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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

or

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

For the transition period from to

Commission file number 001-37929

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

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

Registrant's telephone number, including area code: **+1 (441) 824-8101**

**Clarendon House
2 Church Street
Hamilton HM 11, Bermuda**
(former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x (Do not check if a smaller reporting company)	Smaller reporting company	o

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

The number of shares outstanding of the Registrant's common shares, $0.000017727 par value per share, on December 8, 2016, was 60,249,139.

MYOVANT SCIENCES LTD.

QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2016	March 31, 2016
Assets		
Current assets:		
Cash	73	—
Prepaid expenses and other current assets	38	—
Total current assets	111	—
Deferred initial public offering costs	1,674	—
Property, plant and equipment, net	110	—
Other assets	100	—
Total assets	1,995	—
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accrued expenses and accounts payable	2,526	223
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	4,838	—
Income tax payable	1	—
Total current liabilities	7,365	223
Warrant liability	32,555	—
Total liabilities	39,920	223
Commitments and contingencies (Note 9)		
Shareholders' deficit:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 43,750,684 and 37,231,342 issued and outstanding at September 30, 2016 and March 31, 2016, respectively	1	1
Common shares subscribed	(1)	(1)
Additional paid-in capital	17,415	1,434
Accumulated deficit	(55,340)	(1,657)
Total shareholders' deficit	(37,925)	(223)
Total liabilities and shareholders' deficit	1,995	—

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

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

	Three Months Ended September 30, 2016	Six Months Ended September 30, 2016
Operating expenses:		
Research and development (includes $814 and $1,789 of share-based compensation expense for the three and six months ended September 30, 2016, respectively)	$ 3,753	$ 18,326
General and administrative (includes $1,336 and $2,982 of share-based compensation expense for the three and six months ended September 30, 2016, respectively)	2,967	5,529
Total operating expenses	6,720	23,855
Other expense:		
Changes in the fair value of the warrant liability	(27,984)	(29,817)
Loss before provision for income tax	(34,704)	(53,672)
Income tax expense	8	11
Net loss and comprehensive loss	$ (34,712)	$ (53,683)
Net loss per common share — basic and diluted	$ (0.82)	$ (1.29)
Weighted average common shares outstanding — basic and diluted	42,512,254	41,646,657

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

MYOVANT SCIENCES LTD.
Condensed Consolidated Statement of Shareholders' Deficit
For the Six Months Ended September 30, 2016
(unaudited, in thousands, except share data)

	Common Shares		Common Shares Subscribed	Additional Paid in Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount				
Balance at March 31, 2016	37,231,342	$ 1	(1)	$ 1,434	$ (1,657)	$ (223)
Shares issued to Takeda under the Takeda license agreement	5,077,001	—	—	7,740	—	7,740
Shares issued to settle the warrant liability to Takeda	314,119	—	—	2,639	—	2,639
Share-based compensation expense	1,128,222	—	—	784	—	784
Capital contribution — share-based compensation	—	—	—	3,987	—	3,987
Capital contribution	—	—	—	831	—	831
Net loss	—	—	—	—	(53,683)	(53,683)
Balance at September 30, 2016	43,750,684	$ 1	(1)	$ 17,415	$ (55,340)	$ (37,925)

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

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

	Six Months Ended September 30, 2016
Cash flows from operating activities:	
Net loss	$ (53,683)
Adjustments to reconcile net loss to net cash used in operating activities:	
Share-based compensation	4,771
Depreciation	1
Purchase of in-process research and development expense	13,117
Changes in the fair value of the warrant liability	29,817
Changes in operating assets and liabilities:	
Prepaid expenses and other current assets	(38)
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	4,014
Other assets	(100)
Accrued expenses and accounts payable	1,413
Income tax payable	1
Net cash used in operating activities	(687)
Cash flows from investing activities:	
Net cash used in investing activities	—
Cash flows from financing activities:	
Cash capital contribution from Roivant Sciences Ltd.	831
Deferred initial public offering costs	(71)
Net cash provided by financing activities	760
Net change in cash	73
Cash—beginning of period	—
Cash—end of period	$ 73
Non-cash financing activities:	
Deferred initial public offering costs, unpaid	$ 1,603
Purchase of in-process research and development	$ 13,117
Supplemental disclosure of cash paid:	
Taxes	$ 10

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

MYOVANT SCIENCES LTD.
Notes to Condensed Consolidated Financial Statements

Note 1—Description of Business

Myovant Sciences Ltd. (together with its wholly-owned subsidiaries, the “Company”) is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women’s health 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, MVT-602 (formerly known as RVT-602), for the treatment of female infertility as part of assisted reproduction. The Company was founded on February 2, 2016 as a Bermuda Exempted Limited Company and a wholly-owned subsidiary of Roivant Sciences Ltd. (“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”).

In August 2016, the Company incorporated as its wholly-owned subsidiaries 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. The Company expects that Myovant Sciences GmbH will be the principal operating company for conducting its business and the entity that will hold the Company's intellectual property rights.

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 MVT-602, under development which were licensed from Takeda Pharmaceuticals International AG (“Takeda”) on April 29, 2016 (See Note 3).

