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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 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 o

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

Indicate by check mark 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	o	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. o

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 July 30, 2019, was 89,622,626.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 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*)

	June 30, 2019	March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 226,734	$ 156,074
Prepaid expenses and other current assets	8,693	10,194
Income tax receivable	331	524
Total current assets	235,758	166,792
Property and equipment, net	2,057	2,071
Operating lease right-of-use asset	9,181	—
Other assets	3,877	4,114
Total assets	$ 250,873	$ 172,977
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 10,004	$ 11,019
Interest payable	758	1,077
Accrued expenses	46,258	53,614
Operating lease liability	813	—
Due to Roivant Sciences Ltd. (RSL), Roivant Sciences, Inc. (RSI) and Roivant Sciences GmbH (RSG)	196	121
Current maturities of long-term debt	10,867	6,142
Total current liabilities	68,896	71,973
Deferred rent	—	1,157
Deferred interest payable	3,790	2,273
Long-term operating lease liability	9,550	—
Long-term debt, less current maturities	89,070	93,240
Total liabilities	171,306	168,643
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 89,622,626 and 72,057,490 issued and outstanding at June 30, 2019 and March 31, 2019, respectively	2	1
Additional paid-in capital	649,806	505,851
Accumulated other comprehensive (loss) income	(312)	507
Accumulated deficit	(569,929)	(502,025)
Total shareholders' equity	79,567	4,334
Total liabilities and shareholders' equity	$ 250,873	$ 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 June 30,	
	2019	**2018**
Operating expenses:		
Research and development [1]	$ 51,117	$ 51,341
General and administrative [2]	14,152	8,742
Total operating expenses	65,269	60,083
Interest expense	3,793	1,617
Interest income	(766)	—
Other (income) expense, net	(705)	289
Loss before income taxes	(67,591)	(61,989)
Income tax expense	313	145
Net loss	$ (67,904)	$ (62,134)
Net loss per common share — basic and diluted	$ (0.89)	$ (0.98)
Weighted average common shares outstanding — basic and diluted	76,468,347	63,310,177

[1] Includes $25 and $2,188 of costs allocated from RSL, RSI, and RSG during the three months ended June 30, 2019 and 2018, respectively. Also includes share-based compensation expense (see Note 9).

[2] Includes $198 and $1,225 of costs allocated from RSL, RSI, and RSG during the three months ended June 30, 2019 and 2018, respectively. Also includes share-based compensation expense (see Note 9).

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 June 30,	
	2019	**2018**
Net loss	$ (67,904)	$ (62,134)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	(819)	425
Total other comprehensive (loss) income	(819)	425
Comprehensive loss	$ (68,723)	$ (61,709)

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

	Common Shares		Additional Paid in Capital	Accumulated Other Comprehensive Income	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

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)

	Three Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (67,904)	$ (62,134)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	6,452	4,244
Depreciation and amortization [(1)]	356	91
Amortization of debt discount and issuance costs	555	507
Other items	(713)	425
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,501	(563)
Income tax receivable	193	145
Other assets	237	288
Accounts payable	(1,015)	389
Interest payable	(319)	90
Accrued expenses	(7,568)	8,040
Operating lease liabilities	(178)	—
Due to RSL, RSI and RSG	75	3,247
Deferred rent	—	324
Deferred interest payable	1,517	152
Net cash used in operating activities	(66,811)	(44,755)
Cash flows from investing activities:		
Purchase of property and equipment	(139)	(197)
Net cash used in investing activities	(139)	(197)
Cash flows from financing activities:		
Proceeds from issuance of common shares in “at-the-market” equity offering, net of issuance costs paid	2,546	57,387
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	134,750	—
Proceeds from issuance of common shares in Private Placement with RSL	—	22,500
Proceeds from stock option exercises	314	76
Net cash provided by financing activities	137,610	79,963
Net change in cash, cash equivalents and restricted cash	70,660	35,011
Cash, cash equivalents and restricted cash, beginning of period	157,199	108,624
Cash, cash equivalents and restricted cash, end of period	$ 227,859	$ 143,635
Non-cash financing activities:		
Deferred offering costs included in accounts payable and accrued expenses	$ 212	$ 72

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

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

The Company has incurred, and expects to continue to incur, significant operating losses and negative 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 months ended June 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(G).

(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. 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 three months ended June 30, 2019, the Company incurred net losses of $67.9 million and used $66.8 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 and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements at least through the end of fiscal year 2019. This estimate is based on the Company's current assumptions, including assumptions relating to its ability to manage its spend, that might prove to be wrong, and it could use its available capital resources sooner than it currently expects. These funds will not be sufficient to enable the Company to complete all necessary development activities and commercially launch relugolix. The Company anticipates that it will continue to incur net losses for the foreseeable future.

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

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

(D) 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, 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 June 30, 2019 and 2018, potentially dilutive securities were as follows:

	June 30,	
	2019	2018
Stock options	7,085,337	4,779,727
Restricted stock awards (unvested)	846,165	1,128,221
Restricted stock units (unvested)	38,449	15,000
Warrants	73,310	73,710
Total	8,043,261	5,996,658

(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 June 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.

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

Cash as reported in the 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):

	June 30,	
	2019	2018
Cash and cash equivalents	$ 226,734	$ 143,035
Restricted cash [(1)]	1,125	600
Total cash, cash equivalents and restricted cash	$ 227,859	$ 143,635

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

(F) Fair Value Measurements

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

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

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

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

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

(G) 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 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 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 condensed consolidated statement of operations, and no cumulative-effect adjustment to accumulated deficit. See Note 10 for additional information related to the Company's facility lease.

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 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 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 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 condensed consolidated financial statements and related disclosures.

(H) 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 does not expect that the adoption of this new standard will have a material impact on its 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 expect that the adoption of this new standard will have a material impact on its 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 condensed consolidated financial statements and related disclosures.

Note 3—Fair Value Measurements

As of June 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 in the unaudited condensed consolidated balance sheets.

The following table summarizes these assets as of June 30, 2019 (in thousands):

	June 30, 2019			
	Level 1	Level 2	Level 3	Total Fair Value
Assets:				
Money market funds	$ 41	$ —	$ —	$ 41
Commercial paper	—	121,787	—	121,787
Total assets	$ 41	$ 121,787	$ —	$ 121,828

The following table summarizes these assets as of March 31, 2019 (in thousands):

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

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

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

Note 4—Accrued Expenses

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

	June 30, 2019	March 31, 2019
Accrued R&D expenses	$ 41,554	$ 46,947
Accrued compensation-related expenses	1,632	5,024
Accrued professional service fees	971	370
Accrued other expenses	2,101	1,273
Total accrued expenses	$ 46,258	$ 53,614

Note 5—Financing Arrangements

(A) NovaQuest

In October 2017, the Company, its subsidiaries, as guarantors, and NovaQuest Capital Management, or NovaQuest, entered into (i) a Securities Purchase Agreement, or the NovaQuest Securities Purchase Agreement, and (ii) an Equity Purchase Agreement, or the NovaQuest Equity Purchase Agreement. Pursuant to the NovaQuest Securities Purchase Agreement, the Company had the option, at its discretion, to issue up to $60.0 million aggregate principal amount of notes to NovaQuest and concurrent with each purchase of notes, NovaQuest was obligated to purchase up to $20.0 million of the Company's common shares on a pro rata basis, subject to certain terms and conditions, through December 31, 2018. The equity purchase price for each such purchase was equal to 105% of the average of the volume-weighted average price for the five consecutive trading days immediately prior to the relevant purchase date. The Company committed that it would issue at least $30.0 million aggregate principal amount of notes through December 31, 2018, subject to certain terms and conditions. The Company issued $6.0 million aggregate principal amount in October 2017 and $54.0 million aggregate principal amount in December 2018. With the issuance of $6.0 million aggregate principal amount of notes in October 2017, NovaQuest purchased 138,361 common shares for $2.0 million, and with the issuance of $54.0 million aggregate principal amount of notes in December 2018, NovaQuest purchased 1,082,977 common shares for $18.0 million.

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

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

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

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

	June 30, 2019	March 31, 2019
Principal amount	$ 60,000	$ 60,000
Less: unamortized debt issuance costs	(645)	(756)
Loan payables less unamortized debt issuance costs	59,355	59,244
Less: current maturities	—	—
Long-term debt, net of current maturities and unamortized debt issuance costs	$ 59,355	$ 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 9.50% as of June 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 has been extended from June 1, 2019 to December 1, 2019 as a result of the achievement of a financing milestone during July 2018 and may be further extended until June 1, 2020 if a certain clinical milestone is met, as specified in the Hercules Loan Agreement. Prepayment of the Term Loan is subject to a prepayment charge. The Company is also obligated to pay an end of term charge of 6.55% of the principal amount of the Term Loans funded under the Hercules Loan Agreement, on the earlier of the maturity date or the date that the Term Loans otherwise become due and payable. The Company's obligations under the Hercules Loan Agreement are secured by a first lien security interest in substantially all of the Company's and its subsidiaries' respective assets (other than intellectual property). The Hercules Loan Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant that ceases to apply if the Company achieves both the clinical development and financing milestones as set forth in the Hercules Loan Agreement. In July 2019, the clinical milestone was met and as a result, the Interest-only Period has been extended to June 1, 2020 and the minimum cash covenant ceases to apply.

