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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, 2020
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 3351**

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	☒	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 August 6, 2020, was 90,149,320.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2020

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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, 2020	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 84,726	$ 76,644
Marketable securities	14,970	2,997
Prepaid expenses and other current assets	9,370	8,269
Total current assets	109,066	87,910
Property and equipment, net	2,453	2,497
Operating lease right-of-use asset	10,790	11,146
Other assets	4,373	4,373
Total assets	$ 126,682	$ 105,926
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 5,388	$ 15,334
Interest payable (related party)	24	15
Accrued expenses	28,920	29,060
Deferred revenue	16,667	40,000
Operating lease liability	1,585	1,516
Total current liabilities	52,584	85,925
Long-term operating lease liability	10,571	10,996
Long-term debt, less current maturities (related party)	193,700	113,700
Other	4,437	3,582
Total liabilities	261,292	214,203
Commitments and contingencies (Note 11)		
Shareholders' deficit:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 90,137,012 and 89,833,998 issued and outstanding at June 30, 2020 and March 31, 2020, respectively	2	2
Additional paid-in capital	694,383	684,381
Accumulated other comprehensive loss	(5,121)	(1,646)
Accumulated deficit	(823,874)	(791,014)
Total shareholders' deficit	(134,610)	(108,277)
Total liabilities and shareholders' deficit	$ 126,682	$ 105,926

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,	
	2020	**2019**
License and milestone revenue	$ 33,333	$ —
Operating expenses:		
Research and development	44,186	51,117
General and administrative	22,828	14,152
Total operating expenses	67,014	65,269
Loss from operations	(33,681)	(65,269)
Interest expense	—	3,793
Interest expense (related party)	2,184	—
Interest income	(108)	(766)
Other income, net	(3,569)	(705)
Loss before income taxes	(32,188)	(67,591)
Income tax expense	672	313
Net loss	$ (32,860)	$ (67,904)
Net loss per common share — basic and diluted	$ (0.37)	$ (0.89)
Weighted average common shares outstanding — basic and diluted	89,300,210	76,468,347

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,	
	2020	**2019**
Net loss	$ (32,860)	$ (67,904)
Other comprehensive loss:		
Foreign currency translation adjustment	(3,475)	(819)
Total other comprehensive loss	(3,475)	(819)
Comprehensive loss	$ (36,335)	$ (68,723)

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

MYOVANT SCIENCES LTD.
Condensed Consolidated Statements of Shareholders' (Deficit) Equity
(unaudited; in thousands, except share data)

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' (Deficit) Equity
	Shares	Amount				
Balance at March 31, 2020	89,833,998	$ 2	$ 684,381	$ (1,646)	$ (791,014)	$ (108,277)
Share-based compensation expense	—	—	7,812	—	—	7,812
Issuance of shares upon exercise of stock options and vesting of restricted stock units	303,014	—	2,190	—	—	2,190
Foreign currency translation adjustment	—	—	—	(3,475)	—	(3,475)
Net loss	—	—	—	—	(32,860)	(32,860)
Balance at June 30, 2020	90,137,012	$ 2	$ 694,383	$ (5,121)	$ (823,874)	$ (134,610)

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' (Deficit) 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 from former controlling shareholder — share-based compensation	—	—	42	—	—	42
Capital contribution from former controlling shareholder	—	—	106	—	—	106
Foreign currency translation adjustment	—	—	—	(819)	—	(819)
Issuance of shares upon exercise of stock options and vesting of restricted stock units	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

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,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (32,860)	$ (67,904)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	7,812	6,452
Depreciation and amortization [1]	551	356
Amortization of debt discount and issuance costs	—	555
Foreign currency transaction gain	(3,569)	(705)
Other	94	(8)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,101)	1,501
Income tax receivable	—	193
Other assets	—	237
Accounts payable	(9,946)	(1,015)
Interest payable	—	(319)
Interest payable (related party)	9	—
Accrued expenses	(140)	(7,493)
Deferred revenue	(23,333)	—
Operating lease liabilities	(356)	(178)
Deferred interest payable	—	1,517
Other	855	—
Net cash used in operating activities	(61,984)	(66,811)
Cash flows from investing activities:		
Purchases of marketable securities	(14,973)	—
Maturities of marketable securities	3,000	—
Purchases of property and equipment	(151)	(139)
Net cash used in investing activities	(12,124)	(139)
Cash flows from financing activities:		
Proceeds from issuance of common shares in “at-the-market” equity offering, net of issuance costs paid	—	2,546
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	—	134,750
Proceeds from related party debt financing	80,000	—
Proceeds from stock option exercises	2,190	314
Net cash provided by financing activities	82,190	137,610
Net change in cash, cash equivalents and restricted cash	8,082	70,660
Cash, cash equivalents and restricted cash, beginning of period	78,018	157,199
Cash, cash equivalents and restricted cash, end of period	$ 86,100	$ 227,859
Non-cash financing activities:		
Deferred financing costs included in accrued expenses	$ —	$ 212

[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. (together with its wholly-owned subsidiaries, the "Company") is a healthcare company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. The Company's lead product candidate is relugolix, a once-daily, oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for which the Company has successfully completed multiple Phase 3 clinical studies across three distinct indications. The Company is preparing for potential commercial launches in the United States ("U.S.") of relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) for the treatment of women with heavy menstrual bleeding associated with uterine fibroids or pain associated with endometriosis, and relugolix monotherapy tablet (120 mg) for the treatment of men with advanced prostate cancer, in anticipation of U.S. Food and Drug Administration ("FDA") approval to market in these indications. The Company submitted its New Drug Application ("NDA") to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer in April 2020. This application was accepted for priority review and has a target action date of December 20, 2020. The Company submitted an NDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020. The Company has also announced positive results from two replicate Phase 3 clinical studies evaluating relugolix combination therapy in women with pain associated with endometriosis. The Company is developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG ("Takeda"), a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, granted the Company a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive right to develop and commercialize MVT-602 in all countries worldwide. On March 30, 2020, the Company entered into an exclusive license agreement with Gedeon Richter Plc. ("Richter") for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S. Under this agreement, the Company has retained all of its rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women's health. In March 2020, the Company submitted a Marketing Authorisation Application ("MAA") to the European Medicines Agency ("EMA") for relugolix combination tablet in uterine fibroids. The MAA submission has completed validation and is now under evaluation by the EMA.

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 combination tablet and relugolix monotherapy tablet. The Company's majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma"). As of June 30, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or 54.0%, of the Company's outstanding common shares.

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 combination tablet and relugolix monotherapy tablet. To date, the Company has not generated any product revenue, and it does not expect to generate product revenue unless and until it obtains regulatory approval for at least one of its product candidates. The Company has funded its operations primarily from the issuance and sale of its common shares and from debt financing arrangements.

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 U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. These 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, 2020, filed with the U.S. Securities and Exchange Commission (the "SEC") on May 18, 2020. The unaudited consolidated balance sheet at March 31, 2020 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, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2021, for any other interim period or for any other future year. 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, 2020, filed with the SEC on May 18, 2020.

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 ("ASC") and Accounting Standards Update ("ASU"), issued by the Financial Accounting Standards Board ("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.

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, 2020, the Company incurred net losses of $32.9 million and used $62.0 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 combination tablet and relugolix monotherapy tablet. In addition, the Company expects that its outstanding debt levels will increase in future periods, which will result in an increase in its quarterly interest payment obligations. The Company has not generated any product revenue to date and does not expect to generate product revenue unless and until it obtains regulatory approval for at least one of its product candidates. Based on its current operating plan, the Company expects that its existing cash, cash equivalents, marketable securities, and its ability to borrow under the terms of the Sumitomo Dainippon Pharma Loan Agreement (See Note 5(A)) will be sufficient to fund its operating expenses and capital expenditure requirements at least through the end of the Company's fiscal year ending March 31, 2021. This estimate is based on the Company's current assumptions, including assumptions relating to its ability to manage its spend, that might prove to be wrong, and it could use its available capital resources sooner than it currently expects. Current cash, cash equivalents, marketable securities and amounts available under the Sumitomo Dainippon Pharma Loan Agreement will not be sufficient to enable the Company to complete all necessary development and regulatory activities and commercially launch relugolix combination tablet or relugolix monotherapy tablet. The Company anticipates that it will continue to incur net losses and negative operating cash flows for the foreseeable future.

To continue as a going concern, the Company will need, among other things, additional capital resources. The Company continually assesses multiple options to obtain additional funding to support its operations, including through financing activities in public or private capital markets. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all. Although the Company expects to draw under the Sumitomo Dainippon Pharma Loan Agreement on a quarterly basis, such draws are contingent upon the consent of the Company's board of directors. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the Company's outstanding common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to the Company, in which case the Company would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. ASC 240-40, *Going Concern*, does not allow the Company to consider future financing activities that are uncertain in its assessment of the Company's future cash burn for the purpose of its liquidity assessment. On August 5, 2020, the Company obtained an additional $200.0 million low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma (see Note 12).

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

(B) Use of Estimates

The preparation of 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 consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets and liabilities, and disclosures of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Determinations in which management uses subjective judgments include, but are not limited to, the evaluation of the Company's ability to continue as a going concern, revenue recognition, share-based compensation expenses, research and development ("R&D") expenses and accruals, leases, 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 consolidated financial statements and the reported amounts of revenues and expenses during the reporting period, that are not readily apparent from other sources. Estimates and assumptions are periodically reviewed in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

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

As of June 30, 2020 and 2019, potentially dilutive securities were as follows:

	June 30,	
	2020	2019
Stock options	8,648,078	7,085,337
Restricted stock awards (unvested)	564,111	846,165
Restricted stock units (unvested)	2,771,770	38,449
Performance stock units (unvested)	831,431	—
Warrants	73,710	73,710
Total	12,889,100	8,043,661

(D) 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.

Restricted cash consists of legally restricted deposits held as compensating balances against the Company's corporate credit card program and irrevocable standby letters of credit provided as security for the Company's office lease and sublease.

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

	June 30,	
	2020	2019
Cash and cash equivalents	$ 84,726	$ 226,734
Restricted cash [(1)]	1,374	1,125
Total cash, cash equivalents and restricted cash	$ 86,100	$ 227,859

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

(E) Marketable Securities

Investments in marketable securities are held in a custodial account at a financial institution and managed by the Company's investment advisor based on the Company's investment guidelines. The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities.

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

The Company does not intend to sell its securities that are in an unrealized loss position, and it is unlikely that the Company will be required to sell its securities before recovery of their amortized cost basis, which may be maturity. Factors considered in determining whether a loss is temporary include the length of time and extent to which the fair value has been less than the amortized cost basis and whether the Company intends to sell the security or whether it is more likely than not that the Company would be required to sell the security before recovery of the amortized cost basis. See Note 3 for additional information.

(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, marketable securities, accounts payable and debt obligations. Cash, cash equivalents, and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. Marketable securities are recorded at their estimated fair value and are included in Level 2 of the fair value hierarchy.

(G) Revenue Recognition

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), as subsequently amended, which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company was required to adopt ASC 606 on April 1, 2018. As the Company did not have any effective contracts within the scope of this guidance prior to April 1, 2018, ASC 606 had no impact on the Company's consolidated financial statements and related disclosures upon adoption.

In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

When applying the revenue recognition criteria of ASC 606 to license and collaboration agreements, the Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

- *Licenses of intellectual property*: If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.
- *Milestone payments*: At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.
- *Royalties and commercial milestone payments*: For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

(H) Recently Adopted Accounting Standards

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* ("ASU 2018-13"), which simplifies the fair value measurement disclosure requirements. The Company adopted the new standard on April 1, 2020. The adoption of ASU 2018-13 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (Topic 808)*: Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). This guidance is intended to reduce diversity in practice and clarify the interaction between Topic 808, *Collaborative Arrangements*, and Topic 606, *Revenue from Contracts with Customers*. ASU 2018-18 provided guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606. The Company adopted the new standard on April 1, 2020. The adoption of ASU 2018-18 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40) ("ASU 2018-15"), which amends ASU No. 2015-05, *Customers Accounting for Fees in a Cloud Computing Agreement*, to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement (hosting arrangement) by providing guidance for determining when the arrangement includes a software license. The most significant change will align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal-use software license. Accordingly, the amendments in ASU 2018-15 require an

entity in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as assets related to the service contract and which costs to expense. The Company adopted ASU 2018-15 using the prospective method as of April 1, 2020. The adoption of ASU 2018-15 did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

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

(I) Recently Issued Accounting Standards

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform* (Topic 848)*: Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. These amendments apply only to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. The amendments are effective for all entities as of March 12, 2020 through December 31, 2022. The expedients and exceptions provided by the amendments do not apply to contract modifications made and hedging relationships entered into or evaluated after December 31, 2022, except for hedging relationships existing as of December 31, 2022, that an entity has elected certain optional expedients for and that are retained through the end of the hedging relationship. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326)*: Measurement of Credit Losses on Financial Instruments* ("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. In February 2020, the FASB issued ASU 2020-02, *Financial Instruments-Credit Losses* (Topic 326) *and Leases* (Topic 842) - *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases* (Topic 842), which amends the effective date of the original pronouncement for smaller reporting companies. ASC 2016-13 and its amendments will be effective for annual and interim periods beginning after December 15, 2022 for smaller reporting companies. The Company is currently assessing the impact the adoption of this new standard will have on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* (Topic 740) ("ASU 2019-12"), that eliminates certain exceptions to the general principles in ASC 740 related to intra-period tax allocation, deferred tax liability and general methodology for calculating income taxes. ASU 2019-12 also simplifies U.S. GAAP by making other changes for matters such as, franchise taxes that are partially based on income, transactions with a government that result in a step up in the tax basis of goodwill, separate financial statements of legal entities that are not subject to tax, and enacted changes in tax laws in interim periods. ASU 2019-12 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2020. 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 consolidated financial statements and related disclosures.

Note 3—Investments and Fair Value Measurements

Fair Value Measurements

The following table summarizes the Company's assets that require fair value measurements on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
As of June 30, 2020				
Money market funds [1]	$ 4,988	$ —	$ —	$ 4,988
Commercial paper [2]	—	48,382	—	48,382
Municipal bonds [3]	—	16,617	—	16,617
Total assets	$ 4,988	$ 64,999	$ —	$ 69,987
As of March 31, 2020				
Money market funds [1]	$ 11,348	$ —	$ —	$ 11,348
Commercial paper [4]	—	7,042	—	7,042
Total assets	$ 11,348	$ 7,042	$ —	$ 18,390

[1] Included in cash and cash equivalents.
[2] Includes $41.6 million in cash and cash equivalents and $6.8 million in marketable securities.
[3] Includes $8.4 million in cash and cash equivalents and $8.2 million in marketable securities.
[4] Includes $4.0 million in cash and cash equivalents and $3.0 million in marketable securities.

