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, 2019

or

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

For the transition period from _____ to _____

Commission file number 001-37929

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

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

Registrant's telephone number, including area code: **+44 207 400 3347**

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

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

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

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

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

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

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

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

The number of shares outstanding of the Registrant's common shares, $0.000017727 par value per share, on November 1, 2019, was 89,623,564.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDEDSEPTEMBER 30, 2019

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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, 2019	March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 130,373	$ 156,074
Marketable securities	27,220	—
Prepaid expenses and other current assets	9,969	10,194
Income tax receivable	17	524
Total current assets	167,579	166,792
Property and equipment, net	2,288	2,071
Operating lease right-of-use asset	8,973	—
Other assets	5,162	4,114
Total assets	$ 184,002	$ 172,977
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 5,819	$ 11,019
Interest payable	305	1,077
Accrued expenses	44,380	53,614
Operating lease liability	853	—
Due to Roivant Sciences Ltd. (RSL), Roivant Sciences, Inc. (RSI) and Roivant Sciences GmbH (RSG)	271	121
Current maturities of long-term debt	8,402	6,142
Total current liabilities	60,030	71,973
Deferred rent	—	1,157
Deferred interest payable	5,323	2,273
Long-term operating lease liability	9,320	—
Long-term debt, less current maturities	92,075	93,240
Total liabilities	166,748	168,643
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 89,623,564 and 72,057,490 issued and outstanding at September 30, 2019 and March 31, 2019, respectively	2	1
Additional paid-in capital	657,780	505,851
Accumulated other comprehensive (loss) income	(31)	507
Accumulated deficit	(640,497)	(502,025)
Total shareholders' equity	17,254	4,334
Total liabilities and shareholders' equity	$ 184,002	$ 172,977

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

MYOVANT SCIENCES LTD.

Condensed Consolidated Statements of Operations

(*unaudited; in thousands, except share and per share data*)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development [1]	$ 50,803	$ 53,813	$ 101,920	$ 105,154
General and administrative [2]	16,603	10,310	30,755	19,052
Total operating expenses	67,406	64,123	132,675	124,206
Interest expense	3,788	1,580	7,581	3,197
Interest income	(942)	—	(1,708)	—
Other expense (income), net	121	(21)	(584)	268
Loss before income taxes	(70,373)	(65,682)	(137,964)	(127,671)
Income tax expense	195	88	508	233
Net loss	$ (70,568)	$ (65,770)	$ (138,472)	$ (127,904)
Net loss per common share — basic and diluted	$ (0.79)	$ (0.99)	$ (1.68)	$ (1.97)
Weighted average common shares outstanding — basic and diluted	88,798,398	66,666,876	82,667,061	64,997,698

[1] Includes $26 and $246 of costs allocated from RSL, RSI, and RSG during the three months ended September 30, 2019 and 2018, respectively, and $51 and $2,434 of costs allocated from RSL, RSI, and RSG during the six months ended September 30, 2019 and 2018, respectively. Also includes share-based compensation expense (see Note 10).

[2] Includes $224 and $949 of costs allocated from RSL, RSI, and RSG during the three months ended September 30, 2019 and 2018, respectively, and $422 and $2,174 of costs allocated from RSL, RSI, and RSG during the six months ended September 30, 2019 and 2018, respectively. Also includes share-based compensation expense (see Note 10).

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

MYOVANT SCIENCES LTD.

Condensed Consolidated Statements of Comprehensive Loss

(unaudited; in thousands)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (70,568)	$ (65,770)	$ (138,472)	$ (127,904)
Other comprehensive income (loss):				
Foreign currency translation adjustment	281	(72)	(538)	353
Total other comprehensive income (loss)	281	(72)	(538)	353
Comprehensive loss	$ (70,287)	$ (65,842)	$ (139,010)	$ (127,551)

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

MYOVANT SCIENCES LTD.

Condensed Consolidated Statements of Shareholders' Equity

(unaudited; in thousands, except share data)

	Common Shares		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at March 31, 2019	72,057,490	$ 1	$ 505,851	$ 507	$ (502,025)	$ 4,334
Issuance of shares in connection with "at-the-market" equity offering, net of commissions of $79	106,494	—	2,546	—	—	2,546
Issuance of shares in connection with public equity offering, net of commissions and offering costs of $9,229	17,424,243	1	134,537	—	—	134,538
Share-based compensation expense	—	—	6,410	—	—	6,410
Capital contribution — share-based compensation	—	—	42	—	—	42
Capital contribution from RSI and RSG	—	—	106	—	—	106
Foreign currency translation adjustment	—	—	—	(819)	—	(819)
Issuance of shares upon exercise of stock options and vesting of RSUs	34,399	—	314	—	—	314
Net loss	—	—	—	—	(67,904)	(67,904)
Balance at June 30, 2019	89,622,626	2	649,806	(312)	(569,929)	79,567
Public equity offering, additional offering costs	—	—	(80)	—	—	(80)
Share-based compensation expense	—	—	7,879	—	—	7,879
Capital contribution — share-based compensation	—	—	52	—	—	52
Capital contribution from RSI and RSG	—	—	123	—	—	123
Foreign currency translation adjustment	—	—	—	281	—	281
Issuance of shares upon vesting of RSUs	938	—	—	—	—	—
Net loss	—	—	—	—	(70,568)	(70,568)
Balance at September 30, 2019	89,623,564	$ 2	$ 657,780	$ (31)	$ (640,497)	$ 17,254

	Common Shares		Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at March 31, 2018	60,997,856	$ 1	$ 266,178	$ 24	$ (228,474)	$ 37,729
Issuance of shares in connection with "at-the-market" equity offering, net of commissions and offering costs of $2,110	2,767,129	—	57,315	—	—	57,315
Issuance of shares in connection with Private Placement with RSL	1,110,015	—	22,500	—	—	22,500
Share-based compensation expense	—	—	4,053	—	—	4,053
Capital contribution — share-based compensation	—	—	191	—	—	191
Foreign currency translation adjustment	—	—	—	425	—	425
Issuance of shares upon exercise of stock options	16,218	—	76	—	—	76
Net loss	—	—	—	—	(62,134)	(62,134)
Balance at June 30, 2018	64,891,218	1	350,313	449	(290,608)	60,155
Share-based compensation expense	—	—	4,529	—	—	4,529
Capital contribution — share-based compensation	—	—	196	—	—	196
Capital contribution from RSI and RSG			212			212
Foreign currency translation adjustment	—	—	—	(72)	—	(72)
Issuance of shares in connection with public equity offering, net of commissions and offering costs of $5,110	3,533,399	—	74,391	—	—	74,391
Issuance of shares upon exercise of stock options and vesting of RSUs	60,271	—	460	—	—	460
Net loss	—	—	—	—	(65,770)	(65,770)
Balance at September 30, 2018	68,484,888	$ 1	$ 430,101	$ 377	$ (356,378)	$ 74,101

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

MYOVANT SCIENCES LTD.

Condensed Consolidated Statements of Cash Flows

(unaudited; in thousands)

	Six Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (138,472)	$ (127,904)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	14,383	8,969
Depreciation and amortization [1]	726	191
Amortization of debt discount and issuance costs	1,095	936
Other items	(369)	565
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	225	(3,240)
Income tax receivable	507	233
Other assets	(799)	(96)
Accounts payable	(5,200)	3,781
Interest payable	(772)	18
Accrued expenses	(9,304)	8,176
Operating lease liabilities	(368)	—
Due to RSL, RSI and RSG	150	(1,382)
Deferred rent	—	567
Deferred interest payable	3,050	305
Net cash used in operating activities	(135,148)	(108,881)
Cash flows from investing activities:		
Purchases of marketable securities	(27,160)	—
Purchases of property and equipment	(532)	(390)
Net cash used in investing activities	(27,692)	(390)
Cash flows from financing activities:		
Proceeds from issuance of common shares in “at-the-market” equity offering, net of issuance costs paid	2,546	57,315
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	134,528	74,683
Proceeds from issuance of common shares in Private Placement with RSL	—	22,500
Proceeds from stock option exercises	314	466
Net cash provided by financing activities	137,388	154,964
Net change in cash, cash equivalents and restricted cash	(25,452)	45,693
Cash, cash equivalents and restricted cash, beginning of period	157,199	108,624
Cash, cash equivalents and restricted cash, end of period	$ 131,747	$ 154,317
Non-cash financing activities:		
Unpaid offering costs included in accounts payable and accrued expenses	$ 70	$ 292
Stock options exercised receivables, included in prepaid expenses and other current assets	$ —	$ (70)

[1] Includes amortization of operating lease right-of-use asset.

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

MYOVANT SCIENCES LTD.

Notes to Condensed Consolidated Financial Statements (Unaudited)

Note 1—Description of Business

Myovant Sciences Ltd. (or together with its wholly-owned subsidiaries, the Company) is a healthcare company focused on developing innovative treatments for women's health and prostate cancer. The Company is developing a relugolix combination tablet (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, relugolix 120 mg as a monotherapy for advanced prostate cancer, and an additional product candidate, MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as part of assisted reproduction. Both relugolix and MVT-602 were licensed to the Company by Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016.

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

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

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation

The Company's fiscal year ends on March 31, and its first three fiscal quarters end on June 30, September 30 and December 31. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States, or U.S., generally accepted accounting principles, or 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 unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2019, filed with the U.S. Securities and Exchange Commission, or the SEC, on May 24, 2019. The unaudited consolidated balance sheet at March 31, 2019 has been derived from the audited consolidated financial statements at that date. 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, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2020, for any other interim period or for any other future year.

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

There have been no significant changes in the Company's accounting policies from those disclosed in its Annual Report on Form 10-K for the fiscal year ended March 31, 2019, filed with the SEC on May 24, 2019, except for the adoption of ASU 2016-02, *Leases* (Topic 842), on April 1, 2019. See Note 2(H).

(B) Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, and expenses, including the evaluation of the Company's ability to continue as a going concern, share-based compensation expenses, research and development, or R&D, expenses and accruals, and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses incurred during the reporting period, that are not readily apparent from other sources. Estimates and assumptions are periodically reviewed in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

(C) Going Concern and Management's Plans

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the unaudited condensed consolidated financial statements are issued. During the six months ended September 30, 2019, the Company incurred net losses of $138.5 million and used $135.1 million of cash and cash equivalents in operations. The Company expects to continue to incur significant and increasing operating losses and negative operating cash flows as it continues to develop its product candidates and prepares for potential future regulatory approvals and commercialization of relugolix. The Company has not generated any revenue to date and does not expect to generate product revenue unless and until it successfully completes development and obtains regulatory approval for at least one of its product candidates. Based on its current operating plan, the Company expects that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements at least through the end of the Company's fiscal year ending March 31, 2020. This estimate is based on the Company's current assumptions, including assumptions relating to its ability to manage its spend, that might prove to be wrong, and it could use its available capital resources sooner than it currently expects. Current cash, cash equivalents and marketable securities will not be sufficient to enable the Company to complete all necessary development activities and commercially launch relugolix. The Company anticipates that it will continue to incur net losses for the foreseeable future.

To continue as a going concern, the Company will need, among other things, additional capital resources. The Company continually assesses multiple options to obtain additional funding to support its operations, including through financing activities in public or private capital markets. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all. Although the Company expects to negotiate and enter into a new term loan facility that the Company and Sumitomo Dainippon Pharma, Co. Ltd. ("Sumitomo") agreed to negotiate and enter into, and the Company expects to draw down on this term loan facility on a quarterly basis, after it becomes effective upon the close of the transaction between Roivant Sciences Ltd. and Sumitomo, ASC 240-40, *Going Concern*, does not allow the Company to consider future financing activities that are uncertain in its assessment of the Company's future cash burn for the purpose of its liquidity assessment. For more information on the Company's arrangements with Sumitomo, see Note 13(B), "Subsequent Events—Letter Agreement with Sumitomo Dainippon Pharma, Co. Ltd."

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

(D) Net Loss per Common Share

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

As of September 30, 2019 and 2018, potentially dilutive securities were as follows:

	September 30,	
	2019	2018
Stock options	7,676,460	5,115,494
Restricted stock awards (unvested)	775,651	1,057,707
Restricted stock units (unvested)	753,720	12,500
Performance stock units (unvested)	408,510	—
Warrants	73,710	73,710
Total	9,688,051	6,259,411

(E) Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash. The Company considers all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. As of September 30, 2019, cash and cash equivalent balances are diversified between three financial institutions. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and the issuers of its money market funds and commercial paper. The Company maintains its cash deposits and cash equivalents in highly rated, federally insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments. Interest income consists of interest earned on money market funds and the accretion of discounts to maturity for commercial paper and corporate bonds.

Restricted cash consists of non-interest bearing legally restricted deposits held as compensating balances against the Company's corporate credit card program and an irrevocable standby letter of credit provided as security for the Company's office lease.

Cash as reported on the unaudited condensed consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash and consists of the following (in thousands):

	September 30,	
	2019	2018
Cash and cash equivalents	$ 130,373	$ 153,717
Restricted cash [1]	1,374	600
Total cash, cash equivalents and restricted cash	$ 131,747	$ 154,317

[1] Included in other assets on the unaudited condensed consolidated balance sheets.

(F) Marketable Securities

Investments in marketable securities are held in a custodial account at a financial institution and managed by the Company's investment advisor based on the Company's investment guidelines. The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities. As of September 30, 2019, the Company's marketable securities consisted of commercial paper and highly rated corporate bonds with maturities of greater than three months but less than twelve months at the time of purchase. These short-term commercial paper and corporate debt securities are classified as current assets on the Company's unaudited condensed consolidated balance sheets under the caption marketable securities.

The Company classifies its marketable securities as available-for-sale at the time of purchase and reevaluates such designation at each balance sheet date. Unrealized gains and losses on available-for-sale commercial paper and short-term corporate debt securities are excluded from earnings and are recorded in accumulated other comprehensive (loss) income until realized. Any unrealized losses are evaluated for other-than temporary impairment at each balance sheet date. Realized gains and losses are determined based on the specific identification method and are recorded in other (income) expense, net. See Note 3 for additional information.

(G) Fair Value Measurements

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

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

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

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

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

(H) Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of Topic 842 requires lessees to recognize on the consolidated balance sheets a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases with lease terms greater than twelve months. The lease liability is measured at the present value of the unpaid lease payments and the right-of-use asset is derived from the calculation of the lease liability. Topic 842 also requires lessees to disclose key information about leasing arrangements. Topic 842 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted.

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

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

The most significant impact of the adoption of Topic 842 on the Company's unaudited condensed consolidated financial statements was the recognition of a$9.4 million operating lease right-of-use asset, a$0.8 million current operating lease liability, and a $9.8 million long-term operating lease liability on the Company's unaudited condensed consolidated balance sheet related to its existing facility operating lease. In addition, the Company reclassified the $1.2 million deferred rent liability for its existing facility lease to the related operating lease right-of-use asset. There was no material impact to the Company's unaudited condensed consolidated statement of operations, and no cumulative-effect adjustment to accumulated deficit. See Note 11 for additional information.

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

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

In July 2018, the FASB issued ASU 2018-09, *Codification Improvements,* to make changes to a variety of topics to clarify, correct errors in, or make minor improvements to the ASC. Certain items in the amendments in ASU 2018-09 will be effective for the Company in annual periods beginning after December 15, 2018. The adoption of ASU 2018-09 on April 1, 2019 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures**.**

Other recent accounting pronouncements issued by the FASB, (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the SEC did not, or are not believed by the Company to, have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

(I) Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326): *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU 2016-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. The Company is currently assessing the impact the adoption of this new standard will have on its unaudited condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-13. ASU 2018-13 amends the disclosure requirements in Topic 820 to promote the exercise of discretion by entities when considering fair value measurement disclosures and clarifies that materiality is an appropriate consideration when evaluating fair value measurement disclosure requirements. Certain required disclosures were added, modified, or removed, including removing the required disclosure of the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy. ASU 2018-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. The Company does not currently expect that the adoption of this new standard will have a material impact on its unaudited condensed consolidated financial statements and related disclosures.

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

Note 3—Marketable Securities

As of September 30, 2019, the Company's $27.2 million marketable securities balance consisted of available-for-sale commercial paper and short-term corporate bonds. Unrealized gains on marketable securities as of September 30, 2019 were not material. There were no unrealized losses on marketable securities as of September 30, 2019.

There were no marketable securities as of March 31, 2019.

Note 4—Fair Value Measurements

As of September 30, 2019, and March 31, 2019, assets measured at fair value on a recurring basis consisted of money market funds and commercial paper, which are included in cash and cash equivalents on the unaudited condensed consolidated balance sheets, and short-term corporate bonds and commercial paper, which are included in marketable securities on the unaudited condensed consolidated balance sheets.

