Table of Contents

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-213891
Registration No. 333-214266

PROSPECTUS

14,500,000 Shares

Common Shares

We are offering 14,500,000 common shares. Prior to this offering there has been no public market for our common shares. The initial public offering price is $15.00 per common share.

Our common shares have been authorized for listing on the New York Stock Exchange under the symbol "MYOV." Upon the closing of this offering, we will be a "controlled company" within the meaning of applicable New York Stock Exchange rules.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, and, as such, will be subject to reduced public company reporting requirements.

Investing in our common shares involves a high degree of risk. See "Risk Factors" beginning on page 11.

Consent under the Exchange Control Act 1972 (and its related regulations) has been obtained from the Bermuda Monetary Authority for the issue and transfer of our common shares to and between residents and non-residents of Bermuda for exchange control purposes provided our common shares remain listed on an appointed stock exchange, which includes the New York Stock Exchange. In granting such consent the Bermuda Monetary Authority does not accept any responsibility for our financial soundness or the correctness of any of the statements made or opinions expressed in this prospectus.

	Per Share	Total
Initial public offering price	$ 15.00	$217,500,000
Underwriting discounts and commissions(1)	$ 1.05	$ 15,225,000
Proceeds to us, before expenses	$ 13.95	$202,275,000

(1) See "Underwriting" for additional information regarding underwriting compensation.

Entities affiliated with Pfizer Inc. and BB Biotech AG have each agreed to purchase 2,000,000 of our common shares in this offering at the initial public offering price. The shares purchased by these entities in this offering will be subject to a 180-day lock-up agreement with the underwriters.

We have granted the underwriters the right to purchase up to 2,175,000 additional common shares to cover over-allotments, if any. The underwriters can exercise this right at any time within 30 days after the date of this prospectus.

The underwriters expect to deliver the shares against payment in New York, New York on or about November 1, 2016.

Neither the Securities and Exchange Commission in the United States nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Citigroup **Cowen and Company** **Evercore ISI** **Barclays**

JMP Securities

Baird

Prospectus dated October 26, 2016

TABLE OF CONTENTS

We are responsible for the information contained in this prospectus and in any free writing prospectus we prepare or authorize. We have not, and the underwriters have not, authorized anyone to provide you with different information, and we and the underwriters take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the cover of this prospectus.

Persons who come into possession of this prospectus and any applicable free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common shares, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Unless the context otherwise requires, we use the terms "company," "we," "us" and "our" in this prospectus to refer to Myovant Sciences Ltd. and our wholly-owned subsidiaries. Our fiscal year ends on March 31.

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. 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.

Relugolix has been evaluated in over 1,300 subjects to date, in Phase 1 and multiple large, randomized Phase 2 clinical trials, some of which are ongoing. These trials have produced favorable results in each indication. In these trials, relugolix was shown to be generally well tolerated and to successfully suppress estrogen and progesterone levels in women and testosterone levels in men. The suppression of estrogen and progesterone levels in women has been shown to effectively treat the symptoms of uterine fibroids and endometriosis, and the suppression of testosterone levels in men has been shown to effectively treat advanced prostate cancer.

In a double-blind, placebo-controlled Phase 2 clinical trial in 216 women, relugolix markedly decreased menstrual blood loss associated with uterine fibroids. The result was statistically significant for each treatment arm versus placebo, with the greatest benefit observed at a dose of 40 mg once daily ($p<0.0001$). In a double-blind, placebo-controlled Phase 2 clinical trial in 487 women with endometriosis, relugolix decreased pelvic pain associated with endometriosis. As assessed by the visual analogue scale, a patient-reported scale for the quantification of pain, the decline in pain was statistically significant between each dose arm and placebo, with the greatest benefit observed at a dose of 40 mg once daily ($p<0.0001$).

In two randomized Phase 2 clinical trials in 228 men with advanced prostate cancer, relugolix demonstrated an ability to decrease testosterone to very low levels and to reduce levels of prostate-specific antigen, a key prostate cancer biomarker. These results for relugolix were consistent with those for leuprolide acetate, or leuprolide, a GnRH agonist typically used in androgen deprivation therapy, or ADT, and for degarelix, an injectable GnRH antagonist. Unlike GnRH agonists, relugolix, when orally administered once daily, was shown in these trials to rapidly decrease testosterone levels. In addition, testosterone levels returned to baseline more rapidly after discontinuation of relugolix than after discontinuation of degarelix.

We plan to initiate three multinational Phase 3 clinical programs for relugolix, one in the first quarter of 2017 in women with heavy menstrual bleeding associated with uterine fibroids, a second in the first half of 2017 in women with endometriosis-associated pain, and a third in the first quarter of 2017 in men with advanced prostate cancer. For our uterine fibroid and endometriosis programs, we intend to co-administer relugolix with low-dose estradiol and progestin as add-back therapy. Estradiol is a major estrogen and progestin is a synthetic progestational agent. We expect to report top-line data from each of these Phase 3 programs in 2019.

We plan to develop our second product candidate, RVT-602, an oligopeptide kisspeptin analog, for the treatment of female infertility as part of assisted reproduction. Kisspeptin is a naturally-occurring peptide that stimulates GnRH release. RVT-602 has been evaluated in approximately 150 men, but has not yet been studied in women. In the second half of 2017, we expect to initiate a Phase 1 healthy-volunteer study in women followed by a

Phase 2 proof-of-concept trial for RVT-602. We believe RVT-602 has the potential to be a safer alternative to human chorionic gonadotropin when used as part of assisted reproduction for the treatment of female infertility, based on published data evaluating native kisspeptin in women undergoing assisted reproduction.

The following chart represents our current product candidate pipeline:

Product Candidate	Indication	Phase 1	Phase 2	Phase 3	Upcoming Milestones	Commercial Rights
Relugolix with Add-Back Therapy	Uterine Fibroids—Heavy Menstrual Bleeding				Phase 3 Initiation in First Quarter of 2017[1]	Global, Excluding Takeda Territory[5]
	Endometriosis—Pain				Phase 3 Initiation in First Half of 2017[2]	Global, Excluding Takeda Territory[5]
Relugolix	Advanced Prostate Cancer				Phase 3 Initiation in First Quarter of 2017[3]	Global, Excluding Takeda Territory[5]
RVT-602	Female Infertility as Part of Assisted Reproduction[4]				Phase 1 Initiation in Second Half of 2017	Global

1 Subject to the submission of our investigational new drug application to the U.S. Food and Drug Administration, or FDA, which we expect to occur in 2016.
2 Subject to our End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017.
3 An End of Phase 2 meeting confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial.
4 RVT-602 has been evaluated in Phase 1 and Phase 2a clinical trials conducted by Takeda in men for the treatment of prostate cancer and hypogonadotropic hypogonadism, or a state of low testosterone levels. We plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial.
5 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.

In April 2016, we entered into a license agreement with Takeda Pharmaceuticals International AG, or Takeda, in which we were granted an exclusive, royalty-bearing license to develop and commercialize relugolix and RVT-602. The territory for our exclusive license for relugolix covers all countries worldwide, excluding the Takeda Territory, to which Takeda retains exclusive rights. The territory for our exclusive license for RVT-602 covers all countries worldwide. Takeda is currently conducting two Phase 3 trials evaluating relugolix in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding, respectively. Takeda expects to report top-line data from each of these trials in the second half of 2017, and we expect to submit Takeda's Phase 3 data as part of our new drug application, or NDA, to the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids.

Relugolix

Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins, thereby decreasing the down-stream production of estrogen and progesterone by the ovaries in

women and testosterone by the testes in men. This is a clinically-validated mechanism of action and there is a commercially available injectable GnRH receptor antagonist for the treatment of advanced prostate cancer.

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. During development, relugolix will be co-administered with low-dose estradiol and progestin for the uterine fibroid and endometriosis indications. We believe relugolix with add-back therapy has the potential to be used longer term, unlike the currently approved GnRH agonist therapies, because it may minimize bone mineral density loss in women and improve tolerability. We therefore believe relugolix has the potential to be a best-in-class oral GnRH receptor antagonist for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain. For the treatment of advanced prostate cancer, we believe relugolix has the potential to be both a first-in-class and best-in-class oral GnRH receptor antagonist based upon its high potency and long half-life. A first-in-class product is the first drug, in a class of drugs, approved for the treatment of a medical condition.

We believe relugolix may offer several significant advantages over currently approved injectable therapies, as well as therapies in late-stage clinical development:

- Demonstrated clinical benefit with a favorable safety profile
- Once-daily, oral administration
- Highly potent GnRH receptor antagonist
- Rapid onset of action
- Rapid reversal of hormone suppression
- Longer-term treatment with hormone add-back therapy
- Fixed-dose combination product

Market Opportunity

Uterine fibroids are non-cancerous tumors composed of smooth muscle and fibrous connective tissue that develop in or on the walls of the uterus, which can cause debilitating symptoms such as heavy or painful periods, anemia, or low red blood cell counts, abdominal pain, pregnancy loss and, in some cases, infertility. We estimate approximately 5.0 million women in the United States suffer from symptomatic uterine fibroids, approximately 3.0 million of whom are inadequately treated by current medical therapy and require further treatment. Endometriosis is a gynecological medical condition in which cells from the lining of the uterus grow outside the uterine cavity, most commonly on the ovaries, which can lead to pelvic pain, painful intercourse and, in some cases, infertility. We estimate that approximately 6.0 million women in the United States suffer from symptomatic endometriosis, approximately 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment. The current treatment landscape for our target women's health indications includes both medical and surgical options. For uterine fibroids, medical options include oral contraceptives and GnRH agonists. For endometriosis-associated pain, initial treatment includes oral contraceptives and over-the-counter pain medications. In more severe cases, GnRH agonists are used for short-term treatment and may involve hormone add-back therapy. For many patients suffering from uterine fibroids or endometriosis, medical treatment options are ineffective and surgical intervention is frequently required. In the treatment of both uterine fibroids and endometriosis, surgical intervention may result in postoperative complications or complications with future pregnancy or even preclude the potential for future pregnancy.

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 in the United States each year. Treatment for advanced prostate cancer typically involves treatment with ADT, which are therapies that reduce testosterone to very low levels, commonly referred to as castration levels. GnRH agonists, such as leuprolide depot, or slow-release, injections, are the current standard of care for medical castration, causing long-term desensitization and down-regulation of the GnRH-axis. GnRH agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial exacerbation of clinical symptoms, which is known as clinical or hormonal flare. Other approved forms of ADT include injectable GnRH antagonists, such as degarelix.

Our Strategy

Our goal is to be the leading global biopharmaceutical company focused on the innovative treatment of women's health diseases and other endocrine-related disorders 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 RVT-602
- Expand clinical development of relugolix for additional indications
- Acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of women's health diseases or endocrine-related disorders in a capital-efficient manner
- Maximize the commercial potential of our product candidates

Our Leadership

Lynn Seely, M.D., our Principal Executive Officer, has substantial experience in developing and obtaining approval for drugs for oncology and endocrine-related disorders. Dr. Seely is a board certified endocrinologist and the former Chief Medical Officer of Medivation, Inc. At Medivation, Dr. Seely led the development of Xtandi (enzalutamide) for the treatment of patients with metastatic castration-resistant prostate cancer, which achieved global sales of $1.87 billion in 2015.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common shares. These risks are discussed more fully in the section titled "Risk Factors" and include, among others:

- We have a limited operating history and have never generated any product revenue. We were incorporated in February 2016, and our operations to date have been limited to organizing and staffing our company, acquiring rights to our product candidates and preparing for and advancing our product candidates into clinical development.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- We are heavily dependent on the success of relugolix and RVT-602, our only product candidates, and if relugolix or RVT-602 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.
- 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 and RVT-602.

- Under our amended and restated bye-laws, we may reduce the voting power of your common shares without your consent.
- Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. We estimate that our clinical trials of relugolix and RVT-602 will take at least several years to complete.
- 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.
- 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 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 RVT-602 and any future product candidate.
- We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- We currently have nine employees who are employed by our wholly-owned subsidiary, Myovant Sciences, Inc., and we rely on Roivant Sciences, Inc. to provide various administrative, research and development and other services.
- Prior to our acquisition of the rights to relugolix and RVT-602 in April 2016, we were not involved in the development of either of these product candidates and, as a result, we are dependent on Takeda having accurately reported the results and correctly collected and interpreted the data from all clinical trials conducted to date.

If we are unable to adequately address these and other risks we face, our business, financial condition, operating results and prospects may be adversely affected.

In addition, we are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and therefore we intend to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in this prospectus, our periodic reports and our proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these exemptions for up to five years or until we are no longer an “emerging growth company.”

Relationship with Roivant Sciences Ltd., Roivant Sciences, Inc. and Myovant Sciences, Inc.

Roivant Sciences Ltd. will be our controlling shareholder. We are a majority-owned subsidiary of Roivant Sciences Ltd., a biopharmaceutical company focused on realizing the full value of promising late-stage drug candidates to improve the lives of patients and their families. Upon the closing of this offering, we will be a “controlled company” within the meaning of the corporate governance rules of the New York Stock Exchange, or NYSE. Upon the closing of this offering, Roivant Sciences Ltd. will own, in the aggregate, approximately 61.8% of our outstanding common shares, or approximately 59.4% if the underwriters exercise their option to purchase additional common shares in full. Roivant Sciences Ltd. will be able to exercise control over all matters requiring shareholder approval, including the election of our directors and approval of significant corporate transactions.

Services Agreement with Roivant Sciences, Inc. We and our wholly-owned subsidiary, Myovant Sciences, Inc., have received, and will continue to receive, various services provided by our affiliate, Roivant Sciences, Inc., which is a wholly-owned subsidiary of Roivant Sciences Ltd. These services include, but are not limited to, the identification of potential additional product candidates, project management of clinical trials and other development, administrative and financial activities. Following the completion of this offering, we expect that our reliance on Roivant Sciences, Inc. will decrease over time as we, Myovant Sciences, Inc. and any other current or future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of relugolix and RVT-602. We and Myovant Sciences, Inc. have entered into a services agreement with Roivant Sciences, Inc. in connection with the provision of these services. For a description of this agreement, see the section titled "Certain Relationships and Related Party Transactions—Relationship with Roivant Sciences, Inc.—Services Agreement."

Corporate Information

We are an exempted limited company incorporated under the laws of Bermuda on February 2, 2016. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, 2nd Floor, Hamilton HM11, Bermuda. Our telephone number is +1 (441) 824-8101. Our website address is www.myovant.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common shares.

We have three wholly-owned subsidiaries, including Myovant Sciences, Inc., a Delaware corporation, Myovant Holdings Limited, a private limited company incorporated under the laws of England and Wales, and Myovant Sciences GmbH, a company with limited liability formed under the laws of Switzerland. We expect that Myovant Sciences GmbH will be the principal operating company for conducting our business and the entity which will hold our intellectual property rights in relugolix and RVT-602.

Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

THE OFFERING

Common shares offered by us	14,500,000 common shares
Common shares to be outstanding immediately after this offering	60,227,953 common shares (or 62,699,546 common shares if the underwriters exercise their option to purchase additional common shares in full)
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional 2,175,000 common shares.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $199.8 million, based on the initial public offering price of $15.00 per common share. We intend to use the net proceeds from this offering primarily for the clinical development of our product candidates, relugolix and RVT-602. The remaining proceeds will be used for working capital and general corporate purposes. See the section titled “Use of Proceeds” for additional information.
Controlled company	Upon the closing of this offering, Roivant Sciences Ltd. will beneficially own a controlling interest in us and we will be a “controlled company” under NYSE rules. As a controlled company, we may elect to avail ourselves of the controlled company exemption under the corporate governance requirements of the NYSE.
Risk factors	You should read the section titled “Risk Factors” for a discussion of factors to consider carefully before deciding to invest in our common shares.
NYSE symbol	“MYOV”

Entities affiliated with Pfizer Inc. and BB Biotech AG have each agreed to purchase 2,000,000 of our common shares in this offering at the initial public offering price. The shares purchased by these entities in this offering will be subject to a 180-day lock-up agreement with the underwriters. In October 2016, we and an entity affiliated with Pfizer Inc. entered into a right of first negotiation and board observer agreement. Please see the section titled “Business—Right of First Negotiation and Board Observer Agreement with Pfizer” for information regarding this agreement.

The number of common shares that will be outstanding immediately after this offering is based on 43,590,411 common shares outstanding as of June 30, 2016, and excludes:

- an indeterminate number of capital shares that may be issued after the closing of this offering pursuant to a warrant we issued to Takeda, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us, as determined after such exercise, through April 2017, unless earlier terminated upon a change in control, as further described in the section titled “Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant;” and

- 3,384,667 common shares reserved for future issuance under our 2016 Equity Incentive Plan, as amended, of which stock options for an aggregate of 1,175,311 common shares were granted in August and September 2016, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

Except as otherwise indicated herein, all information in this prospectus, including the number of common shares that will be outstanding after this offering, assumes or gives effect to:

- a 100,000-for-1 stock split effected on April 27, 2016;
- a 1-for-1.7727 reverse stock split effected on October 18, 2016;
- an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of $0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares;
- the issuance of an additional 1,977,269 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda, based upon the sale and issuance of 14,500,000 common shares to investors in this offering at the initial public offering price of $15.00 per common share;
- no exercise by the underwriters of their option to purchase an additional 2,175,000 common shares and no issuance of an additional 296,593 common shares to Takeda as a result thereof, pursuant to the automatic exercise of a warrant we issued to Takeda; and
- the effectiveness of our amended and restated bye-laws immediately prior to the closing of this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statement of operations data for the periods indicated. We derived the consolidated statement of operations data for the period from February 2, 2016 (date of inception) through March 31, 2016 from our audited consolidated financial statements appearing elsewhere in this prospectus. Our consolidated statement of operations data for the three months ended June 30, 2016 and the consolidated balance sheet data as of June 30, 2016 are derived from our unaudited consolidated financial statements appearing elsewhere in this prospectus. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the period ended March 31, 2016 and the three months ended June 30, 2016 are not indicative of the results that may be expected for a full fiscal year or any other future period. You should read this summary consolidated financial data below, together with our consolidated financial statements and related notes thereto appearing elsewhere in this prospectus, as well as the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our fiscal year ends on March 31.

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016
Consolidated Statement of Operations Data:		
Operating expenses:		
Research and development	$ —	$ 14,573,014
General and administrative	1,656,788	2,561,878
Total operating expenses	1,656,788	17,134,892
Other (expense) income:		
Changes in the fair value of the warrant liability	—	(1,832,543)
Loss before provision for income tax	(1,656,788)	(18,967,435)
Income tax expense	—	3,054
Net loss and comprehensive loss	$ (1,656,788)	$(18,970,489)
Net loss per common share—basic and diluted(1)	$ (0.04)	$ (0.47)
Weighted average common shares outstanding—basic and diluted(1)	37,231,342	40,771,548
Pro forma net loss per common share—basic and diluted (unaudited)(2)		$ (0.44)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(2)		42,748,817

(1) See Note 2[J] to our consolidated financial statements for an explanation of the method used to compute basic and diluted net loss per common share.

(2) See Note 1[C] to our consolidated financial statements for an explanation of the method used to compute basic and diluted pro forma net loss per common share.

	As of June 30, 2016	
	Actual	Pro Forma As Adjusted(1) (2)
Consolidated Balance Sheet Data:		
Cash	$ —	$199,775,000
Total assets	523,681	199,775,000
Total liabilities	9,121,775	9,121,775
Accumulated deficit	(20,627,277)	(52,690,407)
Total shareholders' (deficit) equity	(8,598,094)	190,653,225

(1) The pro forma as adjusted balance sheet data gives effect to: (1) the issuance and sale of 14,500,000 common shares in this offering at the initial public offering price of $15.00 per common share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us; (2) an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of $0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares; and (3) the issuance of an additional 1,977,269 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda, based upon the sale and issuance of 14,500,000 common shares to investors in this offering at the initial public offering price of $15.00 per common share. The foregoing issuances to Takeda will increase both accumulated deficit and additional paid-in capital by $32,063,130 (calculated by multiplying an aggregate of 2,137,542 common shares by the initial public offering price of $15.00 per common share).

(2) Total assets are comprised solely of deferred initial public offering costs of $523,681, which, upon the closing of this offering, will be reclassified to additional paid-in capital.

RISK FACTORS

Investing in our common shares involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our consolidated financial statements and the related notes appearing at the end of this prospectus, before making your decision to invest in our common shares. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows and if so our future prospects would likely be materially and adversely affected. If any of such events were to happen, the trading price of our common shares could decline, and you could lose all or part of your investment.

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 RVT-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 RVT-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 to date have not generated any product revenue.

Even if we receive regulatory approval for the sale of relugolix or RVT-602, we do not know when relugolix or RVT-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 RVT-602;
- set an acceptable price for relugolix and RVT-602 and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing and distribution systems for relugolix and RVT-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 third-party manufacturers and have commercial quantities of relugolix and RVT-602 manufactured at acceptable cost 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 U.S. Food and Drug Administration, or 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 RVT-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.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

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. We expect to continue to incur substantial and increasing losses through the projected commercialization of relugolix and RVT-602. Neither relugolix nor RVT-602 has been approved for marketing in the United States and 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 RVT-602, obtain necessary regulatory approvals, and have relugolix and RVT-602 manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize relugolix or RVT-602. If we do successfully obtain regulatory approval to market relugolix or RVT-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 RVT-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 RVT-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. As of June 30, 2016, we had an accumulated deficit of $20.6 million.

We expect our research and development expenses to be significant in connection with our development programs for relugolix and RVT-602. In addition, if we obtain regulatory approval for either relugolix or RVT-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.

Our auditors have issued a going concern opinion on our consolidated financial statements as of March 31, 2016 and for the period from February 2, 2016 (date of inception) to March 31, 2016, expressing substantial doubt that we can continue as an ongoing business due to insufficient capital for us to fund our operations. Our consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to successfully complete this offering, we will need to create alternate financing or operational plans to continue as a going concern.

We are heavily dependent on the success of relugolix and RVT-602, our only product candidates, which are still under clinical development, and if relugolix or RVT-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 RVT-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 or RVT-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 RVT-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 county. 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. Prior to commencing our planned Phase 3 program for the treatment of heavy menstrual bleeding associated with uterine fibroids, we will need to submit our investigational new drug application, or IND, to the FDA, which we expect to occur in 2016. We completed an End of Phase 2 meeting with the FDA for relugolix for this indication in early October 2016. Prior to commencing our planned Phase 3 program for the treatment of endometriosis-associated pain, we will need to complete the End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017.

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 RVT-602 for many reasons, including:

- we may not be able to demonstrate that relugolix or RVT-602 is effective as a treatment for our target indications to the satisfaction of the FDA or other relevant regulatory authority;
- 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 that materially adversely impact our clinical trials;
- the FDA or other relevant regulatory authority may not find the data from preclinical 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 preclinical 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 preclinical 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 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 hormone 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 plan to conduct 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.

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 RVT-602.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize relugolix and RVT-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 RVT-602 and make significant royalty payments in connection with the sale of resulting products.

Even with the net proceeds of this offering, we may require additional capital to complete the development and potential commercialization of our product candidates. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our development program or any future commercialization efforts. 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.

Based upon our current operating plan, we believe that the net proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019. 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. Because the length of time and activities associated with successful development of relugolix and RVT-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 clinical trials for our product candidates;
- 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 the 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 the 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.

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.

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 through equity or debt financings 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 RVT-602.

We have licensed the intellectual property rights covering our current product candidates, relugolix and RVT-602, from Takeda pursuant to the April 2016 license agreement between us and Takeda. If, for any reason, our license agreement is terminated or we otherwise lose those rights, it would adversely affect our business. Our license agreement with Takeda 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 RVT-602.

Pursuant to the license 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 nine employees who are employed by our wholly-owned subsidiary, Myovant Sciences, Inc., and we rely on Roivant Sciences, Inc. to provide various administrative, research and development and other services.

As of September 30, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had nine employees. We rely on the administrative and support and research and development services provided by our affiliate, Roivant Sciences, Inc., a wholly-owned subsidiary of Roivant Sciences Ltd. We and Myovant Sciences, Inc., have entered into a services agreement with Roivant Sciences, Inc. Personnel and support staff that provide services to us under this services agreement 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 this services agreement, Roivant Sciences, Inc. has the discretion to determine which of its employees will perform services under the agreement.

Roivant Sciences, Inc. has limited financing and accounting and other resources. If Roivant Sciences, Inc. fails to perform its obligations in accordance with the terms of the services agreement, it could be difficult for us to operate our business. In addition, the termination of our relationship with Roivant Sciences, Inc. and any delay in appointing or finding a suitable replacement provider (if one exists) could make it difficult for us to operate our business. Any failure by Roivant Sciences, Inc. to effectively manage our administrative, research and development or other services could harm our business, financial condition and results of operations.

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

As of September 30, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had nine employees. We expect to hire, either directly, through Myovant Sciences, Inc. or through any other current or future subsidiary of ours, additional employees for our managerial, clinical, scientific, operational, 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, 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 RVT-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.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors 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 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 and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. 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 pre-clinical 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 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 could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions 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, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of Roivant Sciences, Inc. and our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, 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 preclinical 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 RVT-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 RVT-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 the related litigation and 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 RVT-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.

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 RVT-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. Our planned Phase 3 program for the treatment of heavy menstrual bleeding associated with uterine fibroids is subject to the submission of our IND to the FDA, which we expect to occur in 2016. We completed an End of Phase 2 meeting with the FDA for relugolix for this indication in early October 2016. Our planned Phase 3 program for the treatment of endometriosis-related pain is subject to the completion of an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. Further, we cannot predict with any certainty if or when we might submit an NDA for regulatory approval for relugolix or RVT-602 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 RVT-602, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that our clinical trials of relugolix and RVT-602 will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. The results of early clinical trials of relugolix and RVT-602 therefore may not be predictive of the results of our planned development programs. 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.

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;
- failure to manufacture sufficient quantities of a drug candidate for use in clinical trials;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- adding a sufficient number of clinical trial sites; or
- clinical sites deviating from trial protocol or dropping out of a trial.

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, for example, the FDA's Good Clinical Practice, or 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 RVT-602 could be harmed, and our ability to generate product revenue from relugolix or RVT-602 may be delayed. In addition, any delays in our clinical trials could increase our costs, 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 RVT-602, we were not involved in the development of relugolix or RVT-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, we have had no involvement with or control over the preclinical and clinical development of either relugolix or RVT-602 to date. 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 conducted prior to our acquisition of the rights to relugolix and RVT-602 and having correctly collected and interpreted the data from these trials. To the extent any of these has not occurred, expected development time and costs may be increased which could adversely affect any future revenue from this product candidate.

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

Takeda is currently conducting two Phase 3 trials with relugolix in Japan for the treatment of uterine fibroid-associated pain and heavy menstrual bleeding, respectively. If announcements by Takeda are unfavorable with respect to these clinical trials, our clinical development plans may be adversely affected. Further, even if announcements by Takeda are favorable with respect to these clinical trials, our planned Phase 3 clinical trials for relugolix differ from Takeda's clinical trials and investors should not place undue reliance upon any of Takeda's reported data or other clinical development announcements.

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the effectiveness of relugolix or RVT-602. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. 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 preclinical, nonclinical and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A 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 RVT-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. 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 RVT-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 females, 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 them.

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 RVT-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 initiated a Phase 3 program evaluating elagolix with and without hormone 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 hormone add-back therapy in women with pain associated with endometriosis by the end of 2016. Further, 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. 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 RVT-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 RVT-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.

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

Relugolix and RVT-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 RVT-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 none of relugolix, RVT-602 or 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 RVT-602, we will need to complete additional 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 preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of relugolix and RVT-602 for the specified indication. Further, because we are exploring the use of relugolix 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.

Relugolix and RVT-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 RVT-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 RVT-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.

Across all relugolix clinical trials, a total of 34 serious adverse events were reported in the more than 1,300 relugolix-treated subjects and patients as of July 10, 2016, of which three were reported by the investigator as

possibly related to relugolix, including an event of abnormal liver function tests (moderate grade), one of cerebral infarction (grade unspecified) and one of embolic stroke (grade 2). In addition, concern has been raised by the FDA about a potential increase in the risk of diabetes and certain cardiovascular diseases in men treated with GnRH agonists.

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 RVT-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 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 preclinical 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.

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 registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and 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, including any requirement to implement a REMS. If relugolix or RVT-602 receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA or other regulatory authority may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy 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 relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, and other regulatory agencies alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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 RVT-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.

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;
- 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;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of relugolix and RVT-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 non-technical 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 RVT-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
- 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 RVT-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 U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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 may constrain 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 in order 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 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 of fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment 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 certain 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
- analogous state and foreign laws and regulations, such as state anti-kickback 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; 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; 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, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval for, and commercialize relugolix or RVT-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 RVT-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 payable to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs;
- 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 during 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;
- 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.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President 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, further reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products.

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 also 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 U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We 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.

Third-party payor 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 product candidates 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 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, and on what tier of its

formulary the drug will be placed. 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 and 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.

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 RVT-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 RVT-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 RVT-602 for all human diseases and conditions. Takeda is no longer developing this compound. We expect that the drug substance transferred from Takeda under our license agreement with Takeda will be sufficient for us to complete our planned Phase 3 programs for relugolix and possibly for RVT-602 as well. 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 third-party manufacturers to supply us with sufficient quantities of relugolix and RVT-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 the regulatory requirements, known as current good manufacturing practice, or cGMP, 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 cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell relugolix or RVT-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;
- 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, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. 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 pre-clinical studies that comply with the regulatory requirements known as good laboratory practice, or 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 the GLPs and GCPs, which are 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 in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development, respectively. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant preclinical and nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP pre-clinical studies and 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 GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

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 protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. 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.

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, RVT-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, RVT-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, RVT-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, RVT-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 United States Patent and Trademark Office,

or 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.

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 non-compliance 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. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent 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, RVT-602 or any future product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of relugolix, RVT-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 party review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. We have conducted searches for information in support of patent protection and otherwise evaluating the patent landscape for relugolix and RVT-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 RVT-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.

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

The United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering relugolix, RVT-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.

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, RVT-602 and any future product candidates, and we expect to collaborate with third parties on the development of relugolix, RVT-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. 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 this Offering and Our Common Shares

No public market for our common shares currently exists, and a public market may not develop or be liquid enough for you to sell your shares quickly or at market price.

Prior to this offering, there has not been a public market for our common shares. If an active trading market for our common shares does not develop following this offering, 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 initial public offering price of our common shares has been determined by negotiations between us and representatives of the underwriters, and may not be indicative of the market prices of our common shares that will prevail in the trading market.

The market price of our common shares is likely to be highly volatile, and you may lose some or all of your investment.

The market price of our common shares is likely 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 clinical trials;
- results of clinical trials of relugolix, RVT-602 or those of our competitors;
- any delay in filing an NDA or similar application for relugolix or RVT-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, RVT-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, RVT-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, RVT-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;
- sales of our common shares by us or our shareholders in the future;
- 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. The market price of our common shares may decline below the initial public offering price, and you may lose some or all of your investment.

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 will be a "controlled company" within the meaning of the applicable rules of the NYSE and, as a result, will 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.

Upon the closing of this offering, Roivant Sciences Ltd. will continue to control a majority of the voting power of our outstanding common shares. As a result, we will be 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 the board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;

- that we 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
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We intend to use these exemptions upon the closing of this offering 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.

Roivant Sciences Ltd. will continue to own a significant percentage of our common shares and will be able to exert significant control over matters subject to shareholder approval.

Roivant Sciences Ltd. is currently our majority shareholder, and after this offering is completed, we will continue to be controlled by Roivant Sciences Ltd. Upon the closing of this offering, Roivant Sciences Ltd. will beneficially own approximately 61.8% of the voting power of our outstanding common shares, or approximately 59.4% if the underwriters exercise their option to purchase additional common shares in full. Therefore, even after this offering, Roivant Sciences Ltd. will have the ability to substantially influence us and exert significant control through this ownership position. For example, Roivant Sciences Ltd. will be able to control elections of directors, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Roivant Sciences Ltd.'s interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. So long as it continues to own a significant amount of our equity, Roivant Sciences Ltd. will continue to be able to strongly influence and significantly control our decisions.

If securities or industry analysts do not 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 will depend, 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. 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. Additionally, we are subject to Bermuda legal constraints that may affect our ability to pay dividends on our common shares and make other payments. See "Dividend Policy" for additional information.

Our management will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and our shareholders will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. You may not agree with our decisions, and our use of the proceeds may not yield

any return on your investment. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering. For a period of six months after the closing of this offering, we have agreed to invest any cash and cash equivalents in a non-interest bearing account, and as a result, such investment will not yield a return.

As a result of certain new investors agreeing to participate in this offering, the available public float for our common shares will be reduced and the liquidity of our common shares may be adversely affected.

Entities affiliated with Pfizer Inc. and BB Biotech AG have each agreed to purchase 2,000,000 of our common shares in this offering at the initial public offering price. The common shares purchased by these entities in this offering will be subject to a 180-day lock-up agreement with the underwriters and the purchase by these entities will reduce the available public float for our common shares. As a result, the purchase of common shares by these entities in this offering may reduce the liquidity of our common shares relative to what it would have been had these shares been purchased by other investors or not subject to lock-up agreements.

Future sales of our common shares may depress our share price.

After this offering, based on the 43,590,411 common shares outstanding as of June 30, 2016, there will be 60,227,953 common shares outstanding, assuming no exercise by the underwriters of their option to purchase additional common shares. Sales of a substantial number of our common shares in the public market after this offering, or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities. Of our issued and outstanding common shares, all of the shares sold in this offering will be freely transferable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for the common shares sold to entities affiliated with Pfizer Inc. and BB Biotech AG, each of which has entered into a 180-day lock-up agreement with the underwriters. The remaining 45,727,953 common shares outstanding after this offering will be restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers for 180 days after the date of this prospectus. See the section titled “Shares Eligible for Future Sale—Lock-Up Agreements” for a more detailed description of the lock-up period.

We intend to file a registration statement on Form S-8 under the Securities Act to register the total number of our common shares that may be issued under our equity incentive plans. See the information in the section titled “Shares Eligible for Future Sale—Form S-8 Registration Statements” for a more detailed description of the common shares that will be available for future sale upon the registration and issuance of such common shares, subject to any applicable vesting or lock-up period or other restrictions provided under the terms of the applicable plan or the option agreements entered into with the option holders. Sales of these common shares 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.

If you purchase our common shares in this offering, you will incur immediate and substantial dilution in the book value of your common shares.

The initial public offering price of our common shares is substantially higher than the pro forma as adjusted net tangible book value per common share of our common shares. Therefore, if you purchase our common shares in this offering, you will pay a price per common share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. Based on the initial public offering price of $15.00 per common share, you

will experience immediate dilution of $11.83 per common share, representing the difference between our pro forma as adjusted net tangible book value per common share, after giving effect to this offering, and the initial public offering price. In addition, you will experience further dilution if we issue additional common shares after the closing of this offering pursuant to a warrant we issued to Takeda, exercisable at a price of $0.000017727 per share, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us through April 2017, as further described in the section titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant." Further, the future exercise of any options to purchase our common shares will cause you to experience additional dilution. See the section titled "Dilution" for additional information.

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

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. 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 will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations 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. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

As a result of becoming 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 first fiscal year beginning after the effective date of this offering. 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 are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. 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 the fifth anniversary of the closing of this offering, (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 is held by non-affiliates exceeds $700.0 million as of the prior June 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.

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 this prospectus and 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 will be 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 United States 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. See “Enforcement of Civil Liabilities under United States Federal Securities Laws” for additional information.

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.

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 66 2/3% 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. See the section titled "Description of Share Capital."