There were no liabilities measured at fair value on a recurring basis as of June 30, 2020 or March 31, 2020.

Note 4—Accrued Expenses

As of June 30, 2020, and March 31, 2020, accrued expenses consisted of the following (in thousands):

	June 30, 2020	March 31, 2020
Accrued R&D expenses	$ 15,437	$ 15,500
Accrued compensation-related expenses	6,994	9,309
Accrued commercial expenses	3,190	818
Accrued professional service fees	763	1,126
Accrued other expenses	2,536	2,307
Total accrued expenses	$ 28,920	$ 29,060

Note 5—Related Party Transactions

(A) Sumitomo Dainippon Pharma Co., Ltd.

On December 27, 2019, the Company's former controlling shareholder, Roivant Sciences Ltd. ("Roivant"), completed a transaction (the "Sumitomo-Roivant Transaction") in which all of the Company's outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Dainippon Pharma, resulting in Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, owning 45,008,604, or approximately 50.2%, of the Company's outstanding common shares on December 27, 2019. As of June 30, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or approximately 54.0%, of the Company's outstanding common shares.

Sumitomo Dainippon Pharma Loan Agreement

On December 27, 2019, the Company and its subsidiary, Myovant Sciences GmbH ("MSG"), entered into a Loan Agreement with Sumitomo Dainippon Pharma (the "Sumitomo Dainippon Pharma Loan Agreement"). Pursuant to the Sumitomo Dainippon Pharma Loan Agreement, Sumitomo Dainippon Pharma agreed to make revolving loans to the Company in an aggregate principal amount of up to $400.0 million. On December 30, 2019, the Company borrowed an initial amount of $113.7 million under the Sumitomo Dainippon Pharma Loan Agreement, the proceeds of which were used to repay all outstanding obligations of the Company to NovaQuest Capital Management and Hercules Capital, Inc. and to satisfy certain other fees and expenses. Additional funds may be drawn down by the Company once per calendar quarter, subject to certain terms and conditions, including consent of the Company's board of directors. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the Company's outstanding common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to the Company, in which case the Company would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. Interest is due and payable quarterly, and the outstanding principal amounts are due and payable in full on the five-year anniversary of the closing date of the Sumitomo Dainippon Pharma Loan Agreement. Loans under the Sumitomo Dainippon Pharma Loan Agreement are prepayable at any time without premium or penalty upon 10 business days' prior written notice.

Loans under the Sumitomo Dainippon Pharma Loan Agreement bear interest at a rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter. The Company's obligations under the Sumitomo Dainippon Pharma Loan Agreement are fully and unconditionally guaranteed by the Company and its subsidiaries. The loans and other obligations are senior unsecured obligations of the Company, MSG, and subsidiary guarantees. The Sumitomo Dainippon Pharma Loan Agreement includes customary representations and warranties and affirmative and negative covenants.

The Sumitomo Dainippon Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties, breaches of covenants following any applicable cure period, cross acceleration to certain other debt, failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by the Company or any of its subsidiaries and certain breaches by the Company under the Investor Rights Agreement. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Dainippon Pharma may terminate its obligations to make loans to the Company and declare the principal amount of loans to become immediately due and payable, and Sumitomo Dainippon Pharma may take such other actions as set forth in the Sumitomo Dainippon Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Dainippon Pharma to make loans to the Company would automatically terminate and the principal amount of the loans would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Dainippon Pharma to maintain the loans under the Sumitomo Dainippon Pharma Loan Agreement or within 30 days of a change of control with respect to the Company, the Company would be required to repay the outstanding principal amount of the Loans.

As of June 30, 2020, the outstanding loan balance of $193.7 million is classified as a long-term liability on the Company's unaudited condensed consolidated balance sheets under the caption long-term debt, less current maturities (related party). As of June 30, 2020, approximately $206.3 million of borrowing capacity remains available to the Company, subject to the terms of the Sumitomo Dainippon Pharma Loan Agreement. Interest expense under the Sumitomo Dainippon Pharma Loan Agreement was $2.2 million for the three months ended June 30, 2020 and is included in interest expense (related party) in the Company's unaudited condensed consolidated statements of operations. There was no interest expense (related party) for the three months ended June 30, 2019. On August 5, 2020, the Company obtained an incremental $200.0 million low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma (see Note 12).

Investor Rights Agreement

On December 27, 2019, the Company entered into an Investor Rights Agreement with Sumitomo Dainippon Pharma and Sumitovant (the "Investor Rights Agreement"). Pursuant to the Investor Rights Agreement, among other things, the Company agreed, at the request of Sumitovant, to register for sale, under the Securities Act of 1933, common shares beneficially owned by Sumitovant, subject to specified conditions and limitations. In addition, the Company agreed to periodically provide Sumitovant (i) certain financial statements, projections, capitalization summaries and other information and (ii) access to the Company's books, records, facilities and employees during the Company's normal business hours as Sumitovant may reasonably request, subject to specified limitations.

The Investor Rights Agreement also contains certain protections for the Company's minority shareholders for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially owns more than 50% of the Company's common shares. These protections include: (i) a requirement that Sumitovant vote its shares for the election of independent directors in accordance with the recommendation of the Company's board of directors (the "board") or in the same proportion as the

shareholders not affiliated with Sumitovant vote their shares; (ii) a requirement that the audit committee of the Company's board be composed solely of three independent directors; (iii) a requirement that any transaction proposed by Sumitomo Dainippon Pharma or certain of its affiliates that would increase Sumitomo Dainippon Pharma's beneficial ownership to over 60% of the outstanding voting power of the Company must be approved by the Company's audit committee (if occurring prior to December 27, 2022), and be conditioned on the approval of shareholders not affiliated with Sumitovant approving the transaction by a majority of the common shares held by such shareholders; and a requirement that any related person transactions between Sumitomo Dainippon Pharma or certain of its affiliates and the Company must be approved by the Company's audit committee.

Pursuant to the Investor Rights Agreement, the Company also agreed that at all times that Sumitomo Dainippon Pharma beneficially owns more than 50% of the Company's common shares, Sumitomo Dainippon Pharma, by purchasing common shares in the open market or from the Company in certain specified circumstances, will have the right to maintain its percentage ownership in the Company's common shares in the event of a financing event or acquisition event conducted by the Company, or specified other events, subject to specific conditions.

(B) Sumitovant

On May 18, 2020, the Company and Sumitovant entered into a consulting agreement pursuant to which Sumitovant provides consulting services to the Company to support the Company in commercial planning, commercial launch activities and implementation. Adele Gulfo, Sumitovant's Chief Business and Commercial Development Officer and a member of the Company's board of directors, provides services to the Company on behalf of Sumitovant under the agreement. The term of the engagement is through November 11, 2020, or such earlier time as the Company hires a Chief Commercial Officer, and may be renewed upon the mutual written consent of the parties. Either the Company or Sumitovant may terminate the engagement under the agreement at any time for any reason by giving not less than 15 days prior written notice thereof to the other party. The consulting services will be provided with the aggregate fees not to exceed a total of $120,000 without the Company's prior written approval. For the three months ended June 30, 2020, the Company incurred $114,000 of expense under this consulting agreement, which is included in general and administrative ("G&A") expenses in the accompanying unaudited condensed consolidated statements of operations.

(C) Sunovion Pharmaceuticals Inc.

On August 1, 2020, the Company's subsidiary, MSG, entered into a Market Access Services Agreement (the "Market Access Services Agreement") with Sunovion Pharmaceuticals Inc. ("Sunovion"), a subsidiary of Sumitomo Dainippon Pharma (see Note 12).

(D) Roivant Sciences Ltd.

As a result of the closing of the Sumitomo-Roivant Transaction described above, on December 27, 2019 all of the Company's outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Dainippon Pharma. As a result of the transfer of these common shares, Roivant no longer beneficially owns any common shares of the Company. On December 27, 2019, the then existing Information Sharing and Cooperation Agreement between the Company and Roivant, the then existing Services Agreements between the Company and certain of its subsidiaries and Roivant and certain of its subsidiaries, and the then existing Option Agreement between the Company and Roivant were terminated. For three months ended June 30, 2019, the Company paid or reimbursed Roivant approximately $0.2 million under the terms of the then existing Services Agreements. In addition, the Company recorded share-based compensation expense allocated from Roivant of less than $0.1 million for the three months ended June 30, 2019. No amounts were incurred during the three months ended June 30, 2020.

Roivant purchased 2,424,242 of the Company's common shares in the Company's June 4, 2019 underwritten public equity offering at the same price offered to the public of $8.25 per common share, for a total purchase price of $20.0 million (see Note 7).

Note 6—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, 2020 and 2019 was (2.09)% and (0.46)%, respectively. The Company's effective tax rate is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

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

In response to the COVID-19 pandemic, many governments have enacted or are contemplating measures to provide aid and economic stimulus. These measures include deferring the due dates of tax payments and other changes to income and non-income-based-tax laws as well as providing direct government assistance through grants and forgivable loans. On March 27, 2020, the U.S. Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted in response to the COVID-19 pandemic and the negative impacts that it is having on the global economy and U.S. companies. The CARES Act includes measures to assist companies, including temporary changes to income and non-income-based tax laws. The Company has implemented certain provisions of the CARES Act, such as deferring employer payroll taxes through the end of calendar year 2020. As of June 30, 2020, the Company has deferred $0.8 million of employer payroll taxes, of which 50% are required to be deposited by December 2021 and the remaining 50% by December 2022. The deferred payroll tax liability is included in other liabilities on the accompanying unaudited condensed consolidated balance sheet.

Note 7—Shareholders' Deficit

(A) At-the-Market Equity Offering Program

In April 2018, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("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, the Company issued and sold 106,494 of its common shares under the Sales Agreement. The common shares were sold at a weighted-average price of $24.65 per common share for aggregate net proceeds to the Company of approximately $2.5 million after deducting underwriting commissions paid by the Company. No shares were sold under the Sales Agreement during the three months ended June 30, 2020. As of June 30, 2020, the Company had approximately $10.4 million of capacity available to it under its "at-the-market" equity offering program.

(B) 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 at a public offering price of $8.25 per common share. After deducting the underwriting discounts and commissions and offering costs paid by the Company, the net proceeds to the Company in connection with the underwritten public equity offering, including from the exercise of the underwriters' option to purchase additional common shares, were approximately $134.5 million.

Note 8—Share-Based Compensation

(A) Myovant 2016 Equity Incentive Plan

In June 2016, the Company adopted its 2016 Equity Incentive Plan, 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 the Company's 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, 2020, the number of common shares authorized for issuance increased automatically by 3.6 million shares in accordance with the evergreen provision of the 2016 Plan. As of June 30, 2020, a total of 1.2 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, 2020	7,723,302
Granted	1,571,323
Exercised	(302,076)
Forfeited	(344,471)
Options outstanding at June 30, 2020	8,648,078
Options vested and expected to vest at June 30, 2020	8,648,078
Options exercisable at June 30, 2020	3,236,128

(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, 2020	1,280,312
Granted	2,298,339
Vested	(71,450)
Forfeited	(171,320)
Unvested balance at June 30, 2020	3,335,881

(D) Performance Stock Units

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

	Number of Shares
Unvested balance at March 31, 2020	299,870
Granted	568,976
Vested	—
Forfeited	(37,415)
Unvested balance at June 30, 2020	831,431

The vesting of performance stock units requires that certain performance conditions are achieved during the performance period and is subject to the employee's continued service requirements. During the three months ended June 30, 2020, the Company recognized share-based compensation expense of $0.6 million related to performance stock units for which it determined the vesting to be probable.

(E) Share-Based Compensation Expense

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

	Three Months Ended June 30,	
	2020	2019
Share-based compensation expense recognized as:		
R&D expenses	$ 4,024	$ 2,548
G&A expenses	3,788	3,904
Total	$ 7,812	$ 6,452

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. Total unrecognized share-based compensation expense was approximately $69.3 million as of June 30, 2020 and is expected to be recognized over a weighted-average period of approximately 3.0 years.

Note 9—Leases

At June 30, 2020, the Company has lease agreements, as lessee, for office space in Brisbane, California, which are accounted for as operating leases. The lease agreements do not contain a specified implicit interest rate; therefore, the Company's estimated incremental borrowing rate was used to determine the present value of future minimum lease payments. The lease term for all of the Company's leases includes the non-cancelable period of the lease and any periods covered by renewal options that the Company is reasonably certain to exercise. The Company currently has no other significant operating, financing, or short-term leases.

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

	Three Months Ended June 30,	
	2020	2019
Operating lease cost	$ 729	$ 519
Variable lease cost [(1)]	90	9
Total operating lease cost	$ 819	$ 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.

Certain information related to the Company's operating lease right-of-use assets and operating lease liabilities for its Brisbane, California office space are as follows (in thousands):

	Three Months Ended June 30,	
	2020	2019
Cash paid for operating lease liabilities	$ 729	$ 496
Operating lease right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 9,181

As of June 30, 2020, the Company's operating leases had a weighted average remaining lease term of 5.4 years and a weighted average discount rate of 12.3%.

As of June 30, 2020, maturities of operating lease liabilities were as follows (in thousands):

Years Ended March 31,		
2021 (remainder of year)	$	2,210
2022		3,028
2023		3,127
2024		3,053
2025		2,409
Thereafter		2,898
Total lease payments		16,725
Less imputed interest		(4,569)
Present value of future minimum lease payments		12,156
Less operating lease liability, current portion		(1,585)
Operating lease liability, long-term portion	$	10,571

Note 10—Development and Commercialization Agreement

On March 30, 2020, the Company entered an exclusive license agreement for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand (the “Development and Commercialization Agreement”). Under the agreement, the Company received an upfront payment of $40.0 million on March 31, 2020, is eligible to receive up to $40.0 million in regulatory milestone payments (of which $10.0 million was received in April 2020), $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval. Under the terms of the agreement, the Company will continue to lead global development of relugolix combination tablet. The Company has also agreed to assist Richter in transferring manufacturing technology from the Company’s contract manufacturing organizations to Richter to enable Richter to manufacture relugolix combination tablet. If requested by Richter, the Company has agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to the Company’s agreements with its contract manufacturing organizations. Richter will be responsible for local clinical development, manufacturing, and all commercialization activities for its territories. The Company has also granted Richter an option to collaborate with the Company on relugolix combination tablet for future indications in women’s health other than fertility.