The following table summarizes the Company's assets measured at fair value on a recurring basis and their assigned levels within the fair value hierarchy as of September 30, 2019 (in thousands):

	Level 1	Level 2	Level 3	Total Fair Value
Assets:				
Money market funds	$ 53	$ —	$ —	$ 53
Commercial paper	—	130,953	—	130,953
Corporate bonds	—	12,608	—	12,608
Total assets	$ 53	$ 143,561	$ —	$ 143,614

The following table summarizes the Company's assets measured at fair value on a recurring basis and their assigned levels within the fair value hierarchy as of March 31, 2019 (in thousands):

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

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

There were no liabilities measured at fair value on a recurring basis as of September 30, 2019 or March 31, 2019. There were no transfers of assets or liabilities between the fair value hierarchy levels that occurred during the six months ended September 30, 2019.

Note 5—Accrued Expenses

As of September 30, 2019, and March 31, 2019, accrued expenses consisted of the following (in thousands):

	September 30, 2019	March 31, 2019
Accrued R&D expenses	$ 36,620	$ 46,947
Accrued compensation-related expenses	3,800	5,024
Accrued professional service fees	1,053	370
Accrued other expenses	2,907	1,273
Total accrued expenses	$ 44,380	$ 53,614

Note 6—Financing Arrangements

(A) NovaQuest

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

The Company committed that it would issue at least $30.0 million aggregate principal amount of notes through December 31, 2018, subject to certain terms and conditions. The Company issued $6.0 million aggregate principal amount in October 2017 and $54.0 million aggregate principal amount in December 2018. With the issuance of $6.0 million aggregate principal amount of notes in October 2017, NovaQuest purchased 138,361 common shares for $2.0 million, and with the issuance of $54.0 million aggregate principal amount of notes in December 2018, NovaQuest purchased 1,082,977 common shares for $18.0 million.

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

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

The Company incurred financing costs related to the NovaQuest Securities Purchase Agreement of $1.0 million. During each of the three and six-month periods ended September 30, 2019 and 2018, interest expense included $0.1 million and $0.2 million, respectively, of amortized deferred financing costs related to the NovaQuest notes.

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

	September 30, 2019	March 31, 2019
Principal amount	$ 60,000	$ 60,000
Less: unamortized debt issuance costs	(523)	(756)
Loan payables less unamortized debt issuance costs	59,477	59,244
Less: current maturities	—	—
Long-term debt, net of current maturities and unamortized debt issuance costs	$ 59,477	$ 59,244

(B) Hercules

In October 2017, the Company, its subsidiaries, as guarantors, and Hercules Capital, Inc., or Hercules, entered into a Loan Agreement, or the Hercules Loan Agreement, which provided up to $40.0 million principal amount of term loans, or the Term Loans. A first tranche of $25.0 million principal amount was funded upon execution of the Hercules Loan Agreement in October 2017 and the remaining $15.0 million principal amount was funded in March 2018. The Term Loans bear interest at a variable per annum rate at the greater of (i) the prime rate plus 4.00% and (ii) 8.25%. The interest rate on the Term Loans was 9.00% as of September 30, 2019.

Pursuant to the terms of the Hercules Loan Agreement, the Term Loan Maturity Date has been extended from May 1, 2021 to November 1, 2021 as a result of the achievement of a financing milestone in July 2018. The Company is obligated to make monthly interest payments during the Interest-only Period, subject to certain terms and conditions, followed by monthly installments of principal and interest through the maturity date. The Interest-only Period was extended from June 1, 2019 to December 1, 2019 as a result of the achievement of a financing milestone during July 2018 and was further extended to June 1, 2020 as a result of the achievement of a certain clinical milestone in July 2019. Prepayment of the Term Loans is subject to a prepayment charge. The Company is also obligated to pay an end of term charge of 6.55% of the principal amount of the Term Loans funded under the Hercules Loan Agreement, on the earlier of the maturity date or the date that the Term Loans otherwise become due and payable.

The Company's obligations under the Hercules Loan Agreement are secured by a first lien security interest in substantially all of the Company's and its subsidiaries' respective assets (other than intellectual property). The Hercules Loan Agreement includes customary affirmative and restrictive covenants and representations and warranties. The Hercules Loan Agreement also includes a minimum cash covenant which ceased to apply as a result of the achievement of a certain clinical milestone in July 2019.

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

The Company estimated the fair value of the Warrants using the Black-Scholes model based on the following key assumptions:

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

The Company issued the first tranche of the Term Loans at a discount of $2.1 million, including the relative fair value of the related Warrant, and incurred financing costs of $1.3 million. The second tranche of the Term Loans was issued at a discount of $1.3 million, including the relative fair value of the related Warrant. During the three and six-months ended September 30, 2019, interest expense included $0.4 million and $0.9 million, respectively, of amortized debt discount and issuance costs related to the Term Loans. During the three and six months ended September 30, 2018, interest expense included $0.3 million and $0.7 million, respectively, of amortized debt discount and issuance costs related to the Term Loans.

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

	September 30, 2019	March 31, 2019
Principal amount	$ 40,000	$ 40,000
End of term charge	2,620	2,620
Less: unamortized debt discount and issuance costs	(1,620)	(2,482)
Loan payables less unamortized debt discount and issuance costs	41,000	40,138
Less: current maturities	(8,402)	(6,142)
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 32,598	$ 33,996

Note 7—Related Party Transactions

(A) Services Agreements

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

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

Under the Services Agreements, for the three months ended September 30, 2019 and 2018, the Company incurred expenses (inclusive of third-party pass-through costs billed to the Company) of $0.2 million and $1.0 million, respectively, inclusive of the mark-up. Under the Services Agreements, for the six months ended September 30, 2019 and 2018, the Company incurred expenses (inclusive of third-party pass-through costs billed to the Company) of $0.4 million and $4.2 million, respectively, inclusive of the mark-up. The Company has replaced substantially all of the services previously provided by RSI and RSG with its own internally developed capabilities or external professional service providers.

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

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

In relation to the RSL common share awards and options issued by RSL to RSL, RSI, RSG, and the Company's employees, the Company recorded share-based compensation expense of less than $0.1 million and $0.2 million for the three months ended September 30, 2019 and 2018, respectively, and $0.1 million and $0.4 million for the six months ended September 30, 2019 and 2018, respectively.

(C) Private Placement with RSL

See Note 9(B) for information regarding the Private Placement with RSL.

(D) Underwritten Public Equity Offering of Common Shares

As discussed in Note 9(A), the Company completed an underwritten public equity offering of its common shares on June 4, 2019. RSL purchased 2,424,242 common shares in this offering at the same price offered to the public of $8.25 per common share, for a total purchase price of $20.0 million.

(E) Information Sharing and Cooperation Agreement with RSL

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

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.

(F) Fourth Amended and Restated Bye-Laws

On May 23, 2019, the Company's board of directors approved, and the holder of a majority of the Company's issued and outstanding common shares approved by written consent, an amendment and restatement of the Company's bye-laws, to be the Company's Fourth Amended and Restated Bye-Laws, which amends the Company's bye-laws (1) to establish procedures for the appointment of a majority of the directors on the Company's board by RSL at any time that RSL holds less than 50.0% but more than or equal to 35.0% of the aggregate voting rights attached to the Company's issued and outstanding common shares, and (2) to remove the procedures and requirements of voting rights of such shares that are treated as controlled shares of a U.S. Person whose controlled shares constitute nine and one-half percent (9.5%) or more of the voting power of all of the Company's issued common shares. The Fourth Amended and Restated Bye-Laws became effective on June 26, 2019.

Note 8—Income Taxes

The Company is not subject to taxation under the laws of Bermuda since it was organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. The Company's income tax expense is primarily based on income taxes in the U.S. for federal, state and local taxes. The Company's effective tax rate for the three months ended September 30, 2019 and 2018 was (0.28)% and (0.13)%, respectively. The Company's effective tax rate for the six months ended September 30, 2019 and 2018 was (0.37)% and (0.18)%, respectively. The Company's effective tax rate is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

The Company assesses the realizability of the deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and records a valuation allowance as necessary.

Note 9—Shareholders' Equity

(A) Underwritten Public Equity Offering of Common Shares

On June 4, 2019, the Company completed an underwritten public equity offering of17,424,243 of its common shares (including2,272,727 common shares sold pursuant to the underwriters' exercise in full of their option to purchase additional common shares) at a public offering price of $8.25 per common share. After deducting the underwriting discounts and commissions and offering costs payable by the Company, the net proceeds to the Company in connection with the underwritten public equity offering, including from the exercise of the over-allotment option, were approximately $134.5 million.

(B) Private Placement with RSL

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

(C) At-the-Market Equity Offering Program

In April 2018, the Company entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell its common shares having an aggregate offering price of up to $100.0 million from time to time through an "at-the-market" equity offering program under which Cowen acts as the Company's agent. During the six months ended September 30, 2019 and 2018, the Company issued and sold 106,494 and 2,767,129, respectively, of its common shares under the Sales Agreement. The common shares were sold at a weighted-average price of $24.65 and $21.47 per common share, respectively, for aggregate net proceeds to the Company of approximately $2.5 million and $57.3 million, respectively, after deducting underwriting commissions and offering costs paid by the Company. During the three months ended September 30, 2019 and 2018, no shares were issued and sold under the Sales Agreement. As of September 30, 2019, the Company had approximately $10.4 million of capacity available to it under its "at-the-market" equity offering program.

Note 10—Share-Based Compensation

(A) Myovant 2016 Equity Incentive Plan

In June 2016, the Company adopted its 2016 Equity Incentive Plan, or as amended, the 2016 Plan, under which4.5 million common shares were originally reserved for issuance. Pursuant to the "evergreen" provision contained in the 2016 Plan, the number of common shares reserved for issuance under the 2016 Plan automatically increases on April 1 of each year, commencing on (and including) April 1, 2017 and ending on (and including) April 1, 2026, in an amount equal to 4% of the total number of shares of capital stock outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as determined by the Company's board of directors. On April 1, 2019, the number of common shares authorized for issuance increased automatically by 2.9 million shares in accordance with the evergreen provision of the 2016 Plan. As of September 30, 2019, a total of 1.5 million common shares were available for future issuance under the 2016 Plan.

The Company's employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other share awards under the 2016 Plan.

(B) Stock Option Repricing

On August 26, 2019 (the "repricing date"), the Company's Board of Directors approved a stock option award repricing program (the "repricing") whereby certain previously granted and still outstanding vested and unvested stock option awards held by current employees and certain executives were repriced on a one-for-one basis to $7.78 per share, which represented the closing market price of the Company's common shares on the repricing date. To be eligible to participate in the stock option repricing program, 735,428 vested stock option awards to certain executives as of the repricing date are subject to a one-year exercise restriction period beginning from the repricing date. No other terms of the repriced stock options were modified, and the repriced stock options will continue to vest according to their original vesting schedules and will retain their original expiration dates. As a result of the repricing, 5,095,013 vested and unvested stock options outstanding with original exercise prices ranging from $8.82 to $24.44, and a median exercise price of $17.28 per share, were repriced under this program.

The repricing resulted in incremental stock-based compensation expense of$9.2 million, of which $0.8 million related to vested employee stock option awards and was expensed on the repricing date, $1.1 million related to vested executive stock option awards and is being amortized over a one-year exercise restriction period beginning from the repricing date, and $7.3 million related to unvested stock option awards and is being amortized on a straight-line basis over the approximately 3.2 year remaining weighted average vesting period of those awards.

(C) Stock Options

A summary of stock option activity under the Company's 2016 Plan is as follows:

	Number of Options
Options outstanding at March 31, 2019	5,396,465
Granted	2,470,900
Exercised	(33,461)
Forfeited	(187,444)
Options outstanding at September 30, 2019	7,646,460
Options vested and expected to vest at September 30, 2019	7,646,460
Vested options subject to one-year exercise restriction period beginning on August 26, 2019	735,428
Options exercisable at September 30, 2019	1,684,887

(D) Restricted Stock Awards and Restricted Stock Units

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

	Number of Shares
Unvested balance at March 31, 2019	956,066
Granted	724,554
Vested	(142,904)
Forfeited	(8,345)
Unvested balance at September 30, 2019	1,529,371

(E) Performance Stock Units

On August 26, 2019, the Company's Board of Directors granted performance stock units covering a total of408,510 common shares, of which two-thirds of the shares (272,338 shares) subject to each performance stock unit vests based upon the passage of time, and the remaining one-third of the shares (136,172 shares) subject to each performance stock unit vests only if the Company achieves certain clinical trial and regulatory milestones. Total share-based compensation expense associated with the performance stock units is based on the fair value of the Company's common shares on the grant date, which equals the closing market price of the Company's common shares on the grant date. The Company recognizes the share-based compensation expense related to the performance stock unit awards subject to time-based vesting on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The Company will recognize the share-based compensation expense related to the performance stock unit awards subject to vesting based upon the achievement of certain clinical trial and regulatory milestones only if such milestones are achieved. As of September 30, 2019, the performance conditions had not been met and were deemed not probable of being met.

(F) Share-Based Compensation Expense

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

	Three Months Ended September 30,	
	2019	2018
Share-based compensation expense recognized as:		
R&D expenses	$ 3,618	$ 1,846
G&A expenses	4,313	2,879
Total	$ 7,931	$ 4,725

	Six Months Ended September 30,	
	2019	2018
Share-based compensation expense recognized as:		
R&D expenses	$ 6,166	$ 3,407
G&A expenses	8,217	5,562
Total	$ 14,383	$ 8,969

Share-based compensation expense is included in R&D and G&A expenses in the accompanying unaudited condensed consolidated statements of operations consistent with the grantee's salary. Share-based compensation expense presented in the table above includes share-based compensation expense allocated to the Company by RSL as described in Note 7(B). Total unrecognized share-based compensation expense was approximately $78.2 million as of September 30, 2019 and is expected to be recognized over a weighted-average period of approximately 2.9 years.

(G) RSL RSUs

The Company's Principal Executive Officer was granted 66,845 RSL RSUs during the fiscal year ended March 31, 2017. These RSUs will vest to the extent certain RSL performance criteria are achieved and certain RSL liquidity conditions are satisfied within specified years of the grant date, provided that the Company's Principal Executive Officer has provided continued service to RSL or its subsidiaries through such date. As of September 30, 2019, the performance conditions had not been met and were deemed not probable of being met. For the three and six months ended September 30, 2019 and 2018, the Company recorded no share-based compensation expense related to these RSL RSUs. As of September 30, 2019, there was $0.9 million of unrecognized compensation expense related to unvested RSL RSUs. The Company will recognize this share-based compensation expense upon achievement of the performance and market conditions through the requisite service period.

Note 11—Leases

The Company leases 40,232 square feet of office space located in Brisbane, California pursuant to an operating lease agreement, as amended, that expires in May of 2026. The Company has the option to extend the lease term for an additional seven years but is not reasonably certain that it will exercise the option and has therefore excluded it from the lease term. The lease agreement, as amended, required the Company to deliver an irrevocable standby letter of credit for the duration of the lease in the amount of $0.5 million to the landlord, the amount of which is subject to reduction of approximately $0.2 million if certain conditions are met. The Company currently has no other significant operating, financing, or short-term leases.

The components of operating lease expense for the Company's Brisbane, California office space were as follows (in thousands):

	Three Months Ended September 30, 2019	Six Months Ended September 30, 2019
Operating lease cost	$ 519	$ 1,038
Variable lease cost [1]	46	55
Total operating lease cost	$ 565	$ 1,093

[1] Variable lease cost includes common area maintenance and utilities costs which are not included in operating lease liabilities and which are expensed as incurred.

Supplemental cash flow information related to the Company's operating lease right-of-use asset and operating lease liabilities for its Brisbane, California office space was as follows (in thousands):

	Three Months Ended September 30, 2019	Six Months Ended September 30, 2019
Cash paid for operating lease liabilities	$ 501	$ 997

As of September 30, 2019, the Company's operating lease for its Brisbane, California office space had a weighted average remaining lease term of 6.7 years and a weighted average discount rate of 12.3%. There were no new leases added during the three and six months ended September 30, 2019.

As of September 30, 2019, maturities of operating lease liabilities for the Company's Brisbane, California office space were as follows (in thousands):

Years Ended March 31,	
2020 (remainder of year)	$ 1,009
2021	2,065
2022	2,128
2023	2,200
2024	2,339
Thereafter	5,307
Total lease payments	15,048
Less imputed interest [1]	(4,875)
Present value of future minimum lease payments	10,173
Less operating lease liability, current portion	(853)
Operating lease liability, long-term portion	$ 9,320

[1] The Company's lease contracts do not provide an implicit rate. The imputed interest was determined using the Company's incremental borrowing rate, which represents an estimated rate of interest that it would have to pay to borrow equivalent funds on a collateralized basis over a similar term at the lease inception date.

Note 12—Commitments and Contingencies

(A) Legal Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the loss contingency, including an estimable range, if possible. The Company is currently not involved in any material legal proceedings.

