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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, 2017

or

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

For the transition period from to

Commission file number 001-37929

Myovant Sciences Ltd.
(Exact name of registrant as specified in its charter)

Bermuda	**98-1343578**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
20-22 Bedford Row London, United Kingdom WC1R 4JS	**Not Applicable**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **+44 203 318 9709**

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. (Check one)

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

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

The voting common shares held by non-affiliates of the registrant were not publicly traded as of the second fiscal quarter ended September 30, 2016. The aggregate market value of voting common shares held by non-affiliates of the registrant on October 27, 2016, the date of initial listing, was $192,270,000, based on the last reported sale price of the common shares on The New York Stock Exchange on such date of $13.26 per share.

The number of the Registrant's common shares, $0.000017727 par value per share, outstanding on June 12, 2017, was 60,280,189.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended March 31, 2017. With the exception of the portions of the 2017 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, such document shall not be deemed filed as part of this Form 10-K.

Portions of the proxy statement are incorporated herein by reference into the following parts of this Annual Report on Form 10-K:

Part III, Item 10. Directors, Executive Officers and Corporate Governance;

Part III, Item 11. Executive Compensation;

Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters;

Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence; and

Part III, Item 14. Principal Accounting Fees and Services.

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MYOVANT SCIENCES LTD.

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED MARCH 31, 2017

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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," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural of these words or similar expressions or variations, although not all forward-looking statements contain these identifying 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 projected in the 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 timing of our ongoing clinical trials for our lead product candidate, relugolix;
- our plans to develop and commercialize relugolix;
- 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;
- anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- continued service of our key scientific or management personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our product candidates;
- our anticipated future cash position;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, prospects, growth and strategies; and
- the success of competing drugs that are or may become available.

We have based these forward-looking statements largely on our current expectations and projections about future events, including the responses we expect from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities and financial trends that we believe may affect our financial condition, results of operations, business strategy, nonclinical studies and clinical trials and financial needs. 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, and those discussed 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 U.S. Securities Exchange Commission, or SEC. These risks are not exhaustive. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. 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. 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 report are the property of their respective owners. Unless the context requires otherwise, references in this report to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its subsidiaries.

Item 1. Business

General

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases. Our lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist. We are advancing relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, and advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin agonist, for the treatment of female infertility as part of the hormonal preparation used in assisted reproduction. Both relugolix and MVT-602 are licensed to us by Takeda Pharmaceuticals International AG, or Takeda. Our mission is to become the leading global pharmaceutical company focused on women's health and endocrine diseases.

Relugolix

We are developing relugolix in three indications: heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, 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 levels decreases heavy menstrual bleeding in women with uterine fibroids and improves the pelvic pain associated with endometriosis. Decreasing testosterone slows the growth and progression of advanced prostate cancer and is the central objective of treatment once the disease has recurred following definitive treatment with prostatectomy or radiation therapy or in men presenting with advanced prostate cancer. Injectable GnRH agonists are currently approved to treat uterine fibroids, endometriosis, and prostate cancer, and an injectable GnRH antagonist is approved to treat men with prostate cancer.

In our clinical programs for our target women's health indications, a maximally estrogen-suppressive dose of relugolix (40 mg) will be co-administered orally, once daily with low-dose estradiol and progestin add-back therapy, with the goal of minimizing side-effects typically associated with low estrogen levels (such as bone mineral density loss and hot flashes) while maximizing the benefit of low estrogen levels on symptoms of uterine fibroids and endometriosis. We intend to commercialize relugolix, if approved, in our target women's health indications as a fixed-dose combination product, which is a once-daily single pill containing both relugolix and low-dose estradiol and progestin. The hormonal add-back therapy we intend to use consists of estradiol (1.0 mg) and norethindrone acetate, or NETA, (0.5 mg) and is a formulation currently approved for use to lower the side effect of bone mineral density loss and reduce vasomotor symptoms (hot flashes) in postmenopausal women. We believe relugolix with low-dose hormonal add-back therapy has the potential to have a better safety and tolerability profile than the currently approved GnRH 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. In our clinical program for men with prostate cancer, a maximally testosterone-suppressive dose of relugolix (120 mg) will be administered orally, once daily. We believe relugolix has a well-defined safety profile, based on its evaluation in more than 1,300 study participants to date, in Phase 1 and multiple large, randomized Phase 2 clinical trials, including at doses of 120 mg/day administered to men for more than one year.

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The following table summarizes the status of our relugolix development programs:

Compound	Clinical Indication	Development Stage	Myovant Commercial Rights
Relugolix with Hormonal Add-Back Therapy			
	Uterine Fibroids - Heavy Menstrual Bleeding	Phase 3 - Initiated Q1 2017 (LIBERTY 1 & LIBERTY 2 Trials)	Global, Excluding Takeda Territory[1]
	Endometriosis - Pain	Phase 3 - Planned Initiation Q2 2017	Global, Excluding Takeda Territory[1]
Relugolix			
	Advanced Prostate Cancer	Phase 3 - Initiated Q1 2017 (HERO Trial)	Global, Excluding Takeda Territory[1]

[1] Takeda Territory includes Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam, including, in each case, the territories and possessions of each of the foregoing.

Uterine Fibroids

Uterine fibroids are noncancerous tumors composed of smooth muscle and fibrous connective tissue that develop in or on the walls of the uterus. 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 that are often asymptomatic, 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.

Uterine fibroids are among the most common reproductive tract tumors in women. We estimate approximately 5 million women in the United States suffer from symptoms of uterine fibroids, approximately 3 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 add-back therapy to lower the side effect of bone mineral density loss and reduce vasomotor symptoms generally associated with GnRH agonists. 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 United States alone.

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Our Phase 3 Program for Uterine Fibroids

We are conducting a Phase 3 clinical program consisting of two international, replicate pivotal clinical trials (LIBERTY 1 and LIBERTY 2), which we initiated in January 2017, for relugolix in women with heavy menstrual bleeding associated with uterine fibroids. Women with heavy menstrual bleeding associated with uterine fibroids in the LIBERTY 1 and LIBERTY 2 trials are randomized to one of three arms using 1:1:1 randomization. Women receive treatment with relugolix 40 mg once daily co-administered with commercially available low-dose hormonal add-back therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. We expect to enroll approximately 390 women in each of the two replicate LIBERTY 1 and LIBERTY 2 trials, with 130 women in each of the two active treatment arms and 130 women in the placebo arm.

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 over the last month of treatment as measured by the alkaline hematin method, a quantitative measurement of menstrual blood loss. The secondary efficacy endpoints include measures of change from baseline in hemoglobin, assessment of the impact of therapy on quality-of-life measures, the reduction in uterine and fibroid volume, and pain reduction. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, is also being assessed. If the results of LIBERTY 1 and LIBERTY 2 are favorable, we intend to submit a new drug application, or NDA, to the FDA in 2019. We will conduct a bridging study intended to support approval of the fixed-dose combination of relugolix with low-dose estradiol and progestin. Eligible women completing the LIBERTY 1 or LIBERTY 2 trial will be offered the opportunity to enroll in an active treatment extension study where all patients will receive relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 28-week period, or a total treatment period of 52 weeks, to evaluate the safety of long-term treatment. We may conduct additional clinical trials to further support the commercial potential of relugolix in uterine fibroids in the United States and other major markets.

Takeda Phase 3 Clinical Development for Uterine Fibroids

Takeda is currently conducting two Phase 3 trials for relugolix in Japan, one for the treatment of heavy menstrual bleeding associated with uterine fibroids and one for the treatment of uterine fibroid-associated pain. The first trial is a multicenter, randomized, double-blind noninferiority study to evaluate the efficacy and safety of relugolix in 288 women with heavy menstrual bleeding associated with uterine fibroids. Relugolix 40 mg once daily is administered for 24 weeks, compared with leuprolide administered by subcutaneous injection every four weeks at a dose of 1.88 mg or 3.75 mg. The primary endpoint is the proportion of women who receive a total score of less than 10 on the Pictorial Blood Loss Assessment Chart, or PBAC, a patient-reported outcome measure for evaluation of menstrual blood loss in clinical trials, from week 6 to week 12, which was the same endpoint used in Takeda's Phase 2 trial in women with uterine fibroids. The second Phase 3 trial is a multicenter, randomized, double-blind study evaluating relugolix 40 mg once daily for 12 weeks versus placebo in 64 women having at least moderate pain symptoms associated with uterine fibroids. The primary endpoint is the proportion of women with a maximum Numerical Rating Scale score, or score on a patient-reported assessment of pain, of one or less during the 28 days before the final dose of study drug at week 12.

Preliminary data from these trials are currently anticipated in the second half of 2017. These Phase 3 data will be available to us, and may be used to support our NDA. If Takeda’s Phase 3 program for heavy menstrual bleeding and uterine fibroid-related pain is successful, Takeda plans to seek regulatory approval of relugolix in Japan for these indications in 2018. We will be solely responsible for obtaining FDA approval for relugolix in the United States.

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 United States, 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 United States

suffer from symptomatic endometriosis, 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment.

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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 add-back therapy. The FDA has approved Lupaneta Pack, or leuprolide administered with NETA (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. 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 United States, although hysterectomy is not a cure for endometriosis and pain associated with endometriosis will not necessarily subside following hysterectomy.

Our Phase 3 Clinical Development Plan for Endometriosis

We plan to initiate our Phase 3 clinical program consisting of two international, replicate pivotal clinical trials for relugolix in women with endometriosis-associated pain in the first half of 2017. Women with endometriosis-associated pain in these trials will be randomized to one of three arms using 1:1:1 randomization. Women will receive treatment with relugolix 40 mg once daily co-administered with low-dose hormonal add-back therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. Each of the two replicate trials is expected to enroll approximately 600 women, with 200 women in each of the two active treatment arms and 200 women in the placebo arm. Eligible women completing the initial 24-week period will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 28-week period, or a total treatment period of 52 weeks, to evaluate the safety of longer-term treatment.

The co-primary efficacy endpoints for these 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. If the results of these trials are favorable, we intend to submit an NDA to the FDA in 2019. If not already completed for the uterine fibroid indication, we will conduct a bridging study intended to support approval of the fixed-dose combination of relugolix with low-dose estradiol and progestin. We may conduct additional clinical trials to further support the commercial potential of relugolix in endometriosis in the United States and other major markets.

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 United States. According to the National Cancer Institute, approximately 2.9 million men are currently living with prostate cancer in the United States, and approximately 180,000 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 98.9%.

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: 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.

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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 and follicle-stimulating hormone decrease 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 Clinical Development Plan for Advanced Prostate Cancer

We are conducting a Phase 3 clinical trial, the HERO study, which we initiated in the first quarter of 2017, for relugolix in men with advanced prostate cancer. We believe that the HERO study, if successful, will be sufficient to support the filing of an NDA based on an End-of-Phase 2 meeting held with the US 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 study.

Our Phase 3 HERO trial in men with advanced prostate cancer who require ADT will randomize men 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. We will enroll approximately 1,125 men into this trial, with approximately 750 men enrolled into the active treatment arm and 375 men into the leuprolide arm using a 2:1 randomization scheme. Based on FDA discussions, we are only required to conduct one Phase 3 trial with a single relugolix arm to gain approval in the United States; however, we are including a leuprolide arm to gain approval in other major markets where the demonstration of noninferiority to leuprolide is required.

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 United States 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 United States and other major markets.

MVT-602

As part of our license agreement with Takeda, we acquired the worldwide rights to MVT-602, our second product candidate, which has been evaluated in over 150 men. MVT-602 is an oligopeptide kisspeptin agonist. Kisspeptin 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. We intend to complete a Phase 1 healthy volunteer study in women to be followed by the initiation of a Phase 2 proof-of-concept clinical trial in the second half of 2017 for MVT-602 for the treatment of 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.