The Company determined that the transaction price under the Development and Commercialization Agreement totaled $50.0 million, consisting of the upfront payment of $40.0 million received on March 31, 2020 and a $10.0 million regulatory milestone payment received in April 2020. As of June 30, 2020, the Company did not include any other regulatory milestones, sales-related milestones, or royalties on net sales following regulatory approval in the transaction price given the substantial uncertainty related to their achievement.

The Company concluded that Richter represented a customer and applied relevant guidance from ASC 606 to evaluate the accounting under the Development and Commercialization Agreement. In accordance with this guidance, the Company identified one material combined performance obligation to grant a license to Richter to certain of its intellectual property and to deliver certain clinical and regulatory data packages for relugolix combination therapy, the drug used for both potential indications of uterine fibroids and endometriosis. The Company determined that its grant of a license to Richter to certain of its intellectual property was not distinct from the delivery of certain clinical and regulatory data packages pertaining to relugolix combination therapy. In evaluating the appropriate measure for the Company's performance under the combined performance obligation, the Company determined that revenues should be recognized as data packages are issued to Richter based on the relative value of the data packages delivered to date compared to the totality of the data packages it is obligated to deliver under the Development and Commercialization Agreement. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Based upon the Company's assessment of its progress toward delivering relugolix combination therapy clinical and regulatory data packages to Richter, the Company concluded that as of June 30, 2020, it had satisfied approximately two-thirds of the combined performance obligation. As a result, the Company recognized $33.3 million of the transaction price as revenue during the three months ended June 30, 2020. As the Company currently expects to deliver the remaining substantive relugolix combination therapy data packages to Richter in the fourth quarter of the fiscal year ending March 31, 2021, the Company has recorded the remaining $16.7 million of the transaction price as deferred revenue, a current liability, on the unaudited condensed consolidated balance sheet as of June 30, 2020.

Contract Balances

Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these agreements. Amounts payable to the Company are recorded as accounts receivable when the Company's rights to consideration is unconditional. The following table presents changes in the Company's total contract liabilities during the three months ended June 30, 2020 (in thousands):

	Balance at March 31, 2020	Additions	Deductions	Balance at June 30, 2020
Contract liabilities:				
Deferred revenue, current	$ 40,000	$ 10,000	$ (33,333)	$ 16,667

Deferred revenue related to the Richter Development and Commercialization Agreement as of June 30, 2020, which was comprised of the $50.0 million transaction price, including a $40.0 million upfront payment received in March, 2020 and a $10.0 million regulatory milestone received in April, 2020, less the revenue recognized from the effective date of the contract, will be recognized as revenue as the combined performance obligation is satisfied.

The Company had no receivables or contract assets as of March 31, 2020 or June 30, 2020. During the three months ended June 30, 2020, the Company's contract liabilities, which consisted of deferred revenue, decreased by $23.3 million. This decrease included deductions of $33.3 million related to revenue recognized during the three months ended June 30, 2020, partially offset by additions of $10.0 million related to a regulatory milestone received in April, 2020.

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. For cases in which 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 providers to assist in the performance of its R&D and clinical and commercial manufacturing activities. 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, clinical and commercial 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 agreed to indemnify Sumitomo Dainippon Pharma against certain losses, claims, liabilities and related expenses incurred by Sumitomo Dainippon Pharma, subject to the terms of the Sumitomo Dainippon Pharma Loan Agreement and the Investor Rights Agreement. 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 accruals have been established.

(D) Takeda Agreements

Under the Takeda License Agreement, the Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in the Company's territory, subject to certain agreed reductions. Takeda will pay the Company a royalty at the same rate on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under the Takeda License Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones. As the amount and timing of any potential future payments under the Takeda License Agreement are not probable and estimable, no such potential commitments have been included in the unaudited condensed consolidated balance sheet.

If the Takeda License Agreement is terminated in its entirety or with respect to relugolix for prostate cancer, other than for safety reasons or by the Company for Takeda's uncured material breach, prior to receipt of the first regulatory approval of relugolix for prostate cancer in Japan, then the Company must either reimburse Takeda for its out of pocket costs and expenses directly incurred in connection with Takeda's completion of the relugolix development for prostate cancer, up to an agreed upon cap, or complete by itself the conduct of any clinical studies of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at its cost and expense

Pursuant to a Commercial Manufacturing and Supply Agreement entered into with Takeda (the "Takeda Commercial Supply Agreement"), Takeda agreed to supply the Company and the Company agreed to obtain from Takeda certain quantities of relugolix drug substance according to agreed-upon quality specifications. For relugolix drug substance manufactured or delivered on or after December 31, 2019, 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 will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase orders thereunder, will terminate immediately upon the termination of the Takeda License Agreement in accordance with its terms.

Note 12—Subsequent Events

(A) Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma Loan Agreement

Pursuant to the terms of the Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A)), the Company is permitted to draw down funds once per calendar quarter, subject to certain conditions. In July 2020, the Company borrowed $60.0 million under the Sumitomo Dainippon Pharma Loan Agreement. Subsequent to this draw, approximately $146.3 million of borrowing capacity remains available to the Company.

Sumitomo Dainippon Pharma Loan Commitment

On August 5, 2020, the Company obtained a debt commitment letter (the "2020 Commitment Letter") from Sumitomo Dainippon Pharma, pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma has committed to provide an additional $200.0 million in unsecured revolving commitments (the "New Credit Facility"), the proceeds of which may be used for business operating expenditures of the Company and its subsidiaries. The commitments are in addition to the commitments made available to the Company and its subsidiaries by Sumitomo Dainippon Pharma under the existing Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A)).

The New Credit Facility shall mature on the fifth anniversary of the closing of the New Credit Facility. Sumitomo Dainippon Pharma will have the discretion, to require certain prepayments as Sumitomo Dainippon Pharma may request and/or to not allow the Company to draw down any remaining funds under the New Credit Facility, upon the occurrence of certain material business development transactions. In addition, as a condition to entering into the New Credit Facility, the Company shall be required to enter into an information sharing agreement with Sumitovant which will be on terms to be agreed between the

Company and Sumitovant. The terms and conditions of the New Credit Facility shall otherwise be substantially identical to the terms of the existing Sumitomo Dainippon Pharma Loan Agreement, including with respect to the interest rate margins, except as otherwise agreed between the Company and Sumitomo Dainippon Pharma.

(B) Sunovion Pharmaceuticals Inc.

Market Access Services Agreement

On August 1, 2020, the Company's subsidiary, MSG, entered into the Market Access Services Agreement with Sunovion, a subsidiary of Sumitomo Dainippon Pharma. Pursuant to the Market Access Services Agreement, among other things, Sunovion has agreed to provide to MSG certain market access services with respect to the distribution and sale of relugolix monotherapy (relugolix 120 mg) ("Prostate Cancer Product") and relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) ("Women's Health Product," and collectively with Prostate Cancer Product, the "Products", and each a "Product"), including, among other things: (i) adding the Products to Sunovion's agreements with its third party logistics providers; (ii) adding the Women's Health Product to certain of Sunovion's contracts with wholesalers, group purchasing organizations and integrated delivery networks and negotiating rates for the Products with certain market access customers; (iii) providing order-to-cash services; (iv) providing certain employees to provide market access account director services; (v) performing activities required in connection with supporting and maintaining contracts between the Company and market access customers for the coverage, purchase, or dispensing of the Products; (vi) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to the Products; (vii) providing MSG with price reporting metrics and other information required to allow the Company to comply with applicable government price reporting requirements; (viii) coordinating with MSG and any applicable wholesalers and distributors to address any recalls, investigations, or product holds; (ix) configuring, or causing to be configured, the appropriate software systems to enable Sunovion to perform its obligations under the Market Access Services Agreement; and (x) providing training and certain other ancillary support services to facilitate the foregoing.

MSG, in turn, appointed Sunovion as the exclusive distributor of the Women's Health Product and a non-exclusive distributor of the Prostate Cancer Product, each in the United States, including all of its territories and possessions.

In order to facilitate Sunovion's provision of these services, MSG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by MSG, solely for Sunovion's use in connection with its performance of the contemplated services; (ii) provide Sunovion periodic reports of sales projections and estimated volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which the Products will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of MSG's quality systems solely relate, as reasonably determined by Myovant, to Sunovion's performance of certain regulatory services, at Sunovion's costs; and (v) promptly notify Sunovion in the event relugolix is recalled.

As consideration for the services, MSG will pay Sunovion an agreed-upon monthly service charge for each of the first two years of the Market Access Services Agreement term and any agreed regulatory and training service charges. After the second year of the Market Access Services Agreement term, the monthly service charges will be determined by the parties. In addition, MSG also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services, and (y) establish an escrow fund for use by Sunovion when managing any rebates, chargebacks and similar fees.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent not to renew the Market Access Services Agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the Market Access Services Agreement prior to the end of its term in the event of an uncured material breach by the other party, if there are certain changes of law, or if such other party becomes insolvent or undergoes a change of control. MSG may also terminate the Market Access Services Agreement with respect to one or both Products if Sunovion fails to satisfy certain market access milestones or for convenience upon payment of a break-up fee.

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, 2020 included in our Annual Report on Form 10-K, filed with the SEC on May 18, 2020. 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, (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (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 impact of pandemics, epidemics or outbreaks of infectious diseases, including the effect that the COVID-19 pandemic and related "shelter-in-place" orders and other measures will have on our business operations, financial conditions and results of operations;
- the success and anticipated timing of our clinical studies for relugolix combination therapy (relugolix 40 mg, plus estradiol 1.0 mg and norethindrone acetate 0.5 mg), relugolix 120 mg as a monotherapy, and MVT-602;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical and clinical studies;
- the anticipated designs of our future clinical studies;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for relugolix combination tablet, relugolix monotherapy tablet, MVT-602 and any future product candidates;
- our ability to successfully plan for and commercialize relugolix combination tablet and relugolix monotherapy tablet, if approved;
- our ability to procure sufficient quantities of commercial relugolix drug substance and drug product from approved third party contract manufacturing organizations;
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain coverage 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 new product candidates;
- our ability to hire and retain our key scientific and management personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our product candidates;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, access to capital, prospects, growth and strategies;
- our ability to continue to fund our operations with the cash, cash equivalents, and marketable securities currently on hand, including our expectations for how long these capital resources will enable us to fund our operations;
- our ability to draw under the Sumitomo Dainippon Pharma Loan Agreement and our ability to effect the new debt facility transaction with Sumitomo Dainippon Pharma pursuant to the 2020 Commitment Letter with Sumitomo Dainippon Pharma;

- third party collaboration partners' abilities to perform their obligations under our agreements with them, such as the commercial obligations to be performed by Sunovion and Richter under their respective agreements with us;
- our ability to raise additional capital;
- industry trends;
- developments and projections relating to our competitors or our industry; and
- the success of competing drugs that are or may become available.

Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, particularly in the section titled “Risk Factors” set forth in Part II. Item 1A. of this Quarterly Report on Form 10-Q, and in our other filings with the 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.

Business Overview

We are a healthcare company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Our lead product candidate is relugolix, a once-daily, oral GnRH receptor antagonist for which we have successfully completed multiple Phase 3 clinical studies across three distinct indications. We are preparing for potential commercial launches in the U.S. of relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) for the treatment of women with heavy menstrual bleeding associated with uterine fibroids or pain associated with endometriosis and relugolix monotherapy tablet (120 mg) for the treatment of men with advanced prostate cancer, in anticipation of FDA approval to market in these indications. We submitted our NDA to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer in April 2020. This application was accepted for priority review and has a target action date of December 20, 2020. We submitted an NDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020. We have also announced positive results from two replicate Phase 3 clinical studies evaluating relugolix combination therapy in women with pain associated with endometriosis. We are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as a part of assisted reproduction. Takeda granted us a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive right to develop and commercialize MVT-602 in all countries worldwide. On March 30, 2020, we entered into an exclusive license agreement with Richter for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S. Under this agreement, we have retained all of our rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women’s health. In March 2020, we submitted a MAA to the EMA for relugolix combination tablet in uterine fibroids. The MAA submission has completed validation and is now under evaluation by the EMA.

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 combination tablet and relugolix monotherapy tablet.

Our majority shareholder is Sumitovant, a subsidiary of Sumitomo Dainippon Pharma. As of June 30, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or 54.0%, of our outstanding common shares.

First Fiscal Quarter Ended June 30, 2020 and Recent Corporate Updates

The following summarizes our first fiscal quarter ended June 30, 2020 and recent corporate updates. Additional information about our clinical programs is included in the section titled “Our Product Candidates.”

Relugolix Phase 3 Clinical Programs

- ***Prostate Cancer***: In June 2020, the FDA accepted for Priority Review our NDA for once-daily, oral relugolix (120 mg) for the treatment of men with advanced prostate cancer, setting a target action date of December 20, 2020. In May 2020, efficacy and safety data from the Phase 3 HERO study of relugolix in men with advanced prostate cancer were simultaneously published in the *New England Journal of Medicine* and presented at the American Society of Clinical Oncology (“ASCO”)'s ASCO20 Virtual Scientific Program. In July 2020, these data were also presented in an oral presentation during the American Urological Association (“AUA”)'s 2020 Virtual Experience.
- ***Uterine Fibroids***: In May 2020, we submitted an NDA for once-daily, oral relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of women with heavy menstrual bleeding associated with uterine fibroids. In July 2020, we presented additional data from the Phase 3 LIBERTY program showing improvement in patient-reported outcomes and in hemoglobin levels in women with anemia, as well as detailed data from a separate ovulation inhibition study, at the European Society of Human Reproduction and Embryology (“ESHRE”)'s virtual 36th Annual Meeting.
- ***Endometriosis***: In April 2020, we announced that the SPIRIT 2 Phase 3 study evaluating the efficacy and safety of once-daily, oral relugolix combination therapy in women with pain associated with endometriosis met the co-primary efficacy endpoints with 75.2% and 66.0% of women achieving clinically-meaningful reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. In June 2020, we announced that the replicate SPIRIT 1 Phase 3 study also met the co-primary efficacy endpoints with 74.5% and 58.5% of women achieving clinically-meaningful reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. Relugolix was generally well-tolerated and resulted in minimal bone mineral density loss over 24 weeks in both studies.
- ***Ovulation Inhibition Study***: On April 22, 2020, we announced positive results from an open-label, single-arm ovulation inhibition study of relugolix combination therapy. In July 2020, these data were presented at ESHRE’s virtual 36th Annual Meeting.

