity offering, including from the partial option exercise, were approximately $74.4 million.

As of March 31, 2019 and 2018, we had an accumulated deficit of $502.0 million and $228.5 million, respectively. We had net losses of $273.6 million, $143.3 million, and $83.4 million for the years ended March 31, 2019, 2018 and 2017, respectively. As of March 31, 2019, we had $156.1 million of cash and cash equivalents available to us, as compared to $108.6 million of cash and $92.0 million of financing commitments available to us from NovaQuest as of March 31, 2018.

Financial Operations Overview

Revenue

To date, we have not generated any revenue, and we do not expect to generate any revenue, from the sale of any products unless and until we obtain regulatory approval of and commercialize relugolix, MVT-602, or a potential future product candidate.

Research and Development Expenses

Since our inception, our operations have primarily been limited to the in-licensing of the rights to relugolix and MVT-602, the expansion of our team, and the initiation and ongoing activities of our clinical programs. Our research and development, or R&D, expenses include program-specific costs, as well as unallocated costs.

Program-specific costs primarily include:

- third-party costs, which include expenses incurred under agreements with contract research organizations, or CROs, and contract manufacturing organizations, or 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 studies and clinical trials, and other third-party expenses directly attributable to the development of our product candidates.

Unallocated costs primarily include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel for employees engaged in R&D activities;
- costs allocated to us for activities performed by Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG, under the Services Agreements and share-based compensation expense allocated to us from RSL;
- depreciation expenses for assets used in R&D activities; and
- other expenses, which include the costs of consultants who assist with R&D activities not specific to a program.

R&D expenses also include payments made under third-party license agreements. In the year ended March 31, 2017, R&D expenses also included in-process R&D expense related to our acquisition of rights to our product candidates from Takeda.

R&D activities have been, and will continue to be, central to our business model. We expect our R&D expenses to increase in the near term as we continue to support the clinical development of our relugolix and MVT-602 clinical studies, prepare to seek regulatory approval for our product candidates, establish a medical affairs function, and expand our employee base. Product candidates in later stages of clinical development, such as relugolix, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our share-based compensation expense to increase as we continue to increase our number of R&D employees.

We cannot determine with certainty the duration and costs of the current or future clinical trials of our product candidates. The duration, costs and timing of clinical trials and development of relugolix, MVT-602 and any other product candidates will depend on a variety of factors that include, but are not limited to:

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials 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 drugs 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 trial materials; and
- the efficacy and safety profile of the product candidate.

In addition, the probability of success for relugolix, MVT-602 and any other product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. As a result, we are unable to determine with certainty the duration and completion costs of our clinical programs or when and to what extent we will generate revenue from commercialization and sale of any of our product candidates. Our R&D activities may be subject to change from time to time as we evaluate our priorities and available resources.

General and Administrative Expenses

General and administrative, or G&A, expenses consist primarily of personnel costs, including salaries, benefits, share-based compensation and travel expenses for our executive, finance, human resources, legal, commercial operations and other administrative functions. G&A expenses also include expenses incurred under agreements with third parties relating to legal, accounting, auditing and tax services, rent and facilities costs, information technology costs, general overhead, costs billed to us under the Services Agreements, and share-based compensation expense and other costs allocated to us from RSL.

We anticipate that our G&A expenses will increase in future periods as we expand our operations. These increases will likely include costs related to the hiring of additional personnel, costs to implement and upgrade certain information technology systems, professional fees and additional rent and other facilities related costs. In addition, we expect to incur increased costs associated with establishing sales, marketing, and commercialization functions in advance of potential future regulatory approvals and commercialization of our product candidates. If relugolix or MVT-602 obtains regulatory approval for marketing, we expect sales, marketing, and commercialization costs to be significant.

Changes in the Fair Value of the Takeda Warrant Liability

We remeasured the Takeda warrant liability at fair value during each reporting period in which it was outstanding. The Takeda warrant liability expired on April 30, 2017.

Interest Expense

Interest expense consists of interest payments related to our outstanding debt as well as the associated non-cash amortization of debt discount and issuance costs.

Interest Income

Interest income consists of interest earned on money market funds and the accretion of discounts to maturity for commercial paper.

Results of Operations

The following table summarizes our results of operations for the years ended March 31, 2019, 2018 and 2017, respectively (in thousands):

	Years Ended March 31,		
	2019	**2018**	**2017**
Operating expenses:			
Research and development	$ 222,607	$ 116,832	$ 43,500
General and administrative	42,219	24,231	12,357
Total operating expenses	264,826	141,063	55,857
Changes in the fair value of the Takeda warrant liability	—	—	27,518
Interest expense	8,821	2,046	—
Interest income	(881)	—	—
Other expense (income), net	309	(67)	139
Loss before income taxes	(273,075)	(143,042)	(83,514)
Income tax expense (benefit)	476	213	(74)
Net loss	$ (273,551)	$ (143,255)	$ (83,440)

Research and Development Expenses

For the years ended March 31, 2019, 2018 and 2017, our R&D expenses consisted of the following (in thousands):

	Years Ended March 31,		
	2019	2018	Change
Program-specific costs:			
Relugolix	$ 182,602	$ 96,854	$ 85,748
MVT-602	4,919	1,532	3,387
Unallocated costs:			
Share-based compensation	7,161	3,674	3,487
Personnel expense	23,210	12,174	11,036
Services Agreements	748	761	(13)
Other expense	3,967	1,837	2,130
Total R&D expenses	$ 222,607	$ 116,832	$ 105,775

	Years Ended March 31,		
	2018	2017	Change
Program-specific costs:			
Relugolix	$ 96,854	$ 20,830	$ 76,024
MVT-602	1,532	23	1,509
In-process research and development	—	13,117	(13,117)
Unallocated costs:			
Share-based compensation	3,674	3,893	(219)
Personnel expense	12,174	2,420	9,754
Services Agreements	761	1,870	(1,109)
Other expense	1,837	1,347	490
Total R&D expenses	$ 116,832	$ 43,500	$ 73,332

R&D expenses increased by $105.8 million, to $222.6 million, for the year ended March 31, 2019 compared to $116.8 million for the year ended March 31, 2018, primarily due to expenses as a result of the progress of our ongoing Phase 3 clinical trials of relugolix, as well as additional personnel-related expenses and MVT-602 clinical trial expenses. R&D expenses increased by $73.3 million, to $116.8 million, for the year ended March 31, 2018 compared to $43.5 million for the year ended March 31, 2017, primarily due to increases in expenses as a result of the progress of our Phase 3 clinical trials of relugolix, which were initiated in 2017, as well as additional personnel-related expenses and MVT-602 clinical trial expenses, partially offset by a reduction of in-process research and development expenses which did not recur in the year ended March 31, 2018. The components of our R&D expenses in each period are presented in the paragraphs below.

R&D expenses were $222.6 million for the year ended March 31, 2019, and consisted primarily of CRO, clinical drug supply and other study and manufacturing related costs of $186.4 million, personnel expenses of $23.2 million, share-based compensation expense of $7.2 million, of which $0.2 million was allocated to us by RSL, and costs billed to us under the Services Agreements of $2.3 million, including unallocated personnel expenses and third-party pass thru costs associated with our ongoing clinical and other research programs.

R&D expenses were $116.8 million for the year ended March 31, 2018, and consisted primarily of CRO, clinical drug supply and other study-related costs of $94.4 million, personnel expenses of $12.2 million, share-based compensation expense of $3.7 million, of which $0.3 million was allocated to us by RSL, and costs billed to us under the Services Agreements of $4.2 million, including unallocated personnel expenses and third-party pass thru costs associated with our clinical and other research programs.

R&D expenses were $43.5 million for the year ended March 31, 2017, and consisted primarily of in-process R&D expenses of $13.1 million, which were related to our acquisition of the rights to our product candidates from Takeda and consisted of $7.7 million for the estimated fair value of the 5,077,001 common shares issued to Takeda and $5.4 million for the estimated

fair value of the warrant liability. The remainder consisted primarily of costs billed to us under the Services Agreements of $7.4 million, including unallocated personnel expenses and third-party pass thru costs associated with the preparation of our clinical and other research programs, clinical manufacturing costs of $5.6 million, CRO costs of $4.7 million, and share-based compensation expense of $3.9 million, of which $2.2 million was allocated to us by RSL, and personnel expenses of $2.4 million.

General and Administrative Expenses

G&A expenses increased by $18.0 million, to $42.2 million, for the year ended March 31, 2019 compared to $24.2 million for the year ended March 31, 2018. G&A expenses increased by $11.8 million, to $24.2 million for the year ended March 31, 2018 compared to $12.4 million for the year ended March 31, 2017. The increase in both periods primarily reflects increases in personnel-related expenses, share-based compensation, professional service fees, and other general overhead and administrative expenses to support our headcount growth and expanding operations. The components of our G&A expenses in each period are presented in the paragraphs below.

G&A expenses were $42.2 million for the year ended March 31, 2019, and consisted of personnel-related and general overhead expenses of $21.9 million, share-based compensation expenses of $11.5 million, of which $0.4 million was allocated to us by RSL, costs of $2.5 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass thru costs, legal and professional service fees of $4.2 million and rent and other facilities related costs of $2.1 million.

G&A expenses were $24.2 million for the year ended March 31, 2018, and consisted of personnel-related and general overhead expenses of $9.9 million, share-based compensation expense of $7.9 million, including $0.7 million allocated to us by RSL, legal and professional service fees of $2.9 million, and costs of $3.5 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass thru costs.

G&A expenses were $12.4 million for the year ended March 31, 2017, and consisted of share-based compensation expense of $4.8 million, including $2.7 million of which was allocated to us by RSL, legal and professional service fees of $3.1 million, other personnel-related and general overhead expenses of $2.8 million, and costs of $1.7 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass thru costs.

Changes in the Fair Value of the Takeda Warrant Liability

The change in the fair value of the Takeda warrant liability was recorded as zero for the years ended March 31, 2019 and 2018, as the fair value of the Takeda warrant liability was eliminated in connection with its expiration on April 30, 2017.

The change in the fair value of the Takeda warrant liability was recorded as $27.5 million of expense for the year ended March 31, 2017, as the fair value of the Takeda warrant liability decreased to $0.1 million as of March 31, 2017 from $5.4 million at April 29, 2016, the date of issuance of the warrant to Takeda, primarily due to $32.8 million related to the fair value of the warrant exercised during the year ended March 31, 2017, primarily as a result of the issuance of an additional 1,977,269 common shares to Takeda, pursuant to the automatic exercise of the warrant, based upon the sale and issuance of 14,500,000 common shares to investors in the IPO, partially offset by changes in the assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability.

Interest Expense

Interest expense increased by $6.8 million, to $8.8 million for the year ended March 31, 2019, as compared to $2.0 million for the year ended March 31, 2018. The increase was primarily the result of higher outstanding debt balances under our financing arrangements during the year ended March 31, 2019 as compared to the prior year period.

There was no interest expense for the year ended March 31, 2017.

Interest Income

Interest income was $0.9 million for the year ended March 31, 2019. There was no interest income for the years ended March 31, 2018 or 2017. During the year ended March 31, 2019, we invested a portion of our cash in a combination of money market funds and commercial paper. There were no such investments during the years ended March 31, 2018 or 2017.

Income Tax Expense (Benefit)

Our income tax expense (benefit) for the years ended March 31, 2019, 2018 and 2017 was $0.5 million, $0.2 million, and $(0.1) million, respectively. Our effective tax rate for the years ended March 31, 2019, 2018 and 2017 was (0.17)%, (0.15)% and 0.09%, respectively, and is driven by our jurisdictional earnings by location and a valuation allowance that eliminates our global net deferred tax assets.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily from the issuance and sale of our common shares, from the issuance of notes to NovaQuest and the funds received from our Term Loans with Hercules.

As of March 31, 2019, we had $156.1 million of cash and cash equivalents available to us, as compared to $108.6 million of cash and $92.0 million of financing commitments available to us from NovaQuest as of March 31, 2018.

As of March 31, 2019, we had approximately $13.0 million of capacity available to us under our “at-the-market” equity offering program that we established in April 2018. In April 2019, we issued and sold an additional 106,494 common shares for aggregate net proceeds of $2.5 million pursuant to this program.

Capital Requirements

For the years ended March 31, 2019, 2018 and 2017, we had net losses of $273.6 million, $143.3 million, and $83.4 million, respectively. As of March 31, 2019, we had an accumulated deficit of $502.0 million.

We have incurred, and expect to continue to incur, significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix. We have not generated any revenue to date and do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for at least one of our product candidates. Our operating losses and negative cash flows may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials, anticipated regulatory filings, and our expenditures on other R&D and G&A activities. We anticipate that our capital requirements will be significant as we:

- advance our Phase 3 programs of relugolix 40 mg in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis and relugolix 120 mg as a monotherapy for advanced prostate cancer;
- expand our chemistry, manufacturing, and control and other manufacturing related activities;
- seek to identify, acquire, develop, and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand, and protect our intellectual property portfolio;
- hire scientific, clinical, regulatory, quality, and administrative personnel;
- add operational, accounting, finance, quality, commercial, and management information systems and personnel;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a medical affairs group with a medical scientific liaison team;
- establish a sales, marketing, and distribution infrastructure and increase the scale of our external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- service debt obligations and payment of interest associated with the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement; and
- operate as a public company.

Our primary use of cash has been to fund the development of relugolix and MVT-602. We expect our operating expenses to continue to increase over the near term as we expand our operations to continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix. Based on our current operating plan, we expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the first quarter of our fiscal year ending March 31, 2020. 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. These funds will not be sufficient to enable us to complete all necessary development activities and commercially launch relugolix. We anticipate that we will continue to incur net losses for the foreseeable future. To continue as a going concern, we will need, among other things, additional capital resources. We continually assess multiple options to obtain additional funding to support our operations, including through financing activities in public or private capital markets, financing arrangements with Roivant Sciences, potential business development activities and cost containment measures. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Although we believe that we will continue to raise capital to fund our operations as we have in the past, ASC 240-40, *Going Concern*, does not allow us to consider future financing activities that are not probable of being implemented in our assessment of our future cash burn for the purpose of our liquidity assessment. Due to these uncertainties, there is substantial doubt about our ability to continue as a going concern. If we are unable to raise capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back, or discontinue operations.

Until such time, if ever, as we can generate substantial product revenue from sales of relugolix, MVT-602, or any future product candidate, we expect to finance our operations through a combination of cash and cash equivalents on hand, equity offerings, debt financings, structured transactions such as royalty financings, collaboration, license or development agreements, or other collaborations. 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. Our existing agreements with NovaQuest and Hercules involve, 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, making capital expenditures or declaring dividends.

In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table sets forth a summary of our cash flows (in thousands):

	Years Ended March 31,		
	2019	2018	2017
Net cash used in operating activities	$ (224,088)	$ (117,255)	$ (18,215)
Net cash used in investing activities	$ (1,236)	$ (604)	$ (967)
Net cash provided by financing activities	$ 273,899	$ 45,645	$ 200,020

Operating Activities

For the year ended March 31, 2019, we used $224.1 million in operating activities primarily due to our ongoing development and clinical trials for relugolix and MVT-602. This was primarily attributable to a net loss for the period of $273.6 million, increases of $5.1 million in prepaid expenses and other current assets along with a decrease of $1.8 million in amounts due to RSL, RSI and RSG. These amounts were partially offset by increases of $23.3 million in accrued expenses resulting primarily from an increase in accrued R&D expenses due to the progress of our ongoing clinical trials and an increase in accrued compensation-related expenses as a result of an increase in personnel, $6.4 million in accounts payable due to the progress of our ongoing clinical trials and growth of our company, $2.0 million in deferred interest payable related to our outstanding debt with NovaQuest which is paid on a deferred basis pursuant to the terms of the NovaQuest Securities Purchase Agreement, $18.7 million of non-cash share-based compensation expense as a result of an increase in headcount, and $2.5 million of total depreciation and amortization expense.

For the year ended March 31, 2018, we used $117.3 million in operating activities primarily due to our ongoing development and clinical trials for relugolix. This was primarily attributable to a net loss for the period of $143.3 million, increases of $3.1 million in other assets and $1.9 million in prepaid expenses and other current assets along with a decrease of $1.1 million in amounts due to RSL, RSI and RSG. These amounts were partially offset by an increase in accrued expenses of $18.3 million which was primarily due to the progress of our ongoing Phase 3 clinical trials of relugolix, $11.6 million of non-cash share-based compensation expense as a result of an increase in headcount, an increase in accounts payable of $1.2 million and $0.9 million of total depreciation and amortization expense.

For the year ended March 31, 2017, we used $18.2 million in operating activities. The net loss for the period of $83.4 million was partially offset by $13.1 million of non-cash in-process R&D expenses related to the acquisition of the rights to our product candidates, $8.7 million of non-cash share-based compensation expense, $27.5 million of non-cash changes in the fair value of the Takeda warrant liability, $11.8 million increase in accrued expenses, $4.0 million related to the allocation of personnel expenses by RSL and RSI associated with the preparation of our clinical and other research programs, the formation of our company and corporate matters, and $0.1 million of other expenses.

Investing Activities

For the years ended March 31, 2019, 2018, and 2017, $1.2 million, $0.6 million, and $1.0 million was used in investing activities, all for the purchase of property and equipment.

Financing Activities

For the year ended March 31, 2019, financing activities provided $273.9 million of cash. This was primarily due to the net proceeds of $74.4 million we received from the issuance and sale of 3,533,399 common shares in our underwritten public equity offering (including the partial exercise of the underwriters' over-allotment option), $84.1 million we received from the sale of 3,970,129 common shares through our "at-the-market" equity offering program that we established in April 2018, gross proceeds of $22.5 million we received from the issuance and sale of 1,110,015 common shares to RSL in a private placement, net proceeds from debt financings with NovaQuest of $54.0 million, and net proceeds of $38.0 million from the issuance and sale of 2,286,284 common shares to NovaQuest. In addition, we received cash proceeds of $1.3 million from the exercise of stock options under our 2016 Equity Incentive Plan and paid an annual debt administration fee of $0.3 million to NovaQuest under the NovaQuest Securities Purchase Agreement.

For the year ended March 31, 2018, financing activities provided $45.6 million of cash. This was primarily due to the net proceeds we received from debt financings with NovaQuest and Hercules of $43.8 million and net proceeds from the issuance of common shares to NovaQuest of $1.9 million.

For the year ended March 31, 2017, financing activities provided $200.0 million of cash. This was primarily due to the net proceeds from our IPO, which we completed on November 1, 2016.

Contractual Obligations

The following table provides information with respect to our contractual obligations as of March 31, 2019 and the effect such obligations are expected to have on our liquidity and cash flows in future years (in thousands):

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Debt obligations, including interest and end of term charge	$ 141,346	$ 13,274	$ 85,167	$ 42,905	$ —
Operating lease obligations	16,045	2,006	4,193	4,539	5,307
Total	$ 157,391	$ 15,280	$ 89,360	$ 47,444	$ 5,307

Debt Obligations

Debt obligations reflect our obligations to pay interest on the outstanding principal amount as of March 31, 2019 of $40.0 million under the Hercules Loan Agreement and that of $60.0 million under the NovaQuest Securities Purchase Agreement, respectively, and to make periodic principal repayments, along with an end of term charge of 6.55% of the principal amount at maturity under the Hercules Loan Agreement. Our debt obligation under the Hercules Loan Agreement bears interest at a prime-based variable rate. The related interest on the aggregate principal amounts outstanding to Hercules included in the above table was estimated using the interest rate in effect as of March 31, 2019. See Note 5, “Financing Arrangements,” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further discussion of the Hercules Loan Agreement and NovaQuest Securities Purchase Agreement.

Operating Lease Obligations

Operating lease obligations include future rent payments under an office lease in Brisbane, California, pursuant to a lease agreement (as amended) which expires in May of 2026. We lease 40,232 square feet of office space pursuant to this lease agreement. We have the option to extend the lease term for an additional seven years. The minimum lease payments included in the table above do not include any related common area maintenance charges or real estate taxes. In addition, the lease obligations included in the table above do not include potential rent payments during the optional lease renewal term.

Contract Service Providers

In the course of normal business operations, we enter into agreements with contract service providers to assist in the performance of our R&D activities. Expenditures for CROs and CMOs represent significant clinical development costs. Subject to required notice periods and our obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. These cancelable contracts are not included in the table above. We could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

License Agreement with Takeda

In connection with the Takeda License Agreement, we may be required to pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in our territory. We cannot, at this time, determine when or if royalty payments will be required or what the total amount of such payments may be. Therefore, such payments are not included in the table above. See Note 3, “License Agreement,” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further discussion of the Takeda License Agreement.

Commercial Manufacturing and Supply Agreement with Takeda

In May 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement. Pursuant to the Takeda Commercial Supply Agreement, Takeda has agreed to supply us and we have agreed to obtain from Takeda certain quantities of relugolix drug substance according to agreed-upon quality specifications and in order to commercialize relugolix in accordance with the Takeda Agreement. Under the Takeda Commercial Supply Agreement, we will pay Takeda a fixed price per kilogram of relugolix drug substance through December 31, 2019. We have made and Takeda has accepted an initial firm order to supply relugolix drug substance to us through December 31, 2019. For relugolix drug substance manufactured or delivered on or after such date, 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.

In addition, under the Takeda Commercial Supply Agreement, Takeda has agreed to assist with the transfer of technology and Takeda manufacturing know-how to a second contract manufacturing organization of our subsidiary, Myovant Sciences GmbH. We have agreed to reimburse Takeda for all internal costs, and external costs, charges, and expenses, in each case, reasonably incurred by Takeda in connection with any technology transfer services.

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 automatically renews 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, including the initial firm order for relugolix drug substance through December 31, 2019, will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase order thereunder, will terminate immediately upon the termination of the Takeda 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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the dates of the consolidated financial statements and the reported amounts of expenses incurred during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used in the evaluation of our ability to continue as a going concern, the determination of some of our costs incurred under the Services Agreements, which costs are charged to R&D and G&A expenses, as well as assumptions used to estimate the fair value of common share and option awards. We base our estimates on historical experience and on various other information available to us at the time we make the estimates and judgments that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are inherently uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles.

Our significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies," to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and judgments that we believe are "critical accounting estimates." We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates and judgments relating to share-based compensation, R&D expenses and accruals, income taxes and estimating the fair value of the Takeda warrant liability which expired in April 2017 have the greatest potential impact on our consolidated financial statements. We consider these to be our critical accounting policies and estimates.

Share-Based Compensation

We value share-based payment awards to employees and directors at fair value on the date of grant and we recognize that fair value 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 expense as though all awards are expected to vest. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model, which requires the use of highly subjective assumptions. These assumptions include:

- *Expected Term.* The expected term represents the period that our share-based payment awards are expected to be outstanding and is determined using the simplified method in accordance with the Securities and Exchange

Commission, or SEC, Staff Accounting Bulletin, or SAB, No. 107 and No. 110 (based on the mid-point between the vesting date and the end of the contractual term).

- *Expected Volatility.* Because we did not have an extended trading history for our common shares, the expected volatility was estimated using weighted average measures of implied volatility and the historical volatility of a peer group of companies for a period equal to the expected life of the stock options. Our 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 interest rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of 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 expense associated with time-vesting restricted share awards and restricted stock units 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 the share-based compensation expense related to these awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We estimate share-based compensation expense associated with restricted share awards subject to market conditions on the grant date using a Monte Carlo valuation model. We recognize the resulting fair value as share-based compensation expense ratably over the derived service period regardless of whether the market conditions are satisfied.

RSL restricted stock units granted to our Principal Executive Officer vest upon the achievement of both a performance and market condition, if both are achieved by the contractual expiration date and the Principal Executive Officer has remained in continuous service with RSL or any of its subsidiaries. We will recognize share-based compensation expense related to this award upon the achievement of the performance and market conditions throughout the requisite service period.

Share-based payment awards granted by RSL to RSL, RSI, RSG and our employees are valued by RSL at fair value on the date of grant and that fair value is recognized as share-based compensation expense over the requisite service period. Significant judgment and estimates were used by RSL to estimate the fair value of these awards, as they are not publicly traded. RSL share-based payment awards are subject to specified vesting schedules and requirements (a mix of time-based and performance-based events). The fair value is based on various corporate event-based considerations, including targets for RSL's post-IPO market capitalization and future financing events. The fair value of each RSL option is estimated on the date of grant using the Black-Scholes closed-form option-pricing model. Share-based compensation expense has been and will continue to be allocated to us over the requisite service period over which these RSL share-based payment awards are expected to vest and based on the relative percentage of time utilized by RSL, RSI and RSG employees on our matters.

No tax benefits for share-based compensation has been recognized in the consolidated statements of shareholders' equity (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.

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 trial and clinical manufacturing activities on our behalf, and are expensed as incurred unless there is an alternative future use in other R&D projects. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as R&D.

Our accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial 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 trial 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, expense accruals related to clinical trials and other R&D activities are recognized 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 trial, we adjust our rate of clinical trial expense recognition if actual results differ from our estimates. We make estimates of our clinical trial 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.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that our deferred tax assets will be realizable.

When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. When and if we were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in income tax expense.

Takeda Warrant Liability

We remeasured the Takeda warrant liability at fair value during each reporting period in which it was outstanding based on significant inputs not observable in the market, which caused it to be classified as a Level 3 financial instrument within the fair value hierarchy. The valuation of the Takeda warrant liability used assumptions and estimates we believed would be made by a market participant in making the same valuation. We assessed these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates were obtained. Changes in the fair value of the Takeda warrant liability related to updated assumptions and estimates were recognized in the consolidated statements of operations and comprehensive loss. The Takeda warrant expired on April 30, 2017.

Recent Accounting Pronouncements

For information regarding recently issued accounting pronouncements and the expected impact on our consolidated financial statements, see Note 2, “Summary of Significant Accounting Policies,” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments.

Our investment policy establishes guidelines for the investment of surplus cash in a conservative and diversified investment portfolio which seeks to provide adequate liquidity for our operations while minimizing the loss of any principal. The securities permitted under our investment policy may be subject to market risk related to changes in interest rates and other market factors. We manage our sensitivity to these risks by investing in short-term, investment grade marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we do not believe that a hypothetical 10% change in market rates would have a material impact on the realized value of our investments. As of March 31, 2019, we had cash and cash equivalents of $156.1 million, consisting of commercial paper, money market funds, and non-interest-bearing cash deposits denominated in the U.S. dollar and Swiss franc. As of March 31, 2018, we had cash of $108.6 million, consisting of non-interest bearing cash deposits denominated in the U.S. dollar and Swiss franc.