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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 encouraging results validate the potential use of kisspeptin analogs as a safe alternative to the standard egg maturation trigger in assisted reproduction protocols. To our knowledge, MVT-602 is the only kisspeptin 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 a license agreement with Takeda, or the Takeda Agreement. Pursuant to the Takeda 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 commercialization 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.

Under the Takeda 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, in each case solely for commercialization 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 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 United States. 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.

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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 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 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 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 Agreement for the other party's uncured material breach, challenge to the patents licensed under the Takeda Agreement, or insolvency. Takeda may terminate the Takeda 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 Agreement, we issued 5,077,001 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 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 Agreement with Takeda

In June 2016, we and Takeda's affiliate, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited will supply us, and we will obtain from Takeda Limited, all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. If we request, Takeda Limited will assist us with a technical transfer of the manufacturing process for relugolix to us or our designee and we will pay the expenses related to such transfer.

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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, endometriosis-associated pain, 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) 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) 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 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 United States 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 formal 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 services to us. Under the RSI Services Agreement, we pay or reimburse RSI for any expenses it, or third parties acting on its behalf, incurs for us. For any general and administrative and research and development activities performed by RSI employees, RSI charges back the employee compensation expense plus a pre-determined mark-up. RSI also provided such services prior to the formalization of the RSI Services Agreement, and such costs have been recognized by us in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on our matters. All other costs are billed back at cost. The accompanying consolidated financial statements include third-party expenses that have been paid by RSI and RSL.

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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 also entered into a separate 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 the identification of potential product candidates and project management of clinical trials, as well as other services related to clinical development, administrative, and financial activities. We refer to the services agreement between MSG and RSG and the RSI Services Agreement, collectively, as the Services Agreements.

Our Strategy

Our goal is to be the leading global biopharmaceutical company focused on women's health and endocrine diseases in areas of high unmet medical need, and to improve the lives of millions of patients suffering from these diseases. The key elements of our strategy to achieve this goal include the following:

- rapidly advance clinical development of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain;
- rapidly advance clinical development of relugolix for the treatment of advanced prostate cancer;
- advance clinical development of MVT-602;
- expand clinical development of relugolix for additional indications;
- acquire or in-license additional clinical- or commercial-stage product candidates for women's health or endocrine diseases in a capital-efficient manner; and
- maximize the commercial potential of our product candidates.

Sales and Marketing

We do not have our own 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 United States. 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 have no experience in drug formulation or manufacturing and do not own or operate, and we do not 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 will supply to us and we will obtain from Takeda Limited relugolix drug substance and drug product to be used under our development plans for all ongoing and near-term clinical studies. 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. If we request, Takeda Limited will assist us with a technical transfer of the manufacturing process for relugolix drug substance and drug product to us or our designee and we will pay the expenses related to such transfer.

We expect that manufacturing support provided by Takeda to us under the Takeda Agreement will be sufficient for us to complete our planned Phase 3 programs for relugolix. If approved by the FDA, we also plan to rely on Takeda or other third-party manufacturers to supply us with sufficient commercial quantities of relugolix. We expect that the MVT-602 drug substance transferred from Takeda to us under the Takeda 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 3 clinical studies for MVT-602. We intend to contract with third-party contract manufacturers to complete the additional development and manufacturing activities for this program to fill, finish, supply, store, and distribute the drug product for this program. If there is delay in initiating a new relationship with one or more other third-party manufacturers or a delay in completing technology transfer from Takeda, we could experience delays in our development and commercialization efforts.

Relugolix is a synthetic small molecule that can be manufactured using well-established technologies. We have acquired and continue to acquire data from Takeda related to the chemical synthesis and manufacturing of relugolix drug substance and drug product, and we expect that we will be able to contract with third-party manufacturers for commercial supplies of relugolix on a cost-efficient basis based on our understanding of the conventional technologies utilized in manufacturing relugolix. We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates. In anticipation of receiving marketing approval by a regulatory agency for any one of our products, we intend to enter into agreements with Takeda and/or third-party contract manufacturers for the commercial production of those products.

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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 under current Good Manufacturing Practice, or cGMP, conditions. cGMP is a regulatory standard for the production of pharmaceuticals to be used in humans.

Competition

We consider relugolix's most direct competitor for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain to be elagolix, an oral GnRH receptor antagonist currently in Phase 3 clinical development by AbbVie. ObsEva is also developing an oral GnRH receptor antagonist, OBE2109, for the treatment of endometriosis and uterine fibroids. ObsEva has initiated a Phase 2 clinical trial evaluating multiple doses of OBE2109 in women with endometriosis and reported the initiation of a Phase 3 study in women with uterine fibroids in the first quarter of 2017. We believe the development of multiple GnRH receptor antagonists by other biopharmaceutical firms adds further validation to the therapeutic relevance of GnRH as a target for the treatment of women's health and endocrine diseases.

Further, Allergan is developing ulipristal acetate, a selective progesterone receptor modulator, in the United States for uterine fibroids. Allergan has reported data from two successful Phase 3 clinical trials, and expects to file an NDA with the FDA in 2017 for ulipristal acetate to treat women with heavy menstrual bleeding associated with uterine fibroids.

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.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, academic institutions, and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, and reimbursement. Many of our existing or potential competitors have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries.

Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small 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 candidate non-competitive or obsolete or reduce the demand for our product candidate before we can recover our development and commercialization expenses.

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

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While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the process may provide sufficient basis for a competitor to avoid infringement claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our products or product candidates. Following our execution of the Takeda Agreement, as of June 30, 2016, by virtue of the license of patent rights under the Takeda 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. As they relate to relugolix, these patents and patent applications cover the relugolix molecule and analogs thereof as a composition of matter, the use of relugolix to treat sex-hormone dependent prostate cancer or hysteromyoma (uterine fibroids), as well as methods of manufacturing. The patent family directed to the relugolix composition of matter and methods of use naturally expires in 2024, subject to any extension of patent term that may be available in a particular country. The patent applications directed to methods of manufacturing, if issued, would naturally expire in 2033 subject to any adjustment or extension of patent term that may be available in a particular country. For example, we expect the term of the composition of matter patent to relugolix will be extended up to about five years, or 2029, under the provisions of the Hatch-Waxman Act.

For MVT-602, we are the exclusive worldwide licensee of multiple U.S. patents and patent applications as well as patents and patent applications in numerous foreign jurisdictions. These patents and patent applications cover the MVT-602 molecule as a composition of matter, 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 composition of matter and method of use naturally expires in 2028 in the United States and in 2026 ex-United States, subject to any extension of patent term that may be available in a particular country. The patent applications directed to the sustained-release formulations of MVT-602, if issued, would naturally expire in 2030 and 2031, subject to any adjustment or extension of patent term that may be available in a particular country. For example, in the United States, depending on the development timeline and NDA filing and approval dates, we expect the term of the composition of matter patent to MVT-602 will be extended up to at least three years, or 2031, under the provisions of the Hatch-Waxman Act.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. 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 are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. 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.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses, or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have an adverse impact on us. If third parties prepare and file patent applications in the United States 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.

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Government Regulation

FDA Drug Approval Process

In the United States, 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 United States until the drug has received FDA approval. The steps required before a drug may be marketed in the United States 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 IND 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 United States.

Satisfaction of FDA pre-market 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.

Nonclinical 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 the 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.

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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. 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 United States. 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 product and establishment 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 agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within 10 to 12 months; most applications for priority review drugs are reviewed in six to eight months. 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.

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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.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 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.

Foreign Regulation

In order to market any product outside of the United States, 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 United States 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

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.

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The federal Anti-Kickback Statute makes 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 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. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. 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 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 Anti-Kickback Statute has been violated. Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs.

Additionally, the intent standard under the 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, 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 Affordable Care Act 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.

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 reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,957 and $21,916 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal 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 Affordable Care Act 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.

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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 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 laws 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. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

The Affordable Care Act, through the enactment of the Physician Payments Sunshine Act, imposes, among other things, new 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. Failure to submit timely, accurately, and completely the required information for all payments, transfers of value, and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures."

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, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Additionally, to the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop 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 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 individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Health Reform

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In particular, the Affordable Care Act has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the Affordable Care Act revises the definition of “average manufacturer price”, or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and imposes a significant annual fee on companies that manufacture or import certain branded prescription drug products. In January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the AMP is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Substantial new provisions affecting compliance have also been enacted, which

may require us to modify our business practices with healthcare providers and entities, and a significant number of provisions are not yet, or have only recently become, effective.

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We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. In January 2017, the President of the United States signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In May 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the Affordable Care Act. The U.S. Senate could adopt the American Health Care Act as passed by the U.S. House of Representative or other legislation to amend or replace elements of the Affordable Care Act. Thus, it is uncertain when or if the American Health Care Act will become law. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President of the United States signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. These included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs.

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 United States, 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 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.

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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.

Research and Development

Our research and development expenses totaled $43.5 million for the year ended March 31, 2017 and $0 for the period from February 2, 2016 (date of inception) to March 31, 2016.

Employees

As of March 31, 2017, we had 36 employees. As described above under "—Our Key Agreements—Services Agreements with Roivant Sciences, Inc. and Roivant Sciences GmbH," employees of RSI and RSG provide services to us pursuant to the Services Agreements. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

Corporate Information

We are an exempted limited company 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. We have four direct or indirect wholly-owned subsidiaries, including Myovant Holdings Limited, a private limited company incorporated under the laws of England and Wales, Myovant Sciences, Inc., a Delaware corporation, Myovant Sciences GmbH, a company with limited liability formed under the laws of Switzerland and Myovant Sciences Ireland Limited, a company with limited liability formed under the laws of Ireland. Our principal office is located at 20-22 Bedford Row, London, United Kingdom WC1R 4JS, and our registered office is located in Bermuda at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. We also have business operations at Park Place, 55 Par-La-Ville Road, Hamilton HM11, Bermuda, 2000 Sierra Point Parkway, 9th floor, Brisbane, CA 94005 and c/o OBC Suisse, Aeschenvorstadt 71, 4051 Basel, Switzerland. The telephone number of our registered office in Bermuda is +44 203 318 9709.

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. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements, and other information. The address of the SEC's website is www.sec.gov.

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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 report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results, and financial condition could be seriously harmed and the trading price of our common shares could decline. 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 report.

Risks Related to Our Business, Financial Position, and Capital Requirements

We have a limited operating history and have never generated any product revenue.

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 organizing and staffing our company, acquiring worldwide rights, excluding Japan and certain other Asian countries, to relugolix and worldwide rights to MVT-602, and preparing for and advancing our product candidates into clinical development. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have no meaningful operations upon which to evaluate our business and 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.

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of our product candidates, relugolix, for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-related pain, and advanced prostate cancer, and MVT-602 for the treatment of female infertility as part of assisted reproduction, and obtain the necessary regulatory approvals for their commercialization. We have never been profitable, have no products approved for commercial sale, and have not generated any product revenue.

Even if we receive regulatory approval for the sale of relugolix or MVT-602, we do not know when relugolix or MVT-602 will generate product revenue, if at all. Our ability to generate product revenue depends on a number of factors, including our ability to:

- successfully complete clinical trials and obtain regulatory approval for the marketing of relugolix and MVT-602;
- set an acceptable price for relugolix and MVT-602 and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, and distribution systems for relugolix and MVT-602;
- add operational, financial and management information systems, and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with Takeda or other third-party manufacturers and have commercial quantities of relugolix and MVT-602 manufactured at acceptable cost and quality levels;
- attract and retain an experienced management and advisory team;
- 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; and
- maintain, expand, and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA, and comparable non-U.S. regulatory authorities, to perform studies or

clinical trials in addition to those that we currently anticipate. Even if relugolix or MVT-602 is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of this product. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

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We expect to incur significant losses for the foreseeable future 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 become commercially viable. We have never generated any product revenue, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. Our net loss was $83.4 million for the year ended March 31, 2017 and, as of March 31, 2017, we had an accumulated deficit of $85.1 million.