Note 2—Summary of Significant Accounting Policies

[A] Basis of Presentation:

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

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. These interim unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the period from inception of February 2, 2016 through the period ended March 31, 2016, and unaudited consolidated financial statements for the three months ended June 30, 2016, included in the Company's final prospectus dated October 26, 2016 filed with the Securities and Exchange Commission ("SEC”) on October 27, 2016. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary to present fairly the financial position of the Company and its results of operations and cash flows for the interim periods presented have been included. Operating results for the three and six months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending March 31, 2017, for any other interim period or for any other future year.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”). The condensed consolidated financial statements include the accounts of the Company and MSI, Myovant Holdings Limited and Myovant Sciences GmbH, its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

There have been no significant changes in the Company's accounting policies from those disclosed in its final prospectus filed with the SEC on October 27, 2016.

[B] Use of Estimates:

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed 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 (the "IPO") of its common shares, were capitalized in other assets until the consummation of the IPO. These offering costs were reclassified to additional paid-in capital upon the closing of the IPO on November 1, 2016.

[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] 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.

[H] 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.

[I] 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 three and six months ended September 30, 2016, 1,128,222 restricted share awards and 1,175,311 options to purchase common shares were not included in the calculation of diluted weighted-average common shares outstanding because they were anti-dilutive.

[J] Recently Issued Accounting Pronouncements:

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

In March 2016, the FASB issued ASU No. 2016-09, "Compensation - Stock Compensation (Topic 718): *Improvements to Employee Share-Based Payment Accounting*" (ASU No. 2016-09). This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The standard is effective for 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 MVT-602, in exchange for the following:

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

- The Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in the Company's territory, subject to certain agreed reductions. Takeda will pay the Company a royalty at the same rate as the Company's on net sales of relugolix products for prostate cancer in Japan and certain other Asian countries, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under this license agreement, there are no payments upon the achievement of clinical development or marketing approval milestones.

- The Company issued a warrant to Takeda to purchase an indeterminate number of capital shares. The warrant 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, unless earlier terminated upon a change in control.

For the consideration above, the Company also received a small quantity of relugolix and MVT-602, and certain historical research and development records. The Company did not hire, or receive, any Takeda workforce or employees working on relugolix and MVT-602, or any research, clinical or manufacturing equipment. The Company did not assume any contracts, licenses or agreements between Takeda and any third party with respect to relugolix and MVT-602. The Company will need to independently develop all clinical processes and procedures for its clinical trials through the use of internal and external resources once appropriate and acceptable resources have been identified and obtained. If the license agreement is terminated in its entirety or with respect to relugolix for prostate cancer, other than for safety reasons or by the Company for Takeda's uncured material breach, prior to receipt of the first regulatory approval of relugolix for prostate cancer in Japan, then the Company must either reimburse Takeda for its out of pocket costs and expenses directly incurred in connection with Takeda's completion of the relugolix development for prostate cancer, up to an agreed cap, or complete by itself the conduct of any clinical trials of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at its cost and expense.

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

The estimation of the fair value of the common shares considered factors including the following: the estimated present value of the Company's future cash flows; industry information such as market size and growth; market capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic conditions. 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. 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. The accompanying interim unaudited condensed consolidated financial statements include third-party expenses that have been paid by RSI and RSL.

During the three and six months ended September 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. Under the Services Agreement, for the three and six months ended September 30, 2016, the Company incurred expenses of $3.1 million and $4.1 million, respectively, inclusive of the mark-up.

[B] Option Agreement:

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

[C] Information Sharing and Cooperation Agreement:

In July 2016, the Company entered into an information sharing and cooperation agreement, or the Cooperation Agreement, with RSL. The Cooperation Agreement, among other things: (1) obligates the Company to deliver periodic financial statements and other financial information to RSL and to comply with other specified financial reporting requirements; and (2) requires the Company to supply certain material information to RSL to assist it in preparing any future SEC filings. Subject to specified exceptions, the Cooperation Agreement will terminate upon the earlier of the mutual written consent of the parties or when RSL is no longer required by U.S. GAAP to consolidate the Company's results of operations and financial position, account for its investment in the Company under the equity method of accounting or, by any rule of the SEC, include the Company's separate financial statements in any filings it may make with the SEC.

[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—Shareholders' Equity

[A] Overview:

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

[B] Restricted Share Award and Options Granted:

During the six months ended September 30, 2016, the Company granted a restricted share award for 1,128,222 common shares to the Company's Principal Executive Officer under the 2016 Equity Incentive Plan. No restricted share awards were granted during the three months ended September 30, 2016. During the three and six months ended September 30, 2016, the Company granted options to its employees, consultants and directors to purchase 1,175,311 of its common shares.

[C] Warrant Liability:

During the six months ended September 30, 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 share award for 1,128,222 common shares during that same period. No common shares were issued to Takeda upon the automatic exercise of the warrant as a result of the grant of restricted share awards during the three months ended September 30, 2016. During the three and six months ended September 30, 2016, the Company issued 160,273 common shares to Takeda upon the automatic exercise of the warrant, which was initiated by the grant of options to purchase 1,175,311 common shares during those same periods.

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 organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. The Company's effective income tax rate for the three and six months ended September 30, 2016 was (0.02)%. As of March 31, 2016 and September 30, 2016, there were no significant uncertain tax positions.