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 each of the three-month periods ended June 30, 2019 and 2018, interest expense included $0.4 million of amortized debt discount and issuance costs related to the Term Loans.

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

	June 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	(2,038)	(2,482)
Loan payables less unamortized debt discount and issuance costs	40,582	40,138
Less: current maturities	(10,867)	(6,142)
Long-term debt, net of current maturities and unamortized debt discount and issuance costs	$ 29,715	$ 33,996

Note 6—Related Party Transactions

(A) Services Agreements

In July 2016, the Company entered into a services agreement with RSI, effective April 29, 2016, under which RSI agreed to provide certain administrative and R&D services to the Company. Under this services agreement, the Company pays or reimburses RSI for expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative, or G&A, and R&D activities performed by RSI employees, RSI charges the Company based 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 June 30, 2019 and 2018, the Company incurred expenses (inclusive of third party pass-through costs billed to the Company) of $0.2 million and $3.2 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, respectively, for the three months ended June 30, 2019 and 2018.

(C) Private Placement with RSL

See Note 8(B) for information regarding the Private Placement with RSL.

(D) Underwritten Public Equity Offering of Common Shares

As discussed in Note 8(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 7—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 June 30, 2019 and 2018 was (0.46)% and (0.23)%, respectively, and is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

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 8—Shareholders' Equity

(A) Underwritten Public Equity Offering of Common Shares

On June 4, 2019, the Company completed an underwritten public equity offering of 17,424,243 of its common shares (including 2,272,727 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 estimated 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 three months ended June 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. As of June 30, 2019, the Company had approximately $10.4 million of capacity available to it under its "at-the-market" equity offering program.

Note 9—Share-Based Compensation

(A) Myovant 2016 Equity Incentive Plan

In June 2016, the Company adopted its 2016 Equity Incentive Plan, or as amended, the 2016 Plan, under which 4.5 million common shares were originally reserved for issuance. Pursuant to the "evergreen" provision contained in the 2016 Plan, the number of 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 June 30, 2019, a total of 3.2 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 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	1,849,560
Exercised	(33,461)
Forfeited	(127,227)
Options outstanding at June 30, 2019	7,085,337
Options vested and expected to vest at June 30, 2019	7,085,337
Options exercisable at June 30, 2019	2,013,917

(C) 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	—
Vested	(71,452)
Unvested balance at June 30, 2019	884,614

(D) Share-Based Compensation Expense

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

	Three Months Ended June 30,	
	2019	2018
Share-based compensation expense recognized as:		
R&D expenses	$ 2,548	$ 1,561
G&A expenses	3,904	2,683
Total	$ 6,452	$ 4,244

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 of less than $0.1 million and $0.2 million for the three months ended June 30, 2019 and 2018, respectively. Total unrecognized share-based compensation expense was approximately $65.2 million as of June 30, 2019 and is expected to be recognized over a weighted-average period of approximately 3.09 years.

(E) 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 June 30, 2019, the performance conditions had not been met and were deemed not probable of being met. For the three months ended June 30, 2019 and 2018, the Company recorded no share-based compensation expense related to these RSL RSUs. As of June 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 10—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 June 30, 2019
Operating lease cost	$ 519
Variable lease cost [(1)]	9
Total operating lease cost	$ 528

[(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.

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, except periods and percentages):

	June 30, 2019
Cash paid for operating lease liabilities	$ 496
Operating lease right-of-use asset obtained in exchange for operating lease liabilities	9,181
Weighted average remaining lease term (in years)	6.9
Weighted average discount rate	12.28%

As of June 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)	$ 1,510
2021	2,065
2022	2,128
2023	2,200
2024	2,339
Thereafter	5,307
Total lease payments	15,549
Less imputed interest [(1)]	(5,186)
Present value of future minimum lease payments	10,363
Less operating lease liability, current portion	(813)
Operating lease liability, long-term portion	$ 9,550

[(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 11—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 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 5.

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 40 mg in combination with low-dose estradiol and a progestin, relugolix 120 mg as a monotherapy and MVT-602;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical studies and clinical trials;
- the anticipated designs of our future clinical trials;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for relugolix 40 mg in combination with low-dose estradiol and a progestin, 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 and cash equivalents currently on hand;
- our ability to raise additional capital;
- industry trends;
- developments and projections relating to our competitors or our industry; and
- the success of competing drugs that are or may become available.

Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, particularly in the section titled "Risk Factors" set forth in Part 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 clinical-stage healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer. Our lead product candidate is relugolix, an oral once-daily small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist that is currently being evaluated in multiple Phase 3 clinical trials across three distinct indications. We are advancing relugolix 40 mg in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis, and relugolix 120 mg as a monotherapy for advanced prostate cancer. In addition, we are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as a part of assisted reproduction. Both relugolix and MVT-602 were licensed to us by Takeda Pharmaceuticals International AG, or Takeda, on April 29, 2016.

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. Based on the positive top-line results for LIBERTY 1 and LIBERTY 2, we currently plan to submit a New Drug Application, or NDA, to the FDA in the fourth quarter of calendar year 2019 and the Marketing Authorisation Application to the European Medicines Agency in the first quarter of calendar year 2020. We further expect to announce top-line results from three additional Phase 3 studies of relugolix over the next four quarters.

First Fiscal Quarter Ended June 30, 2019 and Recent Clinical and Corporate Highlights

The following summarizes our first fiscal quarter ended June 30, 2019 and recent clinical and corporate highlights:

Relugolix Phase 3 Clinical Programs

- 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. In the primary endpoint analysis, 73.4% of women receiving once-daily oral relugolix combination therapy achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

- 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 six key secondary endpoints. 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 once-daily, single-tablet regimen of relugolix combination therapy in the NDA submission for approval of the treatment for uterine fibroids.
- Based upon the positive top-line results for LIBERTY 1 and LIBERTY 2, we currently plan to submit an NDA to the FDA in the fourth quarter of calendar year 2019 and the Marketing Authorisation Application to the European Medicines Agency in the first quarter of calendar year 2020. We also expect to submit data from LIBERTY 1 and LIBERTY 2 for presentation and publication in 2019.
- We expect top-line data from the HERO Phase 3 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 in early calendar year 2020. Enrollment of approximately 130 additional men with metastatic prostate cancer in the Phase 3 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 continue to enroll patients in the two replicate SPIRIT 1 and SPIRIT 2 Phase 3 trials evaluating the safety and efficacy of relugolix combination therapy in women with pain associated with endometriosis. We expect to complete enrollment in the SPIRIT 1 and SPIRIT 2 Phase 3 trials later this calendar year, with top-line data for SPIRIT 2 expected in the first quarter of calendar year 2020 and top-line data for SPIRIT 1 expected in the second quarter of calendar year 2020.

MVT-602 Clinical Program

- We presented top-line results from a successful dose-finding pharmacokinetic/pharmacodynamic Phase 2a study of MVT-602, a kisspeptin-1 receptor agonist, in healthy women undergoing a minimal controlled ovarian stimulation protocol 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.

Corporate

- On June 4, 2019, we completed an underwritten public equity offering of 17,424,243 of our common shares (including 2,272,727 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 estimated offering costs payable by us, the net proceeds to us in connection with the underwritten public equity offering, including from the exercise of the over-allotment option, were approximately $134.5 million.
- During the three months ended June 30, 2019, we issued and sold 106,494 of our common shares for aggregate net proceeds to us of approximately $2.5 million, pursuant to our "at-the-market" equity offering program. We currently have approximately $10.4 million of capacity available to us under our "at-the-market" equity offering program.

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 June 30, 2019, and March 31, 2019, we had an accumulated deficit of $569.9 million and $502.0 million, respectively. We had net losses of $67.9 million and $62.1 million for the three months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had $226.7 million of cash and cash equivalents 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, 40 mg in combination with estradiol (1.0 mg) and a progestin (norethindrone acetate, 0.5 mg) administered orally once a day, with the goal of optimizing estradiol levels to maximize the benefit of relugolix on symptoms of uterine fibroids and endometriosis, while maintaining bone health and mitigating side effects from a low-estrogen state such as vasomotor symptoms. We expect to launch in our women's health indications with a single-tablet regimen of relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg 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 will be required for FDA approval and these studies are ongoing. We believe our combination approach with relugolix has the potential to have a better safety and tolerability profile than the currently approved GnRH agonist therapies and has the potential to be used longer-term. The goal of this longer-term treatment is to provide women with uterine fibroids and endometriosis a medical alternative to hysterectomy and other invasive procedures often recommended to treat these conditions. If we are unsuccessful in our attempts to formulate a fixed-dose combination in time for the initial application for marketing authorization in the United States, or U.S., we expect to seek approval for relugolix tablets co-packaged with a commercially available tablet containing both the low-dose estradiol and norethindrone acetate.