(B) Contract Service Providers

In the normal course of business, the Company enters into agreements with contract service provides to assist in the performance of its R&D activities. Expenditures to contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, represent significant costs in the Company's clinical development of its product candidates. Subject to required notice periods and the Company's obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(C) Indemnification Agreements

The Company has agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director was serving at the Company's request in such capacity. The maximum amount of potential future indemnification liability is unlimited; however, the Company holds directors' and officers' liability insurance which limits the Company's exposure and may enable it to recover a portion of any future amounts paid. In the normal course of business, the Company also enters into contracts and agreements with service providers and other parties with which it conducts business that contain indemnification provisions pursuant to which the Company has agreed to indemnify the party against certain types of third-party claims. The Company has not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

(D) Takeda Agreements

Under the Takeda 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 on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under the Takeda License Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones. As the amount and timing of any potential future payments under the Takeda License Agreement are not probable and estimable, no such potential commitments have been included in the unaudited condensed consolidated balance sheet.

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

The initial term of the Takeda Commercial Supply Agreement began on May 30, 2018 and will continue for five years. At the end of the initial term, the Takeda Commercial Supply Agreement will automatically renew for successive one-year terms, unless either party gives notice of termination to the other at least 12 months prior to the end of the then-current term. The Takeda Commercial Supply Agreement may be terminated by either party upon 90 days' notice of an uncured material breach of its terms by the other party, or immediately upon notice to the other party of a party's bankruptcy. Each party will also have the right to terminate the Takeda Commercial Supply Agreement, in whole or in part, for any reason upon 180 days' prior written notice to the other party, provided that any then-open purchase orders, including the initial firm order for relugolix drug substance through December 31, 2019, will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase order thereunder, will terminate immediately upon the termination of the Takeda Agreement in accordance with its terms.

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

(E) Financing Arrangements

The Company has entered into financing arrangements with NovaQuest and Hercules. See Note 6 for additional information.

Note 13—Subsequent Events

(A) Leases

During October 2019, the Company entered into a Sublease Agreement, or sublease, for 20,116 square feet of office space within the same building as its current corporate office space located in Brisbane, California. The sublease term expires on February 29, 2024, with total expected minimum payments over the sublease term of approximately $3.9 million, of which approximately $0.4 million relates to the fiscal year ended March 31, 2020 and approximately $3.5 million relate to each of the fiscal years ended March 31, 2021 through 2024. The sublease required the Company to deliver an irrevocable standby letter of credit to the sublessor for the duration of the lease in the amount of $0.2 million.

(B) Letter Agreement with Sumitomo Dainippon Pharma, Co. Ltd.

On October 31, 2019, the Company's largest shareholder, Roivant Sciences Ltd. ("RSL") and certain of its affiliates (not including the Company) entered into an agreement with Sumitomo Dainippon Pharma, Co. Ltd. ("Sumitomo") (such agreement, the "Sumitomo-Roivant Agreement") which provides that upon the closing of the transactions contemplated thereby (the "Sumitomo Transactions"), a subsidiary of Sumitomo (such entity, the "Acquiring Entity"), will acquire RSL's ownership interest in the Company and become a significant shareholder of the Company. The Company expects that, at or prior to the closing of the Sumitomo Transactions, RSL will ensure that the Acquiring Entity will obtain not less than a majority of the Company's outstanding common shares by purchasing additional common shares at prices not below market trading prices and delivering such shares, or voting rights with respect thereto, to the Acquiring Entity.

On October 31, 2019, in connection with RSL's entry into the Sumitomo-Roivant Agreement, the Company entered into a Letter Agreement with Sumitomo, pursuant to which Sumitomo has committed to enter into an agreement to provide the Company a $350.0 million low-interest, five-year term loan facility (the "Loan Facility"), with no repayments due until the end of the term to fund the Company's operating expenditures. The Company expects to be able to access the Loan Facility on a quarterly basis, subject to certain terms and conditions. The Loan Facility is expected to be entered into and become effective upon or promptly following the closing of the Sumitomo Transactions.

Pursuant to the Letter Agreement, the Company will take certain actions with respect to the composition of its Board of Directors and the committees of the Board of Directors, as well as amending certain provisions of its bye-laws, and in connection with the closing of the Sumitomo Transactions, the Company and Sumitomo will also enter into an Investors Rights Agreement, which will provide, among other things, that for so long as Sumitomo and its affiliates continue to hold at least 50% of the outstanding common shares of the Company, the Company's Board of Directors will continue to include a minimum of three independent directors who, until Sumitomo and its affiliates cease to hold at least 35% of the outstanding common shares of the Company, will have approval rights over certain corporate actions, including related-party transactions between the Company and Sumitomo. The Investors Rights Agreement will further include a standstill provision effective until Sumitomo or its affiliates cease to hold at least 35% of the outstanding common shares of the Company, which provides, among other things, (a) a non-waivable condition requiring approval by a majority of the Company's minority shareholders for any transaction that would cause Sumitomo or its subsidiaries to hold beneficial ownership of the Company of greater than 60% of the outstanding voting power of the Company. Additionally, for a standstill period of three years, any such transaction must also be made on a confidential basis to the Company's independent directors and is subject to approval by a majority of the Company's independent directors, or (b) that such transaction be effected under the circumstances set forth in a specified section of the Company's Bye-Laws having to do with third-party acquisition proposals.

Sumitomo has also agreed that upon the Company's request, the parties will discuss terms upon which Sumitomo will provide the Company access to its U.S. commercial infrastructure and operational support as the Company moves forward with the commercialization of relugolix.

The Company has further agreed, until the closing of the Sumitomo Transactions, to reasonably assist and reasonably cooperate with RSL in complying with the interim operating covenants contained in the Sumitomo-Roivant Agreement that relate to the Company, in which RSL has agreed, among other things, to cause the Company to conduct its business in the ordinary course, including refraining from taking a list of actions without Sumitomo's consent, including (subject to certain limitations) but not limited to incurring additional indebtedness, issuance of equity securities, granting of liens, and sales of assets.

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 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 fiscal year ended March 31, 2019 included in our Annual Report on Form 10-K, filed with the U.S. Securities and Exchange Commission, or the SEC, on May 24, 2019. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its wholly-owned subsidiaries.

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

The forward-looking statements appearing in a number of places throughout this Quarterly Report on Form 10-Q include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- the success and anticipated timing of our clinical trials for relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg), relugolix 120 mg as a monotherapy, and MVT-602;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical studies and clinical trials;
- the anticipated designs of our future clinical trials;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg), including in a single tablet, relugolix 120 mg as a monotherapy, MVT-602 and any future product candidates;
- our plans to commercialize relugolix, if approved;
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain coverage and adequate reimbursement for our products if commercialized;
- the rate and degree of market acceptance and clinical utility of any approved products;
- our ability to initiate and continue relationships with third-party clinical research organizations and manufacturers;
- our ability to quickly and efficiently identify and develop product candidates;
- our ability to hire and retain our key scientific or management personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our product candidates;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, access to capital, prospects, growth and strategies;
- our ability to continue to fund our operations with the cash, cash equivalents, and marketable securities currently on hand, including our expectations as to for how long these capital resources will enable us to fund our operations;
- the anticipated transfer of all of our common shares held by Roivant Sciences Ltd. ("RSL") to Sumitomo Dainippon Pharma, Co. Ltd. ("Sumitomo"), which is expected to result in Sumitomo obtaining voting rights over a majority of our common shares;
- our anticipated transactions contemplated by the Letter Agreement by and between Sumitomo and us;
- the potential for us to obtain a priority review voucher from RSL and Sumitomo and the likelihood and timing of when such priority review voucher is expected to be available and transferred to us;
- our ability to raise additional capital;
- industry trends;
- developments and projections relating to our competitors or our industry; and
- the success of competing drugs that are or may become available.

Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, particularly in the section titled "Risk Factors" set forth in Part II. Item 1A. of this Quarterly Report on Form 10-Q, and in our other filings with the United States, or U.S., Securities and Exchange Commission, or SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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

Business Overview

We are a healthcare company focused on developing innovative treatments for women's health and prostate cancer. Our lead product candidate is relugolix, an oral once-daily small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist that is currently being evaluated in multiple Phase 3 clinical trials across three distinct indications. We are developing a relugolix combination tablet (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, and relugolix 120 mg as a monotherapy for advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as a part of assisted reproduction. Both relugolix and MVT-602 were licensed to us by Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016.

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

On May 14, 2019, we announced that LIBERTY 1, the first of two Phase 3 studies evaluating once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and six key secondary endpoints, and on July 23, 2019, we announced that LIBERTY 2, the second of two Phase 3 studies evaluating relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and the same six key secondary endpoints. On July 23, 2019, we also announced that a separate clinical study of single-tablet relugolix combination therapy met all required and pre-specified U.S. Food and Drug Administration, or FDA, criteria for bioequivalence. The single-tablet regimen is the formulation intended to be offered to women should relugolix combination therapy receive FDA approval.

On November 12, 2019, we announced that RSL and Sumitomo have committed to us a priority review voucher ("PRV") expected to become available in early December 2019. We plan to use the PRV in conjunction with our New Drug Application ("NDA") submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids, potentially decreasing the standard FDA review time. We have decided to defer our NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids until April 2020, which would allow inclusion of the complete 12-month safety data from the LIBERTY open-label extension study, key data that may positively impact the labeled duration of use of the combination tablet. The terms regarding how the PRV will be transferred to us will be determined in connection with the closing of the Roivant-Sumitomo Dainippon Pharma transaction. The transfer is expected to be a related-party transaction and will not involve the issuance of Myovant shares. We also plan to submit a Marketing Authorisation Application (MAA) to the European Medicines Agency in the first quarter of calendar year 2020.

Second Fiscal Quarter Ended September 30, 2019 and Recent Business Highlights

The following summarizes our second fiscal quarter ended September 30, 2019 and recent business highlights:

Relugolix Phase 3 Clinical Programs

- On July 23, 2019, we announced that LIBERTY 2, the second of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and the same six key secondary endpoints as LIBERTY 1. In the primary endpoint analysis, 71.2% of women receiving once-daily relugolix combination therapy achieved the responder criteria compared with 14.7% of women receiving placebo ($p < 0.0001$). The 24-week study achieved the same six key secondary endpoints with statistical significance compared to placebo as those in LIBERTY 1 including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.
- On July 23, 2019, we also announced that a separate clinical study of single-tablet relugolix combination therapy met all required and pre-specified FDA criteria for bioequivalence, providing data necessary to include the one tablet, once-daily dosing regimen of relugolix combination therapy in the NDA submission for approval of the treatment for uterine fibroids.
- In October 2019, results from the LIBERTY 1 and LIBERTY 2 studies were presented in a late-breaking oral presentation at the 2019 American Society for Reproductive Medicines Scientific Congress.
- We expect top-line data from the Phase 3 HERO trial evaluating the safety and efficacy of relugolix 120 mg in 934 men with advanced prostate cancer in the fourth quarter of calendar year 2019, and assuming positive data, we currently plan to submit an NDA to the FDA for our once-daily, oral relugolix monotherapy tablet for men with advanced prostate cancer in the second quarter of calendar year 2020. Enrollment of 139 additional men with metastatic prostate cancer in the HERO study was completed in July 2019. The objective of enrolling these men was to assess the secondary objective of demonstrating that relugolix can delay the time to progression of the lethal state of the disease, castration-resistant prostate cancer, as compared to leuprolide. We currently expect to present top-line results from this additional cohort, including the castration resistance-free survival endpoint, in the third quarter of calendar year 2020.
- In August and October 2019, we completed patient recruitment for the Phase 3 SPIRIT 2 and SPIRIT 1 trials, respectively, evaluating the safety and efficacy of relugolix combination therapy in women with pain associated with endometriosis. We expect to report top-line results from SPIRIT 2 and SPIRIT 1 in the first and second quarters of calendar year 2020, respectively.

Corporate

- On October 31, 2019, we entered into a Letter Agreement with Sumitomo in connection with the Sumitomo-Roivant Agreement pursuant to which Sumitomo will acquire all of our common shares held by RSL. The Letter Agreement provides, among other things, that we will enter into a loan agreement with Sumitomo that will provide us with a $350.0 million term loan, that we will enter into an Investors Rights Agreement that is intended to provide certain protections for minority shareholders, that we will take certain corporate actions, and that until the transactions contemplated by the Sumitomo-Roivant Agreement close we reasonably assist RSL in complying with the interim operating covenants contained in the Sumitomo-Roivant Agreement that relate to us, in which RSL has agreed, among other things, to cause us to conduct our business in the ordinary course, including refraining from taking a list of actions without Sumitomo's consent, including (subject to certain limitations) but not limited to incurring additional indebtedness, issuance of equity securities, granting of liens, and sales of assets. Additional information is included in Note 13(B) to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.
- On November 12, 2019, we announced that Roivant Sciences and Sumitomo have committed to us a priority review voucher ("PRV") expected to become available in early December 2019. We plan to use the PRV in conjunction with our NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids, potentially decreasing the standard FDA review time. We have decided to defer our NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids until April 2020, which would allow inclusion of the complete 12-month safety data from the LIBERTY open-label extension study, key data that may positively impact the labeled duration of use of the combination tablet. The terms regarding how the PRV will be transferred to us will be determined in connection with the closing of the Roivant-Sumitomo Dainippon Pharma transaction. The transfer is expected to be a related-party transaction and will not involve the issuance of Myovant shares.

Financial History

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

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

As of September 30, 2019, and March 31, 2019, we had an accumulated deficit of $640.5 million and $502.0 million, respectively. We had net losses of $70.6 million and $65.8 million for the three months ended September 30, 2019 and 2018, respectively, and $138.5 million and $127.9 million for the six months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had $157.6 million of cash, cash equivalents, and marketable securities available to us, as compared to $156.1 million of cash and cash equivalents available to us as of March 31, 2019.

Our Product Candidates

Relugolix

We are currently developing relugolix in three target indications: heavy menstrual bleeding associated with uterine fibroids; pain associated with endometriosis; and advanced prostate cancer. Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist that binds to and inhibits GnRH receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins (luteinizing hormone and follicle-stimulating hormone), thereby decreasing the downstream production of estrogen and progesterone by the ovaries in women and testosterone by the testes in men.

As a GnRH receptor antagonist, relugolix has a clinically validated mechanism of action in each of our three target indications. Lowering estrogen and progesterone levels has previously been demonstrated to effectively decrease heavy menstrual bleeding in women with uterine fibroids and to reduce the pelvic pain associated with endometriosis. We are developing relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) administered orally once-daily, with the goal of optimizing estradiol levels to achieve the long-term benefit of relugolix on symptoms of uterine fibroids and endometriosis, while maintaining bone health and mitigating side effects from a low-estrogen state such as vasomotor symptoms. We expect to launch in our women's health indications with a single-tablet regimen of relugolix combination therapy administered orally once-daily. We have recently conducted a bioequivalence study to demonstrate the bioequivalence of the single-tablet relugolix combination therapy with the co-administered regimen used in the LIBERTY clinical program (one relugolix 40 mg tablet and one tablet containing estradiol 1.0 mg and norethindrone acetate 0.5 mg). The single tablet met FDA bioequivalence criteria. Twelve-month stability studies are required for FDA approval and we expect results from these studies by the end of calendar year 2019. We believe our combination approach with relugolix has the potential to have a better safety and tolerability profile than the currently approved GnRH agonist therapies and has the potential to be used longer-term. The goal of this longer-term treatment is to provide women with uterine fibroids and endometriosis a medical alternative to hysterectomy and other invasive procedures often recommended to treat these conditions.

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

Myovant Sciences GmbH, our wholly-owned subsidiary, holds global commercial rights to relugolix, excluding Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam, including the territories and possessions of each of the foregoing. In May 2018, Takeda announced that it had entered into a licensing agreement granting ASKA Pharmaceutical Co., Ltd. exclusive commercialization rights to relugolix for uterine fibroids and exclusive development and commercialization rights to relugolix for endometriosis, in each indication in Japan, and in January 2019 Takeda and ASKA Pharmaceutical Co., Ltd. announced that Takeda obtained marketing authorization in Japan for Relumina® Tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids including heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia.

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

We initiated a Phase 3 clinical program in January 2017, evaluating relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids. The program consisted of two multinational, replicate pivotal clinical studies (LIBERTY 1 and LIBERTY 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with uterine fibroids and heavy menstrual bleeding. Women in the LIBERTY 1 and LIBERTY 2 studies underwent a screening period requiring up to two menstrual cycles to document heavy menstrual bleeding and were randomized in a 1:1:1 ratio to one of three groups. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix combination therapy once-daily for an additional 12 weeks, or placebo once-daily for 24 weeks.