Note 7—Share-Based Compensation

[A] Stock Options and Restricted Share Awards Granted to Employees, Consultants and Directors:

In June 2016, the Company adopted its 2016 Equity Incentive Plan (as amended, the "2016 Plan"), under which 4,512,889 common shares are reserved for grant. The Company's employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted share awards, restricted share unit awards, and other share awards under the plan. Each option will have an exercise price equal to the fair market value of the Company's common shares on the date of grant. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company's common shares on the date of grant and the option will have a five-year contractual term. Options that are forfeited or expire are available for future grants.

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

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

For the three and six months ended September 30, 2016, share-based compensation expense related to the restricted share award was $0.4 million.

For the three and six months ended September 30, 2016, the Company recorded share-based compensation expense related to stock options issued to employees, officers and directors of $0.3 million and share-based compensation expense related to stock options issued to non-employees of $0.1 million (Note 7[B][1]). This share-based compensation expense is included in research and development and general and administrative expenses in the accompanying interim unaudited condensed consolidated statements of operations and comprehensive loss.

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

At September 30, 2016, total unrecognized compensation expense related to non-vested options for employees, officers and directors was $14.3 million and is expected to be recognized over the remaining weighted-average service period of 3.92 years.

[B] Share-Based Compensation for Related Parties:

[1] Stock Options Granted to Non-Employees:

In August 2016, the Company granted options to purchase 61,199 common shares to certain consultants, who are also employees of RSI, with an exercise price of $2.38 under the 2016 Plan. As discussed above in Note 7[A], the use of the higher fair value per common share of $15.00, which was reassessed in conjunction with the IPO and after preliminary discussions with the underwriters, increased both recognized and unrecognized share-based compensation expense. For the three and six months ended September 30, 2016, share-based compensation expense related to stock options was $0.1 million. At September 30, 2016, total unrecognized compensation expense related to stock options was $0.7 million, which is expected to be recognized over 1.44 years.

[2] Share-Based Compensation Allocated to the Company by RSL:

In relation to the RSL common share awards and options issued by RSL to RSL and RSI employees, the Company recorded share-based compensation expense of $1.4 million and $4.0 million, respectively, for the three and six months ended September 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 as of March 31, 2016 and September 30, 2016, by level, within the fair value hierarchy:

	As of March 31, 2016				As of September 30, 2016			
				(in thousands)				
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 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 September 30, 2016
Assets:								
Total assets at fair value	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Liabilities:								
Warrant liability	$ —	$ —	$ —	$ —	$ —	$ —	$ 32,555	$ 32,555
Total liabilities at fair value	$ —	$ —	$ —	$ —	$ —	$ —	$ 32,555	$ 32,555

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy that occurred during the six months ended September 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 interim unaudited condensed consolidated statements of operations.

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

The fair value of our warrant liability as of September 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	100.0%
Annualized equity volatility	72.0% - 81.9%
Risk-free interest rate	0.20% - 0.59%

The changes in fair value of the Company's Level 3 warrant liability during the six months ended September 30, 2016 were as follows (in thousands):

Balance at March 31, 2016	$ —
Fair value of the warrant liability issued	5,377
Changes in the fair value of the warrant liability, included in net loss	29,817
Settlements	(2,639)
Balance at September 30, 2016	$ 32,555

For the six months ended September 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 4[A]). As of March 31, 2016 and September 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

[A] Initial Public Offering and Reverse Stock Split:

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

On November 1, 2016, the Company completed its IPO. The Company sold 14,500,000 of its common shares at a public offering price of $15.00 per common share, for gross proceeds of $217.5 million. The Company received net proceeds of $199.8 million, after deducting $15.2 million in underwriting discounts and commissions and $2.5 million in estimated offering expenses. The cash proceeds from the IPO are currently deposited with one banking institution and are substantially in excess of federally insured levels.

[B] Common Shares Issued to Takeda Upon Exercise of Warrant Following Initial Public Offering:

Upon the closing of its IPO, the Company issued an additional 1,977,269 common shares to Takeda, pursuant to the automatic exercise of the warrant, based upon the sale and issuance of 14,500,000 common shares to investors in the IPO.

[C] U.K. Tax Resident and Intellectual Property Assignment to Swiss Subsidiary

In November 2016, the Company moved its principal executive office from Bermuda to the United Kingdom and became a U.K. tax resident, and the Company assigned all of its intellectual property rights to its wholly-owned subsidiary, Myovant Sciences GmbH, a company with limited liability formed under the laws of Switzerland. Myovant Sciences GmbH is the Company’s principal operating subsidiary and the Company remains incorporated in Bermuda.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition, results of operations and cash flows should be read in conjunction with (1) the unaudited interim condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (2) the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the period from February 2, 2016 (date of inception) through March 31, 2016 and the unaudited interim consolidated financial statements for the three months ended June 30, 2016 included in our final prospectus, filed with the Securities and Exchange Commission, or the SEC, on October 27, 2016 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural of these words or similar expressions or variations. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q and in our other filings with the SEC. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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 study participants to date in Phase 1 and multiple large, randomized Phase 2 clinical trials. In the first quarter of 2017, we plan to initiate two replicate multinational Phase 3 trials for relugolix with low-dose hormonal add-back therapy in women with heavy menstrual bleeding associated with uterine fibroids. The U.S. Investigational New Drug application in support of this program was filed with the U. S. Food and Drug Administration, or the FDA, in November 2016. 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. 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. To increase benefit and reduce side effects in the women's health indications, relugolix at a maximally estrogen-suppressive dose (40 mg once daily) is being co-administered with low-dose hormonal add-back therapy to fully suppress estrogen and then add-back a low dose of estrogen and progestin to reduce bone mineral density loss and hot flashes. In the first quarter of 2017, we also plan to initiate a Phase 3 clinical study of relugolix in men with advanced prostate cancer. 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 MVT-602 (formerly known as RVT-602), an oligopeptide kisspeptin analog, for the treatment of female infertility as part of assisted reproduction. Both relugolix and MVT-602 are licensed to us by Takeda Pharmaceuticals International AG, or Takeda.