We also have certain debt that bears interest at a prime-based variable rate. A hypothetical 10% change in this interest rate would have an approximate $0.4 million impact on our annual interest expense. We do not believe we are currently exposed to any material market risk.

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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, shareholders' equity (deficit) and cash flows for each of the three years in the period ended March 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2019, 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, 2019, 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 24, 2019 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has an accumulated deficit, has incurred recurring losses and used significant cash flows in operations, expects continuing future losses and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Iselin, New Jersey

May 24, 2019

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, 2019, 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, 2019, 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, 2019 and 2018, and the related consolidated statements of operations, comprehensive loss, shareholders' equity (deficit) and cash flows for each of the three years in the period ended March 31, 2019, and the related notes and our report dated May 24, 2019 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

Iselin, New Jersey
May 24, 2019

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

	March 31, 2019	March 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 156,074	$ 108,624
Prepaid expenses and other current assets	10,194	5,139
Income tax receivable	524	1,000
Total current assets	166,792	114,763
Property and equipment, net	2,071	1,273
Other assets	4,114	3,065
Total assets	$ 172,977	$ 119,101
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 11,019	$ 4,578
Interest payable	1,077	282
Accrued expenses	53,614	30,265
Due to RSL, RSI and RSG	121	1,960
Current maturities of long-term debt	6,142	—
Total current liabilities	71,973	37,085
Deferred rent	1,157	408
Deferred interest payable	2,273	255
Long-term debt, less current maturities	93,240	43,624
Total liabilities	168,643	81,372
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized,72,057,490 and 60,997,856 issued and outstanding at March 31, 2019 and 2018, respectively	1	1
Additional paid-in capital	505,851	266,178
Accumulated other comprehensive income	507	24
Accumulated deficit	(502,025)	(228,474)
Total shareholders' equity	4,334	37,729
Total liabilities and shareholders' equity	$ 172,977	$ 119,101

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)

	Years Ended March 31,		
	2019	2018	2017
Operating expenses:			
Research and development[1]	$ 222,607	$ 116,832	$ 43,500
General and administrative[2]	42,219	24,231	12,357
Total operating expenses	264,826	141,063	55,857
Changes in the fair value of the Takeda warrant liability	—	—	27,518
Interest expense	8,821	2,046	—
Interest income	(881)	—	—
Other expense (income), net	309	(67)	139
Loss before income taxes	(273,075)	(143,042)	(83,514)
Income tax expense (benefit)	476	213	(74)
Net loss	$ (273,551)	$ (143,255)	$ (83,440)
Net loss per common share — basic and diluted	$ (4.09)	$ (2.41)	$ (1.70)
Weighted average common shares outstanding — basic and diluted	66,910,060	59,520,747	49,184,668

[1] Includes $2,575, $4,537 and $9,669 of costs allocated from RSL, RSI, and RSG during the years ended March 31, 2019, 2018 and 2017, respectively. Also includes share-based compensation expense (see Note 9).

[2] Includes $2,873, $4,182 and $4,409 of costs allocated from RSL, RSI, and RSG during the years ended March 31, 2019, 2018 and 2017, respectively. Also includes share-based compensation expense (see Note 9).

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

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

	Years Ended March 31,		
	2019	**2018**	**2017**
Net loss	$ (273,551)	$ (143,255)	$ (83,440)
Other comprehensive income (loss):			
Foreign currency translation adjustment	483	(116)	140
Total other comprehensive income (loss)	483	(116)	140
Comprehensive loss	$ (273,068)	$ (143,371)	$ (83,300)

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

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

	Common Shares		Common Shares Subscribed	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount					
Balance at March 31, 2016	37,231,342	$ 1	$ (1)	$ 1,434	$ —	$ (1,657)	$ (223)
Sale of common shares in initial public offering, net of discounts, commissions and offering costs of $17,536	14,500,000	—	—	199,964	—	—	199,964
Shares issued to Takeda under the Takeda license agreement	5,077,001	—	—	7,740	—	—	7,740
Shares issued to settle the Takeda warrant liability	2,339,192	—	—	32,843	—	—	32,843
Share-based compensation expense	1,128,222	—	—	3,775	—	—	3,775
Capital contribution — share-based compensation	—	—	—	4,942	—	—	4,942
Capital contribution	—	—	—	1,035	—	—	1,035
Foreign currency translation adjustment	—	—	—	—	140	—	140
Net loss	—	—	—	—	—	(83,440)	(83,440)
Balance at March 31, 2017	60,275,757	$ 1	$ (1)	$ 251,733	$ 140	$ (85,097)	$ 166,776
Adjustment to adopt ASU 2016-09	—	—	—	122	—	(122)	—
Shares issued to settle the Takeda warrant liability	4,432	—	—	58	—	—	58
Share-based compensation expense	564,111	—	—	10,587	—	—	10,587
Capital contribution — share-based compensation	—	—	—	996	—	—	996
Foreign currency translation adjustment	—	—	—	—	(116)	—	(116)
Stock option exercises	15,195	—	—	36	—	—	36
Shares issued to NovaQuest, net of issuance costs of $624	138,361	—	—	1,857	—	—	1,857
Warrants issued with debt financing	—	—	—	789	—	—	789
Settlement of RSL common shares subscribed	—	—	1	—	—	—	1
Net loss	—	—	—	—	—	(143,255)	(143,255)
Balance at March 31, 2018	60,997,856	$ 1	$ —	$ 266,178	$ 24	$ (228,474)	$ 37,729
Issuance of shares in connection with "at-the-market" equity offering, net of commissions and offering costs of $2,919	3,970,129	—	—	84,052	—	—	84,052
Issuance of shares in connection with Private Placement with RSL	1,110,015	—	—	22,500	—	—	22,500
Share-based compensation expense	—	—	—	18,067	—	—	18,067
Capital contribution — share-based compensation	—	—	—	629	—	—	629
Capital contribution from RSI and RSG	—	—	—	752	—	—	752

Foreign currency translation adjustment	—	—	—	—	483	—	483
Issuance of shares in public equity offering, net of commissions and offering costs of $5,110	3,533,399	—	—	74,391	—	—	74,391
Shares issued to NovaQuest, net of issuance costs	2,286,284	—	—	37,982	—	—	37,982
Issuance of shares upon exercise of stock options and vesting of RSUs	159,807	—	—	1,300	—	—	1,300
Net loss	—	—	—	—	—	(273,551)	(273,551)
Balance at March 31, 2019	72,057,490	$ 1	$ —	$ 505,851	$ 507	$ (502,025)	$ 4,334

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

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

	Years Ended March 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (273,551)	$ (143,255)	$ (83,440)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	18,696	11,583	8,717
Depreciation	438	243	61
Amortization of debt discount and issuance costs	2,084	662	—
Acquisition of in-process research and development	—	—	13,117
Changes in the fair value of the Takeda warrant liability	—	—	27,518
Others	1,235	(116)	140
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(5,055)	(1,918)	(3,221)
Deferred tax assets	—	208	(208)
Income tax receivable	476	(895)	(105)
Other assets	76	(3,065)	—
Accounts payable	6,441	1,249	3,329
Interest payable	795	282	—
Accrued expenses	23,349	18,287	11,755
Due to RSL, RSI and RSG	(1,839)	(1,070)	4,009
Deferred rent	749	295	113
Deferred interest payable	2,018	255	—
Net cash used in operating activities	(224,088)	(117,255)	(18,215)
Cash flows from investing activities:			
Purchase of property and equipment	(1,236)	(604)	(967)
Net cash used in investing activities	(1,236)	(604)	(967)
Cash flows from financing activities:			
Cash proceeds from issuance of common shares in initial public offering, net of underwriting discount	—	—	202,275
Initial public offering costs paid	—	—	(2,311)
Cash proceeds from issuance of common shares in public equity offering, net of issuance costs paid	74,391	—	—
Cash proceeds from issuance of common shares in "at-the-market" equity offering, net of issuance costs paid	84,052	—	—
Cash proceeds from issuance of common shares in Private Placement with RSL	22,500	—	—
Cash proceeds from debt financings, net of financing costs paid	53,974	43,751	—
Cash proceeds from issuance of common shares to NovaQuest, net of issuance costs paid	37,982	1,857	—
Cash capital contribution from RSL	—	—	1,035
Settlement of RSL common shares subscribed	—	1	—
Cash proceeds from stock option exercises	1,300	36	—
Cash paid to NovaQuest for annual debt administration fee	(300)	—	—
Due to RSL and RSI for amounts paid on behalf of the Company	—	—	(979)
Net cash provided by financing activities	273,899	45,645	200,020
Net change in cash, cash equivalents and restricted cash	48,575	(72,214)	180,838
Cash, cash equivalents and restricted cash, beginning of period	108,624	180,838	—
Cash, cash equivalents and restricted cash, end of period	$ 157,199	$ 108,624	$ 180,838
Non-cash investing and financing activities:			
Acquisition of in-process research and development	$ —	$ —	$ 13,117
Warrants issued to Hercules	$ —	$ 789	$ —
Supplemental disclosure of cash paid:			
Income taxes	$ —	$ 900	$ 240
Interest	$ 3,923	$ 845	$ —

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

MYOVANT SCIENCES LTD.
Notes to Consolidated Financial Statements

Note 1—Description of Business

Myovant Sciences Ltd. (or together with its wholly owned subsidiaries, the Company) is a clinical-stage healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer. The Company is developing relugolix 40 mg in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, relugolix 120 mg as a monotherapy for advanced prostate cancer, and an additional product candidate, MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as part of assisted reproduction. Both relugolix and MVT-602 were licensed to the Company by Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016.

The Company is an exempted company limited by shares incorporated under the laws of Bermuda in February 2016 under the name Roivant Endocrinology Ltd. The Company changed its name to Myovant Sciences Ltd. in May 2016. Since its inception, the Company has devoted substantially all of its efforts to identifying and in-licensing its product candidates, organizing and staffing the Company, raising capital, preparing for and advancing the clinical development of its product candidates, and preparing for potential future regulatory approvals and commercialization of relugolix.

The Company has incurred, and expects to continue to incur, significant operating losses and negative cash flows as it continues to develop its product candidates and prepares for potential future regulatory approvals and commercialization of relugolix. To date, the Company has not generated any revenue, and it does not expect to generate revenue unless and until it successfully completes development and obtains regulatory approval for at least one of its product candidates. See Note 2(C), "Summary of Significant Accounting Policies—Going Concern and Management's Plans."

On May 14, 2019, the Company announced that LIBERTY 1, the first of two Phase 3 studies of once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and six key secondary endpoints. The Company further expects to announce top-line results from four additional Phase 3 clinical trials over the next three quarters.

Note 2—Summary of Significant Accounting Policies

(A) 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 has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

The accompanying consolidated financial statements have been prepared in accordance with United States, or U.S., generally accepted accounting principles, or 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, or ASC, and Accounting Standards Update, or ASU, issued by the Financial Accounting Standards Board, or FASB. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

(B) Use of Estimates:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, and expenses, including the evaluation of the Company's ability to continue as a going concern, compensation and other expenses allocated to the Company under its services agreements with Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG, each a wholly owned subsidiary of the Company's controlling shareholder, Roivant Sciences Ltd., or RSL, as well as share-based compensation expenses, research and development, or R&D, expenses and accruals, and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses incurred during the reporting period, that are not readily apparent from other sources. Actual results could differ from those estimates.

(C) Going Concern and Management's Plans:

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements

are issued. During the year ended March 31, 2019, the Company incurred net losses of $273.6 million and used $224.1 million of cash and cash equivalents in operations. The Company expects to continue to incur significant and increasing operating losses and negative cash flows as it continues to develop its product candidates and prepares for potential future regulatory approvals and commercialization of relugolix. The Company has not generated any revenue to date and does not expect to generate product revenue unless and until it successfully completes development and obtains regulatory approval for at least one of its product candidates. Based on its current operating plan, the Company expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements through at least the first quarter of its fiscal year ending March 31, 2020. This estimate is based on the Company's current assumptions, including assumptions relating to its ability to manage its spend, that might prove to be wrong, and it could use its available capital resources sooner than it currently expects. These funds will not be sufficient to enable the Company to complete all necessary development activities and commercially launch relugolix. The Company anticipates that it will continue to incur net losses for the foreseeable future.

To continue as a going concern, the Company will need, among other things, additional capital resources. The Company continually assesses multiple options to obtain additional funding to support its operations, including through financing activities in public or private capital markets, financing arrangements with Roivant Sciences, structured transactions such as royalty financings, collaborations, license or development agreements, or other collaborations and cost containment measures. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all. Although the Company believes that it will continue to raise capital to fund its operations as it has in the past, ASC 240-40, *Going Concern*, does not allow the Company to consider future financing activities that are not probable of being implemented in its assessment of the Company's future cash burn for the purpose of its liquidity assessment.

Due to these uncertainties, there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements and footnotes have been prepared on the basis that the Company will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

(D) Risks and Uncertainties:

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, risks of failure or unsatisfactory results of nonclinical studies and clinical trials, the need to obtain additional financing to fund the future development of its product candidates, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of 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, or CROs, and contract manufacturing organizations, or CMOs.

(E) Concentrations of Credit Risk:

Financial instruments that potentially subject the Company to concentrations of credit risk include cash and cash equivalents consisting of money market funds and commercial paper. As of March 31, 2019, cash and cash equivalent balances are diversified between three financial institutions. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and the issuers of its money market funds and commercial paper. 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 experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

(F) Cash, Cash Equivalents, and Restricted Cash:

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash. The Company considers all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. Interest income consists of interest earned on money market funds and the accretion of discounts to maturity for commercial paper.

Restricted cash consists of non-interest bearing legally restricted deposits held as compensating balances against the Company's corporate credit card program and an irrevocable standby letter of credit provided as security for the Company's office lease. Cash as reported in the consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash, and consists of the following (in thousands):

	March 31,		
	2019	2018	2017
Cash and cash equivalents	$ 156,074	$ 108,624	$ 180,838
Restricted cash[(1)]	1,125	—	—
Total cash, cash equivalents and restricted cash	$ 157,199	$ 108,624	$ 180,838

[(1)] Included in other assets on the consolidated balance sheets.

(G) Property and Equipment, net:

Property and equipment, net consisting of computers, equipment, furniture and fixtures, leasehold improvements, and software, is recorded at cost, less accumulated depreciation. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is recorded for property and equipment using the straight-line method over the estimated useful lives of the assets, which range from three to seven years once the asset is installed and placed into service. Leasehold improvements are amortized using the straight-line method over their estimated useful life or the remaining lease term, whichever is shorter.

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.

(H) Operating Leases:

At the inception of a lease, the Company evaluates the lease agreement to determine whether the lease is an operating or capital lease. For operating leases, the Company recognizes rent expense on a straight-line basis over the lease term and records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Where lease agreements contain rent escalation clauses, rent abatements and/or concessions, such as rent holidays and tenant improvement allowances, the Company applies them in the determination of straight-line rent expense over the lease term.

Certain lease agreements also require the Company to make additional payments for taxes, insurance, and other operating expenses incurred during the lease period, which are expensed as incurred.

(I) Debt Issuance Costs and Debt Discount:

Debt issuance costs include the costs of debt financings undertaken by the Company, including legal fees, accounting fees, and other direct costs of the financing. Debt issuance costs related to a recognized debt liability are presented on the consolidated balance sheet as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts, and are amortized to interest expense over the term of the related debt using the effective interest method. Further, debt discounts created as a result of the allocation of proceeds received from a debt issuance to warrants issued in conjunction with the debt issuance are amortized to interest expense under the effective interest method over the life of the recognized debt liability.

(J) Contingencies:

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the FASB on accounting for contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum amount in the range. In the cases where the Company believes that a material reasonably possible loss exists, the Company discloses the facts and circumstances of the contingency, including an estimable range, if possible.

(K) Research and Development Expenses:

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. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. R&D expenses primarily consist of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for employees engaged in R&D activities, payments made under third party license agreements, certain costs allocated to the Company for activities performed by RSI and RSG under services agreements with the Company, as well as

allocated share-based compensation expense from RSL, and expenses from third parties who conduct R&D activities on behalf of the Company. 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.

(L) Share-Based Compensation:

Share-based awards to employees and directors are valued at fair value on the date of grant and that fair value is recognized 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 expense as though all awards are expected to vest. The Company estimates the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model, which requires the use of highly 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, or SEC, Staff Accounting Bulletin, or SAB, No. 107 and No. 110 (based on the mid-point between the vesting date and the end of the contractual term).
- *Expected Volatility.* Because the Company did not have an extended trading history for its common shares, the expected volatility was estimated using weighted average measures of implied volatility and the historical volatility of a peer group of companies for a period equal to the expected life 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 interest rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the stock options.
- *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.

Share-based compensation expense associated with time-vesting restricted share awards and restricted stock units 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 expense related to these awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

Share-based compensation expense associated with restricted share awards subject to market conditions is estimated on the grant date using a Monte Carlo valuation model. The resulting fair value is recognized as share-based compensation expense ratably over the derived service period regardless of whether the market conditions are satisfied.

RSL restricted stock units granted to the Company's Principal Executive Officer vest upon the achievement of both a performance and market condition, if both are achieved by the contractual expiration date and the Principal Executive Officer has remained in continuous service with RSL or any of its subsidiaries. The Company will recognize share-based compensation expense related to this award upon the achievement of the performance and market conditions throughout the requisite service period.

Share-based payment awards granted by RSL to RSL, RSI, RSG and the Company's employees are valued by RSL at fair value on the date of grant and that fair value is recognized as share-based compensation expense over the requisite service period. Significant judgment and estimates were used by RSL to estimate the fair value of these awards, as they are not publicly traded. RSL share-based payment awards are subject to specified vesting schedules and requirements (a mix of time-based and performance-based events). The fair value is based on various corporate event-based considerations, including targets for RSL's post-IPO market capitalization and future financing events. The fair value of each RSL option is estimated on the date of grant using the Black-Scholes closed-form option-pricing model. Share-based compensation expense has been and will continue to be allocated to the Company over the requisite service period over which these RSL share-based payment awards are expected to vest and based on the relative percentage of time utilized by RSL, RSI and RSG employees on the Company's matters.

No tax benefits for share-based compensation has been recognized in the consolidated statements of shareholders' equity (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.

(M) Takeda Warrant Liability:

The Company recorded the Takeda warrant liability at its estimated fair value in the consolidated balance sheets. The Company remeasured the estimated fair value of the Takeda warrant liability each reporting period in which it was outstanding and

recorded the change in the fair value in the consolidated statements of operations and comprehensive loss. The Takeda warrant liability expired on April 30, 2017.

(N) Income Taxes:

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that the Company's deferred tax assets will be realizable.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. Interest and/or penalties related to income tax matters are recognized as a component of income tax expense as incurred.

(O) Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common shareholders by the weighted-average number of common shares outstanding during the period, reduced, where applicable, for outstanding yet unvested shares of restricted common stock. The computation of diluted net loss per common share is based on the weighted-average number of common shares outstanding during the period plus, when their effect is dilutive, incremental shares consisting of shares subject to stock options, restricted stock units, restricted share awards, and warrants. In periods in which the Company reports a net loss, all common share equivalents are deemed anti-dilutive such that basic net loss per common share and diluted net loss per common share are equal. Potentially dilutive common shares have been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net loss. There are no reconciling items used to calculate the weighted-average number of total shares outstanding for basic and diluted net loss per common share.

As of March 31, 2019, 2018 and 2017, potentially dilutive securities were as follows:

	March 31,		
	2019	2018	2017
Stock options	5,396,465	3,549,405	1,525,857
Restricted share awards (unvested)	916,679	1,198,735	1,128,222
Restricted stock units (unvested)	39,387	15,000	—
Warrants	73,710	73,710	—
Total	6,426,241	4,836,850	2,654,079

(P) Fair Value Measurements:

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

Fair value is defined as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the reporting date. As a basis for considering market participant assumptions in fair value measurements, the guidance establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.

- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

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

The Company's financial instruments include cash, cash equivalents consisting of commercial paper and money market funds, accounts payable and debt. Cash, cash equivalents, and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. The carrying value of the Company's debt approximates fair value based on current interest rates for similar types of borrowings and is included in Level 2 of the fair value hierarchy.

(Q) Foreign Currency:

The results of the Company's non-U.S. dollar based functional currency operations are translated to U.S. dollars at the average exchange rates during the period. The Company's assets and liabilities are translated using the current exchange rate as of the balance sheet date and shareholders' equity (deficit) is translated using historical rates. Adjustments resulting from the translation of the financial statements of the Company's foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of shareholders' equity (deficit). Foreign currency exchange transaction gains and losses are included in other expense (income), net in the Company's consolidated statements of operations.

(R) Recently Adopted Accounting Standards:

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows* (Topic 230): *Restricted Cash (a consensus of the FASB Emerging Issues Task Force*, or ASU 2016-18. The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for annual reporting periods beginning after December 15, 2017 and is required to be adopted using a retrospective approach, if applicable, with early adoption permitted. The Company adopted ASU 2016-18 on April 1, 2018. The adoption of ASU 2016-18 did not have a material impact on the Company's consolidated financial statements and related disclosures.

In March 2018, the FASB issued ASU 2018-05, *Income Taxes* (Topic 740): *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* (SAB No. 118), or ASU 2018-05. ASU 2018-05 adds various SEC paragraphs pursuant to the issuance of the December 2017 SEC Staff Accounting Bulletin (SAB) No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act*, which was effective immediately. The SEC issued SAB No. 118 to address concerns about reporting entities' ability to comply timely with the accounting requirements to recognize the effects of the Tax Cuts and Jobs Act in the period of enactment. SAB No. 118 allows disclosure that timely determination of some or all of the income tax effects from the Tax Cuts and Jobs Act are incomplete by the due date of the financial statements and if possible to provide a reasonable estimate. As permitted by SAB No. 118, the Company recorded provisional amounts in the year ended March 31, 2018 and finalized its accounting for these provisional estimates based on guidance, interpretations and all available data in the year ended March 31, 2019. No material adjustments were made to the provisional amounts.

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, or ASU 2016-16. ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets, other than inventory, to be recognized when the transfer occurs. The new standard was effective for the Company on April 1, 2018 and was adopted using a modified retrospective approach. The adoption of this standard resulted in the recognition of a deferred tax asset of $38.7 million with a corresponding valuation allowance of $38.7 million.

(S) Recently Issued Accounting Standards Not Yet Adopted:

(1) Leases:

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. Topic 842 was subsequently amended by ASU 2018-01, *Land Easement Practical Expedient for Transition to Topic 842*; ASU 2018-10, *Codification Improvements to Topic 842, Leases*; and ASU 2018-11, *Targeted Improvements*. The core principle of Topic 842 will require lessees to recognize on the consolidated balance sheets a liability to make lease payments and a right-of-use, or ROU, asset representing its right to use the underlying asset for the lease term for both finance and operating leases with lease terms greater than twelve months. The lease liability will be measured at the present value of the unpaid lease payments and the ROU asset will be derived from the calculation of the lease liability. Lease payments will include fixed and in-substance fixed payments, variable payments based on an index or rate, exercise price of purchase options that are reasonably certain to be exercised, termination penalties, and

probable amounts the lessee will owe under a residual value guarantee. Topic 842 also requires lessees to disclose key information about leasing arrangements. Topic 842 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted.

A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application ("Transition Date"). An entity may choose to use either (i) its effective date or (ii) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company plans to adopt the new standard on April 1, 2019 and use the effective date as its date of initial application.

The new standard provides a number of optional practical expedients in transition. The Company expects to elect the "package of practical expedients," which permits it to not reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs. As a result, the Company will in effect, continue to account for existing leases - i.e. leases for which the commencement date is before April 1, 2019 - in accordance with Topic 840 throughout the entire lease term, including periods after the effective date, with the exception that the Company will apply the new balance sheet recognition guidance for operating leases and apply Topic 842 for remeasurements and modifications after the Transition Date.

While the Company continues to assess all the effects of adoption, the Company believes the most significant effects relate to the recognition of a ROU asset and corresponding liability on its consolidated balance sheet, primarily related to its existing facility operating lease, and providing new disclosures with regards to the Company's leasing activities. The Company currently expects that the adoption of the new standard will result in the recording of a ROU asset of approximately $9.0 million to $10.0 million and a lease liability of approximately $10.0 million to $11.0 million.

(2) Others:

In February 2018, the FASB issued ASU 2018-02, *Income Statement- Reporting Comprehensive Income* (Topic 220): *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, or ASU 2018-02. ASU 2018-02 allows companies to reclassify stranded tax effects resulting from the newly enacted federal corporate income tax rate under the Tax Cuts and Jobs Act, from accumulated other comprehensive (loss) income to retained earnings. ASU 2018-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 and early adoption is permitted. The Company plans to adopt this new standard on April 1, 2019. The Company does not expect that the adoption of ASU 2018-02 will have a material impact on its consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation- Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company plans to adopt the new standard on April 1, 2019. The Company does not expect that the adoption of ASU 2018-07 will have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangibles- Goodwill and Other-Internal-Use Software* (Subtopic 350-40): *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*, or ASU 2018-15, which amends ASC 350-40, *Internal-Use Software*, to include in its scope implementation costs of a cloud computing arrangement that is a service contract. Consequently, the accounting for costs incurred to implement a cloud computing arrangement that is a service arrangement is aligned with the guidance on capitalizing costs associated with developing or obtaining internal-use software. ASU 2018-15 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. The Company is currently assessing the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

Note 3—License Agreement

On April 29, 2016, the Company entered into a license agreement pursuant to which 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, in exchange for the following:

- The Company issued and delivered 5,077,001 of its common shares upon entry into the license agreement.

- The Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in the Company's territory, subject to certain agreed reductions. Takeda will pay the Company a royalty at the same rate as the Company's on net sales of relugolix products for prostate cancer in Japan and certain other Asian countries, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest 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 this license agreement, there are no payments upon the achievement of clinical development or marketing approval milestones.
- The Company issued a warrant to Takeda to purchase an indeterminate number of capital shares. The warrant entitled Takeda, together with its affiliates, to maintain a 12% ownership interest in the Company, as determined after such exercise, through the later of (i) April 30, 2017 or (ii) the final closing of the Company's IPO, unless earlier terminated upon a change in control. The Company issued and delivered a total of 2,343,624 of its common shares to Takeda under this warrant prior to its expiration on April 30, 2017.