We enrolled 388 women in LIBERTY 1 and 382 women in LIBERTY 2. To be enrolled, women must have had a monthly menstrual blood loss volume of at least 80 mL in two consecutive cycles or 160 mL in one cycle, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss from an assessment of collected menstrual products.

Eligible women who completed the LIBERTY 1 or LIBERTY 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women receive relugolix combination therapy for an additional 28-week period for a total treatment period of 52 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment. We expect the 12-month safety results from the open-label extension study in the first quarter of calendar year 2020. Upon completion of this 52-week total treatment period, eligible women can elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy, to evaluate the need for maintenance therapy. We are also conducting a one-year observational study of bone mineral density in women with uterine fibroids or endometriosis to provide additional context for our phase 3 clinical programs.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 was the proportion of all women enrolled who achieved a menstrual blood loss volume of less than 80 mL and at least a 50% reduction in menstrual blood loss volume from baseline during the last 35 days of the 24-week treatment period as measured by the alkaline hematin method. The secondary endpoints included the proportion of women who achieved amenorrhea during the last 35 days of treatment, reduction in pelvic pain, reduction in fibroid volume, reduction in uterine volume, percent change from baseline to week 24 in menstrual blood loss, increase in hemoglobin, and an assessment of the impact of therapy on quality-of-life. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry (DXA), was also assessed.

On May 14, 2019 and July 23, 2019, we announced top-line results for the LIBERTY 1 and LIBERTY 2 studies, respectively. In addition, on July 23, 2019, we announced that a separate clinical study of single-tablet relugolix combination therapy met all required and pre-specified FDA criteria for bioequivalence, providing data necessary to include the one tablet, once-daily dosing regimen of relugolix combination therapy in the NDA submission for approval of the treatment for uterine fibroids.

On November 12, 2019, we announced that Roivant Sciences and Sumitomo have committed to us a priority review voucher (“PRV”) expected to become available in early December 2019. We plan to use the PRV in conjunction with our NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids, potentially decreasing the standard FDA review time. We have decided to defer our NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids until April 2020, which would allow inclusion of the complete 12-month safety data from the LIBERTY open-label extension study, key data that may positively impact the labeled duration of use of the combination tablet. The terms regarding how the PRV will be transferred to us will be determined in connection with the closing of the Roivant-Sumitomo Dainippon Pharma transaction. The transfer is expected to be a related-party transaction and will not involve the issuance of Myovant shares. We also also plan to submit a Marketing Authorisation Application (MAA) to the European Medicines Agency in the first quarter of calendar year 2020.

LIBERTY 1

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

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

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

The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

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

LIBERTY 2

On July 23, 2019, we announced that LIBERTY 2, the second of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, met its primary efficacy endpoint and the same six key secondary endpoints as were achieved in LIBERTY 1. In addition, relugolix combination therapy maintained bone mineral density at levels comparable to placebo over 24 weeks and was generally well tolerated.

In the primary endpoint analysis, 71.2% of women receiving once-daily relugolix combination therapy achieved the responder criteria compared with 14.7% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced a highly significant 84.3% reduction in menstrual blood loss from baseline to Week 24 ($p < 0.0001$). In addition, a significantly greater proportion of women suffering from moderate-to-severe pain from uterine fibroids at baseline experienced no pain or minimal pain during the last 35 days of treatment with relugolix combination therapy compared with women on placebo ($p < 0.0001$).

Changes in bone mineral density were comparable between the relugolix combination therapy and placebo groups at the end of treatment. The distribution of the change in bone mineral density, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by DXA.

The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and a reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was comparable (60.3% vs. 58.9%). In the relugolix combination therapy group, 1.6% of women discontinued treatment early due to adverse events compared with 4.7% in the placebo group. There were no adverse events in the relugolix combination therapy group reported by at least 10% of women and more frequently than in the placebo group. The incidence of hot flashes in the relugolix combination therapy group was similar to placebo (5.6% versus 3.9%). There were no pregnancies in the relugolix combination therapy group and one in the placebo group.

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

We initiated a Phase 3 clinical program in June 2017, evaluating relugolix combination therapy in women with pain associated with endometriosis. The program consists of two multinational replicate pivotal clinical trials, which we refer to as SPIRIT 1 and SPIRIT 2. Each trial randomizes women 1:1:1 to one of three treatment arms: relugolix 40 mg once-daily co-administered in combination with commercially available low-dose hormonal therapy for 24 weeks (1.0 mg estradiol and 0.5 mg norethindrone acetate); relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix 40 mg once-daily co-administered with low-dose hormonal therapy for an additional 12 weeks; or placebo once-daily for a period of 24 weeks. We enrolled 623 patients in the SPIRIT 2 trial and expect to enroll a similar number of patients in the replicate SPIRIT 1 trial. Eligible women completing the initial 24-week period are offered an active treatment extension with relugolix 40 mg once-daily co-administered in combination with low-dose hormonal therapy for an additional 80-week period, or a total treatment period of 104 weeks, to evaluate the safety of longer-term treatment.

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

In August and October 2019, we completed patient recruitment for the SPIRIT 2 and SPIRIT 1 trials, respectively. We expect to report top-line results from SPIRIT 2 and SPIRIT 1 in the first and second quarters of calendar year 2020, respectively.

Our Phase 3 Program for the Treatment of Advanced Prostate Cancer

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

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

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

In addition, we filed an amendment to the HERO study protocol to enroll 139 additional men with metastatic prostate cancer to assess the secondary objective of demonstrating that relugolix can delay the time to progression to the lethal state of the disease, castration-resistant prostate cancer, as compared to leuprolide. We believe that relugolix, a direct GnRH receptor antagonist, has the potential to delay the time to castration-resistant disease as compared with leuprolide, a GnRH agonist, because relugolix more rapidly suppresses testosterone and PSA and more fully suppresses follicle-stimulating hormone than leuprolide. We completed enrollment of this additional cohort of men with metastatic prostate cancer in July 2019, and currently expect to report top-line results from this additional cohort, including the castration resistance-free survival endpoint, in the third quarter of calendar year 2020.

MVT-602

As part of our license agreement with Takeda, or the Takeda License Agreement, we acquired the worldwide rights to MVT-602, our second product candidate, which previously has been evaluated in over 150 men. MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin, the ligand, is a naturally occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. MVT-602 is being developed as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization, or IVF. Approximately 1.5 million assisted reproduction cycles are performed each year worldwide. Further, approximately 25% of women suffering from infertility have problems achieving ovulation, including the inability to produce fully matured eggs or the failure to ovulate, most commonly resulting from hormonal dysfunction in the GnRH-luteinizing hormone/follicle-stimulating hormone axis. We believe MVT-602 has the potential to be a safer alternative to human chorionic gonadotropin as a part of assisted reproduction for the treatment of female infertility.

We believe that MVT-602, an analog of the naturally-occurring kisspeptin peptide in humans, may mimic natural physiology by inducing a luteinizing hormone surge during IVF and other assisted reproductive technologies, enhancing the likelihood of successful egg maturation and ovulation at the right time without the serious side effect of ovarian hyperstimulation syndrome, or OHSS. While assisted reproductive technologies are effective, typically resulting in pregnancy in 20% to 35% of patients, the standard procedure has remained largely unchanged since inception and has potentially serious side effects. The most serious side effect of assisted reproduction is OHSS. Severe OHSS has been reported to occur in up to 2% of the general assisted reproduction population, and in up to 20% of patients at high-risk for developing OHSS. OHSS is thought to occur as a result of the nonphysiologic elevations in luteinizing hormone that occur as a result of egg maturation triggered with human chorionic gonadotropin and to a lesser extent the GnRH receptor agonists.

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

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

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

Financial Operations Overview

Revenue

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

Research and Development Expenses

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

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

Unallocated costs primarily include employee-related expenses, such as salaries, share-based compensation, benefits and travel for employees engaged in R&D activities, and the cost of consultants who assist with R&D activities not specific to a program.

R&D activities have been central to our business model. We expect our overall R&D expenses to decrease over the next few quarters as we expect to complete several of our Phase 3 studies. However, we also expect the decreases in clinical trial expenses will be partially offset by increases in other R&D expenses as we prepare regulatory submissions for our product candidates and establish a medical affairs function, and incur manufacturing expenses in connection with preparations for our anticipated commercial launches of relugolix. Product candidates in later stages of clinical development, such as relugolix, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

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

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to recruit and enroll eligible patients;
- the number of patients who fail to meet the study's inclusion and exclusion criteria;
- the number of study drugs that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals;
- the costs of clinical trial material; and
- the efficacy and safety profile of the product candidate.

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

General and Administrative Expenses

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

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

Interest Expense

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

Interest Income

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

Results of Operations

The following table summarizes our results of operations for thethree and six months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 50,803	$ 53,813	$ 101,920	$ 105,154
General and administrative	16,603	10,310	30,755	19,052
Total operating expenses	67,406	64,123	132,675	124,206
Interest expense	3,788	1,580	7,581	3,197
Interest income	(942)	—	(1,708)	—
Other expense (income), net	121	(21)	(584)	268
Loss before income taxes	(70,373)	(65,682)	(137,964)	(127,671)
Income tax expense	195	88	508	233
Net loss	$ (70,568)	$ (65,770)	$ (138,472)	$ (127,904)

Research and Development Expenses

For the three and six months ended September 30, 2019 and 2018, our R&D expenses consisted of the following (in thousands):

	Three Months Ended September 30,		
	2019	2018	Change
Program-specific costs:			
Relugolix	$ 36,233	$ 43,384	$ (7,151)
MVT-602	255	2,367	(2,112)
Unallocated costs:			
Share-based compensation	3,618	1,846	1,772
Personnel expense	7,738	5,145	2,593
Services Agreements	—	291	(291)
Other expense	2,959	780	2,179
Total R&D expenses	$ 50,803	$ 53,813	$ (3,010)

	Six Months Ended September 30,		
	2019	2018	Change
Program-specific costs:			
Relugolix	$ 75,339	$ 86,223	$ (10,884)
MVT-602	1,075	3,041	(1,966)
Unallocated costs:			
Share-based compensation	6,166	3,407	2,759
Personnel expense [(1)]	15,050	9,926	5,124
Services Agreements	—	748	(748)
Other expense [(1)]	4,290	1,809	2,481
Total R&D expenses	$ 101,920	$ 105,154	$ (3,234)

[(1)] Certain prior period amounts have been reclassified to conform to the current period presentation.

R&D expenses decreased by $3.0 million, to $50.8 million, in the three months ended September 30, 2019 compared to $53.8 million in the three months ended September 30, 2018. R&D expenses in both periods primarily includes expenses related to our Phase 3 clinical studies, manufacturing expenses, as well as personnel-related expenses for employees engaged in R&D activities. R&D expenses related to our clinical studies have continued to decline, driven primarily by the wind down of our LIBERTY Phase 3 studies. The decrease in study costs were partially offset by increases in other R&D expenses related predominantly to our manufacturing activities in connection with preparations for our anticipated commercial launches and regulatory submissions for relugolix in multiple indications and jurisdictions, as well as increases in personnel expenses, share-based compensation expense, and other R&D expenses.

R&D expenses in the three months ended September 30, 2019 consisted primarily of CRO, drug supply and other study and manufacturing related costs of$33.7 million, personnel expenses of $7.7 million, and share-based compensation expense of $3.6 million.

R&D expenses in the three months ended September 30, 2018 consisted primarily of CRO, clinical drug supply and other study-related costs of$45.8 million, personnel expenses of $5.1 million, share-based compensation expense of $1.8 million, $0.1 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements (see Note 7 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q) of $0.2 million, including unallocated personnel expenses and third-party pass-through costs associated with our ongoing clinical and other research programs.

R&D expenses decreased by $3.2 million, to $101.9 million, in the six months ended September 30, 2019 compared to $105.2 million in the six months ended September 30, 2018. R&D expenses in both periods primarily includes expenses related to our Phase 3 clinical studies, manufacturing expenses, as well as personnel-related expenses for employees engaged in R&D activities. R&D expenses for the six months ended September 30, 2018 reflected a ramp up in relugolix Phase 3 study costs primarily related to study enrollment, whereas R&D expenses for the six months ended September 30, 2019 reflect declining relugolix Phase 3 study costs as certain studies are in the process of winding down. The decrease in relugolix Phase 3 study costs were partially offset by increases in other R&D expenses related predominantly to our manufacturing activities in connection with preparations for our anticipated commercial launches and regulatory submissions for relugolix in multiple indications and jurisdictions, as well as increases in personnel expenses, share-based compensation expense, and other R&D expenses.

R&D expenses in the six months ended September 30, 2019 consisted primarily of CRO, drug supply and other study and manufacturing related costs of $74.2 million, personnel expenses of $15.1 million, and share-based compensation expense of $6.2 million.

R&D expenses in the six months ended September 30, 2018 consisted primarily of CRO, clinical drug supply and other study-related costs of $87.7 million, personnel expenses of $9.9 million, share-based compensation expense of $3.4 million, $0.1 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements (see Note 7 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q) of $2.3 million, including unallocated personnel expenses and third-party pass-through costs associated with our ongoing clinical and other research programs.

General and Administrative Expenses

G&A expenses increased by $6.3 million, to $16.6 million, in the three months ended September 30, 2019 compared to $10.3 million in the three months ended September 30, 2018, primarily due to an increase in personnel-related expenses, share-based compensation, professional service fees, expenses related to commercial operations activities in advance of potential future regulatory approvals of relugolix, other general overhead and administrative expenses to support our headcount growth and expanding operations and the assumption of activities previously provided by Roivant Sciences, Inc. ("RSI") and Roivant Sciences GmbH ("RSG") under the Services Agreements, partially offset by a reduction of costs billed to us under the Services Agreements due to a decrease in the level of support provided by RSI and RSG as we have decentralized substantially all of our activities from RSL.

G&A expenses in the three months ended September 30, 2019 consisted primarily of personnel-related, commercial operations, and general overhead expenses of $10.4 million, share-based compensation expense of $4.3 million, professional service fees of $1.1 million, and rent and other facilities related costs of $0.6 million.

G&A expenses in the three months ended September 30, 2018 consisted primarily of personnel-related and general overhead expenses of $5.9 million, share-based compensation expense of $2.9 million, including $0.1 million of which was allocated to us by RSL, professional service fees of $0.6 million, and costs of $0.8 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass-through costs.

G&A expenses increased by $11.7 million, to $30.8 million, in the six months ended September 30, 2019 compared to $19.1 million in the six months ended September 30, 2018, primarily due to an increase in personnel-related expenses, share-based compensation, professional service fees, expenses related to commercial operations activities in advance of potential future regulatory approvals of relugolix, other general overhead and administrative expenses to support our headcount growth and expanding operations and the assumption of activities previously provided by RSI and RSG under the Services Agreements, partially offset by a reduction of costs billed to us under the Services Agreements due to a decrease in the level of support provided by RSI and RSG as we have decentralized substantially all of our activities from RSL.

G&A expenses in the six months ended September 30, 2019 consisted primarily of personnel-related, commercial operations, and general overhead expenses of $18.6 million, share-based compensation expense of $8.2 million, professional service fees of $2.5 million, and rent and other facilities related costs of $1.1 million.

G&A expenses in the six months ended September 30, 2018 consisted primarily of personnel-related and general overhead expenses of $9.9 million, share-based compensation expense of $5.6 million, including $0.2 million of which was allocated to us by RSL, professional service fees of $1.5 million, and costs of $1.9 million billed to us under the Services Agreements, including personnel expenses, overhead allocations and third-party pass-through costs.

Interest Expense

Interest expense was $3.8 million and $1.6 million for the three months ended September 30, 2019 and 2018, respectively, and $7.6 million and $3.2 million for the six months ended September 30, 2019 and 2018, respectively. The increase was primarily the result of higher outstanding debt balances under our financing arrangements during the three and six months ended September 30, 2019 as compared to the prior year periods.

Interest Income

Interest income was $0.9 million and $1.7 million for the three and six months ended September 30, 2019, respectively. There was no interest income for the three and six months ended September 30, 2018. During the three and six months ended September 30, 2019, we invested a portion of our cash in a combination of money market funds, commercial paper, and short-term corporate bonds. There were no such investments in the comparable prior year periods.

Other Expense (Income), net

Other expense (income), net consists of the impact of changes in foreign currency exchange rates on our foreign exchange denominated payables. The impact of foreign exchange rates on our results of operations fluctuates period over period based on our foreign currency exposures resulting from changes in applicable exchange rates associated with our foreign denominated payables.

For the three months ended September 30, 2019, we recorded a foreign exchange loss of $0.1 million, and for the three months ended September 30, 2018, we recorded a foreign exchange gain of less than $0.1 million.

For the six months ended September 30, 2019, we recorded a foreign exchange gain of $0.6 million, and for the six months ended September 30, 2018, we recorded a foreign exchange loss of $0.3 million.