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

In November 2016, we completed our initial public offering, or IPO, in which we sold 14,500,000 common shares at a public offering price of $15.00 per common share. The net proceeds to us were approximately $199.8 million, after deducting $15.2 million in underwriting discounts and commissions and $2.5 million in estimated offering expenses. We intend to use these proceeds to fund our planned Phase 3 registration program for relugolix. As of September 30, 2016, we had an accumulated deficit of $55.3 million. For the three and six months ended September 30, 2016, we recorded net losses of $34.7 million and $53.7 million, respectively.

We have continued to pursue our development plans for relugolix and MVT-602. Among other developments, the U.S. Investigational New Drug application in support of this program was filed with the FDA in November 2016. In addition, Takeda has reported to us its final analysis of data from the Phase 2 prostate cancer study C27002, which it conducted in 125 men with hormone-sensitive advanced prostate cancer from 2014 to 2016. The primary endpoint of the study was the rate of effective sustained castration at week 24, defined as the mean percentage of men who had testosterone concentrations less than 50 ng/dL at all scheduled visits. At 24 weeks, 91% of men treated with both doses of relugolix (80 and 120 mg once daily) achieved effective sustained castration through week 24. Because the lower bound of the 2-sided 95% confidence interval at week 24 was not greater than 90%, the study did not meet the criteria for success for its primary endpoint specified in the statistical analysis plan. Effective sustained castration rates at week 48 were below 90%. In those patients who completed 24 weeks of treatment with relugolix, 95% achieved effective sustained castration at week 24 and 90% achieved effective sustained castration at week 48. Safety data from this trial were consistent with relugolix's mechanism of action and known safety profile. This Phase 2 trial had a small sample size and was not adequately powered to achieve the primary endpoint as analyzed. In addition, patients were not precluded from taking drug holidays, during which their relugolix therapy was interrupted, after the week 24 visit. The final analysis of data from this Phase 2 study does not change our view on the prospects of relugolix in this indication or the timing or design of our planned Phase 3 study, which is expected to enroll approximately 1,125 men for at least 48 weeks of treatment.

In November 2016, we announced the addition to our Board of Directors of Terrie Curran, President of Worldwide Markets for Celgene Corporation's Inflammation & Immunology portfolio. She previously served as Senior Vice President and General Manager of Women's Health and Endocrinology at Merck & Co., Inc. The other members of the Board of Directors are Kathleen Sebelius, former U.S. Secretary of Health and Human Services, Wayne DeVeydt, former Chief Financial Officer of Anthem, Inc., Mark Altmeyer, President and Chief Commercial Officer of Axovant Sciences, Inc., Keith Manchester, Managing Director and head of life sciences at QVT Financial, LP, Vivek Ramaswamy, Founder and Chief Executive Officer of Roivant Sciences, Inc, and Lynn Seely, MD, President & Chief Executive Officer of Myovant Sciences, Inc.

Finally, in November 2016, we leased approximately 20,000 square feet of office space in Brisbane, CA where we are focusing our research and development efforts.

License Agreement with Takeda Pharmaceuticals International AG

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 MVT-602 and products containing relugolix and MVT-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 MVT-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 MVT-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. Refer to Note 3 "License Agreement" in the accompanying notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q 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.

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 markup, 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. 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.

Financial Operations Overview

Revenue

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

Research and Development Expense

Since our incorporation, our operations have primarily been limited to the license of the rights to relugolix and MVT-602 and products containing these compounds. Our research and development expenses include:

• employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for the research and development personnel that we plan to hire;

• costs allocated to us under the Services 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. We expect to significantly increase our research and development expenses 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 MVT-602 and prepare to seek regulatory approval for our product candidates. Product candidates in later stages of clinical development, such as relugolix, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

The duration, costs and timing of clinical trials of relugolix, MVT-602 and any other product candidates will depend on a variety of factors that include, but are not limited to:

• the number of trials required for approval;

• the per patient trial costs;

• the number of patients 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 patients who fail to meet the study's inclusion and exclusion criteria;

• 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;

• the costs of clinical trial material; and

• the efficacy and safety profile of the product candidate.

In addition, the probability of success for relugolix, MVT-602 and any other product 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 New York Stock Exchange, or NYSE, rules and SEC requirements, insurance and investor relations costs. In addition, if relugolix or MVT-602 obtains regulatory approval for marketing, we expect that we would incur expenses associated with building a sales and marketing team.