For the consideration above, the Company also received a small quantity of relugolix and MVT-602, and certain historical R&D records. The Company did not hire, or receive, any Takeda workforce or employees working on relugolix and MVT-602, or any research, clinical or manufacturing equipment. The Company did not assume any contracts, licenses or agreements between Takeda and any third party with respect to relugolix and MVT-602. If the 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 trials of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at its cost and expense.

As the intellectual property and inventory acquired had no alternative future use, the Company recorded $13.1 million as R&D expense at the closing date of the acquisition of the rights, April 29, 2016, which consisted of $7.7 million for the estimated fair value of the 5,077,001 common shares issued and $5.4 million for the estimated fair value of the warrant liability.

The estimation of the fair value of the common shares considered factors including the following: the estimated present value of the Company's future cash flows; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions.

The estimation of the fair value of the warrant liability was determined based on a Monte Carlo simulation model which requires various highly subjective unobservable inputs.

Note 4—Accrued Expenses

As of March 31, 2019 and 2018, accrued expenses consisted of the following (in thousands):

	March 31,	
	2019	2018
Accrued R&D expenses	$ 46,947	$ 25,988
Accrued compensation-related expenses	5,024	2,792
Accrued professional service fees	370	566
Accrued other expenses	1,273	919
Total accrued expenses	$ 53,614	$ 30,265

Note 5—Financing Arrangements

(A) NovaQuest:

In October 2017, the Company, its subsidiaries, as guarantors, and NovaQuest Capital Management, or NovaQuest, entered into (i) a Securities Purchase Agreement, or the NovaQuest Securities Purchase Agreement, and (ii) an Equity Purchase Agreement, or the NovaQuest Equity Purchase Agreement. Pursuant to the NovaQuest Securities Purchase Agreement, the Company had the option, at its discretion, to issue up to $60.0 million aggregate principal amount of notes to NovaQuest and concurrent with each purchase of notes, NovaQuest was obligated to purchase up to $20.0 million of the Company's common shares on a pro rata basis, subject to certain terms and conditions, through December 31, 2018. The equity purchase price for each such purchase was equal to 105% of the average of the volume-weighted average price for the five consecutive trading days immediately prior to the relevant purchase date. The Company committed that it would issue at least $30.0 million aggregate principal amount of notes through December 31, 2018, subject to certain terms and conditions. The Company

issued $6.0 million aggregate principal amount in October 2017 and $54.0 million aggregate principal amount in December 2018. With the issuance of $6.0 million aggregate principal amount of notes in October 2017, NovaQuest purchased 138,361 common shares for $2.0 million, and with the issuance of $54.0 million aggregate principal amount of notes in December 2018, NovaQuest purchased 1,082,977 common shares for $18.0 million.

The notes bear interest at a rate of 15% per annum, of which 5% is payable quarterly, and 10% is payable on a deferred basis on the earlier of the Amortization Date (as defined below) and the repayment in full of the notes. The notes mature on October 16, 2023. The Company will be required to amortize the principal amount of the notes in equal quarterly installments commencing on November 1, 2020, subject to extension at the Company's option to November 1, 2021, or the Amortization Date, provided certain terms and conditions are met. Early redemption of the notes is subject to a redemption charge. The Company's obligations under the NovaQuest Securities Purchase Agreement are secured by a second-lien security interest in substantially all of the Company's and its subsidiaries' respective assets (other than intellectual property). The NovaQuest Securities Purchase Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant that applies commencing on the Amortization Date, and also includes customary events of default. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding note balance and NovaQuest may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the NovaQuest Securities Purchase Agreement.

Pursuant to the NovaQuest Equity Purchase Agreement, NovaQuest committed to purchase up to an additional $20.0 million of the Company's common shares from time to time at the Company's discretion through December 31, 2018, with an option to extend the commitment through December 31, 2019, subject to certain terms and conditions. The Company committed that it would exercise its option to sell and issue a minimum of $10.0 million of its common shares under the NovaQuest Equity Purchase Agreement through December 31, 2018, subject to certain terms and conditions. In December 2018, the Company exercised this option and issued and sold 1,203,307 common shares for $20.0 million. The purchase price for the common shares issued was equal to 105% of the average of the volume-weighted average price for the five consecutive trading days immediately prior to the relevant purchase date.

The Company incurred financing costs related to the NovaQuest Securities Purchase Agreement of $1.0 million. During the years ended March 31, 2019 and 2018, interest expense included $0.4 million and $0.2 million, respectively, of amortized deferred financing costs related to the NovaQuest notes. During the year ended March 31, 2019, the Company paid NovaQuest an annual debt administration fee of $0.3 million, which has been deferred and is being amortized over twelve months.

Outstanding debt obligations to NovaQuest are as follows (in thousands):

	March 31,	
	2019	2018
Principal amount	$ 60,000	$ 6,000
Less: unamortized debt issuance costs	(756)	(854)
Loan payables less unamortized debt issuance costs	59,244	5,146
Less: current maturities	—	—
Long-term debt, net of current maturities and unamortized debt issuance costs	$ 59,244	$ 5,146

(B) Hercules:

In October 2017, the Company, its subsidiaries, as guarantors, and Hercules Capital, Inc., or Hercules, entered into a Loan Agreement, or the Hercules Loan Agreement, which provided up to $40.0 million principal amount of term loans, or the Term Loans. A first tranche of $25.0 million principal amount was funded upon execution of the Hercules Loan Agreement in October 2017 and the remaining $15.0 million principal amount was funded in March 2018. The Term Loans bear interest at a variable per annum rate at the greater of (i) the prime rate plus 4.00% and (ii) 8.25%. The interest rate on the Term Loans was 9.50% as of March 31, 2019. Pursuant to the terms of the Hercules Loan Agreement, the Term Loan Maturity Date has been extended from May 1, 2021 to November 1, 2021 as a result of the achievement of a financing milestone during July 2018. The Company is obligated to make monthly interest payments during the Interest-only Period, subject to certain terms and conditions, followed by monthly installments of principal and interest through the maturity date. The Interest-only Period has been extended from June 1, 2019 to December 1, 2019 as a result of the achievement of a financing milestone during July 2018 and may be further extended until June 1, 2020 if a certain clinical development milestone is met, as specified in the Hercules Loan Agreement. Prepayment of the Term Loan is subject to a prepayment charge. The Company is also obligated to pay an end of term charge of 6.55% of the principal amount of the Term Loans funded under the Hercules Loan Agreement, on the earlier of the maturity date or the date that the Term Loans otherwise become due and payable. The Company's obligations

under the Hercules Loan Agreement are secured by a first-lien security interest in substantially all of the Company's and its subsidiaries' respective assets (other than intellectual property). The Hercules Loan Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant that ceases to apply if the Company achieves both the clinical development and financing milestones as set forth in the Hercules Loan Agreement. The Hercules Loan Agreement also includes customary events of default. Upon the occurrence of an event of default, a default interest rate of an additional 5.00% may be applied to the outstanding principal balance, and Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Hercules Loan Agreement.

Concurrent with each funding of the Term Loans, the Company was required to issue to Hercules a warrant, or the Warrants, to purchase a number of its common shares equal to 3.00% of the principal amount of the relevant Term Loan funded divided by the exercise price, which is based on the lowest three-day volume-weighted average price for the three consecutive trading days prior to the funding date for such Term Loan. The Warrants may be exercised on a cashless basis, and are immediately exercisable through the seventh anniversary of the applicable funding date. In connection with the first tranche funded under the Hercules Loan Agreement, the Company issued a Warrant to Hercules exercisable for an aggregate of 49,800 of its common shares at an exercise price of $15.06 per common share. Concurrent with the funding of the second tranche, the Company issued a Warrant to Hercules exercisable for an aggregate of 23,910 of its common shares at an exercise price of $18.82 per common share. The Company accounted for the Warrants as equity instruments since they were indexed to the Company's common shares and met the criteria for classification in shareholders' equity (deficit). The relative fair value of the Warrants related to the first and second tranche funding were approximately $0.5 million and $0.3 million, respectively, and were treated as a discount to the Term Loans. This amount is being amortized to interest expense using the effective interest method over the life of the Term Loans. The Company estimated the fair value of the Warrants using the Black-Scholes model based on the following key assumptions:

	Tranche 1	Tranche 2
Exercise price	$15.06	$18.82
Common share price on date of issuance	$14.39	$18.96
Volatility	73.2%	72.3%
Risk-free interest rate	2.15%	2.78%
Expected dividend yield	—%	—%
Contractual term (in years)	7.00	7.00

The Company issued the first tranche of the Term Loans at a discount of $2.1 million, including the relative fair value of the related Warrant, and incurred financing costs of $1.3 million. The second tranche of the Term Loans was issued at a discount of $1.3 million, including the relative fair value of the related Warrant. During the years ended March 31, 2019 and 2018, interest expense included $1.7 million and $0.5 million, respectively, of amortized debt discount and issuance costs related to the Term Loans.

Outstanding debt obligations to Hercules are as follows (in thousands):

	March 31,	
	2019	2018
Principal amount	$ 40,000	$ 40,000
End of term charge	2,620	2,620
Less: unamortized debt discount and issuance costs	(2,482)	(4,142)
Loan payables less unamortized debt discount and issuance costs	40,138	38,478
Less: current maturities	(6,142)	—
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 33,996	$ 38,478

(C) Debt Maturities

Annual maturities of debt outstanding as of March 31, 2019 are as follows (in thousands):

Years Ended March 31,		
2020	$	6,142
2021		28,854
2022		32,696
2023		18,462
2024		13,846
Thereafter		—
Total	$	100,000

Note 6—Related Party Transactions

(A) Services Agreements:

In July 2016, the Company entered into a services agreement with RSI, effective April 29, 2016, under which RSI agreed to provide certain administrative and R&D services to the Company. Under this services agreement, the Company pays or reimburses RSI for expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative, or G&A, and R&D activities performed by RSI employees, RSI charges the Company based on the relative percentage of time utilized on Company matters by the respective employee. All other third-party pass thru costs are billed to the Company at cost. The consolidated financial statements include third-party expenses incurred on behalf of the Company that have been paid by RSI and RSL.

In February 2017, the Company and MSI amended and restated the services agreement, effective as of November 11, 2016, to include Myovant Sciences GmbH, or MSG, as a services recipient. In addition, in February 2017, MSG entered into a separate services agreement with RSG, effective as of November 11, 2016, for the provisioning of services by RSG to MSG in relation to services related to clinical development, administrative and finance and accounting activities. The Company refers to the amended and restated services agreement with RSI and the services agreement with RSG, collectively, as the Services Agreements.

Under the Services Agreements, for the years ended March 31, 2019, 2018 and 2017, the Company incurred expenses (inclusive of third party pass thru costs billed to the Company) of $4.8 million, $7.7 million and $9.2 million, respectively, inclusive of the mark-up. These amounts are included in R&D expenses and G&A expenses based upon the nature of the service performed under the Services Agreements. The Company has replaced many of the services previously provided by RSI and RSG with its own internally developed capabilities or external professional service providers. The level of support the Company receives from RSI and RSG is expected to continue to decrease as the Company further decentralizes its activities from RSL.

(B) Share-Based Compensation Expense Allocated to the Company by RSL:

Share-based compensation expense has been and will continue to be allocated to the Company by RSL over the requisite service period over which RSL common share awards and RSL options are expected to vest and based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

In relation to the RSL common share awards and options issued by RSL to RSL, RSI, RSG and the Company's employees, the Company recorded share-based compensation expense of $0.6 million, $1.0 million and $4.9 million, respectively, for the years ended March 31, 2019, 2018 and 2017. Refer to Note 9 for further details.

(C) Private Placement with RSL:

See Note 7(D) for information regarding the Private Placement with RSL.

(D) Option Agreement with RSL:

In June 2016, the Company entered into an option agreement with RSL pursuant to which RSL granted to the Company an option to acquire the rights to products to which RSL or any nonpublic affiliate of RSL acquires the rights (other than a relugolix product or a competing product) for uterine fibroids or endometriosis, or for which the primary target indication is advanced prostate cancer. The Company's option is exercisable at any time during the period commencing upon the completion of its IPO and ending two years following the date of first commercial sale of a relugolix product in a major market country. If the Company elects to exercise its option for a product, it will be required to reimburse RSL for 110% of any payments made by RSL or its affiliate for such product, and will receive an assignment of the agreement through which RSL or its affiliate acquired the rights to such product.

(E) Information Sharing and Cooperation Agreement with RSL:

In July 2016, the Company entered into an information sharing and cooperation agreement, or the Cooperation Agreement, with RSL. The Cooperation Agreement, among other things: (1) obligates the Company to deliver periodic financial statements and other financial information to RSL and to comply with other specified financial reporting requirements; and (2) requires the Company to supply certain material information to RSL to assist it in preparing any future SEC filings. Subject to specified exceptions, the Cooperation Agreement will terminate upon the earlier of the mutual written consent of the parties or when RSL is no longer required by U.S. GAAP to consolidate the Company's financial statements, account for its investment in the Company under the equity method of accounting or, by any rule of the SEC, include the Company's separate financial statements in any filings it may make with the SEC. On May 24, 2019, the Company entered into Amendment No. 1 to the Cooperation Agreement, pursuant to which RSL has agreed, in connection with each of the Company's next three public offerings of its common shares, that RSL will (1) provide to the Company and the underwriter(s) engaged by the Company in

connection with such public offering an indication of interest for RSL to participate as a purchaser in such public offerings, and (2) enter into a customary lock-up agreement with the underwriters in connection with such public offerings.

(F) Manufacture and Supply Agreement:

In June 2016, the Company and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited is supplying the Company, and the Company has obtained from Takeda Limited, all of its requirements for relugolix drug substance and drug product to be used under its development plans for all indications. Takeda Limited is also assisting the Company with a technical transfer of the manufacturing process for relugolix to it and its designee and the Company is paying the expenses related to such transfer.

(G) Commercial Manufacturing and Supply Agreement:

In May 2018, the Company entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement. Pursuant to the Takeda Commercial Supply Agreement, Takeda has agreed to supply the Company and the Company has agreed to obtain from Takeda certain quantities of relugolix drug substance according to agreed-upon quality specifications and in order to commercialize relugolix in accordance with the Takeda Agreement. Under the Takeda Commercial Supply Agreement, the Company will pay Takeda a fixed price per kilogram of relugolix drug substance through December 31, 2019. The Company has made and Takeda has accepted an initial firm order to supply relugolix drug substance to the Company through December 31, 2019. For relugolix drug substance manufactured or delivered on or after such date, the Company 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.

In addition, under the Takeda Commercial Supply Agreement, Takeda has agreed to assist with the transfer of technology and Takeda manufacturing know-how to a second contract manufacturing organization of the Company's subsidiary, Myovant Sciences GmbH. The Company has agreed to reimburse Takeda for all internal costs, and external costs, charges, and expenses, in each case, reasonably incurred by Takeda in connection with any technology transfer services.

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 automatically renews 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, including the initial firm order for relugolix drug substance through December 31, 2019, will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase order thereunder, will terminate immediately upon the termination of the Takeda 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.

Note 7—Shareholders' Equity (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, 2019, the Company had 564,111,242 shares authorized with a par value of $0.000017727 per share.

(B) Initial Public Offering and Reverse Stock Split:

On October 18, 2016, the Company's board of directors approved a 1-for-1.7727 reverse stock split of the Company's outstanding common shares. The reverse stock split became effective on October 18, 2016. These consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

On November 1, 2016, the Company completed its IPO of common shares. The Company sold 14,500,000 common shares at a price of $15.00 per common share, for gross proceeds of $217.5 million. The Company received net proceeds of $200.0 million, after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering costs paid by the Company.

(C) Underwritten Public Equity Offering of Common Shares:

In July and August 2018, the Company completed an underwritten public equity offering of 3,533,399 of its common shares (including 200,065 common shares issued and sold upon the partial exercise of the underwriters' option to purchase additional

shares) at a public offering price of $22.50 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 partial option exercise, were approximately $74.4 million.

(D) Private Placement with RSL:

In April 2018, the Company entered into a share purchase agreement, or the Purchase Agreement, with RSL, its controlling shareholder, pursuant to which the Company sold to RSL 1,110,015 of its common shares at a purchase price of $20.27 per common share, for gross proceeds of $22.5 million, in a private placement, or the Private Placement.

(E) At-the-Market Equity Offering Program:

In April 2018, the Company entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or 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 acts as the Company’s agent. During the year ended March 31, 2019, the Company issued and sold 3,970,129 of its common shares under the Sales Agreement. The common shares were sold at a weighted-average price of $21.91 per common share for aggregate net proceeds to the Company of approximately $84.1 million, after deducting underwriting commissions and offering costs paid by the Company. As of March 31, 2019, the Company had approximately $13.0 million of capacity available to it under its “at-the-market” equity offering program. In April 2019, the Company issued and sold an additional 106,494 common shares for aggregate net proceeds of $2.5 million pursuant to this program.

(F) Issuance of Equity Instruments to NovaQuest and Hercules:

In October 2017, the Company issued and sold 138,361 common shares to NovaQuest for $2.0 million in accordance with the terms of the NovaQuest Securities Purchase Agreement. In December 2018, the Company issued and sold 1,082,977 common shares to NovaQuest for $18.0 million in accordance with the NovaQuest Securities Purchase Agreement and issued and sold 1,203,307 common shares to NovaQuest for $20.0 million in accordance with the NovaQuest Equity Purchase Agreement. In October 2017, the Company issued a Warrant to Hercules exercisable for 49,800 of its common shares at an exercise price of $15.06 per common share and in March 2018, the Company issued a Warrant to Hercules exercisable for an aggregate of 23,910 of its common shares at an exercise price of $18.82 per common share. Additional information is included in Note 5, “Financing Arrangements.”

(G) Takeda Warrant Liability:

During the year ended March 31, 2017, the Company issued 2,339,192 common shares to Takeda upon the automatic exercise of the Takeda warrant, which was due to the issuance of 153,846 common shares initiated by the grant of a restricted share award for 1,128,222 common shares, issuance of 208,077 common shares initiated by the grant of options to purchase 1,525,857 common shares and the issuance of an additional 1,977,269 common shares to Takeda upon the closing of the Company’s IPO, based upon the sale and issuance of 14,500,000 common shares to investors in the IPO. During the year ended March 31, 2018, the Company issued 4,432 common shares to Takeda upon the automatic exercise of the Takeda warrant, which was initiated by the grant of options to purchase 32,500 common shares in April 2017. The warrant expired on April 30, 2017.

Note 8—Income Taxes

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

	Years Ended March 31,		
	2019	2018	2017
Loss before income taxes:			
United States	$ (11,246)	$ (7,229)	$ (2,924)
Switzerland	(247,445)	(129,261)	(29,745)
Bermuda	(14,357)	(6,513)	(50,845)
Other[1]	(27)	(39)	—
Total loss before income taxes	$ (273,075)	$ (143,042)	$ (83,514)
Current taxes:			
United States	$ 473	$ 13	$ 125
Switzerland	—	—	—
Bermuda	—	—	—
Other[1]	3	(8)	9
Total current tax expense	476	5	134
Deferred taxes:			
United States	—	208	(208)
Switzerland	—	—	—
Bermuda	—	—	—
Other[1]	—	—	—
Total deferred tax expense (benefit)	—	208	(208)
Total income tax expense (benefit)	$ 476	$ 213	$ (74)

(1) Primarily United States state and local, Ireland and United Kingdom activity.

A reconciliation of income tax expense (benefit) computed at the Bermuda statutory rate to income tax expense (benefit) reflected in the consolidated financial statements is as follows (dollars in thousands):

	Years Ended March 31,					
	2019		2018		2017	
Income tax benefit at Bermuda statutory rate	$ —	— %	$ —	— %	$ —	— %
Foreign rate differential[2]	(31,252)	11.44	(14,802)	10.35	(7,592)	9.09
Valuation allowance	32,335	(11.83)	13,966	(9.77)	7,378	(8.83)
Tax reform	—	—	1,049	(0.73)	—	—
Other	(607)	0.22	—	—	140	(0.17)
Total income tax expense (benefit)	$ 476	(0.17)%	$ 213	(0.15)%	$ (74)	0.09 %

(2) Primarily related to current tax on United States operations including permanent and temporary differences (e.g. research and development credits, etc.) 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, 2019, 2018 and 2017 was (0.17)%, (0.15)% and 0.09%, 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, 2019 and 2018 are as follows (in thousands):

	March 31,	
	2019	2018
Deferred tax assets:		
Research tax credits	$ 7,224	$ 2,948
Net operating losses[3]	38,194	16,045
Share-based compensation	6,106	2,380
Intangibles[4]	38,673	—
Other	2,539	169
Subtotal	92,736	21,542
Valuation allowance	(92,330)	(21,367)
Deferred tax liabilities:		
Depreciation	(406)	(175)
Total deferred tax assets	$ —	$ —

(3) The Company operates under a tax holiday in Switzerland which is effective through March 31, 2027. The tax holiday is conditional upon the Company meeting certain employment thresholds. The impact of this tax holiday did not impact the Company's income tax expense for the period but has been accounted for in considering the tax effected net operating losses for this jurisdiction disclosed above.

(4) In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, or ASU 2016-16. ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets, other than inventory, to be recognized when the transfer occurs. The new standard was effective for the Company on April 1, 2018 and was adopted using a modified retrospective approach. The adoption of this standard resulted in the recognition of a deferred tax asset of $38.7 million with a corresponding valuation allowance of $38.7 million.

As of March 31, 2019, the Company's net operating losses in Switzerland, Ireland, and the United Kingdom were $376.2 million, $32 thousand, and $14.4 million, respectively. The Switzerland net operating losses will begin to expire on March 31, 2025. The net operating losses in Ireland and the United Kingdom can be carried forward indefinitely with annual usage limitations where applicable. As of March 31, 2019, the Company has research and development credit carryforwards in the United States in the amount of $7.2 million which will begin to expire on March 31, 2037.

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 difficult to overcome, the Company has recorded a valuation allowance of $92.3 million as of March 31, 2019 representing the portion of the deferred tax asset that is not more likely than not to be realized. 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.

The Company is subject to tax and will file 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 tax examinations for tax years ended March 31, 2017 and forward in all applicable income tax jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however the potential tax benefits may impact the results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire. There are no uncertain tax benefits recorded as of March 31, 2019.

Note 9—Share-Based Compensation

(A) Myovant 2016 Equity Incentive Plan:

In June 2016, the Company adopted its 2016 Equity Incentive Plan, or 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 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 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, 2018, the number of common shares authorized for issuance increased automatically by 2.4 million shares in accordance with the evergreen provision of the 2016 Plan. As of March 31, 2019, a total of 2.1 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 share awards, restricted stock unit awards, and other share awards under the 2016 Plan.

(B) Stock Options:

Each option will have an exercise price equal to the fair market value of the Company's common shares on the date of grant. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company's common shares on the date of grant and the option will have a five-year contractual term. Options that are forfeited or expire are available for future grants.

Stock options granted under the 2016 Plan may provide option holders, if approved by the Company's board of directors, the right to exercise their options prior to vesting. In the event that an option holder exercises the unvested portion of any option, such unvested portion will be subject to a repurchase option held by the Company at the lower of (1) the fair market value of its common shares on the date of repurchase and (2) the exercise price of the options. Any common shares underlying such unvested portion will continue to vest in accordance with the original vesting schedule of the option.

A summary of stock option activity and data under the Company's 2016 Plan for the periods presented is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at March 31, 2016	—	$ —	$ —	—	$ —
Granted	1,525,857	$ 5.06	$ 11.90		
Options outstanding at March 31, 2017	1,525,857	$ 5.06	$ 11.90	9.52	$ 10,255
Granted	2,338,116	$ 12.50	$ 8.35		
Exercised	(15,195)	$ 2.38	$ 12.75		
Forfeited	(299,373)	$ 6.64	$ 11.35		
Options outstanding at March 31, 2018	3,549,405	$ 9.84	$ 9.60	9.02	$ 40,557
Granted	2,246,410	$ 21.36	$ 14.10		
Exercised	(154,494)	$ 8.41	$ 10.29		
Forfeited	(244,856)	$ 14.59	$ 11.05		
Options outstanding at March 31, 2019	5,396,465	$ 14.46	$ 11.39	8.51	$ 50,878
Options vested and expected to vest at March 31, 2019	5,396,465	$ 14.46	$ 11.39	8.51	$ 50,878
Options exercisable at March 31, 2019	1,581,810	$ 9.11	$ 9.99	7.87	$ 23,342

As of March 31, 2019, 2018 and 2017, there were 1,581,810, 502,361 and 28,406 vested options, respectively. Additional information regarding options is set forth below (in thousands, except per share data).

	Years Ended March 31,		
	2019	2018	2017
Intrinsic value of options exercised	$ 2,167	$ 181	$ —
Grant date fair value of options vested	$ 11,409	$ 5,831	$ 350
Weighted-average grant date fair value per share of options granted	$ 14.10	$ 8.35	$ 11.90

(C) Restricted Share Awards and Restricted Stock Units:

A summary of restricted share award and restricted stock unit activity under the Company's 2016 Plan for the periods presented is as follows:

	Number of shares	Weighted Average Grant Date Fair Value
Unvested balance at March 31, 2016	—	$ —
Granted	1,128,222	$ 5.10
Unvested balance at March 31, 2017	1,128,222	$ 5.10
Granted	579,111	$ 14.10
Vested	(493,598)	$ 5.10
Unvested balance at March 31, 2018	1,213,735	$ 9.39
Granted	29,700	$ 17.28
Vested	(287,369)	$ 5.21
Unvested balance at March 31, 2019	956,066	$ 10.90

The total fair value of restricted share awards vested during the years ended March 31, 2019 and 2018 was $1.4 million and $2.5 million, respectively. No restricted share awards vested during the year ended March 31, 2017. The total fair value of restricted stock units, or RSUs, vested during the year ended March 31, 2019 was $0.1 million. No RSUs vested during the years ended March 31, 2018 or 2017.