Decreasing testosterone slows the growth and progression of advanced prostate cancer, such as when the disease recurs or the prostate-specific antigen, or PSA, is rising following prostatectomy or radiation therapy. Relugolix monotherapy is in Phase 3 clinical evaluation as a once-daily oral treatment to lower testosterone. It is being evaluated at a three-times higher dose in men with advanced prostate cancer than the women's health indications (120 mg orally once-daily following a single 360-mg loading dose compared to 40 mg 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. 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, a quantitative measurement of menstrual blood loss. 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 once-daily, single-tablet regimen in the NDA submission for approval of the treatment for uterine fibroids. Further review of the underlying data by Myovant is ongoing and may result in additional observations with respect to these studies. Based upon the positive top-line results for LIBERTY 1 and LIBERTY 2, we currently plan to submit an NDA to the FDA in the fourth quarter of calendar year 2019 and the Marketing Authorisation Application to the European Medicines Agency in the first quarter of calendar year 2020. We also expect to submit data from LIBERTY 1 and LIBERTY 2 for presentation and publication in calendar year 2019.

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

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

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

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 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 dual energy x-ray absorptiometry (DXA).

The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and 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 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 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 group was similar to placebo (5.6% versus 3.9%). There were no pregnancies in the relugolix combination 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 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 expect to enroll approximately 600 women in each of the two replicate SPIRIT 1 and SPIRIT 2 trials. Eligible women completing the initial 24-week period are offered an active treatment extension with relugolix 40 mg once-daily co-administered in combination with low-dose hormonal therapy for an additional 80-week period, or a total treatment period of 104 weeks, to evaluate the safety of longer-term treatment.

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

We expect to complete enrollment in the SPIRIT 1 and SPIRIT 2 Phase 3 trials later this calendar year, with top-line data for SPIRIT 2 expected in the first quarter of calendar year 2020 and top-line data for SPIRIT 1 expected in the second quarter of calendar year 2020.

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 in early calendar year 2020.

In addition, we filed an amendment to the Phase 3 HERO study protocol to enroll approximately 130 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.

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

General and Administrative Expenses

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

Results of Operations

The following table summarizes our results of operations for the three months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,	
	2019	2018
Operating expenses:		
Research and development	$ 51,117	$ 51,341
General and administrative	14,152	8,742
Total operating expenses	65,269	60,083
Interest expense	3,793	1,617
Interest income	(766)	—
Other (income) expense, net	(705)	289
Loss before income taxes	(67,591)	(61,989)
Income tax expense	313	145
Net loss	$ (67,904)	$ (62,134)

Research and Development Expenses

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

	Three Months Ended June 30,		
	2019	2018	Change
Program-specific costs:			
Relugolix	$ 39,106	$ 42,839	$ (3,733)
MVT-602	820	674	146
Unallocated costs:			
Share-based compensation	2,548	1,561	987
Personnel expense	7,279	4,781	2,498
Services Agreements	—	457	(457)
Other expense	1,364	1,029	335
Total R&D expenses	$ 51,117	$ 51,341	$ (224)

R&D expenses decreased by $0.2 million, to $51.1 million, in the three months ended June 30, 2019 compared to $51.3 million in the three months ended June 30, 2018. The composition of our R&D expenses in both periods is similar, and primarily includes expenses related to our Phase 3 clinical studies as well as personnel-related expenses for employees engaged in R&D activities. R&D expenses for the three months ended June 30, 2018 reflected a ramp up in relugolix Phase 3 study costs primarily related to study enrollment, whereas R&D expenses for the three months ended June 30, 2019 reflect lower 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 spending related to our preparations to seek regulatory approval for our product candidates.

R&D expenses were $51.1 million in the three months ended June 30, 2019, and consisted primarily of CRO, clinical drug supply and other study and manufacturing related costs of $40.5 million, personnel expenses of $7.3 million, and share-based compensation expense of $2.5 million.

R&D expenses were $51.3 million in the three months ended June 30, 2018, and consisted primarily of CRO, clinical drug supply and other study-related costs of $41.9 million, personnel expenses of $4.8 million, share-based compensation expense of $1.6 million, $0.1 million of which was allocated to us by RSL, and costs billed to us under the Services Agreements (see Note 6 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q) of $2.1 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 $5.4 million, to $14.2 million, in the three months ended June 30, 2019 compared to $8.7 million in the three months ended June 30, 2018, primarily due to an increase in personnel-related expenses, share-based compensation, professional service fees, 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 three months ended June 30, 2019 were $14.2 million, and consisted primarily of personnel-related and general overhead expenses of $8.2 million, share-based compensation expense of $3.9 million, legal and professional fees of $1.4 million, and rent and other facilities related costs of $0.5 million.

G&A expenses in the three months ended June 30, 2018 were $8.7 million, and consisted primarily of personnel-related and general overhead expenses of $4.0 million, share-based compensation expense of $2.7 million, including $0.1 million of which was allocated to us by RSL, legal and professional fees of $0.9 million, and costs of $1.1 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 June 30, 2019 and 2018, respectively. The increase was primarily the result of higher outstanding debt balances under our financing arrangements during the three months ended June 30, 2019 as compared to the prior year period.

Interest Income

Interest income was $0.8 million in the three months ended June 30, 2019. There was no interest income in the three months ended June 30, 2018. During the three months ended June 30, 2019, we invested a portion of our cash in a combination of money market funds and commercial paper. There were no such investments in the comparable prior year period.

Other (Income) Expense, net

Other (income) expense, 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 June 30, 2019, we recorded a foreign exchange gain of $0.7 million, and for the three months ended June 30, 2018, we recorded a foreign exchange loss of $0.3 million. These amounts are included in other (income) expense, net on the unaudited condensed consolidated statements of operations.

Income Tax Expense

Our income tax expense was $0.3 million and $0.1 million for the three months ended June 30, 2019 and 2018, respectively. Our effective tax rate for the three months ended June 30, 2019 and 2018 was (0.46)% and (0.23)%, 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 June 30, 2019, we had $226.7 million of cash and cash equivalents available to us, as compared to $156.1 million of cash and cash equivalents available to us as of March 31, 2019. As of June 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 June 30, 2019 and 2018, we had net losses of $67.9 million and $62.1 million, respectively. As of June 30, 2019, we had an accumulated deficit of $569.9 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 40 mg in combination with low-dose estradiol and a progestin for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis and relugolix 120 mg as a monotherapy for advanced prostate cancer;
- expand our chemistry, manufacturing, and control and other manufacturing related activities;
- seek to identify, acquire, develop, and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand, and protect our intellectual property portfolio;
- hire scientific, clinical, regulatory, quality, and administrative personnel;
- add operational, accounting, finance, quality, commercial, and management information systems and personnel;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a medical affairs group with a medical scientific liaison team;
- establish a sales, marketing, and distribution infrastructure and increase the scale of our external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- service debt obligations and payment of interest associated with the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement; and
- operate as a public company.

Our primary use of cash has been to fund the development of relugolix and MVT-602. We expect our operating expenses to continue to increase over the near term as we expand our operations to continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix. Based on our current operating plan, we expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of fiscal year 2019. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. These funds will not be sufficient to enable us to complete all necessary development activities and commercially launch relugolix. We anticipate that we will continue to incur net losses for the foreseeable future. To continue as a going concern, we will need, among other things, additional capital resources. We continually assess multiple options to obtain additional funding to support our operations, including through financing activities in public or private capital markets, financing arrangements with Roivant Sciences, potential business development activities and cost containment measures. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Although we believe that we will continue to raise capital to fund our operations as we have in the past, ASC 240-40, *Going Concern*, does not allow us to consider future financing activities that are not probable of being implemented in our assessment of our future cash burn for the purpose of our liquidity assessment. Due to these uncertainties, there is substantial doubt about our ability to continue as a going concern. If we are unable to raise capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back, or discontinue operations.

Until such time, if ever, as we can generate substantial product revenue from sales of relugolix, MVT-602, or any future product candidate, we expect to finance our operations through a combination of cash and cash equivalents on hand, equity offerings, debt financings, structured transactions such as royalty financings, collaboration, license or development agreements, or other collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our common shareholders' ownership interest may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common shareholders' rights. Our existing agreements with NovaQuest and Hercules involve, and any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

Cash Flows

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

	Three Months Ended June 30,	
	2019	2018
Net cash used in operating activities	$ (66,811)	$ (44,755)
Net cash used in investing activities	$ (139)	$ (197)
Net cash provided by financing activities	$ 137,610	$ 79,963

Operating Activities

For the three months ended June 30, 2019, we used $66.8 million in operating activities primarily due to our ongoing development and clinical trials for relugolix and MVT-602 and the expansion of our company. This was primarily attributable to a net loss for the period of $67.9 million and decreases of $7.6 million in accrued expenses resulting primarily from a decrease in accrued R&D expenses and accrued compensation-related expenses and $1.0 million in accounts payable due to the timing of vendor invoice payments. These amounts were partially offset by a $1.5 million decrease in prepaid expenses and other current assets, an increase of $1.5 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, $6.5 million of non-cash share-based compensation expense as a result of an increase in headcount, and $0.9 million of total depreciation and amortization expense.

For the three months ended June 30, 2018, we used $44.8 million in operating activities primarily due to our ongoing development and clinical trials for relugolix. This was primarily attributable to a net loss for the period of $62.1 million along with an increase of $0.6 million in prepaid expenses and other current assets. These amounts were partially offset by increases of $8.0 million in accrued expenses which was primarily due to the progress of our ongoing Phase 3 clinical trials of relugolix, $4.2 million of non-cash share-based compensation expense as a result of an increase in headcount, an increase of $3.2 million in amounts due to RSL, RSI and RSG, and $0.6 million of total depreciation and amortization expense.