Results of Operations for the Three and Six Months Ended September 30, 2016

The following table summarizes our results of operations for the three and six months ended September 30, 2016 (in thousands):

	Three Months Ended September 30, 2016	Six Months Ended September 30, 2016
Operating expenses:		
Research and development (includes $814 and $1,789 of share-based compensation expense for the three and six months ended September 30, 2016, respectively)	$ 3,753	$ 18,326
General and administrative (includes $1,336 and $2,982 of share-based compensation expense for the three and six months ended September 30, 2016, respectively)	2,967	5,529
Total operating expenses	6,720	23,855
Changes in the fair value of the warrant liability	(27,984)	(29,817)
Income tax expense	8	11
Net loss and comprehensive loss	$ 34,712	$ 53,683

Research and Development Expenses

Research and development expenses were $3.8 million for the three months ended September 30, 2016, and consisted primarily of share-based compensation expense of $0.8 million allocated to us by Roivant Sciences Ltd. and costs billed to us under the Services Agreement of $2.7 million, including personnel expenses and third-party costs associated with the preparation of our clinical and other research programs.

Research and development expenses were $18.3 million for the six months ended September 30, 2016, and consisted primarily of in-process research and development expenses of $13.1 million, which were related to our acquisition of the rights to our product candidates from Takeda and consisted of $7.7 million for the estimated fair value of the 5,077,001 common shares issued to Takeda and $5.4 million for the estimated fair value of the warrant liability. The remainder consisted of share-based compensation expense of $1.8 million allocated to us by Roivant Sciences Ltd. and costs billed to us under the Services Agreement of $3.2 million, 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 $3.0 million for the three months ended September 30, 2016, and consisted primarily of share-based compensation expense of $1.3 million, primarily related to share-based compensation expense allocated to us by Roivant Sciences, Inc. and Roivant Sciences, Ltd., and costs of $0.3 million 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 $1.0 million and other personnel-related expenses of $0.3 million.

General and administrative expenses were $5.5 million for the six months ended September 30, 2016, and consisted primarily of share-based compensation expense of $3.0 million, primarily related to share-based compensation expense allocated to us by Roivant Sciences, Inc. and Roivant Sciences, Ltd., and costs of $0.9 million 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 $1.3 million and other personnel-related expenses of $0.3 million.

Changes in the Fair Value of the Warrant Liability

The change in the fair value of the warrant liability was $28.0 million for the three months ended September 30, 2016, as the fair value of the warrant liability increased to $32.6 million at September 30, 2016 from $7.0 million at June 30, 2016, 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 $2.4 million related to the fair value of the warrant exercised during the three months ended September 30, 2016.

The change in the fair value of the warrant liability was $29.8 million for the six months ended September 30, 2016, as the fair value of the warrant liability increased to $32.6 million at September 30, 2016 from $5.4 million 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 $2.6 million related to the fair value of the warrant exercised during the six months ended September 30, 2016.

Liquidity and Capital Resources

Overview

In November 2016, we received the proceeds from our IPO, in which we sold 14,500,000 common shares at a public offering price of $15.00 per common share, for gross proceeds of $217.5 million. The net proceeds to us were approximately $199.8 million, after deducting $15.2 million in underwriting discounts and commissions and $2.5 million in estimated offering expenses.

For the period from February 2, 2016 (date of inception) to March 31, 2016 and for the six months ended
September 30, 2016, we had net losses of $1.7 million and $53.7 million, respectively. As of September 30, 2016, we had $0.1 million of cash and had never generated any revenue.

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

• 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 MVT-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.

Our primary use of cash is to fund the development of relugolix for the treatment of uterine fibroids, endometriosis and advanced prostate cancer. We expect that our existing cash, including net proceeds from our IPO, will be sufficient 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. 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, MVT-602 or any future product candidate, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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 six months ended September 30, 2016:

	(in thousands)
Net cash used in operating activities	$ (687)
Net cash used in investing activities	—
Net cash provided by financing activities	760

Operating Activities

For the six months ended September 30, 2016, $0.7 million was used in operating activities. The net loss for the period of $53.7 million was partially offset by $13.1 million of non-cash in-process research and development expenses related to the acquisition of the rights to our product candidates, $4.8 million non-cash share-based compensation, $29.8 million non-cash changes in the fair value of the warrant liability and $4.0 million 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 $1.3 million other expenses.

Investing Activities

For the six months ended September 30, 2016, no cash was used in investing activities.

Financing Activities

For the six months ended September 30, 2016, $0.8 million was provided by financing activities. This was primarily the amount of a capital contribution made by Roivant Sciences, Ltd.

Contractual Obligations

As of September 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 condensed 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 condensed 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.

We believe the estimates and judgments involved in our warrant liability, research and development accruals, share-based compensation and income taxes have the greatest potential impact on our condensed consolidated financial statements, and consider these to be our critical accounting policies and estimates.

While our significant accounting policies are more fully described in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in the footnotes to our audited consolidated financial statements for the period from February 2, 2016 (date of inception) through March 31, 2016 included in our final prospectus filed with the SEC on October 27, 2016 pursuant to Rule 424(b)(4) under the Securities Act.

Recent Accounting Pronouncements

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, 2018, and interim periods within fiscal years beginning after December 15, 2018. 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments. We do not believe we are currently exposed to any material market risk. As of September 30, 2016, we had cash of $0.1 million, consisting of non-interest bearing deposits dominated in the U.S. dollar.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Security and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Principal Executive Officer and our Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016, the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Principal Executive Officer and our Principal Financial and Accounting Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our condensed consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to Our Business, Financial Position and Capital Requirements

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in February 2016, and our operations to date have been limited to organizing and staffing our company, acquiring worldwide rights, excluding Japan and certain other Asian countries, to relugolix, and worldwide rights to MVT-602 (formerly known as 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 MVT-602, for the treatment of female infertility as part of assisted reproduction and obtain the necessary regulatory approvals for their commercialization. We have never been profitable, have no products approved for commercial sale and to date have not generated any product revenue.