(D) Share-Based Compensation Expense:

Share-based compensation expense was as follows (in thousands):

	Years Ended March 31,		
	2019	2018	2017
Share-based compensation expense recognized as:			
R&D expenses	$ 7,161	$ 3,674	$ 3,893
G&A expenses	11,535	7,909	4,824
Total	$ 18,696	$ 11,583	$ 8,717

Share-based compensation expense is included in R&D and G&A expenses in the accompanying consolidated statements of operations consistent with the grantee's salary. Share-based compensation expense presented in the table above includes share-based compensation expense allocated to the Company by RSL as described below in Note 9(E). Of the total share-based compensation expense, amounts recognized for options granted to non-employees were immaterial for all periods presented.

Total unrecognized share-based compensation expense was approximately $45.2 million as of March 31, 2019 and is expected to be recognized over a weighted-average period of approximately 2.83 years.

The Company estimated the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model applying the weighted average assumptions in the following table:

	Years Ended March 31,		
	2019	2018	2017
Expected common share price volatility	71.6%	74.4%	75.5%
Expected risk free interest rate	2.78%	2.04%	1.57%
Expected term, in years	6.23	6.22	6.35
Expected dividend yield	—%	—%	—%

(E) Share-Based Compensation Expense for Related Parties:

(1) Share-Based Compensation Expense Allocated to the Company by RSL:

In relation to the RSL common share awards and RSL options issued by RSL to RSL, RSI, RSG and the Company's employees, the Company recorded share-based compensation expense of $0.6 million, $1.0 million and $4.9 million, respectively, for the years ended March 31, 2019, 2018 and 2017.

The RSL common share awards and RSL options granted by RSL to RSL, RSI, RSG and the Company's employees are valued by RSL at fair value on the date of grant and that fair value is recognized as share-based compensation expense over the requisite service period. Significant judgment and estimates were used by RSL to estimate the fair value of these awards and options, as they are not publicly traded. RSL common share awards and RSL options are subject to specified vesting schedules and requirements (a mix of time-based and performance- based events). The fair value is based on various corporate event-based considerations, including targets for RSL's post-IPO market capitalization and future financing events). The fair value of each RSL option is estimated on the date of grant using the Black-Scholes closed-form option-pricing model.

Share-based compensation expense has been and will continue to be allocated to the Company over the requisite service period over which these RSL common share awards and RSL options are expected to vest and based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

(2) RSL RSUs:

The Company's Principal Executive Officer was granted 66,845 RSL RSUs during the year ended March 31, 2017. These RSUs will vest to the extent certain RSL performance criteria and certain RSL liquidity conditions are satisfied within specified years of the grant date, provided that the Company's Principal Executive Officer has provided continued service to RSL or its subsidiaries through such date. As of March 31, 2019, the performance conditions had not been met and were deemed not probable of being met. For the years ended March 31, 2019, 2018 and 2017, the Company recorded no share-based compensation expense related to these RSL RSUs. As of March 31, 2019, there was $0.9 million of unrecognized compensation expense related to unvested RSL RSUs. The Company will recognize this share-based compensation expense upon achievement of the performance and market conditions through the requisite service period.

Note 10—Fair Value Measurements

As of March 31, 2019, assets measured at fair value on a recurring basis consisted of money market funds and commercial paper, which are included in cash and cash equivalents in the consolidated balance sheet. There were no assets measured at fair value as of March 31, 2018. The following table summarizes these assets (in thousands):

	As of March 31, 2019			
	Level 1	Level 2	Level 3	Total Fair Value
Assets:				
Money market funds	$ 83	$ —	$ —	$ 83
Commercial paper	—	126,050	—	126,050
Total assets	$ 83	$ 126,050	$ —	$ 126,133

Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. Commercial paper is included in Level 2 of the fair value hierarchy and is valued using third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

There were no liabilities measured at fair value on a recurring basis as of March 31, 2019 or 2018. There were no transfers of assets or liabilities between the fair value hierarchy levels that occurred during the years ended March 31, 2019, 2018 or 2017.

Before expiration on April 30, 2017, the Company measured the warrant liability associated with the license agreement with Takeda at fair value based on significant inputs not observable in the market, which caused it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the warrant liability used assumptions and estimates the Company believed would be made by a market participant in making the same valuation. The Company assessed these assumptions and estimates on an ongoing basis through the expiration of the Takeda warrant as additional data impacting the assumptions and estimates was obtained. Changes in the fair value of the warrant liability related to updated assumptions and estimates were recognized as other (expense) income in the consolidated statements of operations.

The fair value of the Takeda warrant liability as of March 31, 2017 was calculated using the following significant unobservable inputs:

Input	Range or Point Estimate Used
Projected time frame to an equity financing	April 2017
Probability of a successful equity financing	2.0%
Annualized equity volatility	73.4%
Risk-free interest rate	0.74%

The changes in fair value of the Takeda warrant liability during the years ended March 31, 2018 and 2017 were as follows (in thousands):

Balance at March 31, 2016	$ —
Fair value of the Takeda warrant liability issued	5,377
Changes in the fair value of the Takeda warrant liability, included in net loss	27,518
Settlements	(32,843)
Balance at March 31, 2017	52
Fair value of the warrant liability issued	—
Changes in the fair value of the warrant liability, included in net loss	—
Settlements	(52)
Balance at March 31, 2018	$ —

For the year ended March 31, 2018, changes in the carrying value of the Takeda warrant liability resulted from settlements related to the fair value of the Takeda warrant automatically exercised.

For the year ended March 31, 2017, changes in the carrying value of the Takeda warrant liability resulted from settlements related to the fair value of the Takeda warrant exercised, partially offset by changes in the fair value of the Takeda warrant liability primarily due to the changes in the estimated probabilities of future financing events, change in the enterprise value of the Company, automatic exercise of the Takeda warrant and the passage of time.

Note 11—Commitments and Contingencies

(A) Operating 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 of 2026. The Company has the option to extend the lease term for an additional seven years. 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, for the duration of the lease.

Future operating lease obligations (excluding the optional lease renewal term) as of March 31, 2019 are as follows (in thousands):

Years Ended March 31,	Operating Leases
2020	$ 2,006
2021	2,065
2022	2,128
2023	2,200
2024	2,339
Thereafter	5,307
Total minimum operating lease payments	$ 16,045

Rent expense for the years ended March 31, 2019, 2018 and 2017 was $2.1 million, $0.9 million and $0.3 million, respectively.

(B) 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 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 reserves were established.

(C) 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 activities. Expenditures to contract research organizations and contract manufacturing organizations represent significant costs in the Company's clinical development of its product candidates. 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, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(D) 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. In the cases where 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.

(E) Others:

The Company has entered into commitments under its license agreement with Takeda (See Note 3) and financing arrangements with NovaQuest and Hercules (See Note 5).

Note 12—Selected Quarterly Financial Data (Unaudited)

The following table presents selected unaudited quarterly financial data of the Company for the years ended March 31, 2019 and 2018. The unaudited quarterly financial data is prepared on the same basis as the audited consolidated financial statements, and in the opinion of management, includes all recurring adjustments necessary for a fair statement of such information. The Company's operating results for any quarter are not necessarily indicative of the operating results for any future quarters or a full year. The net loss per common share amounts for the quarterly periods have been computed separately. Therefore, the sum of quarterly net loss per common share amounts may not equal annual net loss per common share amounts.

	First Quarter Ended June 30, 2018	Second Quarter Ended September 30, 2018	Third Quarter Ended December 31, 2018	Fourth Quarter Ended March 31, 2019	First Quarter Ended June 30, 2017	Second Quarter Ended September 30, 2017	Third Quarter Ended December 31, 2017	Fourth Quarter Ended March 31, 2018
Total operating expenses	$ 60,083	$ 64,123	$ 69,120	$ 71,500	$ 21,890	$ 30,311	$ 41,515	$ 47,347
Net loss	$ (62,134)	$ (65,770)	$ (70,633)	$ (75,014)	$ (23,317)	$ (29,908)	$ (41,777)	$ (48,253)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.98)	$ (0.99)	$ (1.04)	$ (1.07)	$ (0.39)	$ (0.50)	$ (0.70)	$ (0.81)

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. 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

Management is responsible for establishing and maintaining adequate internal control over financial reporting. 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 assessed the effectiveness of our internal control over financial reporting as of March 31, 2019. 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 has concluded that, as of March 31, 2019, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of March 31, 2019 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report, which is included in Part II. Item 8. of this Annual Report on Form 10K.

(3) Changes in Internal Control over Financial Reporting

We continuously seek to improve the efficiency and effectiveness of our internal controls. No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On May 24, 2019, we entered into Amendment No. 1 to our Information Sharing and Cooperation Agreement with Roivant Sciences Limited, or RSL, pursuant to which RSL has agreed, in connection with each of our next three public offerings of our common shares, that RSL will (1) provide to us and the underwriter(s) engaged by us in connection with such public offering an indication of interest for RSL to participate as a purchaser in such public offerings, and (2) enter into a customary lock-up agreement with the underwriters in connection with such public offerings.

On May 23, 2019, our board of directors approved, and the holder of a majority of our issued and outstanding common shares approved by written consent, an amendment and restatement of our bye-laws, to be our Fourth Amended and Restated Bye-Laws, which amends our bye-laws (1) to establish procedures for the appointment of a majority of the directors on our board by RSL at any time that RSL holds less than 50.0% but more than or equal to 35.0% of the aggregate voting rights attached to our issued and outstanding common shares, and (2) to remove the procedures and requirements of voting rights of such shares that are treated as controlled shares of a U.S. Person whose controlled shares constitute nine and one-half percent (9.5%) or more of the voting power of all of our issued common shares. The effective date of the adoption of the Fourth Amended and Restated Bye-Laws is anticipated to be in late June or early July 2019.

PART III.

We intend to file a definitive proxy statement for our 2019 Annual General Meeting of Shareholders, or the 2019 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after March 31, 2019. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2019 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 2019 Proxy Statement under the captions “Election of Directors,” “Information Regarding Board of Directors and Corporate Governance,” “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be contained in our 2019 Proxy Statement under the captions “Information Regarding 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 2019 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 2019 Proxy Statement under the captions “Transactions with Related Persons” and “Information Regarding the Board of Directors and Corporate Governance-Independence of the Board of Directors” and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be contained in our 2019 Proxy Statement under the captions “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, 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 Reports 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		Third Amended and Restated Bye-Laws.	8-K	001-37929	3.1	02/09/2018
3.4	†	Fourth Amended and Restated Bye-Laws (proposed and not effective).				
10.1		Amended and Restated Services Agreement, dated February 13, 2017, by and among Roivant Sciences, Inc., Myovant Sciences, Inc., Myovant Sciences GmbH and the Registrant.	10-Q	001-37929	10.1	02/13/2017
10.2		Services Agreement, dated February 13, 2017, by and among Roivant Sciences GmbH and Myovant Sciences GmbH.	10-Q	001-37929	10.2	02/13/2017
10.3	*	License Agreement, dated April 29, 2016, by and between the Registrant and Takeda Pharmaceuticals International AG, as amended.	S-1	333-213891	10.1	10/25/2016
10.4	*	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.	S-1	333-213891	10.2	10/20/2016
10.5	*	Option Agreement, dated June 1, 2016, by and between Roivant Sciences Ltd. and the Registrant.	S-1	333-213891	10.10	09/30/2016
10.6		Information Sharing and Cooperation Agreement, dated as of July 6, 2016, by and between Roivant Sciences Ltd. and the Registrant.	S-1	333-213891	10.11	09/30/2016
10.7	†	Amendment No.1 to Information Sharing and Cooperation Agreement, dated as of May 24, 2019, by and between Roivant Sciences Ltd. and the Registrant.				
10.8		Right of First Negotiation and Board Observer Agreement, dated October 22, 2016, by and between the Registrant and C.P. Pharmaceuticals International C.V.	S-1	333-213891	10.14	10/24/2016

10.9		Investor Rights Agreement, dated April 29, 2016, by and between the Registrant, Roivant Sciences Ltd. and Takeda Pharmaceuticals International AG.	S-1	333-213891	10.3	09/30/2016
10.10		Loan and Security Agreement, dated October 16, 2017, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, and Myovant Sciences, Inc. and Hercules Capital, Inc.	10-Q	001-37929	10.1	02/13/2018
10.11		Securities Purchase Agreement, dated October 16, 2017, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, and Myovant Sciences, Inc. and NovaQuest Pharma Opportunities Fund IV, L.P.	10-Q	001-37929	10.2	02/13/2018
10.12		Waiver and Amendment to the Securities Purchase Agreement, dated as of March 28, 2018, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, Myovant Sciences, Inc., the Purchasers (as defined therein) and NovaQuest Pharma Opportunities Fund IV, L.P.	10-Q	001-37929	10.3	08/07/2018
10.13		Second Waiver and Amendment to the Securities Purchase Agreement, dated as of March 30, 2018, , dated October 16, 2017, by and among the Registrant, Myovant Holdings Limited, Myovant Sciences GmbH, Myovant Sciences Ireland Limited, Myovant Sciences, Inc., the Purchasers (as defined therein) and NovaQuest Pharma Opportunities Fund IV, L.P.	10-Q	001-37929	10.4	08/07/2018
10.14		Equity Purchase Agreement, dated October 16, 2017, by and among the Registrant and NovaQuest Pharma Opportunities Fund IV, L.P. and NovaQuest Pharma Opportunities Fund IV (Parallel), L.P.	10-Q	001-37929	10.3	02/13/2018
10.15		Warrant Agreement, dated October 16, 2017, issued to Hercules Capital, Inc.	8-K	001-37929	4.1	10/16/2017
10.16		Warrant Agreement, dated March 26, 2018, issued to Hercules Capital, Inc.	8-K	001-37929	4.1	03/30/2018
10.17		Sales Agreement, dated as of April 2, 2018, between Myovant Sciences Ltd. and Cowen and Company, LLC.	8-K	001-37929	1.1	04/03/2018
10.18		Share Purchase Agreement, dated as of April 2, 2018, between Myovant Sciences Ltd. and Roivant Sciences Ltd.	8-K	001-37929	99.1	04/03/2018
10.19	*	Commercial Manufacturing & Supply Agreement, effective as of May 30, 2018, by and between Myovant Sciences GmbH and Takeda Pharmaceutical Company Limited.	10-Q/A	001-37929	10.5	09/17/2018
10.20	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Lynn Seely, M.D. and Myovant Sciences, Inc.	10-Q	001-37929	10.1	11/08/2018
10.21	†+	Restricted Stock Award Agreement, dated May 31, 2017, by and between Myovant Sciences Ltd. and Lynn Seely.				
10.22	+	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
10.23	+	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

10.24	+	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
10.25	+	Employment Agreement, dated as of November 1, 2018, by and between Kim Sablich and Myovant Sciences, Inc.	10-Q	001-37929	10.6	02/07/2019
10.26	+	Form of Indemnification Agreement with directors and executive officers.	S-1	333-213891	10.8	09/30/2016
10.27	+	2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.5	10/20/2016
10.28	+	Forms of Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.6	09/30/2016
10.29	+	Form of Early Exercise Stock Purchase Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.7	09/30/2016
10.30	†+	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended.				
10.31	†+	Form of Restricted Stock Award Agreement under 2016 Equity Incentive Plan, as amended.				
10.32	†+	Non-Employee Director Compensation Policy.				
21.1	†	Subsidiaries of the Registrant.				
23.1	†	Consent of Ernst & Young LLP, 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 XBRL		Instance Document				
101.SCH XBRL		Taxonomy Extension Schema				
101.CAL XBRL		Taxonomy Extension Calculation Linkbase				
101.DEF XBRL		Taxonomy Extension Definition Linkbase				
101.LAB XBRL		Taxonomy Extension Label Linkbase				
101.PRE XBRL		Taxonomy Extension Presentation Linkbase				

† Filed herewith.

+Indicates management contract or compensatory plan.

*Confidential treatment has been granted for portions omitted from this exhibit (indicated by asterisks) and those portions have been separately filed with the SEC.

**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, 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 Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MYOVANT SCIENCES LTD.

By: /s/ Lynn Seely

Lynn Seely
(Principal Executive Officer and Director)

Date: May 24, 2019

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Lynn Seely and Frank Karbe, 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/ Lynn Seely Lynn Seely	Principal Executive Officer and Director	May 24, 2019
/s/ Frank Karbe Frank Karbe	Principal Financial and Accounting Officer	May 24, 2019
/s/ Myrtle Potter Myrtle Potter	Chairperson and Director	May 24, 2019
/s/ Mark Guinan Mark Guinan	Director	May 24, 2019
/s/ Frank Torti Frank Torti	Director	May 24, 2019
/s/ Vivek Ramaswamy Vivek Ramaswamy	Director	May 24, 2019
/s/ Kathleen Sebelius Kathleen Sebelius	Director	May 24, 2019
/s/ Terrie Curran Terrie Curran	Director	May 24, 2019

Exhibit 3.4

FOURTH AMENDED AND RESTATED BYE-LAWS OF

MYOVANT SCIENCES LTD.

(Proposed and Not Effective)

TABLE OF CONTENTS

INTERPRETATION

1. Definitions

1.1 In these Bye-laws, the following words and expressions shall, where not inconsistent with the context, have the following meanings, respectively:

Act	the Companies Act 1981 as amended from time to time;
Alternate Director	an alternate Director appointed in accordance with these Bye-laws;
Audit Committee	the committee of the Board to which is delegated, inter alia, certain oversight responsibilities with respect to (i) the Company's corporate accounting and financial reporting processes, (ii) the Company's systems of internal control over financial reporting and audits of financial statements, (iii) the quality and integrity of the Company's financial statements and reports, (iv) the qualifications, independence and performance of the registered public accounting firm or firms of certified public accountants engaged as the Company's independent outside auditors for the purpose of preparing or issuing an audit report or performing audit services and (v) the performance of the Company's internal audit function and independent auditors and, if the Company does not yet have an internal audit function, the oversight of its design and implementation.
Auditor	includes an individual, company or partnership;
Board	the Board of Directors appointed or elected pursuant to these Bye-laws and acting by resolution in accordance with the Act and these Bye-laws or the Directors present at a meeting of Directors at which there is a quorum;
Code	the United States Internal Revenue Code of 1986, as amended;
Company	the company for which these Bye-laws are approved and confirmed;
Compensation Committee	the committee of the Board to which is delegated, inter alia, the authority to approve executive compensation in satisfaction of the requirements of applicable Designated Stock Exchange Rules
Controlled Shares	all shares of the Company directly, indirectly or constructively owned by a person as determined pursuant to sections 957 and 958 of the Code and the Treasury Regulations promulgated thereunder;
Designated Stock Exchange	the New York Stock Exchange, The Nasdaq Stock Market LLC, or any other stock exchange on which the shares of the Company are listed for trading, for so long as the shares of the Company are there listed;
Designated Stock Exchange Rules	the relevant code, rules and regulations, as amended, from time to time, applicable as a result of the original and continued listing of any shares of the Company on the Designated Stock Exchange;
Director	a director of the Company and shall include an Alternate Director;
Eligible Member	(i) a Member whose Controlled Shares constitute three percent (3%) or more of the voting power of all issued shares of the Company that are eligible to vote at a general meeting and who has held such shares for at least three (3) years or (ii) a group of not more than twenty (20) Members whose Controlled Shares that, in each case, have been held for at least three (3) years constitute, in aggregate, three percent (3%) or more of the voting power of all issued shares of the Company that are eligible to vote at a general meeting;
Independent Director	a Director who is an independent director for purposes of serving on the applicable committee of the Board, as defined in the Designated Stock Exchange Rules, and as determined by the Board;
indirect	when referring to a holder or owner of shares, ownership of shares within the meaning of section 958(a)(2) of the Code;

Member	the person registered in the Register of Members as the holder of shares in the Company and, when two or more persons are so registered as joint holders of shares, means the person whose name stands first in the Register of Members as one of such joint holders or all of such persons, as the context so requires;
Nominating and Corporate Governance Committee	a nominations committee of the Board to which is delegated, inter alia, the authority to identify individuals qualified to become Directors, consistent with criteria approved by the Board, and to select, or to recommend that the Board select, the Director nominees for election to the Board; develop and recommend to the Board a set of corporate governance guidelines applicable to the Company; and oversee the evaluation of the Board and management, in satisfaction of the requirements of applicable Designated Stock Exchange Rules
notice	written notice as further provided in these Bye-laws unless otherwise specifically stated;
Officer	any person appointed by the Board to hold an office in the Company;
Register of Directors and Officers	the register of Directors and officers referred to in these Bye-laws;
Register of Members	the register of members referred to in these Bye-laws;
Resident Representative	any person appointed to act as resident representative and includes any deputy or assistant resident representative;
Roivant	Roivant Sciences Ltd. or any parent or wholly owned subsidiary thereof;
Roivant Director	any Director who is (i) appointed by Roivant during the Trigger Period pursuant to Bye-law 38 or (ii) a director of Roivant or an officer or employee of Roivant or its subsidiaries (other than the Company or its subsidiaries) at or after the time Roivant first appoints a Director during the Trigger Period pursuant to Bye-law 38;
Secretary	the person appointed to perform any or all of the duties of secretary of the Company and includes any deputy or assistant secretary and any person appointed by the Board to perform any of the duties of the Secretary;
Treasury Share	a share of the Company that was or is treated as having been acquired and held by the Company and has been held continuously by the Company since it was so acquired and has not been cancelled;
Trigger Date	the first date on which Roivant holds less than 35.0% of the aggregate voting rights attaching to issued and outstanding shares of the Company;
Trigger Period	any period of time prior to the Trigger Date during which Roivant holds less than 50.0% but more than or equal to 35.0% of the aggregate voting rights attaching to issued and outstanding shares of the Company; and
U.S. Person	a “United States person” as defined in Section 957(c) of the Code.

1.2 In these Bye-laws, where not inconsistent with the context:

(a) words denoting the plural number include the singular number and vice versa;

(b) words denoting the masculine gender include the feminine and neuter genders;

(c) words importing persons include companies, associations or bodies of persons whether corporate or not;

(d) the words:

(i) “may” shall be construed as permissive; and

(ii) “shall” shall be construed as imperative;

(e)a reference to a statutory provision shall be deemed to include any amendment or re-enactment thereof;

(f)the word "corporation" means a corporation whether or not a company within the meaning of the Act;

(g)unless otherwise provided herein, words or expressions defined in the Act shall bear the same meaning in these Bye-laws.

1.3 In these Bye-laws expressions referring to writing or its cognates shall, unless the contrary intention appears, include facsimile, printing, lithography, photography, electronic mail and other modes of representing words in visible form.

1.4 Headings used in these Bye-laws are for convenience only and are not to be used or relied upon in the construction hereof.

SHARES

2. Power to Issue Shares

2.1 Subject to these Bye-laws and to any resolution of the Members to the contrary, and without prejudice to any special rights previously conferred on the holders of any existing shares or class of shares, the Board shall have the power to issue any unissued shares on such terms and conditions as it may determine.

2.2 Subject to the Act, any preference shares may be issued or converted into shares that (at a determinable date or at the option of the Company or the holder) are liable to be redeemed on such terms and in such manner as may be determined by the Board (before the issue or conversion).

2.3 Notwithstanding the foregoing or any other provision of these Bye-laws, the Company may not issue any shares in a manner that the Board determines in its sole discretion may result in a non de minimis adverse tax, legal or regulatory consequence to the Company, any of its subsidiaries or any direct or indirect holder of shares or its affiliates.

3. Power of the Company to Purchase its Shares

3.1 The Company may purchase its own shares for cancellation or acquire them as Treasury Shares in accordance with the Act on such terms as the Board shall think fit.

3.2 The Board may exercise all the powers of the Company to purchase or acquire all or any part of its own shares in accordance with the Act.

3.3 Notwithstanding the foregoing or any other provision of these Bye-laws, any such purchase or acquisition may not be made if the Board determines in its sole discretion that the purchase or acquisition may result in a non de minimis adverse tax, legal or regulatory consequence to the Company, any of its subsidiaries or any direct or indirect holder of shares or its affiliates.

4. Rights Attaching to Shares

4.1 At the date these Bye-laws are adopted, the authorised share capital of the Company is divided into five hundred and sixty four million one hundred and eleven thousand two hundred and forty two (564,111,242) common shares of par value US$0.000017727 each (the "**Common Shares**"), the holders of which shall, subject to these Bye-laws:

(a) be entitled to one vote per share;

(b) be entitled to such dividends as the Board may from time to time declare;

(c) in the event of a winding-up or dissolution of the Company, whether voluntary or involuntary or for the purpose of a reorganisation or otherwise or upon any distribution of capital, be entitled to the surplus assets of the Company; and

(d) generally be entitled to enjoy all of the rights attaching to shares.

4.2 The Board is authorised to provide for the creation and issuance of preference shares (the "**Preference Shares**") in one or more series, and to establish from time to time the number of shares to be included in each such series, and to fix the terms, including designation, powers, preferences, rights, qualifications, limitations and restrictions of the shares of each such series (and, for the avoidance of doubt, such matters and the issuance of such Preference Shares with prior ranking shall not be deemed to vary the rights attached to the Common Shares or, subject to the terms of any other series of Preference Shares, to vary the rights attached to any other series of Preference Shares). The authority of the Board with respect to each series shall include, but not be limited to, determination of the following:

(a) the number of shares constituting that series and the distinctive designation of that series;

(b) the dividend rate on the shares of that series, whether dividends shall be cumulative and, if so, from which date or dates, and the relative rights of priority, if any, of the payment of dividends on shares of that series;

(c) whether that series shall have voting rights, in addition to the voting rights provided by law, and if so, the terms of such voting rights;

(d) whether that series shall have conversion or exchange privileges (including, without limitation, conversion into Common Shares), and, if so, the terms and conditions of such conversion or exchange, including provision for adjustment of the conversion or exchange rate in such events as the Board shall determine;

(e) whether or not the shares of that series shall be redeemable or repurchaseable, and, if so, the terms and conditions of such redemption or repurchase, including the manner of selecting shares for redemption or repurchase if less than all shares are to be redeemed or repurchased, the date or dates upon or after which they shall be redeemable or repurchaseable, and the amount per share payable in case of redemption or repurchase, which amount may vary under different conditions and at different redemption or repurchase dates;

(f) whether that series shall have a sinking fund for the redemption or repurchase of shares of that series, and, if so, the terms and amount of such sinking fund;

(g) the right of the shares of that series to the benefit of conditions and restrictions upon the creation of indebtedness of the Company or any subsidiary, upon the issue of any additional shares (including additional shares of such series or any other series) and upon the payment of dividends or the making of other distributions on, and the purchase, redemption or other acquisition by the Company or any subsidiary of any issued shares of the Company;

(h) the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the Company, and the relative rights of priority, if any, of payment in respect of shares of that series;

(i) the rights of holders of that series to elect or appoint Directors; and

(j) any other relative participating, optional or other special rights, qualifications, limitations or restrictions of that series.