Investing Activities

For the three months ended June 30, 2019 and 2018, $0.1 million and $0.2 million, respectively, was used in investing activities, all for the purchase of property and equipment.

Financing Activities

For the three months ended June 30, 2019, $137.6 million was provided by financing activities. This was primarily due to the net proceeds of $134.8 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 cash proceeds of $0.3 million from the exercise of stock options under our 2016 Equity Incentive Plan.

For the three months ended June 30, 2018, $80.0 million was provided by financing activities. This was primarily due to the net proceeds of $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.

Contractual Obligations

During the three months ended June 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.

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, and experience.

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 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 June 30, 2019 and March 31, 2019, we had cash and cash equivalents of $226.7 million and $156.1 million, respectively, consisting of commercial paper, money market funds, and non-interest-bearing cash deposits denominated in the U.S. dollar and Swiss franc.

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

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 three months ended June 30, 2019, we recorded a foreign exchange gain of $0.7 million, and for the three months ended June 30, 2018, we recorded a foreign exchange loss of $0.3 million. These amounts are included in other (income) expense, 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. Effective April 1, 2019, we adopted Accounting Standards Codification 842, *Leases* (Topic 842). As a result, we have made changes to certain internal controls over financial reporting to address risks associated with the lease accounting and disclosure requirements. This includes the enhancement of our lease evaluation processes and the implementation of controls to address risks associated with the calculation of right-of-use assets and corresponding lease liabilities. 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 June 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 and cash equivalents will be sufficient to fund our business only for a limited amount of time, and if we are not able to raise additional funds, we may be unable to continue as a going concern.

As of June 30, 2019, we had approximately $226.7 million of cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of fiscal year 2019. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. These funds will not be sufficient to enable us to complete all necessary development activities and commercially launch relugolix. We anticipate that we will continue to incur net losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period following the filing of this 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 financing, we may not be able to complete the development of, seek regulatory approval for, and commercialize relugolix or MVT-602.

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

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

Our current funds will not be sufficient for us to 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 on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, when needed, we may have to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or potentially discontinue operations. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current and anticipated product development programs.

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

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our operations through a combination of cash and cash equivalents on hand, equity offerings, debt financings, structured transactions such as royalty financings, collaboration or license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common shareholder. Our existing agreements with NovaQuest and Hercules involve, and any agreements for future debt or preferred equity financings, if available, may involve, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

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

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in February 2016, and our operations to date have been limited to identifying and in-licensing our product candidates, organizing and staffing our company, raising capital, preparing for and advancing 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. Our net loss was $67.9 million and $62.1 million for the three months ended June 30, 2019 and 2018, respectively, and, as of June 30, 2019, we had an accumulated deficit of $569.9 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, ORILISSA™ (elagolix), an oral GnRH receptor antagonist for the management of moderate to severe pain associated with endometriosis, has been approved as monotherapy (150 mg once a day or 200 mg twice a day) by the FDA and launched by AbbVie in August 2018. The launch and commercialization of ORILISSA™ or other competing drugs may limit the revenue from relugolix. If the indication 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 in combination with low-dose estradiol and a progestin for our women's health indications of uterine fibroids and endometriosis, relugolix monotherapy for men with advanced prostate cancer, and MVT-602, which are still under clinical development. If either relugolix or MVT-602 does not receive regulatory approval or is not successfully commercialized, our business will be harmed.

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

Obtaining approval of an NDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authority may delay, limit or deny approval of relugolix or MVT-602. See the Risk Factor titled "The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction which would limit our ability to realize our 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 one or both formulations of relugolix or MVT-602, our ability to generate revenues from relugolix or MVT-602 will depend on our ability to:

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

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

If we are unable to formulate a 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 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 will be required for FDA approval and these studies are ongoing. If we are unsuccessful in our attempts to formulate a single-tablet fixed-dose combination version of relugolix in time for the initial application for market authorization in the U.S., we expect to seek approval for relugolix tablets co-packaged with a commercially available tablet containing both the low-dose estradiol and norethindrone acetate. This would potentially decrease our advantages relative to our competition by requiring patients to take two pills once-daily instead of one pill once-daily until the fixed-dose combination can be developed and approved. If our competitors develop a fixed-dose combination with hormonal therapy before we do, or if we are unable to do so, then we would be at a competitive disadvantage and this could limit our commercial opportunity. We are not aware of any barriers preventing competitors from developing or achieving regulatory approval of a fixed-dose combination.

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. 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.

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

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

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

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

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

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

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

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

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

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

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

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, 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, as well as those of RSI and RSG, and our third-party collaborators, consultants or contractors, may fail or suffer cybersecurity breaches and data leakage, which could result in a material disruption of our business and operations or liabilities that adversely affect our financial performance.

Our computer systems, as well as those of RSI, RSG and our contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other contractors, consultants, and law and accounting firms, may sustain damage or data leakage from computer viruses, unauthorized access or disclosure, data breaches, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, and telecommunication and electrical failures. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our information systems or unauthorized persons, could cause interruptions in our operations and result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, 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 results of the United Kingdom's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

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

For example, Brexit could result in the U.K. or the EU significantly altering its regulations affecting the clearance or approval of our product candidates that are developed in the U.K. Brexit could also affect the clearance or timing of the release of our clinical trial materials into the U.K. or the EU. Any such delays could result in our clinical study sites having insufficient clinical trial materials and could adversely affect the timing and completion of our clinical trials. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the U.K., the EU and elsewhere. In addition, the announcement of Brexit and the withdrawal of the U.K. from the EU have had and may continue to have, particularly in the case of a hard Brexit, a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity and financial condition.

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

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the GDPR, which introduces strict requirements for processing personal data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, significant effort and expense are required to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR and guidance issued by different EU member states may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements. It is also possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Further, Brexit has created uncertainty with regard to data protection regulation in the 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 impact our business and results of operations.

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

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

The use of relugolix, 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 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.

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 or MVT-602. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical testing. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. In addition, the FDA may not agree that clinical trial results are sufficient for approval for any product candidate. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after 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 anticipated NDA submission to the FDA. We cannot provide assurance that the FDA will allow us to use the data from Takeda's clinical trials in support of any NDA that we may submit, and such data may be interpreted differently by the FDA and provide contradictory evidence in support of FDA's evaluation. If it does not, we may be required to perform additional clinical trials.

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

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

We are aware of several companies that are developing and commercializing drugs that would compete against relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, pain associated with endometriosis, and/or advanced prostate cancer and against MVT-602 for the treatment of female infertility as part of assisted reproduction. Many of our current and potential future competitors have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in 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;
- 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 other nontechnical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization. We are currently building our sales and marketing infrastructure; however, we currently do not have an established infrastructure for the sales, marketing, or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so.

We expect to build a focused sales, distribution, and marketing infrastructure to market our product candidates in the U.S., if approved. There are significant expenses and risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, generate sufficient sales, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and 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 firms. We cannot assure you that we will be able to establish or maintain such collaborative arrangements on terms favorable to us, or even if we are able to do so, that they will have effective sales forces. To the extent that we depend on third parties for sales, marketing and distribution, the financial returns to us will depend on our future collaborators' capabilities. If any such future collaborator terminates its collaboration with us or fails to perform or satisfy its obligations to us, the sales, marketing and distribution of our product candidates would be delayed or may not occur and our business and prospects could be materially and adversely affected.

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

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

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

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

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced or no protection over intellectual property rights;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing, and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations 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 recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. The tax legislation enacted on December 22, 2017, titled "an Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," or the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment on certain individuals who fail to maintain qualifying health coverage, commonly known as the individual mandate. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated under the ACA. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans. In 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 recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has already begun the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. 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, which we have not secured. 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 or co-packaged 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

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

Although our common shares are listed on the New York Stock Exchange, or NYSE, we cannot assure you that an active trading market for our common shares will continue to be sustained. In addition, as a result of a large proportion of our common shares being held by passive investors (for example, RSL beneficially owns approximately 45.5% of our outstanding common shares as of June 30, 2019), trading in our common shares has been less liquid than the shares of companies with broader public active institutional investor ownership. If an active market for our common shares is not sustained, your ability to trade our 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:

- any delay in the commencement, enrollment, and ultimate completion of our clinical trials;
- actual or anticipated results of clinical trials of relugolix, MVT-602 or those of our competitors;
- any delay in filing an NDA or similar application for relugolix or MVT-602 and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that NDA or similar application, as the case may be;
- failure to successfully develop and commercialize relugolix, MVT-602 or any future product candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to relugolix, MVT-602, or any future product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for relugolix in combination with low-dose estradiol and a progestin, relugolix monotherapy, MVT-602 or any future product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to maintain effective internal control over financial reporting;
- failure to meet or exceed the estimates and projections of the 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.

RSL beneficially owns approximately 45.5% of our outstanding common shares as of June 30, 2019 and has the right to appoint a majority of the directors constituting our board of directors. As a result, we are 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.

Based on our common shares outstanding as of June 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.