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

- successfully complete clinical trials and obtain regulatory approval for the marketing of relugolix and MVT-602;
- set an acceptable price for relugolix and MVT-602 and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing and distribution systems for relugolix and MVT-602;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with third-party manufacturers and have commercial quantities of relugolix and MVT-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 MVT-602 is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of this product. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any product revenue, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of relugolix and MVT-602. Neither relugolix nor MVT-602 has been approved for marketing in the United States, and they may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of relugolix and MVT-602, obtain necessary regulatory approvals, and have relugolix and MVT-602 manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize relugolix or MVT-602. If we do successfully obtain regulatory approval to market relugolix or MVT-602, our revenue will be dependent, in part, upon, among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for relugolix and MVT-602 and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of relugolix or MVT-602, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common shares and our ability to raise capital and continue operations.

We expect our research and development expenses to be significant in connection with our development programs for relugolix and MVT-602. In addition, if we obtain regulatory approval for either relugolix or MVT-602, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

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

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of relugolix and MVT-602. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of these product candidates. We cannot be certain that relugolix for either of the two women's health indications or for prostate cancer or MVT-602 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market relugolix or MVT-602 in the United States until we receive approval of a new drug application, or NDA, for each, or in any foreign country until they receive the requisite approvals from the appropriate authority in such country. We have not submitted an NDA to the FDA, or any comparable application to any other regulatory authority and do not expect to be in a position to do so for the foreseeable future. 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 submitted our investigational new drug application, or IND, to the FDA, including Phase 3 protocols, in November 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 MVT-602 for many reasons, including:

- we may not be able to demonstrate that relugolix or MVT-602 is effective as a treatment for our target indications to the satisfaction of the FDA or other relevant regulatory authority;
- 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 of relugolix with add-back low-dose estradiol and progestin in order to facilitate patient convenience and compliance and minimize side effects. If we are unsuccessful in our attempts to formulate a fixed-dose combination, we expect to instead seek approval for relugolix as monotherapy to be co-administered with commercially available low-dose estradiol and progestin. This would decrease our advantages relative to our competition by requiring patients to take two pills once daily instead of just one pill once daily. If our competitors develop a fixed-dose combination with 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 MVT-602.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize relugolix and MVT-602. These expenditures will include costs associated with our license agreement with Takeda. Under the terms of this agreement, we are obligated to cover substantial development costs of relugolix and MVT-602 and make significant royalty payments in connection with the sale of resulting products.

We will require additional capital to complete the development and potential commercialization of 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 our existing cash, including the net proceeds from our initial public offering, or our IPO 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 MVT-602 are highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned 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 MVT-602.

We have licensed the intellectual property rights covering our current product candidates, relugolix and MVT-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 MVT-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 a limited number of 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 eight employees. We rely on the administrative 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 eight 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 MVT-602 and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

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 MVT-602 or any future product candidate could be delayed.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of relugolix and MVT-602 in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend 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 MVT-602, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

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

Our product candidates, relugolix and MVT-602, are still in development and will require extensive clinical testing before we are prepared to submit an NDA or other similar application for regulatory approval. We 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 submitted our IND to the FDA, including Phase 3 protocols, in November 2016, but we do not yet have approval to initiate our Phase 3 clinical trials for women with heavy menstrual bleeding associated with uterine fibroids. 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. The Phase 2 prostate cancer study of relugolix, C27002, did not meet the criteria for success for its primary endpoint specified in the statistical analysis plan, highlighting the importance of adequate powering and diligent oversight of patients. If we fail to execute these and other aspects of our planned Phase 3 prostate cancer trial effectively, the trial will not be successful. Further, we cannot predict with any certainty if or when we might submit an NDA for regulatory approval for relugolix or MVT-602 in any indication or whether any such application will be approved by the relevant regulatory authority. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trials of relugolix or MVT-602, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that our clinical trials of relugolix and MVT-602 will take at least several years to complete. 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 MVT-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 MVT-602 could be harmed, and our ability to generate product revenue from relugolix or MVT-602 may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

In addition, because we recently acquired worldwide rights, excluding Japan and certain other Asian countries, to relugolix and worldwide rights to MVT-602, we were not involved in the development of relugolix or MVT-602 prior to April 2016. We may experience difficulties in the transition of this product candidate from Takeda and its affiliates to us, which may result in delays in clinical trials as well as problems in our development efforts and regulatory filings, particularly if we do not receive all of the necessary products, information, reports and data from Takeda and its affiliates in a timely manner. Further, prior to our acquisition of the rights to relugolix and MVT-602 we had no involvement or control over the preclinical or clinical development of either relugolix or MVT-602. We are dependent on Takeda having conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the rights to relugolix and MVT-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. 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. Takeda is also completing an extension of the Phase 2 trial C27002 in prostate cancer. If safety data from this clinical trial are unfavorable, it could negatively impact our ability to successfully complete our Phase 3 prostate cancer clinical trial.