4.3 Any Preference Shares of any series which have been redeemed (whether through the operation of a sinking fund or otherwise) or which, if convertible or exchangeable, have been converted into or exchanged for shares of any other class or classes shall have the status of authorised and unissued Preference Shares of the same series and may be reissued as a part of the series of which they were originally a part or may be reclassified and reissued as part of a new series of Preference Shares to be created by resolution or resolutions of the Board or as part of any other series of Preference Shares, all subject to the conditions and the restrictions on issuance set forth in the resolution or resolutions adopted by the Board providing for the issue of any series of Preference Shares.

4.4 At the discretion of the Board, whether or not in connection with the issuance and sale of any shares or other securities of the Company, the Company may issue securities, contracts, warrants or other instruments evidencing any shares, option rights, securities having conversion or option rights, or obligations on such terms, conditions and other provisions as are fixed by the Board, including, without limiting the generality of this authority, conditions that preclude or limit any person or persons owning or offering to acquire a specified number or percentage of the issued Common Shares, other shares, option rights, securities having conversion or option rights, or obligations of the Company or transferee of the person or persons from exercising, converting, transferring or receiving the shares, option rights, securities having conversion or option rights, or obligations.

4.5 All the rights attaching to a Treasury Share shall be suspended and shall not be exercised by the Company while it holds such Treasury Share and, except where required by the Act, all Treasury Shares shall be excluded from the calculation of any percentage or fraction of the share capital, or shares, of the Company.

5. Calls on Shares

5.1 The Board may make such calls as it thinks fit upon the Members in respect of any moneys (whether in respect of nominal value or premium) unpaid on the shares allotted to or held by such Members (and not made payable at fixed times by the terms and conditions of issue) and, if a call is not paid on or before the day appointed for payment thereof, the Member may at the discretion of the Board be liable to pay the Company interest on the amount of such call at such rate as the Board may determine, from the date when such call was payable up to the actual date of payment. The Board may differentiate between the holders as to the amount of calls to be paid and the times of payment of such calls.

5.2 Any amount which by the terms of allotment of a share becomes payable upon issue or at any fixed date, whether on account of the nominal value of the share or by way of premium, shall for all the purposes of these Bye-laws be deemed to be an amount on which a call has been duly made and payable on the date on which, by the terms of issue, the same becomes payable, and in case of non-payment all the relevant provisions of these Bye-laws as to forfeiture, payment of interest, costs and expenses, forfeiture or otherwise shall apply as if such amount had become payable by virtue of a duly made and notified call.

5.3 The joint holders of a share shall be jointly and severally liable to pay all calls and any interest, costs and expenses in respect thereof.

5.4 The Company may accept from any Member the whole or a part of the amount remaining unpaid on any shares held by him, although no part of that amount has been called up or become payable.

6. Forfeiture of Shares

6.1 If any Member fails to pay, on the day appointed for payment thereof, any call in respect of any share allotted to or held by such Member, the Board may, at any time thereafter during such time as the call remains unpaid, direct the Secretary to forward such Member a notice in writing in the form, or as near thereto as circumstances admit, of the following:

Notice of Liability to Forfeiture for Non-Payment of Call

Myovant Sciences Ltd. (the "**Company**")

You have failed to pay the call of [amount of call] made on the [ ] day of [ ], 20[ ], in respect of the [number] share(s) [number in figures] standing in your name in the Register of Members of the Company, on the [ ] day of [ ], 20[ ], the day appointed for payment of such call. You are hereby notified that unless you pay such call together with interest thereon at the rate of [ ] per annum computed from the said [ ] day of [ ], 20[ ] at the registered office of the Company the share(s) will be liable to be forfeited.

Dated this [ ] day of [], 20[ ]

_____

[Signature of Secretary] By Order of the Board

6.2 If the requirements of such notice are not complied with, any such share may at any time thereafter before the payment of such call and the interest due in respect thereof be forfeited by a resolution of the Board to that effect, and such share shall thereupon become the property of the Company and may be disposed of as the Board shall determine. Without limiting the generality of the foregoing, the disposal may take place by sale, repurchase, redemption or any other method of disposal permitted by and consistent with these Bye-laws and the Act.

6.3 A Member whose share or shares have been so forfeited shall, notwithstanding such forfeiture, be liable to pay to the Company all calls owing on such share or shares at the time of the forfeiture, together with all interest due thereon and any costs and expenses incurred by the Company in connection therewith.

6.4 The Board may accept the surrender of any shares which it is in a position to forfeit on such terms and conditions as may be agreed. Subject to those terms and conditions, a surrendered share shall be treated as if it had been forfeited.

7. Share Certificates

7.1 Every Member shall be entitled to a certificate under the common seal (or a facsimile thereof) of the Company or bearing the signature (or a facsimile thereof) of a Director or Secretary or a person expressly authorized to sign specifying the number and, where appropriate, the class of shares held by such Member and whether the same are fully paid up and, if not, specifying the amount paid on such shares. The Board may by resolution determine, either generally or in a particular case, that any or all signatures on certificates may be printed thereon or affixed by mechanical means.

7.2 The Company shall be under no obligation to complete and deliver a share certificate unless specifically called upon to do so by the person to whom the shares have been allotted.

7.3 If any share certificate shall be proved to the satisfaction of the Board to have been worn out, lost, mislaid, or destroyed the Board may cause a new certificate to be issued and request an indemnity for the lost certificate if it sees fit.

7.4 Notwithstanding any provisions of these Bye-laws:

(a) the Directors shall, subject always to the Act and any other applicable laws and regulations and the facilities and requirements of any relevant system concerned, have power to implement any arrangements they may, in their absolute discretion, think fit in relation to the evidencing of title to and transfer of uncertificated shares and to the extent such arrangements are so implemented, no provision of these Bye-laws shall apply or have effect to the extent that it is in any respect inconsistent with the holding or transfer of shares in uncertificated form; and

(b) unless otherwise determined by the Directors and as permitted by the Act and any other applicable laws and regulations, no person shall be entitled to receive a certificate in respect of any share for so long as the title to that share is evidenced otherwise than by a certificate and for so long as transfers of that share may be made otherwise than by a written instrument.

8. Fractional Shares

The Company may issue its shares in fractional denominations and deal with such fractions to the same extent as its whole shares and shares in fractional denominations shall have in proportion to the respective fractions represented thereby all of the rights of whole shares including (but without limiting the generality of the foregoing) the right to vote, to receive dividends and distributions and to participate in a winding-up.

REGISTRATION OF SHARES

9. Register of Members

9.1 The Board shall cause to be kept in one or more books a Register of Members and shall enter therein the particulars required by the Act.

9.2 The Register of Members shall be open to inspection without charge at the registered office of the Company on every business day, subject to such reasonable restrictions as the Board may impose, so that not less than two hours in each business day be allowed for inspection. The Register of Members may, after notice has been given in accordance with the Act, be closed for any time or times not exceeding in the whole thirty days in each year.

10. Registered Holder Absolute Owner

The Company shall be entitled to treat the registered holder of any share as the absolute owner thereof and accordingly shall not be bound to recognise any equitable claim or other claim to, or interest in, such share on the part of any other person.

11. Transfer of Registered Shares

11.1 An instrument of transfer shall be in writing in the form of the following, or as near thereto as circumstances admit, or in such other form as the Board may accept:

Transfer of a Share or Shares

Myovant Sciences Ltd. (the "**Company**")

FOR VALUE RECEIVED [amount], I, [name of transferor] hereby sell, assign and transfer unto [transferee] of [address], [number] shares of the Company.

DATED this [ ] day of [ ], 20[ ]

Signed by:	In the presence of:
_____	_____
Transferor	Witness
_____	_____
Transferee	Witness
_____	_____

11.2 Such instrument of transfer shall be signed by (or in the case of a party that is a corporation) on behalf of the transferor and transferee, provided that, in the case of a fully paid up share, the Board may accept the instrument signed by or on behalf of the transferor alone. The transferor shall be deemed to remain the holder of such share until the same has been registered as having been transferred to the transferee in the Register of Members.

11.3 The Board may refuse to recognise any instrument of transfer unless it is accompanied by the certificate in respect of the shares to which it relates and by such other evidence as the Board may reasonably require to show the right of the transferor to make the transfer.

11.4 The joint holders of any share may transfer such share to one or more of such joint holders, and the surviving holder or holders of any share previously held by them jointly with a deceased Member may transfer any such share to the executors or administrators of such deceased Member.

11.5 The Board may in its absolute discretion and without assigning any reason therefor refuse to register the transfer of a share which is not fully paid up. The Board shall refuse to register a transfer unless all applicable consents, authorisations and permissions of any governmental body or agency in Bermuda have been obtained. If the Board refuses to register a transfer of any share the Secretary shall, within three months after the date on which the transfer was lodged with the Company, send to the transferor and transferee notice of the refusal.

11.6 Shares may be transferred without a written instrument if transferred by an appointed agent or otherwise in accordance with the Act.

11.7 Notwithstanding anything to the contrary in these Bye-laws, shares that are listed or admitted to trading on an appointed stock exchange may be transferred in accordance with the rules and regulations of such exchange.

11.8 Notwithstanding the foregoing, the Board may decline to approve or register or permit the registration of any transfer of shares if it appears to the Board that any non-de minimis adverse tax, regulatory or legal consequences to the Company, any subsidiary of the Company or any direct or indirect holder of shares or its Affiliates would result from such Transfer.

12 Transmission of Registered Shares

12.1 In the case of the death of a Member, the survivor or survivors where the deceased Member was a joint holder, and the legal personal representatives of the deceased Member where the deceased Member was a sole holder, shall be the only persons recognised by the Company as having any title to the deceased Member's interest in the shares. Nothing herein contained shall release the estate of a deceased joint holder from any liability in respect of any share which had been jointly held by such deceased Member with other persons. Subject to the Act, for the purpose of this Bye-law, legal personal representative means the executor or administrator of a deceased Member or such other person as the Board may, in its absolute discretion, decide as being properly authorised to deal with the shares of a deceased Member.

12.2 Any person becoming entitled to a share in consequence of the death or bankruptcy of any Member may be registered as a Member upon such evidence as the Board may deem sufficient or may elect to nominate some person to be registered as a transferee of such share, and in such case the person becoming entitled shall execute in favour of such nominee an instrument of transfer in writing in the form, or as near thereto as circumstances admit, of the following:

Transfer by a Person Becoming Entitled on Death/Bankruptcy of a Member

Myovant Sciences Ltd. (the "**Company**")

I/We, having become entitled in consequence of the [death/bankruptcy] of [name and address of deceased/bankrupt Member] to [number] share(s) standing in the Register of Members of the Company in the name of the said [name of deceased/bankrupt Member] instead of being registered myself/ourselves, elect to have [name of transferee] (the "**Transferee**") registered as a transferee of such share(s) and I/we do hereby accordingly transfer the said share(s) to the Transferee to hold the same unto the Transferee, his or her executors, administrators and assigns, subject to the conditions on which the same were held at the time of the execution hereof; and the Transferee does hereby agree to take the said share(s) subject to the same conditions.

DATED this [ ] day of [ ], 20[ ]

Signed by:	In the presence of:
_____	_____
Transferor	Witness
_____	_____
Transferee	Witness
_____	_____

12.3 On the presentation of the foregoing materials to the Board, accompanied by such evidence as the Board may require to prove the title of the transferor, the transferee shall be registered as a Member. Notwithstanding the foregoing, the Board shall, in any case, have the same right to decline or suspend registration as it would have had in the case of a transfer of the share by that Member before such Member's death or bankruptcy, as the case may be.

12.4 Where two or more persons are registered as joint holders of a share or shares, then in the event of the death of any joint holder or holders the remaining joint holder or holders shall be absolutely entitled to such share or shares and the Company shall recognise no claim in respect of the estate of any joint holder except in the case of the last survivor of such joint holders.

ALTERATION OF SHARE CAPITAL

13. Power to Alter Capital

13.1 The Company may if authorised by resolution of the Members increase, divide, consolidate, subdivide, change the currency denomination of, diminish or otherwise alter or reduce its share capital in any manner permitted by the Act.

13.2 Where, on any alteration or reduction of share capital, fractions of shares or some other difficulty would arise, the Board may deal with or resolve the same in such manner as it thinks fit.

14. Variation of Rights Attaching to Shares

14.1 If, at any time, the share capital is divided into different classes of shares, the rights attached to any class (unless otherwise provided by the terms of issue of the shares of that class) may, whether or not the Company is being wound-up, be varied with the consent in writing of the holders of three-fourths of the issued shares of that class or with the sanction of a resolution passed by a majority of the votes cast at a separate general meeting of the holders of the shares of the class at which meeting the necessary quorum shall be two persons at least holding or representing by proxy one-third of the issued shares of the class. The rights conferred upon the holders of the shares of any class or series issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the shares of that class or series, be deemed to be varied by the creation or issue of further shares ranking pari passu therewith.

14.2 Notwithstanding the foregoing or any other provision of these Bye-laws, the Company shall not vary or alter the rights attaching to any class of shares if the Board determines in its sole discretion that any non de minimis adverse tax, regulatory or legal consequences to the Company, any subsidiary of the Company, or any direct or indirect holders of shares or its affiliates may result from such variation.

DIVIDENDS AND CAPITALISATION

15. Dividends

15.1 The Board may, subject to these Bye-laws and in accordance with the Act, declare a dividend to be paid to the Members, in proportion to the number of shares held by them, and such dividend may be paid in cash or wholly or partly in specie in which case the Board may fix the value for distribution in specie of any assets. No unpaid dividend shall bear interest as against the Company.

15.2 The Board may fix any date as the record date for determining the Members entitled to receive any dividend.

15.3 The Company may pay dividends in proportion to the amount paid up on each share where a larger amount is paid up on some shares than on others.

15.4 The Board may declare and make such other distributions (in cash or in specie) to the Members as may be lawfully made out of the assets of the Company. No unpaid distribution shall bear interest as against the Company.

16. Power to Set Aside Profits

The Board may, before declaring a dividend, set aside out of the surplus or profits of the Company, such amount as it thinks proper as a reserve to be used to meet contingencies or for equalising dividends or for any other purpose.

17. Method of Payment

17.1 Any dividend or other moneys payable in respect of a share may be paid by cheque or draft sent through the post directed to the address of the Member in the Register of Members (in the case of joint Members, the senior joint holder, seniority being determined by the order in which the names stand in the Register of Members), or by direct transfer to such bank account as such Member may direct. Every such cheque shall be made payable to the order of the person to whom it is sent or to such persons as the Member may direct, and payment of the cheque or draft shall be a good discharge to the Company. Every such cheque or draft shall be sent at the risk of the person entitled to the money represented thereby. If two or more persons are registered as joint holders of any shares any one of them can give an effectual receipt for any dividend paid in respect of such shares.

17.2 The Board may deduct from the dividends or distributions payable to any Member all moneys due from such Member to the Company on account of calls or otherwise.

17.3 Any dividend and/or other moneys payable in respect of a share which has remained unclaimed for 6 years from the date when it became due for payment shall, if the Board so resolves, be forfeited and cease to remain owing by the Company. The payment of any unclaimed dividend or other moneys payable in respect of a share may (but need not) be paid by the Company into an account separate from the Company's own account. Such payment shall not constitute the Company a trustee in respect thereof.

17.4 The Company shall be entitled to cease sending dividend cheques and drafts by post or otherwise to a Member if those instruments have been returned undelivered to, or left uncashed by, that Member on at least two consecutive occasions, or, following one such occasion, reasonable enquiries have failed to establish the Member's new address. The entitlement conferred on the Company by this Bye-law 17.4 in respect of any Member shall cease if the Member claims a dividend or cashes a dividend cheque or draft.

18. Capitalisation

18.1 The Board may capitalise any amount for the time being standing to the credit of any of the Company's share premium or other reserve accounts or to the credit of the profit and loss account or otherwise available for distribution by applying such amount in paying up unissued shares to be allotted as fully paid up bonus shares pro-rata (except in connection with the conversion of shares of one class to shares of another class) to the Members.

18.2 The Board may capitalise any amount for the time being standing to the credit of a reserve account or amounts otherwise available for dividend or distribution by applying such amounts in paying up in full, partly or nil paid up shares of those Members who would have been entitled to such amounts if they were distributed by way of dividend or distribution.

MEETINGS OF MEMBERS

19. Annual General Meetings

Notwithstanding the provisions of the Act entitling the Members of the Company to elect to dispense with the holding of an annual general meeting, an annual general meeting of the Company shall be held in each year (other than the year of incorporation) at such time and place as the Principal Executive Officer or the chairman (if any) or any two Directors or any Director and the Secretary or the Board shall appoint.

20. Special General Meetings

The Principal Executive Officer, the chairman (if any), any two Directors, any Director and the Secretary, or the Board may convene a special general meeting whenever in their judgment such a meeting is necessary.

21. Requisitioned Special General Meetings

The Board shall, on the requisition of Members holding not less than one-tenth of the paid-up share capital of the Company carrying the right to vote at general meetings as at the date of the deposit of the requisition, forthwith proceed to convene a special general meeting and the provisions of the Act shall apply.

22. Notice

22.1 At least 14 days' notice of an annual general meeting shall be given to each Member entitled to attend and vote thereat, stating the date, place and time at which the meeting is to be held, that the election of Directors will take place thereat, and as far as practicable, the other business to be conducted at the meeting.

22.2 At least 10 days' notice of a special general meeting shall be given to each Member entitled to attend and vote thereat, stating the date, time, place and the general nature of the business to be considered at the meeting.

22.3 The Board may fix any date as the record date for determining the Members entitled to receive notice of and to vote at any general meeting.

22.4 A general meeting shall, notwithstanding that it is called on shorter notice than that specified in these Bye-laws, be deemed to have been properly called if it is so agreed by (i) all the Members entitled to attend and vote thereat in the case of an annual general meeting; and (ii) by a majority in number of the Members having the right to attend and vote at the meeting, being a majority together holding not less than 95% in nominal value of the shares giving a right to attend and vote thereat in the case of a special general meeting.

22.5 The accidental omission to give notice of a general meeting to, or the non-receipt of a notice of a general meeting by, any person entitled to receive notice shall not invalidate the proceedings at that meeting.

23. Giving Notice and Access

23.1 A notice may be given by the Company to a Member:

(a) by delivering it to such Member in person, in which case the notice shall be deemed to have been served upon such delivery; or

(b) by sending it by post to such Member's address in the Register of Members, in which case the notice shall be deemed to have been served seven days after the date on which it is deposited, with postage prepaid, in the mail; or

(c) by sending it by courier to such Member's address in the Register of members, in which case the notice shall be deemed to have been served two days after the date on which it is deposited, with courier fees paid, with the courier service; or

(d) by transmitting it by electronic means (including facsimile and electronic mail, but not telephone) in accordance with such directions as may be given by such Member to the Company for such purpose, in which case the notice shall be deemed to have been served at the time that it would in the ordinary course be transmitted; or

(e) by delivering it in accordance with the provisions of the Act pertaining to delivery of electronic records by publication on a website, in which case the notice shall be deemed to have been served at the time when the requirements of the Act in that regard have been met; or in accordance with Bye-law 23.4.

23.2 Any notice required to be given to a Member shall, with respect to any shares held jointly by two or more persons, be given to whichever of such persons is named first in the Register of Members and notice so given shall be sufficient notice to all the holders of such shares.

23.3 In proving service under paragraphs 23.1 (b), (c) and (d), it shall be sufficient to prove that the notice was properly addressed and prepaid, if posted or sent by courier, and the time when it was posted, deposited with the courier, or transmitted by electronic means.

23.4 Where a Member indicates his consent (in a form and manner satisfactory to the Board) to receive information or documents by accessing them on a website rather than by other means, or receipt in this manner is otherwise permitted by the Act, the Board may deliver such information or documents by notifying the Member of their availability and including therein the address of the website, the place on the website where the information or document may be found, and instructions as to how the information or document may be accessed on the website.

23.5 In the case of information or documents delivered in accordance with Bye-law 23.4, service shall be deemed to have occurred when (i) the Member is notified in accordance with that Bye-law; and (ii) the information or document is published on the website.

24. Notice of Nominations and Member Business

24.1 Annual General Meetings

(a) Subject to Roivant's right to appoint Roivant Directors during the Trigger Period pursuant to Bye-law 38, nominations of persons for election as a Director (other than a Roivant Director) or the proposal of other business to be transacted by the Members may be made at an annual general meeting only (i) pursuant to the Company's notice of meeting (or any supplement thereto), subject to Bye-law 38, (ii) by or at the direction of the Board, subject to Bye-law 38 or (iii) subject to any applicable law (including as provided for in Bye-law 24.1(e), in the case of proposals of any business other than in respect of Director nominations), by any Eligible Member of record at the time of giving of notice as provided for in this Bye-law 24.1 who complies with the notice procedures set forth in this Bye-law 24.1;

(b) Subject to Roivant's right to appoint Roivant Directors during the Trigger Period pursuant to Bye-law 38, for Director nominations (other than Roivant Directors) or other business to be properly brought before an annual general meeting by an Eligible Member pursuant to clause (iii) of Bye-law 24.1(a), the Eligible Member must have given timely notice thereof in writing to the Secretary and any such proposed business must constitute a proper matter for Member action. To be timely, an Eligible Member's notice shall be delivered to or mailed and received by the Secretary at the registered office of the Company not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual general meeting; provided, that in the event that the date of the annual general meeting is called for a date that is not less than 30 days before or after such anniversary then to be timely such notice must be received at the registered office of the Company not later than ten days following the earlier of (x) the date on which notice of the annual general meeting was posted to shareholders or (y) if and as applicable, the date on which public announcement (as defined below) of the date of the annual general meeting was made. In no event shall the public announcement of an adjournment or postponement of an annual general meeting commence a new time period (or extend any time period) for the giving of an Eligible

Member's notice as described above. For purposes of Bye-laws 24.1(b) and 24.2, "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, the Associated Press, PR Newswire, Businesswire, Bloomberg or any comparable news service in the United States or, as and when applicable, in a document publicly filed by the Company with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Securities Exchange Act of 1934;

(c) A Member's notice to the Secretary shall set forth (A) as to each person whom the Member proposes to nominate for election or reelection as a Director (other than a Roivant Director) all information relating to such person that is required to be disclosed in solicitations of proxies for election of Directors, or is otherwise required, as and when applicable, in each case pursuant to Section 14(a) of the Securities Exchange Act of 1934 (including such person's written consent to being named in the proxy statement as a nominee and to serving as a Director if elected), (B) as to any other business that the Member proposes to bring before the general meeting, a brief description of the business desired to be brought before the general meeting, the text of the proposal or business, the reasons for conducting such business at the general meeting and any material interest in such business of such Member and the beneficial owner, if any, on whose behalf the proposal is made, and (C) as to the Member giving the notice and the beneficial owner, if any, on whose behalf the proposal is made:

(i) the name and address of such Member (as they appear in the Register of Members) and any such beneficial owner;

(ii) the class or series and number of shares of the Company which are held of record or are beneficially owned by such Member and by any such beneficial owner;

(iii) a description of any agreement, arrangement or understanding between or among such Member and any such beneficial owner, any of their respective affiliates or associates, and any other person or persons (including their names) in connection with the proposal of such nomination or other business;

(iv) a description of any agreement, arrangement or understanding (including, regardless of the form of settlement, any derivative, long or short positions, profit interests, forwards, futures, swaps, options, warrants, convertible securities, share appreciation or similar rights, hedging transactions and borrowed or loaned shares) that has been entered into by or on behalf of, or any other agreement, arrangement or understanding that has been made, the effect or intent of which is to create or mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such Member or any such beneficial owner or any such nominee with respect to the Company's securities (a "Derivative Instrument");

(v) to the extent not disclosed pursuant to clause (iv) above, the principal amount of any indebtedness of the Company or any of its subsidiaries beneficially owned by such Member or by any such beneficial owner, together with the title of the instrument under which such indebtedness was issued and a description of any Derivative Instrument entered into by or on behalf of such Member or such beneficial owner relating to the value or payment of any indebtedness of the Company or any such subsidiary;

(vi) a representation that the Member is a holder of record of shares of the Company entitled to vote at such general meeting and intends to appear in person or by proxy at the general meeting to bring such nomination or other business before the general meeting; and

(vii) a representation as to whether such Member or any such beneficial owner intends or is part of a group that intends to (A) deliver a proxy statement and/or form of proxy to holders of at least the percentage of the voting power of the Company's outstanding shares required to approve or adopt the proposal or to elect each such nominee and/or (B) otherwise to solicit proxies from Members in support of such proposal or nomination;

(d) If requested by the Company, the information required under clauses (ii), (iii), (iv) and (v) of Bye-law 24.1(c) shall be supplemented by such Member and any such beneficial owner not later than 10 days after the record date for notice of the general meeting to disclose such information as of such record date;

(e) Notwithstanding anything to the contrary, the notice requirements set forth herein with respect to the proposal of any business pursuant to this Bye-law 24.1 other than a Director nomination shall be deemed satisfied by a Member if such Member has submitted a proposal to the Company in compliance with Rule 14a-8 promulgated under the Securities and Exchange Act of 1934, as and when applicable to the Company.

24.2 Special General Meetings

(a) Only such business shall be conducted at a special general meeting as shall have been brought before the general meeting in accordance with the Company's notice of meeting pursuant to Bye-laws 22 and 23.

(b) Subject to Roivant's right to appoint Roivant Directors during the Trigger Period pursuant to Bye-law 38, nominations of persons for election as Directors (other than Roivant Directors) at a special general meeting may be made (i) by or at the direction of the Board or (ii) subject to any applicable law, by any Eligible Member of record at the time of giving of notice who complies with the notice procedures set forth in this Bye-law 24.