We expect to continue to incur substantial and increasing losses through the projected commercialization of relugolix and MVT-602. Neither relugolix nor MVT-602 has been approved for marketing in the United States, and they may never receive such approval. As a result, 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. If we do successfully obtain regulatory approval to market relugolix or MVT-602, our revenue will be dependent, in part, upon, 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 that territory. 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, 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 expect our research and development expenses to be significant in connection with our development programs for relugolix and MVT-602. In addition, if we obtain regulatory approval for either relugolix or MVT-602, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

We are heavily dependent on the success of relugolix and MVT-602, our only product candidates, which are still under clinical development, and if either relugolix or MVT-602 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of relugolix and MVT-602. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of these product candidates. We cannot be certain that relugolix for either of our target women's health indications or for advanced prostate cancer or MVT-602 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. 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 United States and other countries that each have differing regulations. We are not permitted to market relugolix or MVT-602 in the United States until we receive approval of a new drug application, or NDA, for each, or in any foreign country until they receive the requisite approvals from the appropriate authority in such country. We have not submitted an NDA to the FDA, or any comparable application to any other regulatory authority and do not expect to be in a position to do so for the foreseeable future.

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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 for many reasons, including:

- we may not be able to demonstrate that relugolix or MVT-602 is effective as a treatment for our target indications to the satisfaction of the FDA or other relevant regulatory authority;
- our NDA or other key regulatory filings may be delayed or rejected due to unanticipated issues, including those related to the FDA's Pharmaceutical Quality/Chemistry, Manufacturing and Control, or CMC, or other guidances, timing of results from supporting studies, database lock, and data conversion, cleaning, and transfer;
- the relevant regulatory authority may require additional clinical trials, which would increase our costs and prolong our development;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authority for marketing approval;
- the FDA or other relevant regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that materially adversely impact our clinical trials;
- the FDA or other relevant regulatory authority may not find the data from nonclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authority may disagree with our interpretation of data from our nonclinical studies and clinical trials or may require that we conduct additional studies;
- the FDA or other relevant regulatory authority may not accept data generated at our clinical trial sites;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application(s) or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authority may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authority may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authority may change its approval policies or adopt new regulations.

If we are unable to formulate a fixed-dose combination version of relugolix with low-dose estradiol and progestin, the development of relugolix may be delayed and its commercial opportunity could be limited.

A key part of our relugolix clinical development strategy is to formulate a fixed-dose combination of relugolix with add-back low-dose estradiol and progestin in order to facilitate patient convenience and compliance and minimize side effects. If we are unsuccessful in our attempts to formulate a fixed-dose combination, we expect to instead seek approval for relugolix as monotherapy to be co-administered with commercially available low-dose estradiol and progestin. This would decrease our advantages relative to our competition by requiring patients to take two pills once daily instead of just one pill once daily. If our competitors develop a fixed-dose combination with hormonal add-back therapy, and 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.

Although we are conducting our Phase 3 clinical trials of relugolix in our target women's health indications with separate administration of relugolix and commercially available low-dose estradiol and progestin products, we intend to conduct bridging studies to support the submission of NDAs for the proposed fixed-dose combination for each of our target women's

health indications. Any such bridging study may be unsuccessful or insufficient to support approval of the fixed-dose combination formulation, which would delay and increase the expenses associated with our development program and limit our commercial opportunity.

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We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of 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 our license agreement with Takeda. Under the terms of this agreement, we are obligated to cover substantial development costs of relugolix and MVT-602 and make significant royalty payments in connection with the sale of resulting products.

We will require additional capital to complete the development and potential commercialization of relugolix and MVT-602. Because the length of time and activities associated with successful development of relugolix and MVT-602 are highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. 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 FDA and other 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.

Based upon our current operating plan, we believe our existing cash will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We cannot be certain that additional funding 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, 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 financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

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Raising additional funds by issuing securities may cause dilution to existing shareholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances, and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. 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 your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve the entry into agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or 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 product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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

We have licensed the intellectual property rights covering our current product candidates, relugolix and MVT-602, from Takeda pursuant to the Takeda Agreement. If, for any reason, the Takeda Agreement is terminated or we otherwise lose those rights, it would adversely affect our business. The Takeda Agreement imposes on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection, and other matters. 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 to Takeda and Takeda may have the right to terminate our license, which would result in us being unable to develop, manufacture, and sell relugolix and MVT-602.

Pursuant to the Takeda Agreement, we and a Takeda affiliate have entered into an agreement for the manufacture and supply of relugolix. Under this agreement, we are required to obtain from Takeda's affiliate all of our requirements for relugolix drug substance and drug product to be used under our development plan. The agreement also provides for Takeda's affiliate to reasonably assist us with a technical transfer of the manufacturing process for relugolix to us or our designee. If Takeda's affiliate fails to fulfill its obligations under this agreement to manufacture and supply relugolix to us or to enable the transfer of the manufacturing process for relugolix to us or our designee, our development of relugolix could be significantly delayed or otherwise adversely affected.

We currently have a limited number of employees who are employed by our wholly-owned subsidiary, Myovant Sciences, Inc., and we rely on Roivant Sciences, Inc. and Roivant Sciences GmbH to provide various administrative, business development, and other services.

As of March 31, 2017, we had 36 employees. We also rely in part on the administrative and support, business development, and other services provided by our affiliates, RSI and RSG, wholly owned subsidiaries of RSL, pursuant to our Services Agreements with RSI and RSG, as described under Item 1. Business "Our Key Agreements—Services Agreements with Roivant Sciences, Inc. and Roivant Sciences GmbH." Personnel and support staff that provide services to us under these services agreements are not required to, and we do not expect that they will, have as their primary responsibility the management and administration of our business or act exclusively for us. Under the Services Agreements, RSI and RSG have the discretion to determine which of their employees will perform services for us. Further, Marianne L. Romeo, our Head of Risk Management, is an employee of RSL and as a result, these officers are unlikely to allocate all of their time and resources to us.

RSI and RSG have limited financing and accounting and other resources. If either RSI or RSG fails to perform its obligations in accordance with the terms of the Services Agreements or to effectively manage our administrative and support, business development or other services, it could be difficult for us to operate our business and our business could be harmed. In the event of a default under or termination of the Services Agreements, we may be unable to contract with substitute service providers on similar terms, in a timely fashion or at all, and the costs of substituting service providers may be substantial. In

addition, in light of RSI's and RSG's familiarity with our assets, a substitute service provider may not be able to provide the same level of service due to lack of pre-existing knowledge or synergies. Any termination of our relationship with RSI or RSG and any delay in appointing or finding a suitable replacement provider, if one exists, could make it difficult for us to operate our business.

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We may not be able to manage our business effectively if we or RSI or RSG are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical, and other businesses. 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, and our ability to implement our business strategy.

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, as well as the key employees of RSI and RSG that provide services to us through the Services Agreements. Our senior management and key employees, as well as those of RSI and RSG, may terminate their position with us or their employment with RSI or RSG, respectively, at any time. Further, neither RSI nor RSG is required pursuant to the Services Agreements to maintain the employment of any of its key employees on our behalf or to cause those individuals to provide services to us. If we lose one or more members of our senior management team or key employees, or those of RSI or RSG, our ability to successfully implement our business strategy 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. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel. We do not maintain “key person” insurance for any of our executives or other employees.

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

We expect to hire, either directly, through MSI or through any other current or future subsidiary of ours, additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, medical affairs, and sales and marketing teams. We may have operational difficulties in connection with identifying, hiring, and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate, and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations across our entities, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize relugolix or MVT-602 and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

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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 standards and requirements, which could have an adverse effect on our results of operations.

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

We may not be successful in our efforts to identify and acquire or in-license additional product candidates.

Part of our strategy involves identifying and acquiring or in-licensing novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- the process by which we identify and decide to acquire product candidates may not be successful;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases.

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves 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 or other development programs. If we are unable to identify and acquire suitable product candidates for clinical development, this would adversely impact our business strategy, our financial position, and share price.

International expansion of our business exposes us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.

Our business strategy incorporates international expansion, including establishing and maintaining operations outside of the United States and establishing and maintaining relationships with distributors and manufacturers globally. Doing 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;

- 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;

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- 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;
- natural disasters, political, and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and
- failure to comply with the 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 and 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 business and operations would suffer in the event of system failures.

Our computer systems, as well as those of RSI, RSG and our CROs and other contractors, consultants, and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, cybercriminals, natural disasters (including hurricanes), terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could 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 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.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and 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 consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that 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 candidate;
- 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 insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. 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 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.

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Risks Related to Clinical Development, Regulatory Approval and Commercialization

Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome.

Our product candidates, relugolix and MVT-602, are still in development and will require extensive clinical testing before we are prepared to submit an NDA or other similar application for regulatory approval. We cannot predict with any 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 authority. 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 may not agree with our proposed endpoints for any clinical trials of relugolix or MVT-602, which may delay the commencement of our planned clinical trials or approval of an NDA. The clinical trial process is also time-consuming. We estimate that our clinical trials of relugolix and MVT-602 will take at least several years to complete.

Failure can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. 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, powering of a clinical study, and diligent oversight of the compliance of those patients enrolled into the trial. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, the results of early clinical trials of relugolix and MVT-602 may not be predictive of the results of our planned development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future study results.

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;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- unanticipated changes in or modifications to clinical trial design;
- failure to manufacture sufficient quantities of a product candidate or placebo or failure to obtain sufficient quantities of concomitant medication for use in clinical trials;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical and other applicable protocols;
- failure to add or adding a sufficient number of clinical trial sites; or
- clinical sites or others deviating from trial protocol, inappropriately unblinding results, or dropping out of a trial.

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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 trial in accordance with regulatory requirements, including, the FDA's current GCP 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 IND or other submissions or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of 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 drop in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition, and results of operations. In addition, many of the factors that cause or lead to a 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 authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation 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, because we recently acquired worldwide rights, excluding Japan and certain other Asian countries, to relugolix and worldwide rights to MVT-602, we were not involved in the development of relugolix or MVT-602 prior to April 2016. We may experience difficulties in the transition of this product candidate from Takeda and its affiliates to us, which may result in delays in clinical trials as well as problems in our development efforts and regulatory filings, particularly if we do not receive all of the necessary products, information, reports, and data from Takeda and its affiliates in a timely manner. Further, prior to our acquisition of the rights to relugolix and 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 protocol, 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 predecessors 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.

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

Takeda is currently conducting two Phase 3 trials for relugolix in women in Japan, one for the treatment of heavy menstrual bleeding associated with uterine fibroids and one for the treatment of uterine fibroid-associated pain. Takeda is also completing an extension of its Phase 2 trial, C27002, for relugolix in men with advanced prostate cancer. If announcements by Takeda regarding these clinical trials are unfavorable, it could negatively impact our clinical development plans for relugolix. Further, even if announcements by Takeda regarding these clinical trials are favorable, investors should not place undue reliance upon any of Takeda's reported data or other clinical development announcements because, among other reasons, the design of our Phase 3 clinical trials for relugolix differ from Takeda's clinical trials.

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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 effectiveness 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. 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.

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, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. 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, 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 may report in clinical trials of our product candidate may make it difficult or impossible to recruit 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 in our 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. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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. Further, it is likely that additional drugs will become available in the future for the treatment of each of our target indications.

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We are aware of several companies that are working to develop drugs that would compete against relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, and advanced prostate cancer and against MVT-602 for the treatment of female infertility as part of assisted reproduction. For example, AbbVie in conjunction with Neurocrine Biosciences, is developing a GnRH receptor antagonist, elagolix, as an oral treatment for endometriosis-associated pain and for heavy menstrual bleeding associated with uterine fibroids. AbbVie has completed two Phase 3 trials for elagolix in women with endometriosis-associated pain and is expected to file an NDA for this indication in 2017. AbbVie has also initiated a Phase 3 program evaluating elagolix with and without hormonal add-back therapy in women with heavy menstrual bleeding associated with uterine fibroids, and AbbVie is expected to commence a Phase 3b trial of elagolix in combination with hormonal add-back therapy in women with pain associated with endometriosis in 2017. Similarly, ObsEva SA, a Swiss-based clinical stage biopharmaceutical company, which completed its IPO in January 2017, reported the commencement of two Phase 3 clinical trials of OBE2109, also a GnRH receptor antagonist, in women with heavy menstrual bleeding associated with uterine fibroids in the first half 2017. 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, as well as their intention to file an NDA for ulipristal acetate in the second half of 2017. Other GnRH receptor antagonists and selective progesterone receptor modulators are also in development. Many of our existing or potential competitors have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small 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.