Income Tax Expense

Our income tax expense was $0.2 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $0.5 million and $0.2 million for the six months ended September 30, 2019 and 2018, respectively. Our effective tax rate for the three months ended September 30, 2019 and 2018 was (0.28)% and (0.13)%, respectively, and (0.37)% and (0.18)% for the six months ended September 30, 2019 and 2018, respectively, and is driven by our jurisdictional earnings by location and a valuation allowance that eliminates our global net deferred tax assets.

Liquidity and Capital Resources

Sources of Liquidity

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

As of September 30, 2019, we had $157.6 million of cash, cash equivalents, and marketable securities available to us, as compared to $156.1 million of cash and cash equivalents available to us as of March 31, 2019. As of September 30, 2019, we had approximately $10.4 million of capacity available to us under our "at-the-market" equity offering program that we established in April 2018.

Capital Requirements

For the three months ended September 30, 2019 and 2018, we had net losses of $70.6 million and $65.8 million, respectively, and for the six months ended September 30, 2019 and 2018, we had net losses of $138.5 million and $127.9 million, respectively. As of September 30, 2019, we had an accumulated deficit of $640.5 million.

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

We anticipate that our capital requirements will be significant as we:

- advance our Phase 3 programs of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis and relugolix 120 mg as a monotherapy for advanced prostate cancer;
- expand our chemistry, manufacturing, and control and other manufacturing related activities;
- seek to identify, acquire, develop, and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand, and protect our intellectual property portfolio;
- hire scientific, clinical, regulatory, quality, and administrative personnel;
- add operational, accounting, finance, quality, commercial, and management information systems and personnel;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a medical affairs group with a medical scientific liaison team;

- establish a sales, marketing, and distribution infrastructure and increase the scale of our external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- service our debt obligations and associated interest payments; and
- operate as a public company.

Our primary use of cash has been to fund the development of relugolix and MVT-602. We expect our operating expenses to continue to increase over the near term as we expand our operations to continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix. Based on our current operating plan, we expect that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of our fiscal year ending March 31, 2020. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our current cash, cash equivalents and marketable securities will not be sufficient to enable us to complete all necessary development activities and commercially launch relugolix. We anticipate that we will continue to incur net losses for the foreseeable future.

To continue as a going concern, we will need, among other things, additional capital resources. We continually assess multiple options to obtain additional funding to support our operations, including through financing activities in public or private capital markets. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Although we expect to negotiate and enter into a new term loan facility that we and Sumitomo agreed to negotiate and enter into, and we expect to draw down on this term loan facility on a quarterly basis, after it becomes effective upon the close of the transaction between Roivant Sciences Ltd. and Sumitomo, ASC 240-40, *Going Concern*, does not allow us to consider future financing activities that are uncertain in our assessment of our future cash burn for the purpose of our liquidity assessment. Due to these uncertainties, there is substantial doubt about our ability to continue as a going concern. If we are unable to raise capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back, or discontinue operations.

Until such time, if ever, as we can generate substantial product revenue from sales of relugolix, MVT-602, or any future product candidate, we expect to finance our operations through a combination of cash, cash equivalents, and marketable securities currently on hand, equity offerings, debt financings, structured transactions such as royalty financings, collaboration, license or development agreements, or other collaborations, as well as draws on the new term loan facility that we have agreed to negotiate and enter into with Sumitomo referenced previously. However, we have agreed, until the closing of the Sumitomo Transactions, to reasonably assist and reasonably cooperate with RSL in complying with the interim operating covenants contained in the Sumitomo-Roivant Agreement that relate to us, in which RSL has agreed, among other things, to cause us to conduct our business in the ordinary course, including refraining from taking a list of actions without Sumitomo's consent, including (subject to certain limitations) but not limited to incurring additional indebtedness, issuance of equity securities, granting of liens, and sales of assets. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our common shareholders' ownership interest may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common shareholders' rights. Our existing financing agreements involve, and any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

Cash Flows

The following table sets forth a summary of our cash flows for the six months ended September 30, 2019 and 2018 (in thousands):

	Six Months Ended September 30,	
	2019	2018
Net cash used in operating activities	$ (135,148)	$ (108,881)
Net cash used in investing activities	$ (27,692)	$ (390)
Net cash provided by financing activities	$ 137,388	$ 154,964

Operating Activities

For the six months ended September 30, 2019, we used $135.1 million in operating activities primarily due to our ongoing development and clinical trials for relugolix and MVT-602, activities related to our preparation for potential regulatory approvals and commercialization of relugolix, and the expansion of our company. This was primarily attributable to a net loss for the period of $138.5 million and decreases of $9.3 million in accrued expenses resulting primarily from a decrease in accrued R&D expenses and accrued compensation-related expenses and $5.2 million in accounts payable due to the timing of vendor invoice payments. These amounts were partially offset by an increase of $3.1 million in deferred interest payable related to our outstanding debt with NovaQuest which is paid on a deferred basis pursuant to the terms of the NovaQuest Securities Purchase Agreement, $14.4 million of non-cash share-based compensation expense as a result of an increase in headcount, and $1.8 million of total depreciation and amortization expense.

For the six months ended September 30, 2018, we used $108.9 million in operating activities primarily due to our ongoing development and clinical trials for relugolix and MVT-602. This was primarily attributable to a net loss for the period of $127.9 million along with an increase of $3.2 million in prepaid expenses and other current assets and a decrease of $1.4 million in amounts due to RSL, RSI, and RSG. These amounts were partially offset by an increase in accrued expenses of $8.2 million and an increase in accounts payable of $3.8 million which were primarily due to the progress of our ongoing Phase 3 clinical trials of relugolix, $9.0 million of non-cash share-based compensation expense as a result of an increase in headcount, and $1.1 million of total depreciation and amortization expense.

Investing Activities

For the six months ended September 30, 2019, $27.7 million was used in investing activities, of which $27.2 million was for the purchase of marketable securities and $0.5 million was for the purchase of property and equipment. For the six months ended September 30, 2018, $0.4 million was used in investing activities, all for the purchase of property and equipment.

Financing Activities

For the six months ended September 30, 2019, $137.4 million was provided by financing activities. This was primarily due to the net proceeds of $134.5 million we received from the issuance and sale of 17,424,243 common shares in our underwritten public equity offering (including the exercise of the underwriters' over-allotment option) and the net proceeds of $2.5 million we received from the sale of 106,494 common shares through our "at-the-market" equity offering program. In addition, we received proceeds of $0.3 million from the exercise of stock options under our 2016 Equity Incentive Plan.

For the six months ended September 30, 2018, $155.0 million was provided by financing activities. This was primarily due to the net proceeds of $74.7 million we received from the issuance and sale of 3,533,399 common shares in our underwritten public equity offering (including the partial exercise of the underwriters' over-allotment option), $57.3 million we received from the sale of 2,767,129 common shares through our "at-the-market" equity offering program, and proceeds of $22.5 million we received from the sale of 1,110,015 common shares to RSL in a private placement. In addition, we received proceeds of $0.5 million from the exercise of stock options under our 2016 Equity Incentive Plan.

Contractual Obligations

During the six months ended September 30, 2019, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended March 31, 2019.

During October 2019, we entered into a Sublease Agreement, or sublease, for 20,116 square feet of office space within the same building as our current corporate office space located in Brisbane, California. The sublease term expires on February 29, 2024, with total expected minimum payments over the sublease term of approximately $3.9 million, of which approximately $0.4 million relates to the fiscal year ended March 31, 2020 and approximately $3.5 million relate to each of the fiscal years ended March 31, 2021 through 2024. The sublease required us to deliver an irrevocable standby letter of credit to the sublessor for the duration of the lease in the amount of $0.2 million.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the dates of the unaudited condensed consolidated financial statements and the reported amounts of expenses incurred during the reporting periods. We base our estimates on historical experience and on various other information available to us at the time we make the estimates and judgments that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known.

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

Our critical accounting policies are more fully described in "Critical Accounting Policies and Significant Judgments and Estimates" in Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K. We believe there have been no material changes to our critical accounting policies and use of estimates as disclosed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2019, filed with the SEC on May 24, 2019, other than to leases upon the adoption of ASU 2016-02,*Leases* (Topic 842), as discussed below.

Leases

Prior to April 1, 2019, we recognized our leases in accordance with ASC 840,*Leases*, and all of our leases were classified as operating leases. Rent expense was recognized on a straight-line basis over the terms of the leases and, accordingly, we recorded the cumulative difference between cash rent payments and the recognition of rent expense as a deferred rent liability. When an operating lease included lease incentives, such as rent abatements or leasehold improvement allowances, or required fixed escalations of the minimum lease payments, the aggregate rental expense, including such incentives or increases, was recognized on a straight-line basis over the term of the lease.

Effective April 1, 2019, we adopted ASU 2016-02,*Leases* (Topic 842), under which all of our outstanding leases continue to be classified as operating leases. Rent expense is recognized on a straight-line basis. When an operating lease includes rent abatements or requires fixed escalations of the minimum lease payments, the aggregate rental expense is recognized on a straight-line basis over the term of the lease. When an operating lease includes lease incentives such as leasehold improvement allowances, the lease incentive is included in the right-of-use asset. Operating lease right-of-use assets and operating lease liabilities are recognized at the commencement date based on the present value of the future minimum lease payments over the lease term. As our leases do not provide an implicit rate, in determining the net present value of lease payments, management used judgment in order to estimate the appropriate incremental borrowing rate, which is the rate incurred to borrow equivalent funds on a collateralized basis over a similar term in a similar economic environment.

Recent Accounting Pronouncements

For information regarding the impact of recently adopted accounting pronouncements and the expected impact of recently issued accounting pronouncements not yet adopted on our consolidated financial statements, see Note 2, "Summary of Significant Accounting Policies," to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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.

Our investment policy establishes guidelines for the investment of cash in a conservative and diversified investment portfolio which seeks to provide adequate liquidity for our operations while minimizing the loss of any principal. The securities permitted under our investment policy may be subject to market risk related to changes in interest rates and other market factors. We manage our sensitivity to these risks by investing in short-term, investment grade marketable securities. Due to the short-term duration of our investment portfolio, the limited amount of investments classified as marketable securities, and the low risk profile of our investments, we do not believe that a hypothetical 10% change in market rates would have a material impact on the realized value of our investments. As of September 30, 2019, we had cash, cash equivalents, and marketable securities of$157.6 million and as of March 31, 2019, we had cash and cash equivalents of $156.1 million.

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

We do not believe that we have any material exposures to foreign currency rate fluctuations. Although we conduct some R&D activities with vendors outside of the U.S., most of our transactions are denominated in U.S. dollars. For the six months ended September 30, 2019, we recorded a foreign exchange gain of $0.6 million, and for the six months ended September 30, 2018, we recorded a foreign exchange loss of $0.3 million. These amounts are included in other expense (income), net on the unaudited condensed consolidated statements of operations.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934 as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at the reasonable assurance level. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

We continually seek to improve the efficiency and effectiveness of our internal control over financial reporting. During the quarter endedSeptember 30, 2019, we implemented a company-wide enterprise resource planning (ERP) system to improve the efficiency of certain financial and related transactional processes. We have completed the implementation of certain processes, including the financial close and reporting and indirect procure-to-pay processes and where appropriate, we have modified the design and operation of certain internal control processes and procedures relating to the new ERP system. As we optimize and implement the remaining functionality under this ERP system over the next several quarters, we will continue to assess the impact on our internal control over financial reporting.

There were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 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 unaudited condensed consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the events described in the following risk factors and the risks described elsewhere in this Quarterly Report on Form 10-Q occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline and you could lose all or part of your investment in our common shares.

Risks Related to Our Business, Financial Position and Capital Requirements

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

As of September 30, 2019, we had approximately $157.6 million of cash, cash equivalents, and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of our fiscal year ending March 31, 2020. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our expenses, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. These funds will not be sufficient to enable us to complete all necessary development activities and commercially launch relugolix. We anticipate that we will continue to incur net losses and negative operating cash flows for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period following the filing of this Quarterly Report on Form 10-Q. We may be forced to delay or reduce the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. Management's plans in this regard are described in Note 2 of the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

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

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

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

Our current funds will not be sufficient for us to complete all necessary development activities and commercially launch relugolix. Accordingly, we will need to obtain substantial further funding through other public or private offerings of our capital shares, debt financings, collaboration or licensing arrangements, or other sources. We cannot be certain that additional capital will be available to us on acceptable terms, or at all. In addition, even if additional capital is available to us, we may need to obtain the consent of Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo, before raising additional capital until the closing of the Sumitomo Transactions (as defined in the first risk factor under "Risks Related to Our Common Shares" below). We also expect that we will not be able to draw on the new loan facility that we have agreed to enter into with Sumitomo until the loan facility becomes effective. The loan facility with Sumitomo is expected to be negotiated, entered into and become effective in connection with the closing of the Sumitomo Transactions. As a result, unexpected disagreements may arise in the negotiations that may delay or prevent the entering into an agreement. Further, such loan facility will only become effective in connection with the closing of the Sumitomo Transactions, which if the closing does not occur will cause such loan facility not to become effective. Even if such loan facility becomes effective, we expect the draws on such facility will be subject to certain terms and conditions. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, when needed, we may have to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or potentially discontinue operations. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and anticipated product development programs.

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

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our operations through a combination of cash, cash equivalents, marketable securities on hand, equity offerings, debt financings, and other structured transactions, such as royalty financings, collaboration or license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common shareholder. Our existing agreements with NovaQuest and Hercules, involve, and any agreements for future debt or preferred equity financings, if available, may involve, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. In addition, pursuant to the Letter Agreement (as defined in the first risk factor under "Risks Related to Our Common Shares" below), we have agreed to reasonably assist and reasonably cooperate with RSL in complying with the interim operating covenants contained in the Sumitomo-Roivant Agreement that relate to the Company, in which RSL has agreed, among other things, to cause the Company to conduct its business in the ordinary course, including refraining from taking a list of actions without Sumitomo's consent, including (subject to certain limitations) but not limited to incurring additional indebtedness, issuance of equity securities, granting of liens, and sales of assets. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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

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

We have incurred significant operating losses and negative operating cash flows since our inception and expect to continue to incur significant operating losses and negative operating cash flows; and we have not generated any revenue from any commercial products and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. Since inception, we have focused most of our efforts on research and development with the goal of achieving regulatory approval and have incurred significant operating losses and negative operating cash flows. Our net loss was $138.5 million and $127.9 million for the six months ended September 30, 2019 and 2018, respectively, and, as of September 30, 2019, we had an accumulated deficit of $640.5 million.

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

We have not obtained marketing approval for relugolix or MVT-602 anywhere in the world, and we may never receive such approval. As a result, we have never generated any product revenue. We are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of relugolix and MVT-602, obtain necessary regulatory approvals, and have relugolix and MVT-602 manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercialize relugolix or MVT-602. Even if we successfully obtain regulatory approvals to market relugolix or MVT-602, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for relugolix and MVT-602 and whether we own the commercial rights for those territories. For example, AbbVie launched ORILISSA™, an oral GnRH receptor antagonist, for the management of moderate to severe pain associated with endometriosis in August 2018 after receiving FDA approval as monotherapy (150 mg once a day or 200 mg twice a day). In the third quarter of 2019, AbbVie also announced its submission of an NDA to the FDA for elagolix (300 mg twice a day) in combination with estradiol and norethindrone acetate, for the management of heavy menstrual bleeding associated with uterine fibroids in women. The launch and commercialization of ORILISSA™ or other competing drugs may limit the revenue from relugolix. If the indication or label approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, or if we are unable to obtain a favorable price for relugolix or MVT-602, we may not generate significant revenue from sales of relugolix or MVT-602, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common shares and our ability to raise capital and continue operations.

We are heavily dependent on the success of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for our women's health indications of uterine fibroids and endometriosis, relugolix monotherapy for men with advanced prostate cancer, and MVT-602, which are still under clinical development. If relugolix combination therapy, relugolix, or MVT-602 does not receive regulatory approval or is not successfully commercialized, our business will be harmed.

We are a clinical-stage biopharmaceutical company with no products approved for commercial sale. We have invested and expect to continue to invest a substantial portion of our efforts and expenditures in the development and advancement of our product candidates, relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg), relugolix, and MVT-602. Our business and our ability to generate revenue depends heavily on the successful clinical development, regulatory approval and commercialization of these product candidates, which may never occur. We currently generate no revenue from sales of any product and have never received regulatory approval for any indication for relugolix combination therapy, relugolix or MVT-602 and may never be able to develop or commercialize a marketable product. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries. We are not permitted to market relugolix combination therapy, relugolix or MVT-602 in the U.S. until we receive approval of NDAs or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries.

Obtaining approval of an NDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authority may delay, limit or deny approval of relugolix combination therapy, relugolix or MVT-602. See the Risk Factor titled "The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction which would limit our ability to realize our product candidates' full market potential." We have not submitted an NDA to the FDA, or any comparable application to any other regulatory authority.