(c) For nominations to be properly brought before a special general meeting by a Member pursuant to Bye-law 24.2(b)(ii), the Member must have given timely notice thereof in writing to the Secretary. To be timely, a Member's notice and nominations of persons for election as Directors (other than Roivant Directors) shall specify whether those persons nominated are nominated as replacements of existing Directors (other than Roivant Directors) and, if so, which Directors they are proposed to replace and (i) be set out in such Member's requisition of a special general meeting made under Bye-law 21 or (ii) be delivered to or mailed and received at the registered office of the Company not later than seven days following the earlier of (x) the date on which notice of the special general meeting was posted to shareholders or (y) as and when applicable, the date on which public announcement of the date of the special general meeting was made.

(d) A Member's notice to the Secretary, including any notice of requisition pursuant to Bye-law 21, shall comply with the notice requirements of Bye-law 24.1(c) and (d).

24.3 General

(a) At the request of the Board, any person nominated by the Board for election as a Director (other than a Roivant Director) shall furnish to the Secretary the information that is required to be set forth in a Member's notice of nomination pursuant to Bye-law 24.1(c).

(b) Subject to Roivant's right to appoint Roivant Directors during the Trigger Period pursuant to Bye-law 38, no person shall be eligible to be nominated by a Member to serve as a Director

of the Company unless nominated in accordance with the procedures set forth in this Bye-law 24.

(c) The chairman of the general meeting shall, if the facts warrant, determine and declare to the general meeting that a nomination was not made in accordance with the procedures prescribed by these Bye-laws or that business was not properly brought before the general meeting, and if he should so determine and declare, the defective nomination shall be disregarded or such business shall not be transacted, as the case may be.

(d) Notwithstanding the foregoing provisions of this Bye-law 24, unless otherwise required by the Act, if the Member (or a qualified representative of the Member) does not appear at the annual or special general meeting to present a nomination or other proposed business, such nomination shall be disregarded or such proposed business shall not be transacted, as the case may be, notwithstanding that proxies in respect of such vote may have been received by the Company. For purposes of this Bye-law 24.3, to be considered a qualified representative of the Member, a person must be a duly authorized officer, manager or partner of such Member or must be authorized by a writing executed by such Member or an electronic transmission delivered by such Member to act for such Member as proxy at the general meeting and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the general meeting.

24.4 Without limiting the foregoing provisions of this Bye-law 24, a Member shall also comply with, when and as applicable, all applicable requirements of the Securities Exchange Act of 1934 and the rules and regulations thereunder with respect to the matters set forth in this Bye-law 24; provided, that any references in these Bye-laws to the Securities Exchange Act of 1934 or the rules and regulations promulgated thereunder are not intended to and shall not limit any requirements applicable to nominations or proposals as to any other business to be considered pursuant to this Bye-law, and compliance with Bye-law 24.1 or 24.2 shall be the exclusive means for a Member to make nominations or submit other business (other than as provided in Bye-law 24.1(e)).

25. Postponement or Cancellation of General Meeting

The Secretary may, and on instruction from the chairman (if any) or the Principal Executive Officer shall, postpone or cancel any general meeting called in accordance with these Bye-laws (other than a meeting requisitioned under these Bye-laws) *provided* that notice of postponement or cancellation is given to each Member before the time for such meeting. Fresh notice of the date, time and place for the postponed or cancelled meeting shall be given to the Members in accordance with these Bye-laws.

26. Electronic Participation and Security at General Meetings

26.1 Members may participate in any general meeting by such telephonic, electronic or other communications facilities or means as permit all persons participating in the meeting to communicate with each other simultaneously and instantaneously, and participation in such a meeting shall constitute presence in person at such meeting.

26.2 The Board may, and at any general meeting, the chairman of such meeting may make any arrangement and impose any requirement or restriction it or he considers appropriate to ensure the security of a general meeting including, without limitation, requirements for evidence of identity to be produced by those attending the meeting, the searching of their personal property and the restriction of items that may be taken into the meeting place. The Board and, at any general meeting, the chairman of such meeting are entitled to refuse entry to a person who refuses to comply with any such arrangements, requirements or restrictions.

27. Quorum at General Meetings

27.1 At any general meeting two or more persons present at the start of the meeting and representing in person or by proxy in excess of 50% of the total issued voting shares in the Company shall form a quorum for the transaction of business.

27.2 If within half an hour from the time appointed for the meeting a quorum is not present, then, in the case of a meeting convened on a requisition, the meeting shall be deemed cancelled and, in any other case, the meeting shall stand adjourned to the same day one week later, at the same time and place or to such other day, time or place as the Secretary may determine. Unless the meeting is adjourned to a specific date, place and time announced at the meeting being adjourned, fresh notice of the date, place and time for the resumption of the adjourned meeting shall be given to each Member entitled to attend and vote thereat in accordance with these Bye-laws.

28. Chairman to Preside at General Meetings

Unless otherwise agreed by a majority of those attending and entitled to vote thereat, the chairman, if there be one, and if not the Principal Executive Officer, if there be one, shall act as chairman at all general meetings at which such person is present. In their absence, a chairman shall be appointed or elected by those present at the meeting and entitled to vote.

29. Voting on Resolutions

29.1 Subject to the Act and these Bye-laws, any question proposed for the consideration of the Members at any general meeting shall be decided by the affirmative votes of a majority of the votes cast in accordance with these Bye-laws and in the case of an equality of votes the resolution shall fail.

29.2 No Member shall be entitled to vote at a general meeting unless such Member has paid all the calls on all shares held by such Member.

29.3 At any general meeting a resolution put to the vote of the meeting shall, in the first instance, be voted upon by a show of hands and, subject to these Bye-laws and any rights or restrictions for the time being lawfully attached to any class of shares, every Member present in person and every person holding a valid proxy at such meeting shall be entitled to one vote and shall cast such vote by raising his hand.

29.4 In the event that a Member participates in a general meeting by telephone, electronic or other communications facilities or means, the chairman of the meeting shall direct the manner in which such Member may cast his vote on a show of hands.

29.5 At any general meeting if an amendment is proposed to any resolution under consideration and the chairman of the meeting rules on whether or not the proposed amendment is out of order, the proceedings on the substantive resolution shall not be invalidated by any error in such ruling.

29.6 At any general meeting a declaration by the chairman of the meeting that a question proposed for consideration has, on a show of hands, been carried, or carried unanimously, or by a particular majority, or lost, and an entry to that effect in a book containing the minutes of the proceedings of the Company shall, subject to these Bye-laws, be conclusive evidence of that fact.

30. Power to Demand a Vote on a Poll

30.1 Notwithstanding the foregoing, a poll may be demanded by any of the following persons:

(a) the chairman of such meeting; or

(b) at least three Members present in person or represented by proxy; or

(c) any Member or Members present in person or represented by proxy and holding between them not less than one-tenth of the total voting rights of all the Members having the right to vote at such meeting; or

(d) any Member or Members present in person or represented by proxy holding shares in the Company conferring the right to vote at such meeting, being shares on which an aggregate sum has been paid up equal to not less than one-tenth of the total amount paid up on all such shares conferring such right.

30.2 Where a poll is demanded, subject to any rights or restrictions for the time being lawfully attached to any class of shares, every person present at such meeting shall have one vote for each share of which such person is the holder or for which such person holds a proxy and such vote shall be counted by ballot as described herein, or in the case of a general meeting at which one or more Members are present by telephone, electronic or other communications facilities or means, in such manner as the chairman of the meeting may direct and the result of such poll shall be deemed to be the resolution of the meeting at which the poll was demanded and shall replace any previous resolution upon the same matter which has been the subject of a show of hands. A person entitled to more than one vote need not use all his votes or cast all the votes he uses in the same way.

30.3 A poll demanded for the purpose of electing a chairman of the meeting or on a question of adjournment shall be taken forthwith. A poll demanded on any other question shall be taken at such time and in such manner during such meeting as the chairman (or acting chairman) of the meeting may direct. Any business other than that upon which a poll has been demanded may be conducted pending the taking of the poll.

30.4 Where a vote is taken by poll, each person physically present and entitled to vote shall be furnished with a ballot paper on which such person shall record his vote in such manner as shall be determined at the meeting having regard to the nature of the question on which the vote is taken. Each ballot paper shall be signed or initialled or otherwise marked so as to identify the voter and the registered holder in the case of a proxy. Each person present by telephone, electronic or other communications facilities or means shall cast his vote in such manner as the chairman shall direct. At the conclusion of the poll, the ballot papers and votes cast in accordance with such directions shall be examined and counted by a committee of not less than two Members or proxy holders appointed by the chairman for the purpose. The result of the poll shall be declared by the chairman.

31. Voting by Joint Holders of Shares

In the case of joint holders, the vote of the senior who tenders a vote (whether in person or by proxy) shall be accepted to the exclusion of the votes of the other joint holders, and for this purpose seniority shall be determined by the order in which the names stand in the Register of Members.

32. Votes of Members – General

Subject to any rights and restrictions for the time being attached to any class or classes or series of shares, every Member shall have one vote for each share carrying the right to vote on the matter in question of which he is the holder.

33. Instrument of Proxy

33.1 A Member may appoint a proxy by (a) an instrument appointing a proxy in writing in substantially the following form or such other form as the Board may determine from time to time or the chairman of the meeting shall accept:

Proxy

Myovant

Sciences Ltd. (the "**Company**")

I/We, [insert names here], being a Member of the Company with [number] shares, HEREBY APPOINT [name] of [address] or failing him, [name] of [address] to be my/our proxy to vote for me/us at the meeting of the Members to be held on the [ ] day of [ ], 20[ ] and at any adjournment thereof. (Any restrictions on voting to be inserted here.)

Signed this [ ] day of [], 20[ ]

_____

Member(s)

or (b) such telephonic, electronic or other means as may be approved by the Board from time to time.

33.2 The appointment of a proxy must be received by the Company at the registered office or at such other place or in such manner as is specified in the notice convening the meeting or in any instrument of proxy sent out by the Company in relation to the meeting at which the person named in the appointment proposes to vote, and an appointment of proxy which is not received in the manner so permitted shall be invalid.

33.3 A Member who is the holder of two or more shares may appoint more than one proxy to represent him and vote on his behalf in respect of different shares.

33.4 The decision of the chairman of any general meeting as to the validity of any appointment of a proxy shall be final.

34. Representation of Corporate Member

34.1 A corporation which is a Member may, by written instrument, authorise such person or persons as it thinks fit to act as its representative at any meeting and any person so authorised shall be entitled to exercise the same powers on behalf of the corporation which such person represents as that corporation could exercise if it were an individual Member, and that Member shall be deemed to be present in person at any such meeting attended by its authorised representative or representatives.

34.2 Notwithstanding the foregoing, the chairman of the meeting may accept such assurances as he thinks fit as to the right of any person to attend and vote at general meetings on behalf of a corporation which is a Member.

35. Adjournment of General Meeting

35.1 The chairman of any general meeting at which a quorum is present may with the consent of Members holding a majority of the voting rights of those Members present in person or by proxy

(and shall if so directed by Members holding a majority of the voting rights of those Members present in person or by proxy), adjourn the meeting.

35.2 In addition, the chairman may adjourn the meeting to another time and place without such consent or direction if it appears to him that:

(a) it is likely to be impracticable to hold or continue that meeting because of the number of Members wishing to attend who are not present; or

(b) the unruly conduct of persons attending the meeting prevents, or is likely to prevent, the orderly continuation of the business of the meeting; or

(c) an adjournment is otherwise necessary so that the business of the meeting may be properly conducted.

35.3 Unless the meeting is adjourned to a specific date, place and time announced at the meeting being adjourned, fresh notice of the date, place and time for the resumption of the adjourned meeting shall be given to each Member entitled to attend and vote thereat in accordance with these Bye-laws.

36. Written Resolutions

36.1 Subject to these Bye-laws anything which may be done by resolution of the Company in general meeting or by resolution of a meeting of any class of the Members may, without a meeting be done by written resolution in accordance with this Bye-law.

36.2 Notice of a written resolution shall be given, and a copy of the resolution shall be circulated to all Members who would be entitled to attend a meeting and vote thereon. The accidental omission to give notice to, or the non-receipt of a notice by, any Member does not invalidate the passing of a resolution.

36.3 A written resolution is passed when it is signed by, or in the case of a Member that is a corporation on behalf of, the Members who at the date that the notice is given represent such majority of votes as would be required if the resolution was voted on at a meeting of Members at which all Members entitled to attend and vote thereat were present and voting.

36.4 A resolution in writing may be signed by any number of counterparts.

36.5 A resolution in writing made in accordance with this Bye-law 36 is as valid as if it had been passed by the Company in general meeting or by a meeting of the relevant class of Members, as the case may be (provided that (i) any such resolution shall be valid only if the signature of the last Member to sign is affixed outside the United States (unless the Board dispenses with this requirement), and (ii) the Board may declare such resolution to be invalid if the Board determines that the use of a resolution in writing would result in a non-de minimis adverse tax, regulatory or legal consequence to the Company, any subsidiary of the Company, or any direct or indirect holder of shares or its affiliates), and any reference in any Bye-law to a meeting at which a resolution is passed or to Members voting in favour of a resolution shall be construed accordingly.

36.6 A resolution in writing made in accordance with this Bye-law 36 shall constitute minutes for the purposes of the Act.

36.7 This Bye-law 36 shall not apply to:

(a) a resolution passed to remove an Auditor from office before the expiration of his term of office; or

(b) a resolution passed for the purpose of removing a Director for cause before the expiration of his term of office.

36.8 For the purposes of this Bye-law 36, the effective date of the resolution is the date when the resolution is signed by, or in the case of a Member that is a corporation whether or not a company within the meaning of the Act, on behalf of, the last Member whose signature results in the necessary voting majority being achieved and any reference in any Bye-law to the date of passing of a resolution is, in relation to a resolution made in accordance with this Bye-law 36, a reference to such date.

37. Directors Attendance at General Meetings

The Directors shall be entitled to receive notice of, attend and be heard at any general meeting.

DIRECTORS AND OFFICERS

38. Number, Election and Term of Directors

38.1 Subject to Roivant's right to appoint Roivant Directors during the Trigger Period pursuant to this Bye-law 38, the Board shall be elected or appointed in the first place at the statutory meeting of the Company and thereafter, except in the case of a casual vacancy, at the annual general meeting or at any special general meeting called for that purpose.

38.2 During the Trigger Period, the Board shall consist of no fewer than five and no more than nine Directors; provided, that Roivant shall, pursuant to the procedures set forth in Bye-law 38.3, have the right, during the Trigger Period, to designate and appoint or reappoint to the Board the minimum number of Roivant Directors necessary to ensure that the Roivant Directors comprise a simple majority of the total number of Directors on the Board and, if necessary, notwithstanding anything to the contrary in these Bye-laws, the number of Directors on the Board shall hereby automatically be increased to allow for the designation and appointment of such additional Roivant Directors as Directors. No person who has engaged in conduct constituting cause for removal pursuant to Bye-law 40.1 may be appointed or reappointed as a Roivant Director. Each Director shall hold office for such term as may be determined by resolution approved by the affirmative vote in a general meeting of the holders of a majority of the aggregate voting rights of the issued and outstanding shares of the Company entitled to vote thereon and voting at the meeting to elect that Director. In the absence of a determination pursuant to this Bye-law 38.2, each Director's term shall last until the next annual general meeting at which his or her successor is elected or appointed pursuant to Bye-law 38.3 or if earlier, the next special general meeting called for the purpose of ending the term of such Director and replacing that Director, in each case, subject to his office being vacated sooner pursuant to Bye-law 41. Notwithstanding the designation and appointment of Roivant Directors, Roivant may, as applicable, nominate and, together with the holders of a majority of the aggregate voting rights of issued and outstanding shares of the Company voting at a meeting, elect Directors who are not Roivant Directors. Outside of the Trigger Period, the size of the Board shall be fixed from time to time hereafter by the Board.

38.3 Each initial Director shall be elected by the affirmative vote in a general meeting of a majority of the aggregate voting rights of issued and outstanding shares of the Company entitled to vote thereon and voting at the meeting, or, if a Roivant Director, shall be designated or appointed by Roivant pursuant to this Bye-law 38. Upon the expiration of the term of any Director, his or her replacement shall be nominated, or appointed, as follows:

(a) During the Trigger Period, Roivant shall have the right to designate and appoint or reappoint Roivant Directors as set forth in Bye-law 38.2;

(b) During the Trigger Period, (i) Eligible Members, pursuant to Bye-law 24, or (ii) the Board, or the Nominating and Corporate Governance Committee if so designated by the Board, shall have the right to nominate the persons who shall stand for election as Directors for the remainder of the places then available for election to the Board (excluding the Roivant Directors), and who shall, if elected, each be entitled to cast one vote on each matter presented to the Board or to any committee thereof of which they are members; and

(c) Outside of the Trigger Period, (i) Eligible Members, pursuant to Bye-law 24, or (ii) the Board, or the Nominating and Corporate Governance Committee if so designated by the Board, shall have the right to nominate the persons who shall stand for election as Directors for all places then available for election to the Board and who shall, if elected, each be entitled to cast one vote on each matter presented to the Board or to any committee thereof of which they are members.

Each Director so nominated (excluding the Roivant Directors) shall be elected by the affirmative vote in a general meeting of the holders of a majority of the aggregate voting rights of issued and outstanding shares of the Company entitled to vote thereon and voting at the meeting. The persons receiving the most votes (up to the number of Directors to be elected, other than Roivant Directors) shall be elected as Directors, and in each case receipt of an absolute majority of the votes cast shall not be a prerequisite to the election of any Director.

38.4 All designations and appointments of Roivant Directors by Roivant shall become effective upon the delivery by Roivant of a duly executed notice to the Secretary (or at such later date as may be specified in such notice), without the requirement for any further vote or approval by the Members or the Board. Roivant may not transfer or otherwise delegate or give a proxy to any third party with respect to its right to appoint Roivant Directors, provided, however, that a majority of the remaining Roivant Directors may appoint a Roivant Director to fill a vacancy in a like manner.

39. Alternate Directors

39.1 Any Director may appoint a person or persons to act as a Director in the alternative to himself by notice deposited with the Secretary.

39.2 Any person so elected or appointed pursuant to this Bye-law 39 shall have all the rights and powers of the Director or Directors for whom such person is elected or appointed in the alternative provided that such person shall not be counted more than once in determining whether or not a quorum is present.

39.3 An Alternate Director shall be entitled to receive notice of all meetings of the Board and to attend and vote at any such meeting at which a Director for whom such Alternate Director was appointed in the alternative is not personally present and generally to perform at such meeting all the functions of such Director for whom such Alternate Director was appointed.

39.4 An Alternate Director’s office shall terminate:

(a) on the occurrence in relation to the Alternate Director of any event which, if it occurred in relation to his appointor, would result in the termination of the appointor’s directorship; or

(b) when the Alternate Director’s appointor revokes the appointment by notice to the Company in writing specifying when the appointment is to terminate; or

(c) if the Alternate Director's appointor ceases for any reason to be a Director.

40. Removal of Directors for Cause

40.1 Subject to subsections (a) through (c) of Bye-law 41.1:

(a) During the Trigger Period, (i) any Roivant Directors may be removed, with or without cause, only by Roivant, by duly executed notice to the Secretary, which is effective upon the delivery by Roivant to the Secretary, without the requirement for any further vote or approval by the Members or the Board, and (ii) Roivant shall promptly remove any Roivant Director who has engaged in conduct constituting cause for removal;

(b) During the Trigger Period, subject to any provision to the contrary in these Bye-laws, and in addition to the right of Members pursuant to Bye-laws 21, 24.2 and 38 to requisition the Board to convene a special general meeting for purposes of ending the term of the then-current Directors (other than Roivant Directors) and replacing them with new Directors, the Members holding a majority of the issued and outstanding shares of the Company may also, at any special general meeting convened and held in accordance with these Bye-laws, by the affirmative vote of all such Members, remove a Director (other than a Roivant Director) for cause, provided that the notice of any such meeting convened for the purpose of removing a Director shall contain a statement of the intention so to do and be served on such Director not less than 14 days before the meeting and at such meeting the Director shall be entitled to be heard on the motion for such Director's removal; and

(c) Outside of the Trigger Period, subject to any provision to the contrary in these Bye-laws, and in addition to the right of Members pursuant to Bye-laws 21, 24.2 and 38 to requisition the Board to convene a special general meeting for purposes of ending the term of the then-current Directors and replacing them with new Directors, the Members holding a majority of the issued and outstanding shares of the Company may also, at any special general meeting convened and held in accordance with these Bye-laws, by the affirmative vote of all such Members, remove a Director for cause, provided that the notice of any such meeting convened for the purpose of removing a Director shall contain a statement of the intention so to do and be served on such Director not less than 14 days before the meeting and at such meeting the Director shall be entitled to be heard on the motion for such Director's removal.

40.2 If a Roivant Director is removed from the Board under subsection (a) of Bye-law 40.1, Roivant may fill the vacancy by duly executed notice to the Secretary, which is effective upon the delivery by Roivant to the Secretary, without the requirement for any further vote or approval by the Members or the Board.

40.3 If a Director (other than, during the Trigger Period, a Roivant Director) is removed from the Board under subsections (b) or (c) of Bye-law 40.1, the Members may fill the vacancy at the meeting at which such Director is removed and a Director so appointed shall hold office until the earliest of (i) the next annual general meeting, (ii) the date such Director's term of office is ended pursuant to Bye-law 38 and (iii) the date such Director's office is otherwise vacated pursuant to Bye-law 41. In the absence of such election or appointment, the Board may fill the vacancy.

40.4 For the purpose of Bye-law 40.1, "cause" shall mean a conviction for a criminal offence involving dishonesty or engaging in conduct which brings the Director or the Company into disrepute and which results in material financial detriment to the Company.

41. Vacancy in the Office of Director

41.1 The office of Director shall be vacated immediately if the Director:

(a) is removed from office pursuant to these Bye-laws or is prohibited from being a Director by law;

(b) is or becomes bankrupt, or makes any arrangement or composition with his creditors generally;

(c) is or becomes of unsound mind or dies;

(d) resigns his office by notice to the Company (unless such other later date is agreed by the Board); or

(e) is not re-elected at an annual general meeting, or at a special general meeting called for the purpose of replacing them with a newly elected Director.

41.2 During the Trigger Period, only Roivant or a majority of the remaining Roivant Directors (pursuant to the procedures set forth in Bye-law 38) shall have the power to appoint any person as a Roivant Director to fill a vacancy on the Board occurring as a result of the death, disability, disqualification, removal or resignation of any Roivant Director prior to the expiration of his or her term. A Roivant Director appointed by a majority of the remaining Roivant Directors to fill a vacancy shall hold office until the earlier of (i) the next annual general meeting or (ii) the date such Roivant Director's office is otherwise vacated.

41.3 At any time, the Members in general meeting or the Board shall have the power to appoint any person as a Director to fill a vacancy on the Board occurring as a result of the death, disability, disqualification or resignation of any Director (other than, during the Trigger Period, a Roivant Director) or as a result of an increase in the size of the Board (other than an automatic increase in the size of the Board to permit the appointment of additional Roivant Directors pursuant to Bye-law 38.3(a)). During the Trigger Period, the power of the Board set forth in this Bye-law 41.3 shall reside in and be exercised by the Directors who are not Roivant Directors.

42. Remuneration of Directors

The remuneration (if any) of the Directors shall be determined by the Board or a committee thereof and shall be deemed to accrue from day to day. The Directors may also be paid all travel, hotel and other expenses properly incurred by them in attending and returning from the meetings of the Board, any committee appointed by the Board, general meetings, or in connection with the business of the Company or their duties as Directors generally.

43. Defect in Appointment

All acts done in good faith by the Board, any Director, a member of a committee appointed by the Board, any person to whom the Board may have delegated any of its powers shall, or any person acting as a Director shall, notwithstanding that it be afterwards discovered that there was some defect in the appointment of any Director or person acting as aforesaid, or that he was, or any of them were, disqualified, be as valid as if every such person had been duly appointed and was qualified to be a Director or act in the relevant capacity.

44. Directors to Manage Business

The business of the Company shall be managed and conducted by the Board. In managing the business of the Company, the Board may exercise all such powers of the Company as are not, by the Act or by these Bye-laws, required to be exercised by the Company in general meeting.

45. Powers of the Board of Directors

The Board may:

(a) appoint, suspend, or remove any manager, secretary, clerk, agent or employee of the Company and may fix their remuneration and determine their duties;

(b) exercise all the powers of the Company to borrow money and to mortgage or charge or otherwise grant a security interest in its undertaking, property and uncalled capital, or any part thereof, and may issue debentures, debenture stock and other securities whether outright or as security for any debt, liability or obligation of the Company or any third party;

(c) appoint one or more Directors to the office of managing director or Principal Executive Officer of the Company, who shall, subject to the control of the Board, supervise and administer all of the general business and affairs of the Company;

(d) appoint a person to act as manager of the Company's day-to-day business and may entrust to and confer upon such manager such powers and duties as it deems appropriate for the transaction or conduct of such business;

(e) by power of attorney, appoint any company, firm, person or body of persons, whether nominated directly or indirectly by the Board, to be an attorney of the Company for such purposes and with such powers, authorities and discretions (not exceeding those vested in or exercisable by the Board) and for such period and subject to such conditions as it may think fit and any such power of attorney may contain such provisions for the protection and convenience of persons dealing with any such attorney as the Board may think fit and may also authorise any such attorney to sub-delegate all or any of the powers, authorities and discretions so vested in the attorney;

(f) procure that the Company pays all expenses incurred in promoting and incorporating the Company and listing the shares of the Company;

(g) delegate any of its powers (including the power to sub-delegate) to a committee of one or more persons appointed by the Board which may consist partly or entirely of non-Directors, provided that every such committee shall conform to such directions as the Board shall impose on them and provided further that (i) the meetings and proceedings of any such committee shall be governed by these Bye-laws regulating the meetings and proceedings of the Board, so far as the same are applicable and are not superseded by directions imposed by the Board; and (ii) each of the Audit Committee, the Nominating and Corporate Governance Committee and the Compensation Committee shall be made up solely of Independent Directors;

(h) delegate any of its powers (including the power to sub-delegate) to any person on such terms and in such manner as the Board may see fit;

(i) present any petition and make any application in connection with the liquidation or reorganisation of the Company;

(j) in connection with the issue of any share, pay such commission and brokerage as may be permitted by law; and

(k) authorise any company, firm, person or body of persons to act on behalf of the Company for any specific purpose and in connection therewith to execute any deed, agreement, document or instrument on behalf of the Company.