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 holds, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of this offering, 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. Roivant Sciences Ltd. and certain of its affiliates will not be 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.

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 tax. We may, however, 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 non-Bermudan tax liability could materially adversely affect our results of operations. For example, we expect that Myovant Sciences GmbH will be the principal operating company for conducting our business and the entity that will hold our intellectual property rights in relugolix and RVT-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.

We and Roivant Sciences Ltd., our principal shareholder, are based in Bermuda, and we currently have subsidiaries in the United Kingdom, Switzerland 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 but also 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 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, 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.

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 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 gains on the sale of our common shares. In addition, special information reporting may be required. See the section titled “Material Bermuda and U.S. Federal Income Tax Considerations—U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Rules.”

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which, 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, may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile) from time to time. Our status may also depend, in part, on how quickly we utilize the cash proceeds from this offering in our business. We believe that we were not a CFC prior to this offering in the current taxable year which will end on March 31, 2017. Based on this belief, with respect to the taxable year beginning in 2016 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the timing of and our ability to obtain and maintain regulatory approval of relugolix and RVT-602;
- our ability to successfully commercialize relugolix and RVT-602, if approved;
- the rate and degree of market acceptance of relugolix and RVT-602, if approved;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectation that the net proceeds from this offering will be sufficient to enable us to conduct our planned clinical development of relugolix and RVT-602, including through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019;
- our ability to maintain intellectual property protection for relugolix and RVT-602;
- our ability to identify and develop new product candidates;
- our ability to identify, recruit and retain key personnel;
- our use of proceeds from this offering;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

You should refer to the section titled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

INDUSTRY AND MARKET DATA

Certain industry data and market data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of management's estimates presented herein are based upon management's review of independent third-party surveys and industry publications prepared by a number of sources and other publicly available information. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications and surveys included in this prospectus is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 14,500,000 common shares in this offering will be approximately $199.8 million, or approximately $230.1 million if the underwriters exercise their option to purchase additional common shares in full, based upon the initial public offering price of $15.00 per common share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for the following purposes:

- approximately $25.0 million to $33.0 million to fund our planned Phase 3 clinical program for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids;
- approximately $30.0 million to $40.0 million to fund our planned Phase 3 clinical program for relugolix for the treatment of endometriosis-associated pain;
- approximately $40.0 million to $50.0 million to fund our planned Phase 3 clinical program for relugolix for the treatment of advanced prostate cancer;
- approximately $3.0 million to $5.0 million to fund a Phase 1 healthy-volunteer study in women followed by a planned proof-of-concept Phase 2 trial for RVT-602 for the treatment of female infertility as part of assisted reproduction; and
- the remainder to fund working capital and general corporate purposes, which may include research and development of relugolix and RVT-602 for other indications.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We believe the net proceeds from this offering, allocated as set forth above, will enable us to conduct each of the indicated planned clinical programs or trials, as applicable, including through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019; however, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies and clinical trials, as well as any collaborations that we may enter into with third parties, and any unforeseen cash needs.

We believe opportunities may exist from time to time to expand our current business through the acquisition or in-license of complementary product candidates. While we have no current agreements or commitments for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending these uses, for a period of six months after the closing of this offering, we plan to invest these net proceeds in a non-interest bearing account. Thereafter, we may choose to invest these net proceeds in short-term, interest bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our operations.

We believe that the net proceeds from this offering will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

DIVIDEND POLICY

We have never declared or paid any dividends on our common shares. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the sole discretion of our board of directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant. In addition, pursuant to Bermuda law, a company may not declare or pay dividends if there are reasonable grounds for believing that (1) the company is, or would after the payment be, unable to pay its liabilities as they become due or (2) that the realizable value of its assets would thereby be less than its liabilities. Under our amended and restated bye-laws, each common share is entitled to dividends if, as and when dividends are declared by our board of directors, subject to any preferred dividend right of the holders of any preference shares.

CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2016:

- on an actual basis; and
- on a pro forma as adjusted basis to give effect to:
  - the issuance and sale of 14,500,000 common shares in this offering at the initial public offering price of $15.00 per common share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us;
  - an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of $0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares;
  - the issuance of an additional 1,977,269 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda, based upon the sale and issuance of 14,500,000 common shares to investors in this offering at the initial public offering price of $15.00 per common share;
  - offsetting increases of $32,063,130 to each of accumulated deficit and additional paid-in capital to account for the aggregate issuance of 2,137,542 common shares to Takeda (calculated by multiplying such shares by the initial public offering price of $15.00 per common share); and
  - the reclassification of deferred initial public offering costs of $523,681 from assets to additional paid-in capital.

You should read this table together with the sections titled “Use of Proceeds,” “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	As of June 30, 2016	
	Actual	Pro Forma As Adjusted
Cash	$ —	$ 199,775,000
Shareholders’ (deficit) equity:		
Common shares, $0.000017727 par value; 564,111,242 shares authorized, 43,590,411 shares issued and outstanding, actual; 564,111,242 shares authorized, 60,227,953 shares issued and outstanding, pro forma as adjusted	$ 773	$ 1,068
Common shares subscribed	(660)	(660)
Additional paid-in capital	12,029,070	243,343,224
Accumulated deficit	(20,627,277)	(52,690,407)
Total shareholders’ (deficit) equity	(8,598,094)	190,653,225
Total capitalization	$ (8,598,094)	$ 190,653,225

The number of common shares outstanding in the table above excludes:

- an indeterminate number of capital shares that may be issued after the closing of this offering pursuant to a warrant we issued to Takeda, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us, as determined after such exercise, through April 2017, unless earlier terminated upon a change in control, as further described in the section titled “Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant;” and
- 3,384,667 common shares reserved for future issuance under our 2016 Equity Incentive Plan, as amended, of which stock options for an aggregate of 1,175,311 common shares, with a weighted-average exercise price of $3.17 per share, were granted in August and September 2016, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

DILUTION

If you invest in our common shares in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per common share and the pro forma as adjusted net tangible book value per common share of our common shares immediately after this offering.

As of June 30, 2016, we had a pro forma net tangible book deficit of $(9.1) million, or $(0.20) per common share. Pro forma net tangible book value per common share is determined by dividing our total tangible assets less total liabilities by the number of outstanding common shares, after giving effect to: (1) an aggregate of 160,273 common shares issued to Takeda in August and September 2016 upon the automatic exercise of a warrant we issued to Takeda at an exercise price of $0.000017727 per share, which was initiated by the grant of stock options for an aggregate of 1,175,311 common shares; and (2) the issuance of an additional 1,977,269 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda, based upon the sale and issuance of 14,500,000 common shares to investors in this offering at the initial public offering price of $15.00 per common share.

After giving effect to the issuance and sale of 14,500,000 common shares in this offering at the initial public offering price of $15.00 per common share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2016 would have been $190.7 million, or $3.17 per common share. This represents an immediate increase in the pro forma as adjusted net tangible book value of $3.37 per common share to our shareholders, and an immediate dilution in the pro forma as adjusted net tangible book value of $11.83 per common share to investors purchasing our common shares in this offering. The following table illustrates this per common share dilution:

Initial public offering price per common share		$15.00
Pro forma net tangible book deficit per common share as of June 30, 2016	$(0.20)	
Increase in pro forma net tangible book value per common share attributable to new investors participating in this offering	3.37	
Pro forma as adjusted net tangible book value per common share after this offering		3.17
Dilution per common share to investors participating in this offering		$11.83

If the underwriters exercise their option in full to purchase an additional 2,175,000 common shares in this offering, the pro forma as adjusted net tangible book value per common share after the offering would be $3.52 per common share, the increase in the pro forma as adjusted net tangible book value per common share to our shareholders would be $3.72 per common share and the dilution to new investors purchasing common shares in this offering would be $11.48 per common share.

The following table sets forth as of June 30, 2016, on the pro forma as adjusted basis described above, the differences between the number of common shares purchased from us, the total consideration paid and the weighted average price per common share paid by our shareholders, including an aggregate of 160,273 common shares issued to Takeda in August and September 2016 and 1,977,269 common shares issuable to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda at an exercise price of $0.000017727 per share, and by investors purchasing our common shares in this offering at the initial public offering price of $15.00 per common share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Weighted Average Price Per Common Share
	Number	Percent	Amount	Percent	
Existing shareholders	45,727,953	76%	$ —	— %	$ —
New investors	14,500,000	24	217,500,000	100	15.00
Total	60,227,953	100%	$217,500,000	100%	

The table and discussion above exclude:

- an indeterminate number of capital shares that may be issued after the closing of this offering pursuant to a warrant we issued to Takeda, which allows Takeda, together with its affiliates, to maintain a 12% ownership interest in us, as determined after such exercise, through April 2017, unless earlier terminated upon a change in control, as further described in the section titled “Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant;” and
- 3,384,667 common shares reserved for future issuance under our 2016 Equity Incentive Plan, as amended, of which stock options for an aggregate of 1,175,311 common shares, with a weighted-average exercise price of $3.17 per share, were granted in August and September 2016, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

To the extent any options are issued under our equity incentive plans, or we issue additional common shares in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated financial data for the periods indicated. We derived the consolidated statement of operations data for the period from February 2, 2016 (date of inception) through March 31, 2016 and the consolidated balance sheet data as of March 31, 2016 from our audited consolidated financial statements appearing elsewhere in this prospectus. Our consolidated statement of operations data for the three months ended June 30, 2016 and the consolidated balance sheet data as of June 30, 2016 are derived from our unaudited consolidated financial statements appearing elsewhere in this prospectus. We have prepared the unaudited consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. The data should be read together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the period ended March 31, 2016 and the three months ended June 30, 2016 are not indicative of the results that may be expected for a full fiscal year or any other future period. Our fiscal year ends on March 31.

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016
Consolidated Statement of Operations Data:		
Operating expenses:		
Research and development	$ —	$ 14,573,014
General and administrative	1,656,788	2,561,878
Total operating expenses	1,656,788	17,134,892
Other (expense) income:		
Changes in the fair value of the warrant liability	—	(1,832,543)
Loss before provision for income tax	(1,656,788)	(18,967,435)
Income tax expense	—	3,054
Net loss and comprehensive loss	$ (1,656,788)	$(18,970,489)
Net loss per common share—basic and diluted(1)	$ (0.04)	$ (0.47)
Weighted average shares outstanding—basic and diluted(1)	37,231,342	40,771,548
Pro forma net loss per common share—basic and diluted (unaudited)(2)		$ (0.44)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)(2)		42,748,817

(1) See Note 2[J] to our consolidated financial statements for an explanation of the method used to compute basic and diluted net loss per common share.

(2) See Note 1[C] to our consolidated financial statements for an explanation of the method used to compute basic and diluted pro forma net loss per common share.

	As of March 31, 2016	As of June 30, 2016
Consolidated Balance Sheet Data:		
Cash	$ —	$ —
Total assets	—	523,681
Total liabilities	222,650	9,121,775
Accumulated deficit	(1,656,788)	(20,627,277)
Total shareholders' deficit	(222,650)	(8,598,094)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes thereto appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our fiscal year ends on March 31.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. 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. Relugolix has been evaluated in over 1,300 subjects to date, in Phase 1 and multiple large, randomized Phase 2 clinical trials, some of which are ongoing. These trials have produced favorable results in each indication. In these trials, relugolix was shown to be generally well tolerated and to successfully suppress estrogen and progesterone levels in women and testosterone levels in men. The suppression of estrogen and progesterone levels in women has been shown to effectively treat the symptoms of uterine fibroids and endometriosis, and the suppression of testosterone levels in men has been shown to effectively treat advanced prostate cancer.

We plan to initiate three multinational Phase 3 clinical programs for relugolix, one in the first quarter of 2017 in women with heavy menstrual bleeding associated with uterine fibroids, a second in the first half of 2017 in women with endometriosis-associated pain, and a third in the first quarter of 2017 in men with advanced prostate cancer. We completed an End of Phase 2 meeting with the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids in early October 2016, and expect to submit our IND, including Phase 3 protocols, for this indication to the FDA in 2016. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to the completion of an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. We expect to report top-line data from each of these Phase 3 programs in 2019. We plan to develop our second product candidate, RVT-602, for the treatment of female infertility as part of assisted reproduction. In the second half of 2017, we expect to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602.

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 RVT-602 and preparing for and advancing our product candidates into clinical development. To date, we have not generated any revenue. As of June 30, 2016, we had an accumulated deficit of $20,627,277. For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016 we recorded net losses of $1,656,788 and $18,970,489, respectively.

License Agreement with Takeda Pharmaceuticals International AG

In April 2016, we entered into a license agreement with Takeda in which we were granted an exclusive, royalty-bearing license to develop and commercialize relugolix and RVT-602 and products containing relugolix and RVT-602. The territory for our exclusive license for relugolix covers all countries worldwide, excluding Japan and certain other Asian countries, which we collectively refer to as the Takeda Territory, to which Takeda retains exclusive rights. The territory for our exclusive license for RVT-602 covers all countries worldwide. We

also granted to Takeda an exclusive, royalty-bearing license in the Takeda Territory to develop and commercialize relugolix and products containing relugolix for all human diseases and conditions. We will pay a fixed, high single-digit royalty on net sales of relugolix or RVT-602 products in our territory, subject to certain agreed reductions, and Takeda will pay us a royalty at the same high single-digit rate on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. See the section titled "Business—License Agreement with Takeda Pharmaceuticals International AG" for additional information.

In connection with this license agreement with Takeda, 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 which allows Takeda, together with its affiliates, to maintain a 12% ownership of us through April 29, 2017, the one-year anniversary of the issuance of the warrant, unless earlier terminated as a result of a change in control. We also entered into an investor rights agreement with Takeda and a manufacture and supply agreement with a Takeda affiliate. See the sections titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG" and "—Investor Rights Agreement" for further information regarding these agreements and the warrant.

Services Agreement with Roivant Sciences, Inc.

In July 2016, we and our wholly-owned subsidiary, Myovant Sciences, Inc., entered into a services agreement with Roivant Sciences, Inc., a wholly-owned subsidiary of Roivant Sciences Ltd., or the Services Agreement, effective April 29, 2016, pursuant to which Roivant Sciences, Inc. provides us with services in relation to the identification of potential product candidates, project management of clinical trials and other development, administrative and financial activities. Under the terms of the Services Agreement, we are obligated to pay or reimburse Roivant Sciences, Inc. for the costs it, or third parties acting on its behalf, incur(s) in providing services to us. In addition, we are obligated to pay to Roivant Sciences, Inc. a pre-determined mark-up, currently equal to 10%, on costs incurred by it in connection with any general and administrative and support services as well as research and development services. Following the closing of this offering, we expect that our reliance on Roivant Sciences, Inc. will decrease over time as we, Myovant Sciences, Inc. and any other future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of relugolix. See the section titled "Certain Relationships and Related Party Transactions—Relationship with Roivant Sciences, Inc.—Services Agreement" for additional information.

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 RVT-602.

Research and Development Expense

Since our incorporation, our operations have primarily been limited to the license of the rights to relugolix and RVT-602 and products containing these compounds. Our research and development expenses for the three months ended June 30, 2016 were $14,573,014 and consisted primarily of in-process research and development expenses of $13,117,000, which consisted of $7,740,000 for the estimated fair value of the 5,077,001 common shares issued to Takeda and $5,377,000 for the estimated fair value of the warrant liability, as well as share-based compensation expense and costs allocated to us under the Services Agreement, including employee-related services and third-party costs. Following the closing of this offering, we expect to significantly increase our research and development efforts as we initiate our Phase 3 programs for relugolix. Research and development expenses will 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 Agreement;

- expenses incurred under agreements with contract research organizations, or CROs, as well as consultants that conduct preclinical studies designed to assist with the lead optimization of our product candidate;
- manufacturing costs in connection with conducting preclinical 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. Product candidates in later stages of clinical development, such as relugolix, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to be significant over the next several years as we increase personnel and compensation costs and commence our potential Phase 3 programs, initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602 and prepare to seek regulatory approval for our product candidates. It is difficult to determine with certainty the duration and completion costs of any clinical trial we may conduct.

The duration, costs and timing of clinical trials of relugolix, RVT-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 that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals; and
- the efficacy and safety profile of the product candidate.

In addition, the probability of success for relugolix, RVT-602 and any other product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

General and Administrative Expense

General and administrative expenses consist primarily of employee salaries and related benefits and share-based compensation for general and administrative personnel services received under the Services Agreement and legal and accounting fees 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 RVT-602 obtains regulatory approval for marketing, we expect that we would incur expenses associated with building a sales and marketing team.

Results of Operations from February 2, 2016 (Date of Inception) to March 31, 2016 and for the Three Months Ended June 30, 2016

The following table sets forth our results of operations for the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016.

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016
Operating expenses:		
Research and development	$ —	$ 14,573,014
General and administrative	1,656,788	2,561,878
Total operating expenses	1,656,788	17,134,892
Other (expense) income:		
Changes in the fair value of the warrant liability	—	(1,832,543)
Income tax expense	—	3,054
Net loss and comprehensive loss	$ (1,656,788)	$ (18,970,489)

Research and Development Expenses

We did not incur any research and development expenses for the period from February 2, 2016 (date of inception) to March 31, 2016.

Research and development expenses were $14,573,014 for the three months ended June 30, 2016, and consisted primarily of in-process research and development expenses of $13,117,000, which were related to our acquisition of the rights to our product candidates and consisted of $7,740,000 for the estimated fair value of the 5,077,001 common shares issued to Takeda and $5,377,000 for the estimated fair value of warrant liability. The remainder consisted of share-based compensation expense of $974,642 allocated to us by Roivant Sciences Ltd. and costs billed to us under the Services Agreement of $476,374, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs.

General and Administrative Expenses

General and administrative expenses were $1,656,788 for the period from February 2, 2016 (date of inception) to March 31, 2016, and consisted primarily of share-based compensation expense of $987,066 and personnel expenses of $441,522 allocated to us from Roivant Sciences, Inc. and Roivant Sciences Ltd. for services provided to us by their employees and $164,116 of legal fees and consulting services associated with the formation of our company and corporate matters.

General and administrative expenses were $2,561,878 for the three months ended June 30, 2016, and consisted of share-based compensation expense of $1,645,860, primarily related to share-based compensation expense allocated to us by Roivant Sciences, Inc. and Roivant Sciences Ltd., and costs of $555,186 billed to us under the Services Agreement, including personnel expenses, overhead allocations and third-party costs. The remainder consisted primarily of legal and professional fees of $278,660 and other personnel related-expenses of $82,172.

Changes in the Fair Value of the Warrant Liability

The change in the fair value of the warrant liability was $1,832,543 as the fair value of the warrant liability increased to $6,975,000 at June 30, 2016 from $5,377,000 at April 29, 2016, the date of issuance of the warrant to Takeda, primarily due to changes in the assumptions regarding probabilities of successful financing events used to estimate the fair value of the liability, partially offset by $234,543 related to the fair value of the warrant exercised during the three months ended June 30, 2016.

Liquidity and Capital Resources

Overview

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016, we had net losses of $1,656,788 and $18,970,489, respectively. As of June 30, 2016, we had no cash and had never generated any revenue. These factors raise substantial doubt about our ability to continue as a going concern.

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 and RVT-602 or any other 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:

- commence our Phase 3 programs of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, endometriosis-related pain and advanced prostate cancer;
- commence a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602 for the treatment of female infertility as part of assisted reproduction;
- 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, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval; and
- begin to operate as a public company.

We intend to use the proceeds of this offering primarily to fund the development of relugolix for the treatment of uterine fibroids, endometriosis and advanced prostate cancer. 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 stock, 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, RVT-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 through equity or debt financings 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 for the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016:

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016
Net cash used in operating activities	$ —	$ —
Net cash used in investing activities	—	—
Net cash provided by financing activities	—	—

Operating Activities

For the period from February 2, 2016 (date of inception) to March 31, 2016, no cash was used in operating activities. The net loss for the period of $1,656,788 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 Roivant Sciences Ltd. and Roivant Sciences, Inc. associated with the formation of our company and corporate matters.

For the three months ended June 30, 2016, no cash was used in operating activities. The net loss for the period of $18,970,489 was primarily offset by $13,117,000 of non-cash in-process research and development expenses related to the acquisition of the rights to our product candidates, $2,620,502 non-cash share-based compensation, $1,832,543 non-cash changes in the fair value of the warrant liability and $1,153,378 allocation of personnel expenses by Roivant Sciences Ltd. and Roivant Sciences, Inc. associated with the preparation of our clinical and other research programs, the formation of our company and corporate matters, and $247,066 other expenses.

Investing Activities

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016, no cash was used in investing activities.

Financing Activities

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016, no cash was provided by financing activities.

Outlook

Based on the expected net proceeds from this offering, our research and development plans and our timing expectations related to the commencement of our Phase 3 programs for relugolix, we expect that the net proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements through unblinding and release of data for at least one of our Phase 3 programs, which we expect to occur in 2019. However, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

Contractual Obligations

As of June 30, 2016, 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.

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 accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, 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 our Services Agreement, 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. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments.

Company Valuation

To estimate certain expenses and record certain transactions, it is necessary for us to estimate the fair value of our common shares. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, our board of directors exercises reasonable judgment and considers numerous objective and subjective factors to determine the best estimate of the fair value of our common shares. See the section titled "—Share-Based Compensation."

Share-Based Compensation

We recognize share-based compensation expense related to stock options and restricted stock awards 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).

Common Share Price. Our board of directors estimates the fair value of our common shares. Given the absence of a public trading market for our common shares, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, our board of directors exercises reasonable judgment and considers a number of objective and subjective factors to determine its best estimate of the fair value of our common shares, as further described below.

Expected Volatility. Prior to this offering we were a privately-held company and did not have any trading history for our common shares and 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 Roivant Sciences Ltd. common share awards and options issued by Roivant Sciences Ltd. to its employees and employees of Roivant Sciences, Inc. Share-based compensation expense is allocated to us by Roivant Sciences Ltd. based upon the relative percentage of time utilized by Roivant Sciences, Inc. employees on our matters. The fair value of the Roivant Sciences Ltd. common share awards are determined on the date of grant and that fair value is recognized over the requisite service period. As Roivant Sciences Ltd. is a non-public entity and its common shares are not publicly traded, the common share awards and options are classified as a Level 3 measurement within the fair value hierarchy due to their unobservable nature. Significant judgment and estimates were used to estimate the fair value of these awards and options, as they are not publicly traded. Roivant Sciences Ltd. common share awards and options are subject to specified vesting schedules and requirements (a combination of time-based, performance-based and corporate event-based vesting terms, including targets for post-IPO market capitalization and future financing events of Roivant Sciences Ltd.). We estimated the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model.

Prior to this offering, the fair value of our common shares was estimated on each grant date by our board of directors. In order to determine the fair value of our common shares, our board of directors considered, among other

things, timely valuations of our 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*. Given the absence of a public trading market for our common shares, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common shares, including (1) our business, financial condition and results of operations, including related industry trends affecting our operations; (2) our forecasted operating performance and projected future cash flows; (3) the illiquid nature of our common shares; (4) the rights and privileges of our common shares; (5) market multiples of our most comparable public peers and (6) market conditions affecting our industry. Since the initial fair value of common shares at April 29, 2016, our probabilities of successful financing events and the hiring our chief executive officer have caused an increase in our estimate of the fair value of our common shares.

In connection with this initial public offering and after preliminary discussions with the underwriters, we reassessed the fair value of: (1) 1,128,222 restricted common shares issued to our Principal Executive Officer in June 2016 with a fair value of $1.52 per common share; (2) 602,743 common shares underlying stock options granted in August 2016 to our employees and consultants with an exercise price of $2.38 per common share; and (3) 572,568 common shares underlying stock options granted in September 2016 to our employees and directors with a weighted-average exercise price of $4.00 per common share. As a result, we determined that the reassessed fair value of the restricted common shares was $4.95 per common share and the reassessed fair value of the common shares underlying the stock options granted in August and September 2016 was $13.50 per common share. This reassessment will increase share-based compensation expense commencing in the three months ended September 30, 2016. As of September 30, 2016, we expect to have $20.7 million of total unrecognized share-based compensation cost, which we expect to recognize over a weighted-average period of 3.68 years. We determined that the amount of share-based compensation related to the June 2016 grant was not material to the three months ended June 30, 2016.

After the closing of this offering, our board of directors will determine the fair value of each common share underlying share-based awards based on the closing price of our common shares as reported by the NYSE on the date of grant.

Warrant Liability

We record the warrant liability at its estimated fair value as a liability in our consolidated balance sheets. We remeasure the estimated fair value of the warrant liability each reporting period and record the changes in the estimated fair value in our consolidated statement of operations as other (expense) income. We measure 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 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 expenses in our consolidated statements of operations.

The warrant liability may change significantly as additional data is 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 market 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 or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the our results of operations in future periods.

Research and Development Expense

We expense research and development costs 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 Roivant Sciences, Inc. under the Services Agreement and expenses from third parties who conduct research and development activities on our behalf. We expense 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.

As the intellectual property and inventory we acquired from Takeda had no alternative future use on the date of acquisition, we recorded them as research and development expense at April 29, 2016, the date we entered into the license agreement with Takeda, which consisted of the estimated fair value of the common shares transferred to Takeda and the estimated fair value of warrant liability. Significant judgment and estimates were used to estimate the fair value of common shares and warrant liability, as they are not publicly traded and are considered Level 3 measurement within the fair value hierarchy. The estimation of the fair value of the common shares considered discounted cash flow analyses and relevant industry and comparable public company data.

Income Taxes

We account for income taxes in accordance with ASC 740, Income Taxes. Under the assets-and-liability method of ASC 740, 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. Under ASC 740, 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.

We account for uncertain tax positions in accordance with the provisions of ASC 740. 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. As of June 30, 2016, we did not have any significant uncertain tax positions.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU No. 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU No. 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued. It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for reporting periods ending after December 15, 2016, with early adoption permitted. We do not expect the adoption of ASU No. 2014-15 will significantly impact our consolidated financial statements and related disclosures.

In November 2015, the FASB, issued ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. This amendment will simplify the presentation of deferred tax assets and liabilities on the balance sheet and require all deferred tax assets and liabilities to be treated as non-current. ASU No. 2015-17 is effective for fiscal years, and interim periods within those fiscal years beginning after December 15, 2016, with early adoption permitted. We adopted ASU No. 2015-17. The adoption of ASU No. 2015-17 did not have a significant impact on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, 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, 2019, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. We are currently evaluating the new standard and its impact on our 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 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 interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. We expect to adopt this guidance when effective and are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Quantitative and Qualitative Disclosures about Market Risk

We did not have any cash or other financial instruments as of June 30, 2016.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. 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. Relugolix has been evaluated in over 1,300 subjects since 2007, in Phase 1 and multiple large, randomized Phase 2 clinical trials conducted in Japan, North America and the United Kingdom, some of which are ongoing. These trials have produced favorable results in each indication. In these trials, relugolix was shown to be generally well tolerated and to successfully suppress estrogen and progesterone levels in women and testosterone levels in men, consistent with its known mechanism of action.

We plan to initiate two multinational Phase 3 clinical programs for relugolix, one in the first quarter of 2017 in women with heavy menstrual bleeding associated with uterine fibroids and the other in the first half of 2017 in women with endometriosis-associated pain. We completed an End of Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids in early October 2016, and expect to submit our investigational new drug application, or IND, including Phase 3 protocols, to the FDA in 2016. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. Based on a completed End of Phase 2 meeting with the FDA, we also plan to initiate a multinational Phase 3 clinical program for relugolix in men with advanced prostate cancer in the first quarter of 2017. We expect to report top-line data from each of these Phase 3 programs in 2019. We plan to develop our second product candidate, RVT-602, for the treatment of female infertility as part of assisted reproduction. In the second half of 2017, we expect to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial for RVT-602. We intend to develop relugolix in additional indications and augment our current pipeline through the acquisition and in-licensing of complementary, clinical-stage product candidates that we believe can be developed and commercialized in a capital-efficient manner.

Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of the gonadotropins, luteinizing hormone, or LH, and follicle-stimulating hormone, or FSH, thereby decreasing the down-stream production of estrogen and progesterone by the ovaries in women and testosterone by the testes in men. This is a clinically-validated mechanism of action, and there is a commercially available injectable GnRH receptor antagonist for the treatment of advanced prostate cancer. The suppression of estrogen and progesterone levels has been shown to effectively treat the symptoms of uterine fibroids and endometriosis, and the suppression of testosterone levels has been shown to effectively treat advanced prostate cancer.

We believe relugolix has the potential to be a best-in-class oral GnRH receptor antagonist for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain and both a first-in-class and best-in-class oral GnRH receptor antagonist for the treatment of advanced prostate cancer. We believe relugolix, as a once-daily oral therapy, has the potential to provide a substantial improvement over the current standards of care provided by injectable GnRH agonists and antagonists for women and men. In addition to its ease of administration, relugolix has been observed to offer advantages based on its mechanism of action as a GnRH antagonist rather than a GnRH agonist. In studies conducted to date, relugolix resulted in a rapid decline in LH and FSH, and therefore rapidly suppressed estrogen and progesterone production by the ovaries or testosterone production by the testes. Hormone suppression was achieved more quickly compared with the GnRH agonists, which initially stimulate these hormones and cause a flare or worsening of symptoms. Unlike GnRH agonists such as leuprolide, relugolix is not a depot, or slow-release, formulation and hormone levels return to baseline more rapidly after it is discontinued, providing more control for patients and their physicians. For example, a more

rapid return of hormone levels to baseline could be advantageous in the management of a concurrent illness, the restoration of fertility in women desiring to attempt pregnancy and the restoration of sexual function and energy levels in men.

We are developing relugolix to be co-administered with low-dose estradiol and progestin as add-back therapy in our target women's health indications to minimize mineral density loss, a known side effect of estrogen suppression, and improve tolerability. Estradiol is a major estrogen and progestin is a synthetic progestational agent. 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. We believe relugolix with add-back therapy has the potential to be used longer-term, unlike the currently approved GnRH agonist therapies. The low-dose estradiol and progestin add-back therapy we plan to use is approximately one-fifth of the dose used in traditional, combined oral contraceptive pills. This low dose is well-known to minimize bone mineral density loss in a hypoestrogenic state.

In April 2016, we entered into a license agreement with Takeda Pharmaceuticals International AG, or Takeda, through which we acquired the worldwide rights, excluding Japan and certain other Asian countries, to develop and commercialize relugolix. In multiple large, randomized Phase 2 clinical trials conducted by Takeda, relugolix has been shown to be generally well tolerated and to effectively suppress estrogen and progesterone levels in women and testosterone levels in men, consistent with its known mechanism of action. Takeda is currently conducting two Phase 3 trials evaluating relugolix in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding, respectively. Takeda expects to report top-line data from each of these trials in the second half of 2017 and, if these trials are successful, Takeda plans to seek regulatory approval of relugolix for these indications in Japan in 2018. We expect to submit Takeda's Phase 3 data as part of our new drug application, or NDA, to the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids.

In the first quarter of 2017, we plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids. We completed an End of Phase 2 meeting with the FDA for this indication in early October 2016, and expect to submit our IND, including Phase 3 protocols, to the FDA in 2016. In the first half of 2017, we also plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of endometriosis-associated pain. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017.

In a double-blind, placebo-controlled Phase 2 clinical trial in 216 women conducted in Japan from 2011 to 2012, relugolix, administered at doses of 10 mg, 20 mg or 40 mg once daily for 12 weeks, markedly decreased menstrual blood loss associated with uterine fibroids. To be included in the trial, women were required to have a baseline menstrual period blood loss score of at least 120 as measured by the Pictorial Blood Assessment Chart, or PBAC, a method for evaluation of menstrual blood loss in clinical trials. A normal menstrual period has a PBAC score of approximately 70. A treatment responder was defined as a woman with a sum of PBAC scores from week 6 through week 12 of less than 10. Of the women enrolled in the relugolix 40 mg once-daily arm, 83.6% were responders and had marked decrease in menstrual blood loss. No women in the placebo arm responded. The result was statistically significant for each treatment arm versus placebo, with the greatest benefit observed at a dose of 40 mg once daily ($p<0.0001$). P-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of 0.05 or less represents statistical significance, meaning there is a less than 1-in-20 likelihood that the observed results occurred by chance. There was a clear dose-dependent response across relugolix treatment arms, including estradiol suppression and the primary efficacy endpoint for heavy menstrual bleeding.

In a double-blind, placebo-controlled Phase 2 clinical trial in 487 women with endometriosis conducted in Japan from 2011 to 2013, relugolix was administered at doses of 10 mg, 20 mg or 40 mg once daily for 12 weeks. The primary endpoint was the change in pelvic pain from week 8 to week 12 as assessed by visual

analogue scale, or VAS, a patient-reported scale for the quantification of pain. The decline in pain was statistically significant between each dose arm and placebo, with the greatest benefit observed at a dose of 40 mg once daily ($p<0.0001$). There was a clear dose-dependent relationship across treatment arms.

Uterine fibroids and endometriosis represent large women's health markets with significant unmet medical need. We estimate approximately 19.0 million women in the United States have uterine fibroids, approximately 5.0 million of whom suffer from symptoms of the disease. Of these women, we estimate approximately 60%, or 3.0 million women in the United States, are inadequately treated by current medical therapy and require further treatment. We estimate approximately 7.5 million women in the United States have endometriosis, approximately 6.0 million of whom suffer from symptoms of the disease. Of these women, we estimate approximately 20%, or 1.2 million women in the United States, are inadequately treated by oral contraceptives and require further treatment.

Neither heavy menstrual bleeding associated with uterine fibroids nor endometriosis-associated pain has any curative medical solution. Current medical therapies include non-steroidal anti-inflammatory drugs, or NSAIDs, oral contraceptives and GnRH agonists, as well as danazol for endometriosis only. In moderate-to-severe cases of both diseases, medical therapies have been shown to be generally ineffective or the clinical benefit is hampered by a trade-off between efficacy and safety profiles, with drugs such as GnRH agonists limited to short-term use. 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. Further, approximately 100,000 endometriosis-related hysterectomies in women of reproductive age are performed in the United States each year. Complications arising from hysterectomy are common, with 17% to 25% of women experiencing post-surgical complications, including ureteral injury, bowel injury, bladder injury, hemorrhage or infection. Other surgical procedures such as myomectomy, or surgical removal of the fibroids, and laparoscopic procedures for endometriosis are commonly performed. We believe an oral therapy that could be used longer-term has the potential to enable women to avoid surgical intervention that may result in postoperative complications or complications with future pregnancy or even preclude the potential for future pregnancy.

An End of Phase 2 meeting in October 2015 for relugolix for the treatment of advanced prostate cancer confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial, which we intend to initiate in the first quarter of 2017. In two randomized Phase 2 clinical trials in 228 men with advanced prostate cancer conducted in North America and the United Kingdom from 2014 to 2016, relugolix, administered orally for 24 weeks, demonstrated an ability to decrease testosterone to very low levels, commonly referred to as castration levels, and to reduce levels of prostate-specific antigen, or PSA, a key prostate cancer biomarker. These results for relugolix were consistent with those for leuprolide acetate, or leuprolide, a GnRH agonist typically used in ADT, and for degarelix, an injectable GnRH antagonist. Unlike GnRH agonists, relugolix, when orally administered once daily, was shown in these trials to rapidly decrease testosterone levels. In addition, testosterone levels returned to baseline more rapidly after discontinuation of relugolix than after discontinuation of leuprolide or degarelix.

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 in the United States each year. Current treatments used when men are first diagnosed with prostate cancer generally include combinations of surgery and radiation therapy. If the disease recurs or spreads beyond the prostate, androgen deprivation therapy, or ADT, is initiated to lower testosterone and block androgen receptor signaling, which helps shrink the cancer. Prostate cancer that recurs and responds to ADT is referred to as advanced prostate cancer. Approximately 650,000 men with advanced prostate cancer are treated with GnRH agonists each year in the United States.