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

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and minority holders of our common shares, on the one hand, and RSL and its shareholders, on the other hand. Certain of our directors and employees have equity interests in RSL and, accordingly, their interests may be aligned with RSL’s interests, which may not always coincide with our corporate interests or the interests of our other shareholders. Further, our other shareholders may not have visibility into the 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, RSI, and RSG. These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the minority holders of our common shares. For example, we are party to an option agreement with RSL pursuant to which RSL granted to us an option to acquire the rights to products to which RSL or any nonpublic affiliate of RSL acquires the rights (other than a relugolix product or a competing product) for uterine fibroids or endometriosis, or for which the primary target indication is advanced prostate cancer. It is possible that we could fail to exercise our option with respect to a product candidate under this agreement and that product candidate is then successfully developed and commercialized by RSL or one of its other subsidiaries or affiliates. Any material transaction between us and RSL, RSI, or RSG is subject to our related party transaction policy, which requires prior approval of such transaction by our Audit Committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to conduct business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

If securities or industry analysts cease to publish research or reports about our business, or publish negative reports about our business, our 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, including RSL and Takeda, or any of our executive officers or directors were to sell a substantial portion of our common shares, or if the market perceived that RSL, Takeda or any of our executive officers or directors intends to sell our common shares, it could negatively affect our common share price.

We have filed a registration statement on Form S-8 under the Securities Act to register the common shares that may be issued under our equity incentive plan. In addition, 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 June 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 and RSL, our controlling shareholder, 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 us, RSL, our controlling shareholder, and our subsidiaries. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws, regulations, principles, and interpretations. 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. Our status may also depend, in part, on how quickly we utilize the cash proceeds from our IPO and subsequent financings in our business. With respect to the taxable year that ended on March 31, 2019, we believe that we were not a PFIC; however, with respect to the 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.				
10.1	Amendment No.1 to Information Sharing and Cooperation Agreement, dated as of May 24, 2019, by and between Roivant Sciences Ltd. and the Registrant.	10-K	001-37929	10.7	05/24/2019
31.1†	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1††**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2††**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	XBRL Taxonomy Extension Schema				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase				
101.DEF	XBRL Taxonomy Extension Definition Linkbase				
101.LAB	XBRL Taxonomy Extension Label Linkbase				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase				
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: August 6, 2019

Exhibit 3.3

FOURTH AMENDED AND RESTATED BYE-LAWS OF

MYOVANT SCIENCES LTD.

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INTERPRETATION

1. Definitions

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

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

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

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

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

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

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

(d) the words:

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

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

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

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

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

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

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

SHARES

2. Power to Issue Shares

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

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

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

3. Power of the Company to Purchase its Shares

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

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

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

4. Rights Attaching to Shares

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

(a) be entitled to one vote per share;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Calls on Shares

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

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

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

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

6. Forfeiture of Shares

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

Notice of Liability to Forfeiture for Non-Payment of Call

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

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

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

_____

[Signature of Secretary] By Order of the Board

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

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

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

7. Share Certificates

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

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

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

7.4 Notwithstanding any provisions of these Bye-laws:

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

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

8. Fractional Shares

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

REGISTRATION OF SHARES

9. Register of Members

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

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

10. Registered Holder Absolute Owner

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

11. Transfer of Registered Shares

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

Transfer of a Share or Shares

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

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

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

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

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

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

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

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

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

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

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

12 Transmission of Registered Shares

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

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

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

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

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

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

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

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

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

ALTERATION OF SHARE CAPITAL

13. Power to Alter Capital

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

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

14. Variation of Rights Attaching to Shares

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

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

DIVIDENDS AND CAPITALISATION

15. Dividends

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

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

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

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

16. Power to Set Aside Profits

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

17. Method of Payment

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

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

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

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

18. Capitalisation

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

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

MEETINGS OF MEMBERS

19. Annual General Meetings

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

20. Special General Meetings

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

21. Requisitioned Special General Meetings

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

22. Notice

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

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

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

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

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

23. Giving Notice and Access

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

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

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

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

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

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

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

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

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

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

24. Notice of Nominations and Member Business

24.1 Annual General Meetings

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

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

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

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

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

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

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

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

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

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

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

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

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

24.2 Special General Meetings

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

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

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

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

24.3 General

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

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

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

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

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

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

25. Postponement or Cancellation of General Meeting

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

26. Electronic Participation and Security at General Meetings

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

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

27. Quorum at General Meetings

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

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

28. Chairman to Preside at General Meetings

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

29. Voting on Resolutions

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

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

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

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

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

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

30. Power to Demand a Vote on a Poll

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

(a) the chairman of such meeting; or

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

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

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

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

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

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

31. Voting by Joint Holders of Shares

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

32. Votes of Members – General

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

33. Instrument of Proxy

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

Proxy

Myovant

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

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

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

_____

Member(s)

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

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

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

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

34. Representation of Corporate Member

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

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

35. Adjournment of General Meeting

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

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

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

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

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

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

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

36. Written Resolutions

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

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

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

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

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

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

36.7 This Bye-law 36 shall not apply to:

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

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

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

37. Directors Attendance at General Meetings

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

DIRECTORS AND OFFICERS

38. Number, Election and Term of Directors

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

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

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

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

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

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

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

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

39. Alternate Directors

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

39.2 Any person so elected or appointed pursuant to this Bye-law 39 shall have all the rights and powers of the Director or Directors for whom such person is elected or appointed in the alternative provided that such person shall not be counted more than once in determining whether or not a quorum is present.

39.3 An Alternate Director shall be entitled to receive notice of all meetings of the Board and to attend and vote at any such meeting at which a Director for whom such Alternate Director was appointed in the alternative is not personally present and generally to perform at such meeting all the functions of such Director for whom such Alternate Director was appointed.

39.4 An Alternate Director's office shall terminate:

(a) on the occurrence in relation to the Alternate Director of any event which, if it occurred in relation to his appointor, would result in the termination of the appointor's directorship; or

(b) when the Alternate Director's appointor revokes the appointment by notice to the Company in writing specifying when the appointment is to terminate; or

(c) if the Alternate Director's appointor ceases for any reason to be a Director.

40. Removal of Directors for Cause

40.1 Subject to subsections (a) through (c) of Bye-law 41.1:

(a) During the Trigger Period, (i) any Roivant Directors may be removed, with or without cause, only by Roivant, by duly executed notice to the Secretary, which is effective upon the delivery by Roivant to the Secretary, without the requirement for any further vote or approval by the Members or the Board, and (ii) Roivant shall promptly remove any Roivant Director who has engaged in conduct constituting cause for removal;

(b) During the Trigger Period, subject to any provision to the contrary in these Bye-laws, and in addition to the right of Members pursuant to Bye-laws 21, 24.2 and 38 to requisition the Board to convene a special general meeting for purposes of ending the term of the then-current Directors (other than Roivant Directors) and replacing them with new Directors, the Members holding a majority of the issued and outstanding shares of the Company may also, at any special general meeting convened and held in accordance with these Bye-laws, by the affirmative vote of all such Members, remove a Director (other than a Roivant Director) for cause, provided that the notice of any such meeting convened for the purpose of removing a Director shall contain a statement of the intention so to do and be served on such Director not less than 14 days before the meeting and at such meeting the Director shall be entitled to be heard on the motion for such Director's removal; and

(c) Outside of the Trigger Period, subject to any provision to the contrary in these Bye-laws, and in addition to the right of Members pursuant to Bye-laws 21, 24.2 and 38 to requisition the Board to convene a special general meeting for purposes of ending the term of the then-current Directors and replacing them with new Directors, the Members holding a majority of the issued and outstanding shares of the Company may also, at any special general meeting convened and held in accordance with these Bye-laws, by the affirmative vote of all such Members, remove a Director for cause, provided that the notice of any such meeting convened for the purpose of removing a Director shall contain a statement of the intention so to do and be served on such Director not less than 14 days before the meeting and at such meeting the Director shall be entitled to be heard on the motion for such Director's removal.

40.2 If a Roivant Director is removed from the Board under subsection (a) of Bye-law 40.1, Roivant may fill the vacancy by duly executed notice to the Secretary, which is effective upon the delivery by Roivant to the Secretary, without the requirement for any further vote or approval by the Members or the Board.

40.3 If a Director (other than, during the Trigger Period, a Roivant Director) is removed from the Board under subsections (b) or (c) of Bye-law 40.1, the Members may fill the vacancy at the meeting at which such Director is removed and a Director so appointed shall hold office until the earliest of (i) the next annual general meeting, (ii) the date such Director's term of office is ended pursuant to Bye-law 38 and (iii) the date such Director's office is otherwise vacated pursuant to Bye-law 41. In the absence of such election or appointment, the Board may fill the vacancy.

40.4 For the purpose of Bye-law 40.1, "cause" shall mean a conviction for a criminal offence involving dishonesty or engaging in conduct which brings the Director or the Company into disrepute and which results in material financial detriment to the Company.

41. Vacancy in the Office of Director

41.1 The office of Director shall be vacated immediately if the Director:

(a) is removed from office pursuant to these Bye-laws or is prohibited from being a Director by law;

(b) is or becomes bankrupt, or makes any arrangement or composition with his creditors generally;

(c) is or becomes of unsound mind or dies;

(d) resigns his office by notice to the Company (unless such other later date is agreed by the Board); or

(e) is not re-elected at an annual general meeting, or at a special general meeting called for the purpose of replacing them with a newly elected Director.