Sumitomo Dainippon Pharma Loan Commitment

On August 5, 2020, we obtained the 2020 Commitment Letter from Sumitomo Dainippon Pharma, pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma has committed to provide an additional $200.0 million low-interest, five-year unsecured revolving term loan commitment, the proceeds of which may be used for business operating expenditures of us and our subsidiaries. The commitments are in addition to the commitments made available to us and our subsidiaries by Sumitomo Dainippon Pharma under the existing Sumitomo Dainippon Pharma Loan Agreement. Additional information is included in Note 12, “Subsequent Events,” to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Market Access Services Agreement

On August 1, 2020, our subsidiary, MSG, entered into a Market Access Services Agreement (the “Market Access Services Agreement”) with Sunovion Pharmaceuticals Inc. (“Sunovion”), a subsidiary of Sumitomo Dainippon Pharma pursuant to which, among other things, Sunovion has agreed to provide to MSG certain market access services with respect to the distribution and sale of relugolix monotherapy (relugolix 120 mg) and relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg). MSG, in turn, appointed Sunovion as the exclusive distributor of relugolix combination tablet and a non-exclusive distributor of relugolix monotherapy, each in the United States, including all of its territories and possessions. Additional information is included in Note 12, “Subsequent Events,” to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Manufacturing Update

In June 2020, the FDA issued a warning letter to Takeda following a routine inspection of aseptic finished pharmaceuticals (drug product) manufacturing at Takeda’s manufacturing facility located at Takeda 4720, Mitsui, Hikari, Yamaguchi (the “Hikari Facility”). The warning letter indicated that the FDA was not satisfied with Takeda’s response to an FDA Form 483 issued to Takeda following the inspection and cited significant violations of cGMP for finished pharmaceuticals. The Hikari Facility is one of two contract manufacturing organizations included in our regulatory filings for the manufacture of relugolix drug substance (“API”). We will procure the commercial relugolix drug substance needed for our anticipated launches solely

from Excella GmbH & Co. KG ("Excella"), the second contract manufacturing organization included in our regulatory filings. We do not expect that the issues relating to the Hikari Facility will have an effect on the FDA's target action dates for any of our regulatory filings or our launch readiness.

COVID-19 Pandemic

In December 2019, an outbreak of a novel strain of coronavirus, or COVID-19, was identified. Due to the rapid and global spread of the virus, in March 2020, the World Health Organization categorized COVID-19 as a pandemic and it continues to spread throughout the U.S. and other countries across the world. To limit the spread of COVID-19, governments have taken various actions including the issuance of stay-at-home orders, closing schools, restricting travel, and social distancing guidelines and causing some businesses to suspend operations. It remains unclear how long these measures will remain in place and whether these measures will be effective.

Our priorities during the COVID-19 pandemic are protecting the health and safety of our employees while continuing our mission to redefine care for women and for men. We believe the safety measures we are taking in response to the COVID-19 pandemic meet or exceed the guidance required from government and public health officials. Beginning in mid-March 2020, substantially all of our workforce began working from home and we curtailed employee travel. We have adopted remote working tools to minimize the disruption to our business activities. At this time, we have not identified a material change to our productivity as a result of these measures, but this could change, particularly if restricted travel, closed schools, and shelter-in-place orders are not removed or significantly eased.

To date, the impact of the COVID-19 pandemic on our ability to advance our clinical studies, regulatory activities, and preparation for the potential commercialization of our product candidates has been limited and all of our publicly announced milestones remain on track. We submitted our NDA to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer in April 2020 and for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020. Our NDA for advanced prostate cancer has been accepted by the FDA for Priority Review with a target action date of December 20, 2020. Regulatory agency pre-approval inspections are limited and it is not clear if virtual inspections are acceptable due to COVID-19 and this may impact the FDA's review process and timing of potential approval of these product candidates. Should relugolix monotherapy tablet or relugolix combination tablet receive regulatory approval, we will likely commercially launch these products in the COVID-19 environment. In response to the COVID-19 pandemic, health professionals may reduce staffing and reduce or postpone appointments with patients, or patients may cancel or miss appointments, resulting in fewer prescriptions. In addition, if our product candidates receive regulatory approval, our sales teams would likely have to make presentations to physicians and the medical community solely by virtual means instead of in-person, which could reduce the number of medical professionals we are able to present to, and these virtual meetings may not be as successful as in-person meetings. At this time, we do not anticipate a substantial impact from the COVID-19 pandemic on our supply chain and ability to launch relugolix monotherapy or relugolix combination tablet.

The ultimate impact of the COVID-19 pandemic is highly uncertain and we do not yet know the full extent of potential delays or impacts on our business, our financial results, our clinical trials, our supply chains, our pre-launch commercial readiness activities, end user demand for our products, if approved, healthcare systems or the global economy as a whole. The extent to which the COVID-19 pandemic impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. As such, it is uncertain as to the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations. Refer to the risk factor titled "Business interruptions resulting from effects of pandemics or epidemics such as the novel strain of the coronavirus known as COVID-19, may materially and adversely affect our business and financial condition," as well as other risk factors included in the section titled "Risk Factors" set forth in Part II. Item 1A.

On March 27, 2020, the CARES Act was enacted in response to the COVID-19 pandemic and the negative impacts that it is having on the global economy and U.S. companies. The CARES Act includes various financial measures to assist companies, including temporary changes to income and non-income-based tax laws. The Company has implemented certain provisions of the CARES Act, such as deferring employer payroll taxes through the end of calendar year 2020. As of June 30, 2020, the Company has deferred $0.8 million of employer payroll taxes, of which 50% are required to be deposited by December 2021 and the remaining 50% by December 2022. The deferred payroll tax liability is included in other liabilities on the accompanying unaudited condensed consolidated balance sheet.

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 combination tablet and relugolix monotherapy tablet. To date, we have not generated any product revenue, and we do not expect to generate product revenue unless and until we obtain regulatory approval for one of our product candidates. We have funded our operations primarily from the issuance and sale of our common shares and from debt financing arrangements.

As of June 30, 2020, and March 31, 2020, we had an accumulated deficit of $823.9 million and $791.0 million, respectively. We had net losses of $32.9 million and $67.9 million for the three months ended June 30, 2020 and 2019, respectively, and $289.0 million for the fiscal year ended March 31, 2020. As of June 30, 2020, we had cash, cash equivalents, marketable securities and committed funding available to us of $306.0 million consisting of $99.7 million of cash, cash equivalents, and marketable securities and $206.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement, as compared to cash, cash equivalents, marketable securities and committed funding available to us of $365.9 million, consisting of $79.6 million of cash, cash equivalents, and marketable securities and $286.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement as of March 31, 2020. We are permitted to request quarterly draws under the Sumitomo Dainippon Pharma Loan Agreement, subject to certain terms and conditions, including consent of our board of directors. In July 2020, we borrowed an additional $60.0 million under the Sumitomo Dainippon Pharma Loan Agreement. On August 5, 2020, we obtained an incremental $200.0 million, low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma.

Our Product Candidates

Relugolix

We are currently developing relugolix in three 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 (“LH”) and follicle-stimulating hormone (“FSH”)), 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 targeted indications. The direct and rapid action of relugolix on the pituitary-gonadal axis is distinct from approved luteinizing hormone-releasing hormone (“LHRH”) agonists which are administered as depot injections and result in an initial surge in levels of gonadotropins, and estrogen and progesterone or testosterone, before resulting in pituitary desensitization and a fall in hormone levels over weeks. Approved LHRH agonist injections such as leuprolide acetate are used in women to treat the symptoms of uterine fibroids and endometriosis, but the adoption and duration of use is limited due to bone mineral density loss and vasomotor symptoms.

We are developing relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) administered orally once-daily, with the goal of optimizing estradiol levels to achieve the long-term benefit of relugolix on symptoms of uterine fibroids and endometriosis, while maintaining bone health and mitigating side effects from a low-estrogen state, such as vasomotor symptoms. We have successfully completed a bioequivalence study, which demonstrated the bioequivalence of our relugolix combination tablet with relugolix combination therapy, the co-administered regimen used in the LIBERTY and SPIRIT clinical programs (one relugolix 40 mg tablet plus one tablet containing estradiol 1.0 mg and norethindrone acetate 0.5 mg). We expect to launch in the women’s health indications with our single-tablet regimen.

Lowering estrogen and progesterone levels has been demonstrated, including in our two replicate Phase 3 LIBERTY studies, to effectively decrease heavy menstrual bleeding and pain in women with uterine fibroids. Similarly, relugolix combination therapy has been demonstrated in our two replicate Phase 3 SPIRIT studies to reduce pelvic pain associated with endometriosis. Relugolix combination therapy achieved these results while maintaining a generally well-tolerated safety profile. We believe our combination approach has the potential to have a better safety and tolerability profile than the currently approved LHRH agonist therapies and has the potential to be used longer-term. We further believe our single tablet combination approach also has certain benefits over other oral GnRH antagonist therapies that are currently approved or in development. The goal of our relugolix combination tablet is to provide women with uterine fibroids and endometriosis a once-daily oral medical alternative to hysterectomy and other invasive procedures often recommended to treat these conditions that is suitable for long-term use.

Decreasing testosterone slows the growth and progression of advanced prostate cancer, such as when the disease recurs or the prostate-specific antigen (“PSA”) is rising following prostatectomy or radiation therapy, when the disease progresses locally in the prostate bed, or when it becomes metastatic. We demonstrated in our Phase 3 HERO program that relugolix can achieve

sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks in 96.7% of patients with a once-daily oral treatment. Relugolix was compared to the standard-of-care leuprolide injections in the HERO study and demonstrated superiority to leuprolide in the cumulative proportion of patients achieving sustained testosterone suppression (96.7% vs 88.0%). Data from this study are the basis for the NDA submission for relugolix in advanced prostate cancer. We are developing a distinct therapeutic candidate, relugolix monotherapy (120 mg), for men with advanced prostate cancer which, if approved, we expect to commercialize as a separately branded product from our relugolix combination tablet.

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, which we refer to as LIBERTY 1 and LIBERTY 2. 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 could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy, and to evaluate the need for maintenance therapy. We currently expect to present data from the LIBERTY randomized withdrawal study in the first quarter of calendar year 2021. 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. We currently expect to present data from the uterine fibroids cohort in the prospective observational bone mineral density study in the third quarter of calendar year 2020.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 was the proportion of all women enrolled who achieved a menstrual blood loss volume of less than 80 mL and at least a 50% reduction in menstrual blood loss volume from baseline during the last 35 days of the 24-week treatment period as measured by the alkaline hematin method. The secondary endpoints included the proportion of women who achieved amenorrhea (defined as no or negligible blood loss) 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 relugolix combination tablet met all required and pre-specified FDA criteria for bioequivalence, providing data necessary to include the one tablet, once-daily dosing regimen of relugolix combination tablet in the NDA submission for approval of the treatment for uterine fibroids. In December 2019, we successfully completed one-year stability studies, which are required for FDA approval of relugolix combination tablet. On February 10, 2020, we announced positive safety and efficacy data from the Phase 3 LIBERTY long-term extension study with an 87.7% response rate and, on average, an 89.9% reduction in menstrual blood loss from baseline.

On March 9, 2020, we announced the submission of a MAA to the EMA for relugolix combination tablet for the treatment of women with moderate to severe symptoms associated with uterine fibroids. The application has completed validation and is now under evaluation by the EMA. In May 2020, we submitted an NDA to the FDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids.

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 heavy menstrual bleeding associated with uterine fibroids, 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 achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50 percent or greater reduction from baseline in menstrual blood loss volume during the last 35 days of the 24-week treatment period measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline, a clinically relevant secondary endpoint.

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

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

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was comparable (62% vs. 66%). In the relugolix combination therapy group, 5% of women discontinued treatment early due to adverse events compared with 4% in the placebo group. The only adverse event in the relugolix combination therapy arm occurring in at least 10% of women and more frequently than in the placebo arm was hot flash (11% versus 8%). There were no pregnancies in the relugolix combination therapy group and one in the placebo group. There were two serious adverse events related to the 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 heavy menstrual bleeding associated with uterine fibroids, met its primary efficacy endpoint and the same six key secondary endpoints as were achieved in LIBERTY 1. Also as observed in LIBERTY 1, 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 oral relugolix combination therapy achieved the responder criteria compared with 14.7% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced a highly significant 84.3% reduction in menstrual blood loss from baseline to week 24 ($p < 0.0001$). In addition, a significantly greater proportion of women suffering from moderate-to-severe pain from uterine fibroids at baseline experienced no pain or minimal pain during the last 35 days of treatment with relugolix combination therapy compared with women on placebo ($p < 0.0001$).

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

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

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

LIBERTY Long-Term Extension Study

On February 10, 2020, we announced positive safety and efficacy data from the Phase 3 LIBERTY long-term extension study of once-daily, oral relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids.

In the primary endpoint analysis, 87.7% of women achieved the responder criteria 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. The primary endpoint result in the Phase 3 LIBERTY long-term extension study was consistent with LIBERTY 1 and LIBERTY 2, demonstrating a durability of response through one year. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline at one year.

Changes in bone mineral density through one year, as assessed by DXA every three months, demonstrated maintenance of bone density and were consistent with those in LIBERTY 1 and LIBERTY 2. The adverse events over one year were consistent with those observed in LIBERTY 1 and LIBERTY 2, with no new safety signals. Adverse events reported in more than 10% of women treated with relugolix combination therapy for one-year and more frequently than those reported in the placebo group after 6 months included only hot flashes. There were no pregnancies reported in the relugolix combination therapy group.

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

We initiated a Phase 3 clinical program in June 2017, evaluating relugolix combination therapy in women with pain associated with endometriosis. The program consists of two multinational, replicate pivotal clinical studies, which we refer to as SPIRIT 1 and SPIRIT 2. Each study randomized women 1:1:1 to one of three treatment arms. 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 623 and 638 patients in the SPIRIT 2 and SPIRIT 1 studies, respectively. To be enrolled, women must have had a surgical diagnosis of endometriosis in the last 10 years and moderate-to-severe dysmenorrhea (menstrual pelvic pain) and non-menstrual pelvic pain.

Eligible women who completed the SPIRIT 1 or SPIRIT 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 80-week period, resulting in a total treatment period of up to 104 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment. We currently expect to announce one-year efficacy and safety data from the SPIRIT extension study in the first quarter of calendar year 2021.

The co-primary efficacy endpoints for the SPIRIT 1 and SPIRIT 2 studies were the proportion of all women enrolled with reductions in both dysmenorrhea and non-menstrual pelvic pain, as assessed by an endometriosis-specific patient questionnaire based on the Numerical Rating Scale (“NRS”) completed daily on an electronic patient diary, with no increase in background pain medication. The NRS is an 11-point scale with 0 representing “no pain” and 10 representing “the worst pain you can imagine.” Secondary endpoints included additional questionnaires assessing functional changes associated with endometriosis-specific pain and quality of life, and the use of pain medications to treat endometriosis, including opioid medications. Safety, including bone mineral density changes as measured by DXA, was also assessed.