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

The availability 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 in order 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.

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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, 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 United States and by similar regulatory authorities outside the United States. 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, 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 any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

The time required to obtain approval of an NDA by the FDA 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 planned Phase 3 programs, and for approval of MVT-602, we will need to complete additional Phase 1, Phase 2, and Phase 3 clinical trials. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Securing marketing approval 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 co-administered with low-dose hormonal add-back therapy as a longer-term therapy for the treatment of heavy menstrual bleeding associated with uterine fibroids and of endometriosis-associated pain, we expect to submit data with respect to a large patient population. 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 approval, 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 caused by relugolix or MVT-602 could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for relugolix or MVT-602 or any future product candidates, our ability to obtain regulatory approval 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, concern has been raised by the FDA about a potential increase in the risk of diabetes and certain cardiovascular diseases in men with prostate cancer treated with GnRH agonists.

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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 REMS 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;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical trials;
- we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- 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 its 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. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States 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 foreign 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 in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

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Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future development 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 current GMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, recordkeeping, and current GCP 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 RVT-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 we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the United States, 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, and other foreign regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in 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;
- 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 United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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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.

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 and 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;
- the prevalence and severity of any side effects;
- the content of the approved product label;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement; 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 either of these product candidates to find 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.

We do not have any 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. In order 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 expect to build a focused sales, distribution, and marketing infrastructure to market our product candidates in the United States, 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 leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. 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 effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs; and

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- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing 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 a product, and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of our product candidates, if approved, for certain markets overseas; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenue we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

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 or otherwise at an earlier stage than otherwise would be ideal and we may be required to relinquish 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 many 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 commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If either relugolix or MVT-602 is approved for commercialization, we intend to enter into agreements with third parties to market it in certain jurisdictions outside the United States. 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 protection for 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 United States;
- potential noncompliance with the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act 2010, and similar antibribery and anticorruption laws in other jurisdictions;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

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- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, and fires.

We have no prior experience in these areas, 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, health care 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, 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 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 civil False Claims Act;

- the federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; 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 HIPAA 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, 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 most providers 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;

- 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

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- analogous state and foreign laws and regulations, such as state antikickback and false claims laws, 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 or marketing expenditures; 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, 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 United States 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 March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, 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 health industry, and impose additional health 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. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

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- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred. For example, in January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. In January 2017, the President of the United States signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In May 2017, following the passage of the budget resolution for fiscal year 2017, the United States House of Representatives passed legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the Affordable Care Act. The United States Senate could adopt the American Health Care Act as passed by the United States House of Representatives or other legislation to amend or replace elements of the Affordable Care Act. Thus, it is uncertain when or if the American Health Care Act will become law. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President of the United States signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included further 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 stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, 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 have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs.

Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We expect that additional state and federal healthcare reform measures 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 product candidates or additional pricing pressures.

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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 United States, 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 United States 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, following approval.

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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 have no experience in drug formulation or manufacturing and 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. Takeda has retained rights to further develop and commercialize relugolix in Japan and certain other Asian countries, and Takeda is continuing to develop relugolix in Japan. In April 2016, we acquired exclusive worldwide rights to MVT-602 for all human diseases and conditions. Takeda is no longer developing this compound. We expect that manufacturing support provided by Takeda under our license agreement with Takeda will be sufficient for us to complete our planned Phase 3 programs for relugolix. We expect that the MVT-602 drug substance transferred from Takeda to us under the Takeda 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 3 clinical studies for MVT-602. However, the drug substance transferred from Takeda may not meet our quality standards and may be disqualified from use in our planned clinical programs. Further, we will be dependent on third parties to help formulate and manufacture a fixed-dose combination of relugolix and low-dose estradiol and 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.

We also will rely on Takeda or 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. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit 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 current GMP requirements for 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 others, 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 a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws 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 design a fixed-dose combination product of relugolix and low-dose estradiol and progestin;
- failure of the drug substance transferred from Takeda 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 cGMP 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;

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- 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 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 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 intend to rely 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 GLP requirements. We also do not currently have the ability to independently conduct any clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

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

We and our CROs will be 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 and 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 sponsors of those studies.

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While we will have agreements governing their activities, our CROs will not be our employees, and we will 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.

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 intend to 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.

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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, 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 United States 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 United States 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.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover relugolix, MVT-602 or any future product candidate in the United States 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 invalidate a patent or prevent a patent from issuing from a pending patent application. 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 and companion diagnostic 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 in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we 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, 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 United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

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Moreover, we may be subject to a third party pre-issuance submission of prior art to 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. 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 United States 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. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is 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 the intellectual property rights covering our current product candidates from Takeda. If, for any reason, our license agreement with Takeda is terminated or we otherwise lose those rights, it could adversely affect our business. Our license agreement with Takeda 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.

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Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate 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 United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States 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. We have conducted searches for information in support of patent protection and otherwise evaluating the patent landscape for relugolix and MVT-602, and, based on these searches and evaluations to date, we do not believe that there are valid patents which contain granted claims that could be asserted with respect to relugolix or MVT-602. However, we may be incorrect.

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 patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover 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.

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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 United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future 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 United States. 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 United States 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 United States has recently enacted and implemented wide-ranging patent reform legislation. The United States 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 United States 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 United States. 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.

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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 research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. 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. MSI is currently a defendant in a lawsuit alleging such claims with respect to one of its employees. 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 develop or be sustained. In addition, as a result of RSL beneficially owning approximately 61.8% of our outstanding common shares, trading in our common shares may be less liquid than the shares of companies with broader public ownership. If an active market for our common shares is not sustained, you may not be able to sell your shares quickly or at the market price. 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;
- results of clinical trials of relugolix, MVT-602 or those of our competitors;

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- 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 United States 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, 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 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;
- 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 our common shares by us or our shareholders in the future;
- 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 volume of our common shares;
- general economic, industry, and market conditions; 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.

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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 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, including the requirements:

- that a majority of its board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- to have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- to have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

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 March 31, 2017, RSL beneficially owns approximately 61.8% of the voting power of our outstanding common shares and has the ability to substantially influence us through this ownership position. For example, RSL and its shareholders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. 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.

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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 do 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 and trading volume 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 cover us downgrade our common shares or change their opinion of 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 or trading volume 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. 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, could depress our 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 shares sold in our IPO, as well as shares issued upon the exercise of options granted to persons other than our officers and directors, 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 plans. Sales of these common shares may have an adverse effect on the trading price of our common shares. In addition, in the future we may issue 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.

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We have incurred and will continue to incur substantial 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. 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 financial 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 of our board of directors or members of senior management.

As a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common shares.

We will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending March 31, 2018. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act. We will be required to disclose significant changes made in our internal control procedures on a quarterly basis.

We have begun the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal control, if we 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. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could 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, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, 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 restrict our future access to the capital markets.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following November 1, 2021, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common shares that are held

by non-affiliates exceeds $700.0 million as of the prior September 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

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

We are a Bermuda exempted 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 United States, 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 United States and may afford less protection to our shareholders.

We are organized 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 United States, 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 United States.

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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.

We have anti-takeover provisions in our bye-laws that may discourage a change of control.

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

- a classified board of directors with staggered three-year terms;
- directors only to be removed for cause;
- an affirmative vote of 66⅔% of our voting shares for certain "business combination" transactions that have not been approved by our board of directors;
- restrictions on the time period in which directors may be nominated; and
- our board of directors to determine the powers, preferences, and rights of our preference shares and to issue the preference shares without shareholder approval.

These anti-takeover defenses 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 these provisions may adversely affect the prevailing market price of our common shares if the provisions are viewed as discouraging takeover attempts in the future. These provisions could also discourage proxy contests, make it more difficult for you and other shareholders to elect directors of your choosing, and cause us to take corporate actions other than those you desire.

The voting power of your common shares may be reduced without your further consent.

Under our amended and restated bye-laws, in the event that any U.S. person holds, directly, indirectly or constructively, 9.5% or more of the total voting power of our issued share capital, excluding any U.S. person that held, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of our IPO, the aggregate votes conferred by the common shares held by such person (or by any person through which such U.S. person indirectly or constructively holds shares) will be reduced by our board of directors to the extent necessary such that the common shares held, directly, indirectly or constructively, by such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares. RSL and certain of its affiliates are not subject to these provisions. Further, our board of directors may determine that shares shall carry different or no voting rights as it reasonably determines, based on the advice of counsel, to be appropriate to (1) avoid the existence of any U.S. person who holds 9.5% or more of the total voting power of our issued share capital or (2) avoid adverse tax, legal or regulatory consequences to us, any subsidiary of ours or any holder of our common shares or its affiliates. These provisions may discourage potential investors from acquiring a stake or making a significant investment in our company, as well as discourage a takeover attempt, which may prevent our shareholders from receiving the benefit of any such transactions as well as adversely affect the prevailing market price of our common shares if viewed as discouraging takeover attempts in the future.

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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. legislation, a company which is centrally managed and controlled in the United Kingdom is regarded as resident in the United Kingdom for taxation purposes. 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 materially adversely affect our results of operations. For example, Myovant Sciences GmbH is our principal operating company for conducting our business and the entity that holds our intellectual property rights in relugolix and MVT-602. The establishment of this Swiss entity as our principal operating company and the transfer of our intellectual property rights to this entity may result in a higher overall effective tax rate.

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.

RSL, our principal shareholder, is based in Bermuda. We currently have subsidiaries in the United Kingdom, Switzerland, Ireland, and the United States. 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, our parent company, 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 arms' length and that appropriate documentation is 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. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. In particular, there is uncertainty as to any future U.S. tax legislation on corporate tax rates, as well as uncertainty as to the U.S. tax consequences of income derived from intellectual property held overseas in low tax jurisdictions.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' 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.

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), the United States, Bermuda, and other jurisdictions, as well as being affected by certain changes currently proposed by the Organisation 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.

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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 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. 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 composition of our income and the composition and value of our assets (assuming we are not a "controlled foreign corporation," or a CFC, under Section 957(a) of the Internal Revenue Code of 1986, as amended, or the Code, for the year being tested, which may be determined in large part by reference to the market value of our common shares, which may be volatile) from time to time. Our status may also depend, in part, on how quickly we utilize the cash proceeds from our IPO in our business. We believe that we were not a CFC at any point prior to our IPO and after our IPO in the taxable years that ended on March 31, 2016 and March 31, 2017. Based on this belief, with respect to the taxable year that ended on March 31, 2017 and foreseeable future taxable years, we presently do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets. 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.

In the event that we receive passive income in the future that would cause us to be a PFIC, we would expect to evaluate and may implement alternative structures and arrangements including structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. The failure or inability to implement such structures or arrangements may have an adverse impact on the determination of whether we are classified as a PFIC.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal offices are located at 20-22 Bedford Row, London, United Kingdom WC1R 4JS. 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 believe that all of our 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

On or about October 24, 2016, AbbVie filed a complaint for injunctive and other relief against an employee of MSI, Laura Williams, M.D. and MSI in the Circuit Court of the Nineteenth Judicial Circuit, Lake County, Illinois, asserting claims for breach of contract and misappropriation of trade secrets against Dr. Williams only, and a claim against MSI for alleged tortious interference with Dr. Williams' employee agreement with AbbVie.