41.2 During the Trigger Period, only Roivant or a majority of the remaining Roivant Directors (pursuant to the procedures set forth in Bye-law 38) shall have the power to appoint any person as a Roivant Director to fill a vacancy on the Board occurring as a result of the death, disability, disqualification, removal or resignation of any Roivant Director prior to the expiration of his or her term. A Roivant Director appointed by a majority of the remaining Roivant Directors to fill a vacancy shall hold office until the earlier of (i) the next annual general meeting or (ii) the date such Roivant Director's office is otherwise vacated.

41.3 At any time, the Members in general meeting or the Board shall have the power to appoint any person as a Director to fill a vacancy on the Board occurring as a result of the death, disability, disqualification or resignation of any Director (other than, during the Trigger Period, a Roivant Director) or as a result of an increase in the size of the Board (other than an automatic increase in the size of the Board to permit the appointment of additional Roivant Directors pursuant to Bye-law 38.3(a)). During the Trigger Period, the power of the Board set forth in this Bye-law 41.3 shall reside in and be exercised by the Directors who are not Roivant Directors.

42. Remuneration of Directors

The remuneration (if any) of the Directors shall be determined by the Board or a committee thereof and shall be deemed to accrue from day to day. The Directors may also be paid all travel, hotel and other expenses properly incurred by them in attending and returning from the meetings of the Board, any committee appointed by the Board, general meetings, or in connection with the business of the Company or their duties as Directors generally.

43. Defect in Appointment

All acts done in good faith by the Board, any Director, a member of a committee appointed by the Board, any person to whom the Board may have delegated any of its powers shall, or any person acting as a Director shall, notwithstanding that it be afterwards discovered that there was some defect in the appointment of any Director or person acting as aforesaid, or that he was, or any of them were, disqualified, be as valid as if every such person had been duly appointed and was qualified to be a Director or act in the relevant capacity.

44. Directors to Manage Business

The business of the Company shall be managed and conducted by the Board. In managing the business of the Company, the Board may exercise all such powers of the Company as are not, by the Act or by these Bye-laws, required to be exercised by the Company in general meeting.

45. Powers of the Board of Directors

The Board may:

(a) appoint, suspend, or remove any manager, secretary, clerk, agent or employee of the Company and may fix their remuneration and determine their duties;

(b) exercise all the powers of the Company to borrow money and to mortgage or charge or otherwise grant a security interest in its undertaking, property and uncalled capital, or any part thereof, and may issue debentures, debenture stock and other securities whether outright or as security for any debt, liability or obligation of the Company or any third party;

(c) appoint one or more Directors to the office of managing director or Principal Executive Officer of the Company, who shall, subject to the control of the Board, supervise and administer all of the general business and affairs of the Company;

(d) appoint a person to act as manager of the Company's day-to-day business and may entrust to and confer upon such manager such powers and duties as it deems appropriate for the transaction or conduct of such business;

(e) by power of attorney, appoint any company, firm, person or body of persons, whether nominated directly or indirectly by the Board, to be an attorney of the Company for such purposes and with such powers, authorities and discretions (not exceeding those vested in or exercisable by the Board) and for such period and subject to such conditions as it may think fit and any such power of attorney may contain such provisions for the protection and convenience of persons dealing with any such attorney as the Board may think fit and may also authorise any such attorney to sub-delegate all or any of the powers, authorities and discretions so vested in the attorney;

(f) procure that the Company pays all expenses incurred in promoting and incorporating the Company and listing the shares of the Company;

(g) delegate any of its powers (including the power to sub-delegate) to a committee of one or more persons appointed by the Board which may consist partly or entirely of non-Directors, provided that every such committee shall conform to such directions as the Board shall impose on them and provided further that (i) the meetings and proceedings of any such committee shall be governed by these Bye-laws regulating the meetings and proceedings of the Board, so far as the same are applicable and are not superseded by directions imposed by the Board; and (ii) each of the Audit Committee, the Nominating and Corporate Governance Committee and the Compensation Committee shall be made up solely of Independent Directors;

(h) delegate any of its powers (including the power to sub-delegate) to any person on such terms and in such manner as the Board may see fit;

(i) present any petition and make any application in connection with the liquidation or reorganisation of the Company;

(j) in connection with the issue of any share, pay such commission and brokerage as may be permitted by law; and

(k) authorise any company, firm, person or body of persons to act on behalf of the Company for any specific purpose and in connection therewith to execute any deed, agreement, document or instrument on behalf of the Company.

46. Register of Directors and Officers

The Board shall cause to be kept in one or more books at the registered office of the Company a Register of Directors and Officers and shall enter therein the particulars required by the Act.

47. Appointment of Officers

The Board may appoint such officers (who may or may not be Directors) as the Board may determine for such terms as the Board deems fit.

48. Appointment of Secretary

The Secretary shall be appointed by the Board from time to time for such terms as the Board deems fit.

49. Duties of Officers

The Officers shall have such powers and perform such duties in the management, business and affairs of the Company as may be delegated to them by the Board from time to time.

50. Remuneration of Officers

The Officers shall receive such remuneration as the Board may determine.

51. Conflicts of Interest

51.1 Any Director, or any Director's firm, partner or any company with whom any Director is associated, may act in any capacity for, be employed by or render services to the Company and such Director or such Director's firm, partner or company shall be entitled to remuneration as if such Director were not a Director. Nothing herein contained shall authorise a Director or Director's firm, partner or company to act as Auditor to the Company.

51.2 If a Director or an immediate family member of a Director is directly or indirectly interested in a contract or proposed contract or arrangement with the Company such Director shall declare the nature of such interest as required by the Act.

51.3 Following a declaration being made pursuant to this Bye-law, a Director may not vote in respect of a contract or proposed contract or arrangement in which such Director is interested, and may not be counted in the quorum for such meeting, unless the chairman of the relevant Board meeting determines that such Director is not disqualified from voting. For the avoidance of doubt, no Director or immediate family member shall be considered "interested" with respect to any transaction in which all of the Members participate or are offered to participate. The chairman of a Board meeting may require a Director to leave the meeting to enable the Board to discuss and/or vote on a matter in which the chairman considers the Director or an immediate family member of the Director to be interested. If a majority in number of the Directors in attendance at a Board meeting considers the chairman of the meeting or an immediate family member of the chairman to be interested in a particular matter, they may require the chairman to leave the meeting to enable the Board to discuss and/or vote on such matter.

For the purpose of this Bye-law 51, "immediate family member" means, in relation to a Director, his child, step-child, parent, step-parent, spouse, civil partner, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law or any person (other than a tenant or employee) sharing the household of the Director.

52. Indemnification and Exculpation of Directors and Officers

52.1 The Directors, Resident Representative, Secretary and other Officers (such term to include any person appointed to any committee by the Board) acting in relation to any of the affairs of the Company or any subsidiary thereof and the liquidator or trustees (if any) acting in relation to any of the affairs of the Company or any subsidiary thereof and every one of them (whether for the time being or formerly), and their heirs, executors and administrators (each of which an "indemnified party"), shall be indemnified and secured harmless out of the assets of the Company from and against all actions, costs, charges, losses, damages and expenses which they or any of them, their heirs, executors or administrators, shall or may incur or sustain by or by reason of any act done, concurred in or omitted in or about the execution of their duty, or supposed duty, or in their respective offices or trusts, and no indemnified party shall be answerable for the acts, receipts, neglects or defaults of the others of them or for joining in any receipts for the sake of conformity, or for any bankers or other persons with whom any moneys or effects belonging to the Company shall or may be lodged or deposited for safe custody, or for insufficiency or deficiency of any security upon which any moneys of or belonging to the Company shall be placed out on or invested, or for any other loss, misfortune or damage which may happen in the execution of their respective offices or trusts, or in relation thereto, provided that this indemnity shall not extend to any matter in respect of any fraud or dishonesty to the extent prohibited by the Act in relation to the Company which may attach to any of the indemnified parties. Each Member agrees to waive any claim or right of action such Member might have, whether individually or by or in the right of the Company, against any Director or Officer on account of any action taken by such Director or Officer, or the failure of such Director or Officer to take any action in the performance of his duties with or for the Company or any subsidiary thereof, provided that such waiver shall not extend to any matter in respect of any fraud or dishonesty in relation to the Company which may attach to such Director or Officer.

52.2 The Company may purchase and maintain insurance for the benefit of any Director or Officer against any liability incurred by him under the Act in his capacity as a Director or Officer or indemnifying such Director or Officer in respect of any loss arising or liability attaching to him by virtue of any rule of law in respect of any negligence, default, breach of duty or breach of trust of which the Director or Officer may be guilty in relation to the Company or any subsidiary thereof.

52.3 The Company may advance moneys to a Director or Officer for the costs, charges and expenses incurred by the Director or Officer in defending any civil or criminal proceedings against him, on condition that the Director or Officer shall repay the advance if any allegation of fraud or dishonesty in relation to the Company is proved against him.