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the effectiveness of relugolix or MVT-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 future failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDAs to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize relugolix and MVT-602 and generate product revenue.

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

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the study, our ability to obtain and maintain patient consents and the risk that patients enrolled in clinical trials will drop out of the trials before completion. Furthermore, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop relugolix and MVT-602, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

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

Drug development is highly competitive and subject to rapid and significant technological advancements. As a significant unmet medical need exists for the treatment of each of uterine fibroids, endometriosis and advanced prostate cancer, as well as infertility in 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 MVT-602 for the treatment of female infertility as part of assisted reproduction. For example, AbbVie in conjunction with Neurocrine Biosciences, is developing a GnRH receptor antagonist, elagolix, as an oral treatment for endometriosis-associated pain and for heavy menstrual bleeding associated with uterine fibroids. AbbVie has 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 MVT-602 is differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

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

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make relugolix or MVT-602 less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA or other regulatory authority approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

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

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

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither relugolix, MVT-602 nor any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

The time required to obtain approval of an NDA by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authority. Prior to submitting an NDA to the FDA or any comparable application to any other foreign regulatory authorities for approval of relugolix, we will need to complete our planned Phase 3 programs, and for approval of MVT-602, we will need to complete additional Phase1, 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 MVT-602 for the specified indication. Further, because we are exploring the use of relugolix co-administered with low-dose hormone add-back therapy as a longer-term treatment for the heavy menstrual bleeding associated with uterine fibroids and of endometriosis-associated pain, we expect to submit data with respect to a large patient population. Even if we obtain approval for this patient population, we may not achieve labeling for longer than six months duration of therapy. 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 MVT-602 may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by relugolix or MVT-602 could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for relugolix or MVT-602 or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

Across all relugolix clinical trials, a total of 34 serious adverse events were reported in the more than 1,300 relugolix-treated study participants 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 MVT-602.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for, or commercialize, it in any other jurisdiction, which would limit our ability to realize its full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by 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 MVT-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 MVT-602 or any future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

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

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

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other 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 MVT-602, if approved, for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs; and
- 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 gain the necessary resources or to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in a product and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of our product candidates, if approved, for certain markets overseas; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenue we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

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

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

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

If either relugolix or MVT-602 is approved for commercialization, we intend to enter into agreements with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the 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 MVT-602 and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of relugolix or MVT-602, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

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

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents 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 MVT-602, and any future product candidate.

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While relugolix and MVT-602 were being developed by Takeda, they were also being manufactured by Takeda. Takeda has retained rights to further develop and commercialize relugolix in Japan and certain other Asian countries, and Takeda is continuing to develop relugolix in Japan. In April 2016, we acquired exclusive, worldwide rights to MVT-602 for all human diseases and conditions. Takeda is no longer developing this compound. We expect that 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 MVT-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 MVT-602 to be used, if approved, for the commercialization of each. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with 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 MVT-602, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;

- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- 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 relationships 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, MVT-602 and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover relugolix, MVT-602 or any future product candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover relugolix, MVT-602 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The 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, MVT-602 or any future product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of relugolix, MVT-602 and any future product candidate.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter 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 MVT-602, and, based on these searches and evaluations to date, we do not believe that there are valid patents which contain granted claims that could be asserted with respect to relugolix or MVT-602. However, we may be incorrect.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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

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

Because we expect to rely on third parties to manufacture relugolix, MVT-602 and any future product candidates, and we expect to collaborate with third parties on the development of relugolix, MVT-602 and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Our Common Shares

The public market for our common shares may not be liquid enough for you to sell your shares quickly or at market price.

Prior to our IPO, there was no public market for our common shares. The trading market for our common shares may not be liquid enough for you to sell your shares quickly or at the prevailing market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration.

The market price of our common shares 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, MVT-602 or those of our competitors;

• any delay in filing an NDA or similar application for relugolix or MVT-602 and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that NDA or similar application, as the case may be;

• failure to successfully develop and commercialize relugolix, MVT-602 or any future product candidate;

• inability to obtain additional funding;

• regulatory or legal developments in the United States or other countries or jurisdictions applicable to relugolix, MVT-602 or any future product candidate;

• adverse regulatory decisions;

• changes in the structure of healthcare payment systems;

• inability to obtain adequate product supply for relugolix, MVT-602 or any future product candidate, or the inability to do so at acceptable prices;

• introduction of new products, services or technologies by our competitors;

• failure to meet or exceed financial projections we provide to the public;

• failure to meet or exceed the estimates and projections of the investment community;

• changes in the market valuations of similar companies;

• market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;

• announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

• significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

• additions or departures of key scientific or management personnel;

• 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.

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

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

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

Roivant Sciences Ltd. controls a majority of the voting power of our outstanding common shares. As a result, we are a "controlled company" within the meaning of the NYSE corporate governance requirements. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements:

• that a majority of 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 have elected to use certain of these exemptions and we may continue to use all or some of these exemptions in the future. As a result, you may not have the same protections afforded to shareholders of companies that are subject to all of the NYSE corporate governance requirements.

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

Based on our common shares outstanding as of September 30, 2016, Roivant Sciences Ltd. beneficially owns approximately 61.8% of the voting power of our outstanding common shares. As a result, Roivant Sciences Ltd. has the ability to substantially influence us and exert significant control through this ownership position. For example, Roivant Sciences Ltd. is 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 depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common shares or change their opinion of our common shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. 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.