On January 27, 2017, AbbVie sought court approval to file a first amended complaint which, among other things, alleged claims for tortious interference with contract and misappropriation of trade secrets against MSI and Dr. Seely, our Principal Executive Officer. MSI and Dr. Seely deny both claims and subsequently filed a motion to dismiss the claims against them for lack of personal jurisdiction and other legal defects in the first amended complaint. On April 7, 2017, the court granted Dr. Seely's motion to dismiss and dismissed her from the case. The court denied MSI's motion to dismiss, and MSI answered the complaint on May 23, 2017, denying any and all liability to AbbVie.

On May 24, 2017, the court entered an order granting a preliminary injunction which enjoined Dr. Williams from working in any capacity at MSI and from having any communications relating to the development of relugolix or elagolix with anyone associated with MSI or RSL. The court order also enjoins Dr. Williams from using or disclosing any of AbbVie's confidential information and trade secrets. While it is not possible to determine the outcome of this matter, we believe its resolution will not have a material adverse effect on our business, financial condition or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II.

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

Market Information for Common Shares

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

The following table reflects the range of the high and low sale price per common share, as reported on the NYSE, for the periods indicated. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	Common Share Price	
	High	**Low**
Year Ended March 31, 2017		

Third Quarter [1]	$ 15.50	$ 10.25
Fourth Quarter	$ 12.93	$ 10.30

[1] Our common shares commenced trading on the NYSE on October 27, 2016.

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Shareholders

American Stock Transfer & Trust Company is the transfer agent and registrar for our common shares. As of the close of business on June 12, 2017, we had four holders of record. The actual number of stockholders is greater than this number of record holders and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividend Policy

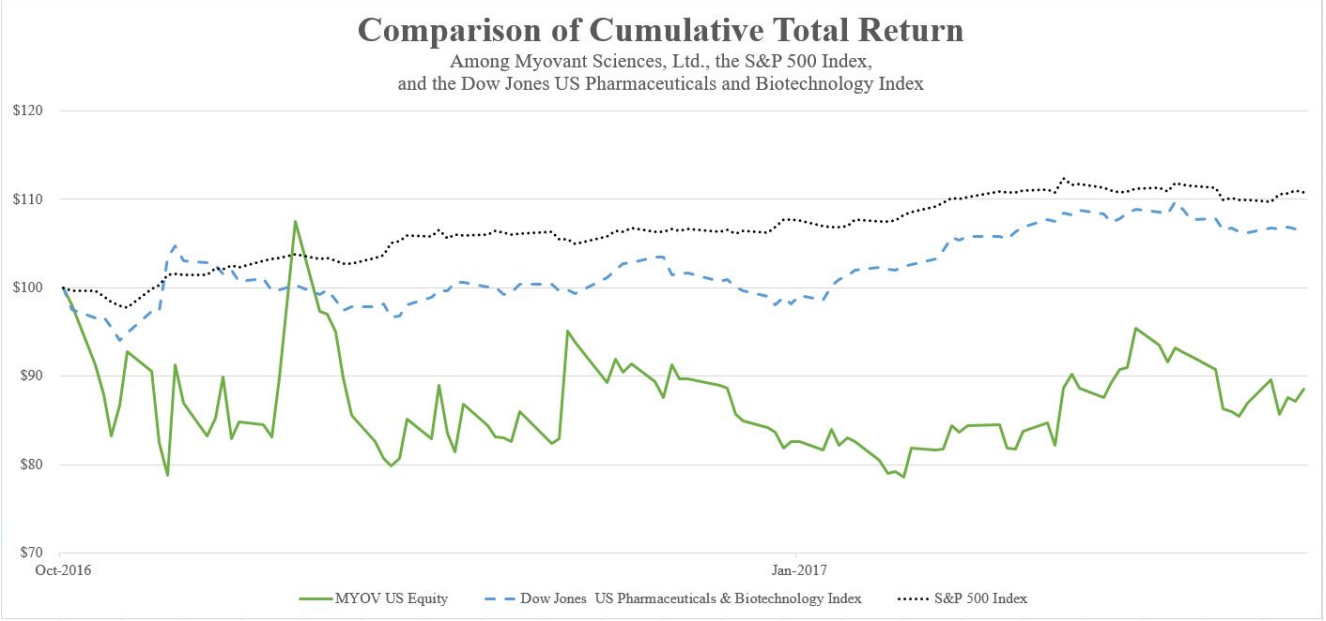
We have never declared or paid cash dividends on our common shares. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

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, 2017, 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 "filed" 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

- We issued 37,231,342 common shares to RSL, our majority shareholder for $660, or $0.000017727 per common share.
-

We issued 5,077,001 common shares to Takeda in connection with the execution of that certain license agreement by and between us and Takeda.

- We issued 1,128,222 common shares to Lynn Seely, M.D., our principal executive officer, pursuant to a restricted stock grant.

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- We issued 1,977,269 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by our IPO of 14,500,000 shares at a price of $15.00 per share.
- We granted options to purchase 2,386,127 common shares to our employees, consultants, officers, and directors, with a weighted average exercise price of $7.94 under the 2016 Plan.
- We issued 366,355 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of options to purchase of 1,558,357 and 1,128,222 common shares pursuant to a restricted stock grant.

The sale and issuance of the securities listed above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

Purchases of Equity Securities by the Issuer

None.

Use of Proceeds from Initial Public Offering

On November 1, 2016, we closed our IPO, in which we issued and sold 14,500,000 common shares at a public offering price of $15.00 per share, for gross proceeds of $217.5 million. All of the common shares issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-213891), which was declared effective by the SEC on October 26, 2016. Citigroup Global Markets Inc., Cowen and Company, LLC, Evercore Group L.L.C. and Barclays Capital Inc. acted as book-running managers for our IPO. 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 expenses.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

We have been using and will continue to use the net proceeds from our IPO primarily to fund the nonclinical and clinical development of relugolix and MVT-602, to expand our internal research and development capabilities, and for general corporate purposes.

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed by us with the SEC on October 27, 2016, pursuant to Rule 424(b) under the Securities Act.

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Item 6. Selected Financial Data

In the table below, we provide you with our selected consolidated financial data for the periods presented. We have prepared this information using our audited consolidated financial statements. You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and related notes included in this Annual Report on Form 10-K and "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

	Year Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Statements of Operations Data	(In thousands, except share and per share data)	
Operating expenses:		
Research and development expenses (includes $3,893 and $0 of share-based compensation expense for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016, respectively	$ 43,500	$ —
General and administrative expenses (includes $4,824 and $987 of share-based compensation expense for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016, respectively	12,357	1,657
Total operating expenses	55,857	1,657
Other expense:		
Changes in the fair value of the warrant liability	27,518	—
Other expense	139	—
Loss before provision for income tax	(83,514)	(1,657)
Income tax benefit	(74)	—
Net loss	$ (83,440)	$ (1,657)
Net loss per common share — basic and diluted	$ (1.70)	$ (0.04)
Weighted average common shares outstanding — basic and diluted	49,184,668	37,231,342

	As of March 31,	
	2017	2016
Balance Sheet Data	(In thousands)	
Cash	$ 180,838	$ —
Working capital	165,827	(223)
Total assets	185,278	—
Long-term liabilities	165	—
Accumulated deficit	(85,097)	(1,657)
Total shareholders' equity	166,776	(223)

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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

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases. Our goal is to be the leading global biopharmaceutical company focused on women's health and endocrine diseases in areas of high unmet medical need. Our lead product candidate is relugolix, an oral once-daily small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist. We are advancing relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain and advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin agonist, for the treatment of female infertility as a part of the hormonal preparation for assisted reproduction. Both relugolix and MVT-602 are licensed to us by Takeda. Our products in development, their stage of development and the indications which they are intended to address are described in more detail in Part I, Item 1. Business of this Annual Report on Form 10-K.

We were incorporated in February 2016, and our operations to date have been limited to organizing and staffing our company, acquiring the rights to relugolix and MVT-602 and preparing for and advancing our product candidates into clinical development. To date, we have not generated any revenue. We have funded our operations primarily from the issuance and sale of our common stock.

In November 2016, we completed our IPO, in which we sold 14,500,000 common shares at a price of $15.00 per 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 expenses.

As of March 31, 2017, we had an accumulated deficit of $85.1 million. For the year ended March 31, 2017 and the period from February 2, 2016 (date of inception) to March 31, 2016, we recorded net losses of $83.4 million and $1.7 million, respectively.

We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance product candidates through clinical trials;
- pursue regulatory approval of product candidates;
- operate as a public company; and
- continue our nonclinical programs and clinical development efforts.

Financial Operations Overview

Revenue

We have not generated any revenue, and we do not expect to generate any revenue, from the sale of any products unless or until we obtain regulatory approval of and commercialize relugolix or MVT-602.

Research and Development Expense

Since our incorporation, 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 of our Phase 3 programs. Our research and development expenses include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for the research and development personnel that we plan to hire;
- costs allocated to us under the Services Agreements;

- expenses incurred under or in connection with agreements with CROs as well as consultants and other vendors that conduct or participate in clinical and nonclinical studies designed to further the development of our product candidates;

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- manufacturing and supply costs in connection with conducting nonclinical and clinical studies;
- costs for sponsored research; and
- depreciation expense for assets used in research and development activities.

Research and development activities will continue to be central to our business model. We expect our research and development expenses to increase significantly over the next several years as we conduct our Phase 3 programs, expand our employee base and increase personnel related expenses, conduct a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for MVT-602 and prepare to seek regulatory approval for our product candidates. 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.

The duration, costs and timing of clinical trials 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 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 material; 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.

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General and Administrative Expense

General and administrative expenses consist primarily of personnel related expenses, share-based compensation, legal and accounting fees, general overhead expenses and costs billed to us under our Services Agreements and consulting services relating to our formation and corporate matters.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers, and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with NYSE rules and SEC requirements, insurance and investor relations costs. In addition, if relugolix or MVT-602 obtains regulatory approval for marketing, we expect that we would incur expenses associated with building medical affairs, sales and marketing teams.

Results of Operations for the Year Ended March 31, 2017 and Period from February 2, 2016 (Date of Inception) to March 31, 2016

The following table summarizes our results of operations for the year ended March 31, 2017 and the period from February 2, 2016 (date of inception) to March 31, 2016 (in thousands):

	Year Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Operating expenses:		
Research and development (includes $3,893 and $0 of share-based compensation expense for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016, respectively)	$ 43,500	$ —
General and administrative (includes $4,824 and $987 of share-based compensation expense for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016, respectively)	12,357	1,657
Total operating expenses	55,857	1,657
Changes in the fair value of the warrant liability	27,518	—
Other expense	139	—
Income tax benefit	(74)	—
Net loss	$ 83,440	$ 1,657

Research and Development Expenses

Research and development expenses were $43.5 million for the year ended March 31, 2017, and consisted primarily of in-process research and development 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 personnel expenses and third-party costs associated with the preparation of our clinical and other research programs, CMC costs of $5.6 million, CRO costs of $4.7 million, and share-based compensation expense of $3.9 million, $2.2 million of which was allocated to us by RSL. We did not incur any research and development expenses for the period from February 2, 2016 (date of inception) to March 31, 2016.

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General and Administrative Expenses

General and administrative expenses were $12.4 million for the year ended March 31, 2017, and consisted primarily of share-based compensation expense of $4.8 million, including $2.7 million allocated to us by RSL, legal and professional 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 costs.

General and administrative expenses were $1.7 million for the period from February 2, 2016 (date of inception) to March 31, 2016, and consisted primarily of share-based compensation expense of $1.0 million, including $1.0 million allocated to us by RSL, and legal and professional fees of $0.2 million, costs of $0.4 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party costs. The remainder consisted primarily of other personnel-related and general overhead expenses of $0.1 million.

Changes in the Fair Value of the Warrant Liability

The change in the fair value of the warrant liability was recorded as $27.5 million of expense for the year ended March 31, 2017, as the fair value of the warrant liability decreased to $0.1 million at 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 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. The warrant expired on April 30, 2017.