On April 22, 2020 and June 23, 2020, we announced top-line results from the SPIRIT 2 study and SPIRIT 1 study, respectively.

SPIRIT 1

On June 23, 2020, we announced that SPIRIT 1, the second of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with pain associated with endometriosis, met its co-primary efficacy endpoints and all seven key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated and resulted in minimal bone mineral density loss over 24 weeks.

Relugolix combination therapy achieved both co-primary endpoints by demonstrating clinically meaningful pain reductions for 74.5% of women with dysmenorrhea (menstrual pain) and 58.5% of women with non-menstrual pelvic pain, compared to 26.9% and 39.6% of women in the placebo group, respectively (p-values < 0.0001). On average, women receiving relugolix combination therapy had a 73.3% reduction on the 11-point (0 to 10) NRS for dysmenorrhea from 7.3 (severe pain) to 1.8 (mild pain).

All seven key secondary endpoints measured at Week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the Endometriosis Health Profile-30 (EHP-30) pain domain, greater proportions of women not using analgesics (p-values < 0.0001), changes in

mean non-menstrual pelvic pain (p = 0.0002), greater proportions of women not using opioids (p = 0.0005), and changes in mean dyspareunia (painful intercourse) (p = 0.0149).

Relugolix combination therapy was generally well-tolerated with minimal bone mineral density loss over 24 weeks. The overall incidence of adverse events in the relugolix combination and placebo groups was similar (71.2% vs. 66.0%). In the relugolix combination therapy group, 3.8% of women had adverse events leading to discontinuation of treatment versus 1.9% in the placebo group. The only reported adverse events in at least 10% of women in the relugolix combination group were headache and hot flashes. There was one pregnancy in the relugolix combination group and three in the placebo group.

SPIRIT 2

On April 22, 2020, we announced that SPIRIT 2, the first of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with pain associated with endometriosis, met its co-primary efficacy endpoints and six key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated including minimal bone mineral density loss over 24 weeks.

In the co-primary endpoint analysis of SPIRIT 2, 75.2% of women receiving once-daily oral relugolix combination therapy achieved a clinically meaningful reduction in dysmenorrhea versus 30.4% of women in the placebo group (p < 0.0001). For non-menstrual pelvic pain, relugolix combination therapy achieved a clinically meaningful reduction in 66.0% of women versus 42.6% of women in the placebo group (p < 0.0001). On average, women receiving relugolix combination therapy had a 75.1% reduction on the 11-point (0 to 10) NRS for dysmenorrhea from 7.2 (severe pain) to 1.7 (mild pain).

Six key secondary endpoints measured at Week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the Endometriosis Health Profile-30 (EHP-30) pain domain, a greater proportion of women not using opioids (all p-values < 0.0001), changes in non-menstrual pelvic pain (p = 0.0012), and dyspareunia (painful intercourse) (p = 0.0489). An endpoint evaluating change in analgesic use did not achieve statistical significance.

Relugolix combination therapy was generally well-tolerated with minimal bone mineral density loss over 24 weeks. The overall incidence of adverse events in the relugolix combination therapy and placebo groups was similar (80.6% vs. 75.0%). In the relugolix combination therapy group, 5.3% of women discontinued treatment early due to adverse events versus 3.9% in the placebo group. The most frequently reported adverse events, reported in at least 10% of women in the relugolix combination therapy group, were headache, nasopharyngitis, and hot flashes. There were three pregnancies in the relugolix combination therapy group and five in the placebo group.

Bioequivalence Study of Relugolix Combination Therapy and Relugolix Combination Tablet

On July 23, 2019, we announced that a separate clinical study of our relugolix combination tablet met all required and pre-specified criteria for bioequivalence to the two tablets (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) used in our Phase 3 uterine fibroid and endometriosis clinical studies, providing data necessary to include the once-daily dosing regimen of relugolix combination tablet in our NDA and MAA submissions for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis.

Ovulation Inhibition Study

On April 22, 2020, we announced results from an open-label, single-arm ovulation inhibition study consisting of a pre-treatment period to confirm ovulatory status, an 84-day treatment period (three cycles) to assess the effects of relugolix combination therapy on ovulation inhibition, and a post-treatment follow-up period to determine the time to the return of ovulation. Ovulation inhibition was based on the Hoogland-Skouby scale. In this study, relugolix combination therapy achieved 100% ovulation inhibition in 67 healthy women with no women ovulating during the 84-day treatment period, as evaluated by the Hoogland-Skouby assessment scale (score < 5). Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment with an average time to ovulation of 23.5 days.

In July 2020, we presented data from the ovulation inhibition study and additional data from the LIBERTY program showing improvement in patient-reported outcomes and in hemoglobin levels in women with anemia during the European Society of Human Reproduction and Embryology (“ESHRE”) virtual 36th Annual Meeting.

Our Phase 3 Program for the Treatment of Advanced Prostate Cancer

We initiated a Phase 3 clinical study in March 2017, evaluating the safety and efficacy of relugolix monotherapy in men with advanced prostate cancer, which we refer to as the HERO study. The HERO study randomized 934 men with advanced prostate cancer who required medical therapy to lower testosterone serum levels, also known as androgen deprivation therapy, 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 study with a single relugolix arm to gain approval for relugolix in men with advanced prostate cancer in the U.S. Nonetheless, we designed the study 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.

We enrolled 934 men in the HERO study for the primary endpoint analysis. To be enrolled, men must have had advanced prostate cancer that required androgen deprivation therapy for at least 48 weeks and included prostate cancer defined as biochemical or clinical relapse, advanced localized disease or newly diagnosed metastatic disease. Screening PSA was > 2.0 ng/mL and serum testosterone levels within the normal range. We filed an amendment to the HERO study protocol to enroll 139 additional men with metastatic prostate cancer and to add 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, that completed enrollment in July 2019. We believe that relugolix, a direct GnRH receptor antagonist, has the potential to delay the time to castration-resistant disease as compared with leuprolide, an LHRH agonist, because relugolix more rapidly suppresses testosterone and PSA and more fully suppresses FSH than leuprolide. We currently expect to report additional data from the HERO study measuring castration resistance-free survival in the cohort of 434 men with metastatic prostate cancer, comprising 295 men from the original HERO study and the additional cohort of 139 men, in the third quarter of calendar year 2020. We may conduct additional clinical studies to further support the commercial potential of relugolix in prostate cancer in the U.S. and other major markets.

The primary efficacy endpoint for HERO accepted by the FDA was testosterone suppression (< 50 ng/dL) from week 5, day 1 through week 48, day 7. Relugolix monotherapy was required to demonstrate that the lower bound of the 2-sided 95% confidence interval for the percent of patients achieving testosterone suppression through 48 weeks was at least 90%. Testosterone suppression is an approvable endpoint in the U.S. and several hormonal therapies have been approved based on this endpoint. The secondary endpoints included rapid suppression of testosterone at Day 4 and Day 15, profound suppression of testosterone at Day 15, rapid suppression of PSA at Day 15, and suppression of FSH at Week 24. Testosterone recovery was also evaluated in a subset of men eligible to discontinue ADT at the completion for the 48-week study treatment.

On November 19, 2019, we announced that the Phase 3 HERO study evaluating the safety and efficacy of once-daily, oral relugolix monotherapy over 48 weeks in 934 men with advanced prostate cancer met its primary efficacy endpoint with 96.7% (95% CI: 94.9%, 97.9%) of men achieving sustained testosterone suppression to castrate levels. The study also met all tested key secondary endpoints, while demonstrating 54% fewer major adverse cardiovascular events as compared with leuprolide injections administered every 3 months. Men in the relugolix group had a 54% lower risk of major adverse cardiovascular events compared to men in the leuprolide acetate group (2.9% vs. 6.2%, respectively). Additionally, in men with a history of these events, the relugolix group had 80% fewer major adverse cardiovascular events reported compared to the leuprolide acetate group (3.6% vs. 17.8%, respectively). More than 90% of men in the HERO study had at least one cardiovascular risk factor, including lifestyle risk factors such as tobacco use and obesity, comorbidities such as diabetes and hypertension, and prior history of a major adverse cardiovascular event.

The five key secondary endpoints also demonstrated superiority to leuprolide acetate, including rapid suppression of testosterone at Day 4 and Day 15, profound suppression of testosterone at Day 15, rapid suppression of PSA at Day 15, and suppression of FSH at Week 24 (all p-values < 0.0001). In addition, relugolix demonstrated non-inferiority to leuprolide acetate on sustained testosterone suppression through 48 weeks (96.7% vs. 88.8%, respectively) with a between-group difference of 7.9% (95% CI: 4.1%, 11.8%), the primary endpoint required for regulatory submissions outside of the U.S. Superiority to leuprolide was also achieved as the lower bound of the 95% confidence interval for the between-group difference was greater than 0 (p-value < 0.0001). In addition, the pharmacodynamic results showed no testosterone flare after initiation of relugolix and mean testosterone levels returned to normal levels within 90 days after treatment discontinuation in a subset of 184 patients.

The overall incidence of adverse events in the relugolix and leuprolide acetate groups was comparable (92.9% vs. 93.5%, respectively). In the relugolix group, 3.5% of men discontinued the study early due to adverse events compared with 2.6% of men in the leuprolide acetate group. The most frequently reported adverse events, reported in at least 10% of men in the relugolix group, were hot flashes, fatigue, constipation, diarrhea, and arthralgia (defined as pain in a joint). Major adverse cardiovascular events were reported in 2.9% of men in the relugolix group versus 6.2% of men in the leuprolide acetate group in a prespecified safety analysis. These events included non-fatal myocardial infarction, non-fatal stroke, and all-cause mortality and were not adjudicated.

In May 2020, efficacy and safety data from the Phase 3 HERO study were simultaneously published in the *New England Journal of Medicine* and presented at the American Society of Clinical Oncology (“ASCO”)'s ASCO20 Virtual Scientific

Program. In July 2020, these data were also presented in an oral presentation during the American Urological Association (“AUA”)'s 2020 Virtual Experience. Detailed secondary endpoint data showed notable differences in the rapid and profound suppression of testosterone, PSA response, and testosterone recovery after discontinuation of treatment. In the relugolix group, testosterone suppression to less than 50 ng/dL was achieved in 56.0% of men by Day 4 and 98.7% by Day 15, compared to 0.0% by Day 4 and 12.1% by Day 15 for men in the leuprolide acetate group. Additionally, in the relugolix group, profound testosterone suppression to less than 20 ng/dL was achieved in 78.4% of men at Day 15, compared to 1.0% at Day 15 for men in the leuprolide acetate group. A higher proportion of men in the relugolix group achieved a 50% reduction in PSA by Day 15 and confirmed at Day 29 compared to those in the leuprolide acetate group (79.4% vs. 19.8%, respectively). Within 90 days of treatment discontinuation, 54% of men in the relugolix group achieved normal testosterone levels (≥ 280 ng/dL) with a mean testosterone level of 288.4 ng/dL, compared to 3% of men in the leuprolide acetate group with a mean testosterone level of 58.6 ng/dL.

On April 21, 2020, we announced the submission of an NDA to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer. In June 2020, the FDA accepted for Priority Review this NDA, setting a target action date of December 20, 2020. In its acceptance letter, the FDA also stated that it is currently not planning to hold an advisory committee meeting for this application. If approved, relugolix would be the first and only oral GnRH receptor antagonist treatment for men with advanced prostate cancer.

MVT-602

As part of our license agreement with Takeda, we acquired the worldwide rights to MVT-602, our second product candidate, which previously had 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.

In October 2018, we presented data from a Phase 1 study of MVT-602 at the American Society of Reproductive Medicine 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 LH concentrations and expected effects on FSH 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 LH concentrations and expected post-dose increases in FSH 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 and Embryology in Vienna, Austria in June 2019. The study demonstrated that MVT-602 was generally well-tolerated and produced the desired LH surge associated with high and dose-dependent rates of ovulation in healthy women following a minimal controlled ovarian stimulation protocol. This study provides 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 product 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 combination tablet, relugolix monotherapy tablet, MVT-602, or a potential future product candidate. Our revenue to date has been solely derived from the upfront and regulatory milestone payments we received from Richter under the Development and Commercialization Agreement.

Research and Development Expenses

Our R&D expenses to date have been primarily limited to the clinical development of our product candidates including the conduct of multiple Phase 3 and earlier clinical studies, the expansion of our team, and the initiation of activities in preparation for our anticipated commercial launches such as the establishment of our medical affairs function, as well as regulatory and certain manufacturing activities. Our R&D expenses include program-specific costs, as well as costs that are not allocated to a specific program.

Program-specific costs primarily include third-party costs, which include expenses incurred under agreements with contract research organizations ("CROs") and contract manufacturing organizations ("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 and clinical studies, as well as costs related to manufacturing activities in connection with preparations for our anticipated commercial launches and regulatory submissions for relugolix combination tablet and relugolix monotherapy tablet, 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 including clinical operations, biostatistics, regulatory, and medical affairs, and the cost of contractors and consultants who assist with R&D activities not specific to a program.

R&D activities have been, and will continue to be, central to our business model. Product candidates in later stages of clinical development, such as relugolix, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical studies. We expect our overall R&D expenses to continue to be a significant area of spend, but with the completion of our Phase 3 HERO, LIBERTY, and SPIRIT studies and the submission of our NDAs for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer and relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids, we expect our overall R&D expenses to decrease. However, we expect the decreases in Phase 3 clinical study expenses will be partially offset by increases in other R&D expenses as we prepare additional regulatory submissions for our product candidates, conduct additional clinical studies such as the LIBERTY randomized withdrawal study and SPIRIT long-term extension study, establish a medical affairs function, and incur manufacturing expenses in connection with preparations for our anticipated commercial launches of relugolix combination tablet and relugolix monotherapy tablet.

The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors that include, but are not limited to: the number of studies required for approval; the per patient study costs; the number of patients who participate in the studies; the number of sites included in the studies; the countries in which the studies 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 drug doses that patients receive; the drop-out or discontinuation rates of patients; the potential additional safety monitoring or other studies requested by regulatory agencies; the duration of patient follow-up; the timing and receipt of regulatory approvals; the costs of clinical study materials; and the efficacy and safety profile of the product candidate.