Even if we receive regulatory approval for any or all of the formulations of relugolix combination therapy, relugolix or MVT-602, our ability to generate revenues from relugolix combination therapy, relugolix or MVT-602 will depend on our ability to:

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

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

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

GnRH receptor antagonists, like relugolix, may cause loss of bone mineral density due to the induced hypoestrogenic state that may limit duration of use. This risk, and a related risk of hot flush or vasomotor symptoms, may be mitigated by the co-administration of relugolix in combination with low-dose estradiol and a progestin. A key part of our relugolix clinical development strategy is to formulate a single-tablet fixed-dose combination of relugolix with low-dose estradiol and a progestin to maintain bone health and mitigate side effects of a low-estrogen state such as vasomotor symptoms, and to facilitate patient convenience and compliance. We have conducted a bioequivalence study to demonstrate the bioequivalence of the single-tablet relugolix combination therapy with the co-administered regimen used in the LIBERTY clinical program (one relugolix 40 mg tablet and one tablet containing estradiol 1.0 mg and norethindrone acetate 0.5 mg). The single-tablet relugolix combination therapy met FDA bioequivalence criteria. Twelve-month stability studies are required for FDA approval and we expect to obtain the results of such studies by the end of calendar year 2019. If we are unsuccessful in our attempts to formulate a single-tablet fixed-dose combination version of relugolix or if our competitors develop a fixed-dose combination with hormonal therapy before we do, 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.

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

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

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

Each of these agreements include customary affirmative and restrictive covenants and representations and warranties. For example, under the NovaQuest Securities Purchase Agreement, a minimum cash covenant applies commencing on November 1, 2020 (or November 1, 2021 if extended pursuant to the terms of the NovaQuest Securities Purchase Agreement). Other restrictive covenants include limitations on additional indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), transfers, mergers or acquisitions, taxes, corporate changes and deposit accounts. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders.

Additionally, the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement each also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, cross acceleration to certain debt, certain events relating to bankruptcy or insolvency and certain events relating to U.K. or Irish pension plans. Upon the occurrence of an event of default under the NovaQuest Securities Purchase Agreement, a default interest rate of an additional 5.0% will apply to the outstanding obligations under the NovaQuest Securities Purchase Agreement, and NovaQuest, as the agent for the holders of the notes, may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the NovaQuest Securities Purchase Agreement. Upon the occurrence of an event of default under the Hercules Loan Agreement, a default interest rate of an additional 5.0% may be applied to the outstanding obligations under the Hercules Loan Agreement, and Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Hercules Loan Agreement. In addition, upon the occurrence of certain bankruptcy and insolvency events, our obligations under the notes issued pursuant to the NovaQuest Securities Purchase Agreement and our obligations under the Hercules Loan Agreement would automatically become due and payable. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, we may be required to obtain a waiver from each of NovaQuest and Hercules to enable the transactions contemplated by the Letter Agreement (as defined in the first risk factor under "Risks Related to Our Common Shares" below) to not trigger our repayment obligations to NovaQuest and Hercules which, if we are required to do and are unable to obtain, may result in our being required to repay our outstanding obligations to NovaQuest and Hercules in connection with the closing of the Sumitomo Transactions (as defined in the first risk factor under "Risks Related to Our Common Shares" below). In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. NovaQuest and Hercules could also exercise their rights to take possession and dispose of the collateral securing our obligations, which collateral includes all of our and our subsidiaries' respective assets other than intellectual property. Our business, financial condition and results of operations could be substantially harmed as a result of any of these events.

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

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

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

In addition, we may choose to focus our efforts and resources on potential product candidates that ultimately prove to be unsuccessful. Further, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract management's attention from our primary business. If we are unable to identify and acquire or in-license suitable product candidates, we will be unable to diversify our product risk. We believe that any such failure could have a significant negative impact on our prospects because the risk of failure of any particular development program in the pharmaceutical field is high.

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

In June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited, or Takeda Limited, entered into an agreement for the manufacture and clinical supply of relugolix. Under this agreement, Takeda Limited is supplying us, and we are obtaining from Takeda Limited, all of our requirements for relugolix drug substance and drug product to be used under our development plans for all indications. On May 30, 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda, or the Takeda Commercial Supply Agreement, pursuant to which Takeda will manufacture and supply us with relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. If Takeda fails to fulfill its obligations to manufacture and supply clinical and/or commercial quantities of relugolix, our development plans and commercialization of relugolix, if approved, could be significantly delayed or otherwise adversely affected.

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

We expect to hire additional employees for our managerial team and other teams supporting G&A, commercial, clinical, medical affairs, operations and other functions. The market for talent in our industry is very competitive. Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, more favorable risk profiles and a longer operating history in the biopharmaceutical industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. In addition, the decrease in the market price of our common shares may make the attraction and retention of personnel more challenging. Due to these reasons, we may not be able to attract or retain qualified personnel.

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

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

We expect to expand our organization and hire additional employees. Our management is expected to have increasing responsibilities to identify, recruit, maintain, motivate, and integrate additional employees, consultants and contractors which may divert a disproportionate amount of its time and attention away from our day-to-day activities. The expected growth may also require significant capital expenditures and divert financial resources from other projects. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be adversely affected, and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to complete clinical development, obtain regulatory approval, and commercialize relugolix, MVT-602 or any potential future product candidate may be adversely affected.

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

We are exposed to the risk that our employees, contractors, advisers, including principal investigators, consultants, commercial collaborators, service providers, and other vendors, or those of our affiliates, may engage in fraudulent, illegal activity, or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other regulatory bodies, including: those laws that require the reporting of true, complete, and accurate information to such regulatory bodies; laws that require manufacturing by current Good Manufacturing Practice, or cGMP, standards; federal, state and foreign healthcare fraud and abuse laws and data privacy laws; or laws and regulations that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive regulations intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations, and other abusive practices. See the Risk Factors titled "Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties," "International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S.," and "If we obtain approval to market any products outside of the U.S., a variety of risks associated with international operations could materially adversely affect our business." These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We have a Code of Business Conduct and Ethics and other corporate compliance policies, but it is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred.

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

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S.

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

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, privacy and cybersecurity laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- possible failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- business interruptions resulting from geopolitical actions, economic instability, or natural disasters, including, but not limited to, wars and terrorism, political unrest, outbreak of disease, earthquakes, boycotts, curtailment of trade, and other business restrictions;
- failure to comply with foreign laws, regulations, standards and regulatory guidance governing the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Protection Regulation, or the GDPR, which introduced strict requirements for processing personal data of individuals within the EU; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

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

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

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

The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of personal and confidential information stored in our or our third-party providers' systems, portable media or storage devises. We could also experience a business interruption, theft of or unauthorized access to personal or confidential information, intellectual property or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our information system infrastructure or lead to data leakage, either internally or at our third-party providers, and could result in liabilities that adversely affect our financial performance. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent services interruptions or security breaches.

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

In June 2016, a majority of the eligible members of the electorate in the U.K. voted to withdraw from the EU in a national referendum, commonly referred to as "Brexit." Pursuant to Article 50 of the Treaty on European Union, the U.K. will cease to be an EU Member State either on the effective date of a withdrawal agreement (entry into such a withdrawal agreement will require approval of the U.K. Parliament) or, failing that, two years following the U.K.'s notification of its intention to leave the EU (known as the "Brexit Date"), unless the European Council (together with the U.K.) unanimously decides to extend the two year period. On March 29, 2017, the U.K. formally notified the European Council of its intention to leave the EU. It is unclear how long it will take to negotiate a withdrawal agreement, but it appears likely that Brexit will continue to involve a process of lengthy negotiations between the U.K. and the EU to determine the future terms of the U.K.'s relationship with the EU. Given that no formal withdrawal arrangements have been agreed, there have been several extensions to the Brexit Date and the U.K. has yet to formally leave the EU. On October 28, 2019, the EU granted the U.K. a further extension to the Brexit Date until January 31, 2020. Under the terms of the extension, the Brexit Date may be earlier than January 31, 2020, if a formal withdrawal agreement is ratified by Parliament. In addition, the U.K. will hold a general election on December 12, 2019. Until the post-election government is formed, there can be no guarantee or certainty as to which form Brexit will take and on which terms a withdrawal agreement with the EU will be agreed, if at all.

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and certain of our product candidates are derived from EU directives and regulations, Brexit (in any form) could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, as a result of the uncertainty surrounding Brexit, the European Medicines Agency (knows as the "EMA") relocated to Amsterdam from London. Following Brexit, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including certain of our product candidates, will be required in the U.K., the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of certain of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. or the EU for certain of our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. In the near term, there is a risk of disrupted import and export processes due to a lack of administrative processing capacity by the respective U.K. and EU customs agencies that may delay time-sensitive shipments and may negatively impact our product supply chain. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used.

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

Use of social media platforms presents new risks.

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

The failure to successfully implement an enterprise resource planning system could adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

During the three months ended September 30, 2019, we completed the first phase of a company-wide enterprise resource planning, or ERP, system implementation to upgrade certain existing business, operational, and finance processes and to ensure our operations are adequately scalable in support of our anticipated commercial launches. ERP implementations are complex and time-consuming projects that require transformations of business, operational, and finance processes. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations. The implementation of the new ERP system has required, and will continue to require, the investment of significant financial and human resources. Any disruptions, delays, or deficiencies in the design or the ongoing maintenance and optimization of the new ERP system could adversely affect our ability to accurately maintain our books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected and could cause us to fail to comply with the U.S. Securities and Exchange Commission, or the SEC, reporting obligations related to our management's assessment of our internal control over financial reporting, and could result in the issuance of an adverse opinion on the effectiveness of internal control over financial reporting by our independent registered public accounting firm. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business following the implementation of the ERP system, our business and results of operations could be harmed.

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

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

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

The product liability and clinical trial insurance we currently carry, and any additional product liability and clinical trial insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for relugolix or MVT-602, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our common share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

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

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

Risks Related to Clinical Development, Regulatory Approval and Commercialization

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

Our product candidates are still in development and will require extensive clinical testing resulting in sufficiently positive outcomes before we are prepared to submit an NDA or other similar application for regulatory approval. We cannot predict with certainty if or when we might submit an NDA for regulatory approval for relugolix or MVT-602 in any indication or whether any such application will be approved by the relevant regulatory authorities. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For example, the FDA or other regulatory authorities may not agree with our proposed plans for any clinical trials of relugolix or MVT-602, which may delay the approval of an NDA or similar application. The clinical trial process is also very time-consuming. Roivant and Sumitomo have committed to us a priority review voucher expected to become available in early December 2019. We plan to use the priority review voucher in conjunction with our NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids, potentially decreasing the standard FDA review time. However, we currently do not have a contractual right to acquire such priority review voucher. A failure to successfully acquire such priority review voucher may delay the timeline of the review process by the FDA and our timeline to obtain regulatory approval or commercialize relugolix for the treatment of heavy menstrual bleeding and uterine fibroids. Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of an NDA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. For example, Takeda's Phase 2 trial for relugolix in men with advanced prostate cancer, C27002, did not meet the criteria for success for its primary endpoint specified in the statistical analysis plan, highlighting the importance of appropriate selection of the primary endpoint, statistical powering of a clinical study, and diligent oversight of the treatment compliance of those patients enrolled into the trial. A number of companies in the biopharmaceutical industry have suffered significant setbacks in or the discontinuation of advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, we may publicly disclose top-line or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, on May 14, 2019 and July 23, 2019, we announced top-line data for the LIBERTY 1 and LIBERTY 2 trials, the two replicate Phase 3 studies of once-daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding. We make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Positive results from any of our clinical trials of relugolix and MVT-602 may not be predictive of the results of any of our other ongoing and potential future clinical trials, and there can be no assurance that the results of studies conducted by third parties will be viewed favorably or are indicative of our own future study results. Product candidates in clinical trials, including Phase 3 clinical trials, often fail to show the desired safety and efficacy outcomes despite having progressed successfully through prior stages of preclinical and clinical testing. Even where we achieve positive results in clinical trials, subsequent clinical trials may fail, even if those subsequent trials are designed similarly to their predecessors.

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

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

- premature discontinuation of study participants from clinical trials or missing data;
- failure to manufacture or release sufficient quantities of relugolix, MVT-602, estradiol, progestin or placebo or failure to obtain sufficient quantities of concomitant medication, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of study results.

Further, we, the FDA or an institutional review board, or IRB, or other regulatory authority may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a clinical trial in accordance with regulatory requirements, including, the FDA's current Good Clinical Practice, or cGCP, or cGMP regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our Investigational New Drug application, or IND, or other submissions or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the timing for commencement or completion of current or future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of relugolix or MVT-602 could be harmed, and our ability to generate product revenue from relugolix or MVT-602 may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our common share price, slow down the regulatory approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition, and results of operations. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

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

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

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

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

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

Takeda has developed relugolix for the treatment of women with uterine fibroid-associated pain and heavy menstrual bleeding in Japan. Takeda reported positive top-line results from its two Phase 3 clinical trials in Japan in women with uterine fibroids and announced that it had obtained market authorization in Japan from the Ministry of Health, Labor and Welfare for Relumina® Tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids, including heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia. Favorable announcements by Takeda do not guarantee that the results of our clinical trials will also be favorable as the designs of our Phase 3 clinical trials differ from those of Takeda. Further, if clinical trial or post marketing adverse events regarding Relumina® are reported, or subsequent announcements by Takeda regarding relugolix are unfavorable, it could negatively impact our clinical development plans for or opinions of the FDA or other regulatory authorities with respect to relugolix. Additionally, the Phase 3 data from the Takeda trials of Relumina® will be available to us, and may be used to support our submissions to relevant regulatory authorities. We cannot provide assurance that the FDA will allow us to use the data from Takeda's clinical trials in support of any NDA that we may submit, and such data may be interpreted differently by the FDA and provide contradictory evidence in support of FDA's evaluation. If the FDA does not allow us to use the data from Takeda's clinical trials, we may be required to perform additional clinical trials.

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

Drug development is highly competitive and subject to rapid and significant technological advancements. As a significant unmet medical need exists for the treatment of each of uterine fibroids, endometriosis, and advanced prostate cancer, as well as infertility in women, there are several large and small pharmaceutical companies focused on delivering therapies for the treatment of these indications. For example, AbbVie launched ORILISSA™, an oral GnRH receptor antagonist, for the management of moderate to severe pain associated with endometriosis in August 2018 after receiving FDA approval as monotherapy (150 mg once a day or 200 mg twice a day). In the third quarter of 2019, AbbVie also announced its submission of an NDA to the FDA for elagolix (300 mg twice a day) in combination with estradiol and norethindrone acetate, for the management of heavy menstrual bleeding associated with uterine fibroids in women. Further, it is likely that additional drugs will become available in the future for the treatment of each of our target indications.

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

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

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

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

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

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

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

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

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

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

The time required to obtain approval of an NDA by the FDA or similar regulatory authorities outside of the U.S. is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authority. Prior to submitting an NDA to the FDA or any comparable application to any other foreign regulatory authorities for approval of relugolix, we will need to complete our ongoing Phase 3 programs for relugolix, and for approval of MVT-602, we will need to complete Phase 2 and Phase 3 clinical trials. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approvals may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Securing marketing approvals requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of relugolix and MVT-602 for the specified indication. Further, because we are exploring the use of relugolix in combination with low-dose estradiol and a progestin as a longer-term therapy (i.e., greater than 6 months) for the treatment of heavy menstrual bleeding associated with uterine fibroids and for the treatment of pain associated with endometriosis, we expect to be required to submit data on a patient population followed for at least one year.

We expect to rely on third-party CROs and consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Delays or errors in the submission of applications for marketing approval or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approvals, commercialize our product candidates, and generate product revenue.

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

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

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

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

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

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing relugolix or MVT-602.

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

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

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

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

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or the FDA or other regulatory authorities may require that contraindications, warnings or precautions-including in some cases, a boxed warning-be included in the product labeling. If relugolix or MVT-602 receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, and if regulatory authorities believe that we are in violation of these restrictions, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the U.S., and other comparable regulations in foreign jurisdictions, relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorney Generals and other foreign regulatory agencies alleging violations of U.S. federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements may yield various results, including:

- restrictions on the manufacture of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- requirement of a REMS (or equivalent outside the U.S.);
- Warning or Untitled Letters;

- withdrawal or recall of the products from the market;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

Even if one of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue or become profitable. The degree of market acceptance of a product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments, including the convenience and ease or duration of administration;
- the prevalence and severity of any side effects;
- the content of the approved product label and our ability to make compelling product claims;
- the effectiveness of sales and marketing efforts;
- the patient out-of-pocket costs in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the willingness of the potential patient population to try new therapies and of physicians to prescribe these therapies;
- the breadth and cost of distribution support;
- the availability of third-party payor coverage and adequate reimbursement;
- whether diagnosis and treatment rates increase for the diseases our products treat; and
- any restrictions on the use of our product together with other medications.