Liquidity and Capital Resources

As of March 31, 2017, we had a cash balance of $180.8 million. In November 2016, we received net proceeds from our IPO of approximately $200.0 million, after deducting $15.2 million in underwriting discounts and commissions and $2.3 million in offering expenses. Prior to our IPO, our operations have been financed primarily by RSL.

For the year ended March 31, 2017 and for the period from February 2, 2016 (date of inception) to March 31, 2016, we had net losses of $83.4 million and $1.7 million, respectively. As of March 31, 2017, we had $180.8 million of cash and had never generated any revenue.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for relugolix, MVT-602 or any future product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially as we:

- advance our Phase 3 programs of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-related pain, and advanced prostate cancer;
- conduct a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for MVT-602 for the treatment of female infertility as part of assisted reproduction;
- expand our CMC 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, financial, quality, and management information systems;

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a medical affairs group with a medical scientific liaison team;

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- ultimately 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; and

- operate as a public company.

Our primary use of cash is to fund the development of relugolix for the treatment of uterine fibroids, endometriosis, and advanced prostate cancer. As the competitive environment, particularly for the women's health indications, continues to evolve, the development expenses for these programs are expected to increase. Despite that, we expect that our existing cash will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. These funds will not be sufficient to enable us to complete all necessary development and commercially launch relugolix. Accordingly, we will be required to obtain further funding through other public or private offerings of our capital share, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of relugolix or potentially 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 cash needs through a combination of equity offerings, debt financings, and potential collaboration, license or development agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may 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):

	Year Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Net cash used in operating activities	$ (18,215)	$ —
Net cash used in investing activities	(967)	—
Net cash provided by financing activities	200,020	—

Operating Activities

For the year ended March 31, 2017, $18.2 million was used 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 research and development expenses related to the acquisition of the rights to our product candidates, $8.7 million non-cash share-based compensation, $27.5 million non-cash changes in the fair value of the warrant liability, $11.8 million increase in accrued liabilities, $4.0 million 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 other expenses.

For the period from February 2, 2016 (date of inception) to March 31, 2016, no cash was used in operating activities. The net loss of $1.7 million for the period was offset by an increase in our accrued expenses primarily attributable to legal and professional fees and consulting services and an allocation of personnel expenses by RSL and RSI associated with the formation of our company and corporate matters.

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Investing Activities

For the year ended March 31, 2017, $1.0 million was used in investing activities, all for the purchase of fixed assets. For the period from February 2, 2016 (date of inception) to March 31, 2016, no cash was used in investing activities.

Financing Activities

For the year ended March 31, 2017, $200.0 million was provided by financing activities. This was primarily due to the net proceeds of our IPO, which we completed on November 1, 2016. For the period from February 2, 2016 (date of inception) to March 31, 2016, no cash was provided by financing activities.

Contractual Obligations

As of March 31, 2017, we did not have any ongoing material financial commitments, such as lines of credit or guarantees, that we expect to affect our liquidity over the next several years. The following table provides information with respect to contractual obligations as of March 31, 2017:

Contractual Obligations (in thousands)	Total	Under 1 year	1-2 years	2-3 years	3-4 years	4-5 years	Over 5 years
Lease obligations	$ 5,327	581	926	968	993	1,016	843
Total	$ 5,327	581	926	968	993	1,016	843

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 under SEC rules.

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. 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, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses 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 determination of some of our costs incurred under the Services Agreements with RSG, RSI and MSI, which costs are charged to research and development and general and administrative expense, as well as assumptions used to estimate the fair value of our common shares and stock awards. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions 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 relating to our warrant liability, share-based compensation, research and development accruals and income taxes described below have the greatest potential impact on our consolidated financial statements and are "critical accounting estimates."

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Warrant Liability

We remeasure the warrant liability at fair value each reporting period based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the warrant liability uses assumptions and estimates we believe would be made by a market participant in making the same valuation. We assess these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the warrant liability related to updated assumptions and estimates are recognized as other (expense) income in the accompanying consolidated statements of operations and comprehensive loss.

The warrant liability may change significantly as additional data are obtained, impacting our assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a financing event. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts.

Share-Based Compensation

We recognize share-based compensation expense related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of forfeitures. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We recognize share-based compensation expense related to stock options granted to non-employees issued in exchange for services based on the estimated fair value of the awards on the date of grant, net of forfeitures. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model; however, the fair value of the stock options granted to non-employees is remeasured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of share-based awards. These assumptions include:

Expected Term. Our expected term represents the period that our share-based awards are expected to be outstanding and is determined using the simplified method (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 our 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 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.

In addition to the Black-Scholes assumptions, we estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. The impact from any forfeiture rate adjustment would be recognized in full in the period of adjustment and if the actual number of future forfeitures differs from our estimates, we might be required to record adjustments to share-based compensation in future periods.

A significant component of total share-based compensation expense relates to the RSL common share awards and RSL options issued by RSL to RSI employees. For the year ended March 31, 2017 and the period from February 2, 2016 (date of inception) to March 31, 2016, we recorded share-based compensation expense of $4.9 million and $1.0 million, respectively, in relation to the RSL common share awards and RSL stock options issued by RSL to RSI employees. RSL common share awards are subject to specified vesting schedules and requirements (a mix of time-based, performance-based, and corporate event-based, including targets for RSL's post-IPO market capitalization and future financing events). We estimated the fair value of each RSL option on the date of grant using the Black-Scholes closed-form option-pricing model.

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Research and Development Expense Accruals

Research and development costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. 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 research and development. Research and development costs are charged to expense when incurred and primarily consist of certain costs charged by RSI under the RSI Services Agreement (see Note 5 in the accompanying notes to consolidated financial statements included in this Annual Report on Form 10-K) and expenses from third parties who conduct research and development activities on our behalf.

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 tax expense.

Recent Accounting Pronouncements

For detailed information regarding recently issued accounting pronouncements and the expected impact on our financial statements, see Note 2 "Summary of Significant Accounting Policies" in the accompanying notes to consolidated financial statements included 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. We do not believe we are currently exposed to any material market risk. As of March 31, 2017, we had cash of $180.8 million, consisting of non-interest bearing deposits denominated in the U.S. dollar and Swiss franc.

Item 8. Financial Statements and Supplementary Data

All financial statements and schedules required to be filed hereunder are listed in the Index to Financial Statements and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2017, the end of the period covered by this report. The term “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

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Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2017 at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended March 31, 2017 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive and chief executive officer, does not expect that our disclosure controls and procedures or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Myovant have been detected.

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Item 9B. Other Information

None.

PART III.

We will file a definitive proxy statement for our 2017 annual meeting of shareholders (the "2017 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2017 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 2017 Proxy Statement under the captions "Discussion of Proposals," "Information About Corporate Governance," "Information About Our 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 2017 Proxy Statement under the captions "Information About Corporate Governance" and "Executive Compensation" and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters

The information required by this item will be contained in our 2017 Proxy Statement under the captions "Principal Shareholders," "Information About Our Executive Officers," 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 2017 Proxy Statement under the caption "Certain Relationships and Related Party Transactions" and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be contained in our 2017 Proxy Statement under the captions "Independent Registered Public Accounting Firm Fees and Other Matters" and "Discussion of Proposals" and is incorporated herein by reference.

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PART IV. FINANCIAL INFORMATION

Item 15. Exhibits and Financial Statements Schedules

(a) Documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements. The Consolidated Financial Statements are included as Appendix A hereto and are filed as part of this Annual Report on Form 10-K. The Consolidated Financial Statements include:

(2) Exhibits. The exhibits set forth on the Exhibit Index following the signature page to this annual report are filed as part of this Annual Report on Form 10-K. This list of exhibits identifies each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K.

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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: June 14, 2017

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	June 14, 2017
/s/ Frank Karbe Frank Karbe	Principal Financial and Accounting Officer	June 14, 2017
/s/ Mark Altmeyer Mark Altmeyer	Director	June 14, 2017
/s/ Wayne DeVeydt Wayne DeVeydt	Director	June 14, 2017
/s/ Keith Manchester Keith Manchester	Director	June 14, 2017
/s/ Vivek Ramaswamy Vivek Ramaswamy	Director	June 14, 2017
/s/ Kathleen Sebelius Kathleen Sebelius	Director	June 14, 2017

/s/ Terrie Curran	Director	June 14, 2017
Terrie Curran		

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INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS OF MYOVANT SCIENCES LTD.

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of Myovant Sciences Ltd. as of March 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, shareholders' equity (deficit) and cash flows for the year ended March 31, 2017 and the period from February 2, 2016 (date of inception) to March 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Myovant Sciences Ltd. at March 31, 2017 and 2016, and the consolidated results of its operations and its cash flows for the year ended March 31, 2017 and the period from February 2, 2016 (date of inception) to March 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Iselin, New Jersey
June 14, 2017

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

	March 31, 2017	March 31, 2016
Assets		
Current assets:		
Cash	$ 180,838	$ —
Prepaid expenses and other current assets	3,221	—
Income tax receivable	105	—
Total current assets	184,164	—
Deferred tax assets	208	—
Property and equipment, net	906	—
Other assets	—	—
Total assets	$ 185,278	$ —
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,329	$ —
Accrued expenses	11,978	223
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	3,030	—
Total current liabilities	18,337	223
Warrant liability	52	—
Deferred rent	113	—
Total liabilities	18,502	223
Commitments and contingencies (Note 10)		
Shareholders' equity (deficit):		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 60,275,757 and 37,231,342 issued and outstanding at March 31, 2017 and March 31, 2016, respectively	1	1
Common shares subscribed	(1)	(1)
Accumulated other comprehensive income	140	—
Additional paid-in capital	251,733	1,434
Accumulated deficit	(85,097)	(1,657)
Total shareholders' equity (deficit)	166,776	(223)
Total liabilities and shareholders' equity (deficit)	$ 185,278	$ —

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

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

	Year Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Operating expenses:		
Research and development (includes $3,893 and $0 of share-based compensation expense for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016, respectively)	$ 43,500	$ —
General and administrative (includes $4,824 and $987 of share-based compensation expense for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016, respectively)	12,357	1,657
Total operating expenses	55,857	1,657
Other expense:		
Changes in the fair value of the warrant liability	27,518	—
Other expense	139	—
Loss before provision for income tax	(83,514)	(1,657)
Income tax benefit	(74)	—
Net loss	$ (83,440)	$ (1,657)
Net loss per common share — basic and diluted	$ (1.70)	$ (0.04)
Weighted average common shares outstanding — basic and diluted	49,184,668	37,231,342

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

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

	Year Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Net loss	$ (83,440)	$ (1,657)
Other comprehensive income:		
Foreign currency translation adjustment	140	—
Total other comprehensive income	140	—
Comprehensive loss	$ (83,300)	$ (1,657)

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

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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 February 2, 2016	37,231,342	$ 1	$ (1)	$ —	$ —	$ —	$ —
Capital contribution	—	—	—	1,434	—	—	1,434
Net loss	—	—	—	—	—	(1,657)	(1,657)
Balance at March 31, 2016	37,231,342	$ 1	$ (1)	$ 1,434	$ —	$ (1,657)	$ (223)
Sale of common shares in initial public offering ($15.00 per share), net of underwriting discounts and commissions and offering expenses 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 warrant liability to Takeda	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
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

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

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

	Year Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Cash flows from operating activities:		
Net loss	$ (83,440)	$ (1,657)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	8,717	1,434
Depreciation	61	—
Purchase of in-process research and development expense	13,117	—
Changes in the fair value of the warrant liability	27,518	—
Unrealized currency translation	140	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,221)	—
Income tax receivable	(105)	—
Deferred tax assets	(208)	—
Accounts payable	3,329	—
Accrued expenses	11,755	223
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	4,009	—
Deferred rent	113	—
Net cash used in operating activities	(18,215)	—
Cash flows from investing activities:		
Purchase of furniture and equipment	(967)	—
Net cash used in investing activities	(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 capital contribution from Roivant Sciences Ltd.	1,035	—
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc. for amounts paid on behalf of the Company	(979)	—
Net cash provided by financing activities	200,020	—
Net change in cash	180,838	—
Cash—beginning of period	—	—
Cash—end of period	$ 180,838	$ —
Non-cash investing and financing activities:		
Purchase of in-process research and development	$ 13,117	$ —
Supplemental disclosure of cash paid:		
Income taxes	$ 240	$ —

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

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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 biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases. The Company is developing its lead product candidate, relugolix, for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain and advanced prostate cancer, and its second product candidate, MVT-602 (formerly known as RVT-602), for the treatment of female infertility as part of assisted reproduction.