As part of our license agreement with Takeda, we also acquired the worldwide rights to RVT-602, our second product candidate. RVT-602 is an oligopeptide kisspeptin analog. Kisspeptin is a naturally-occurring

peptide in humans that plays a key role in egg maturation and ovulation by increasing the release of LH and FSH through the stimulation of GnRH secretion. In the second half of 2017, we plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept clinical trial for RVT-602 for the treatment of female infertility as part of assisted reproduction. 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-LH/FSH axis. We believe RVT-602 may mimic natural physiology by inducing the release of LH during assisted reproduction, thereby enhancing the likelihood of successful egg maturation and ovulation at the right time during the cycle without the potential for the uncommon but serious side effects associated with current hormone-stimulation treatment options. We believe RVT-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.

The following chart represents our current product candidate pipeline:

	Product Candidate	Indication	Phase 1	Phase 2	Phase 3	Upcoming Milestones	Myovant Commercial Rights
Myovant	Relugolix with Add-Back Therapy	Uterine Fibroids—Heavy Menstrual Bleeding				Phase 3 Initiation in First Quarter of 2017[1]	Global, Excluding Takeda Territory[5]
		Endometriosis—Pain				Phase 3 Initiation in First Half of 2017[2]	Global, Excluding Takeda Territory[5]
	Relugolix	Advanced Prostate Cancer				Phase 3 Initiation in First Quarter of 2017[3]	Global, Excluding Takeda Territory[5]
	RVT-602	Female Infertility as part of Assisted Reproduction[4]				Phase 1 Initiation in Second Half of 2017	Global

1 Subject to the submission of our IND to the FDA, which we expect to occur in 2016.
2 Subject to our End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017.
3 An End of Phase 2 meeting confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial.
4 RVT-602 has been evaluated in Phase 1 and Phase 2a clinical trials conducted by Takeda in men for the treatment of prostate cancer and hypogonadotropic hypogonadism, or a state of low testosterone levels. We plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept trial.
5 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.

The following chart represents the anticipated near-term milestones for Takeda's development of relugolix in Japan:

	Product Candidate	Indication	Phase 1	Phase 2	Phase 3	Upcoming Milestones	Takeda Commercial Rights
Takeda	Relugolix	Uterine Fibroids—Pain				Top-line Data in Third Quarter of 2017	Takeda Territory[1]
		Uterine Fibroids—Heavy Menstrual Bleeding				Top-line Data in Fourth Quarter of 2017	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.

Our Strategy

Our goal is to be the leading global biopharmaceutical company focused on the innovative treatment of women's health diseases and other endocrine-related disorders in areas of high unmet medical need, and 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 relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain.*** In the first quarter of 2017, we plan to initiate two replicate multinational Phase 3 trials for relugolix with add-back therapy in women with heavy menstrual bleeding associated with uterine fibroids. In the first half of 2017, we plan to initiate two replicate multinational Phase 3 trials for relugolix co-administered with add-back therapy in women with endometriosis-associated pain. We completed an End of Phase 2 meeting with the FDA for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids in early October 2016, and expect to submit our IND, including Phase 3 protocols, to the FDA in 2016. The commencement of our Phase 3 program in women with endometriosis-associated pain is subject to an End of Phase 2 meeting with the FDA, which we expect to occur in the first quarter of 2017. We expect to report top-line data from each of these Phase 3 programs in 2019. If the results of these planned Phase 3 trials are favorable, we intend to submit NDAs to the FDA in 2019 and may submit comparable submissions to other regulatory authorities to obtain marketing approval for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain, respectively. Takeda is currently conducting two Phase 3 trials in Japan for relugolix for the treatment of uterine fibroid-related pain and heavy menstrual bleeding, respectively, and if the results are favorable, Takeda intends to apply for marketing approval in Japan.
- ***Rapidly advance relugolix for the treatment of advanced prostate cancer.*** In the first quarter of 2017, we plan to initiate a multinational Phase 3 clinical trial for relugolix in men with advanced prostate cancer. We expect to report top-line data from this Phase 3 trial in 2019. If the results of this planned Phase 3 trial are favorable, we intend to submit an NDA to the FDA and may submit comparable submissions to other regulatory authorities to obtain marketing approval for relugolix for the treatment of advanced prostate cancer.
- ***Advance clinical development of RVT-602.*** In the second half of 2017, we plan to initiate a Phase 1 healthy-volunteer study in women followed by a Phase 2 proof-of-concept clinical trial of RVT-602 to assess the potential of this oral kisspeptin analog as a treatment to enhance egg maturation in women as part of assisted reproduction, such as in vitro fertilization, or IVF, with a decreased risk of the uncommon but serious side effects associated with current hormone stimulation treatment options.

- ***Expand development of relugolix for additional indications.*** We intend to explore the development of relugolix for additional indications, including polycystic ovary syndrome and precocious puberty.
- ***Acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of women's health diseases or endocrine-related disorders in a capital efficient manner.*** In addition to relugolix and RVT-602, we intend to identify, acquire, develop and commercialize novel, clinical- or commercial-stage product candidates with clinically-validated mechanisms of action in a capital-efficient manner.
- ***Maximize the commercial potential of our product candidates.*** We plan to independently commercialize our product candidates, including relugolix and RVT-602, in the United States and selectively in other territories. Takeda plans to commercialize relugolix in Japan and certain other Asian countries. We may opportunistically seek additional strategic collaborations to maximize the commercial opportunities for our product candidates outside of the United States.

Relugolix

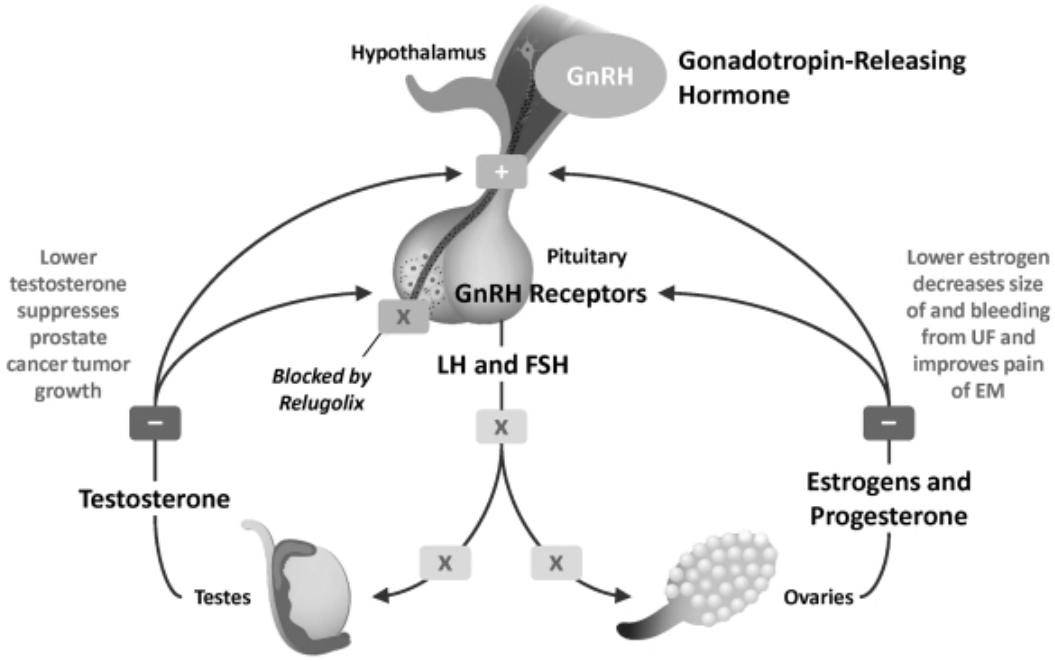
Relugolix is an oral, once-daily, small molecule that acts as a potent antagonist of the GnRH receptor and has a long half-life. The half maximal inhibitory concentration, or IC_{50}, of relugolix, a measure of its potency, is 0.12 nanomolar, or nM, and the half-life, or the time when approximately 50% of relugolix is cleared from the body, is 37 to 42 hours. Relugolix binds to receptors in the anterior pituitary gland to inhibit the release of the gonadotropins, LH and FSH, decreasing the production of estrogen and progesterone in the ovaries, and testosterone in the testes. GnRH antagonists such as relugolix exhibit a classical competitive and reversible blockade of GnRH receptors on the cell membrane of the gonadotropic cells in the pituitary and result in rapid lowering of hormone levels. By contrast, approved agents such as GnRH agonists first stimulate the GnRH receptors, thereby initially increasing hormone levels, which can result in an initial worsening of clinical symptoms, known as hormonal flare. After this initial increase, the pituitary eventually becomes desensitized to the stimulation due to down-regulation of the GnRH receptors, ultimately resulting in a decrease in gonadotropin secretion and hormone levels.

In women, both LH and FSH regulate the secretion of estrogen and progesterone from the ovaries. Suppression of gonadotropin secretion using GnRH antagonists may be an effective treatment for hormone-dependent gynecological diseases such as uterine fibroids or endometriosis due to the direct and immediate inhibition of GnRH action. Lowering estrogen levels in women has been shown to decrease bleeding from, and the size of, uterine fibroids and reduce the pain associated with endometriosis. GnRH antagonists, such as relugolix, rapidly downregulate the gonadotropin-gonadal axis without the transient increase of gonadotropin secretion and the resulting flare associated with use of GnRH agonists such as leuprolide. Once treatment with relugolix is discontinued, estrogen and progesterone levels have been shown to return to baseline within four weeks, on average.

In men, LH stimulates the production of testosterone by the testes. Testosterone is a strong growth factor for prostate cancer. ADT with a GnRH agonist such as leuprolide is the most commonly used treatment to reduce testosterone levels in advanced prostate cancer. GnRH agonists, when administered continuously, have been shown to suppress testosterone secretion by down-regulating gonadotropin secretion from the pituitary, and thereby slow prostate cancer growth. However, the agonists initially stimulate hormonal production and require co-administration with an anti-androgen such as bicalutamide to prevent flare of symptoms in many men, a treatment known as complete androgen blockade. In contrast, GnRH antagonists directly inhibit production of LH, rapidly decrease testosterone levels, do not result in flare of symptoms and do not require co-administration with an anti-androgen. In men, this rapid decrease in testosterone to very low levels, or chemical castration, coupled with the absence of an initial testosterone flare, may allow men to avoid exacerbation of bone pain, increase in urinary symptoms or development of neurologic evidence of disease. Furthermore, once treatment with relugolix is discontinued, testosterone levels have been shown to return to baseline within four weeks, on average.

We believe oral administration of GnRH antagonists may offer flexibility in dosing duration and regimen for both men and women without the inconvenience or potential discomfort of injectable depot formulations. Additionally, hormone levels have been observed to return to baseline more rapidly after discontinuing oral relugolix compared to GnRH agonist depot formulations.

Relugolix Mechanism of Action



Potential Advantages of Relugolix

We believe relugolix has the potential to be a best-in-class oral GnRH receptor antagonist for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-related pain and both a first-in-class and best-in-class oral GnRH receptor antagonist for the treatment of advanced prostate cancer. We believe relugolix may offer significant advantages over currently approved injectable therapies, as well as therapies in late-stage clinical development, based on the following:

- ***Demonstrated Clinical Benefit with a Favorable Safety Profile.*** Relugolix has been evaluated in over 1,300 subjects to date, in Phase 1 and multiple large, randomized Phase 2 clinical trials, some of which are ongoing. In these trials, relugolix has demonstrated clinical benefit for the treatment of symptoms associated with uterine fibroids and endometriosis and advanced prostate cancer, and was observed to be generally well tolerated, consistent with its mechanism of action.
- ***Once-Daily, Oral Administration.*** Based on the existing clinical data, we believe relugolix is the only oral GnRH antagonist in development with the potency and half-life necessary to suppress estrogen and progesterone levels in women and testosterone levels in men with once-daily dosing for our target women's health indications and advanced prostate cancer, respectively. Additionally, we believe once-daily administration of relugolix, if approved, would provide significant advantages over therapies requiring twice-daily doses, such as greater convenience for patients and increased compliance leading to potentially better outcomes.

- ***Rapid Onset of Action.*** In clinical trials conducted to date, relugolix was observed to directly and rapidly decrease the release of LH and FSH and suppress estrogen and progesterone in women and testosterone in men. Further, clinical data to date suggest that relugolix suppresses hormone levels in less than a week and without causing a symptomatic hormonal flare generally associated with GnRH agonists, which take up to three to four weeks to lower hormone levels.
- ***Rapid Reversal of Hormone Suppression.*** In a Phase 2 trial, relugolix has been shown to allow hormone levels to return to baseline more rapidly than the GnRH antagonist depot formulation, degarelix, after discontinuation. The option of rapid return to baseline hormone levels may be an advantage for patients wanting to eliminate any unwanted effects of hormone suppression. For example, women can quickly discontinue treatment for fertility needs, if desired. The ability to reverse effects may also be beneficial in the treatment of prostate cancer by enabling the more rapid return of testosterone levels during intermittent, as opposed to continuous, testosterone suppression with ADT.
- ***Longer-Term Treatment with Add-Back Therapy.*** We plan to commercialize relugolix, if approved, for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain as a fixed-dose combination of relugolix with low-dose estradiol and progestin add-back therapy to minimize bone mineral density loss and other hypoestrogenic symptoms, such as hot flash, commonly associated with GnRH agonists and antagonists. We believe this strategy of suppressing estrogen levels with an oral GnRH antagonist and then adding back the appropriate dose of estradiol and progestin to minimize bone mineral density loss may allow longer-term use in women, and thereby potentially avoiding invasive surgical procedures.
- ***Fixed-Dose Combination.*** We are developing relugolix to be co-administered with hormone add-back therapy in a single pill, taken once daily. We believe that a fixed-dose combination therapy offers the potential to enhance patient compliance. In addition, we believe that a fixed-dose combination may potentially improve patient outcomes by ensuring that the add-back therapy is always taken to address known class side effects, such as bone mineral density loss and hot flash. Finally, we believe that a fixed-dose combination product may offer a meaningful commercial benefit by distinguishing from competitive products that cannot be administered as one combination pill, once daily.

Women's Health Indications

Uterine Fibroids Overview

Uterine fibroids are non-cancerous 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, progesterone and human growth hormone all play important roles 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 social embarrassment.

Uterine fibroids are among the most common reproductive tract tumors in women. We estimate approximately 5.0 million women in the United States suffer from symptomatic uterine fibroids, approximately 3.0 million of whom are inadequately treated by current medical therapy and require further treatment.

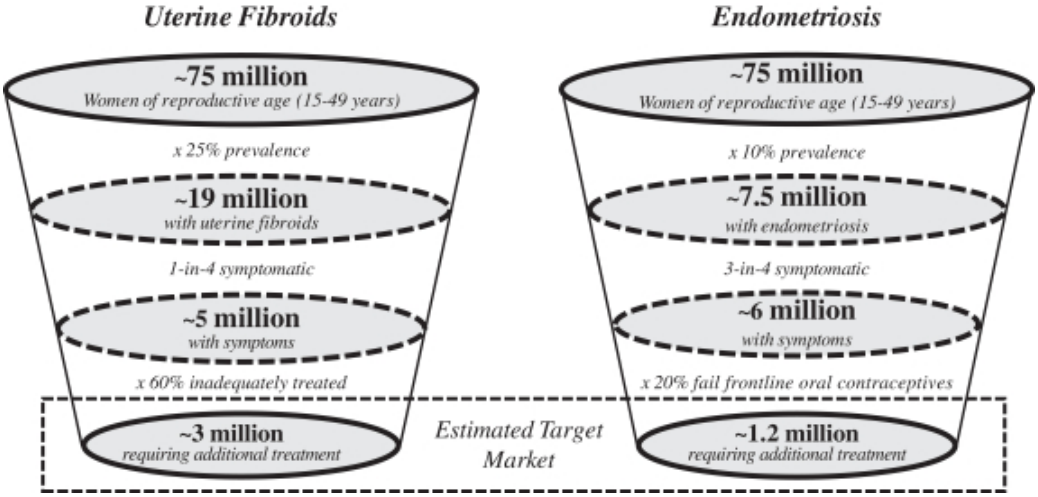
Endometriosis Overview

Endometriosis is a gynecological medical condition in which cells from the lining of the uterus grow outside the uterine cavity, most commonly on the ovaries. The uterine cavity is normally lined with endometrial cells that are under the influence of estrogen and progesterone, which cause the cells to grow, differentiate and shed on a monthly basis. Endometriosis lesions outside the uterus exhibit a pattern of hormonal responsiveness similar to

that of the lining of the uterus. During the menstrual cycle, the lesions grow, differentiate and shed into the abdomen, thereby inducing a cascade of inflammatory events that may lead to non-menstrual pelvic pain, pain during menstruation, painful intercourse and, in some cases, infertility.

According to the Endometriosis Foundation, endometriosis affects an estimated 1-in-10 women during their reproductive years. We estimate that approximately 6.0 million women in the United States suffer from symptomatic endometriosis, approximately 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment.

United States Epidemiology



Treatment Landscape for Women's Health Indications

Uterine Fibroids

The current approach to treating uterine fibroids includes both medical and surgical options. The choice of treatment approach 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 and GnRH agonists. GnRH agonists are used for short-term therapy and may involve low-dose estradiol and progestin hormone add-back therapy to minimize bone mineral density loss 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 or 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.

Lowering estrogen levels decreases the size of uterine fibroids and associated bleeding. Two classes of drugs commonly used for the treatment of heavy menstrual bleeding associated with uterine fibroids in the United States: oral contraceptives, which include estrogen and/or progesterone, and GnRH agonists. The current standard of care for the treatment of patients with mild symptoms includes the use of oral contraceptives or

NSAIDs which are generally prescribed at the time of initial diagnosis. These therapeutic options, however, often do not provide sufficient relief to patients with moderate-to-severe symptoms, who require additional treatment to relieve excessive bleeding and pain.

Leuprolide, marketed as Lupron by AbbVie, is currently the only GnRH agonist approved by the FDA for the management of endometriosis and the pre-operative treatment of patients with anemia caused by uterine fibroids, when co-administered with iron. Leuprolide is also marketed as Leuplin by Takeda in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding. In each case, leuprolide is only indicated for short-term use of six months or less due to the bone mineral density loss associated with longer-term use. Ulipristal acetate, or ulipristal, a selective progesterone receptor modulator, is marketed by Gedeon Richter in Europe as Esmya and as Fibristal in Canada for preoperative treatment of moderate-to-severe symptoms of uterine fibroids. Esmya recently received approval from the European Medicines Agency, or EMA, for the long-term management of uterine fibroid-related symptoms.

Endometriosis

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 are used for short-term treatment and may involve hormone add-back therapy, similar to the use of GnRH agonists for the treatment of uterine fibroids. The FDA has approved Lupaneta Pack, or leuprolide administered with norethindrone acetate, or NETA, 5 mg, to treat pain associated with endometriosis while minimizing bone mineral density loss. For many patients, surgical intervention is ultimately undertaken to relieve pain. After treatment with hormone therapy or conservative surgery, such as ablation of endometriotic lesions, recurrence of endometriosis and related symptoms is common. Approximately 100,000 endometriosis-related hysterectomies are performed each year in the United States.

Other Treatments in Development for Women's Health Indications

AbbVie, in conjunction with Neurocrine Biosciences, is developing an oral GnRH receptor antagonist, elagolix, as a treatment for moderate-to-severe endometriosis-associated pain and for heavy menstrual bleeding associated with uterine fibroids. AbbVie has reported data from two Phase 3 trials in endometriosis and expects to receive FDA marketing approval for that indication in 2018.

In January 2015, AbbVie announced results from its first Phase 3 trial for elagolix in 872 women with moderate-to-severe endometriosis-associated pain. Elagolix doses of 150 mg once daily and 200 mg twice daily were evaluated, and both met the trial's co-primary endpoints ($p<0.001$) of reducing scores of non-menstrual pelvic pain and menstrual pain at three and six months, as measured by the Daily Assessment of Endometriosis Pain scale (previously referred to as the modified Biberoglu and Behrman Score). This scale is a daily questionnaire about menstrual and non-menstrual pelvic pain and painful intercourse administered to patients using an electronic diary. Responder rates at six months for menstrual pain or non-menstrual pelvic pain, respectively, were 23.1% and 34.9% for placebo, 42.1% and 45.7% for elagolix 150 mg once daily, and 75.3% and 62.1% for elagolix 200 mg twice daily. The most common adverse events were hot flash, headache, nausea and fatigue. Women in the placebo arm had a 0.53% increase in bone mineral density at six months, compared with a 0.32% and 2.64% loss in bone mineral density at six months in the elagolix 150 mg once-daily and 200 mg twice-daily arms, respectively.

In February 2016, AbbVie announced top-line results from its second, similarly designed Phase 3 trial for elagolix. After six months of continuous treatment, both doses of elagolix (150 mg once daily and 200 mg twice daily) met the trial's co-primary endpoints of reducing scores of non-menstrual pelvic pain and menstrual pain associated with endometriosis, at three and six months, as measured by the Daily Assessment of Endometriosis Pain scale. Responder rates from this second Phase 3 trial were consistent with results from AbbVie's first Phase

3 trial. Women in the placebo arm had a 0.49% increase in bone mineral density at six months, compared with a 0.71% and 2.45% loss in bone mineral density at six months in the elagolix 150 mg once-daily and 200 mg twice-daily arms, respectively.

AbbVie has initiated a Phase 3 program evaluating elagolix 300 mg twice daily, with and without hormone add-back therapy with estradiol and NETA, or E2/NETA, compared with placebo in women with heavy menstrual bleeding associated with uterine fibroids. In addition, AbbVie is expected to commence a Phase 3b trial of elagolix in combination with E2/NETA in women with pain associated with endometriosis by the end of this year.

AbbVie recently reported data from a Phase 2b trial evaluating elagolix 300 mg twice daily and elagolix 300 mg twice daily in combination with E2/NETA compared with placebo in women with heavy menstrual bleeding associated with uterine fibroids. A responder was defined as a woman with a blood loss less than 80 mL with at least a 50% improvement in blood loss from baseline, as assessed by the alkaline hematin method. In this trial, 91.9% of women in the 300 mg twice-daily arm and 79.0% of women in the 300 mg twice daily in combination with E2/NETA arm responded compared to 26.6% of women in the placebo arm. In this six-month Phase 2b trial, bone mineral density loss was 3.59% in the elagolix 300 mg twice-daily arm and 0.12% in the elagolix 300 mg twice-daily in combination with E2/NETA arm compared to bone mineral density increase of 0.78% in the placebo arm.

ObsEva SA, or ObsEva, is developing OBE2109, an oral GnRH antagonist for the treatment of endometriosis and uterine fibroids. ObsEva in-licensed OBE2109 from Kissei Pharmaceutical Company, Ltd., a Japanese company, and is initiating a Phase 2 clinical trial evaluating multiple doses in women with endometriosis and may start a Phase 3 study in women with uterine fibroids in the first quarter of 2017. ObsEva has not publicly discussed using hormone add-back therapy as part of its current clinical trial design.

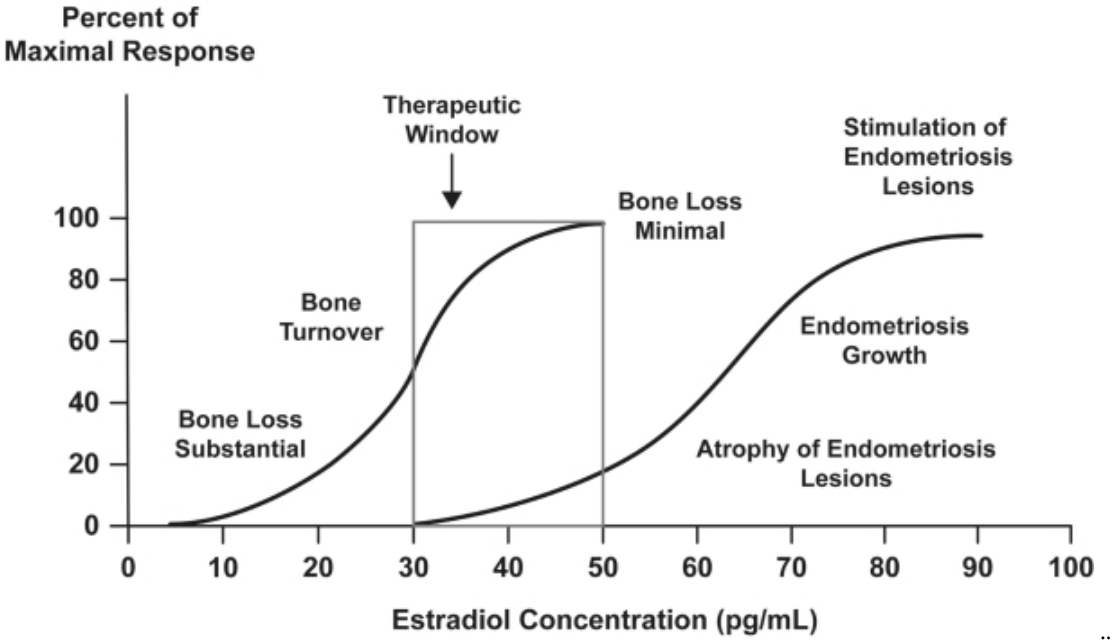
Allergan owns the rights to ulipristal in the United States. In May 2016, Allergan announced results from one of two Phase 3 clinical trials evaluating the efficacy and safety of ulipristal in uterine fibroids. The trial included 101 women randomized to ulipristal at 5 mg or 10 mg once daily, or 56 to placebo for a 12-week course, or one cycle, followed by a 12-week treatment-free period. The study met all co-primary and secondary endpoints with both ulipristal arms achieving significant results over placebo. The co-primary endpoints were percentage of patients with absence of uterine bleeding and time to absence of uterine bleeding. The most common side effects of ulipristal treatment in this study were hypertension, increased blood creatine phosphokinase, hot flash and acne. Allergan expects to report results of their second Phase 3 clinical trial in late 2016 and is expected to file an NDA with the FDA in 2017. Ulipristal is only being evaluated in the United States as a cyclic therapy for short-term use due to concerns related to endometrial effects. Other side effects of ulipristal include hot flash, headache, functional ovarian cysts, vertigo, nausea, acne, sweating, muscle pain and tiredness.

Our Solution for Women's Health Indications

Our goal is to develop and commercialize relugolix for women with uterine fibroids or endometriosis as a once-daily, fixed-dose combination of relugolix and low-dose estradiol and progestin, with the same dose for each indication. We believe a once-daily, single-pill fixed-dose combination product would offer substantial improvement to the current injectable depot GnRH agonists that are the current standard of care for the treatment of uterine fibroids and endometriosis. For example, we believe relugolix with add-back therapy has the potential for longer-term use in women because treatment duration will not be limited by bone mineral density loss, a common side effect associated with GnRh agonists.

Several randomized clinical trials have validated the approach of suppressing estrogen levels with a GnRH agonist and adding back low-dose estrogen and/or progestin to improve safety and tolerability. These results are consistent with the "estrogen hypothesis," which suggests that different tissue types have different sensitivities to

estrogen. Takeda conducted or funded two trials supporting this hypothesis, one from 1993 to 1997 and a second from 1997 to 2000. Third-party investigators completed a third trial supporting this hypothesis in 2013. As shown in the diagram below, we believe that at estradiol concentrations between 30-50 pg/mL, the majority of symptomatic benefits associated with estrogen suppression are preserved, while side effects, including bone mineral density loss, are minimized. We believe that relugolix administered as a once-daily, single-pill fixed-dose combination product with hormone add-back therapy will achieve this estradiol target in a majority of women. With the hormone add-back therapy, we intend to maximize clinical benefit with an acceptable safety profile to provide women with the option of longer-term medical therapy as an alternative to invasive surgical procedures.

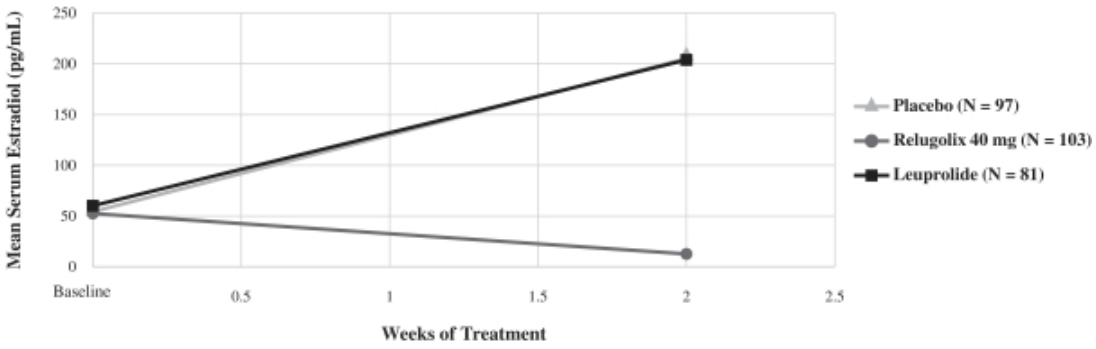


Source: Barbieri, Am J Obstet Gyn, 1992

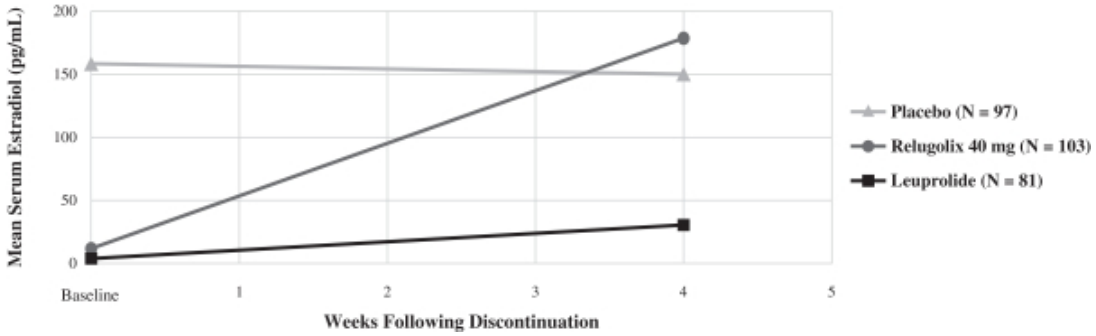
Relugolix has been shown to rapidly suppress estrogen and progesterone levels in women, avoiding the initial increase in these hormones and the accompanying flare of clinical symptoms, such as an increase in menstrual bleeding, frequently observed following initiation of treatment with a GnRH agonist. Further, relugolix may allow hormone levels to return to baseline more rapidly than degarelix, after the drug is discontinued. The option of rapid return to baseline hormone levels may be a significant advantage for patients wanting to eliminate any unwanted effects of hormone suppression. An oral, once-daily GnRH receptor antagonist such as relugolix may provide patients and their physicians with more control. For example, more rapid return of hormonal levels to baseline could be advantageous in the management of a concurrent illness, the restoration of fertility for women desiring to attempt pregnancy or the restoration of sexual function and energy levels in men. Accordingly, we believe there is a significant opportunity to both improve clinical outcomes and address known safety and tolerability issues generally associated with GnRH agonists.

The following graphs show mean serum estradiol concentrations following initiation and discontinuation of administration of placebo, relugolix 40 mg or leuprolide treatment. The first graph shows the mean serum estradiol at baseline, which in this analysis was immediately prior to the start of treatment, and at two weeks after the start of treatment. In this analysis, the mean serum estradiol concentration in women treated with relugolix, which as a GnRH antagonist directly suppresses estradiol levels, decreased after two weeks of treatment. The mean estradiol concentration in women treated with leuprolide, which as a GnRH agonist first stimulates and then suppresses estradiol levels, remained similar to the mean estradiol concentration observed in women administered placebo after two weeks of treatment. The second graph shows the mean serum estradiol at baseline, which in this analysis was at the end of a 24-week treatment period, and at four weeks after the discontinuation of treatment. The baseline shows that both relugolix and leuprolide suppressed estradiol to very low levels after 24 weeks of treatment. In this analysis, relugolix was observed to have faster reversal of estradiol suppression as compared to leuprolide, resulting in a mean serum estradiol concentration similar to the mean serum estradiol concentration observed in women administered placebo four weeks after discontinuation of treatment. Estradiol levels in women of reproductive age fluctuate between 50 pg/mL and 275 pg/mL during the normal menstrual cycle. No statistical comparisons were conducted. This analysis of serum estradiol concentrations was performed by third-party investigators in connection with Takeda's completed Phase 2 trial for relugolix for the treatment of endometriosis-related pelvic pain described below.

Serum Estradiol Following Treatment Initiation



Serum Estradiol Following Treatment Discontinuation



Phase 3 Clinical Development for Women's Health Indications

In the first quarter of 2017, we plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids. We completed an End of Phase 2 meeting with the FDA for this indication in early October 2016, and expect to

submit our IND, including Phase 3 protocols, to the FDA in 2016. In the first half of 2017, we also plan to initiate a multinational Phase 3 program, composed of two replicate clinical trials, for relugolix for the treatment of endometriosis-associated pain. In 2007, Takeda submitted an IND for relugolix (also known as TAK-385) to the FDA for the treatment of endometriosis and, in May 2016, Takeda transferred this IND to us. We expect to hold an End of Phase 2 meeting with the FDA in the first quarter of 2017 to request confirmation that there are no additional clinical trials or nonclinical studies required to support the initiation of our Phase 3 program for endometriosis and that our planned trials, if successful, will be sufficient to support the submission of an NDA in that indication.

Takeda Phase 3 Clinical Development for Uterine Fibroids

Takeda is currently conducting two Phase 3 trials with relugolix in Japan for the treatment of uterine fibroid-associated pain and heavy menstrual bleeding, respectively. The first 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. The second study is a multi-center, randomized, double-blind non-inferiority study to evaluate the efficacy and safety of relugolix in 288 women with symptomatic uterine fibroids. Relugolix 40 mg once daily will be 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 will be the proportion of women who receive a total score of less than 10 on the PBAC, the same endpoint used in the Phase 2 trial.

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 uterine fibroid-related pain and heavy menstrual bleeding is successful, Takeda plans to seek regulatory approval of relugolix in Japan for the treatment of uterine fibroid-related pain and heavy menstrual bleeding in 2018. Prior to our acquisition of the rights to develop and commercialize relugolix, if approved, for the treatment of heavy menstrual bleeding associated with uterine fibroids in the United States, Takeda had not submitted an IND for relugolix to the FDA for this indication. We will be solely responsible for obtaining FDA approval for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids.

Our Planned Phase 3 Program for Uterine Fibroids

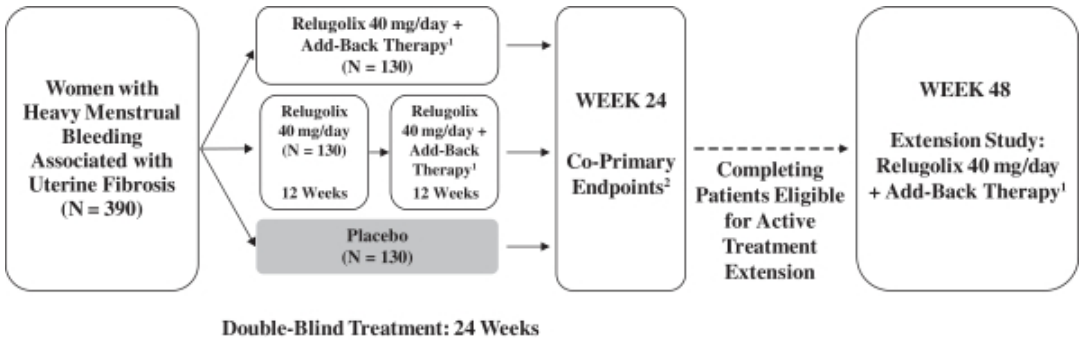
Our two proposed replicate Phase 3 clinical trials in women with heavy menstrual bleeding associated with uterine fibroids will randomize women to one of three arms using 1:1:1 randomization. Women will receive treatment with relugolix 40 mg once daily co-administered with commercially available low-dose hormone 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 hormone add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. All patients completing the initial 24-week period will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormone add-back therapy for an additional 24-week period, or a total treatment period of 48 weeks, to evaluate the safety of long-term treatment. Each of the two replicate trials is expected to enroll approximately 390 women, with 130 women in each active treatment arm and 130 women in the placebo arm.