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

Sales of a substantial number of our common shares in the public market, 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. All of the shares sold in our IPO are freely transferable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for common shares sold to Pfizer Inc. and BB Biotech AG, which are subject to lock-up agreements until April 21, 2017. The 43,750,684 common shares outstanding as of September 30, 2016 are restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers until April 21, 2017.

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. Sales of these common shares may have an adverse effect on the trading price of our common shares. In addition, in the future we may issue common shares or other securities if we need to raise additional capital. The number of our new common shares issued in connection with raising additional capital could constitute a material portion of our then outstanding common shares.

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 expect 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.

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

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

We 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 November 1, 2021, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common shares that are held by non-affiliates exceeds $700.0 million as of the prior September 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

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

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

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

We are a Bermuda exempted company. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the 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.

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 66⅔% of our voting shares for certain "business combination" transactions that have not been approved by our board of directors;

• restrictions on the time period in which directors may be nominated; and

• our board of directors to determine the powers, preferences and rights of our preference shares and to issue the preference shares without shareholder approval.

These anti-takeover defenses could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common shares if the provisions are viewed as discouraging takeover attempts in the future. These provisions could also discourage proxy contests, make it more difficult for you and other shareholders to elect directors of your choosing and cause us to take corporate actions other than those you desire.

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

Under our amended and restated bye-laws, in the event that any U.S. person holds, directly, indirectly or constructively, 9.5% or more of the total voting power of our issued share capital, excluding any U.S. person that held, directly, indirectly or constructively, 9.5% or more of the total voting power of issued share capital immediately prior to the closing of our IPO, the aggregate votes conferred by the common shares held by such person (or by any person through which such U.S. person indirectly or constructively holds shares) will be reduced by our board of directors to the extent necessary such that the common shares held, directly, indirectly or constructively, by such U.S. person will constitute less than 9.5% of the voting power of all issued and outstanding shares. 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 MVT-602. The establishment of this Swiss entity as our principal operating company and the transfer of our intellectual property rights to this entity may result in a higher overall effective tax rate.

The intended tax effects of our corporate structure and intercompany arrangements depend on the application of the tax laws of various jurisdictions and on how we operate our business.

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.

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 our IPO in our business. We believe that we were not a CFC prior to our IPO 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) **Recent Sales of Unregistered Equity Securities**

In August 2016, (1) we granted options to purchase 602,743 common shares to our employees and consultants, with an exercise price of $2.38 under the 2016 Plan and (2) we 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) we granted options to purchase 572,568 common shares to our employees, officers and directors, with an exercise price of $4.00 under the 2016 Plan and (2) we 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.

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

(b) **Use of Proceeds**

On November 1, 2016, we closed our IPO, in which we issued and sold 14,500,000 common shares at a public offering price of $15.00 per common share, for gross proceeds of $217.5 million. All of the common shares issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-213891), which was declared effective by the SEC on October 26, 2016. Citigroup Global Markets Inc., Cowen and Company, LLC, Evercore Group L.L.C. and Barclays Capital Inc. acted as book-running managers for our IPO. The net proceeds to us were approximately $199.8 million, after deducting $15.2 million in underwriting discounts and commissions and $2.5 million in estimated offering expenses. Substantially all of the cash proceeds are currently deposited with one banking institution and is substantially all in excess of insured levels.

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

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MYOVANT SCIENCES LTD.

By: /s/ Frank Karbe

Frank Karbe
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Date: December 9, 2016

Exhibit Index

Exhibit Number	Description of Document
3.1	Certificate of Incorporation. (1)
3.2	Memorandum of Association. (2)
3.3	Amended and Restated Bye-laws. (3)
10.1	Services Agreement, dated as of July 6, 2016, by and among Roivant Sciences, Inc., Myovant Sciences, Inc. and the Registrant. (4)
10.2	Information Sharing and Cooperation Agreement, dated as of July 6, 2016, by and between Roivant Sciences Ltd. and the Registrant. (5)
10.3	Offer Letter, dated September 20, 2016, by and between Frank Karbe and Myovant Sciences, Inc. (6)
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS XBRL	Instance Document
101.SCH XBRL	Taxonomy Extension Schema
101.CAL XBRL	Taxonomy Extension Calculation Linkbase
101.DEF XBRL	Taxonomy Extension Definition Linkbase
101.LAB XBRL	Taxonomy Extension Label Linkbase
101.PRE XBRL	Taxonomy Extension Presentation Linkbase

(1) Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-213891), filed on September 30, 2016.

(2) Incorporated herein by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-213891), filed on September 30, 2016.

(3) Incorporated herein by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-213891), filed on October 17, 2016.

(4) Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-213891), filed on September 30, 2016.

(5) Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-213891), filed on September 30, 2016.

(6) Incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-213891), filed on September 30, 2016.

* These certifications are being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 31.1

CERTIFICATION

I, Lynn Seely, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Myovant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 9, 2016

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Myovant Sciences Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 9, 2016

By: /s/ Frank Karbe
Frank Karbe
Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Vivek Ramaswamy, Principal Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 9, 2016

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gregory Weinhoff, Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 9, 2016

By: /s/ Frank Karbe

Frank Karbe

Principal Financial Officer