The Company was founded on February 2, 2016 as a Bermuda Exempted Limited Company and a wholly-owned subsidiary of Roivant Sciences Ltd., or RSL, under the name Roivant Endocrinology Ltd. The Company changed its name to Myovant Sciences Ltd., or MSL in May 2016. In April 2016, Roivant Endocrinology Inc., or REI, a wholly-owned subsidiary of the Company was formed and based in the United States of America and subsequently changed its name to Myovant Sciences, Inc., or MSI. In August 2016, the Company incorporated as its wholly-owned subsidiaries Myovant Holdings Limited, or MHL, a private limited company incorporated under the laws of England and Wales, and Myovant Sciences GmbH, or MSG, a company with limited liability formed under the laws of Switzerland. In November 2016, the Company moved its principal executive office from Bermuda to the United Kingdom and became a U.K. tax resident, and the Company assigned all of its intellectual property rights to MSG. MSG is the Company's principal operating subsidiary and the Company remains incorporated in Bermuda. The Company also has a wholly-owned subsidiary, Myovant Sciences Ireland Limited, a company with limited liability formed under the laws of Ireland.

Since its inception, the Company has devoted substantially all of its efforts to organizing the Company, acquiring its drug development programs and preparing for and advancing its product candidates into clinical development. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company has two product candidates, relugolix and MVT-602, under development which were licensed from Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016 (See Note 3). The Company has incurred and expects to continue to incur significant and increasing operating losses at least for the next several years. The Company does not expect to generate revenue unless and until it successfully completes development and obtains regulatory approval for one of its products in development. The Company may be required to obtain further funding through other public or private offerings of its share capital, debt financing, collaboration and licensing arrangements or other sources. Adequate additional funding may not be available to the Company on acceptable terms, or at all.

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation:

The Company's fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30 and December 31.

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB. The consolidated financial statements include the accounts of the Company and MSI, MSL and MSG, its wholly-owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

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(B) Use of Estimates:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions 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 compensation expense 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 RSL, as well as share-based compensation and research and development costs. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

(C) Risks and Uncertainties:

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, third-party service providers such as contract research organizations and protection of intellectual property rights.

(D) Concentrations of Credit Risk:

Financial instruments that potentially subject the Company to concentration of credit risk include cash. At March 31, 2017, substantially all of the cash balances are deposited in two banking institutions and are all in excess of insured levels.

(E) Property and Equipment:

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

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

(F) 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 of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

(G) Deferred Offering Costs:

Deferred offering costs, which consisted of direct costs related to the Company's initial public offering, or IPO, of its common shares, were capitalized in other assets until the consummation of the IPO. These offering costs were reclassified to additional paid-in capital upon the closing of the IPO on November 1, 2016.

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(H) Research and Development Expense:

Research and development 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. 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 research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of revenue over the remaining useful life of the asset. Research and development expenses primarily consist of the intellectual property and research and development materials acquired, certain costs charged by RSI under its services agreement with the Company, and expenses from third parties who conduct research and development activities on behalf of the Company. The Company expenses in-process research and development projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. For the year ended March 31, 2017, the Company recorded $43.5 million of research and development expense, of which $3.9 million was attributable to share-based compensation expense. For the period from February 2, 2015 (date of inception) to March 31, 2016, the Company did not incur any research and development expense.

(I) Warrant Liability:

The Company records the warrant liability at its estimated fair value as a liability in the consolidated balance sheets. The Company remeasures the estimated fair value of the warrant liability each reporting period and records the changes in the fair value in the consolidated statements of operations as other (expense) income (See Note 9).

(J) 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.

(K) Share-Based Compensation:

Share-based awards to employees and directors are valued at fair value on the date of the grant and that fair value is recognized as share-based compensation expense on a straight-line basis over the requisite service period of the entire award. The Company values its stock options using the Black-Scholes option pricing model. Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate, the fair value of the Company’s common shares and anticipated forfeiture of the share-based awards. Since the Company has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the Securities and Exchange Commission-approved “simplified method” noted under the provisions of Staff Accounting Bulletin No. 107 with the continued use of this method extended under the provisions of Staff Accounting Bulletin No. 110. The risk-free interest rate is based on the rates paid on securities issued by the United States Treasury with a term approximating the expected life of the equity award. The expected share price volatility for the Company’s common shares is estimated by taking the average historical price volatility for industry peers. Estimates of pre-vesting award forfeitures are based on the Company’s expectations of future employee turnover. The Company will adjust its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

The Company accounts for share-based payments to non-employees issued in exchange for services based upon the fair value of the equity instruments issued. Compensation expense for stock options issued to non-employees is calculated using the Black-Scholes option pricing model and is recorded over the service performance period. Options subject to vesting are required to be periodically remeasured over their service performance period, which is generally the same as the vesting period.

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(L) 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. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholders by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. For the year ended March 31, 2017, 1,128,222 restricted share awards and 1,525,857 options to purchase common shares were not included in the calculation of diluted weighted-average common shares outstanding because they were anti-dilutive.

(M) Recently Issued Accounting Pronouncements:

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 310-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," which provides guidance on determining when and how to disclose going-concern uncertainties in the financial statements. This new ASU requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if “conditions or events raise substantial doubt about the entity’s ability to continue as a going concern.” The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. This guidance has been adopted as of March 31, 2017 and it did not have a material impact on the consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)” (ASU No. 2016-02), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lessees to present the assets and liabilities that arise from leases on their balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the new standard and its impact on the Company’s consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, “Compensation - Stock Compensation (Topic 718): *Improvements to Employee Share-Based Payment Accounting*” (ASU No. 2016-09). This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

(N) Foreign Currency:

The Company has operations in the United States, the United Kingdom and Switzerland. The results of its 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 is translated using historical rates. Adjustments resulting from the translation of the financial statements of the Company’s foreign subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of shareholders’ equity. Foreign exchange transaction gains and losses are included in other income (loss) in the Company’s results of operations.

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 common shares upon entry into the license agreement.

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- 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 entitles 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 our IPO, unless earlier terminated upon a change in control.

For the consideration above, the Company also received a small quantity of relugolix and MVT-602, and certain historical research and development 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. The Company will need to independently develop all clinical processes and procedures for its clinical trials through the use of internal and external resources once appropriate and acceptable resources have been identified and obtained. 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 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 research and development 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 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 (See Note 9).

Note 4—Accrued Expenses

As of March 31, 2017 and 2016, accrued expenses consisted of the following (in thousands):

	March 31, 2017	March 31, 2016
Research and development expenses	$ 9,737	$ —
Salaries, bonuses, and other compensation expenses	797	—
Legal expenses	481	164
Other expenses	963	59
Total accrued expenses	$ 11,978	$ 223

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Note 5—Related Party Transactions

(A) Services Agreements:

In July 2016, the Company entered into a formal services agreement with RSI (the "Services Agreement") effective April 29, 2016, under which RSI agreed to provide certain administrative and research and development services to the Company. Under the Services Agreement, the Company pays or reimburses RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI employees, RSI charges back the employee compensation expense plus a pre-determined mark-up. RSI also provided such services prior to the formalization of the Services Agreement, and such costs have been recognized by the Company in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters, which the Company believes is reasonable. All other costs are billed back at cost. The accompanying consolidated financial statements include third-party expenses that have been paid by RSI and RSL.

During the year ended March 31, 2017, RSL and RSI provided certain administrative services on behalf of the Company during the formative period of the Company. Total compensation expense, inclusive of base salary, fringe benefits and share-based compensation, is proportionately allocated to the Company based upon the relative percentage of time utilized on the Company's matters. Under the Services Agreement, for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016, the Company incurred expenses of $9.2 million and $0.4 million, respectively, inclusive of the mark-up.

In February 2017, in connection with the contribution and assignment of all of the Company's intellectual property rights to MSG, the Company and MSI amended and restated the Services Agreement, effective as of November 11, 2016, to include MSG as a recipient of from MSI. In addition, in February 2017, MSG entered into a separate services agreement with RSG, a wholly-owned subsidiary of RSL, effective as of November 11, 2016, for the provisioning of services by RSG to MSG in relation to the identification of potential product candidates and project management of clinical trials, as well as other services related to clinical development, administrative and financial activities. Under the terms of both services agreements, the Company is obligated to pay or reimburse RSI and RSG for the costs they, or third parties acting on their behalf, incur in providing services to us, including administrative and support services, as well as research and development services. In addition, the Company is obligated to pay to RSI and RSG a pre-determined mark-up on the costs incurred directly by RSI and RSG in connection with any general and administrative and research and development services.

(B) Option Agreement:

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.

(C) Information Sharing and Cooperation Agreement:

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 results of operations and financial position, 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.

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(D) Manufacture and Supply Agreement:

In June 2016, the Company and Takeda's affiliate, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited will supply the Company, and the Company will obtain from Takeda Limited, all of its requirements for relugolix drug substance and drug product to be used under its development plans for all indications. If the Company requests, Takeda Limited will assist it with a technical transfer of the manufacturing process for relugolix to it or its designee and the Company will pay the expenses related to such transfer.

Note 6—Shareholders' Equity

(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, 2017, the Company had 564,111,242 shares authorized with a par value of $0.000017727 per share.

(B) Restricted Share Award and Options Granted:

During the year ended March 31, 2017, the Company granted a restricted share award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Equity Incentive Plan. During the year ended March 31, 2017, the Company granted options to its employees, consultants and directors to purchase 1,525,857 of its common shares.

(C) 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 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 shares at a price of $15.00 per 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 expenses. The cash proceeds from the IPO are currently deposited with one banking institution and are substantially in excess of federally insured levels.

(D) 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 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 its employees, consultants and directors to purchase 1,525,857 common shares and the issuance of an additional 1,977,269 common shares to Takeda, upon the closing of its IPO, based upon the sale and issuance of 14,500,000 common shares to investors in the IPO. The warrant expired on April 30, 2017.

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Note 7—Income Taxes

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

	Year ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Loss before income taxes:		
United States	$ (2,924)	$ —
Switzerland	(29,745)	—
Bermuda	(50,845)	(1,657)
Total loss before income taxes	$ (83,514)	$ (1,657)
Current taxes:		
United States	$ 134	$ —
Switzerland	—	—
Bermuda	—	—
Total current tax expense	134	—
Deferred taxes:		
United States	(208)	—
Switzerland	—	—
Bermuda	—	—
Total deferred tax benefit	(208)	—
Total income tax benefit	$ (74)	$ —

A reconciliation of income tax benefit computed at the Bermuda statutory rate to income tax benefit reflected in the financial statements is as follows:

	Year ended March 31, 2017		Period from February 2, 2016 (Date of Inception) to March 31, 2016	
	in 000s	%	in 000s	%
Income tax benefit at Bermuda statutory rate	$ —	— %	$ —	—%
Foreign rate differential	(7,592)	9.09	—	—
Valuation allowance	7,378	(8.83)	—	—
Other	140	(0.17)	—	—
Total income tax benefit	$ (74)	0.09 %	$ —	—%

The Company's provision for income taxes is based primarily on income taxes in the United States for federal, state and local income taxes. The Company's effective tax rate for the years ended March 31, 2017 and 2016 was 0.09% and 0.00%, respectively, primarily due to the organization of the Company as a Bermuda Exempted Limited Company, for which there is no current tax regime, due to United States permanent unfavorable differences, and a valuation allowance that effectively eliminates the Company's net deferred tax assets in the United States. As of March 31, 2017, the Company had an aggregate income tax receivable of $0.1 million from various federal, state, and local jurisdictions.