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

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

To market any product that may be approved, we must build our sales, distribution, marketing, managerial, and certain other capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization. We are currently building our sales and marketing infrastructure; however, we currently do not have an established infrastructure for the sales, marketing, or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. We expect to build a focused sales, distribution, and marketing infrastructure to market our product candidates in the U.S., if approved. There are significant expenses and risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, generate sufficient sales, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and market access teams. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities could delay any product launch, which would adversely impact its commercialization. For example, if the commercial launch of relugolix or MVT-602, if approved, for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

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

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

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

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

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

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, and fires.

Also, see the Risk Factor titled "International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S." We have no prior experience in these countries, and many biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support channels, charitable organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval. Such laws include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal Civil False Claims Act;
- the federal false claims and civil monetary penalties laws, including the Federal Civil False Claims Act which can be enforced by individuals, on behalf of the government, through civil whistleblower or qui tam actions, prohibits, among other things, individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing-houses, and certain healthcare providers, known as covered entities, and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of health or other personal data that are applicable to or affect our operations;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, as well as state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits, and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price, and other harm to our business, financial condition, and results of operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Changes in legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize relugolix or MVT-602 and affect the prices we may obtain.

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

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

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

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. The tax legislation enacted on December 22, 2017, titled "an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," or the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment on certain individuals who fail to maintain qualifying health coverage, commonly known as the individual mandate. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated under the ACA. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans. In December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

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

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has already begun the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. Although a number of the existing measures, and other potential proposals may require authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

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

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

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

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

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on Takeda and its affiliates and other third parties to produce clinical and commercial supplies of drug substance and drug product.

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While relugolix and MVT-602 were being developed by Takeda, they were also being manufactured by Takeda and third-party CMOs. Takeda has retained rights to further develop and commercialize relugolix in Japan and certain other Asian countries and has announced that it has entered into a licensing agreement granting ASKA Pharmaceutical Co., Ltd. exclusive commercialization rights to relugolix for uterine fibroids and exclusive development and commercialization rights to relugolix for endometriosis, in each indication in Japan. We expect that manufacturing support provided by Takeda will be sufficient for us to complete our ongoing Phase 3 programs for relugolix.

Takeda is no longer developing MVT-602. Additional process development and manufacturing would be required for us to complete further Phase 2 and Phase 3 clinical studies for MVT-602. Third-party vendors may be difficult to identify for MVT-602 process and formulation development and manufacturing due to special capabilities required and they may not be able to meet our quality standards.

Any significant delay in the supply of a product candidate, or the raw material components thereof, due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

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

Both relugolix and MVT-602 are potent hormonal therapies and therefore require specialized manufacturing facilities. Depending on actual commercial demand, additional third-party manufacturing facilities will have to be established to meet the demand through technology transfer, process validation and regulatory approval before product manufactured at the new facilities can be marketed. Any delay in the technology transfer and process validation could limit adequate supply to meet our commercial demand.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- delay or inability to develop a fixed-dose combination of relugolix and low-dose estradiol and a progestin;

- failure of the drug substance transferred from Takeda or our other CMOs to meet our product specifications and quality requirements;
- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations, and standards, including GMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell relugolix monotherapy, a fixed-dose single-tablet combination product of relugolix and low-dose estradiol and a progestin, or MVT-602, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the manufacture of another company's products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

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

We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell any of our product candidates, if approved.

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

Suppliers of key components and materials must be named in the NDA or marketing authorization application filed with the FDA, the EMA, or other regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money, and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the regulatory authorities following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval, the regulatory authority may suspend the manufacturing operations. If the manufacturing operations of any single suppliers for any of our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet demand, which could harm our business. In addition, if delivery of materials from our suppliers was interrupted for any reason, we may be unable to ship commercial products that may be approved for marketing or supply our products in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are made only at one facility, which we may not be able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers we depend on, including in the event of a disaster, including an earthquake, equipment failure, or other difficulty, may negatively impact our development and commercialization efforts.

If we were to encounter any of these difficulties, our ability to provide our products, if approved, and product candidates to patients would be jeopardized.

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

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

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

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

While we have agreements governing their activities, our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our (or their own) clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop could be harmed, our costs could increase, and our ability to generate revenue could be delayed.

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

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms or in a timely manner. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition, and prospects.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to relugolix, MVT-602, and any future product candidates. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

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

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

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

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

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

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering relugolix, MVT-602 or any future product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, *inter partes* review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe.

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

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

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Shares

RSL, our largest shareholder, has entered into an agreement with Sumitomo pursuant to which an affiliate of Sumitomo is to acquire all of our common shares held by RSL, which we expect will result in Sumitomo obtaining voting rights over a majority of our common shares. We have entered into a Letter Agreement with Sumitomo which provides certain arrangements related to our financing, board structure, and other corporate governance matters. The above events may affect the price of our common shares and have other effects on our company.

On October 31, 2019, RSL and certain of its affiliates (not including us) entered into an agreement with Sumitomo (the "Sumitomo-Roivant Agreement"), which provides that upon the closing of the transactions contemplated thereby (the "Sumitomo Transactions"), a subsidiary of Sumitomo (such entity, the "Acquiring Entity") will acquire RSL's ownership interest in us and become our significant shareholder. At or prior to the closing of the Sumitomo Transactions, RSL will ensure that the Acquiring Entity will obtain not less than a majority of our outstanding common shares by purchasing additional common shares at prices not below market trading prices and delivering such shares, or voting rights with respect thereto, to the Acquiring Entity.

As previously announced in our current report on Form 8-K filed on October 31, 2019, we have entered into a Letter Agreement with Sumitomo, or the Letter Agreement, which provides, among other things, the following: (i) our Board has approved the transactions contemplated by the Sumitomo-Roivant Agreement relating to the acquisition of our common shares held by RSL; (ii) subject to and at or prior to the closing of the Sumitomo Transactions, the Board will replace the three currently serving RSL-selected directors with three Sumitomo-selected directors, appoint two Sumitomo-selected directors to the Nominating and Corporate Governance Committee to replace two currently serving members, and appoint one Sumitomo-selected director to the Compensation Committee to replace one currently serving member; (iii) subject to the closing of the Sumitomo Transactions, we will enter into a secured low-interest Loan Agreement with Sumitomo under which Sumitomo will commit to provide us a five-year term loan facility of US$350 million with a total interest rate in the single digits subject to further transfer pricing analysis and otherwise on mutually agreed terms; (iv) we will amend our Bye-Laws to remove the requirement that each of the Nominating and Corporate Governance Committee and the Compensation Committee be made up solely of independent directors, provided that the Audit Committee shall continue to be made up solely of independent directors, and provide that our Board delegates to the Nominating and Corporate Governance Committee the right to fix the size of the Board and fill vacancies on the Board, other than three Independent Directors and their direct or indirect successors; and (v) at the closing of the Sumitomo Transactions, we will enter into an Investor Rights Agreement with the Acquiring Entity which provides certain voting arrangements.

Further, pursuant to the Letter Agreement, we have agreed, until the closing of the Sumitomo Transactions, to reasonably assist and reasonably cooperate with RSL in complying with the interim operating covenants contained in the Sumitomo-Roivant Agreement that relate to Myovant, in which RSL has agreed, among other things, to cause Myovant to conduct its business in the ordinary course, including refraining from taking a list of actions without Sumitomo's consent, including (subject to certain limitations) but not limited to incurring additional indebtedness, issuance of equity securities, granting of liens, and sales of assets.

A number of factors could adversely affect our business or our stock price during the pendency or following the closing of the Sumitomo Transactions, including:

- we expect Sumitomo to be able to control certain matters requiring our shareholders' approval upon the closing of the Sumitomo Transactions. See the Risk Factor titled "RSL owns a significant percentage of our common shares and is able to exert significant control over matters subject to shareholder approval, and we expect Sumitomo will have significant control upon the closing of the Sumitomo Transactions;"
- following the closing of the Sumitomo Transactions, the Acquiring Entity could take corporate actions that our other shareholders may not view as beneficial;
- the benefits we anticipate from the Sumitomo Transactions may not occur or may occur in a less pronounced way than we currently expect;
- if the Sumitomo Transactions are consummated, the vesting of certain equity awards under our equity incentive plan will accelerate subject to certain conditions, which could adversely affect the market price of our common shares in the event that the holders of those equity awards elect to exercise their vested awards and sell the underlying common shares;
- the pendency of the Sumitomo Transactions create uncertainty for our employees, which could make it difficult to attract and retain qualified management and commercial, scientific and clinical personnel;
- during the pendency of the Sumitomo Transactions, pursuant to the Letter Agreement, we have agreed to reasonably assist and reasonably cooperate with RSL in complying with certain customary pre-closing covenants, and the restrictions imposed by these covenants on our operations could limit our ability to raise needed capital and management's ability to respond to changing circumstances;

- during the pendency of the Sumitomo Transactions, the Acquiring Entity's review of our business and liabilities will require assistance from our management, which may divert their attention from our primary business or other development programs; and
- the Sumitomo Transactions may increase the risk of litigation, which could distract management and negatively impact our business.

In addition, the Sumitomo Transactions and the arrangements in the Letter Agreement may result in unanticipated risks or other unintended consequences our business and on investor perception that could have a significant impact on the market price of our common shares.

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

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

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

The market price of our common shares has been and is likely to continue to be highly volatile and may be subject to significant fluctuations in response to a variety of factors, including the following:

- inability to obtain additional funding, or investor perception that we may be unable to obtain additional funding or funding on desirable terms;
- the sale by RSL to Sumitomo of our common shares currently held by RSL;
- the acquisition by RSL of additional common shares to satisfy its commitment that the Acquiring Entity will obtain not less than a majority of our outstanding common shares;
- any delay in the commencement, enrollment, and ultimate completion of our clinical trials;
- actual or anticipated results of clinical trials of relugolix combination therapy, relugolix, MVT-602 or those of our competitors;
- any delay in filing an NDA or similar application for relugolix combination therapy, 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 combination therapy, relugolix, MVT-602 or any future product candidate;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to relugolix combination therapy, 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 combination therapy, 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 maintain effective internal control over financial reporting;
- failure to meet or exceed the estimates and projections of the investor community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;
- significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- short sales of our common shares;
- sales of a substantial number of our common shares in the public market, or the perception in the market that the holders of a large number of our common shares intend to sell common shares;
- sales or purchases of our common shares by our executive officers;
- issuance of additional shares of our common shares, or the perception that such issuances may occur, including through our "at-the-market" equity offering program;
- negative coverage in the media or analyst reports, whether accurate or not;
- issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;
- trading liquidity of our common shares;
- investors' general perception of our company and our business;
- general political, economic, industry, and market conditions;
- effects of natural or man-made catastrophic events; and
- the other factors described in this "Risk Factors" section.

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

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

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

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

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

RSL owns a significant percentage of our common shares and is able to exert significant control over matters subject to shareholder approval, and we expect Sumitomo will have significant control upon the closing of the Sumitomo Transactions.

Based on our common shares outstanding as of September 30, 2019, RSL beneficially owns approximately 45.5% of our outstanding common shares and has the ability to substantially influence us through this ownership position. In addition, our Bye-Laws provide that at anytime that RSL owns between 35% and 50% of our common shares, RSL will have the right to appoint directors constituting a simple majority of our board of directors. As a result, until RSL owns less than 35% of our outstanding common shares, RSL will be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL's interests may not always coincide with our corporate interests or the interests of other shareholders, and it may act in a manner with which you may not agree or that may not be in the best interests of our other shareholders. Further, RSL is a privately-held company whose ownership and governance structure is not transparent to our other shareholders.

There may be changes to the management or ownership of RSL that could impact RSL's interests in a way that may not coincide with our corporate interests or the interests of other shareholders. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence or effectively control our decisions.

We expect Sumitomo will have voting control over not less than 50% of our common shares following the closing of the Sumitomo Transactions and therefore we expect Sumitomo to be able to strongly influence or effectively control certain of our decisions; however, so long as Sumitomo owns 35% or more of our common shares, Sumitomo will not be able to control approval of transactions between us and Sumitomo (which will be subject to approval by our independent directors).

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

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

In addition, we are party to certain related party agreements with RSL and its affiliates. These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the minority holders of our common shares. For example, we are party to an option agreement with RSL pursuant to which RSL granted to us an option to acquire the rights to products to which RSL or any nonpublic affiliate of RSL acquires the rights (other than a relugolix product or a competing product) for uterine fibroids or endometriosis, or for which the primary target indication is advanced prostate cancer. It is possible that we could fail to exercise our option with respect to a product candidate under this agreement and that product candidate is then successfully developed and commercialized by RSL or one of its other subsidiaries or affiliates. Any material transaction between us and RSL and its affiliates is subject to our related party transaction policy, which requires prior approval of such transaction by our Audit Committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to conduct business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

Following the closing of the Sumitomo Transactions, many of these potential conflicts with respect to RSL will cease to exist, but we expect that Sumitomo will assume voting control over not less than 50% of our common shares and will have three of its designees serving on our board of directors, which may give rise to new conflicts of interest, including with these Sumitomo-selected directors.

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

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

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

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

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

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

All of the common shares sold in our initial public offering, through our "at-the market" equity offering program and in our 2018 and 2019 public equity offerings, as well as shares issued upon the exercise of stock options granted to persons other than our officers and directors and other shares held by our non-affiliated shareholders, are freely transferable without restrictions or further registration under the Securities Act. If our major shareholders, or any of our executive officers or directors were to sell a substantial portion of our common shares, or if the market perceived that our major shareholders or any of our executive officers or directors intends to sell our common shares, it could negatively affect our common share price.

We have filed a registration statement on Form S-8 under the Securities Act to register the common shares that may be issued under our equity incentive plan. In addition, for so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer," we can utilize a shelf registration statement currently on file with the SEC to allow us to issue an unlimited number of securities from time to time. The issuance of such securities may have an adverse effect on the trading price of our common shares. The number of our new common shares issued in connection with raising additional capital could constitute a material portion of our then outstanding common shares and result in dilution to the market price of our common shares.

In April 2018, we entered into an "at-the-market" sales agreement with Cowen and Company, LLC, or Cowen pursuant to which we may sell from time to time, common shares having an aggregate offering price of up to $100.0 million through Cowen, acting as our agent. Through September 30, 2019, we have sold an aggregate of 4,076,623 common shares for aggregate net proceeds of approximately $86.6 million pursuant to this "at-the-market" equity offering program. Whether we choose to affect future sales under the "at-the-market" equity offering program will depend on a number of factors, including, among others, market conditions and the trading price of our common shares relative to other sources of capital. The issuance from time to time of common shares through our "at-the-market" equity offering program or in any other equity offering, or the perception that such sales may occur, could have the effect of depressing the market price of our common shares.

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

As a public company, we have incurred and will continue to incur significant legal, accounting, and other expenses and these expenses will continue to increase further. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE, and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel devote a substantial amount of time to compliance with these requirements. Moreover, changing rules and regulations may increase our legal and accounting compliance costs and make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations, and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management.

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

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of the end of each fiscal year. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, we are also required to include in our annual report an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm, which could negatively impact the value of our common shares. We are also required to disclose significant changes in our internal control over financial reporting on a quarterly basis.

During the evaluation and testing process of our internal control over financial reporting, if we or our independent registered public accounting firm identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective and our independent registered public accounting firm will be required to issue an adverse opinion on the effectiveness of our internal control over financial reporting. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by the NYSE, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. If our disclosure controls and procedures are ineffective in the future, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common shares to decline.

We are an exempted company limited by shares incorporated under the laws of Bermuda and it may be difficult for you to enforce judgments against us or our directors and executive officers.

We are an exempted company limited by shares incorporated under the laws of Bermuda. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the U.S. judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the U.S., against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

Bermuda law differs from the laws in effect in the U.S. and may afford less protection to our shareholders.

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, or the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits, and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than those who actually approved it.

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

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

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes the NYSE. Additionally, we have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments, and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on the NYSE or another appointed stock exchange.

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

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

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

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

We are incorporated under the laws of Bermuda, where we are not subject to any income or withholding taxes. We are centrally managed and controlled in the U.K., and under current U.K. tax law, a company which is centrally managed and controlled in the U.K. is regarded as resident in the U.K. for taxation purposes. Accordingly, we expect to be subject to U.K. taxation on our income and gains, and subject to U.K.'s controlled foreign company rules, except where an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the U.K. could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could adversely affect our results of operations.