The primary efficacy endpoint for these trials is expected to be the percentage of responders with less than 80 mL uterine blood loss per menstrual cycle and at least a 50% reduction from baseline to last month of treatment in menstrual blood volume as measured by the alkaline hematin method, a quantitative measurement of menstrual blood loss. The secondary efficacy endpoints are expected to include the change from baseline in hemoglobin, the reduction in uterine and fibroid volume and pain reduction. 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. We expect the safety database at the time of

NDA submission to be sufficient to support dosing for 12 months or longer. We will conduct a bridging study to demonstrate bioequivalence of the fixed-dose combination of relugolix with low-dose estradiol and progestin to co-administered relugolix with low-dose estradiol and progestin. 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.

The following graphic represents the anticipated trial design for each of our two replicate Phase 3 trials for relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids:

Anticipated Phase 3 Trial Design for Relugolix for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids



[1]Commercially available low-dose estradiol and progestin.
[2]The percentage of women with less than 80 mL uterine blood loss per menstrual cycle and at least a 50% reduction in menstrual blood volume from baseline to last month of treatment as measured by the alkaline hematin method.

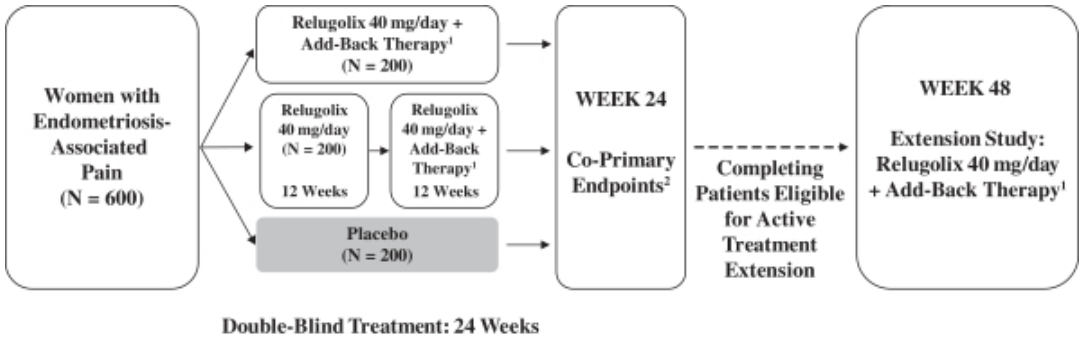
Our Planned Phase 3 Program for Endometriosis

Our two proposed replicate Phase 3 clinical trials in women with endometriosis-associated pain will randomize women to one of three arms using 1:1:1 randomization. Women will receive treatment with relugolix 40 mg once daily co-administered with commercially-available, low-dose hormone 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 hormone add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. All women completing the initial 24-week period will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormone add-back therapy for an additional 24 weeks, or a total treatment period of 48 weeks, to evaluate the safety of long-term treatment. Each of the two replicate trials is expected to enroll approximately 600 women, with 200 women in each active treatment arm and 200 women in the placebo arm.

The co-primary efficacy endpoints for these trials is expected to be the percentage of responders with reductions in non-menstrual pelvic pain and menstrual pain, as assessed by an endometriosis-specific patient questionnaire administered daily. Secondary endpoints will include additional questionnaires assessing 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. We expect the safety database at the time of NDA submission to be sufficient to support dosing for 12 months or longer. If not already completed for the uterine fibroid indication, we will conduct a bridging study to demonstrate bioequivalence of the fixed-dose combination of relugolix with low-dose estradiol and progestin to co-administered 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.

The following graphic represents the anticipated trial design for each of our two replicate Phase 3 trials for relugolix for the treatment of endometriosis-associated pain:

Anticipated Phase 3 Trial Design for Relugolix for the Treatment of Endometriosis-Associated Pain



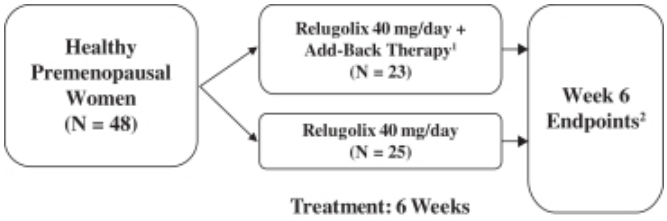
[1]Commercially available low-dose estradiol and a progestin.
[2]Reduction in dysmenorrhea, or painful menstruation, and non-menstrual pelvic pain as assessed using the Symptoms of Endometriosis Scale, a daily patient questionnaire for the assessment of endometriosis-associated pain, scored on the Numeric Rating Scale, a universal pain screening scale which asks patients to indicate the intensity of pain on a scale of 0-10.

Phase 1 Pharmacokinetic and Pharmacodynamic Trial for Relugolix with Add-Back Therapy

We recently completed a six-week Phase 1 clinical trial in 48 healthy premenopausal women, evaluating the pharmacokinetics and pharmacodynamics of relugolix 40 mg administered with and without add-back therapy. The add-back therapy used in this Phase 1 clinical trial, 1 mg estradiol and 0.5 mg norethindrone acetate, is the same low-dose estradiol and progestin add-back therapy that we intend to use in each of our planned Phase 3 trials. In this Phase 1 clinical trial, the plasma concentrations of relugolix and add-back therapy were measured, as well as LH, FSH, estradiol, and progesterone levels. Early biomarkers of bone mineral density loss were also assessed.

The following graphic represents the trial design for our Phase 1 pharmacokinetic and pharmacodynamics trial for relugolix with add-back therapy:

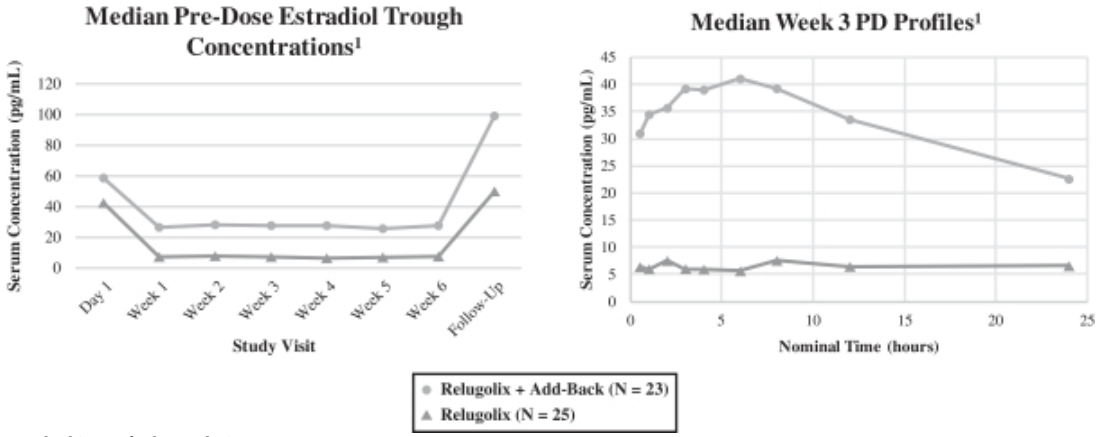
Phase 1 Pharmacokinetic and Pharmacodynamic Trial Design for Relugolix with Add-Back Therapy



1 Commercially available low-dose estradiol and progestin.
2 Primary endpoints include steady-state pharmacokinetic parameters of relugolix, estradiol, norethindrone and ethinyl estradiol; area under the concentration-time curve; predose concentration, average concentration, maximum concentration, time to maximum concentration and elimination half-life of relugolix. Secondary endpoints include safety and tolerability parameters and hot flash.

Estradiol levels were sampled before doses of relugolix to determine the median trough plasma concentrations of estradiol in women receiving relugolix with or without add-back therapy. The median pre-dose estradiol trough levels are depicted below in graph on the left. The median pharmacokinetic profiles of estradiol at week 3 in women receiving relugolix with or without hormone add-back therapy are presented below in the graph on the right. These data demonstrate that the trough levels are above the desired target minimum estradiol concentration of 20 pg/mL. The pharmacokinetic profile of estradiol demonstrates the achievement of estradiol levels throughout the day in the target range of 20 to 50 pg/mL.

In this Phase 1 clinical trial, this hormone add-back therapy achieved estradiol levels above 20 pg/mL, the level demonstrated to protect women from bone mineral density loss, yet generally below 50 pg/mL, which we believe will maximize the benefit of low estrogen levels on the heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain. We believe this strategy of maximal estrogen suppression coupled with adding back low-dose estradiol and progestin may preserve much of relugolix's clinical benefit while minimizing bone mineral density loss and improving tolerability, thereby potentially enabling longer-term use.



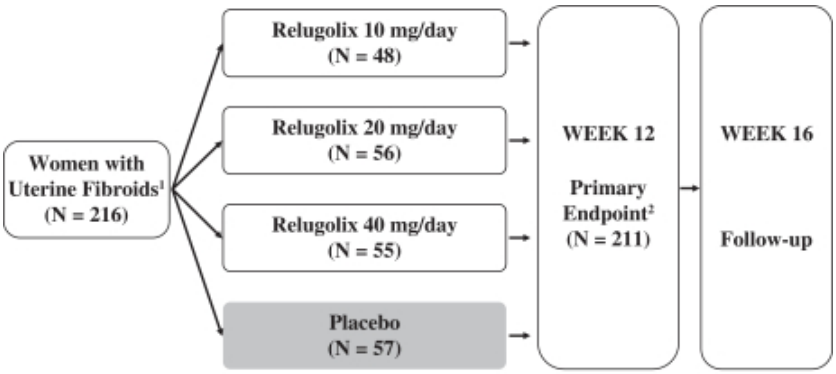
[1] Data shown are preliminary and subject to further analysis.

Existing Clinical Data in Women's Health Indications

Uterine Fibroids

Takeda completed a Phase 2 clinical trial (TAK-385/CCT-001) in women with uterine fibroids in Japan. A total of 216 women were randomized to relugolix at doses of 10 mg, 20 mg or 40 mg once daily administered orally, or placebo, each administered for 12 weeks. The following graphic represents the trial design for TAK-385/CCT-001:

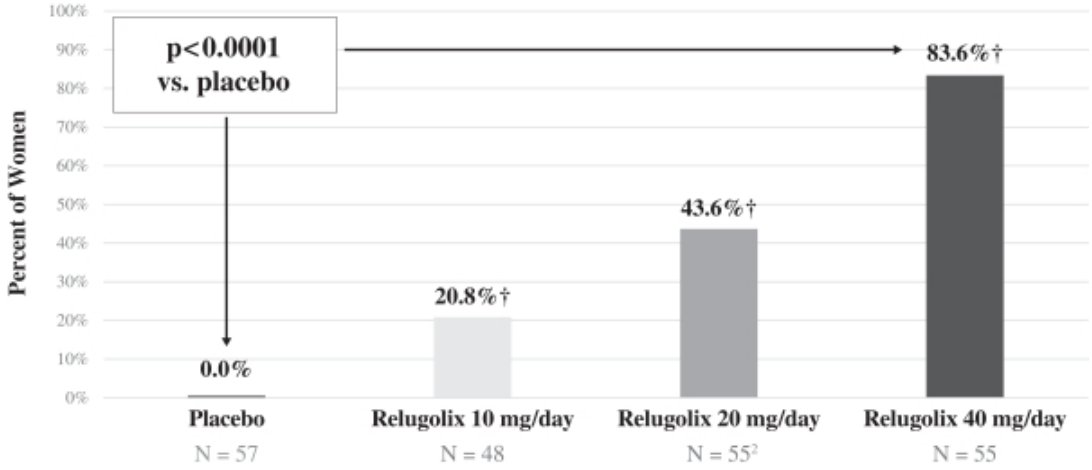
Trial Design for Completed Phase 2 Trial for Relugolix for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids



[1]Premenopausal females aged 20 years or older with a diagnosis of UF, with a total PBAC score ≥120.
[2]Decrease in menstrual blood loss as measured by percent of patients with a total PBAC score from week 6 to week 12 of <10.

The Phase 2 trial demonstrated dose-dependent decreases in menstrual blood loss and an increase in mean blood hemoglobin concentration, and suggested a reduction in fibroid and uterine volumes as compared with placebo. To be included in the trial, women were required to have a baseline PBAC score of at least 120, confirming heavy menstrual bleeding, in addition to uterine fibroids confirmed by ultrasound, magnetic resonance imaging, computed tomography or laparoscopy. A responder for the primary endpoint analysis was defined as a patient with a sum of PBAC scores from week 6 through week 12 of less than 10. In the relugolix 40 mg once-daily dose arm, 83.6% of women were responders and had marked decrease in menstrual blood loss compared with 0% in the placebo arm ($p<0.0001$). Further, in the 40 mg once-daily arm, 72.7% of women achieved amenorrhea from week 6 through week 12 compared with 0% in the placebo arm. Although all doses evaluated (10 mg, 20 mg and 40 mg once daily) demonstrated significant improvements in menstrual blood loss compared with placebo, the benefit was greatest at the 40 mg once-daily dose. Secondary efficacy endpoints, including mean change in myoma volume, uterine volume, and hemoglobin, also demonstrated dose-dependent clinical benefit. Women in the 40 mg once-daily treatment arm experienced decreases in myoma and uterine volume at 12 weeks of 48.8% and 50.7%, respectively, compared to patients receiving placebo. Further, women receiving 40 mg relugolix once-daily experienced a mean increase in hemoglobin at 12 weeks of 0.72 g/dL compared to patients receiving placebo. Mean estradiol levels were fully suppressed below the assay lower limit of quantification of 10 pg/mL at a dose of 40 mg once daily (<10 pg/mL in 75% of patients). On the basis of the findings observed in this trial, we believe 40 mg once-daily relugolix to be an appropriate dose for Phase 3 evaluation in heavy menstrual bleeding associated with uterine fibroids.

Percent of Women with Markedly Decreased Blood Loss at End of Treatment Period[1]
(Primary Endpoint of PBAC <10)

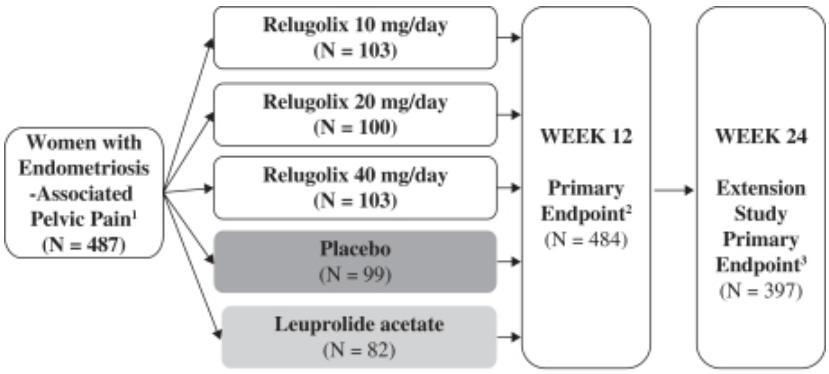


[1] Data shown is from the relugolix CCT-001 study using PBAC method of assessing blood loss during week 6 to week 12.
[2] 56 patients were randomized to relugolix 20mg/day; 55 were included in the analysis.
† Statistically significant difference with p<0.001 observed for each relugolix treatment arm versus placebo.

Endometriosis

In a Phase 2 clinical trial (TAK-385/CCT-101) with an extension study (TAK-385/OCT-101) of women with endometriosis, 487 women were randomized to relugolix at doses of 10 mg, 20 mg or 40 mg administered orally once daily for 12 weeks, to placebo for 12 weeks, or to leuprolide, 3.75 mg administered subcutaneously every four weeks for 12 weeks. The following graphic represents the trial design for TAK-385/CCT-101 and TAK-385/OCT-101:

Trial Design for Completed Phase 2 Trial for Relugolix for the Treatment of Endometriosis-Associated Pelvic Pain

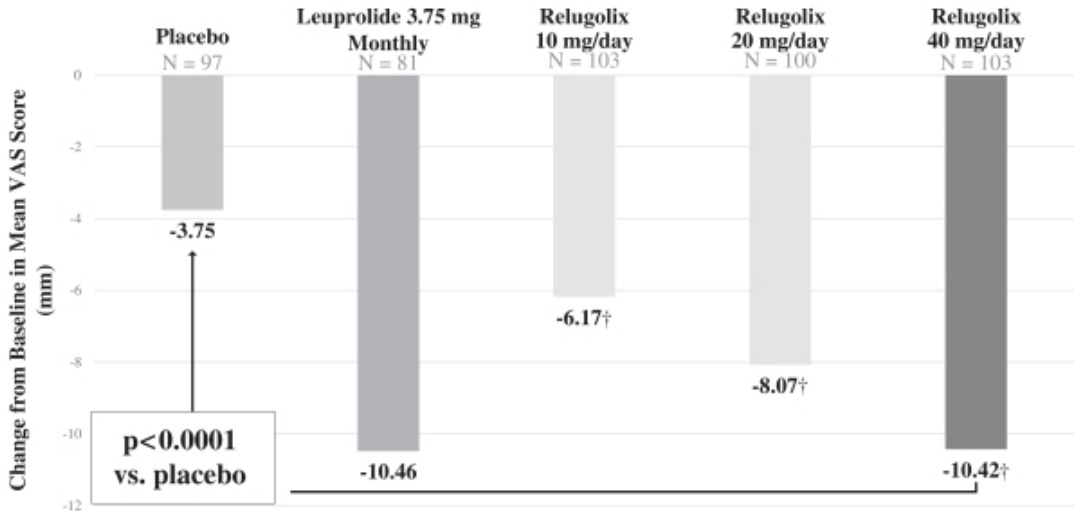


[1]Premenopausal females aged 20 years or older with diagnosis of endometriosis within the past five years.
[2]Change in VAS score for pelvic pain.
[3]Safety measures, including bone mineral density loss, and adverse events.

The trial demonstrated dose-dependent decreases from baseline in pelvic pain. Pelvic pain, including both non-menstrual pelvic pain and menstrual pain, was assessed by VAS score. The primary endpoint was the change

from baseline in mean VAS score for pelvic pain from week 8 through week 12. The mean pelvic pain VAS scores at baseline for the four groups ranged between 14.6 mm to 15.6 mm. The mean change from baseline in the VAS score was -10.42 mm in the relugolix 40 mg arm versus -3.75 mm in the placebo arm ($p<0.0001$). All doses were significantly better than placebo, with the greatest benefit observed at the highest dose evaluated, 40 mg once daily. The mean change from baseline in the VAS score for the leuprolide arm was -10.46 mm, which was similar to that of the relugolix 40 mg arm. Secondary efficacy endpoints also demonstrated clinical benefit. Secondary efficacy endpoints included individual VAS scores for non-menstrual pelvic pain, menstrual pain and painful intercourse during the treatment period; the modified Biberoglu and Behrman score for pelvic pain, a commonly used endometriosis-specific patient questionnaire; use of analgesics to treat pelvic pain; proportion of women achieving amenorrhea, or the absence of menstrual blood loss; and quality of life using the endometriosis health profile-30 questionnaire. Clinical improvement was observed on all pain endpoints, including dose-dependent responses in mean VAS score for dysmenorrhea, mean modified Biberoglu and Behrman score for pelvic pain and mean modified Biberoglu and Berhman score for dysmenorrhea. In the 40 mg once-daily treatment arm, mean changes on these endpoints were -29.7, -0.325, and -1.16, respectively, compared to -5.21, -0.178, and -0.172 for patients receiving placebo. The proportion of days in which the women used analgesics and the amount of menstrual bleeding both decreased, while the proportion of women who achieved amenorrhea increased in a time-dependent manner depending on relugolix dose level. The effects of relugolix on pelvic pain were maintained and estradiol levels suppressed for the duration of the study in the 397 women who enrolled in the extension study and received an additional 12 weeks of treatment, or a total of 24 weeks of treatment. On the basis of the efficacy findings observed in this trial, we believe 40 mg once-daily relugolix to be an appropriate dose for Phase 3 evaluation in endometriosis-associated pain. Four weeks after treatment discontinuation, median estradiol levels had returned to above baseline levels in the relugolix 40 mg arm (137 pg/mL), whereas median levels in the leuprolide arm remained suppressed (11 pg/mL).

Change from Baseline in Patient-Reported Pelvic Pain Score at End of Treatment[1]
(Primary Endpoint of VAS Score)



[1] Data shown is from the relugolix 12-week CCT-101 study, data measured from the VAS score over the last four weeks of treatment.
† Statistically significant difference with $p<0.05$ observed for each relugolix treatment arm versus placebo.

The table below sets forth what we believe to be key characteristics of the product candidates, relugolix and elagolix.

Key Characteristics of Relugolix and Elagolix

	Relugolix[1]	Elagolix[2]
Observed Half-life	37 - 42 hours	2 - 6 hours
Observed Potency[3]	IC_{50} = 0.12 nM	IC_{50} = 1.5 nM
Phase 3 Dose Frequency	Uterine Fibroids[4]: Once daily (planned) Endometriosis[5]: Once daily (planned)	Uterine Fibroids[4]: Twice daily Endometriosis[5]: Once or twice daily
Phase 3 Dose by Indication	Uterine Fibroids[4]: 40 mg once daily (planned) Endometriosis[5]: 40 mg once daily (planned)	Uterine Fibroids[4]: 300 mg twice daily Endometriosis[5]: 150 mg once daily, or 200 mg twice daily
Dose at Which Maximum Estrogen Suppression Observed	40 mg once daily	200 mg - 300 mg twice daily
Use of Add-back Therapy in Phase 3	Uterine Fibroids[4]: Phase 3 clinical trials planned to start first quarter of 2017 with add-back therapy Endometriosis[5]: Phase 3 clinical trials planned to start first half of 2017 with add-back therapy	Uterine Fibroids[4]: Phase 3 clinical trials with and without add-back therapy started in 2016 Endometriosis[5]: Not in initial Phase 3 trials; Phase 3b with add-back therapy expected to start in 2016
Food Effect	Yes: Dosed on empty stomach once daily	Yes: Dosed on empty stomach up to twice daily
Clinical Trials Ongoing in Prostate Cancer	Yes: Phase 2 clinical trials ongoing; Phase 3 clinical trial planned to start in first quarter of 2017	No

[1] Based on the results of clinical trials to date and our Phase 3 development plan for relugolix.
[2] Based on publicly available nonclinical and clinical data to date and Phase 3 development plan for elagolix.
[3] IC_{50} is a quantitative measure of the drug concentration needed to inhibit a given biological process by half; a lower IC_{50} indicates a more potent drug.
[4] Target indication of heavy menstrual bleeding associated with uterine fibroids.
[5] Target indication of endometriosis-associated pain.

Relugolix, administered at a once daily dose of 40 mg, was observed in clinical trials to suppress estrogen levels below the limit of detection in most women. At these very low estrogen levels, for example less than 20 pg/mL, relugolix also decreases bone mineral density to a level that is unsafe for long-term clinical use. The decrease in bone mineral density was also observed with doses of elagolix and leuprolide that maximally suppress estrogen levels. In the Phase 2 endometriosis study in Japanese women of relugolix 40 mg once daily, bone mineral density at the lumbar spine decreased 4.9% over 24 weeks of treatment. Leuprolide 3.75 mg monthly injections decreased bone mineral density by 4.4% in the same time period. In this same Phase 2 endometriosis study, the placebo group had a bone mineral density decrease of 0.2%. In a Phase 2 study of elagolix 300 mg administered twice daily to North American women with uterine fibroids, bone mineral density decreased 3.6% over six months of treatment. In this study, the placebo group had a bone mineral density increase of 0.8%.

Suppressing estrogen levels to low levels provides a consistent baseline upon which to add back low-dose estradiol and progestin in a controlled fashion. In our Phase 1 clinical trial for relugolix with and without add-back therapy, this hormone add-back therapy achieved estradiol levels above 20 pg/mL, the level demonstrated to protect women from bone mineral density loss, yet generally below 50 pg/mL, which we believe will maximize the benefit of low estrogen levels on the heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain. We believe this strategy of maximal estrogen suppression coupled with adding back low-dose estradiol and progestin may preserve much of relugolix's clinical benefit while minimizing bone mineral density loss and improving tolerability, thereby potentially enabling longer-term use.

Based on the existing clinical data, we believe relugolix is the only oral GnRH antagonist in development with the potency and half-life necessary to suppress estrogen and progesterone levels in women and testosterone levels in men with once-daily dosing for our target women's health indications and advanced prostate cancer, respectively.

Advanced Prostate Cancer

Overview

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 either: PSA biochemical relapse following primary surgical or radiation therapy of curative intent; newly diagnosed metastatic prostate cancer; or advanced localized disease for which immediate radiation or surgical therapy is not indicated. The cure rate following surgery, depending on the stage of the cancer, is about 70% overall and, following radiation, about 50% to 60%. Approximately 25% to 30% of men will, therefore, progress to advanced disease, excluding those with metastatic disease at the time of diagnosis.

First-line treatment for advanced prostate cancer typically involves treatment with androgen deprivation therapies, or ADT, which are therapies that drastically 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 men with prostate cancer progress, they remain on ADT while other therapies are added, typically until death.

Treatment Landscape for Advanced Prostate Cancer

Currently, most men with prostate cancer in developed countries receive medical rather than surgical castration. GnRH agonists, such as long-acting leuprolide depot injections, are the current standard-of-care for achieving medical castration, causing long-term desensitization and down regulation of the LH-gonadal axis. Approximately 650,000 men with advanced prostate cancer are treated with GnRH agonists each year in the United States. GnRH agonists may be associated with mechanism-of-action limitations. For example, overstimulation of GnRH receptors on the pituitary promotes an initial testosterone surge that not only delays the onset of testosterone suppression, but also may result in a potentially detrimental initial exacerbation of clinical symptoms such as bone pain in advanced disease, known as a clinical or hormonal flare. Importantly, testosterone surges, also known as microsurges, can also occur following repeated administration of GnRH agonists.

In 2008, degarelix (marketed as Firmagon), an injectable GnRH antagonist, was approved by the FDA as an alternative form of ADT. In 2009, degarelix was approved by the European Medicines Agency for the treatment

of patients with advanced prostate cancer. As a GnRH antagonist, degarelix achieves, within the first one to two weeks of administration, suppression of testosterone to castration levels and a corresponding decrease in PSA levels with no initial agonist activity. Recent nonclinical research and an independent third-party meta-analysis of multiple trials evaluating ADT, suggest that GnRH antagonists, such as degarelix, may have an additional advantage on cardiac safety. In the meta-analysis, among men with pre-existing cardiovascular disease, the risk of cardiac events within one year of initiating therapy was significantly lower among men treated with a GnRH antagonist compared with GnRH agonists; however, such differences require confirmation in future prospective studies. We believe degarelix has not achieved significant market acceptance because of the need for monthly depot injections in large aggregate volumes. We are not currently aware of any other GnRH antagonist in clinical development as an ADT for prostate cancer.

Our Solution for Advanced Prostate Cancer

When compared to a GnRH agonist such as leuprolide, we believe relugolix may offer several potential advantages based on its oral administration, rapid onset of testosterone suppression within four days, absence of clinical hormonal flare, no need for anti-androgen therapy to protect the patient from flare symptoms, and rapid return to baseline testosterone levels after the last dose, which may result in more rapid improvements in quality of life, such as higher energy levels and restored sexual function. This may be particularly beneficial to men undergoing intermittent, rather than continuous, ADT.

When compared to an injectable GnRH antagonist such as degarelix, we believe relugolix may offer several advantages, while retaining the same benefits of GnRH antagonist pharmacology compared with GnRH agonists. In particular, relugolix is designed to be administered orally, rather than as a painful monthly injection, and may provide a more rapid return to baseline testosterone levels after the last dose.

Our Phase 3 Clinical Development Plan for Advanced Prostate Cancer

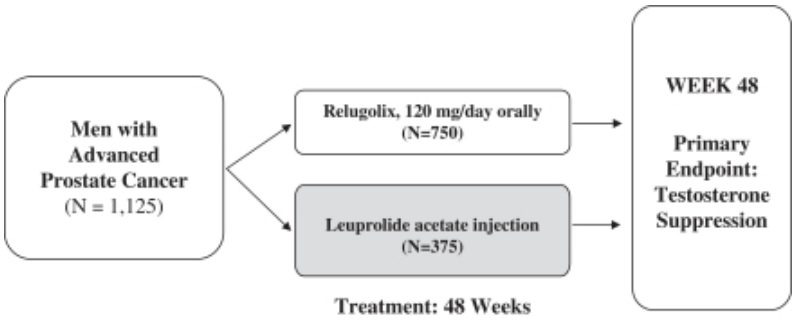
We intend to initiate a Phase 3 trial for relugolix for the treatment of advanced prostate cancer in the first quarter of 2017. In 2013, Takeda submitted an IND to the FDA for relugolix (also known as TAK-385) for the treatment of advanced prostate cancer and, in May 2016, Takeda transferred this IND to us. An End of Phase 2 meeting in October 2015 confirmed that there are no additional clinical trials or nonclinical studies required to support the initiation of a Phase 3 trial. Moreover, we believe that this Phase 3 trial, if successful, will be sufficient to support the filing of an NDA. The European Scientific Advice procedure and an End of Phase 2 meeting with the Japanese health authority have also been completed.

Our planned Phase 3 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 plan to 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 plan to include a leuprolide arm to gain approval in other major markets where the demonstration of non-inferiority to leuprolide is required.

The primary efficacy endpoint accepted by the FDA will be testosterone suppression (£ 50 ng/dL) from week 5, day 1 through week 48, day 7. Relugolix must demonstrate that the lower bound of the 95% confidence interval of the percent of patients achieving testosterone suppression is at least 90%. The secondary efficacy endpoint will be PSA reduction as a percentage change from baseline. Testosterone reduction is an approvable endpoint in the United States and several other 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.

The following graphic represents the anticipated trial design for our Phase 3 clinical trial for relugolix for the treatment of advanced prostate cancer:

Anticipated Phase 3 Trial Design for Relugolix for the Treatment of Advanced Prostate Cancer



Existing Clinical Data

In a Phase 1 study of healthy men, relugolix at daily doses of 80 mg to 180 mg for up to 28 days achieved and maintained serum testosterone at castration levels of £ 50 ng/dL (N = ~15/arm). Less testosterone suppression was observed at daily doses of 40 mg and 60 mg for up to 14 days (N = 6/arm). Data from this study guided the selection of the relugolix doses used in Takeda's Phase 2 clinical trials for relugolix for the treatment of advanced prostate cancer.

In 2014, two Phase 2 clinical trials of relugolix (C27002 and C27003) in men with advanced prostate cancer requiring ADT were initiated. Study C27002, which remains ongoing, enrolled patients with advanced prostate cancer, including either: 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. In this open-label, parallel group study, men in North America were enrolled to receive oral relugolix at a daily dose of 80 mg or 120 mg (after a single oral loading dose of 320 mg) (N = 50 in each arm) or to receive GnRH agonist therapy (leuprolide 22.5 mg administered subcutaneously every 12 weeks, N = 25) for up to 48 weeks. Study C27003, which is completed, enrolled men in North America or the United Kingdom requiring six months ADT as neoadjuvant and adjuvant therapy to external beam radiation therapy. Patients were randomized to relugolix 120 mg once daily (after a single oral loading dose of 320 mg) (N = 65) or to degarelix 80 mg intramuscularly every four weeks (N = 38) for 24 weeks (after a single loading dose of 240 mg).

Trial Design for Phase 2 Trials for Relugolix for the Treatment of Advanced Prostate Cancer

Study	Relugolix vs. Lupron C27002	Relugolix vs. Degarelix C27003
No. of Patients	125 men (with hormone-sensitive advanced prostate cancer)	103 men (receiving neoadjuvant/adjuvant therapy to external beam radiotherapy)
Location (Date)	North America (2014 - ongoing)	North America United Kingdom (2014 - 2015)
Design	80 mg or 120 mg relugolix or leuprolide 22.5 mg 12-week depot injection	120 mg relugolix or degarelix 80 mg 4-week depot injection
Treatment Duration	48 weeks plus 48-week safety extension	24 weeks with 12 weeks of follow-up
Analyses Performed	Interim analysis performed after ~75 patients treated for at least 24 weeks	Final analysis

In study C27002, a pre-specified interim analysis was conducted after a combined 75 patients completed at least 24 weeks of treatment in either of the two relugolix arms. Results from the interim analysis demonstrated that both doses of oral, once daily relugolix, 80 mg and 120 mg, rapidly reduced testosterone levels below the castration threshold (£50 ng/dL) and maintained these levels through at least 48 weeks. These data are comparable to testosterone levels achieved by leuprolide 22.5 mg every 3 months, although no statistical comparisons were conducted between the two arms.

Phase 2 Trials for Relugolix for the Treatment of Advanced Prostate Cancer

Sustained Castration Rates[1] in Phase 2 Trials
Mean percentage of men achieving <50 ng/dL testosterone

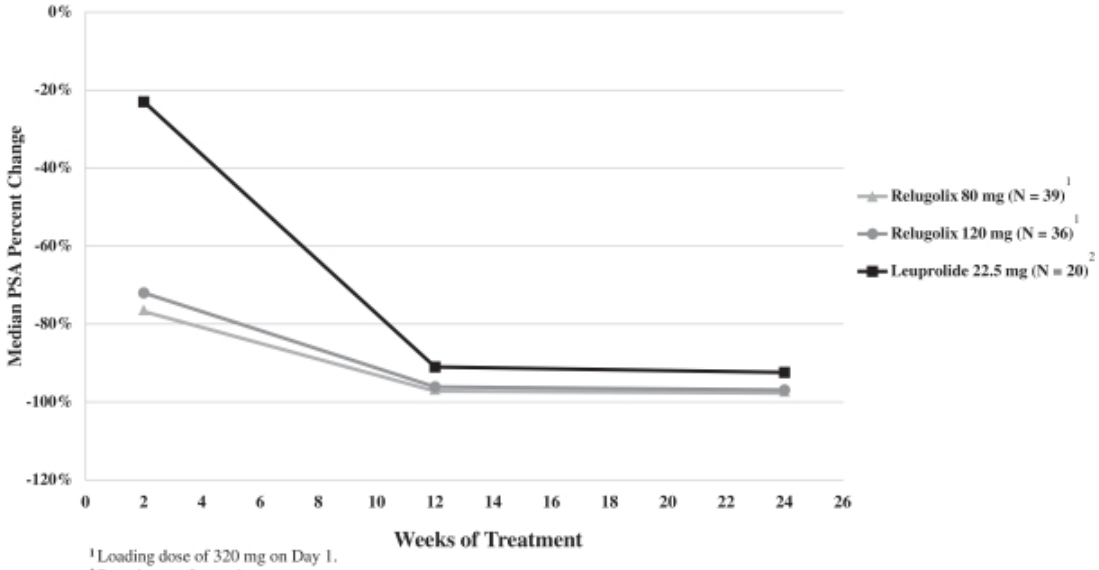
Time point	Study C27002			Study C27003	
	Interim Analysis			Final Analysis	
	Relugolix 80 mg[2] N = 39	**Relugolix 120 mg[2] N = 36**	**Lupron 22.5 mg[3] N = 20**	**Relugolix 120 mg[2] N = 65**	**Degarelix 80 mg[4] N = 38**
24 weeks (95% CI)	**92%** (79.1, 98.4)	**92%** (77.5, 98.2)	**95%** (75.1, 99.9)	**93%** (77.9, 99.2)	**85%** (62.1, 96.8)
48 weeks (95% CI)	**90%** (75.8, 97.1)	**92%** (77.5, 98.2)	**95%** (75.1, 99.9)	**N/A**	**N/A**

[1] At each visit after week 4 through end of the treatment period.
[2] Loading dose of 320 mg on day 1.
[3] Dosed every 3 months.
[4] Loading dose of 240 mg on day 1, then dosed every month.
CI = Confidence Interval

After two weeks of treatment, the median percent change in PSA for the relugolix 120 mg arm was 72.0%, compared to 23.0% in the leuprolide arm. PSA reductions in the relugolix arms were sustained through 24 weeks of treatment. In the relugolix 120 mg arm, 83% of patients achieved a PSA reduction from baseline of at least 50%, compared to 20% of patients in the leuprolide group.