In addition, the probability of success for relugolix combination tablet, relugolix monotherapy tablet, MVT-602 and any other product candidates, if approved, will depend on numerous factors, including competition, manufacturing capability and commercial viability. As a result, we are unable to determine with certainty to what extent we will generate product revenue from commercialization and sale of any of our product candidates that receive regulatory approval. 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

G&A expenses consist primarily of personnel costs, such as salaries, benefits, share-based compensation and travel expenses for our executive, finance, human resources, legal, commercial operations and other administrative functions. G&A expenses also include expenses incurred under agreements with third parties relating to legal, accounting, auditing and tax services, rent and facilities costs, information technology costs, commercial operations, and general overhead.

We expect that our G&A expenses will increase in future periods primarily driven by the anticipated organizational growth to support our commercial readiness activities and commercial launch if our product candidates are approved. 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 facilities-related costs. In particular, we expect to incur increased costs associated with establishing sales, marketing, and commercialization functions in advance of potential regulatory approvals and commercialization of our product candidates. If relugolix combination tablet, relugolix monotherapy tablet, 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 expense related to our previously outstanding debt with Hercules Capital, Inc. ("Hercules") and NovaQuest Capital Management ("NovaQuest"), which we repaid on December 31, 2019, as well as the associated non-cash amortization of debt discounts and issuance costs.

Interest Expense (Related Party)

Interest expense (related party) consists of interest expense pursuant to the Sumitomo Dainippon Pharma Loan Agreement, which bears interest at a rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter. The anticipated increases in our outstanding debt under the Sumitomo Dainippon Pharma Loan Agreement is expected to result in an increase in interest expense (related party) in future periods.

Interest Income

Interest income consists primarily of interest earned on cash and cash equivalents and the accretion of discounts to maturity for marketable securities.

Other Income, Net

Other income, net consists of the impact of changes in foreign currency exchange rates on our foreign exchange denominated liabilities. 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 liabilities.

Results of Operations

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,	
	2020	2019
License and milestone revenue	$ 33,333	$ —
Operating expenses:		
Research and development	44,186	51,117
General and administrative	22,828	14,152
Total operating expenses	67,014	65,269
Loss from operations	(33,681)	(65,269)
Interest expense	—	3,793
Interest expense (related party)	2,184	—
Interest income	(108)	(766)
Other income, net	(3,569)	(705)
Loss before income taxes	(32,188)	(67,591)
Income tax expense	672	313
Net loss	$ (32,860)	$ (67,904)

License and Milestone Revenue

License and milestone revenue for the three months ended June 30, 2020 was $33.3 million and represents the partial recognition of revenue associated with the $40.0 million upfront payment and a $10.0 million regulatory milestone payment under the Richter Development and Commercialization Agreement. We recognize revenue as we satisfy our combined performance obligation to Richter. There were no such amounts in the comparable prior year period.

Research and Development Expenses

For the three months ended June 30, 2020 and 2019, our R&D expenses consisted of the following (in thousands):

	Three Months Ended June 30,		
	2020	2019	Change
Program-specific costs:			
Relugolix	$ 25,893	$ 39,106	$ (13,213)
MVT-602	224	820	(596)
Unallocated costs:			
Share-based compensation	4,024	2,548	1,476
Personnel expense	11,836	7,279	4,557
Other expense	2,209	1,364	845
Total R&D expenses	$ 44,186	$ 51,117	$ (6,931)

R&D expenses decreased by $6.9 million, to $44.2 million, in the three months ended June 30, 2020 compared to $51.1 million in the three months ended June 30, 2019. The decrease in R&D expenses for three months ended June 30, 2020 reflects a decrease in clinical study costs as a result of the completion and wind down of our Phase 3 LIBERTY, HERO, and SPIRIT studies. This decrease was partially offset by an increase in other R&D expenses related predominantly to regulatory activities in connection with regulatory submissions for relugolix combination tablet and relugolix monotherapy tablet, including fees related to our NDA submissions for relugolix combination tablet for heavy menstrual bleeding associated with uterine fibroids and relugolix monotherapy tablet for advanced prostate cancer, expenses associated with the build out of our medical affairs organization in connection with preparations for our anticipated commercial launches, as well as an increase in personnel expenses.

R&D expenses for the three months ended June 30, 2020 consisted primarily of program-specific costs composed of CRO, drug supply and other study, regulatory, and manufacturing related costs of $20.3 million, personnel expenses of $11.8 million, fees related to our NDA submissions for relugolix combination tablet for heavy menstrual bleeding associated with uterine fibroids and relugolix monotherapy tablet for advanced prostate cancer of $5.8 million, share-based compensation expense of $4.0 million, and other R&D costs of $2.2 million, which primarily includes contractors, consultants, and information technology costs.

R&D expenses in the three months ended June 30, 2019 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.

General and Administrative Expenses

G&A expenses increased by $8.7 million, to $22.8 million, in the three months ended June 30, 2020 compared to $14.2 million in the three months ended June 30, 2019, primarily due to increases in expenses related to commercial operations activities in advance of potential future regulatory approvals of relugolix combination tablet and relugolix monotherapy tablet, personnel expenses, and other general overhead, administrative, and information technology expenses to support our organizational growth.

G&A expenses in the three months ended June 30, 2020 consisted primarily of personnel expenses of $7.6 million, commercial operations expenses of $5.6 million, share-based compensation expense of $3.8 million, general overhead, administrative and information technology expenses of $3.5 million, professional service fees of $1.3 million, and rent and other facilities-related costs of $0.8 million.

G&A expenses in the three months ended June 30, 2019 consisted primarily of personnel expenses of $3.9 million, share-based compensation expense of $3.9 million, general overhead, administrative and information technology expenses of $3.2 million, professional service fees of $1.4 million, commercial operations expenses of $1.1 million, and rent and other facilities-related costs of $0.5 million.

Interest Expense

Interest expense was $2.2 million in the three months ended June 30, 2020, related to the Sumitomo Dainippon Pharma Loan Agreement, compared to $3.8 million in the three months ended June 30, 2019, related to our previously outstanding financing arrangements with NovaQuest and Hercules. The decrease in interest expense was driven by lower interest rates associated with

the Sumitomo Dainippon Pharma Loan Agreement as compared to the previously outstanding obligations to NovaQuest and Hercules, which were repaid in December 2019. We expect our interest expense to increase in future periods as a result of further anticipated draws under the Sumitomo Dainippon Pharma Loan Agreement.

Interest Income

Interest income decreased by $0.7 million, to $0.1 million for the three months ended June 30, 2020 compared to $0.8 million for the three months ended June 30, 2019. The decrease was primarily due to decreases in interest rates and lower balances in cash equivalents and marketable securities relative to the prior year period.

Other Income, Net

For the three months ended June 30, 2020, we recorded a foreign exchange gain of $3.6 million, and for the three months ended June 30, 2019, we recorded a foreign exchange gain of $0.7 million. This increase was primarily the result of a foreign currency exchange gain on our outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement.

Income Tax Expense

Our income tax expense was $0.7 million and $0.3 million for the three months ended June 30, 2020 and 2019, respectively. Our effective tax rate for the three months ended June 30, 2020 and 2019 was (2.09)% and (0.46)%, 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

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares and from debt financing arrangements. As of June 30, 2020, we had cash, cash equivalents, marketable securities, and committed funding available to us of $306.0 million, consisting of $99.7 million of cash, cash equivalents, and marketable securities and $206.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Agreement, as compared to cash, cash equivalents, marketable securities, and committed funding available to us of $365.9 million, consisting of $79.6 million of cash, cash equivalents, and marketable securities and $286.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement as of March 31, 2020. Additional funds under the Sumitomo Dainippon Pharma Loan Agreement may be drawn down by us no more than once per calendar quarter, subject to certain terms and conditions, including consent of our board of directors. In July 2020, we borrowed an additional $60.0 million under the Sumitomo Dainippon Pharma Loan Agreement. For additional information about the Sumitomo Dainippon Pharma Loan Agreement, see Note 5(A) to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. On August 5, 2020, we obtained an incremental $200.0 million, low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma.

Pursuant to the Richter Development and Commercialization Agreement, we received an upfront payment of $40.0 million in March 2020, and are eligible to receive up to $40.0 million in regulatory milestones (of which $10.0 million was received in April 2020), up to $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval.

As of June 30, 2020, 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, 2020 and 2019, we had net losses of $32.9 million and $67.9 million, respectively. As of June 30, 2020, we had an accumulated deficit of $823.9 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 combination tablet and relugolix monotherapy tablet. We have not generated any product revenue to date and do not expect to generate product revenue unless and until we 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 studies, anticipated regulatory filings, pre-commercialization efforts and our expenditures on other R&D and G&A activities.

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

- submit NDAs and other regulatory filings for our product candidates;

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

Our primary use of cash has been to fund the development of relugolix combination therapy, relugolix monotherapy, 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 combination tablet and relugolix monotherapy tablet. In addition, we expect that our outstanding debt levels will increase in future periods, which will result in an increase in our quarterly interest payment obligations.

Based on our current operating plan, we expect that our cash, cash equivalents, marketable securities and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of our fiscal year ending March 31, 2021. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our current cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement will not be sufficient to enable us to complete all necessary development and regulatory activities and commercially launch relugolix combination tablet or relugolix monotherapy tablet. We anticipate that we will continue to incur net losses and negative operating cash flows for the foreseeable future.

To continue as a going concern, we will need, among other things, additional capital resources. We continually assess multiple options to obtain additional funding to support our operations, including through financing activities in public or private capital markets. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Although we expect to draw under the Sumitomo Dainippon Pharma Loan Agreement on a quarterly basis, such draws are contingent upon the consent of our board of directors. If Sumitomo Dainippon Pharma fails to own at least a majority of our common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to us, in which case we would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. ASC 240-40, *Going Concern*, does not allow us to consider future financing activities that are uncertain in our assessment of our future cash burn for the purpose of our liquidity assessment. Due to these uncertainties, there is substantial doubt about our ability to continue as a going concern. If we are unable to raise capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back, or discontinue operations. On August 5, 2020, we obtained an incremental $200.0 million, low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma.

Until such time, if ever, as we can generate substantial product revenue from sales of relugolix combination tablet, relugolix monotherapy tablet, MVT-602, or any future product candidate, we expect to fund our operations through a combination of cash, cash equivalents, and marketable securities currently on hand, equity offerings, debt financings, structured transactions such as royalty financings, collaboration, license or development agreements, or other collaborations, as well as quarterly draws under the Sumitomo Dainippon Pharma Loan Agreement, subject to the consent of our board of directors. 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. The Sumitomo Dainippon Pharma Loan Agreement involves, 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, raising capital through equity offerings, 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, 2020 and 2019 (in thousands):

	Three Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (61,984)	$ (66,811)
Net cash used in investing activities	$ (12,124)	$ (139)
Net cash provided by financing activities	$ 82,190	$ 137,610

Operating Activities

For the three months ended June 30, 2020, we used $62.0 million in operating activities primarily due to our ongoing development and clinical studies, activities related to our preparation for potential regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet, and the expansion of our company. This was primarily attributable to a net loss for the period of $32.9 million, decreases of $9.9 million in accounts payable due to the timing of vendor invoice payments and $23.3 million in deferred revenue consisting of the recognition of $33.3 million of previously deferred revenue, partially offset by an increase in deferred revenue of $10.0 million related to a regulatory milestone payment we received from Richter in April 2020, and a non-cash foreign currency transaction gain of $3.6 million related to the Sumitomo Dainippon Pharma debt outstanding. These amounts were partially offset by $7.8 million of non-cash share-based compensation expense and $0.6 million of total depreciation and amortization expense.

For the three months ended June 30, 2019, we used $66.8 million in operating activities primarily due to our ongoing development and clinical studies 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 along with a decrease of $7.5 million in accrued expenses resulting primarily from a decrease in accrued R&D expenses and accrued compensation-related expenses and a decrease of $1.0 million in accounts payable due to the timing of vendor invoice payments. These amounts were partially offset by a decrease of $1.5 million in prepaid expenses and other current assets, an increase of $1.5 million in deferred interest payable related to our prior debt with NovaQuest, $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.

Investing Activities

For the three months ended June 30, 2020, we used $12.1 million in investing activities, of which $12.0 million was for the purchase of marketable securities, net of maturities, and $0.2 million was for the purchase of property and equipment.

For the three months ended June 30, 2019, we used $0.1 million in investing activities for the purchase of property and equipment.

Financing Activities

For the three months ended June 30, 2020, $82.2 million was provided by financing activities. This was primarily due to proceeds of $80.0 million borrowed under the Sumitomo Dainippon Pharma Loan Agreement and proceeds of $2.2 million from the exercise of stock options under our 2016 Equity Incentive Plan.

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 and $2.5 million we received from the sale of 106,494 common shares through our “at-the-market” equity offering program. In addition, we received proceeds of $0.3 million from the exercise of stock options under our 2016 Equity Incentive Plan.

Contractual Obligations

During the three months ended June 30, 2020, 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, 2020, other than additional draws under the Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A) to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

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 revenues and expenses during the reporting periods. We base our estimates on historical experience and on various other information available to us at the time we make the estimates and judgments that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known.

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

Our critical accounting policies are more fully described in "Critical Accounting Policies and Significant Judgments and Estimates" in Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020, filed with the SEC on May 18, 2020. 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.

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

Under SEC rules and regulations, because we are considered to be a “smaller reporting company,” we are not required to provide information in this Item 3.

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. No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2020 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 Financial Position and Capital Requirements

We believe our current cash, cash equivalents, marketable securities, and current borrowing capacity under our Sumitomo Dainippon Pharma Loan Agreement will not be sufficient for us to fund our anticipated level of operations until we become cash flow positive. If we fail to obtain additional capital, including from the potential additional capital we may obtain from Sumitomo Dainippon Pharma as described in its 2020 Commitment Letter to us, we will not be able to complete the development of, seek regulatory approval for, and commercialize our product candidates.

As of June 30, 2020, we had cash, cash equivalents, marketable securities, and committed funding available to us of $306.0 million consisting of $99.7 million of cash, cash equivalents, and marketable securities and $206.3 million of borrowing capacity available to us under our Sumitomo Dainippon Pharma Loan Agreement for which we can draw upon on a quarterly basis subject to certain terms and conditions, including the consent of our board of directors. In July 2020, we borrowed an additional $60.0 million under this agreement. Based on our current operating plan, we believe that our existing cash, cash equivalents, marketable securities, and borrowing capacity currently available to us under the Sumitomo Dainippon Pharma Loan Agreement will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of our fiscal year ending March 31, 2021. 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. We anticipate that we will continue to incur net losses and negative operating cash flows for the foreseeable future.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our product candidates. 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 studies for our product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by 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, including securing regulatory approval for commercial production;
- 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 and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement will not be sufficient to enable us to complete all necessary development and regulatory activities and commercially launch relugolix combination tablet or relugolix monotherapy tablet. 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 required to delay, limit, reduce, or terminate our drug development programs, commercialization efforts, and/or limit or cease our operations if we are unable to obtain additional capital, including from the potential additional capital Sumitomo Dainippon Pharma may provide to us as described in its 2020 Commitment Letter to us described below, 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 are required to meet certain terms and conditions to draw down funds under the Sumitomo Dainippon Pharma Loan Agreement. If we are unable to meet such terms and conditions, we may not be able to access funding from the Sumitomo Dainippon Pharma Loan Agreement.