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

We are incorporated under the laws of Bermuda. We currently have subsidiaries in the U.K., Switzerland, Ireland, and the U.S. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between our subsidiaries and us. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws, regulations, principles, and interpretations. In addition, our effective tax rate and the availability of any tax holidays could be adversely affected if we do not obtain favorable tax rulings from certain taxing authorities. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. We continue to assess the impact of such changes in tax laws on our business and may determine that changes to our structure, practice, tax positions or the manner in which we conduct our business are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Changes in our effective tax rate may reduce our net income in future periods.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the U.K. and Switzerland), the U.S., Bermuda, and other jurisdictions, as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation was to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties, and reputational damage, which could adversely affect our business, results of our operations, and our financial condition.

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

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

A non-U.S. corporation is considered a CFC if more than 50 percent of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by U.S. shareholders (U.S. persons who own stock representing 10% or more of the vote or value of all outstanding stock of such non-U.S. corporation) on any day during the taxable year of such non-U.S. corporation. Certain U.S. shareholders of a CFC generally are required to include currently in gross income such shareholders' share of the CFC's "Subpart F income", a portion of the CFC's earnings to the extent the CFC holds certain U.S. property, and a portion of the CFC's "global intangible low-taxed income" (as defined under Section 951A of the Code). Such U.S. shareholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such shareholders. "Subpart F income" includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC. "Global intangible low-taxed income" may include most of the remainder of a CFC's income over a deemed return on its tangible assets.

We believe that we and our non-U.S. subsidiaries are classified as CFCs in the current taxable year. For U.S. holders who hold 10% or more of the vote or value of our common shares, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income and of any such shareholder's share of our accumulated non-U.S. earnings and profits (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the Code with respect to such shareholder, and being subject to certain reporting requirements with the U.S. Internal Revenue Service. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the vote or value of our common shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing our common shares.

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

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares. In addition, special information reporting may be required.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile. With respect to the taxable year that ended on March 31, 2019, we believe that we were not a PFIC; however, with respect to the foreseeable future taxable years, because the PFIC tests are based upon the value of our assets, including any goodwill and going concern value, and the nature and composition of our income and assets, which cannot be known at this time, we cannot predict whether we will or will not be classified as a PFIC. Because the determination of whether we are a PFIC for any taxable year is a fact-intensive determination made annually after the end of each taxable year, and because certain aspects of the PFIC rules are uncertain, we cannot provide any assurances regarding our PFIC status for the current or future taxable years.

We have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether we are classified as a PFIC. In addition, recently proposed U.S. Treasury Regulations, which we are continuing to assess the impact of, may also adversely affect the treatment of these structures and arrangements with respect to our PFIC status.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description of Document	Schedule / Form	File No.	Exhibit No.	Filing Date
3.1	Certificate of Incorporation.	S-1	333-213891	3.1	09/30/2016
3.2	Memorandum of Association.	S-1	333-213891	3.2	09/30/2016
3.3	Fourth Amended and Restated Bye-laws.	10-Q	001-37929	3.3	08/06/2019
10.1†	Form of Amendment No.1 to the Stock Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.				
10.2†	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended (2019 Form).				
31.1†	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1††**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2††**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase				
104	Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				

†Filed herewith.

†† Furnished herewith.

** 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 Exchange Act, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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: November 12, 2019

Exhibit 10.1

MYOVANT SCIENCES, LTD.

AMENDMENT NO. 1 TO THE STOCK OPTION GRANT NOTICE

THIS AMENDMENT NO. 1 TO THE STOCK OPTION GRANT NOTICE (this "**Amendment**") is entered into as of August 26, 2019, by and between Myovant Sciences, Ltd. (the "**Company**"), and [Name][1] ("**Optionholder**").

RECITALS

WHEREAS, the Company and Optionholder entered into that certain Stock Option Grant Notice and Option Agreement pursuant to which the Company granted the Optionholder an option set forth on Exhibit A attached hereto (such option being this "**Option**"; and such Option Agreement being the "**Option Agreement**"); and

WHEREAS, the Company and Optionholder desire to amend certain terms of the Stock Option Grant Notice to the Option Agreement; and the Compensation Committee of the Board of Directors has adopted resolutions approving such changes.

NOW, THEREFORE, the parties agree that the Exercise Schedule in the Stock Option Grant Notice is amended by adding the following language:

(a) Optionholder shall not exercise any portion of the Option that has vested as of August 26, 2019 (the "**Effective Date**") which vested portion is set forth on Exhibit A attached hereto (the "**Vested Option**"), for a period of one year commencing on the Effective Date and ending on the first anniversary date of the Effective Date (the "**Non-Exercise Period**").

(b) If during the Non-Exercise Period, the Optionholder's Continuous Service is terminated for Cause or the Optionholder resigns other than for Good Reason, the Vested Option shall terminate immediately upon such Optionholder's termination of Continuous Service, and the Optionholder shall be prohibited from exercising the Vested Option from and after the time of such termination of Continuous Service. **Good Reason**" shall mean the occurrence of any of the following events without the Optionholder's consent: (i) reduction of the Optionholder's base salary as initially set forth or as the same may be increased from time to time; (ii) material reduction in the Optionholder's authority, duties or responsibilities, as compared to the Optionholder's authority, duties or responsibilities immediately prior to such reduction, without limiting the foregoing, including a change in the Optionholder's reporting responsibilities; (iii) failure or refusal of a successor to the Company to materially assume the Company's obligations under this Agreement in the event of a Change of Control; or (iv) once a principal location of employment is selected, a change in the Optionholder's principal location of employment, resulting in an increase in the Optionholder's one-way driving distance by more than thirty (30) miles from the Optionholder's then current principal residence on file with the Company; *provided, however*, that any resignation by the Optionholder shall only be deemed for Good Reason pursuant to this definition if: (1) the Optionholder gives the Company written notice of the Optionholder's intent to terminate for Good Reason within ninety (90) days following the first occurrence of the condition(s) that Optionholder believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice; and (3) the Optionholder voluntarily terminates his employment within thirty (30) days following the end of the above referenced 30-day period.

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[1] Each of Frank Karbe, Matthew Lang, Juan Camilo Arjona Ferreira entered into an Amendment to the Option Agreement in this form with respect to each of his affected options.

(c) If during the Non-Exercise Period, the Optionholder's Continuous Service is terminated by the Company without Cause or the Optionholder resigns for Good Reason, the Optionholder may exercise the Vested Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination of Continuous Service absent the Non-Exercise Period) within the period of time ending on the earlier of (i) the date three (3) months following the termination of the Optionholder's Continuous Service, and (ii) the expiration of the term of this Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise the Vested Option within the applicable time frame, such Vested Option shall terminate.

(d) If during the Non-Exercise Period, a Optionholder's Continuous Service terminates as a result of the Optionholder's Disability, the Optionholder may exercise the Vested Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination of Continuous Service absent the Non-Exercise Period), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service, and (ii) the expiration of the term of this Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise the Vested Option within the applicable time frame, the Vested Option (as applicable) shall terminate.

(e) If during the Non-Exercise Period, (i) a Optionholder's Continuous Service terminates as a result of the Optionholder's death, or (ii) the Optionholder dies within the period (if any) specified in the Option Agreement for exercisability after the termination of the Optionholder's Continuous Service (for a reason other than death), then the Vested Option may be exercised (to the extent the Optionholder was entitled to exercise such Option as of the date of death absent the Non-Exercise Period) by the Optionholder's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated to exercise the Vested Option upon the Optionholder's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Option Agreement), and (ii) the expiration of the term of such Option as set forth in the Option Agreement. If, after the Optionholder's death, the Option is not exercised within the applicable time frame, the Option (as applicable) shall terminate.

(f) The exercise price of this Option is amended to be equal to the closing price of the Company's Common Shares as listed on the New York Stock Exchange on the Effective Date.

(g) Except to the extent amended hereby, the Option Agreement, and all of its terms and provisions, shall remain in full force and effect.

This Amendment may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this AMENDMENT NO. 1 TO STOCK OPTION GRANT NOTICE as of the date set forth in the first paragraph hereof.

MYOVANT SCIENCES, LTD.:

By:_____
Name:
Its:

IN WITNESS WHEREOF, the parties hereto have executed this AMENDMENT NO. 1 TO STOCK OPTION GRANT NOTICE as of the date set forth in the first paragraph hereof.

OPTIONHOLDER:

_____

[Name]

Exhibit A

Option and Vested Portion as of Effective Date

Exhibit 10.2

MYOVANT SCIENCES LTD.

RESTRICTED STOCK UNIT GRANT NOTICE
(2016 EQUITY INCENTIVE PLAN)

Myovant Sciences Ltd. (the "***Company***"), pursuant to its 2016 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company's Common Stock ("***Restricted Stock Units***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "***Restricted Stock Unit Grant Notice***"), and in the Plan and the Restricted Stock Unit Award Agreement (the "***Award Agreement***"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Restricted Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Restricted Stock Units:	_____

Vesting Schedule: [_____, subject to Participant's Continuous Service through each such vesting date.]

Issuance Schedule: Subject to any Capitalization Adjustment, one share of Common Stock (or its cash equivalent, at the discretion of the Company) will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Mandatory Sale to Cover Withholding Taxes: As a condition for acceptance of this Award, to the fullest extent permitted under the Plan and applicable law, Withholding Taxes will be satisfied through the sale of a number of the shares subject to the Award as determined in accordance with Section 11 of the Award Agreement and the remittance of the cash proceeds to the Company. Under the Award Agreement, the Company is authorized and directed by Participant to make payment from the cash proceeds of this sale directly to the appropriate taxing authorities in an amount equal to the taxes required to be withheld. *The mandatory sale of shares to cover Withholding Taxes is imposed by the Company on Participant in connection with the receipt of this Award, and it is intended to comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act and be interpreted to meet the requirements of Rule 10b5-1(c)*.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award, with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant, (ii) the written employment agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

	MYOVANT SCIENCES LTD.	**Participant**
By:	/s/ Lynn Seely	
	Title: Principal Executive Officer	Signature
	Date: August 26, 2019	Date:

ATTACHMENTS: Award Agreement and 2016 Equity Incentive Plan

ATTACHMENT I

MYOVANT SCIENCES LTD.

2016 EQUITY INCENTIVE PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Restricted Stock Unit Grant Notice (the "***Grant Notice***") and this Restricted Stock Unit Award Agreement (the "***Agreement***"), Myovant Sciences Ltd. (the "***Company***") has awarded you ("***Participant***") a Restricted Stock Unit Award (the "***Award***") pursuant to the Company's 2016 Equity Incentive Plan (the "***Plan***") for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. GRANT OF THE AWARD. This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Restricted Stock Units/shares of Common Stock subject to the Award. Notwithstanding the foregoing, the Company reserves the right to issue you the cash equivalent of Common Stock, in part or in full satisfaction of the delivery of Common Stock in connection with the vesting of the Restricted Stock Units, and, to the extent applicable, references in this Agreement and the Grant Notice to Common Stock issuable in connection with your Restricted Stock Units will include the potential issuance of its cash equivalent pursuant to such right. This Award was granted in consideration of your services to the Company.

2. VESTING. Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice. Vesting will cease upon the termination of your Continuous Service and the Restricted Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the shares of Common Stock to be issued in respect of such portion of the Award.

3. NUMBER OF SHARES. The number of Restricted Stock Units subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

4. SECURITIES LAW COMPLIANCE. You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. TRANSFER RESTRICTIONS. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) Death. Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order, marital settlement agreement or other divorce or separation instrument as permitted by applicable law that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

6. DATE OF ISSUANCE.

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the withholding obligations set forth in Section 11 of this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***"

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established Company-approved 10b5-1 trading plan or pursuant to the mandatory "same-day sale" commitment described in Section 11 hereof then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, when you are permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established Company-approved 10b5-1 trading plan or pursuant to the mandatory "same-day sale" commitment described in Section 11 hereof, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

7. DIVIDENDS. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; provided, however, that this sentence will not apply with respect to any shares of Common Stock that are delivered to you in connection with your Award after such shares have been delivered to you.

8. RESTRICTIVE LEGENDS. The shares of Common Stock issued in respect of your Award shall be endorsed with appropriate legends as determined by the Company.

9. EXECUTION OF DOCUMENTS. You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

10. AWARD NOT A SERVICE CONTRACT.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice may not be earned unless (in addition to any other conditions described in the Grant Notice and this Agreement) you continue as an employee, director or consultant at the will of the Company and affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "***reorganization***"). You acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to terminate your Continuous Service at any time, with or without your cause or notice, or to conduct a reorganization.

11. WITHHOLDING OBLIGATION.

(a) On each vesting date, and on or before the time you receive a distribution of the shares of Common Stock in respect of your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby agree to make adequate provision for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "***Withholding Taxes***"). Specifically, pursuant to section 11(d), you have agreed to a "same-day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you have irrevocably agreed to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer committed to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates. If, for any reason, such "same-day sale" commitment pursuant to section 11(d) does not result in sufficient proceeds to satisfy the Withholding Taxes, the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or an Affiliate; (ii) causing you to tender a cash payment (which may be in the form of a check, electronic wire transfer or other method permitted by the Company); or (iii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with your Restricted Stock Units with a fair market value (measured as of the date shares of Common Stock are issued to you) equal to the amount of such Withholding Taxes; *provided, however*, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income.

(b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Common Stock.

(c) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

(d) You hereby acknowledge and agree to the following:

(i) You hereby appoint E*Trade, or any other entity that provides the equity platform which is chosen by the Company to manage the shares under the Plan, from time to time, as your agent (the "***Agent***"), and authorize the Agent:

(1) To sell on the open market at the then prevailing market price(s), on your behalf, as soon as practicable on or after each date on which Shares vest, the number (rounded up to the next whole number) of the shares of Common Stock to be delivered to you in connection with the vesting of those Shares sufficient to generate proceeds to cover (A) the Withholding Taxes that you are required to pay pursuant to the Plan and this Award Agreement as a result of the Shares vesting (or being issued, as applicable) and (B) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto; and

(2) To remit any funds from the same-day sale of the number of the shares of Common Stock referenced in (1) to the Company and to remit any remaining funds to you.

(ii) You hereby authorize the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold pursuant to this Section 11(d).

(iii) You understand that the Agent may effect sales as provided in this Section 11(d) in one or more sales and that the average price for executions resulting from bunched orders will be assigned to your account. In addition, you acknowledge that it may not be possible to sell shares of Common Stock as provided by in this Section 11(d) due to (A) a legal or contractual restriction applicable to you or the Agent, (B) a market disruption, or (C) rules governing order execution priority on the national exchange where the Common Stock may be traded. In the event of the Agent's inability to sell shares of Common Stock, you will continue to be responsible for the timely payment to the Company of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld, including but not limited to those amounts specified in this Section 11(d).

(iv) You acknowledge that regardless of any other term or condition of this Section 11(d), the Agent will not be liable to you for (A) special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or (B) any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control.

(v) You hereby agree to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of this Section 11(d). The Agent is a third-party beneficiary of this Section 11(d).

(vi) You hereby agree that if you have signed the Grant Notice at a time that you are in possession of material non-public information, unless you inform the Company in writing that you are not in agreement with the provisions of this Section 11(d) within five business days following the date you cease to be in possession of material non-public information, your not providing such written determination shall be a determination and agreement that you have agreed to the provisions set forth in this Section 11(d) on such date as you have ceased to be in possession of material non-public information.

(vii) This Section 11(d) shall terminate not later than the date on which all Withholding Taxes arising in connection with the vesting of your Award have been satisfied.

12. TAX CONSEQUENCES. The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

13. UNSECURED OBLIGATION. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. NOTICES. Any notice or request required or permitted hereunder shall be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

15. HEADINGS. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

16. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

18. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

19. SEVERABILITY. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. OTHER DOCUMENTS. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

21. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

22. COMPLIANCE WITH SECTION 409A OF THE CODE. This Award is intended to be exempt from the application of Section 409A of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and any ambiguities herein shall be interpreted accordingly. Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and determined to be deferred compensation subject to Section 409A of the Code, this Award shall comply with Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. If it is determined that the Award is deferred compensation subject to Section 409A and you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "Separation from Service" (as defined in Section 409A), then the issuance of any shares that would otherwise be made upon the date of your Separation from Service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the Separation from Service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

* * * * *

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and Participant upon the signing by Participant of the Restricted Stock Unit Grant Notice to which it is attached.

ATTACHMENT II

2016 EQUITY INCENTIVE PLAN

Exhibit 31.1

CERTIFICATION

I, Lynn Seely, certify that:

1. I have reviewed this 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 12, 2019

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, certify that:

1. I have reviewed this Form 10-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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

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

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 12, 2019

By: /s/ Frank Karbe

Frank Karbe

Principal Financial and Accounting Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Lynn Seely, Principal Executive Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of her knowledge:

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

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

Date: November 12, 2019

By: /s/ Lynn Seely
Lynn Seely
Principal Executive Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Myovant Sciences Ltd. (the "Company") for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Frank Karbe, Principal Financial Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of his knowledge:

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

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

Date: November 12, 2019

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

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.