PSA Reduction in Phase 2 Trials

Median Percentage Change from Baseline



[1] Loading dose of 320 mg on Day 1.
[2] Dosed every 3 months.

PSA Reduction in Phase 2 Trials

Percentage of subjects with ≥50% or ≥90% reduction from baseline

Criteria		Study C27002	
		Relugolix 120 mg[1] N = 36	Leuprolide 22.5 mg[2] N = 20
% of subjects (N) with PSA Reduction at 4 weeks	≥50% PSA reduction	83% (N=30)	20% (N=4)
	≥90% PSA reduction	8% (N=3)	0% (N=0)

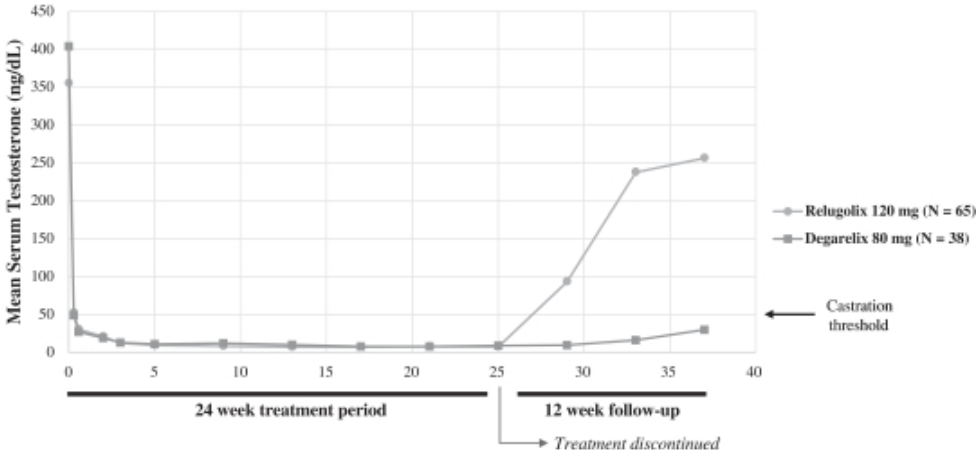
[1] Loading dose of 320 mg on day 1.
[2] Dosed every three months.

Study C27003 demonstrated rapid and sustained suppression of testosterone levels for the 24 week treatment duration. Importantly, in this study, the testosterone recovery following the last dose of treatment was more rapid in the relugolix arm than in the degarelix arm. Baseline testosterone levels were similar between the

two arms (356 ng/dL and 404 ng/dL in the relugolix and degarelix groups, respectively), but at 12 weeks after discontinuing therapy, the median testosterone levels were 257 ng/dL and 30 ng/dL, respectively. No statistical comparisons were made between the two arms.

Phase 2 Trial (C27003) for Relugolix for the Treatment of Advanced Prostate Cancer

Recovery of Testosterone Levels after Discontinuation of Treatment



On the basis of the efficacy findings observed in these two Phase 2 trials, we believe relugolix 120 mg once daily (following a single loading dose of 360 mg) to be an appropriate dose for Phase 3 evaluation in men with advanced prostate cancer.

Completed Phase 1 Clinical and Preclinical Studies of Relugolix

Phase 1 Clinical Trials

Phase 1 clinical trials with relugolix conducted in 862 healthy adults in the United States, Japan and the United Kingdom demonstrated similar pharmacokinetic profiles after single and multiple dosing across these populations. In healthy, premenopausal women receiving single and multiple doses of relugolix, median LH, FSH and estradiol concentrations were suppressed in a dose-dependent manner when compared with subjects receiving placebo. The duration of suppression appeared to increase with increasing single doses of relugolix ranging from 10 mg to 80 mg. In healthy men, relugolix achieved and maintained testosterone at castration levels (£ 50 ng/dL) at daily doses of 80 mg to 180 mg for up to 28 days of dosing. Less robust testosterone suppression was observed at daily doses of 40 mg and 60 mg. The following chart summarizes the Phase 1 clinical trials completed by Takeda for relugolix:

Summary of Relugolix Phase 1 Clinical Trials

TAK-385_101: A Double-Blind, Randomized, Placebo-Controlled, Sequential-Panel, Ascending Single- and Multiple-Dose Study to Evaluate the Effect of TAK-385 on Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Premenopausal Women

Location (Date)	Subject Description	Number of Subjects	Key Findings
United States (2007-2008)	Healthy premenopausal women	N = 120 (99 relugolix / 21 placebo)	• Generally well tolerated following single doses of 1 mg to 80 mg and 14-day once-daily doses of 10 mg to 40 mg • Frequency of adverse events was similar between placebo and relugolix with no apparent dose relationship • Dosing with food reduced absorption of relugolix • Relugolix suppressed mean concentrations of endogenous LH, FSH, and estradiol following repeat doses in dose-dependent manner

TAK-385/CPH-001: A Phase I, Double-Blind, Randomized, Placebo-Controlled, Sequential-Panel, Ascending Single- and Multiple-Dose Study to Evaluate the Effect of TAK-385 on Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Premenopausal Women

Location (Date)	Subject Description	Number of Subjects	Key Findings
Japan (2007-2008)	Healthy premenopausal women	N = 144 (120 relugolix / 24 placebo)	• Generally well tolerated following single doses of 1 mg to 80 mg and 14-day once-daily doses of 10 mg to 40 mg

TAK-385_102: A Phase 1, Open-label Study to Evaluate the Pharmacokinetic Drug-Drug Interaction Between Multiple Doses of TAK-385 and a Panel of Cytochrome P-450 Substrates Administered Concomitantly as an Indiana Cocktail in Healthy Subjects

Location (Date)	Subject Description	Number of Subjects	Key Findings
United States (2008)	Healthy subjects	N = 16	• Multiple dosing with 20 mg oral once-daily relugolix for 7 days does not have a relevant effect on the pharmacokinetic profile of substrates for drug metabolizing enzymes CYP1A2, CYP2C9, CYP2D6, and CYP3A4

TAK-385/CPH-010: An Open-Label, Drug-Drug Interaction Study to Evaluate the Effects of Multiple Oral Doses of Erythromycin on the Pharmacokinetics of a Single Oral Dose of TAK-385 in Healthy Adult Male and Female Subjects

Location (Date)	Subject Description	Number of Subjects	Key Findings
Japan (2012)	Healthy subjects	N = 20	• When 20 mg single-dose relugolix was administered in combination with erythromycin, the plasma exposure of relugolix was increased ~6-fold, likely as a result of increased oral bioavailability and/or absorption • The incidence of adverse events known to occur due to the pharmacological effect of relugolix was higher in the combination period than that in the relugolix only period • All adverse events were mild and recovered without any treatment

C27001: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Dose, Inpatient and Outpatient Study in Healthy Men to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy for Testosterone Lowering of TAK-385, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist

Location (Date)	Subject Description	Number of Subjects	Key Findings
United Kingdom (2011-2012)	Healthy men	N = 176 (128 relugolix / 48 placebo)	• Sustained, lower-threshold medical castration of <50 ng/dL was consistently achieved with once-daily 80 mg, 160 mg, or 180 mg relugolix for 28 days, and rapid reductions in serum testosterone were achieved by using a loading dose approach (320 mg or 360 mg). • Single and multiple doses administered were generally well tolerated

TAK-385_106: A Randomized, Double-Blind, Placebo- and Positive-Controlled (Open-Label Moxifloxacin), 4-Arm Parallel-Group Study to Evaluate the Effect of TAK-385 on Cardiac Repolarization in Healthy Subjects

Location (Date)	Subject Description	Number of Subjects	Key Findings
United States (2013)	Healthy subjects	N = 280 (140 relugolix/ 70 placebo/ 70 moxifloxacin)	• Single doses of 60 mg and 360 mg relugolix had no effect on cardiac repolarization (QTc interval) • Both doses were generally well tolerated in healthy subjects

C27005: An Open-label, Drug-Drug Interaction Study to Evaluate the Effects of Multiple Oral Doses of Fluconazole and Atorvastatin on the Pharmacokinetics of a Single Oral Dose of TAK-385 in Healthy Subjects

Location (Date)	Subject Description	Number of Subjects	Key Findings
United States (2014)	Healthy subjects	N = 40	• Fluconazole or atorvastatin did not result in a clinically relevant change in relugolix exposure, suggesting CYP3A inhibition is not the dominant mechanism of the previously observed interaction with erythromycin in TAK-385/CPH-010, rather increased oral bioavailability due to P-glycoprotein inhibition

TAK-385-1009: An Open-Label, Single-Centre, Two-Part, Phase 1, Mass Balance Study to Assess the Absorption, Distribution, Metabolism, Excretion, and Absolute Bioavailability of Orally Administered [^{14}C]-TAK-385 in Healthy Male Subjects

Location (Date)	Subject Description	Number of Subjects	Key Findings
United Kingdom (2014)	Healthy males	N = 12	• After oral administration of a radiolabeled dose of relugolix, the majority of radioactivity was recovered in the feces as a metabolite, with little in the urine. • There were no major circulating relugolix metabolites • Oral availability of relugolix was determined to be ~12%

TAK-385-1010: An Open-label, Randomized, Three-Way Crossover Study Evaluating the Relative Bioavailability and Effect of Food on TAK-385 Tablet Formulations in Healthy Subjects

Location (Date)	Subject Description	Number of Subjects	Key Findings
United States (2015)	Healthy subjects	N = 54	• Relative bioavailability of two new tablet formulations was similar compared to existing tablet formation • Dosing with food reduced absorption of relugolix

Preclinical Studies

In a series of in vitro and in vivo pharmacological studies conducted by Takeda, relugolix was observed to be a potent and highly selective antagonist for human GnRH receptor. Administration of elagolix in targeting the human GnRH receptor resulted in reductions in reproductive organ weights of male mice, suggesting that relugolix suppressed blood testosterone levels. Orally administered relugolix suppressed the hypothalamic-pituitary axis in castrated cynomolgus monkeys at doses of 1 mg/kg and higher.

In nonclinical pharmacokinetic studies, oral relugolix showed rapid absorption and elimination, with low oral bioavailability. Oral bioavailability is a measure of absorption and is the fraction of an administered dose that reaches the systemic circulation of unchanged drug, one of the principal pharmacokinetic properties of drugs. Relugolix has been evaluated for safety in single-dose studies in rats and monkeys and in repeat-dose toxicity studies in mice, rats and monkeys. Genotoxicity, carcinogenicity, reproductive toxicity and phototoxicity studies have also been performed. No safety issues have been identified from nonclinical studies that would preclude the continued development of relugolix in humans. Studies conducted to date have shown that relugolix is not mutagenic or clastogenic (a mutagenic agent giving rise to or inducing disruption or breakages of chromosomes) and it was not observed to be carcinogenic in two-year mouse and rat toxicity studies.

Summary of Pharmacokinetic and Safety Data for Relugolix

As of July 2015, Takeda had completed or had ongoing 15 Phase 1 or Phase 2 clinical trials for relugolix in a total of 1,839 subjects. Of these, 1,309 subjects, including 792 women and 517 men, had been administered relugolix. Overall, relugolix has been generally well tolerated in the Phase 1 and 2 trials. No safety issues of concern were identified that preclude the continued development of relugolix based on assessments of adverse events, physical examinations, vital sign measurements, clinical laboratory values and electrocardiogram findings. Importantly, in a dedicated study evaluating the impact of relugolix on electrocardiograms, relugolix did not prolong the corrected QT interval. Relugolix treatment results in rapid, dose-dependent suppression of estradiol in women and testosterone in men. The predominant half-life is 37 to 42 hours. Relugolix has low oral bioavailability (average 11.6%), presumably due to intestinal efflux by the Permeability-glycoprotein, or P-gp, transporter. Relugolix is highly metabolized, and there are no major circulating metabolites. Clinical drug-drug interaction studies suggest the exposure of relugolix is increased by P-gp inhibitors. Food was shown to decrease the extent of relugolix absorption. The pharmacokinetics and pharmacodynamics of relugolix have been evaluated and appear similar in American and Japanese volunteers, despite the lower mean body mass index observed in Japanese volunteers.

The overall safety profile of relugolix in clinical studies was consistent with its known mechanism of action as a GnRH receptor antagonist, including bone mineral density loss, hot flash, headache, loss of energy, mood swings, decreased libido and decreased muscle mass. The majority of adverse events have been mild and resolved without treatment.

In the Phase 2 trial of women with uterine fibroids and heavy menstrual bleeding, the most common treatment-emergent adverse events in the relugolix 40 mg once-daily arm, occurring in at least 10% of women included hot flash, nasopharyngitis, abnormal bleeding from the uterus, abnormally heavy menstrual bleeding, headache and genital hemorrhage. In the Phase 2 trial of women with pelvic pain and endometriosis, the most common treatment-emergent adverse events in the relugolix 40 mg once-daily arm, occurring in at least 10% of women included hot flash, abnormal

bleeding from the uterus, nasopharyngitis, and abnormally heavy menstrual bleeding. The majority of events of abnormal bleeding from the uterus, abnormally heavy menstrual bleeding and genital hemorrhage in both trials were reported in the first 28 days as estradiol and progesterone levels were falling. A very high proportion of women in each study achieved amenorrhea, including 72.7% in the uterine fibroids trial and 73.4% in the endometriosis trial. The common adverse events observed with relugolix in women with uterine fibroids or endometriosis were generally consistent with its mechanism of action and those observed with leuprolide.

In an interim analysis of the Phase 2 prostate cancer study C27002, the most common treatment-emergent adverse events occurring in at least 10% of men with advanced prostate cancer in the relugolix 80 mg or 120 mg once-daily arms, or leuprolide arm, included hot flash, alanine aminotransferase increase, fatigue, cataract, aspartate aminotransferase increase, diabetes mellitus, hyperhidrosis, muscle spasm, injection site reaction, frequent daytime urination and weight decrease. The common adverse events observed with relugolix in men with prostate cancer were generally consistent with its mechanism of action and those observed with leuprolide.

Across all relugolix clinical trials, a total of 34 serious adverse events were reported in the more than 1,300 relugolix-treated subjects and patients as of July 10, 2016, of which three were reported by the investigator as possibly related to relugolix, including an event of abnormal liver function tests (moderate grade), one of cerebral infarction (grade unspecified) and one of embolic stroke (grade 2). Three deaths (grade 5 events) have occurred in patients treated with relugolix; all deaths occurred in the prostate cancer study, C27002, and were assessed as unrelated to relugolix.

Bone mineral density decreases were observed at 12 and 24 weeks in premenopausal women treated with relugolix 40 mg once daily and were similar to those observed with leuprolide (3.75 mg subcutaneously administered every four weeks) over the same duration, consistent with the near complete estrogen suppression observed in the trials. Specifically, in the Phase 2 trial for relugolix for the treatment of uterine fibroids, the mean loss in bone mineral density in the relugolix 40 mg once-daily arm was 2.3% at week 12.

The following tables show the incidence of adverse events occurring in greater than 10% of women and the bone mineral density loss following administration of placebo, relugolix 40 mg or leuprolide in the Phase 2 trial for relugolix for the treatment of endometriosis.

Incidence of Adverse Events Occurring in ≥10% in Placebo, Relugolix 40 mg, and Leuprolide Arms in Phase 2 Trial in Women with Pelvic Pain and Endometriosis			
Adverse Events	Week 12 Analysis of Safety Population Number (%) of Patients Reporting Event		
	Placebo (N = 97)	Relugolix 40 mg/day[1] (N=103)	Leuprolide (N = 81)
Irregular Menstrual Bleeding	4 (4.1%)	25 (24.3%)	32 (39.5%)
Heavy Menstrual Bleeding	4 (4.1%)	13 (12.6%)	9 (11.1%)
Hot Flashes	8 (8.2%)	54 (52.4%)	34 (42.0%)
Nasopharyngitis	21 (21.6%)	22 (21.4%)	15 (18.5%)

Bone Mineral Density					
Mean Bone Mineral Density Loss at 24 weeks	Placebo (N = 75)	Relugolix 10 mg/day[1] (N = 81)	Relugolix 20 mg/day[1] (N = 77)	Relugolix 40 mg/day[1] (N = 88)	Leuprolide (N = 64)
	0.2%	1.6%	2.6%	4.9%	4.4%

[1]Relugolix administered without low-dose hormonal add-back therapy.

On the basis of the efficacy findings observed in this trial, we believe relugolix 40 mg once daily to be an appropriate dose for Phase 3 evaluation in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain. The purpose of co-administration with low-dose estradiol and progestin as add-back therapy, is to prevent bone mineral density loss and increase tolerability by ameliorating hot flash and other symptoms consistent with a hypoestrogenic state while maintaining the improvement in clinical symptoms, in support of longer-term dosing.

RVT-602

Overview

As part of our license agreement with Takeda, we acquired the worldwide rights to RVT-602, our second product candidate, which has been evaluated in over 150 men. RVT-602 is an oligopeptide kisspeptin analog. 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. In the second half of 2017, we plan to initiate a Phase 1 healthy volunteer study in women followed by a Phase 2 proof-of-concept clinical trial for RVT-602 for the treatment of female infertility in women as part of assisted reproduction, such as IVF. We expect to submit an IND, or other comparable application, to the FDA or foreign regulatory authorities in the first

half of 2017. 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-LH/FSH axis. We believe RVT-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.

Female Infertility and Assisted Reproduction

Kisspeptin plays a key role in egg maturation and ovulation by increasing the release of LH and FSH through the stimulation of GnRH secretion. During the process of egg maturation, FSH stimulates an ovarian follicle, the sac which contains the developing egg, to grow and the egg within it to develop. When the egg is appropriately mature, a surge of LH occurs. Approximately 24 to 36 hours after the LH surge, the follicle bursts releasing the egg into the Fallopian tube. When hormonal imbalances occur, the processes of egg maturation and ovulation can be disrupted, decreasing a woman's chances for pregnancy and resulting in female infertility.

A major cause of female infertility is hormone imbalance, with approximately 85% related to hypothalamic-pituitary dysfunction. Fertility specialists use a group of medications, including GnRH agonists, to temporarily correct ovulatory problems and increase a woman's chance for pregnancy. IVF is a method of assisted reproduction that involves surgically removing an egg from the woman's ovary and combining it with sperm in a laboratory dish. If the egg is fertilized, resulting in an embryo, the embryo is transferred to the woman's uterus. Every assisted reproduction cycle includes the following essential steps as part of the ultimate goal of pregnancy: (1) maturation of the ovarian follicles, which control the release of an egg in the ovaries, with preparations of LH and FSH; (2) prevention of premature ovulation by treating with a GnRH agonist to prevent release of LH; (3) triggering egg maturation at the appropriate time with human chorionic gonadotropin or a GnRH agonist; (4) egg retrieval and fertilization; and (5) transplantation of fertilized egg followed by biochemical tests for pregnancy.

Current Treatment Landscape for Assisted Reproduction

Current treatments used in assisted reproduction cycles include preparations of FSH and LH administered to stimulate multiple follicles and eggs to grow and mature, followed by a GnRH agonist to prevent premature ovulation. At the right time, human chorionic gonadotropin or a GnRH agonist is administered as an injection to stimulate ovulation of the mature egg. Ovarian hyperstimulation syndrome, or OHSS, results from an abnormal enlargement of the ovarian follicles following egg maturation and stimulation with human chorionic gonadotropin or GnRH agonists (step 3 in the assisted reproduction cycle). Severe OHSS is characterized by ovarian enlargement, accumulation of fluid in the abdomen, nausea and vomiting, fluid in the chest cavity, and can even result in kidney and lung failure and death.

Our Solution

We believe RVT-602, an analog of the naturally-occurring kisspeptin peptide in humans, may mimic natural physiology by inducing the LH 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 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 non-physiologic elevations in LH 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 LH, kisspeptin analogs, such as RVT-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 these agents as a safe alternative to the standard egg maturation trigger in every assisted reproduction protocol. To our knowledge, RVT-602 is the only kisspeptin analog in clinical development and thus has the potential to become a safe alternative egg-maturation trigger in this space.

Our Phase 2 Clinical Development Plan

RVT-602 was initially developed by Takeda as an ADT for prostate cancer and, with a different dosing regimen, as a treatment for hypogonadotropic hypogonadism, or a state of low testosterone levels in men. Both acute and continuous administrations of RVT-602 have been studied in human males. Phase 1 trials demonstrated that RVT-602 in single doses as low as 1 µg given by subcutaneous injection was a potent stimulus of LH and testosterone concentrations, while continuous infusion of RVT-602 ultimately results in reversible suppression of testosterone. Over 150 men have been treated to date. In April 2016, we acquired exclusive, worldwide rights to RVT-602 for all human diseases and conditions. Takeda is no longer developing this compound. Although RVT-602 may have potential as a treatment for prostate cancer and hypogonadotropic hypogonadism. We believe RVT-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.

To explore this hypothesis, in the second half of 2017, we plan to initiate a Phase 1 single-ascending dose safety and pharmacokinetic/pharmacodynamic study in healthy female volunteers. This is expected to be followed by an open-label proof-of-concept Phase 2 study in women undergoing IVF. The objective of the Phase 2 study will be to further evaluate the safety of RVT-602 in women undergoing assisted reproduction, particularly with respect to the occurrence of OHSS.

Pharmacokinetic and Safety Data for RVT-602

RVT-602 has been studied in five Phase 1 trials, conducted between June 2008 and September 2011, involving men aged 50 to 79 who were either healthy or had prostate cancer. The pharmacokinetics of single and repeated doses of RVT-602 or as administered by infusion is predictable as a function of dose, and is stable over time. Single doses as low as 1 µg potently stimulate LH and testosterone release in healthy males, while repeated higher doses or continuous subcutaneous infusion rapidly down regulate the pituitary-testicular axis. The overall safety profile was favorable. Non-severe or non-serious adverse events included hot flash, loose stools, diarrhea, dizziness, orthostatic hypotension, headache and injection site reactions.

In vitro and in vivo pharmacological studies have shown that RVT-602 is a potent agonist of kisspeptin receptors. Continuous subcutaneous administration of RVT-602 was effective in lowering plasma testosterone levels in rats, dogs, monkeys and humans, suggesting that it has potential as an ADT in advanced prostate cancer, while low-dose and intermittent RVT-602 therapy may be effective as a stimulatory agent for secondary hypogonadotropic hypogonadism, as well as for late onset hypogonadism, in humans.

Safety pharmacology studies showed that there were no effects on the cardiovascular, respiratory and central nervous systems, with the exception of a slight and transient decrease in body temperature in rats at the subcutaneous dose of 3 mg/kg and higher. In toxicity studies, subcutaneous doses of RVT-602 were well tolerated in rats and dogs. In rats, subcutaneous treatment with RVT-602 resulted in localized atrophy of the seminiferous tubules at single or repeated doses as low as 0.003 mg/kg, and this lesion did not resolve 13 weeks after cessation of treatment. The RVT-602-induced focal atrophy in the rat testis appears to be species-specific, as such changes were not noted in dogs. Similar species specificity has been observed for GnRH agonists. RVT-602 is not mutagenic or clastogenic.

The overall safety profile to date and the observed effects on the pituitary-gonadal axis in animals and humans support the continued development of RVT-602. We believe that RVT-602 may promote ovulation in a physiologic manner during IVF without the life-threatening side effect of OHSS. Therefore, we plan to explore the utility of RVT-602 for the treatment of female infertility as part of assisted reproductive technology, such as IVF, specifically as a potential replacement for human chorionic gonadotropin.

License Agreement with Takeda Pharmaceuticals International AG

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 the compound TAK-385, which we now refer to as relugolix, and the compound TAK-448, which we now refer to as RVT-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 non-exclusive license in the Takeda Territory to manufacture relugolix and to conduct development of relugolix for prostate cancer, solely for our territory. The territory for our exclusive license for RVT-602 covers all countries worldwide. Our license includes a right of reference to regulatory materials related to relugolix and RVT-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 non-exclusive rights to conduct development and manufacturing as described above. We also granted to Takeda a non-exclusive license in our territory to manufacture relugolix and RVT-602 and to conduct development of relugolix for uterine fibroids and endometriosis, in each case solely for 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 RVT-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 RVT-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 RVT-602 in our territory and must use commercially reasonable efforts to do so in each country in our territory in which we obtain regulatory approval. Takeda is solely responsible, at its expense, for all activities related to the commercialization of relugolix in the Takeda Territory, and must use diligent efforts to commercialize relugolix for prostate cancer in the Takeda Territory following receipt of regulatory approval.

We will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and RVT-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 Roivant Sciences Ltd., 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 RVT-602 for prostate cancer in the Takeda Territory. If, during such period, we or any of our non-public 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 them 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 also entered into an investor rights agreement with Takeda. Please see the sections titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG" and "—Investor Rights Agreement" for further information regarding these agreements and the warrant.

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, contingent upon the closing of the sale of at least $30.0 million of our common shares to the Pfizer Affiliate in this offering or in a concurrent private placement, we have agreed to grant to the Pfizer Affiliate a right of first negotiation with respect to any transaction that we would propose to a third party involving (1) the license or sale of rights to develop and commercialize relugolix or RVT-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 (2) 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 closing of this offering, (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 this offering or in a concurrent private placement, (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 this offering, (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 this offering or in a concurrent private placement, (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.

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 product manufacturing, storage and distribution, or testing. While relugolix was being developed by Takeda, it was also being manufactured by 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 to 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.

We expect that the existing drug substance transferred from Takeda to us under the Takeda Agreement will be sufficient for us to complete our planned Phase 3 programs for relugolix. If relugolix is approved by the FDA for commercial use, we also will rely on Takeda or other third-party manufacturers to supply us with sufficient commercial quantities of relugolix. In addition, we expect that the RVT-602 drug substance transferred from Takeda to us under the Takeda Agreement will be sufficient for us to complete our planned Phase 3 program for RVT-602. We intend to contract with a third party to fill, finish, supply, store and distribute the drug product for this program, if necessary. If we are unable to continue our relationship with Takeda or initiate a new relationship with one or more other third-party manufacturers, we could experience delays in our commercialization efforts as we locate and qualify new manufacturers.

Relugolix is a small molecule that can be manufactured using commercially available technologies. We acquired data from Takeda related to the chemical synthesis and manufacturing of relugolix, 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 simple structure and synthesis of the compound.

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, a GnRH receptor antagonist in

development at AbbVie that is currently in Phase 3 development. ObsEva is also developing an oral GnRH antagonist, OBE2109, for the treatment of endometriosis and uterine fibroids. ObsEva is initiating a Phase 2 clinical trial evaluating multiple doses in women with endometriosis and may start a Phase 3 study in women with uterine fibroids in the first quarter 2017. Further, Allergan is developing ulipristal, a selective progesterone receptor modulator, in the United States for uterine fibroids and expects to file an NDA with the FDA in 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 diseases and other endocrine-related disorders.

In addition to other GnRH receptor antagonists in active development, we are aware of many 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, RVT-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.

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 RVT-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 RVT-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 RVT-602 molecule as a composition of matter, and its use in treating advanced prostate cancer, as well as certain sustained release formulations containing RVT-602. The patent family directed to the RVT-602 composition of matter and method of use naturally expires in 2028 in the U.S. and in 2026 ex-U.S., 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 RVT-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, we expect the term of the composition of matter patent to RVT-602 will be extended up to about 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 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 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.

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 at any time during the product development process may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs warning or untitled letters, imposition of a clinical hold, withdrawal of approval, 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 pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's GLP regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with 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 advisory committee review, if applicable
- 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 cGMPs; 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.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. An IND sponsor must submit the results of preclinical testing 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 preclinical 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, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted 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 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. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

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 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 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 preclinical, 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 sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

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 may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

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 GCPs. 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 cGMPs 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. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under 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. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. Such supplements are typically reviewed within 10 months of receipt.

Post-Approval Requirements

Once an NDA is approved, a product may be subject to certain 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, 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 cGMPs 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 cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. 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 mandatory revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the 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.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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.

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, directly or indirectly, 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. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, civil money penalties and exclusion from participation in federal healthcare programs.

Moreover, 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, 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 $5,500 and $11,000 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.

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 a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, to the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

HIPAA, as amended by 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. 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 criminal penalties.

The Affordable Care Act imposed, 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." Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices or require the tracking and reporting of gifts, compensation or other remuneration to physicians.

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 control 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 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, 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 revised the definition of "average manufacturer price" for calculating and reporting

Medicaid drug rebates on outpatient prescription drug prices and imposed a significant annual fee on companies that manufacture or import certain branded prescription drug products. 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.

We continue to evaluate the effect that the Affordable Care Act will have on our business. 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 candidate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President 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.

Moreover, the Drug Supply Chain Security Act, imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, which will be phased in over several years beginning in 2016. Among the requirements of this 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 product candidates, once 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 health programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the U.S., private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products 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 any future product candidates, will therefore depend substantially on the extent to which the costs of our product candidates, and any future product candidates, will be paid by third-party payors. Additionally, the market for our product candidates, and any future product candidates, 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 be a time-consuming process.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls and transparency requirements, restrictions on reimbursement and requirements for substitution of 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.

Employees

As of September 30, 2016, we had no employees, and our wholly-owned subsidiary, Myovant Sciences, Inc., had nine employees, including seven who are engaged in research and development activities. The employees of Myovant Sciences, Inc. provide services to us pursuant to an intercompany services agreement between us and Myovant Sciences, Inc.

Facilities

Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, Hamilton HM11, Bermuda. In anticipation of conducting extensive research and development and building out the functions, personnel and facilities necessary for commercialization of relugolix and RVT-602, if approved, we have established an indirect, wholly-owned subsidiary, Myovant Sciences GmbH, with its principal offices in Basel, Switzerland. We expect that Myovant Sciences GmbH will be the principal operating company for conducting our business and the entity that will hold our intellectual property rights in relugolix and RVT-602.

Our wholly-owned subsidiary, Myovant Sciences, Inc., leases approximately 11,689 square feet of office space in Brisbane, California on a month to month basis for clinical research and development operations and administrative functions. Our affiliate, Roivant Sciences GmbH, leases office space in Basel, Switzerland and our controlling shareholder, Roivant Sciences Ltd., leases office space in Hamilton, Bermuda for business development, intellectual property management and other administrative functions. We anticipate that Myovant Sciences GmbH will sublease space from Roivant Sciences GmbH in Basel, from which we will conduct business development, intellectual property management, commercial preparation and clinical research and development activities. Our affiliate, Roivant Sciences, Inc., leases office space in New York, New York and Durham, North Carolina for clinical and non-clinical research and development operations and finance operations. We do not anticipate that Myovant Sciences, Inc. will separately sublease space in New York or North Carolina, and the clinical research and development and other activities in those locations will be carried out by Roivant Sciences, Inc. at our direction in accordance with our services agreement with Roivant Sciences, Inc. See “Certain Relationships and Related Party Transactions—Relationship with Roivant Sciences, Inc.—

Services Agreement" for additional information regarding this agreement. We intend to add new facilities or expand our existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information concerning our executive officers, including their ages as of September 30, 2016:

Name	Age	Position
Executive Officers		
Lynn Seely, M.D.*	57	Principal Executive Officer and Director
Frank Karbe*	48	Principal Financial and Accounting Officer
Marianne L. Romeo**	48	Head, Global Transactions & Risk Management
Non-Employee Directors		
Mark Altmeyer	56	Director
Wayne DeVeydt(1)(2)	46	Director
Keith Manchester, M.D.(2)(3)	47	Director
Vivek Ramaswamy	31	Director
Kathleen Sebelius(1)(2)(3)	68	Director

* Employee of our wholly-owned subsidiary, Myovant Sciences, Inc. Such employee provides services to us pursuant to an intercompany services agreement between us and Myovant Sciences, Inc.

** Co-employee of our controlling shareholder, Roivant Sciences Ltd., and our affiliate, Axovant Sciences Ltd.

(1) Member of the audit committee. Mr. DeVeydt serves as the chair of this committee.

(2) Member of the compensation committee. Ms. Sebelius serves as the chair of this committee.

(3) Member of the nominating and corporate governance committee. Dr. Manchester serves as the chair of this committee.

Lynn Seely, M.D. has served as our Principal Executive Officer and as the President and Chief Executive Officer of Myovant Sciences, Inc. since May 2016. From March 2005 to October 2015, Dr. Seely served as Chief Medical Officer of Medivation, Inc. where she served on the Executive Committee and led the development of Xtandi for the treatment of metastatic castration-resistant prostate cancer from IND-enabling studies through to NDA approval and post-approval clinical studies. Dr. Seely was responsible for building the clinical organization at Medivation, as well as the regulatory, quality, project management, medical affairs and biologics manufacturing functions. Dr. Seely currently serves on the board of directors of Blueprint Medicines Corporation, and she previously served as Vice-President of Clinical Development at Anesiva, Inc. (formerly Corgentech) and at Cytyc Health Corporation. Dr. Seely has served on the board of directors of Blueprint Medicines Corporation since April 2016. Dr. Seely received an M.D. from the University of Oklahoma College of Medicine and completed her residency in internal medicine at Yale-New Haven Hospital. After serving as Chief Resident in Internal Medicine at Yale University School of Medicine, she completed her basic science and clinical fellowship in endocrinology and metabolism at the University of California, San Diego.

Frank Karbe has served as our Principal Financial and Accounting Officer and as the interim Chief Financial Officer of Myovant Sciences, Inc. since September 2016. From September 2014 to July 2016, Mr. Karbe served as President of The Color Run, a global mass participation events platform. From January 2004 to June 2014, Mr. Karbe was the Executive Vice President and Chief Financial Officer of Exelixis, Inc., a publicly-traded biotechnology company. Prior to joining Exelixis in 2004, Mr. Karbe worked as an investment banker for Goldman Sachs & Co., where he served most recently as Vice President in the healthcare group focusing on corporate finance and mergers and acquisitions in the biotechnology industry. Prior to joining Goldman Sachs in 1997, Mr. Karbe held various positions in the finance department of The Royal Dutch/Shell Group in Europe. Mr. Karbe currently serves on the board of directors of Arbutus Biopharma Corporation and Kolltan Pharmaceuticals, Inc. Mr. Karbe received his Diplom-Kaufmann from the WHU-Otto Beisheim Graduate School of Management, Koblenz, Germany.