52.4 No amendment or repeal of any provision of this Bye-law 52 shall alter, to the detriment of any person, the right of such person to the indemnification or advancement of expenses related to a claim based on an act or failure to act which took place prior to such amendments.

MEETINGS OF THE BOARD OF DIRECTORS

53. Board Meetings

The Board may meet for the transaction of business, adjourn, and otherwise regulate its meetings as it sees fit. A resolution put to the vote at a meeting of the Board shall be carried by the affirmative votes of a majority of the votes cast and in the case of an equality of votes the resolution shall fail.

54. Notice of Board Meetings

The chairman (if any) or the Principal Executive Officer or a majority of the Directors then in office may, and the Secretary on the requisition of a Director shall, at any time summon a meeting of the Board. Notice of a meeting of the Board shall be deemed to be duly given to a Director if it is given to such Director verbally (including in person or by telephone) or otherwise communicated or sent to such Director by post, electronic

means or other mode of representing words in a visible form at such Director's last known address or in accordance with any other instructions given by such Director to the Company for this purpose at least 48 hours prior to such Board meeting, unless each Director attends or gives his prior written consent to the meeting being held on such shorter notice.

55. Electronic Participation in Meetings

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

56. Quorum at Board Meetings

The quorum necessary for the transaction of business at a meeting of the Board shall be a majority of the Directors then in office.

57. Board to Continue in the Event of Vacancy

The Board may act notwithstanding any vacancy in its number but, if and so long as its number is reduced below the number fixed by these Bye-laws as the quorum necessary for the transaction of business at meetings of the Board, the continuing Directors or Director may act for the purpose of (i) summoning a general meeting; or (ii) preserving the assets of the Company.

58. Chairman to Preside

Unless otherwise agreed by a majority of the Directors attending, the Chairman, if there be one, shall act as chairman at all meetings of the Board at which such person is present. In his absence a chairman shall be appointed or elected by the Directors present at the meeting.

59. Written Resolutions

59.1 Subject to these Bye-laws, anything which may be done by resolution of the Board at a meeting duly called and constituted may be done without a meeting by unanimous written resolution in accordance with this Bye-law 59.

59.2 A resolution signed by all the Directors, which may be in counterparts, shall be as valid as if it had been passed at a meeting of the Board duly called and constituted, such resolution to be effective on the date on which the last Director signs the resolution, provided, that (i) any such resolution shall be valid only if the signature of the last Director to sign is affixed outside the United States (unless the Board dispenses with this requirement), and (i) the Board may declare such resolution to be invalid if the Board determines that the use of a resolution in writing would result in a non-de minimis adverse tax, regulatory or legal consequence to the Company, any subsidiary of the Company, or any direct or indirect holder of shares or its affiliates. For the purposes of this Bye-law only, "the Directors" shall not include an Alternate Director.

59.3 A resolution in writing made in accordance with this Bye-law 59 shall constitute minutes for the purposes of the Act.

60. Validity of Prior Acts of the Board

No regulation or alteration to these Bye-laws made by the Company in general meeting shall invalidate any prior act of the Board which would have been valid if that regulation or alteration had not been made.

CORPORATE RECORDS

61. Minutes

The Board shall cause minutes to be duly entered in books provided for the purpose:

(a) of all elections and appointments of Officers;

(b) of the names of the Directors present at each meeting of the Board and of any committee appointed by the Board; and

(c) of all resolutions and proceedings of general meetings of the Members, meetings of the Board, and meetings of committees appointed by the Board.

62. Place Where Corporate Records Kept

Minutes prepared in accordance with the Act and these Bye-laws shall be kept by the Secretary at the registered office of the Company.

63. Form and Use of Seal

63.1 The Company may adopt a seal in such form as the Board may determine. The Board may adopt one or more duplicate seals for use in or outside Bermuda.

63.2 A seal may, but need not be affixed to any deed, instrument, share certificate or document, and if the seal is to be affixed thereto, it shall be attested by the signature of (i) any Director; or (ii) any Officer; or (iii) the Secretary; or (iv) any person authorized by the Board for that purpose.

63.3 A Resident Representative may, but need not, affix the seal of the Company to certify the authenticity of any copies of documents.

ACCOUNTS

64. Books of Account

64.1 The Board shall cause to be kept proper records of account with respect to all transactions of the Company and in particular with respect to:

(a) all sums of money received and expended by the Company and the matters in respect of which the receipt and expenditure relates;

(b) all sales and purchases of goods by the Company; and

(c) all assets and liabilities of the Company.

64.2 Such records of account shall be kept at the registered office of the Company, or subject to the Act, at such other place as the Board thinks fit and shall be available for inspection by the Directors during normal business hours.

65. Financial Year End

The financial year end of the Company may be determined by resolution of the Board and failing such resolution shall be 31st March in each year.

AUDITS

66. Annual Audit

Subject to any rights to waive laying of accounts or appointment of an Auditor pursuant to the Act, the accounts of the Company shall be audited at least once in every year.

67. Appointment of Auditor

67.1 Subject to the Act, the Members shall appoint an auditor to the Company to hold office for such term as the Members deem fit until a successor is appointed.

67.2 The Auditor may be a Member but no Director, Officer or employee of the Company shall, during his continuance in office, be eligible to act as an Auditor of the Company.

68. Remuneration of Auditor

The remuneration of the Auditor shall be fixed by the Company in general meeting or in such manner as the Members may determine. In the case of an Auditor appointed pursuant to Bye-law 67, the remuneration of the Auditor shall be fixed by the Board.

69. Duties of Auditor

69.1 The financial statements provided for by these Bye-laws shall be audited by the Auditor in accordance with generally accepted auditing standards. The Auditor shall make a written report thereon in accordance with generally accepted auditing standards.

69.2 The generally accepted auditing standards referred to in this Bye-law may be those of a country or jurisdiction other than Bermuda or such other generally accepted auditing standards as may be provided for in the Act. If so, the financial statements and the report of the Auditor shall identify the generally accepted auditing standards used.

70. Access to Records

The Auditor shall at all reasonable times have access to all books kept by the Company and to all accounts and vouchers relating thereto, and the Auditor may call on the Directors or Officers of the Company for any information in their possession relating to the books or affairs of the Company.

71. Financial Statements

Subject to any rights to waive laying of accounts pursuant to the Act, financial statements as required by the Act shall be laid before the Members in general meeting. A resolution in writing made in accordance with Bye-law 36 receiving, accepting, adopting, approving or otherwise acknowledging financial statements shall be deemed to be the laying of such statements before the Members in general meeting.

72. Distribution of Auditor's report

The report of the Auditor shall be submitted to the Members in general meeting.

73. Vacancy in the Office of Auditor

If the office of Auditor becomes vacant by the resignation or death or the Auditor, or by the Auditor becoming incapable of acting by reason of illness or other disability at a time when the Auditor's services are required, the vacancy thereby created shall be filled in accordance with the Act.

BUSINESS COMBINATIONS

74. Business Combinations

74.1 (a) Any Business Combination with any Interested Shareholder within a period of three years following the time of the transaction in which the person become an Interested Shareholder must be approved by the Board and authorised at an annual or special general meeting, by the affirmative vote of at least 66 and 2/3% of the issued and outstanding voting shares of the Company that are not owned by the Interested Shareholder unless:

(i) prior to the time that the person became an Interested Shareholder, the Board approved either the Business Combination or the transaction which resulted in the person becoming an Interested Shareholder; or

(ii) upon consummation of the transaction which resulted in the person becoming an Interested Shareholder, the Interested Shareholder owned at least 85% of the number of issued and outstanding voting shares of the Company at the time the transaction commenced, excluding for the purposes of determining the number of shares issued and outstanding those shares owned (i) by persons who are Directors and also officers and (ii) employee share plans in which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer.

(b) The restrictions contained in this Bye-law 74.1 shall not apply if:

(i) a Member becomes an Interested Shareholder inadvertently and (i) as soon as practicable divests itself of ownership of sufficient shares so that the Member ceases to be an Interested Shareholder; and (ii) would not, at any time within the three-year period immediately prior to a Business Combination between the Company and such Member, have been an Interested Shareholder but for the inadvertent acquisition of ownership; or

(ii) the Business Combination is proposed prior to the consummation or abandonment of, and subsequent to the earlier of the public announcement or the notice required hereunder of, a proposed transaction which (i) constitutes one of the transactions described in the following sentence; (ii) is with or by a person who either was not an Interested Shareholder during the previous three years or who became an Interested Shareholder with the approval of the Board; and (iii) is approved or not opposed by a majority of the members of the Board then in office who were Directors prior to any person becoming an Interested Shareholder during the previous three years or were recommended for election or elected to succeed such Directors by resolution of the Board approved by a majority of such Directors. The proposed transactions referred to in the preceding sentence are limited to:

(a) a merger, amalgamation or consolidation of the Company (except an amalgamation or merger in respect of which, pursuant to the Act, no vote of the shareholders of the Company is required);

(b) a sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions), whether as part of a dissolution or otherwise, of assets of the Company or of any entity directly or indirectly wholly-owned or majority-owned by the Company (other than to the Company or any entity directly or indirectly wholly-owned by the Company) having an aggregate market value equal to 50% or more of either the aggregate market value of all of the assets of the Company determined

on a consolidated basis or the aggregate market value of all the issued and outstanding shares of the Company; or

(c) a proposed tender or exchange offer for 50% or more of the issued and outstanding voting shares of the Company.