On December 27, 2019, we, one of our subsidiaries and Sumitomo Dainippon Pharma entered into the Sumitomo Dainippon Pharma Loan Agreement, pursuant to which Sumitomo Dainippon Pharma agreed to make revolving loans to us in an aggregate principal amount up to $400.0 million. As of June 30, 2020, approximately $206.3 million of borrowing capacity remained available to us under the Sumitomo Dainippon Pharma Loan Agreement. In July 2020, we borrowed an additional $60.0 million under this agreement. We may draw down additional funds under the Sumitomo Dainippon Pharma Loan Agreement once per calendar quarter, subject to certain terms and conditions, including the consent of our board of directors and no change of control having occurred with respect to us. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the outstanding common shares of Myovant, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to us, in which case we would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. Furthermore, within 30 days of a change of control having occurred with respect to us, we will be obligated to repay the outstanding amount of loans and accrued interest under the Sumitomo Dainippon Pharma Loan Agreement. We may not be able to meet such terms and conditions in the future and may not be able to secure additional funds.

We may not be able to obtain funding through public or private offerings of our capital shares, debt financings, collaboration or licensing arrangements, or other sources.

As discussed above, our current cash, cash equivalents, marketable securities, and amounts currently available to us under the Sumitomo Dainippon Pharma Loan Agreement will not be sufficient for us to complete all necessary development and regulatory activities and commercially launch our product candidates. Accordingly, we will need to raise additional capital to fund our operations. On August 5, 2020, we obtained a debt commitment letter (the "2020 Commitment Letter") from Sumitomo Dainippon Pharma, pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma has agreed to negotiate with us $200.0 million in unsecured revolving commitments (the "New Credit Facility"), the proceeds of which may be used for our business operating expenditures. Such New Credit Facility would be in addition to the commitments made available to us by Sumitomo Dainippon Pharma under the existing Sumitomo Dainippon Pharma Loan Agreement. Sumitomo Dainippon Pharma will have the discretion to require certain prepayments as Sumitomo Dainippon Pharma may request and/or to not allow us to draw down any remaining funds under the New Credit Facility, upon the occurrence of certain material business development transactions. In addition, as a condition to entering into the New Credit Facility, we are required to enter into an information sharing agreement with Sumitovant which will be on terms to be agreed between Sumitovant and us. The New Credit Facility described in the 2020 Commitment Letter will not be available to us until we negotiate and enter into a definitive agreement with Sumitomo Dainippon Pharma and the New Credit Facility becomes effective. As a result, if the conditions set forth in the 2020 Commitment Letter are not met or unexpected disagreements arise in the negotiations, that may delay or prevent the entering into an agreement and the New Credit Facility may not become effective. We cannot be certain that additional capital, including the potential additional capital Sumitomo Dainippon Pharma may provide to us as set forth in the 2020 Commitment Letter will be available to us on acceptable terms, or at all.

Even if additional capital is available to us, under the terms of the Sumitomo Dainippon Pharma Loan Agreement and the agreement governing the New Credit Facility, we may not raise additional capital without obtaining the consent of Sumitomo Dainippon Pharma. 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 and commercialization 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 and commercialization efforts.

Raising additional funds may cause dilution to existing shareholders and/or may restrict our operations or require us to relinquish proprietary rights.

As discussed above, we will need to raise additional capital to fund our operations. To the extent that we raise additional capital by issuing equity or convertible debt securities, our existing shareholders' ownership interest 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. 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 raising additional capital, 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 expect to incur significant operating losses and negative operating cash flows for the foreseeable future, and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. Since inception, we have incurred significant operating losses and negative operating cash flows. 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 our product candidates. If we obtain regulatory approval for our product candidates, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we may never achieve or maintain profitability.

Risks Related to Our Business Operations

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

We have invested and expect to continue to invest a substantial portion of our efforts and expenditures in the development and advancement of our product candidates, relugolix combination tablet, relugolix monotherapy tablet, and MVT-602. Our ability to generate product revenue and achieve profitability depends heavily on our ability to complete the development of our product candidates, obtain necessary regulatory approvals for, and have our product candidates manufactured and successfully marketed, which may never occur. 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 our product candidates in the U.S. until we receive approval of NDAs or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries.

Obtaining approval of an NDA or similar foreign 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 our product candidates. The process of responding to the FDA information requests in the review process, potentially preparing for and appearing at a public advisory committee and preparing our manufacturers and investigators to successfully complete inspections by the FDA during the approval process requires significant human and financial resources. Despite efforts at compliance, from time to time, we or our partners may receive notices of manufacturing, quality-related, or other observations following inspections by regulatory authorities, as well as official agency correspondence regarding compliance. For example, in June 2020, the FDA issued a warning letter to Takeda following a routine inspection of aseptic finished pharmaceuticals (drug product) manufacturing at Takeda's manufacturing facility located at Takeda 4720, Mitsui, Hikari, Yamaguchi (the "Hikari Facility"). The Hikari Facility is one of two contract manufacturing organizations included in our regulatory filings for the manufacture of relugolix drug substance ("API"). The warning letter indicated that the FDA was not satisfied with Takeda's response to an FDA Form 483 issued to Takeda following the inspection and cited significant violations of cGMP for finished pharmaceuticals. Although API manufacturing was not included in the scope of the FDA's inspection that led to the warning letter, the Hikari Facility is classified under one FDA Establishment Identifier and the facility has a common quality system. We will now procure the commercial relugolix drug substance needed for our anticipated launches solely from Excella GmbH & Co. KG ("Excella"), the second contract manufacturing organization included in our regulatory filings, pursuant to the Commercial Manufacturing and Supply Agreement we have with Excella. Due to the warning letter, we will remove the Hikari Facility as a manufacturing site from our regulatory filings as may be required until Takeda corrects the violations noted in the warning letter to the satisfaction of the regulatory authorities. We cannot predict if or when Takeda will correct the violations

and deviations to the satisfaction of the FDA, EMA or any other regulatory agency or whether the regulatory agencies will be satisfied with Takeda's responses. The COVID-19 pandemic may also cause delays in the remediation and re-inspection process. We also face the risk that Excella or our other contract manufacturing organizations may face adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approval and/or the COVID-19 pandemic. If Excella or our other contract manufacturing organizations fail to fulfill their obligations to manufacture and supply relugolix drug substance and drug product needed for our anticipated launches, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections or other reasons, our development plans and commercialization of relugolix, if approved, could be significantly delayed or otherwise adversely affected.

Even if we receive regulatory approval for our product candidates, our ability to generate product revenues from our product candidates will depend upon the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, whether we own the commercial rights for those territories, and our ability to:

- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- establish effective sales, marketing, and distribution systems in jurisdictions around the world for our product candidates;
- initiate and continue relationships with third-party manufacturers and have adequate commercial quantities of our product candidates manufactured at acceptable cost and quality levels, including maintaining current good manufacturing practice ("cGMP") and Quality Systems Regulation standards required by various regulatory agencies;
- attract and retain experienced management, employees and consultants;
- achieve broad market acceptance of our products in the medical community and with third-party payors and consumers;
- launch commercial sales of our products, whether alone or in collaboration with others;
- establish the safety and efficacy of our product candidates in comparison to competing products, including through differentiated approved labeling; 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.

The terms of the Sumitomo Dainippon Pharma Loan Agreement place restrictions on our operating and financial flexibility.

Our obligations under the Sumitomo Dainippon Pharma Loan Agreement are senior unsecured obligations including customary representations and warranties as well as affirmative and negative covenants, that are guaranteed on a full and unconditional basis by all our subsidiaries.

The negative covenants include limitations on additional indebtedness, liens, certain corporate changes, certain restricted payments, investments transactions with affiliates, entry into certain restrictive agreements, change in the nature of business, and use of proceeds. 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 Sumitomo Dainippon Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties and certain covenants following any applicable cure period, cross acceleration to certain debt, other failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, certain breaches by us under our Investor Rights Agreement with Sumitovant and Sumitomo Dainippon Pharma, dated December 27, 2019 and failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by us or any of our subsidiaries. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Dainippon Pharma may terminate its obligations to make loans to us and declare the principal amount of all outstanding loans and other obligations under the Sumitomo Dainippon Pharma Loan Agreement to become immediately due and payable, and Sumitomo Dainippon Pharma may take such other actions as set forth in the Sumitomo Dainippon Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Dainippon Pharma to make loans to us would automatically terminate and the principal amount of all outstanding loans and other obligations due under the Sumitomo Dainippon Pharma Loan Agreement would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Dainippon Pharma to maintain the loans under the Sumitomo Dainippon Pharma Loan Agreement, we would be required to repay the outstanding principal amount of the loans and if a change of control occurs with respect to us, we would be required to repay the outstanding

principal amount of the loans within 30 days of such change of control. We may not have enough available funds 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. 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 do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of drug substance and drug product and, if they do not perform as we expect, could result in delay in our ability to develop and commercialize our products.

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 contract manufacturing organizations ("CMOs"). In June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited ("Takeda Limited") entered into an agreement for the manufacture and clinical supply of relugolix pursuant to which Takeda Limited supplied us with, and we obtained from Takeda, all of our requirements for relugolix drug substance and drug product that were used under our development plans for all indications. In May 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda pursuant to which Takeda agreed to manufacture and supply us with certain commercial relugolix drug substance quantities. In addition, in April 2019, we entered into a Commercial Manufacturing and Supply Agreement with Excella pursuant to which Excella agreed to manufacture and supply us with certain commercial relugolix drug substance quantities. We listed both Takeda and Excella as contract manufacturing organizations in our regulatory filings for the manufacture of relugolix drug substance.

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

If we need to replace a third-party manufacturer, or if any of our third-party manufacturers experience adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approvals and/or the COVID-19 pandemic, we could experience a significant delay in the supply of a product candidate, which could result in a considerable delay in completing our clinical studies, product testing, and potential regulatory approval of our product candidates. In addition, the commercial launch of our product candidates could be delayed and there could be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the regulatory authorities pursuant to inspections that will be conducted after we submit our regulatory applications to such regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing

partners for compliance with cGMP requirements and other regulations and laws for the manufacture of relugolix drug substance and drug product. 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 and any applications that we submit to the FDA or other regulatory authorities that list those manufacturing facilities may be negatively affected. Our third-party contract manufacturing facilities must also be in an acceptable state of cGMP compliance and not be subject to a cGMP related regulatory or enforcement action that limits their ability to manufacture drug substance or drug product. If any of the drug substance supplied by a contract manufacturing partner cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections or other reasons, our development plans and commercialization of relugolix, if approved, could be significantly delayed or otherwise adversely affected. The FDA or other regulatory authority may withhold approval of any pending regulatory applications or supplements in which non-complaint manufacturing facilities are listed.

In June 2020, Takeda received a warning letter from the FDA which indicated that the FDA was not satisfied with Takeda's response to an FDA Form 483 issued to Takeda following its routine inspection of aseptic finished pharmaceuticals manufacturing at Takeda's Hikari Facility. We now plan to procure the commercial relugolix drug substance needed for our anticipated launches solely from Excella and will remove the Hikari Facility as a manufacturing site from our regulatory filings as may be required until Takeda corrects the violations noted in the warning letter to the satisfaction of the regulatory authorities. We cannot predict if or when Takeda will correct the violations and deviations to the satisfaction of the FDA, EMA or any other regulatory agency or whether the regulatory agencies will be satisfied with Takeda's responses. The COVID-19 pandemic may also cause delays in the remediation and re-inspection process. We also face the risk that Excella or our other contract manufacturing organizations may face adverse developments, including with respect to adverse findings during regulatory inspections, delays in regulatory approval and/or the COVID-19 pandemic. If Excella or our other contract manufacturing organizations fail to fulfill timely their obligations to manufacture and supply relugolix drug substance and drug product needed for our anticipated launches, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections or other reasons, our development plans and commercialization of relugolix, if approved, could be significantly delayed or otherwise adversely affected.

Our product candidates contain highly potent compounds 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 manufacture relugolix combination tablet or relugolix monotherapy tablet;
- failure of the drug substance transferred from a CMO to meet our product specifications and quality requirements;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations, and standards, including cGMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing and quality 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 combination tablet, relugolix monotherapy tablet, 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;
- adverse inspection findings by the FDA or other regulatory authorities at third-party manufacturing facilities and/or failure to remediate such findings;

- cGMP regulatory or enforcement action at our third-party manufacturing facilities that limit their ability to manufacture drug substance or drug product for commercial use;
- 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 study 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 the FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production.

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

We expect to hire additional employees and consultants. The market for talent in our industry is very competitive, especially in the San Francisco Bay Area where we have substantial operations. Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, more favorable risk profiles and a longer operating history in the biopharmaceutical industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. It is particularly difficult to hire new employees during the COVID-19 pandemic as conducting interviews remotely makes it more difficult to ensure we are recruiting and hiring high-quality employees, and the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity.

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. If we lose one or more members of our senior management team or key employees or unable to attract and retain other personnel to accomplish our business objectives, our ability to successfully implement our business strategies could be seriously harmed.

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 our product candidates or any potential future product candidate may be adversely affected.

Our or our affiliates' employees, independent contractors, third-party manufacturers, principal investigators, consultants, commercial collaboration partners, service providers, and other vendors, 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 third-party manufacturers, principal investigators, consultants, commercial collaboration partners, 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 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," and "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., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows." 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 studies, creating fraudulent data in our nonclinical or clinical studies 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.

Business interruptions resulting from effects of pandemics or epidemics such as the novel strain of the coronavirus known as COVID-19, may materially and adversely affect our business and financial condition.