Marianne L. Romeo has served as our Head, Global Transactions & Risk Management since February 2016. Ms. Romeo has served as Head, Global Transactions & Risk Management of Roivant Sciences Ltd. since October 2014 and Axovant Sciences Ltd. since March 2015. Previously, Ms. Romeo had a 20 year career with Marsh Inc. in risk consulting and insurance brokerage, most recently serving as Managing Director and Head of Casualty from 2008 to 2014 and Senior Vice President and Healthcare Practice Leader from 2003 to 2008 for Bowring Marsh (Bermuda) Ltd., an international insurance placement broker and wholly owned subsidiary of Marsh Inc. During her time at Bowring Marsh, Ms. Romeo served in various functional roles, including excess casualty brokerage, risk management consulting, and business management. Ms. Romeo established the Healthcare Practice within Marsh's Bermuda operation in 2003 and continues to serve on the Board of the Bermuda Society for Healthcare Risk Management (BSHRM). Ms. Romeo has served on the board of directors of Axovant Sciences Ltd. since March 2015. Ms. Romeo received her B.Sc. in Manufacturing Engineering, *cum laude*, from Tufts University and her M.S. in Occupational Health and Environmental Science from the City University of New York, Hunter College.

Mark Altmeyer has served as a member of our board of directors since September 2016. Since March 2015, Mr. Altmeyer has served as the President and Chief Commercial Officer of Axovant Sciences, Inc., a wholly-owned subsidiary of Axovant Sciences Ltd. From February 2009 to December 2014, Mr. Altmeyer served as Chief Executive Officer and President of Otsuka America Pharmaceutical, Inc. Prior to his time at Otsuka, Mr. Altmeyer served in a number of executive leadership roles at Bristol-Myers Squibb, including Senior Vice President, Global Commercialization from 2006 to 2008 and Senior Vice President, Neuroscience Business Unit from 2002 to 2005 during the approval and launch of Abilify, a branded drug used to treat multiple psychiatric conditions, including schizophrenia, depression and bipolar disorder. Mr. Altmeyer received his B.A. from Middlebury College and his M.B.A. from Harvard Business School. We believe Mr. Altmeyer's extensive experience serving in executive leadership roles at pharmaceutical companies qualifies him to serve on our board of directors.

Wayne S. DeVeydt has served as a member of our board of directors since September 2016. From May 2007 to May 2016, Mr. DeVeydt served as Executive Vice President and Chief Financial Officer at Anthem, Inc., a health insurance company. From March 2005 to May 2007, he served as Anthem's Senior Vice President and Chief Accounting Officer and also served as Chief of Staff to the Chairman and Chief Executive Officer from 2006 to 2007. Prior to joining Anthem, Mr. DeVeydt served as an audit partner at PricewaterhouseCoopers LLP, focused on companies in the national managed care and insurance industries. Mr. DeVeydt currently serves on the board of directors of NiSource Inc. Mr. DeVeydt received his Bachelor of Science in Business Administration from the University of Missouri in St. Louis. We believe Mr. DeVeydt's significant experience in corporate governance, risk management and finance and accounting matters qualifies him to serve on our board of directors.

Keith Manchester, M.D. has served as a member of our board of directors since September 2016. He is also a member of the board of directors of Roivant Sciences Ltd., a position he has held since May 2014, and of Arbutus Biopharma, a position he has held since March 2015. Dr. Manchester currently serves as a Managing Director and Head of Life Sciences for QVT Financial LP, an investment firm, where he has been employed since 2005, and focuses on investments in both publicly-traded and privately-owned life sciences companies. Prior to joining QVT Financial, Dr. Manchester was Vice President of Business Development from 2002 to 2004 and Director of Business Development from 2000 to 2002 at Applied Molecular Evolution, Inc., a biotechnology company. From 1999 to 2000, Dr. Manchester was an associate at Vestar Capital Partners, a private equity firm. From 1997 to 1999, Dr. Manchester was an investment banker in the healthcare group at Goldman, Sachs & Co. Dr. Manchester received his A.B. degree from Harvard College and his M.D. from Harvard Medical School. We believe Dr. Manchester's medical background, significant knowledge of the life sciences industry and his experience as a life sciences investor qualify him to serve on our board of directors.

Vivek Ramaswamy has served as a member of our board of directors since September 2016. Since March 2015, Mr. Ramaswamy has served as the Principal Executive Officer of Axovant Sciences Ltd. and the Chief

Executive Officer of its wholly-owned subsidiary, Axovant Sciences, Inc. Mr. Ramaswamy also currently serves as President and Chief Executive Officer of Roivant Sciences, Inc., a drug development and commercialization company that is wholly-owned by Roivant Sciences Ltd., a position he has held since May 2014. From August 2007 to May 2014, Mr. Ramaswamy was a member of the investment team at QVT Financial LP. In addition, in 2007, Mr. Ramaswamy co-founded and served as the President of Campus Venture Network, a technology company that was acquired in 2009. Mr. Ramaswamy currently serves as member of the board of directors of Axovant Sciences Ltd. and Roivant Sciences Ltd., as well as chairman of the board of directors of Arbutus Biopharma Corporation. Mr. Ramaswamy received his A.B. degree, *summa cum laude*, in Biology from Harvard College and a J.D. from Yale Law School. We believe that Mr. Ramaswamy's experience as Chief Executive Officer of Roivant Sciences, Inc. and Axovant Sciences, Inc., and his experience as a life sciences investor and as a member of the board of directors of publicly-traded biotechnology companies, qualify him to serve on our board of directors.

Kathleen Sebelius has served as a member of our board of directors since September 2016. From 2009 to June 2014, Ms. Sebelius served as U.S. Secretary of Health and Human Services, or HHS. As Secretary of HHS, she presided over 11 operating divisions, including the Centers for Disease Control and Prevention, Food and Drug Administration and National Institutes of Health and oversaw the passage and implementation of the Affordable Care Act. From 2003 to 2009, Ms. Sebelius was Governor of Kansas. From 1995 until 2003, Ms. Sebelius held the position of Kansas Insurance Commissioner, and from 1987 to 1995, she served in the Kansas House of Representatives. Ms. Sebelius currently serves on the board of directors of Dermira, Inc., Humacyte, Inc., Grand Rounds, Inc. and Hampton Creek, Inc. Ms. Sebelius received her B.A. in political science from Trinity Washington University and her Master of Public Administration from the University of Kansas. We believe that Ms. Sebelius' extensive experience in executive leadership and public health qualify her to serve on our board of directors.

Family Relationships

There are no family relationships between our board of directors and our executive officers.

Board of Directors

In accordance with our amended and restated bye-laws, which will become effective upon the closing of this offering, our board of directors will be divided into three classes, each of which will consist, as nearly as possible, of one-third of the total number of directors constituting our entire board and which will serve staggered three-year terms. At each general meeting of shareholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- Class I, which will consist of Mark Altmeyer and Keith Manchester, M.D., and their term will expire at our first general meeting of shareholders to be held after the completion of this offering;
- Class II, which will consist of Kathleen Sebelius and Lynn Seely, M.D., and their term will expire at our second general meeting of shareholders to be held after the completion of this offering; and
- Class III, which will consist of Wayne S. DeVeydt and Vivek Ramaswamy, and their term will expire at our third general meeting of shareholders to be held after the completion of this offering.

Our amended and restated bye-laws will provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors has determined that Messrs. Altmeyer and DeVeydt and Ms. Sebelius representing three of the six members of our board of directors, are independent, as that term is defined under the applicable rules and regulations of the SEC and NYSE rules. Our board of directors has determined that (1) Dr. Seely, by virtue of her position as our Principal Executive Officer, (2) Dr. Manchester, by virtue of his affiliation with Roivant Sciences Ltd., and (3) Mr. Ramaswamy, by virtue of his affiliation with Roivant Sciences Ltd., are not independent under applicable SEC and NYSE rules.

After the closing of this offering, we will be a "controlled company" within the meaning of applicable NYSE rules because more than 50% of the voting power for the election of directors will be held by Roivant Sciences Ltd. Under NYSE rules, as a "controlled company," we will be exempt from the NYSE corporate governance requirements that our nominating and corporate governance committee and compensation committee consist solely of independent directors. We may rely on these exemptions from the corporate governance requirements until we are no longer a "controlled company" or until our board determines to no longer rely on these exemptions. It is currently contemplated that neither our compensation committee nor our nominating and corporate governance committee will consist entirely of independent directors. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of the NYSE. We may continue to rely on these exemptions so long as we are allowed to as a "controlled company."

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will have the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business.

Audit Committee

Our audit committee will review our internal accounting procedures and consult with and review the services provided by our independent registered public accountants. Our audit committee consists of two directors, Mr. DeVeydt and Ms. Sebelius. Mr. DeVeydt is the chair of the audit committee, and our board of directors has determined that Mr. DeVeydt is an audit committee financial expert, as defined by SEC rules and regulations.

The controlled company exemption does not modify the independence requirements for an audit committee, and we intend to comply with the requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the applicable NYSE rules. Under Rule 10A-3 of the Exchange Act, we are permitted to phase in our compliance with the independent audit committee requirements set forth in Rule 10A-3 of the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. We are relying on this phase in exception and expect that all three members of our audit committee will be determined by our board of directors to be independent within one year of our listing on the NYSE. Our board of directors has determined that such reliance will not materially and adversely affect the ability of our audit committee to act independently and to satisfy the other requirements set forth in Rule 10A-3 of the Exchange Act.

Our board of directors has determined that each of Mr. DeVeydt and Ms. Sebelius is an independent director under NYSE rules and each of Mr. DeVeydt and Ms. Sebelius is independent under Rule 10A-3 of the Exchange Act. We intend to continue to evaluate the requirements applicable to us and we intend to comply with future requirements to the extent that they become applicable to our audit committee.

The principal duties and responsibilities of our audit committee will include:

- recommending and retaining an independent registered public accounting firm to serve as independent auditor to audit our financial statements, overseeing the independent auditor's work and determining the independent auditor's compensation;
- approving in advance all audit services and non-audit services to be provided to us by our independent auditor;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor's review of our quarterly financial statements; and
- conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices.

Compensation Committee

Our compensation committee will review and determine the compensation of all our executive officers. Our compensation committee consists of three directors, Mr. DeVeydt, Dr. Manchester and Ms. Sebelius, each of whom is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act. Ms. Sebelius is the chair of the compensation committee. As a controlled company, we intend to rely upon the exemption from the requirement that we have a compensation committee composed entirely of independent directors. The principal duties and responsibilities of our compensation committee will include:

- establishing and approving, and making recommendations to the board of directors regarding, performance goals and objectives relevant to the compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting, or recommending to the full board of directors for approval, the chief executive officer's compensation, including incentive-based and equity-based compensation, based on that evaluation;
- setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;
- exercising administrative authority under our equity incentive plan and employee benefit plans;
- establishing policies and making recommendations to our board of directors regarding director compensation;
- reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and
- preparing a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of two directors, Dr. Manchester and Ms. Sebelius. Dr. Manchester is the chair of the nominating and corporate governance committee. As a controlled company, we intend to rely upon the exemption from the requirement that we have a nominating and corporate governance committee composed entirely of independent directors. The nominating and corporate governance committee's responsibilities will include:

- assessing the need for new directors and identifying individuals qualified to become directors;

- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- assessing individual director performance, participation and qualifications;
- developing and recommending to the board corporate governance principles;
- monitoring the effectiveness of the board and the quality of the relationship between management and the board; and
- overseeing an annual evaluation of the board's performance.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.myovant.com. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Compensation Committee Interlocks and Insider Participation

None of our directors who serve as a member of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

Director Compensation

We provide cash and equity-based compensation to our directors for the time and effort necessary to serve as a member of our board of directors. Each of Mr. DeVeydt and Ms. Sebelius is entitled to receive $40,000 in annual director fees for his or her service on our board of directors. In September 2016, we granted Messrs. Altmeyer and DeVeydt and Ms. Sebelius options to purchase 33,846, 42,308 and 33,846 of our common shares, respectively, with an exercise price of $5.11 per share. Each of these options vests over a period of three years. The option will vest as to one third of the shares on the first anniversary of the option grant date and the balance will vest in a series of eight equal quarterly installments thereafter. All common shares underlying these options will become fully vested upon a change in control, as defined in our 2016 Equity Incentive Plan.

We expect that our board of directors will adopt a director compensation policy for non-employee directors following the closing of this offering. Pursuant to this policy, we expect that any director who is also an employee of ours or our subsidiary will not receive any additional compensation for his or her service as a director.

2016 Director Compensation

During the fiscal year ended March 31, 2016, our sole director was Roivant Sciences Ltd., our majority shareholder.

EXECUTIVE COMPENSATION

2016 Summary Compensation Table

During the fiscal year ended March 31, 2016, Marianne A. Romeo, our Head, Global Transactions & Risk Management, was our only executive officer. Ms. Romeo is a co-employee of Roivant Sciences Ltd. and Axovant Sciences Ltd. Although we did not pay Ms. Romeo any compensation for her services as our executive officer during the fiscal year ended March 31, 2016, we have recorded $7,400 in allocated compensation expense from Roivant Sciences Ltd. related to Ms. Romeo's services during such period.

Outstanding Equity Awards at March 31, 2016

As of March 31, 2016, Ms. Romeo did not hold any Myovant Sciences Ltd. equity awards. In September 2016, we granted Ms. Romeo an option to purchase 14,102 of our common shares, with an exercise price of $2.42 per share. This option will vest as to 25% of the shares on the first anniversary of the option grant date, and the balance will vest in a series of 12 equal quarterly installments thereafter.

Employment Arrangements

Lynn Seely, M.D.

In May 2016, our wholly-owned subsidiary, Myovant Sciences, Inc., entered into an employment agreement with Dr. Seely, pursuant to which she will serve as its President and Chief Executive Officer. The agreement provides for an annual base salary of $300,000, which may be increased from time to time in the discretion of the board of directors of Myovant Sciences, Inc. Dr. Seely will be eligible to earn an annual discretionary cash bonus with a target of 50% of base salary based on the board of directors' assessment of her individual performance as well as company performance.

In June 2016, pursuant to the terms of her employment agreement, we granted Dr. Seely a restricted stock award of 1,128,222 common shares. Twenty-five percent of the shares will vest and be released from our right of repurchase on the first anniversary of Dr. Seely's commencement of employment, and the balance will vest in a series of 12 equal quarterly installments thereafter, in each case so long as Dr. Seely remains in continuous employment with Myovant Sciences, Inc. through the applicable vesting date. Dr. Seely is entitled to receive an equity award of 66,845 restricted stock units in Roivant Sciences Ltd., our majority shareholder. The restricted stock units will vest to the extent certain performance criteria are achieved and certain liquidity conditions are satisfied within eight years of the grant date. On the later of the first anniversary of Dr. Seely's commencement of employment and the completion of our initial public offering, and subject to the approval by our board of directors, Dr. Seely will receive an additional restricted stock award of 564,111 common shares. These restricted shares will vest based on our stock price following an initial public offering, as follows: 1/3rd of the shares will vest if the stock price exceeds two times the initial public offering price, an additional 1/3rd of the shares will vest if our stock price is four times the initial public offering price, and the final 1/3rd of the shares will vest if our stock price exceeds six times the initial public offering price, provided Dr. Seely remains employed on each vesting milestone. Finally, Dr. Seely will be eligible to receive additional discretionary annual equity incentive awards in amounts commensurate with her position as President and Chief Executive Officer, which will vest over a four-year vesting period. These grants will be based upon meeting performance metrics to be mutually agreed upon in writing within 60 days following her commencement of employment, and revised annually thereafter.

Dr. Seely will also participate in benefit plans and arrangements made available to similarly situated executives, will accrue four weeks of vacation per year and has entered into our standard form of non-disclosure and inventions assignment agreement.

If her employment is terminated by Myovant Sciences, Inc. without "cause" or by Dr. Seely for "good reason" (each as defined in the employment agreement), then, subject to the execution of an effective release, Dr. Seely will receive (a) a lump sum payment equal to the sum of her base salary and target bonus, (b) reimbursement of COBRA premiums for the first 12 months of COBRA coverage or a direct payment of equivalent value, if the COBRA reimbursement is not permitted pursuant to applicable law and (c) vesting of 50% of her then-unvested equity awards (100% if the termination occurs within 18 months following a change of

control). If any amounts would be subject to excise tax under Section 280G of the Internal Revenue Code, the amounts will either be paid in full (and subject to the tax), or cut back so that no excise tax applies, whichever would put Dr. Seely in a better after-tax position.

Frank Karbe

In September 2016, our wholly-owned subsidiary, Myovant Sciences, Inc., entered into an offer letter with Mr. Karbe, pursuant to which he will serve as its Interim Chief Financial Officer. The offer letter provides for an annual base salary of $300,000. Mr. Karbe is eligible to earn a one-time discretionary performance bonus of $150,000 if he is employed on the first anniversary of his start date. During the first six months of his employment, Mr. Karbe will be expected to devote 50% of his time to his duties. In September 2016, pursuant to the terms of his offer letter, we granted Mr. Karbe an option to purchase 225,644 of our common shares with an exercise price of $5.11 per share. The option will vest as to 28,205 shares on the six-month anniversary of his start date, 28,205 shares will vest on the first anniversary of his start date and the balance will vest in a series of 12 equal quarterly installments thereafter.

2016 Equity Incentive Plan

In June 2016, our board of directors and our shareholders adopted our 2016 Equity Incentive Plan, or the 2016 Plan. In September 2016, our board of directors amended the 2016 Plan and our shareholders ratified such amendments. The 2016 Plan, as amended, became effective upon the execution of the underwriting agreement related to this offering. The description of the 2016 Plan set forth below, reflects the 2016 Plan, as amended. Our 2016 Plan provides for the grant of incentive options within the meaning of Section 422 of the Internal Revenue Code, or the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. The 2016 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares

The maximum number of common shares that may be issued under the 2016 Plan is 4,512,889 shares. The number of common shares reserved for issuance under the 2016 Plan will automatically increase on April 1 of each year, for a period of ten years, from April 1, 2017 continuing through April 1, 2026, by 4% of the total number of our common shares outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as may be determined by our board of directors or the compensation committee. The maximum number of common shares that may be issued pursuant to the exercise of incentive options under the 2016 Plan is 22,564,449.

Shares issued under the 2016 Plan may be authorized but unissued or reacquired common shares. Shares subject to stock awards granted under the 2016 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of common shares available for issuance under the 2016 Plan. Additionally, common shares issued pursuant to stock awards under the 2016 Plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under the 2016 Plan.

Administration

Our board of directors, or a duly authorized committee thereof, will have the authority to administer the 2016 Plan. Our board of directors will delegate its authority to administer the 2016 Plan to our compensation committee under the terms of the compensation committee's charter. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees other than officers to receive specified stock

awards and (2) determine the number of our common shares to be subject to such stock awards. Subject to the terms of the 2016 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of common shares subject to each stock award, the fair market value of a common share, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under the 2016 Plan.

The administrator has the power to modify outstanding awards under our 2016 Plan. Subject to the terms of the 2016 Plan, the administrator has the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Section 162(m) Limits

At such time as necessary for compliance with Section 162(m) of the Code, no participant may be granted stock awards covering more than 1,128,222 common shares under the 2016 Plan during any fiscal year pursuant to options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common shares on the date of grant. Additionally, no participant may be granted in a fiscal year a performance stock award covering more than 1,128,222 common shares or a performance cash award having a maximum value in excess of $1.0 million under the 2016 Plan. These limitations enable us to grant awards that will be exempt from the $1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code.

Performance Awards

The 2016 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To enable us to grant performance-based awards that will qualify, our compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

Changes to Capital Structure

In the event there is a specified type of change in our capital structure, such as a split, reverse split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under our 2016 plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options, (4) the class and maximum number of shares subject to stock awards that can be granted to any person in a calendar year (as established under the 2016 Plan pursuant to Section 162(m) of the Code), and (5) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions

The 2016 Plan provides that in the event of a specified corporate transaction, including without limitation a consolidation, merger, or similar transaction involving our company, the sale of all or substantially all of the assets of our company, the direct or indirect acquisition by a person or persons acting as a group of ownership of shares representing a majority of the then outstanding share capital of our company, the administrator will determine how to treat each outstanding stock award. The administrator may:

- arrange for the assumption, continuation or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;

- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by us;
- cancel the stock award prior to the transaction in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the stock award; or
- make a payment, in such form as determined by the administrator, equal to the excess, if any, of the value of the property that would have been received if such award was exercised immediately prior to the effective time of the corporate transaction over any exercise price payable.

The administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner. The administrator may take different actions with respect to the vested and unvested portions of a stock award.

Change in Control

The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. In the absence of such a provision, no such acceleration of the stock award will occur.

Plan Amendment or Termination

Our board has the authority to amend, suspend, or terminate the 2016 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No incentive options may be granted after the tenth anniversary of the earlier of (1) the date the 2016 Plan was adopted by our board, or (2) the date the 2016 Plan was approved by our shareholders.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell our common shares on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since our inception on February 2, 2016 to which we have been a participant in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or holders of more than 5% of our share capital, or any members of their immediate family, had or will have a direct or indirect material interest.

Relationship with Takeda Pharmaceuticals International AG

In April 2016, we entered in a series of agreements with Takeda Pharmaceuticals International AG, or Takeda, and its affiliate as discussed below.

License Agreement

In April 2016, we entered into a license agreement with Takeda. Pursuant to this license agreement, Takeda granted to us an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize the compound TAK-385, which we now refer to as relugolix, and the compound TAK-448, which we now refer to as RVT-602, and products containing these compounds for all human diseases and condition. See the section titled “Business—License Agreement with Takeda Pharmaceuticals International AG” for a further description of the terms of this license agreement.

Manufacture and Supply Agreement

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. We expect the costs associated with the manufacture and supply of relugolix under this agreement to be approximately $25.0 million.

Subscription Agreement

In April 2016, we entered into a subscription agreement with Takeda, pursuant to which we issued 5,077,001 common shares to Takeda. Takeda did not pay any cash consideration for the common shares.

Warrant

In April 2016, we issued a warrant to purchase an indeterminate number of capital shares to Takeda. This warrant entitles Takeda, to purchase, at any time following our issuance of any class of capital shares, that number of capital shares of such class that would allow Takeda, together with its affiliates, to maintain a 12% ownership in us, as determined after such exercise. The exercise price of this warrant is $0.000017727 per share and contains an automatic net exercise provision. Upon the closing of this offering, pursuant to the terms of this warrant, we will automatically issue 1,977,269 common shares to Takeda, based upon the sale and issuance of 14,500,000 common shares to investors in this offering. If the underwriters exercise their option to purchase additional common shares in full, we would issue an additional 296,593 common shares to Takeda. This warrant will terminate upon the earlier of (1) the day after the one year anniversary of its issuance, or (2) upon a change in control in Myovant, unless such change in control results in a privately-held entity in which the holders of 40% or more of the equity securities, calculated on a fully-diluted basis, of the surviving entity are held by persons and entities who were affiliates of Myovant prior to such change in control.

Relationship with Roivant Sciences Ltd.

Option Agreement

In June 2016, we entered into an option agreement with Roivant Sciences Ltd. pursuant to which Roivant Sciences Ltd. granted to us an option to acquire the rights to products to which Roivant Sciences Ltd. or any non-public affiliate of Roivant Sciences Ltd. acquires the rights (other than a relugolix product or a competing product, as described in the section titled "Business—License Agreement with Takeda Pharmaceuticals International AG") 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 upon the completion of this offering 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 Roivant Sciences Ltd. for 110% of any payments made by Roivant Sciences Ltd. or its affiliate for such product, and will receive an assignment of the agreement through which Roivant Sciences Ltd. 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 Roivant Sciences Ltd. The Cooperation Agreement, among other things: (1) obligates us to deliver periodic financial statements and other financial information to Roivant Sciences Ltd. and to comply with other specified financial reporting requirements; and (2) requires us to supply certain material information to Roivant Sciences Ltd. 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 Roivant Sciences Ltd. is no longer required by 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.

Relationship with Roivant Sciences, Inc.

Services Agreement

In July 2016, we and our wholly-owned subsidiary, Myovant Sciences, Inc., entered into a services agreement with Roivant Sciences, Inc., a wholly-owned subsidiary of Roivant Sciences Ltd., or the Services Agreement effective as of April 29, 2016, pursuant to which Roivant Sciences, Inc. provides us with services in relation to the identification of potential product candidates, project management of clinical trials and other development, administrative and financial activities. Following the completion of this offering, we expect that our reliance on Roivant Sciences, Inc. will decrease over time as we, Myovant Sciences, Inc. and any other future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of relugolix and RVT-602. The Services Agreement will continue in perpetuity until terminated by either party upon 60 days written notice.

Under the terms of the Services Agreement, we are obligated to pay or reimburse Roivant Sciences, Inc. for the costs it, or third parties acting on its behalf, incur(s) in providing services to us. In addition, we are obligated to pay to Roivant Sciences, Inc. a pre-determined mark-up, currently equal to 10%, on costs incurred by it in connection with any general and administrative and support services as well as research and development services.

Administrative and support services include, but are not limited to, payroll, general administrative, corporate and public relations, investor relations, financial marketing, activities in connection with raising capital, accounting and auditing, tax, health, safety, environmental and regulatory affairs, staffing and recruiting, benefits, information and technology services, purchasing and legal services. Research and development services include, but are not limited to, preparatory assistance in respect of the identification of product candidates,

performance and oversight of due diligence to evaluate potential product candidates, management and oversight of external consultants in connection with potential product candidate investment opportunities, participation in meetings with regulatory authorities related to product candidates, development of plans for potential clinical trials, selection of manufacturers of product candidates, management and oversight of clinical trials and product manufacturing, analysis of clinical trial data and management of regulatory filings and approval processes.

Under the Services Agreement, Roivant Sciences, Inc. has agreed to indemnify us and Myovant Sciences, Inc., and each our respective officers, employees and directors against all losses arising out of, due to or in connection with the provision of services (or the failure to provide services) under the Services Agreement, except to the extent such losses are the result of the gross negligence or willful misconduct of such indemnified parties. Such indemnification obligations will not exceed the payments made by us and by Myovant Sciences, Inc. under the Services Agreement for the specific service that allegedly caused or was related to the losses during the period in which such alleged losses were incurred.

Investor Rights Agreement

In April 2016, we entered into an investor rights agreement with Takeda and Roivant Sciences Ltd. After the closing of this offering, pursuant to the terms of this agreement, these shareholders will be entitled to rights with respect to the registration of their common shares under the Securities Act of 1933, as amended, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. For a description of these registration rights, see the section titled “Description of Share Capital—Registration Rights.”

Employment Arrangements

Lynn Seely, M.D., our Principal Executive Officer, and Frank Karbe, our Principal Financial and Accounting Officer, have entered into employment arrangements with our wholly-owned subsidiary, Myovant Sciences, Inc. For additional information regarding the employment arrangements, see the section titled “Executive Compensation—Employment Arrangements.” In addition, Marianne L. Romeo, our Head, Global Transactions & Risk Management, is also a co-employee of Roivant Sciences Ltd., our majority shareholder, and Axovant Sciences Ltd., our affiliate.

Other Transactions

We have and intend to continue to grant equity awards to members of our board of directors and our executive officers. For a description of these equity awards, see the sections titled “Management—Director Compensation” and “Executive Compensation—Employment Arrangements.”

Indemnification Agreements

In connection with this offering, we will enter into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Bermuda law. See the section titled “Description of Share Capital—Indemnification of Directors and Officers” for additional information regarding indemnification under Bermuda law and our amended and restated bye-laws.

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy became effective

immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including Roivant Sciences Ltd., and any of their respective immediate family members and any entity owned or controlled by such persons. Any transaction contemplated by the option agreement with Roivant Sciences Ltd., as described in the section titled "—Option Agreement" above, will also be subject to this policy.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

PRINCIPAL SHAREHOLDERS

The following table sets forth the beneficial ownership of our common shares as of September 30, 2016 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common shares;
- each of our executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

The percentage ownership information before the offering is based upon 43,750,684 common shares outstanding as of September 30, 2016. The percentage ownership information after the offering assumes the (1) sale and issuance of 14,500,000 common shares in this offering and no exercise by the underwriters of their option to purchase additional common shares; and (2) the issuance of an additional 1,977,269 common shares to Takeda upon the closing of this offering pursuant to the automatic exercise of a warrant we issued to Takeda.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include common shares issuable pursuant to the exercise of options that are either immediately exercisable or exercisable on or before November 29, 2016, which is 60 days after September 30, 2016. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons or entities listed in the table is c/o Myovant Sciences Ltd. Clarendon House, 2 Church Street, Hamilton HM11, Bermuda.

	Shares Beneficially Owned Before this Offering		Shares Beneficially Owned After this Offering	
Name of Beneficial Owner	Shares	%	Shares	%
5% Shareholders				
Roivant Sciences Ltd.(1)	37,231,342	85.1%	37,231,342	61.8
Takeda Pharmaceuticals International AG(2)	5,391,120	12.3	7,368,389	12.2
Executive Officers and Directors				
Lynn Seely, M.D.(3)	1,128,222	2.6	1,128,222	1.9
Frank Karbe	—	—	—	—
Marianne L. Romeo.	—	—	—	—
Mark Altmeyer	—	—	—	—
Wayne DeVeydt	—	—	—	—
Keith Manchester, M.D.(4)	—	—	—	—
Vivek Ramaswamy(5)	—	—	—	—
Kathleen Sebelius	—	—	—	—
All current directors and executive officers as a group (8 persons)	1,128,222	2.6	1,128,222	1.9

(1) Consists of 37,231,342 common shares directly owned by Roivant Sciences Ltd. (“Roivant”). Under Roivant’s internal governance arrangements, dispositive decisions over these shares require the approval of the majority of Roivant’s board of directors, including (i) at least two “independent directors” (within the meaning of that term under Roivant’s bye-laws), or (ii) if there is only one such independent director, that sole independent director. Vivek Ramaswamy, Ilan Oren, Keith Manchester, M.D., Andrew Lo, Ph.D. and Patrick Machado comprise the board of directors of Roivant. The approval of Dr. Lo and Mr. Machado, as an independent directors of Roivant (and, to the extent that each one is the only independent director of

Roivant then serving, the sole approval of Dr. Lo or Mr. Machado, as applicable), is needed to dispose of the common shares directly owned by Roivant and, accordingly, each of Dr. Lo and Mr. Machado may be deemed an indirect beneficial owner over the common shares directly owned by Roivant. Each of Dr. Lo and Mr. Machado disclaims beneficial ownership in the common shares except to the extent of his respective pecuniary interest therein. Additionally, any one of Roivant's three major shareholders (the "Major Shareholders"), voting unanimously with the other Major Shareholders, has the right to override certain decisions of the board of directors of Roivant, including with respect to dispositions of common shares directly owned by Roivant (the "Override Right"). The three Major Shareholders of Roivant are Dexxon Holdings Ltd. ("Dexxon"), QVT Fund V LP ("QVT Fund") and the Viking Funds. The Viking Funds are comprised of Viking Global Opportunities Illiquid Investments Sub-Master LP, Viking Global Equities LP, Viking Global Equities II LP, VGE III Portfolio Ltd. and Viking Long Fund Master Ltd. (the "Viking Funds"). With this Override Right, each of the Major Shareholders, along with certain affiliates of the Major Shareholders named below with voting and investment control over the Major Shareholders, may be deemed to share dispositive power and over the common shares directly owned by Roivant. The affiliates of the Major Shareholders that may be deemed indirect beneficial owners of the common shares indirectly beneficially owned by each of the Major Shareholders and directly owned by Roivant include the following: (i) Dan Oren, the sole director of Dexxon, insofar as voting and dispositive decisions of Dexxon are made by its sole director; (ii) QVT Financial LP, as the investment manager for QVT Fund, QVT Financial GP LLC, as the general partner of QVT Financial LP, and QVT Associates GP LLC, as the general partner of the QVT Fund; and (iii) Viking Global Performance LLC, as the general partner of Viking Global Equities LP and Viking Global Equities II LP and the investment manager for VGE III Portfolio Ltd., Viking Global Opportunities Portfolio GP LLC, as the general partner of Viking Global Opportunities Illiquid Investments Sub-Master LP, and Viking Long Fund GP LLC, as the investment manager for Viking Long Fund Master Ltd. (Viking Global Performance LLC, Viking Global Opportunities Portfolio GP LLC and Viking Long Fund GP LLC, collectively with the Viking Funds, the "Viking Shareholders"). Each of the Major Shareholders and each of their affiliates thereof named above disclaims beneficial ownership in the common shares owned by Roivant except to the extent of their pecuniary interest therein. The principal business address of Dr. Lo, Mr. Machado and Roivant is Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. The principal business address of Dexxon and Mr. Oren is 1 Dexcel Street, Or Akiva 30600000, Israel. The principal business address of QVT Financial, QVT Financial GP LLC and QVT Associates GP LLC is 1177 Avenue of the Americas, 9th Floor, New York, New York 10036. The registered office of the QVT Fund is located at 190 Elgin Avenue, George Town, Grand Cayman KY1-9005, Cayman Islands. The principal business address of each of the Viking Shareholders is 55 Railroad Avenue, Greenwich, Connecticut 06830.

(2) Shares beneficially owned after this offering includes 1,977,269 common shares issuable upon the closing of this offering pursuant to the automatic exercise of a warrant held by Takeda Pharmaceuticals International AG ("Takeda"), based upon the sale and issuance of 14,500,000 common shares to investors in this offering. See the section titled "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant" for a description of the terms of this warrant. Takeda's percentage ownership before and after this offering is equal to 12.0% on a fully-diluted basis, after giving effect to stock options for 1,175,311 common shares outstanding as of September 30, 2016. The principal business address of Takeda is Thurgauerstrasse 130, 8152 Glattpark—Opfikon Zurich, Switzerland.

(3) Represents 1,128,222 common shares subject to a repurchase right held by us. Twenty-five percent of the shares will vest and be released from our right of repurchase on the first anniversary of Dr. Seely's commencement of employment, and the balance will vest in a series of 12 quarterly installments, subject to Dr. Seely's continuous employment with Myovant Sciences, Inc. through each applicable vesting date. The principal business address of Dr. Seely is c/o Myovant Sciences, Inc., 320 West 37th Street, 5th Floor, New York, NewYork 10018.

(4) Dr. Manchester is a director of Roivant Sciences Ltd., but does not have voting and dispositive power over the shares held of record by Roivant Sciences Ltd., as further described in footnote (1).

(5) Mr. Ramaswamy is a director of Roivant Sciences Ltd., but does not have voting and dispositive power over the shares held of record by Roivant Sciences Ltd., as further described in footnote (1).

DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and provisions of our memorandum of association and amended and restated bye-laws are summaries. You should also refer to the memorandum of association and the amended and restated bye-laws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

We are an exempted company incorporated under the laws of Bermuda. We are registered with the Registrar of Companies in Bermuda under registration number 51163. We were incorporated on February 2, 2016 under the name Roivant Endocrinology Ltd. We changed our name to Myovant Sciences Ltd. in May 2016. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, 2nd Floor, Hamilton HM11, Bermuda.

The objects of our business are unrestricted, and Myovant Sciences Ltd. has the capacity of a natural person. We can therefore undertake activities without restriction on our capacity.

In connection with this offering, our shareholders approved certain amendments to our bye-laws that will become effective upon the closing of this offering. The following description assumes that such amendments have become effective.

Since our incorporation, other than a subdivision of our authorized and issued share capital, there have been no material changes to our share capital, mergers, amalgamations or consolidations of us or any of our subsidiaries, no material changes in the mode of conducting our business, no material changes in the types of products produced or services rendered. There have been no bankruptcy, receivership or similar proceedings with respect to us or our subsidiaries.

There have been no public takeover offers by third parties for our shares nor any public takeover offers by us for the shares of another company that have occurred during the last or current financial years.

Initial settlement of our common shares will take place on the closing date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities registered through DTC's book-entry transfer system. Each person beneficially owning common shares registered through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the common shares.