46. Register of Directors and Officers

The Board shall cause to be kept in one or more books at the registered office of the Company a Register of Directors and Officers and shall enter therein the particulars required by the Act.

47. Appointment of Officers

The Board may appoint such officers (who may or may not be Directors) as the Board may determine for such terms as the Board deems fit.

48. Appointment of Secretary

The Secretary shall be appointed by the Board from time to time for such terms as the Board deems fit.

49. Duties of Officers

The Officers shall have such powers and perform such duties in the management, business and affairs of the Company as may be delegated to them by the Board from time to time.

50. Remuneration of Officers

The Officers shall receive such remuneration as the Board may determine.

51. Conflicts of Interest

51.1 Any Director, or any Director's firm, partner or any company with whom any Director is associated, may act in any capacity for, be employed by or render services to the Company and such Director or such Director's firm, partner or company shall be entitled to remuneration as if such Director were not a Director. Nothing herein contained shall authorise a Director or Director's firm, partner or company to act as Auditor to the Company.

51.2 If a Director or an immediate family member of a Director is directly or indirectly interested in a contract or proposed contract or arrangement with the Company such Director shall declare the nature of such interest as required by the Act.

51.3 Following a declaration being made pursuant to this Bye-law, a Director may not vote in respect of a contract or proposed contract or arrangement in which such Director is interested, and may not be counted in the quorum for such meeting, unless the chairman of the relevant Board meeting determines that such Director is not disqualified from voting. For the avoidance of doubt, no Director or immediate family member shall be considered "interested" with respect to any transaction in which all of the Members participate or are offered to participate. The chairman of a Board meeting may require a Director to leave the meeting to enable the Board to discuss and/or vote on a matter in which the chairman considers the Director or an immediate family member of the Director to be interested. If a majority in number of the Directors in attendance at a Board meeting considers the chairman of the meeting or an immediate family member of the chairman to be interested in a particular matter, they may require the chairman to leave the meeting to enable the Board to discuss and/or vote on such matter.

For the purpose of this Bye-law 51, "immediate family member" means, in relation to a Director, his child, step-child, parent, step-parent, spouse, civil partner, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law or any person (other than a tenant or employee) sharing the household of the Director.

52. Indemnification and Exculpation of Directors and Officers

52.1 The Directors, Resident Representative, Secretary and other Officers (such term to include any person appointed to any committee by the Board) acting in relation to any of the affairs of the Company or any subsidiary thereof and the liquidator or trustees (if any) acting in relation to any of the affairs of the Company or any subsidiary thereof and every one of them (whether for the time being or formerly), and their heirs, executors and administrators (each of which an "indemnified party"), shall be indemnified and secured harmless out of the assets of the Company from and against all actions, costs, charges, losses, damages and expenses which they or any of them, their heirs, executors or administrators, shall or may incur or sustain by or by reason of any act done, concurred in or omitted in or about the execution of their duty, or supposed duty, or in their respective offices or trusts, and no indemnified party shall be answerable for the acts, receipts, neglects or defaults of the others of them or for joining in any receipts for the sake of conformity, or for any bankers or other persons with whom any moneys or effects belonging to the Company shall or may be lodged or deposited for safe custody, or for insufficiency or deficiency of any security upon which any moneys of or belonging to the Company shall be placed out on or invested, or for any other loss, misfortune or damage which may happen in the execution of their respective offices or trusts, or in relation thereto, provided that this indemnity shall not extend to any matter in respect of any fraud or dishonesty to the extent prohibited by the Act in relation to the Company which may attach to any of the indemnified parties. Each Member agrees to waive any claim or right of action such Member might have, whether individually or by or in the right of the Company, against any Director or Officer on account of any action taken by such Director or Officer, or the failure of such Director or Officer to take any action in the performance of his duties with or for the Company or any subsidiary thereof, provided that such waiver shall not extend to any matter in respect of any fraud or dishonesty in relation to the Company which may attach to such Director or Officer.

52.2 The Company may purchase and maintain insurance for the benefit of any Director or Officer against any liability incurred by him under the Act in his capacity as a Director or Officer or indemnifying such Director or Officer in respect of any loss arising or liability attaching to him by virtue of any rule of law in respect of any negligence, default, breach of duty or breach of trust of which the Director or Officer may be guilty in relation to the Company or any subsidiary thereof.

52.3 The Company may advance moneys to a Director or Officer for the costs, charges and expenses incurred by the Director or Officer in defending any civil or criminal proceedings against him, on condition that the Director or Officer shall repay the advance if any allegation of fraud or dishonesty in relation to the Company is proved against him.

52.4 No amendment or repeal of any provision of this Bye-law 52 shall alter, to the detriment of any person, the right of such person to the indemnification or advancement of expenses related to a claim based on an act or failure to act which took place prior to such amendments.

MEETINGS OF THE BOARD OF DIRECTORS

53. Board Meetings

The Board may meet for the transaction of business, adjourn, and otherwise regulate its meetings as it sees fit. A resolution put to the vote at a meeting of the Board shall be carried by the affirmative votes of a majority of the votes cast and in the case of an equality of votes the resolution shall fail.

54. Notice of Board Meetings

The chairman (if any) or the Principal Executive Officer or a majority of the Directors then in office may, and the Secretary on the requisition of a Director shall, at any time summon a meeting of the Board. Notice of a meeting of the Board shall be deemed to be duly given to a Director if it is given to such Director verbally (including in person or by telephone) or otherwise communicated or sent to such Director by post, electronic

means or other mode of representing words in a visible form at such Director's last known address or in accordance with any other instructions given by such Director to the Company for this purpose at least 48 hours prior to such Board meeting, unless each Director attends or gives his prior written consent to the meeting being held on such shorter notice.

55. Electronic Participation in Meetings

Directors may participate in any meeting by such telephonic, electronic, or other communications facilities or means as permit all persons participating in the meeting to communicate with each other simultaneously and instantaneously, and participation in such a meeting shall constitute presence in person at such meeting.

56. Quorum at Board Meetings

The quorum necessary for the transaction of business at a meeting of the Board shall be a majority of the Directors then in office.

57. Board to Continue in the Event of Vacancy

The Board may act notwithstanding any vacancy in its number but, if and so long as its number is reduced below the number fixed by these Bye-laws as the quorum necessary for the transaction of business at meetings of the Board, the continuing Directors or Director may act for the purpose of (i) summoning a general meeting; or (ii) preserving the assets of the Company.

58. Chairman to Preside

Unless otherwise agreed by a majority of the Directors attending, the Chairman, if there be one, shall act as chairman at all meetings of the Board at which such person is present. In his absence a chairman shall be appointed or elected by the Directors present at the meeting.

59. Written Resolutions

59.1 Subject to these Bye-laws, anything which may be done by resolution of the Board at a meeting duly called and constituted may be done without a meeting by unanimous written resolution in accordance with this Bye-law 59.

59.2 A resolution signed by all the Directors, which may be in counterparts, shall be as valid as if it had been passed at a meeting of the Board duly called and constituted, such resolution to be effective on the date on which the last Director signs the resolution, provided, that (i) any such resolution shall be valid only if the signature of the last Director to sign is affixed outside the United States (unless the Board dispenses with this requirement), and (i) the Board may declare such resolution to be invalid if the Board determines that the use of a resolution in writing would result in a non-de minimis adverse tax, regulatory or legal consequence to the Company, any subsidiary of the Company, or any direct or indirect holder of shares or its affiliates. For the purposes of this Bye-law only, "the Directors" shall not include an Alternate Director.

59.3 A resolution in writing made in accordance with this Bye-law 59 shall constitute minutes for the purposes of the Act.

60. Validity of Prior Acts of the Board

No regulation or alteration to these Bye-laws made by the Company in general meeting shall invalidate any prior act of the Board which would have been valid if that regulation or alteration had not been made.

CORPORATE RECORDS

61. Minutes

The Board shall cause minutes to be duly entered in books provided for the purpose:

(a) of all elections and appointments of Officers;

(b) of the names of the Directors present at each meeting of the Board and of any committee appointed by the Board; and

(c) of all resolutions and proceedings of general meetings of the Members, meetings of the Board, and meetings of committees appointed by the Board.

62. Place Where Corporate Records Kept

Minutes prepared in accordance with the Act and these Bye-laws shall be kept by the Secretary at the registered office of the Company.

63. Form and Use of Seal

63.1 The Company may adopt a seal in such form as the Board may determine. The Board may adopt one or more duplicate seals for use in or outside Bermuda.

63.2 A seal may, but need not be affixed to any deed, instrument, share certificate or document, and if the seal is to be affixed thereto, it shall be attested by the signature of (i) any Director; or (ii) any Officer; or (iii) the Secretary; or (iv) any person authorized by the Board for that purpose.

63.3 A Resident Representative may, but need not, affix the seal of the Company to certify the authenticity of any copies of documents.

ACCOUNTS

64. Books of Account

64.1 The Board shall cause to be kept proper records of account with respect to all transactions of the Company and in particular with respect to:

(a) all sums of money received and expended by the Company and the matters in respect of which the receipt and expenditure relates;

(b) all sales and purchases of goods by the Company; and

(c) all assets and liabilities of the Company.

64.2 Such records of account shall be kept at the registered office of the Company, or subject to the Act, at such other place as the Board thinks fit and shall be available for inspection by the Directors during normal business hours.

65. Financial Year End

The financial year end of the Company may be determined by resolution of the Board and failing such resolution shall be 31st March in each year.

AUDITS

66. Annual Audit

Subject to any rights to waive laying of accounts or appointment of an Auditor pursuant to the Act, the accounts of the Company shall be audited at least once in every year.

67. Appointment of Auditor

67.1 Subject to the Act, the Members shall appoint an auditor to the Company to hold office for such term as the Members deem fit until a successor is appointed.

67.2 The Auditor may be a Member but no Director, Officer or employee of the Company shall, during his continuance in office, be eligible to act as an Auditor of the Company.

68. Remuneration of Auditor

The remuneration of the Auditor shall be fixed by the Company in general meeting or in such manner as the Members may determine. In the case of an Auditor appointed pursuant to Bye-law 67, the remuneration of the Auditor shall be fixed by the Board.

69. Duties of Auditor

69.1 The financial statements provided for by these Bye-laws shall be audited by the Auditor in accordance with generally accepted auditing standards. The Auditor shall make a written report thereon in accordance with generally accepted auditing standards.

69.2 The generally accepted auditing standards referred to in this Bye-law may be those of a country or jurisdiction other than Bermuda or such other generally accepted auditing standards as may be provided for in the Act. If so, the financial statements and the report of the Auditor shall identify the generally accepted auditing standards used.

70. Access to Records

The Auditor shall at all reasonable times have access to all books kept by the Company and to all accounts and vouchers relating thereto, and the Auditor may call on the Directors or Officers of the Company for any information in their possession relating to the books or affairs of the Company.

71. Financial Statements

Subject to any rights to waive laying of accounts pursuant to the Act, financial statements as required by the Act shall be laid before the Members in general meeting. A resolution in writing made in accordance with Bye-law 36 receiving, accepting, adopting, approving or otherwise acknowledging financial statements shall be deemed to be the laying of such statements before the Members in general meeting.

72. Distribution of Auditor's report

The report of the Auditor shall be submitted to the Members in general meeting.

73. Vacancy in the Office of Auditor

If the office of Auditor becomes vacant by the resignation or death or the Auditor, or by the Auditor becoming incapable of acting by reason of illness or other disability at a time when the Auditor's services are required, the vacancy thereby created shall be filled in accordance with the Act.

BUSINESS COMBINATIONS

74. Business Combinations

74.1 (a) Any Business Combination with any Interested Shareholder within a period of three years following the time of the transaction in which the person become an Interested Shareholder must be approved by the Board and authorised at an annual or special general meeting, by the affirmative vote of at least 66 and 2/3% of the issued and outstanding voting shares of the Company that are not owned by the Interested Shareholder unless:

(i) prior to the time that the person became an Interested Shareholder, the Board approved either the Business Combination or the transaction which resulted in the person becoming an Interested Shareholder; or

(ii) upon consummation of the transaction which resulted in the person becoming an Interested Shareholder, the Interested Shareholder owned at least 85% of the number of issued and outstanding voting shares of the Company at the time the transaction commenced, excluding for the purposes of determining the number of shares issued and outstanding those shares owned (i) by persons who are Directors and also officers and (ii) employee share plans in which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer.

(b) The restrictions contained in this Bye-law 74.1 shall not apply if:

(i) a Member becomes an Interested Shareholder inadvertently and (i) as soon as practicable divests itself of ownership of sufficient shares so that the Member ceases to be an Interested Shareholder; and (ii) would not, at any time within the three-year period immediately prior to a Business Combination between the Company and such Member, have been an Interested Shareholder but for the inadvertent acquisition of ownership; or

(ii) the Business Combination is proposed prior to the consummation or abandonment of, and subsequent to the earlier of the public announcement or the notice required hereunder of, a proposed transaction which (i) constitutes one of the transactions described in the following sentence; (ii) is with or by a person who either was not an Interested Shareholder during the previous three years or who became an Interested Shareholder with the approval of the Board; and (iii) is approved or not opposed by a majority of the members of the Board then in office who were Directors prior to any person becoming an Interested Shareholder during the previous three years or were recommended for election or elected to succeed such Directors by resolution of the Board approved by a majority of such Directors. The proposed transactions referred to in the preceding sentence are limited to:

(a) a merger, amalgamation or consolidation of the Company (except an amalgamation or merger in respect of which, pursuant to the Act, no vote of the shareholders of the Company is required);

(b) a sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions), whether as part of a dissolution or otherwise, of assets of the Company or of any entity directly or indirectly wholly-owned or majority-owned by the Company (other than to the Company or any entity directly or indirectly wholly-owned by the Company) having an aggregate market value equal to 50% or more of either the aggregate market value of all of the assets of the Company determined

on a consolidated basis or the aggregate market value of all the issued and outstanding shares of the Company; or

(c) a proposed tender or exchange offer for 50% or more of the issued and outstanding voting shares of the Company.

The Company shall give not less than 20 days notice to all Interested Shareholders prior to the consummation of any of the transactions described in subparagraphs (a) or (b) of the second sentence of this paragraph (ii).

(c) For the purpose of this Bye-law 74 only, the term:

(i) "affiliate" means a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, another person;

(ii) "associate," when used to indicate a relationship with any person, means: (i) any company, partnership, unincorporated association or other entity of which such person is a director, officer or partner or is, directly or indirectly, the owner of 20% or more of any class of voting shares; (ii) any trust or other estate in which such person has at least a 20% beneficial interest or as to which such person serves as trustee or in a similar fiduciary capacity; and (iii) any relative or spouse of such person, or any relative of such spouse, who has the same residence as such person;

(iii) "Business Combination," when used in reference to the Company and any Interested Shareholder of the Company, means:

(a) any merger, amalgamation or consolidation of the Company or any entity directly or indirectly wholly-owned or majority-owned by the Company, wherever incorporated, with (A) the Interested Shareholder or any of its affiliates, or (B) with any other company, partnership, unincorporated association or other entity if the merger, amalgamation or consolidation is caused by the Interested Shareholder;

(b) any sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions), except proportionately as a shareholder of the Company, to or with the Interested Shareholder, whether as part of a dissolution or otherwise, of assets of the Company or of any entity directly or indirectly wholly-owned or majority-owned by the Company which assets have an aggregate market value equal to 10% or more of either the aggregate market value of all the assets of the Company determined on a consolidated basis or the aggregate market value of all the issued and outstanding shares of the Company;

(c) any transaction which results in the issuance or transfer by the Company or by any entity directly or indirectly wholly-owned or majority-owned by the Company of any shares of the Company, or any share of such entity, to the Interested Shareholder, except: (A) pursuant to the exercise, exchange or conversion of securities exercisable for, exchangeable for or convertible into shares of the Company, or shares of any such entity, which securities were issued and outstanding prior to the time that the Interested Shareholder became such; (B) pursuant to a dividend or distribution paid or made, or the exercise, exchange or conversion of securities exercisable for, exchangeable for or convertible into shares of the Company, or shares of any such entity, which security is distributed, pro rata to all holders of a class or series of

shares subsequent to the time the Interested Shareholder became such; (C) pursuant to an exchange offer by the Company to purchase shares made on the same terms to all holders of such shares; or (D) any issuance or transfer of shares by the Company; provided however, that in no case under items (B) -(D) of this subparagraph shall there be an increase in the Interested Shareholder's proportionate share of any class or series of shares;

(d) any transaction involving the Company or any entity directly or indirectly wholly-owned or majority-owned by the Company which has the effect, directly or indirectly, of increasing the proportionate share of any class or series of shares, or securities convertible into any class or series of shares of the Company, or shares of any such entity, or securities convertible into such shares, which is owned by the Interested Shareholder, except as a result of immaterial changes due to fractional share adjustments or as a result of any repurchase or redemption of any shares not caused, directly or indirectly, by the Interested Shareholder; or

(e) any receipt by the Interested Shareholder of the benefit, directly or indirectly (except proportionately as a shareholder of the Company), of any loans, advances, guarantees, pledges or other financial benefits (other than those expressly permitted in subparagraphs (a)-(d) of this paragraph) provided by or through the Company or any entity directly or indirectly wholly-owned or majority-owned by the Company;

(iv) "control," including the terms "controlling," "controlled by" and "under common control with," means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting shares, by contract or otherwise. A person who is the owner of 20% or more of the issued and outstanding voting shares of any company, partnership, unincorporated association or other entity shall be presumed to have control of such entity, in the absence of proof by a preponderance of the evidence to the contrary; provided that notwithstanding the foregoing, such presumption of control shall not apply where such person holds voting shares, in good faith and not for the purpose of circumventing this provision, as an agent, bank, broker, nominee, custodian or trustee for one or more owners who do not individually or as a group have control of such entity;

(v) "Interested Shareholder" means any person (other than the Company and any entity directly or indirectly wholly-owned or majority-owned by the Company) that (i) is the owner of 15% or more of the issued and outstanding voting shares of the Company, (ii) is an affiliate or associate of the Company and was the owner of 15% or more of the issued and outstanding voting shares of the Company at any time within the three year period immediately prior to the date on which it is sought to be determined whether such person is an Interested Shareholder or (iii) is an affiliate or associate of any person listed in (i) or (ii) above; provided, however, that the term "Interested Shareholder" shall not include any person whose ownership of shares in excess of the 15% limitation set forth herein is the result of action taken solely by the Company unless such person referred to in this proviso acquires additional voting shares of the Company otherwise than as a result of further corporate action not caused, directly or indirectly, by such person. For the purpose of determining whether a person is an Interested Shareholder, the voting shares of the Company deemed to be issued and outstanding shall include voting shares deemed to be owned by the person through application of paragraph (viii) below, but shall not include any other unissued shares which may be issuable pursuant to any agreement,

arrangement or understanding, or upon exercise of conversion rights, warrants or options, or otherwise;

(vi) "person" means any individual, company, partnership, unincorporated association or other entity;

(vii) "voting shares" means, with respect to any company, shares of any class or series entitled to vote generally in the election of Directors and, with respect to any entity that is not a company, any equity interest entitled to vote generally in the election of the governing body of such entity;

(viii) "owner," including the terms "own" and "owned," when used with respect to any shares, means a person that individually or with or through any of its affiliates or associates:

(a) beneficially owns such shares, directly or indirectly; or

(b) has (A) the right to acquire such shares (whether such right is exercisable immediately or only after the passage of time) pursuant to any agreement, arrangement or understanding, or upon the exercise of conversion rights, exchange rights, warrants or options, or otherwise; provided, however, that a person shall not be deemed the owner of shares tendered pursuant to a tender or exchange offer made by such person or any of such person's affiliates or associates until such tendered shares are accepted for purchase or exchange; or (B) the right to vote such shares pursuant to any agreement, arrangement or understanding; provided, however, that a person shall not be deemed the owner of any shares because of such person's right to vote such shares if the agreement, arrangement or understanding to vote such shares arises solely from a revocable proxy or consent given in response to a proxy or consent solicitation made to 10 or more persons; or

(c) has any agreement, arrangement or understanding for the purpose of acquiring, holding, voting (except voting pursuant to a revocable proxy or consent as described in item (B) of subparagraph (b) of this paragraph), or disposing of such shares with any other person that beneficially owns, or whose affiliates or associates beneficially own, directly or indirectly, such shares.

74.2 In respect of any Business Combination to which the restrictions contained in Bye-law 74.1 do not apply but which the Act requires to be approved by the Members, the necessary general meeting quorum and Members' approval shall be as set out in Bye-laws 27 and 29 respectively.

74.3 The Board shall ensure that the bye-laws or constitutional documents of each entity wholly-owned or majority-owned by the Company shall contain any provisions necessary to ensure that the intent of Bye-law 74.1, as it relates to the actions of such entities, is achieved.

VOLUNTARY WINDING-UP AND DISSOLUTION

75. Winding-Up

If the Company shall be wound up the liquidator may, with the sanction of a resolution of the Members, divide amongst the Members in specie or in kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and may, for such purpose, set such value as he deems fair upon any property to be divided as aforesaid and may determine how such division shall be carried out as

between the Members or different classes of Members. The liquidator may, with the like sanction, vest the whole or any part of such assets in the trustees upon such trusts for the benefit of the Members as the liquidator shall think fit, but so that no Member shall be compelled to accept any shares or other securities or assets whereon there is any liability.

CHANGES TO CONSTITUTION

76. Changes to Bye-laws

76.1 Prior to the Trigger Date, Bye-laws 24, 38, 39, 40, 41, this Bye-law 76, and the Roivant rights contained therein, may not be rescinded, altered or amended without the affirmative vote of at least 66 and 2/3% of the issued and outstanding voting shares of the Company.

76.2 Subject to Bye-law 76.1, no Bye-law may be rescinded, altered or amended and no new Bye-law may be made save in accordance with the Act and until the same has been approved by a resolution of the Board and by a resolution of the Members.

77. Changes to the Memorandum of Association

No alteration or amendment to the Memorandum of Association may be made save in accordance with the Act and until same has been approved by a resolution of the Board and by a resolution of the Members.

78. Discontinuance

The Board may exercise all the powers of the Company to discontinue the Company to a jurisdiction outside Bermuda pursuant to the Act.

79. Amalgamation or Merger

Any resolution proposed for consideration at any general meeting to approve the amalgamation or merger of the Company with any other company, wherever incorporated, shall (other than in respect of any amalgamation or merger constituting a Business Combination to which the restrictions in Bye-law 76 shall apply) require the approval of a simple majority of votes cast at such meeting and the quorum for such meeting shall be that required in Bye-law 27 and a poll may be demanded in respect of such resolution in accordance with the provisions of Bye-law 30.

Exhibit 10.7

AMENDMENT NO. 1 TO INFORMATION SHARING AND COOPERATION AGREEMENT

This Amendment No. 1 to that certain Information Sharing and Cooperation Agreement, dated as of July 6, 2016 (the "Original Agreement"), by and between Roivant Sciences Ltd., a Bermuda exempted company ("Roivant"), and Myovant Sciences Ltd., a Bermuda exempted company ("Myovant"), is entered into as of May 24, 2019 (the "Amendment"). Roivant and Myovant are referred to herein each as a Party and, together, as the Parties.

WHEREAS, the Parties desire to amend the Original Agreement as set forth herein, and for the Original Agreement to otherwise continue unmodified except as specifically modified herein.

NOW, THEREFORE, in consideration of the foregoing and of the mutual promises and agreements hereafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Roivant Indication of Interest.**

WHEREAS, Myovant may in the future pursue one or more underwritten public offerings of its common shares (each a "Public Offering"); and

WHEREAS, the Parties agree that it is in the best interests of the Parties and their respective shareholders for Roivant to participate as a purchaser in such Public Offerings by Myovant.

NOW, THEREFORE, Roivant agrees that in connection with the next three (3) Public Offerings approved by the Myovant Board, Roivant will provide to Myovant and the underwriter(s) engaged by Myovant in connection with each such Public Offering an indication of interest for Roivant to participate as a purchaser in each such Public Offering (a "Roivant Indication of Interest").

2. **Roivant Lock-Up Agreements.**

WHEREAS, pursuant to this Amendment, Roivant has agreed to provide a Roivant Indication of Interest in connection with the next three (3) Public Offerings by Myovant; and

WHEREAS, the Parties agree that it is desirable for the successful execution of any Public Offering by Myovant that Roivant agree to enter into a customary "lock-up" agreement, including such customary exclusions as may be negotiated between Roivant and the underwriter(s) in connection with a Public Offering, for the benefit of Myovant and the underwriter(s) of such Public Offering (a "Lock-Up Agreement").

NOW, THEREFORE, Roivant agrees that, in connection with any Public Offering in which Roivant is required to provide a Roivant Indication of Interest pursuant to this Amendment, it will enter into a Lock-Up Agreement.

3. **No Other Modification.**

Except as expressly amended hereby, the Original Agreement and all other documents, agreements and instruments relating thereto are and shall be unmodified and remain in full force and effect in accordance with their respective terms. This Amendment shall be deemed to form an integral part of the Original Agreement. In the event of any inconsistency or conflict between the provisions of the Original Agreement and this Amendment, the provisions of this Amendment will prevail and govern. All references to the "Agreement" in the Agreement shall hereinafter refer to the Agreement as amended by this Amendment.

4. **Governing Law.**

This Amendment shall be governed by and construed and interpreted in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof that would result in the application of any law other than the laws of the State of New York.

5. Counterparts.

This Amendment may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument. This Amendment may also be executed and delivered by facsimile or electronically-transmitted signature.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the date first set forth above.

ROIVANT SCIENCES LTD.

By: /s/ Marianne L. Romeo

Name: Marianne L. Romeo

Title: Head, Global Transactions & Risk Management

MYOVANT SCIENCES LTD.

By: /s/ Frank Karbe

Name: Frank Karbe

Title: Principal Financial and Accounting Officer

Exhibit 10.21

EXECUTION COPY

MYOVANT SCIENCES LTD.

RESTRICTED STOCK AWARD AGREEMENT

This Restricted Stock Award Agreement (this "***Agreement***"), dated May 31, 2017 (the "***Grant Date***"), is made by and between Myovant Sciences Ltd., a Bermuda exempted limited company (the "***Parent***") and Lynn Seely (the "***Participant***").