Deferred taxes reflect the tax effects of the differences between the amounts records as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at March 31, 2017 are as follows (in thousands):

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	March 31, 2017	March 31, 2016
Research tax credits	$ 163	$ —
Other	300	—
Depreciation	(255)	—
Swiss net operating loss	6,019	—
Share-based compensation	1,382	—
Subtotal	7,609	—
Valuation allowance	(7,401)	—
Total deferred tax assets	$ 208	$ —

The Company assesses the realizability of the deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and record a valuation allowance as necessary. As a result of this assessment, a valuation allowance of $1.4 million related to share-based compensation and $6.0 million related to Swiss net operating loss carryforward has been recorded as of March 31, 2017. The Swiss net operating loss carryforward expires in year 2024. The Company believes that it is more likely than not, given the weight of available evidence, that all other deferred tax assets will be realized. 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.

The Company files income tax returns in the United States federal, state and local jurisdictions. MSI will file its initial United States federal, state and local income tax returns for the fiscal year ended March 31, 2017 in December 2017. The Company is subject to tax examinations for fiscal year 2016 and forward in all applicable income tax jurisdictions.

Note 8—Share-Based Compensation

Stock Options:

In June 2016, the Company adopted its 2016 Equity Incentive Plan (as amended, the "2016 Plan"), under which 4,512,889 common shares are reserved for grant. 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 share unit awards, and other share awards under the plan. 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 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.

At March 31, 2017, a total of 1,858,810 common shares were available for future issuance under the 2016 Plan.

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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.

	Year Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Expected common share price volatility	75.5%	—%
Expected risk free interest rate	1.57%	—%
Expected term, in years	6.35	—
Expected dividend yield	—%	—%

The following table presents a summary of option activity and data under the Company's stock incentive plans through March 31, 2017:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
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	10,255,341
Options vested and expected to vest at March 31, 2017	1,471,815	5.06	11.90	9.52	9,890,661
Options exercisable at March 31, 2017	200	11.19	9.56	9.88	110

At March 31, 2017, there were 200 vested options outstanding.

(A) Stock Options and Restricted Share Award Granted to Employees and Directors:

In June 2016, the Company granted a restricted share award for 1,128,222 common shares to the Company’s Principal Executive Officer under the 2016 Plan. In August 2016, the Company granted options to purchase 541,544 common shares to certain employees of the Company, with an exercise price of $2.38 under the 2016 Plan. In September 2016, the Company granted options to purchase 572,568 common shares to certain employees, officers and directors of the Company, with a weighted average exercise price of $4.00 under the 2016 Plan. During the year ended March 31, 2017, the Company granted options to purchase 1,464,458 common shares to certain employees and directors of the Company.

For the year ended March 31, 2017, share-based compensation expense related to the restricted share award was $1.2 million.

For the year ended March 31, 2017, the Company recorded share-based compensation expense related to stock options issued to employees, officers and directors of $2.2 million and share-based compensation expense related to stock options issued to non-employees of $0.4 million (Note 8(B)(1)). This share-based compensation expense is included in research and development and general and administrative expenses in the accompanying consolidated statements of operations.

There was no share-based compensation expense for the period from February 2, 2016 (date of inception) to March 31, 2016.

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In connection with the IPO and after preliminary discussions with the underwriters, the Company reassessed the fair value of: (1) 1,128,222 restricted common shares issued to our Principal Executive Officer in June 2016 with an initial fair value of $1.52 per common share; (2) 602,743 common shares underlying stock options granted in August 2016 (including options to purchase 61,199 common shares granted to certain consultants as described below in Note 8(B)(1)) with an exercise price of $2.38 per common share; and (3) 572,568 common shares underlying stock options granted in September 2016 to the Company's employees, officers and directors with a weighted-average exercise price of $4.00 per common share. As a result, the Company determined that the reassessed fair value of the restricted common shares was $5.10 per common share and the reassessed fair value of the common shares underlying the stock options granted in August and September 2016 was $15.00 per common share, which was the initial public offering price of the Company's common shares in the IPO. The use of this higher fair value per common share increased the weighted-average fair value of the stock options granted in August and September 2016 to $13.44 per common share and $12.78 per common share, respectively. Prior to the IPO, the fair value of the common shares underlying the Company's stock options was estimated on each grant date by the board of directors. In order to determine the fair value of the Company's common shares underlying granted stock options, the board of directors considered, among other things, timely valuations of the common shares prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The use of this higher share price increased both recognized and unrecognized share-based compensation expense.

At March 31, 2017, total unrecognized compensation expense related to non-vested options for employees, officers and directors was $15.1 million and is expected to be recognized over the remaining weighted-average service period of 3.48 years.

(B) Share-Based Compensation for Related Parties:

(1) Stock Options Granted to Non-Employees:

During the year ended March 31, 2017, the Company granted options to purchase 61,399 common shares to certain consultants, who are also employees of RSI, with a weighted average exercise price of $2.41 under the 2016 Plan. As discussed above in Note 8(A), the use of the higher fair value per common share of $15.00, which was reassessed in conjunction with the IPO and after preliminary discussions with the underwriters, increased both recognized and unrecognized share-based compensation expense. For the year ended March 31, 2017, share-based compensation expense related to stock options granted to consultants was $0.4 million. At March 31, 2017, total unrecognized compensation expense related to stock options granted to consultants was $0.3 million, which is expected to be recognized over 0.94 years.

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

In relation to the RSL common share awards and options issued by RSL to RSL and RSI employees, the Company recorded share-based compensation expense of $4.9 million and $1.0 million, respectively, for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016.

Share-based compensation expense is allocated to the Company by RSL based upon the relative percentage of time utilized by RSL and RSI employees on Company matters.

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

Compensation expense will be allocated to the Company over the required service period over which these RSL common share awards and RSL options would vest and is based upon the relative percentage of time utilized by RSL and RSI employees on Company matters.

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(3) RSL Restricted Stock Unit ("RSUs"):

Lynn Seely, M.D., our Principal Executive Officer, was granted 66,845 restricted stock units (“RSUs”) of RSL during the year ended March 31, 2017. The RSUs have a requisite service period of eight years and have no dividend rights. The RSUs will vest upon the achievement of both a performance and liquidity condition, if both are achieved within the requisite service period. As of March 31, 2017, the performance conditions had not been met and were deemed not probable of being met. For the year ended March 31, 2017, the Company recorded no share-based compensation expense related to the RSUs that were issued. At March 31, 2017, there was $0.6 million of unrecognized compensation expense related to non-vested RSUs. The Company will recognize the expense upon achievement of the performance and market conditions through the requisite service period.

Note 9— Fair Value Measurements

The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company’s Level 3 assets and liabilities consist of the warrant liability associated with the license agreement with Takeda. The fair value of the warrant liability was determined based on a Monte Carlo simulation model which requires various highly subjective unobservable inputs. The significant unobservable inputs used in the fair value measurement are the probability of a future financing event; the expected date or dates of a future financing event; the potential size of a future financing event; the enterprise value of the Company; and the expected volatility in the Company’s valuation.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

The following table sets forth the Company’s assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2017 and March 31, 2016, by level, within the fair value hierarchy:

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	As of March 31, 2017				As of March 31, 2016			
				(in thousands)				
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2016
Assets:								
Total assets at fair value	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Liabilities:								
Warrant liability	$ —	$ —	$ 52	$ 52	$ —	$ —	$ —	$ —
Total liabilities at fair value	$ —	$ —	$ 52	$ 52	$ —	$ —	$ —	$ —

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the year ended March 31, 2017.

Level 3 Disclosures

The Company measures the warrant liability at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the warrant liability uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an ongoing basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the warrant liability related to updated assumptions and estimates are recognized as other (expense) income in the accompanying consolidated statements of operations.

The warrant liability may change significantly as additional data are obtained, impacting the Company's assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability. In evaluating this information, considerable judgment is required to interpret the data used to develop the assumptions and estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a financing event. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

The fair value of our 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 Company's Level 3 warrant liability during the year ended March 31, 2017 were as follows (in thousands):

Balance at March 31, 2016	$ —
Fair value of the warrant liability issued	5,377
Changes in the fair value of the warrant liability, included in net loss	27,518

Settlements	(32,843)
Balance at March 31, 2017	$ 52

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For the year ended March 31, 2017, changes in the carrying value of the warrant liability resulted from settlements related to the fair value of the warrant exercised, partially offset by changes in the fair value of the 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 warrant and the passage of time.

Note 10—Commitments and Contingencies

The Company entered into certain commitments under the Takeda license agreement (See Note 3), amended its services agreement with RSI and entered into a separate service agreement with RSG (See Note 5(A)). As of March 31, 2016 and March 31, 2017, the Company did not have any ongoing material financial commitments. The Company expects to enter into other commitments as the business further develops.

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such loss can be reasonably estimated. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

Currently, the Company is party to a legal proceeding as described in Part I, Item 3, Legal Proceedings, of this Annual Report on Form 10-K. The Company believes that it is not probable that a liability has been incurred and that the amount of any such liability cannot be reasonably estimated. As a result, the Company has not recorded a loss contingency related to this legal proceeding. While it is not possible to determine the outcome of the matter, the Company believes the resolution of such matter will not have a material adverse effect on its business, financial condition or results of operations.

The following table provides information with respect to contractual obligations as of March 31, 2017:

Contractual Obligations (in thousands)	Total	Under 1 year	1-2 years	2-3 years	3-4 years	4-5 years	Over 5 years
Lease obligations	$ 5,327	$ 581	$ 926	$ 968	$ 993	$ 1,016	$ 843
Total	$ 5,327	$ 581	$ 926	$ 968	$ 993	$ 1,016	$ 843

Note 11—Selected Quarterly Data (Unaudited)

The following table presents selected quarterly financial data for the year ended March 31, 2017 and the period from February 2, 2016 (Date of Inception) to March 31, 2016.

	First Quarter Ended June 30, 2016 [1]	Second Quarter Ended September 30, 2016	Third Quarter Ended December 31, 2016	Fourth Quarter Ended March 31, 2017	Period from February 2, 2016 (Date of Inception) to March 31, 2016
Total operating expenses	$ 17,135	$ 6,720	$ 9,056	$ 22,946	$ 1,657
Net loss	(18,970)	(34,712)	(8,083)	(21,675)	(1,657)
Net loss per share attributable to common shareholders - basic and diluted	(0.47)	(0.82)	(0.15)	(0.37)	(0.04)

(1)

On April 29, 2016, the Company entered into a license agreement with Takeda. As a result of this transaction, the Company recorded $13.1 million as research and development expense at the closing date of the acquisition of the rights, 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 warrant liability. Please refer to Note 3 for further details.

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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		Second Amended and Restated Bye-Laws.	S-1	333-213891	3.4	10/17/2016
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		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
10.8		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
10.9	*	Warrant, dated April 29, 2016, issued to Takeda Pharmaceuticals International AG.	S-1	333-213891	10.4	09/30/2016
10.10	+	2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.5	10/20/2016
10.11	+	Forms of Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.6	09/30/2016
10.12	+	Form of Early Exercise Stock Purchase Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.7	09/30/2016
10.13	+		S-1		10.8	09/30/2016

		Form of Indemnification Agreement with directors and executive officers.		333-213891		
10.14	+	Employment Agreement, dated as of May 31, 2016, by and between Lynn Seely, M.D. and Myovant Sciences, Inc.	S-1	333-213891	10.12	09/30/2016
10.15	+	Offer Letter, dated September 20, 2016, by and between Frank Karbe and Myovant Sciences, Inc.	S-1	333-213891	10.13	09/30/2016
10.16	+	Employment Agreement, dated April 3, 2017, between Frank Karbe and Myovant Sciences, Inc.	8-K	001-37929	10.1	04/03/2017
10.17	+†	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended.				

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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

† 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.