The Company shall give not less than 20 days notice to all Interested Shareholders prior to the consummation of any of the transactions described in subparagraphs (a) or (b) of the second sentence of this paragraph (ii).

(c) For the purpose of this Bye-law 74 only, the term:

(i) "affiliate" means a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, another person;

(ii) "associate," when used to indicate a relationship with any person, means: (i) any company, partnership, unincorporated association or other entity of which such person is a director, officer or partner or is, directly or indirectly, the owner of 20% or more of any class of voting shares; (ii) any trust or other estate in which such person has at least a 20% beneficial interest or as to which such person serves as trustee or in a similar fiduciary capacity; and (iii) any relative or spouse of such person, or any relative of such spouse, who has the same residence as such person;

(iii) "Business Combination," when used in reference to the Company and any Interested Shareholder of the Company, means:

(a) any merger, amalgamation or consolidation of the Company or any entity directly or indirectly wholly-owned or majority-owned by the Company, wherever incorporated, with (A) the Interested Shareholder or any of its affiliates, or (B) with any other company, partnership, unincorporated association or other entity if the merger, amalgamation or consolidation is caused by the Interested Shareholder;

(b) any sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions), except proportionately as a shareholder of the Company, to or with the Interested Shareholder, whether as part of a dissolution or otherwise, of assets of the Company or of any entity directly or indirectly wholly-owned or majority-owned by the Company which assets have an aggregate market value equal to 10% or more of either the aggregate market value of all the assets of the Company determined on a consolidated basis or the aggregate market value of all the issued and outstanding shares of the Company;

(c) any transaction which results in the issuance or transfer by the Company or by any entity directly or indirectly wholly-owned or majority-owned by the Company of any shares of the Company, or any share of such entity, to the Interested Shareholder, except: (A) pursuant to the exercise, exchange or conversion of securities exercisable for, exchangeable for or convertible into shares of the Company, or shares of any such entity, which securities were issued and outstanding prior to the time that the Interested Shareholder became such; (B) pursuant to a dividend or distribution paid or made, or the exercise, exchange or conversion of securities exercisable for, exchangeable for or convertible into shares of the Company, or shares of any such entity, which security is distributed, pro rata to all holders of a class or series of

shares subsequent to the time the Interested Shareholder became such; (C) pursuant to an exchange offer by the Company to purchase shares made on the same terms to all holders of such shares; or (D) any issuance or transfer of shares by the Company; provided however, that in no case under items (B) -(D) of this subparagraph shall there be an increase in the Interested Shareholder's proportionate share of any class or series of shares;

(d) any transaction involving the Company or any entity directly or indirectly wholly-owned or majority-owned by the Company which has the effect, directly or indirectly, of increasing the proportionate share of any class or series of shares, or securities convertible into any class or series of shares of the Company, or shares of any such entity, or securities convertible into such shares, which is owned by the Interested Shareholder, except as a result of immaterial changes due to fractional share adjustments or as a result of any repurchase or redemption of any shares not caused, directly or indirectly, by the Interested Shareholder; or

(e) any receipt by the Interested Shareholder of the benefit, directly or indirectly (except proportionately as a shareholder of the Company), of any loans, advances, guarantees, pledges or other financial benefits (other than those expressly permitted in subparagraphs (a)-(d) of this paragraph) provided by or through the Company or any entity directly or indirectly wholly-owned or majority-owned by the Company;

(iv) "control," including the terms "controlling," "controlled by" and "under common control with," means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting shares, by contract or otherwise. A person who is the owner of 20% or more of the issued and outstanding voting shares of any company, partnership, unincorporated association or other entity shall be presumed to have control of such entity, in the absence of proof by a preponderance of the evidence to the contrary; provided that notwithstanding the foregoing, such presumption of control shall not apply where such person holds voting shares, in good faith and not for the purpose of circumventing this provision, as an agent, bank, broker, nominee, custodian or trustee for one or more owners who do not individually or as a group have control of such entity;

(v) "Interested Shareholder" means any person (other than the Company and any entity directly or indirectly wholly-owned or majority-owned by the Company) that (i) is the owner of 15% or more of the issued and outstanding voting shares of the Company, (ii) is an affiliate or associate of the Company and was the owner of 15% or more of the issued and outstanding voting shares of the Company at any time within the three year period immediately prior to the date on which it is sought to be determined whether such person is an Interested Shareholder or (iii) is an affiliate or associate of any person listed in (i) or (ii) above; provided, however, that the term "Interested Shareholder" shall not include any person whose ownership of shares in excess of the 15% limitation set forth herein is the result of action taken solely by the Company unless such person referred to in this proviso acquires additional voting shares of the Company otherwise than as a result of further corporate action not caused, directly or indirectly, by such person. For the purpose of determining whether a person is an Interested Shareholder, the voting shares of the Company deemed to be issued and outstanding shall include voting shares deemed to be owned by the person through application of paragraph (viii) below, but shall not include any other unissued shares which may be issuable pursuant to any agreement,

arrangement or understanding, or upon exercise of conversion rights, warrants or options, or otherwise;

(vi) "person" means any individual, company, partnership, unincorporated association or other entity;

(vii) "voting shares" means, with respect to any company, shares of any class or series entitled to vote generally in the election of Directors and, with respect to any entity that is not a company, any equity interest entitled to vote generally in the election of the governing body of such entity;

(viii) "owner," including the terms "own" and "owned," when used with respect to any shares, means a person that individually or with or through any of its affiliates or associates:

(a) beneficially owns such shares, directly or indirectly; or

(b) has (A) the right to acquire such shares (whether such right is exercisable immediately or only after the passage of time) pursuant to any agreement, arrangement or understanding, or upon the exercise of conversion rights, exchange rights, warrants or options, or otherwise; provided, however, that a person shall not be deemed the owner of shares tendered pursuant to a tender or exchange offer made by such person or any of such person's affiliates or associates until such tendered shares are accepted for purchase or exchange; or (B) the right to vote such shares pursuant to any agreement, arrangement or understanding; provided, however, that a person shall not be deemed the owner of any shares because of such person's right to vote such shares if the agreement, arrangement or understanding to vote such shares arises solely from a revocable proxy or consent given in response to a proxy or consent solicitation made to 10 or more persons; or

(c) has any agreement, arrangement or understanding for the purpose of acquiring, holding, voting (except voting pursuant to a revocable proxy or consent as described in item (B) of subparagraph (b) of this paragraph), or disposing of such shares with any other person that beneficially owns, or whose affiliates or associates beneficially own, directly or indirectly, such shares.

74.2 In respect of any Business Combination to which the restrictions contained in Bye-law 74.1 do not apply but which the Act requires to be approved by the Members, the necessary general meeting quorum and Members' approval shall be as set out in Bye-laws 27 and 29 respectively.

74.3 The Board shall ensure that the bye-laws or constitutional documents of each entity wholly-owned or majority-owned by the Company shall contain any provisions necessary to ensure that the intent of Bye-law 74.1, as it relates to the actions of such entities, is achieved.

VOLUNTARY WINDING-UP AND DISSOLUTION

75. Winding-Up

If the Company shall be wound up the liquidator may, with the sanction of a resolution of the Members, divide amongst the Members in specie or in kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and may, for such purpose, set such value as he deems fair upon any property to be divided as aforesaid and may determine how such division shall be carried out as

between the Members or different classes of Members. The liquidator may, with the like sanction, vest the whole or any part of such assets in the trustees upon such trusts for the benefit of the Members as the liquidator shall think fit, but so that no Member shall be compelled to accept any shares or other securities or assets whereon there is any liability.

CHANGES TO CONSTITUTION

76. Changes to Bye-laws

76.1 Prior to the Trigger Date, Bye-laws 24, 38, 39, 40, 41, this Bye-law 76, and the Roivant rights contained therein, may not be rescinded, altered or amended without the affirmative vote of at least 66 and 2/3% of the issued and outstanding voting shares of the Company.

76.2 Subject to Bye-law 76.1, no Bye-law may be rescinded, altered or amended and no new Bye-law may be made save in accordance with the Act and until the same has been approved by a resolution of the Board and by a resolution of the Members.

77. Changes to the Memorandum of Association

No alteration or amendment to the Memorandum of Association may be made save in accordance with the Act and until same has been approved by a resolution of the Board and by a resolution of the Members.

78. Discontinuance

The Board may exercise all the powers of the Company to discontinue the Company to a jurisdiction outside Bermuda pursuant to the Act.

79. Amalgamation or Merger

Any resolution proposed for consideration at any general meeting to approve the amalgamation or merger of the Company with any other company, wherever incorporated, shall (other than in respect of any amalgamation or merger constituting a Business Combination to which the restrictions in Bye-law 76 shall apply) require the approval of a simple majority of votes cast at such meeting and the quorum for such meeting shall be that required in Bye-law 27 and a poll may be demanded in respect of such resolution in accordance with the provisions of Bye-law 30.

Exhibit 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: August 6, 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: August 6, 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 June 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: August 6, 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 June 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: August 6, 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.