Share Capital

Immediately following the closing of this offering, our authorized share capital will consist of 564,111,242 common shares, $0.000017727 par value per common share. As of June 30, 2016, we had 43,590,411 common shares issued and outstanding. All of our issued and outstanding common shares prior to the closing of this offering are fully paid. Pursuant to our amended and restated bye-laws, subject to the requirements of the NYSE, and to any resolution of the shareholders to the contrary, our board of directors is authorized to issue any of our authorized but unissued shares. There are no limitations on the right of non-Bermudians or non-residents of Bermuda to hold or vote our shares provided our common shares remain listed on an appointed stock exchange, which includes the NYSE.

Common Shares

Holders of common shares have no pre-emptive, redemption, conversion or sinking fund rights. Holders of common shares are entitled to one vote per share on all matters submitted to a vote of holders of common shares,

subject to the limitations described below. Unless a different majority is required by law or by our amended and restated bye-laws, resolutions to be approved by holders of common shares require approval by a simple majority of votes cast at a meeting at which a quorum is present.

Under our amended and restated bye-laws, any U.S. person, other than any excluded person, as described below, whose controlled shares, as defined below, would constitute 9.5% or more of the total voting power of our issued share capital, would have their aggregate votes reduced by our board of directors to the extent necessary such that the controlled shares of such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares. These reductions will be made on an automatic basis pursuant to the procedures set forth in our amended and restated bye-laws, and are intended to reduce the risk of us becoming a CFC for U.S. federal income tax purposes as a result of more than 50% of the voting power or value of our issued and outstanding shares being owned, directly or indirectly by a United States person that possesses, directly or indirectly, 10% or more of the total voting power of our issued share capital. Under these provisions, certain shareholders may have their voting rights reduced to less than one vote per share, while other shareholders may have voting rights in excess of one vote per share. Any person, including any U.S. person, whose controlled shares constitute 9.5% or more of the total voting power of our issued share capital immediately prior to the closing of this offering, will be exempt from the foregoing voting restrictions. As a result, we expect that Roivant Sciences Ltd. and certain of its affiliates will be exempt from these restrictions. For purposes of this paragraph, "controlled shares" means all shares of Myovant Sciences Ltd. directly, indirectly or constructively owned by any person, as determined pursuant to Sections 957 and 958 of the Code and the Treasury Regulations promulgated thereunder. Further, our board of directors may determine that shares shall carry different voting rights as it reasonably determines, based on the advice of counsel, to be appropriate to avoid the existence of a U.S. person whose controlled shares constitute 9.5% or more of the total voting power of our issued share capital.

In addition, under our amended and restated bye-laws, shares shall not carry voting rights to the extent that our board of directors reasonably determines, based on the advice of counsel, that it is necessary to do so to avoid adverse tax, legal or regulatory consequences to us, any of our subsidiaries or any direct or indirect holder of our common shares or its affiliates, provided that our board of directors will use reasonable efforts to afford equal treatment to similarly situated shareholders to the extent possible under the circumstances. Other than as set forth in our amended and restated bye-laws, shareholder voting rights may only be altered with the consent of our shareholders as set forth under "—Variation of Rights" below.

In the event of our liquidation, dissolution or winding up, the holders of common shares are entitled to share equally and ratably in our assets, if any, remaining after the payment of all of our debts and liabilities, subject to any liquidation preference on any issued and outstanding preference shares.

Preference Shares

Pursuant to Bermuda law and our amended and restated bye-laws, our board of directors may, by resolution, establish one or more series of preference shares having such number of shares, designations, dividend rates, relative voting rights, conversion or exchange rights, redemption rights, liquidation rights, rights to elect or appoint directors and other relative participation, optional or other special rights, qualifications, limitations or restrictions as may be fixed by the board of directors without any further shareholder approval. Such rights, preferences, powers and limitations, as may be established, could have the effect of discouraging an attempt to obtain control of our company.

Dividend Rights

Under Bermuda law, a company may not declare or pay dividends if there are reasonable grounds for believing that (1) the company is, or would after the payment be, unable to pay its liabilities as they become due; or (2) that the realizable value of its assets would thereby be less than its liabilities. Under our amended and restated bye-laws, each common share is entitled to dividends if, as and when dividends are declared by our board of directors, subject to any preferred dividend right of the holders of any preference shares. We do not anticipate paying cash dividends in the foreseeable future.

Variation of Rights

If at any time we have more than one class of shares, the rights attaching to any class, unless otherwise provided for by the terms of issue of the relevant class, may be varied either: (1) with the consent in writing of the holders of 75% of the issued shares of that class; or (2) with the sanction of a resolution passed by a majority of the votes cast at a general meeting of the relevant class of shareholders at which a quorum consisting of at least two persons holding or representing one-third of the issued shares of the relevant class is present. Our amended and restated bye-laws specify that the creation or issue of shares ranking equally with existing shares will not, unless expressly provided by the terms of issue of existing shares, vary the rights attached to existing shares. In addition, the creation or issue of preference shares ranking prior to common shares will not be deemed to vary the rights attached to common shares or, subject to the terms of any other class or series of preference shares, to vary the rights attached to any other class or series of preference shares.

Transfer of Shares

Our board of directors may, in its absolute discretion and without assigning any reason, refuse to register the transfer of a share on the basis that it is not fully paid. Our board of directors may also refuse to recognize an instrument of transfer of a share unless it is accompanied by the relevant share certificate and such other evidence of the transferor's right to make the transfer as our board of directors shall reasonably require or unless all applicable consents, authorizations and permissions of any governmental agency or body in Bermuda have been obtained or if it appears to our board of directors that certain tax, regulatory or legal consequences for us, any subsidiary of ours, holders of our common shares or their affiliates would result from the transfer. Subject to these restrictions, a holder of common shares may transfer the title to all or any of his common shares by completing a form of transfer in the form set out in our amended and restated bye-laws (or as near thereto as circumstances admit) or in such other common form as our board of directors may accept. The instrument of transfer must be signed by the transferor and transferee, although in the case of a fully paid share our board of directors may accept the instrument signed only by the transferor.

Meetings of Shareholders

Under Bermuda law, a company is required to convene at least one general meeting of shareholders each calendar year, which we refer to as the annual general meeting. While Bermuda law permits the shareholders to waive the requirement to hold an annual general meeting by resolution (either for a specific year or a period of time or indefinitely), our amended and restated bye-laws provide that, notwithstanding, an annual general meeting shall be held in each year.

Bermuda law provides that a special general meeting of shareholders may be called by the board of directors of a company and must be called upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings. Bermuda law also requires that shareholders be given at least five days' advance notice of a general meeting, but the accidental omission to give notice to any person does not invalidate the proceedings at a meeting. Our amended and restated bye-laws provide that our principal executive officer or the chairman or any two directors or any director and the secretary or board of directors may convene an annual general meeting and our principal executive officer or the chairman or any two directors or any director and the secretary or our board of directors may convene a special general meeting. Under our amended and restated bye-laws, at least 14 days' notice of an annual general meeting or ten days' notice of a special general meeting must be given to each shareholder entitled to vote at such meeting. This notice requirement is subject to the ability to hold such meetings on shorter notice if such notice is agreed: (1) in the case of an annual general meeting by all of the shareholders entitled to attend and vote at such meeting; or (2) in the case of a special general meeting by a majority in number of the shareholders entitled to attend and vote at the meeting holding not less than 95% in nominal value of the shares entitled to vote at such meeting. Subject to the rules of the NYSE, the quorum required for a general meeting of shareholders is two or more persons present in person at the start of the meeting and representing in person or by proxy in excess of 50% of all issued and outstanding common shares.

Access to Books and Records and Dissemination of Information

Members of the general public have a right to inspect the public documents of a company available at the office of the Registrar of Companies in Bermuda. These documents include a company's amended and restated memorandum of association, including its objects and powers, and certain alterations to the amended and restated memorandum of association. The shareholders have the additional right to inspect the bye-laws of the company, minutes of general meetings and the company's audited financial statements, which must be presented in the annual general meeting. The register of members of a company is also open to inspection by shareholders and by members of the general public without charge. The register of members is required to be open for inspection for not less than two hours in any business day (subject to the ability of a company to close the register of members for not more than thirty days in a year). A company is required to maintain its share register in Bermuda but may, subject to the provisions of the Companies Act establish a branch register outside of Bermuda. A company is required to keep at its registered office a register of directors and officers that is open for inspection for not less than two hours in any business day by members of the public without charge. Bermuda law does not, however, provide a general right for shareholders to inspect or obtain copies of any other corporate records.

Election and Removal of Directors

Our amended and restated bye-laws provide that our board of directors shall consist of such number of directors as the board of directors may determine. Upon the closing of this offering, our board of directors will consist of six directors. Our board of directors will be divided into three classes that are, as nearly as possible, of equal size. Each class of directors will be elected for a three-year term of office, but the terms will be staggered so that the term of only one class of directors expires at each annual general meeting. The initial terms of the Class I, Class II and Class III directors will expire in 2017, 2018 and 2019, respectively. At each succeeding annual general meeting, successors to the class of directors whose term expires at the annual general meeting will be elected for a three-year term.

A shareholder holding any percentage of the common shares in issue may propose for election as a director someone who is not an existing director or is not proposed by our board of directors. Where a director is to be elected at an annual general meeting, notice of any such proposal for election must be given not less than 90 days nor more than 120 days before the anniversary of the last annual general meeting prior to the giving of the notice or, in the event the annual general meeting is called for a date that is not less than 30 days before or after such anniversary the notice must be given not later than ten days following the earlier of the date on which notice of the annual general meeting was posted to shareholders or the date on which public disclosure of the date of the annual general meeting was made. Where a director is to be elected at a special general meeting; provided, that our board of directors has determined that shareholders may nominate persons for election at such special general meeting, that notice must be given not later than seven days following the earlier of the date on which notice of the special general meeting was posted to shareholders or the date on which public disclosure of the date of the special general meeting was made.

A director may be removed, only with cause, by the shareholders, provided notice of the shareholders meeting convened to remove the director is given to the director. The notice must contain a statement of the intention to remove the director and a summary of the facts justifying the removal and must be served on the director not less than 14 days before the meeting. The director is entitled to attend the meeting and be heard on the motion for his removal.

Proceedings of Board of Directors

Our amended and restated bye-laws provide that our business is to be managed and conducted by our board of directors. Bermuda law permits individual and corporate directors and there is no requirement in our bye-laws or Bermuda law that directors hold any of our shares. There is also no requirement in our amended and restated bye-laws or Bermuda law that our directors must retire at a certain age.

The compensation of our directors will be determined by the board of directors, and there is no requirement that a specified number or percentage of "independent" directors must approve any such determination. Our directors may also be paid all travel, hotel and other reasonable out-of-pocket expenses properly incurred by them in connection with our business or their duties as directors.

A director who discloses a direct or indirect interest in any contract or arrangement with us as required by Bermuda law will not be entitled to vote in respect of any such contract or arrangement in which he or she is interested unless the chairman of the relevant meeting of the Board of Directors determines that such director is not disqualified from voting.

Indemnification of Directors and Officers

Section 98 of the Companies Act provides generally that a Bermuda company may indemnify its directors, officers and auditors against any liability which by virtue of any rule of law would otherwise be imposed on them in respect of any negligence, default, breach of duty or breach of trust, except in cases where such liability arises from fraud or dishonesty of which such director, officer or auditor may be guilty in relation to the company. Section 98 further provides that a Bermuda company may indemnify its directors, officers and auditors against any liability incurred by them in defending any proceedings, whether civil or criminal, in which judgment is awarded in their favor or in which they are acquitted or granted relief by the Supreme Court of Bermuda pursuant to Section 281 of the Companies Act.

Our amended and restated bye-laws provide that we shall indemnify our officers and directors in respect of their actions and omissions, except in respect of their fraud or dishonesty, and that we shall advance funds to our officers and directors for expenses incurred in their defense upon receipt of an undertaking to repay the funds if any allegation of fraud or dishonesty is proved. Our amended and restated bye-laws provide that the shareholders waive all claims or rights of action that they might have, individually or in right of the company, against any of the company's directors or officers for any act or failure to act in the performance of such director's or officer's duties, except in respect of any fraud or dishonesty of such director or officer. Section 98A of the Companies Act permits us to purchase and maintain insurance for the benefit of any officer or director in respect of any loss or liability attaching to him in respect of any negligence, default, breach of duty or breach of trust, whether or not we may otherwise indemnify such officer or director. We have purchased and maintain a directors' and officers' liability policy for such purpose.

Amendment of Memorandum of Association and Bye-laws

Bermuda law provides that the memorandum of association of a company may be amended by a resolution passed at a general meeting of shareholders. Our amended and restated bye-laws provide that no bye-law shall be rescinded, altered or amended, and no new bye-law shall be made, unless it shall have been approved by a resolution of our board of directors and by a resolution of our shareholders. Bye-laws relating to election of directors, classes of directors, term of office of directors, removal of directors, business combinations and changes to the bye-laws shall not be rescinded, altered or amended without a resolution of our board of directors including the affirmative vote of 66 2/3% of the directors then in office and a resolution of our shareholders including the affirmative vote of 66 2/3% of all votes entitled to be cast on the resolution.

Under Bermuda law, the holders of an aggregate of not less than 20% in par value of a company's issued share capital or any class thereof have the right to apply to the Supreme Court of Bermuda for an annulment of any amendment of the memorandum of association adopted by shareholders at any general meeting, other than an amendment that alters or reduces a company's share capital as provided in the Companies Act. Where such an application is made, the amendment becomes effective only to the extent that it is confirmed by the Supreme Court of Bermuda. An application for an annulment of an amendment of the memorandum of association must be made within 21 days after the date on which the resolution altering the company's memorandum of association is passed and may be made on behalf of persons entitled to make the application by one or more of their number as they may appoint in writing for the purpose. No application may be made by shareholders voting in favor of the amendment.

Amalgamations and Mergers

The amalgamation or merger of a Bermuda company with another company or corporation (other than certain affiliated companies) requires the amalgamation or merger agreement to be approved by the company's board of directors and by its shareholders. Unless the company's bye-laws provide otherwise, the approval of 75% of the shareholders voting at such meeting is required to approve the amalgamation or merger agreement, and the quorum for such meeting must be two or more persons holding or representing more than one-third of the issued shares of the company. Our amended and restated bye-laws provide that the approval of a simple majority of shareholders voting at a meeting to approve the amalgamation or merger agreement shall be sufficient, and the quorum for such meeting shall be two or more persons holding or representing more than 50% of the issued voting shares.

Under Bermuda law, in the event of an amalgamation or merger of a Bermuda company with another company or corporation, a shareholder of the Bermuda company who did not vote in favor of the amalgamation or merger and who is not satisfied that fair value has been offered for such shareholder's shares may, within one month of notice of the shareholders meeting, apply to the Supreme Court of Bermuda to appraise the fair value of those shares.

Business Combinations

Although the Companies Act does not contain specific provisions regarding "business combinations" between companies organized under the laws of Bermuda and "interested shareholders," we have included these provisions in our bye-laws. Specifically, our bye-laws contain provisions which prohibit us from engaging in a business combination with an interested shareholder for a period of three years after the date of the transaction in which the person became an interested shareholder, unless, in addition to any other approval that may be required by applicable law:

- prior to the date of the transaction that resulted in the shareholder becoming an interested shareholder, our board of directors approved either the business combination or the transaction that resulted in the shareholder becoming an interested shareholder;
- upon consummation of the transaction that resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of our issued and voting shares outstanding at the time the transaction commenced; or
- after the date of the transaction that resulted in the shareholder becoming an interested shareholder, the business combination is approved by our board of directors and authorized at an annual or special meeting of shareholders by the affirmative vote of at least 66^{2}/3% of our issued and outstanding voting shares that are not owned by the interested shareholder.

For purposes of these provisions, a "business combination" includes recapitalizations, mergers, amalgamations, consolidations, exchanges, asset sales, leases, certain issues or transfers of shares or other securities and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is any person or entity that beneficially owns 15% or more of our issued and outstanding voting shares and any person or entity affiliated with or controlling or controlled by that person or entity.

Shareholder Suits

Class actions and derivative actions are generally not available to shareholders under Bermuda law. 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 that which 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 part of the 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.

Our amended and restated bye-laws contain a provision by virtue of which our shareholders waive any claim or right of action that they have, both individually and on our behalf, against any director or officer in relation to any action or failure to take action by such director or officer, except in respect of any fraud or dishonesty of such director or officer. We have been advised by the SEC that in the opinion of the SEC, the operation of this provision as a waiver of the right to sue for violations of federal securities laws would likely be unenforceable in U.S. courts.

Capitalization of Profits and Reserves

Pursuant to our amended and restated bye-laws, our board of directors may (1) capitalize any part of the amount of our share premium or other reserve accounts or any amount credited to our profit and loss account or otherwise available for distribution by applying such sum in paying up unissued shares to be allotted as fully paid bonus shares pro rata (except in connection with the conversion of shares) to the shareholders; or (2) capitalize any sum standing to the credit of a reserve account or sums otherwise available for dividend or distribution by paying up in full, partly paid or nil paid shares of those shareholders who would have been entitled to such sums if they were distributed by way of dividend or distribution.

Untraced Shareholders

Our amended and restated bye-laws provide that our board of directors may forfeit any dividend or other monies payable in respect of any shares that remain unclaimed for six years from the date when such monies became due for payment. In addition, we are entitled to cease sending dividend warrants and checks by post or otherwise to a shareholder if such instruments have been returned undelivered to, or left uncashed by, such shareholder on at least two consecutive occasions or, following one such occasion, reasonable enquires have failed to establish the shareholder's new address. This entitlement ceases if the shareholder claims a dividend or cashes a dividend check or a warrant.

Certain Provisions of Bermuda Law

We have been designated by the Bermuda Monetary Authority as a non-resident for Bermuda exchange control purposes. This designation allows us to engage in transactions in currencies other than the Bermudan dollar, and there are no restrictions on our ability to transfer funds (other than funds denominated in Bermudan dollars) in and out of Bermuda or to pay dividends to U.S. residents who are holders of our common shares.

The Bermuda Monetary Authority has given its consent for the issue and free transferability of all of the common shares that are the subject of this offering to and between residents and non-residents of Bermuda for exchange control purposes, provided our shares remain listed on an appointed stock exchange, which includes the NYSE. Approvals or permissions given by the Bermuda Monetary Authority do not constitute a guarantee by the Bermuda Monetary Authority as to our performance or our creditworthiness. Accordingly, in giving such consent or permissions, neither the Bermuda Monetary Authority nor the Registrar of Companies in Bermuda shall be liable for the financial soundness, performance or default of our business or for the correctness of any opinions or statements expressed in this prospectus. Certain issues and transfers of common shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. 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.

In accordance with Bermuda law, share certificates are only issued in the names of companies, partnerships or individuals. In the case of a shareholder acting in a special capacity (for example as a trustee), certificates may, at the request of the shareholder, record the capacity in which the shareholder is acting. Notwithstanding such recording of any special capacity, we are not bound to investigate or see to the execution of any such trust.

Takeda Warrant

In April 2016, we issued a warrant to purchase an indeterminate number of our capital shares to Takeda. This warrant entitles Takeda to purchase, at any time, following our issuance of any class of capital shares, that number of capital shares of such class that would allow Takeda, together with its affiliates, to maintain 12% ownership of us, as determined after such exercise. See "Certain Relationships and Related Party Transactions—Relationship with Takeda Pharmaceuticals International AG—Warrant" for a further description of the terms of this warrant.

Registration Rights

In April 2016, we entered into an investor rights agreement with Takeda and Roivant Sciences Ltd. which provides these shareholders with certain registration rights. The registration of our common shares pursuant to the exercise of registration rights described below would enable these shareholders to sell these common shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and transfer taxes, of the shares registered pursuant to the piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specific conditions, to limit the number of shares such holders may include. The piggyback and Form S-3 registration rights described below will expire upon the earlier of (1) five years after the effective date of the registration statement, of which this prospectus forms a part, (2) at such time as a shareholder can sell all of its shares under Rule 144 of the Securities Act during any three month period or (3) in the event of a change of control or liquidation of our company.

Piggyback Registration Rights

In connection with this offering, Takeda and Roivant Sciences Ltd., were entitled to, and have waived, their right to include their common shares in this offering. If we propose to register the offer and sale of any of our securities under the Securities Act either for our own account or for the account of other security holders, the holders of these common shares will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act including a registration statement on Form S-3 as discussed below, other than with respect to a registration statement relating to the sale of securities to employees pursuant to an equity incentive plan, relating to an SEC Rule 145 transaction or where the registration statement would not include substantially the same information required to offer such securities, these shareholders are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of common shares included in the registration, to include their common shares in the registration.

Form S-3 Registration Rights

Takeda and Roivant Sciences Ltd. are entitled to certain Form S-3 registration rights. These shareholders may request that we register their common shares on Form S-3 if we are qualified to file a registration statement on Form S-3. Such request for registration on Form S-3 must cover securities the aggregate offering price of which, before payment of underwriting discounts, commissions and transfer taxes, is at least $5 million.

Transfer Agent and Registrar

A register of holders of the common shares will be maintained by Codan Services Limited in Bermuda, and a branch register will be maintained in the United States by American Stock Transfer & Trust Company, LLC, which will also serve as transfer agent. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

Listing

Our common shares have been authorized for listing on the NYSE under the trading symbol " MYOV."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common shares. Future sales of our common shares in the public market after this offering, or the perception that these sales could occur, could adversely affect prevailing market prices for our common shares and could impair our future ability to raise equity capital.

Based on the number of common shares outstanding as of June 30, 2016, upon the closing of this offering and assuming no exercise by the underwriters of their option to purchase additional common shares, 60,227,953 common shares will be outstanding. All of the common shares sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for the shares sold to entities affiliated with Pfizer Inc. or BB Biotech AG. The remaining 45,727,953 common shares held by existing shareholders, including the 160,273 common shares issued to Takeda in August and September 2016 and the 1,977,269 common shares to be issued to Takeda upon the closing of this offering pursuant to the automatic exercise of the warrant we issued to Takeda, are restricted securities, as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act.

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the common shares sold in this offering and the restricted securities will be available for sale in the public market as follows:

- the 4,000,000 common shares purchased by entities affiliated with Pfizer Inc. and BB Biotech AG will be eligible for sale in the public market upon the expiration of lock-up agreements 180 days after the date of this prospectus;
- the remaining 10,500,000 common shares sold in this offering will be eligible for immediate sale upon the closing of this offering; and
- 45,727,953 common shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Rule 144

In general, persons who have beneficially owned our common shares for at least six months, and any affiliate of the company who owns our common shares, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of common shares under Rule 144 if:

- the common shares have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the common shares for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of common shares without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of our common shares then outstanding, which will equal approximately 602,280 shares immediately after the closing of this offering based on the number of shares outstanding as of June 30, 2016; or
- the average weekly trading volume of our common shares on the NYSE during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Our employees, executive officers or directors who purchase shares under a written compensatory plan or contract will be entitled to rely on the resale provisions of Rule 701, but any holders of Rule 701 shares will be required to wait until 90 days after the date of this prospectus before selling their shares. However, all our Rule 701 shares are subject to lock-up agreements as described below and in the section titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

As soon as practicable after the closing of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the our common shares that are issuable pursuant to our 2016 Plan. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-Up Agreements

We and the holders of all of our common shares outstanding on the date of this prospectus, including each of our executive officers, directors and option holders, have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our common shares, any options or warrants to purchase our common shares, or any securities convertible into, or exchangeable for or that represent the right to receive our common shares, without the prior written consent of Citigroup Global Markets Inc. for a period of 180 days from the date of this prospectus.

In addition, entities affiliated with Pfizer Inc. and BB Biotech AG have each agreed to purchase 2,000,000 of our common shares in this offering at the initial public offering price. The shares purchased by these entities will also be subject to a 180-day lock-up agreement with the underwriters on substantially similar terms as the lock-up agreements entered into with each of our executive officers, directors and option holders.

BERMUDA COMPANY CONSIDERATIONS

Our corporate affairs are governed by our memorandum of association and bye-laws and by the corporate law of Bermuda. The provisions of the Companies Act, which applies to us, differ in certain material respects from laws generally applicable to U.S. companies incorporated in the State of Delaware and their stockholders. The following is a summary of significant differences between the Companies Act (including modifications adopted pursuant to our bye-laws) and Bermuda common law applicable to us and our shareholders and the provisions of the Delaware General Corporation Law applicable to U.S. companies organized under the laws of Delaware and their stockholders.

Bermuda	Delaware
Shareholder Meetings	
• May be called by the board of directors and must be called upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings.	• May be held at such time or place as designated in the certificate of incorporation or the bylaws, or if not so designated, as determined by the board of directors.
• May be held in or outside Bermuda.	• May be held in or outside of Delaware.
• Notice:	• Notice:
• Shareholders must be given at least five days' advance notice of a general meeting, but the unintentional failure to give notice to any person does not invalidate the proceedings at a meeting.	• Written notice shall be given not less than ten nor more than 60 days before the meeting.
• Notice of general meetings must specify the place, the day and hour of the meeting and in the case of special general meetings, the general nature of the business to be considered.	• Whenever stockholders are required to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, and the means of remote communication, if any.
• Our bye-laws provide that at least 14 days' notice of an annual general meeting and 10 days' notice of a special general meeting must be given to each shareholder entitled to vote at such meeting.	
Shareholders' Voting Rights	
• Shareholders may act by written consent to elect directors. Shareholders may not act by written consent to remove a director or auditor.	• With limited exceptions, stockholders may act by written consent to elect directors unless prohibited by the certificate of incorporation.
• Generally, except as otherwise provided in the bye-laws, or the Companies Act, any action or resolution requiring approval of the shareholders may be passed by a simple majority of votes cast. Any person authorized to vote may authorize another person or persons to act for him or her by proxy.	• Any person authorized to vote may authorize another person or persons to act for him or her by proxy.
• The voting rights of shareholders are regulated by a company's bye-laws and, in certain circumstances, by the Companies Act. The bye-laws may specify the number to constitute a quorum and if the bye-laws permit, a general meeting of the shareholders of a company may be held with only one individual present if the requirement for a quorum is satisfied.	• For stock corporations, the certificate of incorporation or bylaws may specify the number to constitute a quorum, but in no event shall a quorum consist of less than one-third of shares entitled to vote at a meeting. In the absence of such specifications, a majority of shares entitled to vote shall constitute a quorum.

Bermuda	Delaware
Subject to the rules of the NYSE, our bye-laws provide that the quorum required for a general meeting of shareholders is two or more persons present in person at the start of the meeting and representing in person or by proxy in excess of 50% of all issued and outstanding common shares.	
• Our bye-laws provide that, 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 holds, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of this offering, 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. Our bye-laws further provide that, 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.	
• Our bye-laws provide that when a quorum is once present in general meeting it is not broken by the subsequent withdrawal of any shareholders.	• When a quorum is once present to organize a meeting, it is not broken by the subsequent withdrawal of any stockholders.
• The bye-laws may provide for cumulative voting, although our bye-laws do not.	• The certificate of incorporation may provide for cumulative voting.
• The amalgamation or merger of a Bermuda company with another company or corporation (other than certain affiliated companies) requires the amalgamation or merger agreement to be approved by the company's board of directors and by its shareholders. Unless the company's bye-laws provide otherwise, the approval of 75% of the shareholders voting at such meeting is required to approve the amalgamation or merger agreement, and the quorum for such meeting must be two or more persons holding or representing more than one-third of the issued shares of the company.	• Any two or more corporations existing under the laws of the state may merge into a single corporation pursuant to a board resolution and upon the majority vote by stockholders of each constituent corporation at an annual or special meeting.

Bermuda	Delaware
• Every company may at any meeting of its board of directors sell, lease or exchange all or substantially all of its property and assets as its board of directors deems expedient and in the best interests of the company to do so when authorized by a resolution adopted by the holders of a majority of issued and outstanding shares of a company entitled to vote.	• Every corporation may at any meeting of the board sell, lease or exchange all or substantially all of its property and assets as its board deems expedient and for the best interests of the corporation when so authorized by a resolution adopted by the holders of a majority of the outstanding stock of a corporation entitled to vote.
• Any company that is the wholly owned subsidiary of a holding company, or one or more companies which are wholly owned subsidiaries of the same holding company, may amalgamate or merge without the vote or consent of shareholders provided that the approval of the board of directors is obtained and that a director or officer of each such company signs a statutory solvency declaration in respect of the relevant company.	• Any corporation owning at least 90% of the outstanding shares of each class of another corporation may merge the other corporation into itself and assume all of its obligations without the vote or consent of stockholders; however, in case the parent corporation is not the surviving corporation, the proposed merger shall be approved by a majority of the outstanding stock of the parent corporation entitled to vote at a duly called stockholder meeting.
• Any mortgage, charge or pledge of a company's property and assets may be authorized without the consent of shareholders subject to any restrictions under the bye-laws.	• Any mortgage or pledge of a corporation's property and assets may be authorized without the vote or consent of stockholders, except to the extent that the certificate of incorporation otherwise provides.
Directors	
• The board of directors must consist of at least one director.	• The board of directors must consist of at least one member.
• The number of directors is fixed by the bye-laws, and any changes to such number must be approved by the board of directors and/or the shareholders in accordance with the company's bye-laws.	• Number of board members shall be fixed by the bylaws, unless the certificate of incorporation fixes the number of directors, in which case a change in the number shall be made only by amendment of the certificate of incorporation.
• Removal:	• Removal:
• Under our bye-laws, any or all directors may be removed only with cause by the holders of a majority of the shares entitled to vote at a special meeting convened and held in accordance with the bye-laws for the purpose of such removal.	• Any or all of the directors may be removed, with or without cause, by the holders of a majority of the shares entitled to vote unless the certificate of incorporation otherwise provides. • In the case of a classified board, stockholders may effect removal of any or all directors only for cause.

Bermuda	Delaware
Duties of Directors	
• The Companies Act authorizes the directors of a company, subject to its bye-laws, to exercise all powers of the company except those that are required by the Companies Act or the company's bye-laws to be exercised by the shareholders of the company. Our bye-laws provide that our business is to be managed and conducted by our Board of Directors. At common law, members of a board of directors owe a fiduciary duty to the company to act in good faith in their dealings with or on behalf of the company and exercise their powers and fulfill the duties of their office honestly. This duty includes the following essential elements: • a duty to act in good faith in the best interests of the company; • a duty not to make a personal profit from opportunities that arise from the office of director; • a duty to avoid conflicts of interest; and • a duty to exercise powers for the purpose for which such powers were intended.	• Under Delaware law, the business and affairs of a corporation are managed by or under the direction of its board of directors. In exercising their powers, directors are charged with a fiduciary duty of care to protect the interests of the corporation and a fiduciary duty of loyalty to act in the best interests of its stockholders. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to stockholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its stockholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the stockholders generally.
• The Companies Act imposes a duty on directors and officers of a Bermuda company: • to act honestly and in good faith with a view to the best interests of the company; and • to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.	• In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.
• The Companies Act also imposes various duties on directors and officers of a company with respect to certain matters of management and administration of the company. Under Bermuda law, directors and officers generally owe fiduciary duties to the company itself, not to the company's individual shareholders, creditors or any class thereof. Our shareholders may not have a direct cause of action against our directors.	

Bermuda	Delaware
Takeovers	
• An acquiring party is generally able to acquire compulsorily the common shares of minority holders of a company in the following ways:	• Delaware law provides that a parent corporation, by resolution of its board of directors and without any stockholder vote, may merge with any subsidiary of which it owns at least 90% of each class of its capital stock. Upon any such merger, and in the event the parent corporate does not own all of the stock of the subsidiary, dissenting stockholders of the subsidiary are entitled to certain appraisal rights.
• By a procedure under the Companies Act known as a "scheme of arrangement." A scheme of arrangement could be effected by obtaining the agreement of the company and of holders of common shares, representing in the aggregate a majority in number and at least 75% in value of the common shareholders present and voting at a court ordered meeting held to consider the scheme of arrangement. The scheme of arrangement must then be sanctioned by the Bermuda Supreme Court. If a scheme of arrangement receives all necessary agreements and sanctions, upon the filing of the court order with the Registrar of Companies in Bermuda, all holders of common shares could be compelled to sell their shares under the terms of the scheme of arrangement.	• Delaware law also provides, subject to certain exceptions, that if a person acquires 15% of voting stock of a company, the person is an "interested stockholder" and may not engage in "business combinations" with the company for a period of three years from the time the person acquired 15% or more of voting stock.
• By acquiring pursuant to a tender offer 90% of the shares or class of shares not already owned by, or by a nominee for, the acquiring party (the offeror), or any of its subsidiaries. If an offeror has, within four months after the making of an offer for all the shares or class of shares not owned by, or by a nominee for, the offeror, or any of its subsidiaries, obtained the approval of the holders of 90% or more of all the shares to which the offer relates, the offeror may, at any time within two months beginning with the date on which the approval was obtained, by notice compulsorily acquire the shares of any nontendering shareholder on the same terms as the original offer unless the Supreme Court of Bermuda (on application made within a one-month period from the date of the offeror's notice of its intention to acquire such shares) orders otherwise.	
• Where the acquiring party or parties hold not less than 95% of the shares or a class of shares of the company, by acquiring, pursuant to a notice given to the remaining shareholders or class of shareholders, the shares of such remaining shareholders or class of shareholders. When this notice is given, the acquiring party is entitled and bound to acquire the shares of the remaining shareholders on the terms set out in the notice, unless a remaining shareholder, within one month of receiving such notice, applies to the Supreme Court of Bermuda for an appraisal of the value of their shares. This provision only applies where the acquiring party offers the same terms to all holders of shares whose shares are being acquired.	

Bermuda	Delaware
Dissenter's Rights of Appraisal	
• A dissenting shareholder (that did not vote in favor of the amalgamation or merger) of a Bermuda exempted company is entitled to be paid the fair value of his or her shares in an amalgamation or merger.	• With limited exceptions, appraisal rights shall be available for the shares of any class or series of stock of a corporation in a merger or consolidation. • The certificate of incorporation may provide that appraisal rights are available for shares as a result of an amendment to the certificate of incorporation, any merger or consolidation or the sale of all or substantially all of the assets.
Dissolution	
• Under Bermuda law, a solvent company may be wound up by way of a shareholders' voluntary liquidation. Prior to the company entering liquidation, a majority of the directors shall each make a statutory declaration, which states that the directors have made a full enquiry into the affairs of the company and have formed the opinion that the company will be able to pay its debts within a period of 12 months of the commencement of the winding up and must file the statutory declaration with the Registrar of Companies in Bermuda. The general meeting will be convened primarily for the purposes of passing a resolution that the company be wound up voluntarily and appointing a liquidator. The winding up of the company is deemed to commence at the time of the passing of the resolution.	• Under Delaware law, a corporation may voluntarily dissolve (1) if a majority of the board of directors adopts a resolution to that effect and the holders of a majority of the issued and outstanding shares entitled to vote thereon vote for such dissolution; or (2) if all stockholders entitled to vote thereon consent in writing to such dissolution.
Shareholders' Derivative Actions	
• Class actions and derivative actions are generally not available to shareholders under Bermuda law. 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 that which actually approved it.	• In any derivative suit instituted by a stockholder of a corporation, it shall be averred in the complaint that the plaintiff was a stockholder of the corporation at the time of the transaction of which he complains or that such stockholder's stock thereafter devolved upon such stockholder by operation of law.

MATERIAL BERMUDA AND U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a discussion of the material Bermuda and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our common shares.

Bermuda Tax Considerations

At the present time, there is no Bermuda withholding tax, capital gains tax, capital transfer tax, estate duty or inheritance tax payable by our shareholders in respect of our common shares. We have obtained an assurance from the Minister of Finance of Bermuda under the Exempted Undertakings Tax Protection Act 1966 that, in the event that any legislation is enacted in Bermuda imposing any tax computed on any capital asset, gain or appreciation or any tax in the nature of estate duty or inheritance tax, such tax shall not, until March 31, 2035, be applicable to our common shares, except insofar as such tax applies to persons ordinarily resident in Bermuda.