1. Definitions. Capitalized terms used but not defined herein have the meaning set forth in the Myovant Sciences Ltd. 2016 Equity Incentive Plan, as amended and restated (the "***Plan***").

2. Grant of Restricted Stock. Subject to the provisions of this Agreement and the provisions of the Plan, the Parent hereby grants to the Participant 564,111 restricted shares of Common Stock of the Parent (the "***Restricted Shares***").

3. Vesting and Forfeiture.

(i) *Generally*. Except as set forth below in clauses (ii) and (iii) of this Section 3, one-hundred percent (100%) of the Restricted Shares will vest and become non-forfeitable, as follows: (a) one-third (1/3rd) of the Restricted Shares will vest if the price per share of Parent Common Stock exceeds $30.00 for a continuous 5-day VWAP period, which represents two times (2x) the price per share of Parent Common Stock on the date of the initial public offering, (b) an additional one-third (1/3rd) of the Restricted Shares will vest if the share price exceeds $60.00 for a continuous 5-day VWAP period, and (c) the final one-third (1/3rd) of the Restricted Shares will vest if the share price exceeds $90.00 for a continuous 5-day VWAP period, provided, however, that the Restricted Shares described in this clause (i) will only vest and become non-forfeitable on each such vesting date if, and only if, the Participant remains in Continuous Service with Myovant Sciences, Inc. (the "Company") on each applicable vesting date. For purposes of this section, "VWAP" means the dollar volume-weighted average price of the Parent's Common Stock calculated for each trading day during the entirety of the regular trading period for each such trading day over the applicable period.

(ii) Termination of Continuous Service. Notwithstanding the foregoing and subject to clause (iii) below, if the Participant's Continuous Service ceases for any reason, all unvested Restricted Shares shall be forfeited; provided, however, that if the Participant's Continuous Service ceases because the Participant is terminated without Cause or if the Participant resigns for Good Reason, each as defined in the Participant's employment agreement with the Company, dated May 30, 2016 (the "Employment Agreement"), fifty-percent (50%) of the Participant's then unvested Restricted Shares shall immediately vest and become non-forfeitable. If the Participant's Continuous Service ceases because the Participant is terminated for any other reason, all unvested Restricted Shares shall be forfeited. Upon the forfeiture of any Restricted Shares pursuant to this Section 3, the Participant shall have no further right with respect to such Restricted Shares.

(iii) *Change of Control*. Notwithstanding the foregoing, in the event the Participant's Continuous Service is terminated by the Company without Cause or by the Participant for Good Reason after a Change of Control (but not before a Change of Control), one-hundred percent (100%) of the Participant's then unvested Restricted Shares shall immediately vest and become non-forfeitable. For the avoidance of doubt, for purposes of this Agreement, the definition of "Change of Control" shall be governed by the definition as used in the Employment Agreement (notwithstanding the definition under the Plan).

4. Taxes.

(i) *Withholding*. The Participant shall be required to pay, in cash, to the Parent, and the Parent and its Affiliates shall have the right and are hereby authorized to withhold from this Restricted Stock Award or from any compensation or other amount owing to the Participant, the amount of any applicable withholding taxes with respect to the Restricted Shares upon the applicable vesting date, or the date the value of any shares of Common Stock first becomes includible in the Participant's gross income for income tax purposes, and to take such other action as may be necessary in the opinion of the Parent to satisfy all obligations for payment of such taxes. Regardless of any action the Parent or the Company may take with respect to any or all tax withholding obligations, the Participant acknowledges that the ultimate liability for all such taxes is and remains the Participant's responsibility (or that of the Participant's beneficiary).

(ii) *83(b) Election*. The Participant hereby acknowledges that the Participant has been advised by the Company and the Parent to seek independent tax advice from the Participant's advisors regarding the availability and advisability of making an election under Section 83(b) of the Internal Revenue Code of 1986, as amended, and that any such election, if made, must be made within 30 days of the Grant Date. The Participant expressly acknowledges that the Participant is solely responsible for filing any such Section 83(b) election with the appropriate governmental authorities, irrespective of the fact that such election is also delivered to the Parent.

5. Rights as a Shareholder. The Participant shall be the record owner of the Restricted Shares unless or until such Restricted Share is forfeited pursuant to Section 3 above or is otherwise transferred, and as record owner shall be entitled to all rights of a common shareholder of the Parent. Any dividends paid on the Restricted Shares shall be subject to the same vesting and forfeiture restrictions as apply to the Restricted Shares.

6. Evidence of Shares; Legend. The Participant agrees that, in the Parent's discretion, the Participant's ownership of the Restricted Shares may be evidenced solely by a "book entry" (*i.e.*, a computerized or manual entry) in the records of the Parent or its designated stock transfer agent in the Participant's name, which shall be subject to a stop transfer order consistent with this Agreement and the legend set forth below. If, however, during the period in which the restrictions remain in place, the Restricted Shares are evidenced by a stock certificate or certificates, registered in the Participant's name, the Participant acknowledges that upon receipt of such stock certificate or certificates, such certificates shall bear the following legend and such other legends as may be required by law or contract:

> "These shares have been issued pursuant to the Myovant Sciences Ltd. 2016 Equity Incentive Plan, as amended and restated (the "Plan") and are subject to forfeiture to Myovant Sciences Ltd. in accordance with the terms of the Plan and an Agreement between Myovant Sciences Ltd. and the person in whose name the certificate is registered. These shares may not be sold, transferred, pledged, assigned, encumbered, alienated, hypothecated or otherwise disposed of except in accordance with the terms of the Plan and said Agreement."

The Participant agrees that upon receipt of any such stock certificates for the Restricted Shares the Participant shall deposit each such certificate with the Parent, or such other escrow holder as the Board may appoint, together with a stock power endorsed in blank or other appropriate instrument of transfer, to be held by the Parent or such escrow holder until the applicable vesting date. Upon expiration of the applicable portion of the restrictions, a certificate or certificates representing the shares of Common Stock as to which the period of restriction has so lapsed shall be delivered to the Participant by the Parent, subject to satisfaction of any tax obligations in accordance with Section 4 hereof; provided, however, that such shares of Common Stock may nevertheless be evidenced on a noncertificated basis, to the extent not prohibited by applicable law or the rules of any stock exchange.

7. Transferability. The Restricted Shares may not, at any time prior to becoming vested pursuant to Section 3 above, be transferred, sold, assigned, pledged, hypothecated or otherwise alienated; provided, however, that

the Board may, in its discretion, permit the Restricted Shares to be transferred subject to such conditions and limitations as may be imposed by the Board.

8. No Right as Employee or Consultant. Subject to the Employment Agreement, neither the grant of the Restricted Shares nor any terms contained in this Agreement shall (i) affect in any manner whatsoever the right or power of the Company to terminate the Participant's Continuous Service for any reason, with or without cause, (ii) if applicable, affect the Participant's status as an at-will employee of the Company who is subject to termination of Continuous Service without cause, (iii) confer upon the Participant any right to remain employed by or in service to the Company, (iv) interfere in any way with the right of the Company at any time to terminate such employment or service, or (v) affect the right of the Company to increase or decrease the Participant's other compensation.

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

10. Compliance with Laws and Regulations. The Restricted Shares and the obligation of the Parent to deliver shares hereunder shall be subject in all respects to (i) all applicable Federal and state laws, rules and regulations and (ii) any registration, qualification, approvals or other requirements imposed by any government or regulatory agency or body which the Committee shall, in its discretion, determine to be necessary or applicable.

11. Notices. All notices by the Participant or the Participant's successors or permitted assigns shall be addressed to the Parent, Clarendon House, 2 Church Street; Hamilton HM 11, Attention: General Counsel, or such other address as the Parent may from time to time specify. All notices to the Participant shall be addressed to the Participant at the Participant's address in the Company's records.

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

IN WITNESS WHEREOF, the Parent has caused this Agreement to be executed by its duly authorized officer.

Myovant Sciences Ltd.

/s/ Frank Karbe

Name: Frank Karbe
Title: CFO

The undersigned hereby acknowledges, effective as of the date first stated above, that the Participant has carefully read this Agreement and agrees to be bound by all of the provisions set forth herein.

GRANTEE:

/s/ Lynn Seely

Signature

Lynn Seely

Name

July 31, 2017

Date

Exhibit 10.30

MYOVANT SCIENCES LTD.
RESTRICTED STOCK UNIT GRANT NOTICE
(2016 EQUITY INCENTIVE PLAN)

Myovant Sciences Ltd. (the "***Company***"), pursuant to its 2016 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company's Common Stock ("***Restricted Stock Units***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "***Restricted Stock Unit Grant Notice***"), and in the Plan and the Restricted Stock Unit Award Agreement (the "***Award Agreement***"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Restricted Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Restricted Stock Units:	_____

Vesting Schedule: [_____, subject to Participant's Continuous Service through each such vesting date.]

Issuance Schedule: Subject to any Capitalization Adjustment, one share of Common Stock (or its cash equivalent, at the discretion of the Company) will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award, with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant, (ii) the written employment agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

MYOVANT SCIENCES LTD.	**PARTICIPANT**
By: _____	By: _____
Signature	Signature
Title: _____	Date: _____
Date: _____	

ATTACHMENTS: Award Agreement and 2016 Equity Incentive Plan

ATTACHMENT I

MYOVANT SCIENCES LTD.

2016 EQUITY INCENTIVE PLAN
RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Restricted Stock Unit Grant Notice (the "***Grant Notice***") and this Restricted Stock Unit Award Agreement (the "***Agreement***"), Myovant Sciences Ltd. (the "***Company***") has awarded you ("***Participant***") a Restricted Stock Unit Award (the "***Award***") pursuant to the Company's 2016 Equity Incentive Plan (the "***Plan***") for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. GRANT OF THE AWARD. This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Restricted Stock Units/shares of Common Stock subject to the Award. Notwithstanding the foregoing, the Company reserves the right to issue you the cash equivalent of Common Stock, in part or in full satisfaction of the delivery of Common Stock in connection with the vesting of the Restricted Stock Units, and, to the extent applicable, references in this Agreement and the Grant Notice to Common Stock issuable in connection with your Restricted Stock Units will include the potential issuance of its cash equivalent pursuant to such right. This Award was granted in consideration of your services to the Company.

2. VESTING. Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice. Vesting will cease upon the termination of your Continuous Service and the Restricted Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the shares of Common Stock to be issued in respect of such portion of the Award.

3. NUMBER OF SHARES. The number of Restricted Stock Units subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

4. SECURITIES LAW COMPLIANCE. You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. TRANSFER RESTRICTIONS. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) Death. Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to

receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order, marital settlement agreement or other divorce or separation instrument as permitted by applicable law that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

6. DATE OF ISSUANCE.

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation set forth in Section 11 of this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***".

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***10b5-1 Arrangement***")), *and*

(ii) either (1) a Withholding Obligation does not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Obligation by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer pursuant to Section 11 of this Agreement (including but not limited to a commitment under a 10b5-1 Arrangement) and (C) not to permit you to pay your Withholding Obligation in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

7. DIVIDENDS. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; provided, however,

that this sentence will not apply with respect to any shares of Common Stock that are delivered to you in connection with your Award after such shares have been delivered to you.

8. RESTRICTIVE LEGENDS. The shares of Common Stock issued in respect of your Award shall be endorsed with appropriate legends as determined by the Company.

9. EXECUTION OF DOCUMENTS. You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

10. AWARD NOT A SERVICE CONTRACT.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice may not be earned unless (in addition to any other conditions described in the Grant Notice and this Agreement) you continue as an employee, director or consultant at the will of the Company and affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "***reorganization***"). You acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to terminate your Continuous Service at any time, with or without your cause or notice, or to conduct a reorganization.

11. WITHHOLDING OBLIGATION.

(a) On each vesting date, and on or before the time you receive a distribution of the shares of Common Stock in respect of your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision, including in cash, for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "***Withholding Obligation***").

(b) By accepting this Award, you acknowledge and agree that the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Obligation relating to your Restricted Stock Units by any of the following means or by a combination of such means: (i) causing you to pay any portion of the Withholding Obligation in cash; (ii) withholding from any compensation otherwise payable to you by the Company; (iii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued pursuant to Section 6) equal to the amount of such Withholding Obligation; provided, however, that the number of such

shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Withholding Obligation using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and *provided*, further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Board or the Company's Compensation Committee; and/or (iv) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***"), pursuant to this authorization and without further consent, whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Obligation and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Obligation directly to the Company and/or its Affiliates. Unless the Withholding Obligation is satisfied, the Company shall have no obligation to deliver to you any Common Stock or any other consideration pursuant to this Award.

(c) In the event the Withholding Obligation arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Withholding Obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. TAX CONSEQUENCES. The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

13. UNSECURED OBLIGATION. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

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

15. HEADINGS. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

16. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

18. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

19. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. OTHER DOCUMENTS. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

21. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

22. COMPLIANCE WITH SECTION 409A OF THE CODE. This Award is intended to be exempt from the application of Section 409A of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and any ambiguities herein shall be interpreted accordingly. Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and determined to be deferred compensation subject

to Section 409A of the Code, this Award shall comply with Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. If it is determined that the Award is deferred compensation subject to Section 409A and you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "Separation from Service" (as defined in Section 409A), then the issuance of any shares that would otherwise be made upon the date of your Separation from Service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the Separation from Service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

* * * * *

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.

ATTACHMENT II

2016 EQUITY INCENTIVE PLAN

Exhibit 10.31

MYOVANT SCIENCES LTD.
RESTRICTED STOCK AWARD AGREEMENT
(2016 EQUITY INCENTIVE PLAN)

This Restricted Stock Award Agreement (the "***Agreement***"), dated _____ (the "***Grant Date***"), is made by and between Myovant Sciences Ltd., a Bermuda exempted limited company (the "***Parent***") and _____ (the "***Participant***").

1. Definitions. Capitalized terms used but not defined herein have the meaning set forth in the Myovant Sciences Ltd. 2016 Equity Incentive Plan (the "***Plan***").

2. Grant of Restricted Stock. Subject to the provisions of this Agreement and the provisions of the Plan, the Parent hereby grants to the Participant _____ restricted shares of Common Stock of the Parent (the "***Restricted Shares***").

3. Vesting and Forfeiture.

(i) *Generally*. Except as set forth below in clauses (ii) and (iii), one-hundred percent (100%) of the Restricted Shares will vest and become non-forfeitable, as follows: Twentyfive percent (25%) of the Restricted Shares will vest and become non-forfeitable on the first anniversary of the Start Date (as defined in the Participant's employment agreement with Myovant Sciences, Inc. (the "Company"), dated _____(the "Employment Agreement")) and the remaining balance will vest and become non-forfeitable in a series of twelve (12) successive equal quarterly installments measured from the first anniversary of the Start Date; provided, however, that the Restricted Shares described in this clause (i) will only vest and become non-forfeitable on each such vesting date if, and only if, the Participant remains in Continuous Service with the Company on each applicable vesting date.

(ii) *Termination of Continuous Service*. Notwithstanding the foregoing and subject to clause (iii) below, if the Participant's Continuous Service ceases for any reason, all unvested Restricted Shares shall be forfeited; provided, however, that if the Participant's Continuous Service ceases because the Participant is terminated without Cause or if the Participant resigns for Good Reason (each as defined in the Employment Agreement), fifty-percent (50%) of the Participant's then unvested Restricted Shares shall immediately vest and become nonforfeitable. If the Participant's Continuous Service ceases because the Participant is terminated for any other reason, all unvested Restricted Shares shall be forfeited. Upon the forfeiture of any Restricted Shares pursuant to this Section 3, the Participant shall have no further right with respect to such Restricted Shares.

(iii) *Change of Control*. Notwithstanding the foregoing, in the event the Participant's Continuous Service is terminated by the Company without Cause or by the Participant for Good Reason on or before the eighteen (18) month anniversary of a Change of Control (as defined in the Employment Agreement), one-hundred percent (100%) of the Participant's then unvested Restricted Shares shall immediately vest and become non-forfeitable. For the avoidance of doubt, for purposes of this Agreement, the definition of "Change of Control" shall be governed by the definition as used in the Employment Agreement (notwithstanding the definition under the Plan).

4. Taxes.

(i) *Withholding*. The Participant shall be required to pay, in cash, to the Parent, and the Parent and its Affiliates shall have the right and are hereby authorized to withhold from this Restricted Stock Award or from any compensation or other amount owing to the Participant, the amount of any applicable withholding taxes with respect to the Restricted Shares upon the applicable vesting date, or the date the value of any shares of Common Stock first

becomes includible in the Participant's gross income for income tax purposes, and to take such other action as may be necessary in the opinion of the Parent to satisfy all obligations for payment of such taxes. Regardless of any action the Parent or the Company may take with respect to any or all tax withholding obligations, the Participant acknowledges that the ultimate liability for all such taxes is and remains the Participant's responsibility (or that of the Participant's beneficiary).

(ii) *83(b) Election*. The Participant hereby acknowledges that the Participant has been advised by the Company and the Parent to seek independent tax advice from the Participant's advisors regarding the availability and advisability of making an election under Section 83(b) of the Internal Revenue Code of 1986, as amended, and that any such election, if made, must be made within 30 days of the Grant Date. The Participant expressly acknowledges that the Participant is solely responsible for filing any such Section 83(b) election with the appropriate governmental authorities, irrespective of the fact that such election is also delivered to the Parent.

5. Rights as a Shareholder. The Participant shall be the record owner of the Restricted Shares unless or until such Restricted Share is forfeited pursuant to Section 3 above or is otherwise transferred, and as record owner shall be entitled to all rights of a common shareholder of the Parent. Any dividends paid on the Restricted Shares shall be subject to the same vesting and forfeiture restrictions as apply to the Restricted Shares.

6. Evidence of Shares; Legend. The Participant agrees that, in the Parent's discretion, the Participant's ownership of the Restricted Shares may be evidenced solely by a "book entry" (*i.e.*, a computerized or manual entry) in the records of the Parent or its designated stock transfer agent in the Participant's name, which shall be subject to a stop transfer order consistent with this Agreement and the legend set forth below. If, however, during the period in which the restrictions remain in place, the Restricted Shares are evidenced by a stock certificate or certificates, registered in the Participant's name, the Participant acknowledges that upon receipt of such stock certificate or certificates, such certificates shall bear the following legend and such other legends as may be required by law or contract:

> "These shares have been issued pursuant to the Myovant Sciences Ltd. 2016 Equity Incentive Plan (the "Plan") and are subject to forfeiture to Myovant Sciences Ltd. in accordance with the terms of the Plan and an Agreement between Myovant Sciences Ltd. and the person in whose name the certificate is registered. These shares may not be sold, transferred, pledged, assigned, encumbered, alienated, hypothecated or otherwise disposed of except in accordance with the terms of the Plan and said Agreement."

The Participant agrees that upon receipt of any such stock certificates for the Restricted Shares the Participant shall deposit each such certificate with the Parent, or such other escrow holder as the Board may appoint, together with a stock power endorsed in blank or other appropriate instrument of transfer, to be held by the Parent or such escrow holder until the applicable vesting date. Upon expiration of the applicable portion of the restrictions, a certificate or certificates representing the shares of Common Stock as to which the period of restriction has so lapsed shall be delivered to the Participant by the Parent, subject to satisfaction of any tax obligations in accordance with Section 4 hereof; provided, however, that such shares of Common Stock may nevertheless be evidenced on a non-certificated basis, to the extent not prohibited by applicable law or the rules of any stock exchange.

7. Transferability. The Restricted Shares may not, at any time prior to becoming vested pursuant to Section 3 above, be transferred, sold, assigned, pledged, hypothecated or otherwise alienated; provided, however, that the Board may, in its discretion, permit the Restricted Shares to be transferred subject to such conditions and limitations as may be imposed by the Board.

8. No Right as Employee or Consultant. Neither the grant of the Restricted Shares nor any terms contained in this Agreement shall (i) affect in any manner whatsoever the right or power of the Company to terminate the Participant's Continuous Service for any reason, with or without cause, (ii) if applicable, affect the Participant's status as an at-will employee of the Company who is subject to termination of Continuous Service without cause,

(iii) confer upon the Participant any right to remain employed by or in service to the Company, (iv) interfere in any way with the right of the Company at any time to terminate such employment or service, or (v) affect the right of the Company to increase or decrease the Participant's other compensation.

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

10. Compliance with Laws and Regulations. The Restricted Shares and the obligation of the Parent to deliver shares hereunder shall be subject in all respects to (i) all applicable Federal and state laws, rules and regulations and (ii) any registration, qualification, approvals or other requirements imposed by any government or regulatory agency or body which the Committee shall, in its discretion, determine to be necessary or applicable.

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

12. Notices. All notices by the Participant or the Participant's successors or permitted assigns shall be addressed to the Parent, Clarendon House, 2 Church Street; Hamilton HM 11, Attention: General Counsel, or such other address as the Parent may from time to time specify. All notices to the Participant shall be addressed to the Participant at the Participant's address in the Company's records.

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

IN WITNESS WHEREOF, the Parent has caused this Agreement to be executed by its duly authorized officer.

Myovant Sciences Ltd.

By: _____

Name:

Title:

The undersigned hereby acknowledges, effective as of the date first stated above, that the Participant has carefully read this Agreement and agrees to be bound by all of the provisions set forth herein.

GRANTEE:

_____

Signature

_____

Name

_____

Date

Exhibit 10.32

Non-Executive Director Compensation Policy
of
Myovant Sciences Ltd. (this "Policy")
(effective April 1, 2019)

Non-Executive Directors[1] of Myovant Sciences, Ltd. (the "***Company***") are compensated for service on the Board of Directors of the Company (the ***"Board***") through a combination of cash retainer and equity grants. In addition, the Company reimburses Non-Executive Directors for reasonable expenses incurred in serving as a Non-Executive Director. The Compensation Committee may, in its discretion, determine that a Non-Executive Director shall not receive compensation pursuant to this Policy.

Cash Compensation

As of April 1, 2019, annual retainers are paid in the following amounts to Non-Executive Directors:

Annual Retainer	$	40,000
Additional Annual Retainer for Non-Executive Chairman	$	35,000
Additional Annual Retainer for Lead Independent Director	$	15,000
Additional Annual Retainer for Committee Chairs:		
Audit Committee	$	20,000
Compensation Committee	$	14,500
Nominating and Corporate Governance Committee	$	10,000
Additional Annual Retainer for Committee Members:		
Audit Committee	$	10,000
Compensation Committee	$	7,250
Nominating and Corporate Governance Committee	$	5,000

All annual retainers will be paid in cash quarterly in arrears promptly following the end of the applicable fiscal quarter.

Equity Compensation

Upon initial election to the Board, each Non-Executive Director shall receive an initial option grant to purchase 45,000 common shares of the Company. The initial option grant will be automatically granted, without further action, on the date on which the Non-Executive Director's service as a director begins and will vest as to 1/3 of the shares on the first anniversary of the grant date, with the balance of the shares vesting in eight equal quarterly installments thereafter, subject to the applicable Non-Executive Director's continued service through the vesting date.

Each Non-Executive Director who is elected or appointed as a director at least three calendar months prior to an Annual General Meeting of Shareholders (the "***Annual Meeting***") and whose service as a director will continue after such Annual Meeting shall receive an annual grant of an option to purchase common shares of the Company, with an aggregate value of $266,200, on the date of the Annual Meeting. Such aggregate dollar value is converted to a number of options utilizing the Black-Scholes option pricing model and the dollar volume-weighted average closing price of common shares of the Company for all of the trading days during the 30 trading day period ending on (and including) the last trading day immediately preceding the applicable date of the Annual Meeting (or such other methodology the Compensation Committee may determine prior to the grant of an award becoming effective). The annual option grant will be automatically granted, without further action, on the date of the applicable Annual Meeting

[1]For purposes of this Policy, a "Non-Executive Director" shall mean any member of the Board of Directors who is not an executive officer of the Company.

and will vest in full on the earlier to occur of (i) the first (1st) anniversary of the date of grant and (ii) the date immediately prior to the date of the Annual Meeting for the year following the year in which the grant is made, subject in each case to continued service through the vesting date.

Option grants: (i) have an exercise price equal to the closing price of common shares of the Company on the New York Stock Exchange on the grant date; (ii) are subject to the applicable Non-Executive Director's continued service through the vesting date; (iii) expire on the ten-year anniversary of the grant date; and (iv) are subject to all applicable terms of the 2016 Equity Incentive Plan of the Company and applicable equity award agreements thereunder.

Effectiveness, Amendment, Modification and Termination

This Policy may be amended, modified or terminated by the Compensation Committee or the Board in the future at its sole discretion.

* * * *

Exhibit 21.1

Subsidiaries

of

Myovant Sciences Ltd.

Name of Subsidiary	**Jurisdiction of Incorporation or Organization**
Myovant Sciences, Inc.	Delaware
Myovant Holdings Ltd.	England and Wales
Myovant Sciences GmbH	Switzerland
Myovant Sciences Ireland Limited	Ireland
Myovant Treasury, Inc.	Delaware
Myovant Treasury Holdings, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements of Myovant Sciences Ltd.:

(1) Registration Statement (Form S-8 No. 333-218057) pertaining to the 2016 Equity Incentive Plan,

(2) Registration Statement (Form S-8 No. 333-228277) pertaining to the 2016 Equity Incentive Plan, and

(3) Registration Statement (Form S-3 No. 333-221526);

of our reports dated May 24, 2019, with respect to the consolidated financial statements of Myovant Sciences Ltd. and the effectiveness of internal control over financial reporting of Myovant Sciences Ltd. included in this Annual Report (Form 10-K) of Myovant Sciences Ltd. for the year ended March 31, 2019.

/s/ Ernst & Young LLP

Iselin, New Jersey

May 24, 2019

Exhibit 31.1

CERTIFICATION

I, Lynn Seely, certify that:

1. I have reviewed this Form 10-K of Myovant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 24, 2019

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, certify that:

1. I have reviewed this Form 10-K of Myovant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 24, 2019

By: /s/ Frank Karbe

Frank Karbe

Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Myovant Sciences Ltd. (the "Company") for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lynn Seely, Principal Executive Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 24, 2019

By: /s/ Lynn Seely
Lynn Seely
Principal Executive Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Myovant Sciences Ltd. (the "Company") for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Frank Karbe, Principal Financial Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 24, 2019

By: /s/ Frank Karbe
Frank Karbe
Principal Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.