U.S. Federal Income Tax Considerations

The following are the material U.S. federal income tax consequences to U.S. Holders (as defined below) of owning and disposing of common shares acquired in this offering. This discussion does not address any aspects of U.S. taxation other than U.S. federal income taxation, does not address any U.S. state, local or non-U.S. tax considerations, and does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire common shares. This discussion applies only to U.S. Holders that hold their common shares as capital assets for U.S. federal income tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances including alternative minimum, gift, and estate tax consequences, and does not address the tax consequences applicable to U.S. Holders subject to special rules, such as:

- a holder of common shares who actually or constructively owns or is deemed to own 10% or more of the total combined voting power of all classes of our shares entitled to vote;
- a U.S. Holder who is also resident or ordinarily resident in Bermuda for Bermuda tax purposes or who is otherwise subject to Bermuda income tax or capital gains tax with respect to our common shares;
- a bank or other financial institution;
- an insurance company;
- a dealer or trader in securities who uses a mark-to-market method of tax accounting;
- a person holding common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or integrated transaction or a person entering into a constructive sale with respect to common shares;
- a U.S. Holder whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- an entity classified as a partnership or other pass-through entity for U.S. federal income tax purposes, including persons that will hold our common shares through such an entity;
- a tax-exempt entity, including an "individual retirement account" or "Roth IRA" or retirement plan;
- a U.S. expatriate;
- a real estate investment trust;
- a regulated investment company;
- a person who acquired our common shares pursuant to the exercise of an employee stock option or otherwise as compensation; or
- a person holding our common shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding common shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of common shares.

This discussion is based on the Code, administrative pronouncements, judicial decisions and final, temporary and proposed U.S. Treasury regulations all as of the date hereof, any of which is subject to change, possibly with retroactive effect, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the Internal Revenue Service, or IRS, will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of the common shares or that such a position would not be sustained.

A "U.S. Holder" is a beneficial owner of common shares that for U.S. federal income tax purposes is:

- an individual citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States or any political subdivision thereof; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the ability to control all of the substantial decisions of such trust, or if such trust has a valid election in effect to be treated as a United States person; or
- an estate the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of common shares in their particular circumstances.

Subject to the discussion below under "Passive Foreign Investment Company Rules," this discussion assumes that we are a foreign corporation that is not, and will not become, a passive foreign investment company, or PFIC, as described below.

Taxation of Distributions

Although we do not currently plan to pay dividends, any future distributions paid on common shares (including the amount of any foreign taxes withheld therefrom) will be treated as taxable dividends to a U.S. Holder to the extent of such U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent that a distribution paid to a U.S. Holder with respect to our common shares exceeds such U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated as a non-taxable return of capital to the extent of the U.S. Holder's basis in the common shares (determined on a share-by-share basis), will reduce (but not below zero) such basis, and thereafter generally will be treated as a capital gain. See "—Sale or Other Taxable Disposition of Common Shares" below. We may not maintain calculations of our earnings and profits under U.S. federal income tax principles. Accordingly, distributions, if any, generally will be reported to U.S. Holders as dividends.

Dividends received by a non-corporate U.S. Holder are eligible to be taxed at reduced rates, if we are a "qualified foreign corporation" and certain other applicable requirements, including holding period requirements, are met. The reduced rate applicable to dividends paid to non-corporate U.S. Holders is not available for dividends paid by a PFIC (described below) or in certain other situations, including if we are not a qualified foreign corporation. A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on common shares which are readily tradable on an established securities market in the United States. The common

shares are expected to be listed on the NYSE, which is an established securities market in the United States, and we expect the common shares to be readily tradable on the NYSE. However, there can be no assurance that the common shares will be considered readily tradable on an established securities market in the United States in later years. Subject to the discussion under "Passive Foreign Investment Company Rules," below, such dividends will generally be "qualified dividend income" (which is taxed at a reduced rate) in the hands of non-corporate U.S. Holders, including individuals, provided that the holding period requirement and certain other requirements are met. Dividends received by a corporate U.S. Holder will not be eligible for the dividends-received deduction generally available to U.S. corporate shareholders under the Code for dividends received from certain U.S. and non-U.S. corporations.

For foreign tax credit limitation purposes, distributions paid on the common shares that are treated as dividends will be treated as income from sources outside the United States and will generally constitute passive category income.

Sale or Other Taxable Disposition of Common Shares

For U.S. federal income tax purposes, gain or loss recognized on the sale or other taxable disposition of common shares generally will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's adjusted tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. Long-term capital gains recognized by non-corporate U.S. Holders are taxable at reduced rates. There are limitations on the deductibility of capital losses. Any such capital gain or loss will generally be U.S.-source gain or loss for foreign tax credit limitation purposes.

If the consideration received for the common shares is paid in foreign currency, the amount realized will be the U.S. dollar value of the payment received translated at the spot rate of exchange on the date of disposition. A U.S. Holder may realize additional gain or loss upon the subsequent sale or disposition of such currency, which will generally be treated as U.S. source ordinary income or loss. If the common shares are treated as traded on an established securities market and the relevant holder is either a cash basis taxpayer or an accrual basis taxpayer who has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), such holder will determine the U.S. dollar value of the amount realized in a foreign currency by translating the amount received at the spot rate of exchange on the settlement date of the disposition. If the common shares are not treated as traded on an established securities market, or the relevant U.S. Holder is an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, such U.S. Holder will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of disposition (as determined above) and the U.S. dollar value of the currency received at the spot rate on the settlement date. Any such foreign currency gain or loss will generally be U.S. source ordinary income or loss.

Passive Foreign Investment Company Rules

In general, a corporation organized outside the United States will be a PFIC in any taxable year in which either (1) at least 75% of its gross income is "passive income" or (2) on average at least 50% of the value of its assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from commodities transactions and from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income may include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. The average value of a corporation's assets for this purpose, in the case of a corporation whose shares are publicly traded for the taxable year, generally is the average of their fair market value at the end of each quarter. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

We believe that we were not a CFC prior to this offering in the current taxable year which will end on March 31, 2017. Based on this belief, we do not believe we were a PFIC in the taxable year that ended March 31, 2016 and based on the nature of our business, the projected composition of our income and the projected composition and estimated fair market values of our assets, we do not expect to be a PFIC in the taxable year commencing April 1, 2016. However, there can be no assurances in this regard, or that the IRS will agree with our conclusion, because we expect to hold following this offering a substantial amount of cash, and the calculation of the value of our assets may be based in part on the value of our shares, which may fluctuate considerably after this offering. 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. In addition, there can be no assurances regarding our PFIC status in one or more subsequent years to the extent that our activities change, and our United States counsel expresses no opinion with respect to our PFIC status (including the impact of our potential status as a CFC) in the taxable year that ended March 31, 2016 or the taxable year commencing April 1, 2016, and also expresses no opinion with respect to our predictions regarding our PFIC status in the future.

If we are a PFIC in any taxable year during which a U.S. Holder owns our shares, such U.S. Holder could be liable for additional taxes and interest charges upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for the shares, and (2) any gain recognized on a sale, exchange or other taxable disposition, including a pledge, of the shares, whether or not we continue to be a PFIC. In these circumstances, the tax will be determined by allocating such distribution or gain ratably over the U.S. Holder's holding period for the shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax. If we are a PFIC for any year during which a U.S. Holder holds the shares, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds the shares, unless we cease to meet the requirements for PFIC status and the U.S. Holder makes a "deemed sale" election with respect to the shares. If such election is made, the U.S. Holder will be deemed to have sold the shares it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described above. After the deemed sale election, the U.S. Holder's shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds the shares and one of our non-United States subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder generally would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be subject to the rules described above on certain distributions by the lower-tier PFIC and a disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Each U.S. Holder is advised to consult its tax advisors regarding the application of the PFIC rules to any of our subsidiaries.

The tax consequences that would apply if we were a PFIC would be different from those described above if a timely and valid "mark-to-market" election is made by a U.S. Holder for the shares held by such U.S. Holder. An electing U.S. Holder generally would take into account as ordinary income each year, the excess of the fair market value of the shares held at the end of the taxable year over the adjusted tax basis of such shares. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such shares over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted as a result of the mark-to-market election. The U.S. Holder's tax basis in the shares would be adjusted to reflect any income or loss recognized as a result of the

mark-to-market election. Any gain from a sale, exchange or other taxable disposition of the shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other taxable disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss. If, after having been a PFIC for a taxable year, we cease to be classified as a PFIC, the U.S. Holder would not be required to take into account any latent gain or loss in the manner described above and any gain or loss recognized on the sale or exchange of the shares would be classified as a capital gain or loss.

A mark-to-market election is available to a U.S. Holder only for "marketable stock." Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. The shares will be marketable stock as long as they remain listed on a qualified exchange, such as the NYSE, and are regularly traded. A mark-to-market election will not apply to the shares for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any subsidiary that we own. Accordingly, a U.S. Holder may continue to be subject to the PFIC rules with respect to any lower-tier PFICs notwithstanding the U.S. Holder's mark-to-market election for our shares.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. Holder were able to make a valid "qualified electing fund," or QEF, election. As we do not expect to provide U.S. Holders with the information required in order to permit a QEF election, prospective investors should assume that a QEF election will not be available.

Each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information.

Medicare Tax

In general, a United states person that is an individual or estate, or a trust that does not fall into a special class of trusts that is exempt from such tax, is subject to a 3.8% tax on the lesser of (1) the United States person's "net investment income" for the relevant taxable year and (2) the excess of the United States person's modified adjusted gross income for the taxable year over a certain threshold (which in the case of individuals will be between $125,000 and $250,000, depending on the individual's circumstances). A U.S. holder's net investment income will include its gross dividend income and its net gains from the disposition of our common shares, unless such dividends or net gains are derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). If you are a United States person that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of the Medicare tax to your income and gains in respect of your investment in our common shares.

Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our common shares, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (1) the U.S. Holder is a corporation or other exempt recipient or (2) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Each U.S. Holder is urged to consult with its tax advisor concerning the United States federal income tax consequences of purchasing, holding, and disposing of our common shares if we are or become classified as a PFIC, including the procedure for, and the possibility and consequences of, making a purging or mark-to-market election. We cannot provide any assurances that the IRS will agree with our annual determinations of our PFIC status.

UNDERWRITING

Citigroup Global Markets Inc., Cowen and Company, LLC, Evercore Group L.L.C. and Barclays Capital Inc. are acting as book-running managers of this offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each of the underwriters named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of common shares indicated below.

Underwriter	Number of Common Shares
Citigroup Global Markets Inc.	4,712,500
Cowen and Company, LLC	2,900,000
Evercore Group L.L.C.	2,537,500
Barclays Capital Inc.	2,537,500
JMP Securities LLC	1,087,500
Robert W. Baird & Co. Incorporated	725,000
Total	14,500,000

The underwriting agreement provides that the obligations of the underwriters to purchase the common shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of the common shares (other than those covered by the underwriters' option to purchase additional common shares described below) if they purchase any of the common shares.

Common shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover page of this prospectus. Any common shares sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed $0.63 per common share. If all the common shares are not sold at the initial offering price, the underwriters may change the initial offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

If the underwriters sell more common shares than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 2,175,000 additional common shares at the initial public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional common shares approximately proportionate to that underwriter's initial purchase commitment set forth in the table above. Any common shares issued or sold under the option will be issued and sold on the same terms and conditions as the other common shares that are the subject of this offering.

We, our executive officers, our board of directors and all of our other shareholders and optionholders have agreed that, subject to specified limited exceptions, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup Global Markets Inc., offer, sell, contract to sell, pledge or otherwise dispose of any common shares or any securities convertible into, or exercisable or exchangeable for, our common shares. Citigroup Global Markets Inc. in its sole discretion may release any of the securities subject to these lock-up agreements at any time, which, in the case of our management board members and supervisory board members, shall be with notice.

Prior to this offering, there has been no public market for our common shares. Consequently, the initial public offering price for our common shares will be determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price will be our results of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management board, and currently prevailing general

conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our Company. We cannot assure you, however, that the price at which our common shares will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our common shares will develop and continue after this offering.

Our common shares have been authorized for listing on the NYSE under the symbol “MYOV.”

The following table shows the per share and total underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase additional common shares.

	Paid by Myovant	
	No Exercise	Full Exercise
Per common share	$ 1.05	$ 1.05
Total	$ 15,225,000	$ 17,508,750

We estimate that our portion of the total expenses of this offering, exclusive of underwriting discounts and commissions payable by us, will be approximately $2.5 million. We have also agreed to reimburse the underwriters for expenses in an amount of up to $25,000 relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

In connection with this offering, the underwriters may purchase and sell our common shares in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the underwriters’ option to purchase additional common shares, and other transactions that would stabilize, maintain or otherwise affect the price of our common shares.

- Short sales involve secondary market sales by the underwriters of a greater number of common shares than they are required to purchase in this offering.
  - “Covered” short sales are sales of common shares in an amount up to the number of common shares represented by the underwriters’ option to purchase additional common shares.
  - “Naked” short sales are sales of common shares in an amount in excess of the number of common shares represented by the underwriters’ option to purchase additional common shares.
- Covering transactions involve purchases of common shares either pursuant to the underwriters’ option to purchase additional common shares or in the open market in order to cover short positions.
  - To close a naked short position, the underwriters must purchase common shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common shares in the open market after pricing that could adversely affect investors who purchase in this offering.
  - To close a covered short position, the underwriters must purchase common shares in the open market or must exercise their option to purchase additional common shares. In determining the source of common shares to close the covered short position, the underwriters will consider, among other things, the price of common shares available for purchase in the open market as compared to the price at which they may purchase common shares through the underwriters’ option to purchase additional common shares.
- Stabilizing transactions involve bids to purchase common shares so long as the stabilizing bids do not exceed a specified maximum, to stabilize the price of the common shares.

Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common shares. They may also cause the price of the common shares to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these

transactions on the NYSE, in the over-the-counter market or otherwise. The underwriters are not required to engage in any of these transactions, and they may discontinue them at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act or the Exchange Act, and to contribute to payments the underwriters may be required to make because of any of those liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more of the underwriters or their respective affiliates. The representatives may agree with us to allocate a number of common shares to underwriters for sale to their online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' or their respective affiliates' websites and any information contained in any other website maintained by any of the underwriters or their respective affiliates is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors in this offering.

Other Relationships

The underwriters are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriters and their respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (which may include bank loans and/or credit default swaps) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Entities affiliated with Pfizer Inc. and BB Biotech AG have each agreed to purchase 2,000,000 of our common shares in this offering at the initial public offering price. The shares purchased by these entities in this offering will be subject to a 180-day lock-up agreement with the underwriters.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), an offer to the public of any common shares which are the subject of the offering contemplated by this prospectus supplement and the accompanying prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor, as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or

- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer common shares to the public" in relation to the common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common shares to be offered so as to enable an investor to decide to purchase or subscribe to the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Notice to Prospective Investors in United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Bermuda

Securities may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act 2003 of Bermuda which regulates the sale of securities in Bermuda and it is not intended for any offer or sale of common shares to the public to take place in Bermuda.

Notice to Prospective Investors in Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to Prospective Investors in Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to professional investors, as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong ("SFO") and any rules made under that Ordinance; or in other circumstances which do not result in the document being a prospectus, as defined in the Companies Ordinance (Cap. 32) of Hong Kong ("CO") or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors, as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Notice to Prospective Investors in Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the initial purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the common shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:
  - to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
  - where no consideration is or will be given for the transfer;
  - where the transfer is by operation of law;
  - as specified in Section 276(7) of the SFA; or
  - as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Switzerland

The common shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a of the CO or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing relating to the common shares or this offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to this offering, the Company or the common shares has been or will be filed with or approved by any Swiss regulatory authority.

Notice to Prospective Investors in Canada

The common shares may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the Underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the common shares and certain other matters of Bermuda law will be passed upon for us by Conyers Dill & Pearman Limited, our special Bermuda counsel. Certain other legal matters will be passed upon for us by Cooley LLP, Palo Alto, California, and for the underwriters by Latham & Watkins LLP, New York, New York.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at March 31, 2016 and for the period from February 2, 2016 (date of inception) to March 31, 2016, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the financial statements). We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the common shares being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common shares offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at www.myovant.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

EXCHANGE CONTROLS

The permission of the Bermuda Monetary Authority is required, pursuant to the provisions of the Exchange Control Act 1972 and related regulations, for all issuances and transfers of shares (which includes our common shares) of Bermuda companies to or from a non-resident of Bermuda for exchange control purposes, other than in cases where the Bermuda Monetary Authority has granted a general permission. The Bermuda Monetary Authority, in its notice to the public dated June 1, 2005, has granted a general permission for the issue and subsequent transfer of any securities of a Bermuda company from or to a non-resident of Bermuda for exchange control purposes for so long as any "Equity Securities" of the company (which would include our common shares) are listed on an "Appointed Stock Exchange" (which would include the NYSE). Certain issues and transfers of common shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. 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.

ENFORCEMENT OF CIVIL LIABILITIES UNDER UNITED STATES FEDERAL SECURITIES LAWS

We are a Bermuda exempted company. As a result, the rights of holders of our common shares will be 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 other jurisdictions. It may be difficult for investors to enforce in the United States judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. Our registered office address is Clarendon House, 2 Church Street, Hamilton HM11, Bermuda, and we also have business operations at Park Place, 55 Par-La-Ville Road, 2nd Floor, Hamilton HM11, Bermuda.

We have been advised by our special Bermuda counsel that there is no treaty in force between the United States and Bermuda providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. As a result, whether a U.S. judgment would be enforceable in Bermuda against us or our directors and officers depends on whether the U.S. court that entered the judgment is recognized by a Bermuda court as having jurisdiction over us or our directors and officers, as determined by reference to Bermuda conflict of law rules. The courts of Bermuda would recognize as a valid judgment, a final and conclusive judgment in personam obtained in a U.S. court pursuant to which a sum of money is payable (other than a sum of money payable in respect of multiple damages, taxes or other charges of a like nature or in respect of a fine or other penalty). The courts of Bermuda would give a judgment based on such a U.S. judgment as long as (1) the U.S. court had proper jurisdiction over the parties subject to the judgment; (2) the U.S. court did not contravene the rules of natural justice of Bermuda; (3) the U.S. judgment was not obtained by fraud; (4) the enforcement of the U.S. judgment would not be contrary to the public policy of Bermuda; (5) no new admissible evidence relevant to the action is submitted prior to the rendering of the judgment by the courts of Bermuda; (6) there is due compliance with the correct procedures under the laws of Bermuda; and (7) the U.S. judgment is not inconsistent with any judgment of the courts of Bermuda in respect of the same matter.

In addition, and irrespective of jurisdictional issues, the Bermuda courts will not enforce a U.S. federal securities law that is either penal or contrary to Bermuda public policy. We have been advised that an action brought pursuant to a public or penal law, the purpose of which is the enforcement of a sanction, power or right at the instance of the state in its sovereign capacity, is unlikely to be entertained by a Bermuda court. Certain remedies available under the laws of U.S. jurisdictions, including certain remedies under U.S. federal securities laws, would not be available under Bermuda law or enforceable in a Bermuda court, as they are likely to be contrary to Bermuda public policy. Further, it may not be possible to pursue direct claims in Bermuda against us or our directors and officers for alleged violations of U.S. federal securities laws because these laws are unlikely to have extraterritorial effect and do not have force of law in Bermuda. A Bermuda court may, however, impose civil liability on us or our directors and officers if the facts alleged and proved in the Bermuda proceedings constitute or give rise to a cause of action under the applicable governing law, not being a foreign public, penal or revenue law.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Myovant Sciences Ltd. as of March 31, 2016, and the related statements of operations and comprehensive loss, shareholder's deficit and cash flows for 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 audit.

We conducted our audit 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 audit 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 audit provides a reasonable basis for our opinion.

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

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has insufficient capital to fund its operations which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Metro Park, New Jersey
July 8, 2016,
except for Note 11,
as to which the date is October 19, 2016

MYOVANT SCIENCES LTD.

CONSOLIDATED BALANCE SHEETS

	As of March 31, 2016	As of June 30, 2016 (unaudited)
Assets		
Deferred initial public offering costs	$ —	$ 523,681
Total assets	$ —	$ 523,681
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accrued expenses and accounts payable	$ 222,650	$ 990,343
Due to Roivant Sciences Ltd. and Roivant Science, Inc.	—	1,153,378
Income tax payable	—	3,054
Total current liabilities	$ 222,650	$ 2,146,775
Warrant liability	—	6,975,000
Total liabilities	$ 222,650	$ 9,121,775
Commitments and contingencies (Note 9)		
Shareholders' deficit:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 37,231,342, 43,590,411 and 60,227,953 issued and outstanding at March 31, 2016, June 30, 2016 and June 30, 2016 pro forma, respectively	660	773
Common shares subscribed	(660)	(660)
Additional paid-capital	1,434,138	12,029,070
Accumulated deficit	(1,656,788)	(20,627,277)
Total shareholders' deficit	$ (222,650)	$ (8,598,094)
Total liabilities and shareholders' deficit	$ —	$ 523,681

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

MYOVANT SCIENCES LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016 (unaudited)
Operating expenses:		
Research and development	$ —	$ 14,573,014
General and administrative	1,656,788	2,561,878
Total operating expenses	1,656,788	17,134,892
Other (expense) income:		
Changes in the fair value of the warrant liability	—	(1,832,543)
Loss before provision for income tax	(1,656,788)	(18,967,435)
Income tax expense	—	3,054
Net loss and comprehensive loss	$ (1,656,788)	$(18,970,489)
Net loss per common share—basic and diluted	$ (0.04)	$ (0.47)
Weighted average common shares outstanding—basic and diluted	37,231,342	40,771,548
Pro forma net loss per common share—basic and diluted (unaudited)		$ (0.44)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)		42,748,817

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

MYOVANT SCIENCES LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
FOR THE PERIOD FROM FEBRUARY 2, 2016 (DATE OF INCEPTION) TO MARCH 31, 2016 AND FOR THE THREE MONTHS ENDED JUNE 30, 2016 (UNAUDITED)

	Common Stock		Common Stock Subscribed	Additional Paid-in Capital	Accumulated Deficit	Total Shareholder's Deficit
	Shares	Amount				
Balance at February 2, 2016	37,231,342	$ 660	$ (660)	$ —	$ —	$ —
Capital contribution	—	—	—	1,434,138	—	1,434,138
Net loss	—	—	—	—	(1,656,788)	(1,656,788)
Balance at March 31, 2016	37,231,342	$ 660	$ (660)	$ 1,434,138	$ (1,656,788)	$ (222,650)
Shares issued to Takeda under the Takeda license agreement	5,077,001	90	—	7,739,910	—	7,740,000
Share-based compensation expense	1,128,222	20	—	18,278	—	18,298
Shares issued for the warrant liability, under the Takeda license agreement	153,846	3	—	234,540	—	234,543
Capital contribution - share based compensation	—	—	—	2,602,204		2,602,204
Net loss	—	—	—	—	(18,970,489)	(18,970,489)
Balance at June 30, 2016 (unaudited)	43,590,411	$ 773	$ (660)	$ 12,029,070	$ (20,627,277)	$ (8,598,094)

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

MYOVANT SCIENCES LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Period from February 2, 2016 (Date of Inception) to March 31, 2016	Three Months Ended June 30, 2016 (unaudited)
Cash flows from operating activities:		
Net loss	$ (1,656,788)	$(18,970,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,434,138	2,620,502
Purchase of in-process research and development expenses	—	13,117,000
Changes in the fair value of the warrant liability	—	1,832,543
Changes in operating assets and liabilities:		
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	—	1,153,378
Income tax payable	—	3,054
Accrued expenses and accounts payable	222,650	244,012
Net cash used in operating activities	—	—
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Net cash provided by financing activities	—	—
Net change in cash	—	—
Cash—beginning of period	—	—
Cash—end of period	$ —	$ —
Noncash financing activities:		
Deferred initial public offering costs, unpaid	$ —	$ 523,681
Purchase of in-process research and development	$ —	$ 13,117,000

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

MYOVANT SCIENCES LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited as of June 30, 2016 and for the three months ended June 30, 2016)

Note 1—Description of Business and Liquidity

[A] Description of Business:

Myovant Sciences Ltd. and its subsidiaries (the "Company") is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. 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, 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. ("RSL"), under the name Roivant Endocrinology Ltd. The Company changed its name to Myovant Sciences Ltd. ("MSL") in May 2016. In April 2016, Roivant Endocrinology Inc. ("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. ("MSI"). The Company's fiscal year ends on March 31.

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. The Company has two product candidates, relugolix and RVT-602, under development which were licensed from Takeda Pharmaceuticals International AG ("Takeda") on April 29, 2016 (See Note 3).

[B] Unaudited Interim Consolidated Financial Information:

The accompanying interim consolidated balance sheet as of June 30, 2016 and the consolidated statements of operations, cash flows and shareholder's deficit for the three months ended June 30, 2016 are unaudited. The unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles and on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of our financial position at June 30, 2016 and the consolidated results of operations and cash flows for the three months ended June 30, 2016. The results for the three months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending March 31, 2017 or for any future period.

[C] Unaudited Pro Forma Information:

The unaudited pro forma net loss per share is computed using the weighted average number of common shares outstanding after giving effect to the issuance of 1,977,269 additional common shares to Takeda upon the closing of the Company's initial public offering, as if such exercise had occurred at the beginning of the period presented, pursuant to the automatic exercise of a warrant held by Takeda.

[D] Liquidity:

The Company has not been capitalized with sufficient funding to conduct its operations. Certain other costs of conducting the Company's operations were paid by RSL or RSL's wholly-owned subsidiary, Roivant Sciences, Inc. ("RSI"), and will be reimbursed by the Company upon receipt of additional external funding pursuant to a services agreement with RSI and MSI. The Company has not generated any revenues and does not anticipate generating any revenues in the foreseeable future. Since the Company has no available cash or credit facilities, the Company is dependent upon RSL and its affiliates to provide services and funding to support the operations of the Company until, at least, such time as external financing is completed.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. The Company anticipates incurring additional losses until such time, if ever, that it can obtain marketing approval to sell, and then generate significant sales, of its product candidates that are currently in development. Substantial additional financing will be needed by the Company to fund its operations and to develop and commercialize its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company will seek to obtain additional capital through the sale of debt or equity financings or other arrangements to fund operations; however, there can be no assurance that the Company will be able to raise needed capital under acceptable terms, if at all. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company's ability to pay dividends or make other distributions to shareholders. If the Company is unable to obtain such additional financing, operations would need to be scaled back or discontinued. The Company is currently exploring external financing alternatives which will be needed by the Company to fund its operations.

The Company's future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the success of its research and development program; (iii) the development of competitive therapies by other biotechnology and pharmaceutical companies, (iv) the Company's ability to manage growth of the organization; (v) the Company's ability to protect its proprietary technology; and, ultimately; (vi) regulatory approval and market acceptance of the Company's product candidates.

Note 2—Summary of Significant Accounting Policies

[A] Basis of Presentation:

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

[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, expenses 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] Deferred Offering Costs:

Deferred offering costs, which consisted of direct costs related to the Company's initial public offering of its common stock, are being capitalized in other assets until the consummation of the initial public offering. These offering costs will be reclassified to additional paid-in capital upon the closing of the Company's initial public offering.

[E] 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.

[F] Warrant Liability:

The Company records the warrant liability at its estimated fair value as a liability in the consolidated balance sheet. The Company remeasures the estimated fair value of the warrant liability each reporting period and records the changes in the fair value in the statement of operations as other (expense) income (See Note 8).

[G] Company Valuation:

To estimate certain expenses and record certain transactions, it is necessary for the Company to estimate the fair value of its common shares. Given the absence of a public trading market, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation", the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of its common shares (See Note 3).

[H] 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.

[I] 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 over the requisite service period. 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 U.S. Treasury with a term approximating the expected life of the equity award. The expected share price volatility for the Company's common shares is estimated by taking the average historical price volatility for industry peers. 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.

[J] 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 period from February 2, 2016 (date of inception) to March 31, 2016, there were no instruments outstanding that would be anti-dilutive. For the three months ended June 30, 2016, 1,128,222 restricted stock awards were not included in the calculation of diluted weighted-average common shares outstanding because they were anti-dilutive.

[K] Recently Issued Accounting Pronouncements:

In August 2014, the FASB issued ASU No. 2014-15, "*Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*" (ASU No. 2014-15). ASU No. 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU No. 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued. It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new

standard will be effective for reporting periods ending after December 15, 2016, with early adoption permitted. Management does not expect the adoption of ASU No. 2014-15 will significantly impact its consolidated financial statements and disclosures.

In November 2015, the FASB issued ASU No. 2015-17, "*Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*" (ASU No. 2015-17). This amendment will simplify the presentation of deferred tax assets and liabilities on the balance sheet and require all deferred tax assets and liabilities to be treated as non-current. ASU No. 2015-17 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The Company has adopted ASU No. 2015-17. The adoption of ASU No. 2015-17 did not have a significant impact on the Company's 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, 2019, and interim periods within fiscal years beginning after December 15, 2019. 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 interim and annual reporting periods beginning after December 15, 2016, 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.

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 RVT-602, in exchange for the following:

- The Company issued and delivered 5,077,001 common shares at closing.
- The Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and RVT-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) the one-year anniversary of the issuance of the warrant (April 2017) or (ii) the final closing of an initial public offering as per the agreement, unless earlier terminated upon a change in control.

For the consideration above, the Company also received a small quantity of relugolix and RVT-602, and certain historical research and development records. The Company did not hire, or receive, any Takeda workforce or employees working on relugolix and RVT-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 RVT-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 $13,117,000 as research and development expense at the closing date of the acquisition of the rights, April 29, 2016, which consisted of $7,740,000 for the estimated fair value of the 5,077,001 common shares issued and $5,377,000 for the estimated fair value of warrant liability. Significant judgment and estimates were used to estimate the fair value of common shares and warrant liability, as they are not publicly traded and are considered Level 3 measurement within the fair value hierarchy.

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. No events have come to the attention of the Company's management between the date of the most recent valuation and the balance sheet date which would have a material impact on the valuation of the Company.

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 8).

Note 4—Related Party Transactions

[A] Services Agreement:

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 during the formative period of the Company. Under the Services Agreement, the Company will pay or reimburse 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 will charge 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. All other costs will be billed back at cost.

During the period from February 2, 2016 (date of inception) to March 31, 2016 and the three months ended June 30, 2016, 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. A significant component of total compensation expense allocated back to the Company relates to the RSL common share awards and RSL options issued by RSL to RSL and RSI employees.

For the period from February 2, 2016 (date of inception) to March 31, 2016 the amount of salary and fringe benefits and share-based compensation allocated to the Company was $1,390,798. For the three months ended June, 30, 2016 the share-based compensation allocated to the Company was $2,602,204. For the three months ended June 30, 2016, salary and fringe benefits were included in the $1,031,559 that was billed to the Company under the Services Agreement.

[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 initial public offering 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.

[D] Manufacture and Supply Agreement:

In June 2016, the Company and Takeda's affiliate, Takeda Pharmaceutical Company Limited ("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 5—Shareholder's Deficit

[A] Overview:

The Company's Memorandum of Association, filed on February 2, 2016 in Bermuda, authorized the creation of one class of shares. As of June 30, 2016, the Company had 564,111,242 shares authorized with a par value of $0.000017727 per share.

[B] Restricted Stock Award:

In June 2016, the Company granted a restricted stock award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Equity Incentive Plan.

[C] Warrant Liability:

In June 2016, the Company issued 153,846 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of a restricted stock award for 1,128,222 common shares.

Note 6—Income Taxes

The Company's provision for income taxes is based on income taxes in the United States for federal, state and local income taxes. The Company is not subject to taxation under the laws of Bermuda since it is was organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. The Company's effective tax rate for the period from February 2, 2016 (date of inception) to March 31, 2016 and for the three months ended June 30, 2016 was 0.0% and (0.02)%, respectively. As of March 31, 2016 and June 30, 2016, there were no significant uncertain tax positions.

Note 7—Share-Based Compensation

[A] Stock Options and Restricted Stock Awards Granted:

In June 2016, the Company adopted its 2016 Equity Incentive Plan (the "2016 Plan"), under which 4,230,834 common shares are reserved for grant. The Company's employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards under the plan. Generally, 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. As of June 30, 2016, no stock options had been granted by the Company.

In June 2016, the Company granted a restricted stock award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Plan.

For the period from February 2, 2016 (date of inception) to March 31, 2016, there was no share-based compensation expense. For the three months ended June 30, 2016, share-based compensation expense was $18,298. At June 30, 2016, total unrecognized compensation expense related to non-vested restricted stock award was $1,701,702 and is expected to be recognized over the remaining weighted-average service period of 3.92 years.

[B] Share-Based Compensation Allocated to the Company:

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 $987,066 and $2,602,204, respectively, for the period from February 2, 2016 (date of inception) to March 31, 2016 and the three months ended June 30, 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 RSI employees on Company matters.

Note 8—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 at March 31, 2016 and June 30, 2016, by level, within the fair value hierarchy:

	As of March 31, 2016				As of June 30, 2016			
	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	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2016
Assets:								
Total assets at fair value	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Liabilities:								
Warrant liability	$ —	$ —	$ —	$ —	$ —	$ —	$ 6,975,000	$ 6,975,000
Total liabilities at fair value	$ —	$ —	$ —	$ —	$ —	$ —	$ 6,975,000	$ 6,975,000

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the three months ended June 30, 2016.

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 expenses in the accompanying condensed consolidated statements of operations.

The warrant liability may change significantly as additional data is 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 June 30, 2016 was calculated using the following significant unobservable inputs:

Input	Range or Point Estimate Used
Projected time frame to an equity financing	Oct. 2016 – Oct. 2017
Probability of a successful equity financing	60.0%
Annualized equity volatility	72.0% - 81.9%
Risk-free interest rate	0.29% - 0.45%

The changes in fair value of the Company's Level 3 warrant liability during the three months ended June 30, 2016 were as follows:

Balance at March 31, 2016	$ —
Fair value of the warrant liability issued	5,377,000
Changes in the fair value of the warrant liability, included in net loss	1,832,543
Settlements	(234,543)
Balance at June 30, 2016	$6,975,000

For the three months ended June 30, 2016, changes in the carrying value of the warrant liability resulted from changes in the fair value of the warrant liability primarily due to 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 9—Commitments and Contingencies

The Company entered into certain commitments under the Takeda license agreement (See Note 3), and a services agreement with RSI (See Note 10). As of March 31, 2016 and June 30, 2016, the Company did not have any ongoing material financial commitments. The Company expects to enter into other commitments as the business further develops.

Note 10—Subsequent Events

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 during the formative period of the Company. Under the Services Agreement, the Company will pay or reimburse 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 will charge back the employee compensation expense plus a pre-determined markup. 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 (See Note 4). Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost.

In August 2016, (1) the Company granted options to purchase 602,743 common shares to certain employees and consultants of the Company, with an exercise price of $2.38 under the 2016 plan and (2) the Company issued 82,194 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of options to purchase 602,743 common shares.

In September 2016, (1) the Company granted options to purchase 572,568 common shares to certain employees and directors of the Company, with a weighted-average exercise price of $4.00 under the 2016 plan and (2) the Company issued 78,079 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of options to purchase 572,568 common shares.

Note 11—Reverse Common 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. The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

14,500,000 Shares

Common Shares

PROSPECTUS

October 26, 2016

Citigroup

Cowen and Company

Evercore ISI

Barclays

JMP Securities

Baird

Through and including November 20, 2016 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common shares, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.