The majority of our employees are located in the U.S., primarily in the San Francisco Bay Area, with the rest of our employees located mainly in Switzerland. Our employees have been subject to "shelter-in-place" orders resulting from the COVID-19 pandemic that require our employees to work from home with limited exceptions. Our business may be negatively impacted from having all employees working remotely. For example, employees may be less efficient given competing priorities with home-schooling or caring for sick family members, and employee engagement and productivity may decrease from the stress of the COVID-19 pandemic resulting in delays in the progress of our business. In addition, we rely on third parties in the U.S. and in various parts of the world to assist in the conduct of our clinical studies and to supply us with sufficient drug supplies. Our ability to ensure continuous clinical drug supply to patients and our ability to ensure continuous patient follow up and data monitoring for our ongoing clinical studies may be adversely impacted. Likewise, while we currently expect that the drug supply we have on hand is sufficient to support our ongoing clinical studies and anticipated commercial launches, our supply chain for raw materials, drug substance and drug product is worldwide, and the continued spread of the coronavirus and the duration of its impact on the ability of our suppliers to operate could negatively impact our manufacturing supply chain for relugolix combination tablet and relugolix monotherapy tablet. If disruptions to our supply chain persist for an extended period of time, our clinical study timelines, our financial condition and our results of operations may be negatively impacted.

In order to successfully commercialize our product candidates, we need to continue to expand our capabilities, including the hiring of qualified employees, engage potential prescribers in scientific exchange, build commercial infrastructure, conduct market research, develop promotional campaigns and resources, and engage payers in scientific exchange to demonstrate the value of our products and negotiate favorable contracts. The COVID-19 pandemic is making this work more difficult and may result in delays. Conducting interviews remotely makes it more difficult to ensure we are recruiting and hiring high-quality employees, and the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity. Our medical affairs team needs to ensure our scientific data are presented and published and our regional medical advisors need to engage potential prescribers in scientific exchange. Multiple medical conferences have been canceled and postponed resulting in fewer opportunities to present our scientific data and our medical affairs team members can only communicate virtually making it more difficult to educate and engage in scientific exchange. Travel restrictions may make it more difficult for us to maximize the potential of our third-party market access, marketing and distribution capabilities, such as our relationships with Sunovion and Richter and provide adequate collaboration and oversight. The COVID-19 pandemic may negatively impact our ability to attract the human resources required to build out our commercial capabilities and may negatively impact our ability to rapidly and effectively educate potential prescribers and payers and, if significant delays result, commercialize our product candidates. The extent to which the coronavirus and global efforts to contain its spread will impact our operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the coronavirus outbreak. In addition, the current COVID-19 pandemic may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

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., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows.

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the U.S., and establishing and maintaining relationships with healthcare providers, payors, government officials, distributors, manufacturers and other third parties globally in case any of our product candidates is approved for marketing outside of the U.S.

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, immigration and labor laws, privacy and cybersecurity laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- 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, pricing and insurance 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 or no protection over intellectual property rights;
- business interruptions resulting from geopolitical actions, economic instability, or natural disasters, including, but not limited to, wars and terrorism, economic weakness, inflation, political instability in particular foreign economies and markets, boycotts, curtailment of trade, labor disputes, unexpected changes in tariffs, and other business restrictions, outbreak of disease (such as the COVID-19 pandemic), fires, earthquakes, hurricane, tornado, severe storm, power outage, system failure, typhoons or floods;
- 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 (the "GDPR") which introduced strict requirements for processing personal data of individuals within the EU;
- 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;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

Any of these risks, if encountered, could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows. We have no prior experience in certain countries, and many biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

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

On January 31, 2020, the U.K. withdrew from the EU. The U.K.'s withdrawal from the EU is commonly referred to as Brexit. Under the withdrawal agreement agreed between the U.K. and the EU, the U.K. will be subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules will continue to apply. During the Transition Period, negotiations between the U.K. and the EU are expected to continue in relation to the future customs and trading relationship between the U.K. and the EU following the expiration of the Transition Period. Due to the current COVID-19 global pandemic, negotiations between the U.K. and the EU scheduled for March, April and May have either been postponed or occurring in a reduced forum via video conference. There is, therefore, an increased likelihood that the Transition Period may need to be extended beyond December 31, 2020 (although it remains the position of the U.K. government that it will not be extended).

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and certain of our product candidates are derived from EU directives and regulations, Brexit following the Transition Period could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process

for authorization of drug products, including certain of our product candidates, will be required in the U.K., the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of certain of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles.

If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. or the EU for certain of our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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

Our computer systems, as well as those of our CROs, CMOs, third-party collaboration partners, and other contractors, consultants, and law and accounting firms, may sustain damage or data leakage from computer viruses, unauthorized access or disclosure, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, and telecommunication and electrical failures. We rely on our third-party providers to implement effective security and data recovery measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical study data from completed, ongoing or planned clinical studies 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, access or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, suffer reputational damage, and the further development of any current or future product candidate could be delayed.

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, the California enacted the California Consumer Privacy Act (“CCPA”) took 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 study 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 studies 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 has 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.

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

We have implemented and continue to optimize a company-wide enterprise resource planning ("ERP") system to upgrade certain existing business, operational, and finance processes and to ensure our operations are adequately scalable in support of our anticipated commercial launches. ERP implementations are complex and time-consuming projects that require transformations of business, operational, and finance processes. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations. The implementation of the ERP system has required, and will continue to require, the investment of significant financial and human resources.

Any disruptions, delays, or deficiencies in the design or the ongoing maintenance and optimization of the ERP system could adversely affect our ability to accurately maintain our books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if the ERP system does not operate as intended, the effectiveness of our internal controls over financial reporting could be adversely affected and could cause us to fail to comply with the SEC reporting obligations related to our management's assessment of our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business following the implementation or optimization of the ERP system, our business and results of operations could be harmed.

The phase-out of the London Interbank Offered Rate ("LIBOR") or the replacement of LIBOR with a different reference rate, may adversely affect interest rates.

On July 27, 2017, the Financial Conduct Authority (the authority that regulates LIBOR) announced that it would phase out LIBOR by the end of 2021. It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021, or if alternative rates or benchmarks will be adopted. The interest rate under the Sumitomo Dainippon Pharma Loan Agreement is, and the interest under the New Credit Facility is expected to be, calculated based on LIBOR and, when this occurs, we may need to agree with Sumitomo Dainippon Pharma to a new method of calculating the interest rate under the Sumitomo Dainippon Pharma Loan Agreement and, if entered into, the New Credit Facility, which we may not be able to do. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates and result in higher borrowing costs. This could materially and adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the potential changes to LIBOR or the establishment and use of alternative rates or benchmarks.

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

The use of any of our product candidates in clinical studies 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, healthcare 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 in which 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 studies;

- 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 study insurance we currently carry, and any additional product liability and clinical study 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 any of our product candidates, 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.

Use of social media platforms presents risks of inappropriate or harmful disclosures which could harm our business.

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.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

Clinical studies are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes. Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We cannot predict with any certainty the timing for commencement or completion of current or future clinical studies.

Any product candidate 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. Human clinical studies 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 studies of relugolix combination therapy, relugolix monotherapy or MVT-602, which may delay the approval of an NDA or similar application. The clinical study process is also very time-consuming. The commencement and completion of clinical studies may be delayed by several factors, including:

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

- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols, including missed assessments or impeded access to study sites due to government or institutional stay-at-home or shelter-in-place measures during the COVID-19 pandemic;
- premature discontinuation of study participants from clinical studies or missing data, including from patients unable to come to study visits during the COVID-19 pandemic;
- 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 studies;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of study patients or study results.

Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We, the FDA or an institutional review board ("IRB") or other regulatory authority may suspend our clinical studies at any time if it appears that we or our collaborators are failing to conduct a clinical study in accordance with regulatory requirements, including, the FDA's current Good Clinical Practices ("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 ("IND") or other submissions or the manner in which the clinical studies are conducted. In addition, product candidates in later stages of clinical development may fail to show the desired safety and efficacy outcomes despite having progressed successfully through prior stages of preclinical and clinical testing. Results from clinical studies may require further evaluation, delaying the next stage of clinical development or submission of an NDA. Therefore, we cannot predict with any certainty the timing for commencement or completion of current or future clinical studies. If we experience delays in the commencement or completion of our clinical studies, or if we terminate a clinical study prior to completion, the commercial prospects of any product candidates could be harmed, and our ability to generate product revenue from any product candidates may be delayed. In addition, any delays in our clinical studies 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 studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Moreover, principal investigators for our clinical studies 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 study site and the utility of the clinical study itself may be jeopardized. Clinical study sites, CROs and manufacturing sites may be inspected for compliance with cGCP or cGMP. Any questions about data integrity or significant quality issues 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.

We are dependent on the research and development of relugolix and MVT-602 previously conducted by Takeda, and if Takeda did not conduct this research and development in compliance with applicable requirements this could result in increased costs and delays in our development of these product candidates.

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 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 studies 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 studies 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 nonclinical 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 studies 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 studies 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 studies. Enrollment in our clinical studies may be slower than we anticipated, leading to delays in our development timelines. Patient enrollment and retention in clinical studies depends on many factors, including the size of the patient population, the nature of the study protocol, our ability to recruit clinical study 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 studies 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 studies will drop out of the studies before completion. In addition, unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as the COVID-19 pandemic, in or around the countries in which we conduct our clinical studies, could delay the commencement or rate of completion of our clinical studies. Furthermore, any negative results we, Takeda or Richter may report in clinical studies of our product candidates may make it difficult or impossible to recruit, enroll, and retain patients in other clinical studies 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 studies. 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 studies, delaying or potentially preventing us from completing clinical studies. 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 our product candidates, or could render further development impossible.

The results of our clinical studies may not support our proposed claims for our product candidates. The results of previous clinical studies may not be predictive of future results, and interim or top-line data may be subject to change or qualification based on the complete analysis of data.

Even if our clinical studies are completed as planned, we cannot be certain that their results will support the efficacy or safety of our product candidates. For example, product candidates may not meet the criteria for success for their 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 study. Success in nonclinical testing and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the results of later clinical studies will replicate the results of prior clinical studies and nonclinical testing. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical study as a whole will be successful. In addition, the FDA may not agree that clinical study results are sufficient for approval for any product candidate, or even if approved, may not support a label that is capable of competing with existing treatments. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical studies, 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. Positive results from any of our clinical studies may not be predictive of the results of any of our other ongoing and potential future clinical studies, 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. 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, audit and verification of the data related to the particular study. 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.

A future failure of a clinical study 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 studies 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 our product candidates 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 studies in Japan in women with uterine fibroids and has 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 studies will also be favorable as the designs of our clinical studies differ from those of Takeda. Further, if clinical study 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. We cannot provide assurance that the FDA or other health authorities will allow us to use the data from Takeda's clinical studies in support of any NDA or marketing authorization application that we may submit, and such data may be interpreted differently by the regulatory authorities and provide contradictory evidence in support of FDA's (or other regulatory authority) evaluation. If the FDA or other regulatory authorities do not allow us to use the data from Takeda's clinical studies, we may be required to perform additional clinical studies.

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. Further, it is likely that additional drugs are being developed or 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 combination tablet and relugolix monotherapy tablet 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 and 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. 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. Competition may reduce the number and types of patients available to us to participate in our clinical studies, because some patients who might have opted to enroll in our studies may instead opt to enroll in a study being conducted by one of our competitors or opt to take an approved product. 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. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors.

The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain required regulatory approvals, we will not be able to commercialize relugolix combination tablet, relugolix monotherapy tablet, or MVT-602, and our ability to generate product revenue will be materially impaired.

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 studies and depends upon numerous factors, including the substantial discretion of the regulatory authority. 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. Obtaining approval of an NDA from the FDA or a regulatory approval from a regulatory authority outside the U.S. is an expensive process. The submission of NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees. We may incur additional costs in the fiscal year 2020 with the anticipated submission of NDAs to the FDA, including the fees associated with NDA and foreign equivalent submissions.

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 combination tablet, relugolix monotherapy tablet, and MVT-602 for the specified indication. The process of responding to the FDA information requests in the review process and preparing for and appearing at a public advisory committee will require significant human and financial resources. If the information from our completed clinical studies are insufficient to support regulatory approvals, we may have to complete ongoing or additional clinical studies. For example, GnRH receptor antagonists, like relugolix, when taken alone, 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 flash 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 has been to formulate a single-tablet fixed-dose combination of relugolix with low-dose estradiol and a progestin (relugolix combination tablet) to maintain bone health and mitigate side effects of a low-estrogen state such as vasomotor symptoms, and to facilitate patient convenience and compliance. For our uterine fibroids NDA, we expect to submit data on a patient population followed

for at least one year. If the FDA concludes that the data from these studies are insufficient to support regulatory approvals, we may be required to conduct further studies and we could face delays and increased expenses associated with our development programs and our commercial opportunity could be limited. If we are not able to obtain required regulatory approvals for relugolix combination tablet or if our competitors obtain regulatory approval of a fixed-dose combination with hormonal therapy before we do, we would be at a competitive disadvantage and this could limit our commercial opportunity.

We rely on third-party CROs and consultants to assist us in submitting 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 approvals 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. Also, see the Risk Factor titled "We are heavily dependent on the success of relugolix combination tablet for our women's health indications of uterine fibroids and endometriosis, relugolix monotherapy tablet for men with advanced prostate cancer, and MVT-602, which are still under clinical development. If relugolix combination tablet, relugolix monotherapy tablet or MVT-602 does not receive regulatory approval or is not successfully commercialized, our business will be harmed." In addition, any adverse developments with respect to our contract manufacturing organizations, including adverse findings during inspections such as occurred with the Hikari Facility, or delays related to the COVID-19 pandemic may also ultimately delay or affect our ability to obtain regulatory approvals, commercialize our product candidates, and generate product revenue.

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.

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 studies 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 studies 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. We are reliant, in part, upon the regulatory expertise of Richter to gain approval for relugolix combination tablet in the licensed territories and are completely reliant on Richter to generate revenue in the licensed territories. If we or Richter 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.

Relugolix combination therapy, relugolix monotherapy 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 combination therapy, relugolix monotherapy, or MVT-602 could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical studies for relugolix combination therapy, relugolix monotherapy 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 study 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, as 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 (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 studies;
- 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 studies;
- we may be required to repeat a nonclinical or clinical study or terminate a program, even if other studies or studies 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 combination tablet, relugolix monotherapy tablet or MVT-602.

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 studies 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. Even if relugolix combination tablet, relugolix monotherapy tablet or MVT-602 receives marketing approval, if the indication approved by regulatory authorities is narrower than we expect or the accompanying label limits the approved use of our product, our sales of products could be limited and we may not generate significant revenue from sales of our products.

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. The FDA does not regulate the behavior of physicians in their choice of treatments and physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. However, the FDA does restrict manufacturer's communications on the subject of off-label use of their products. 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 those discussed in the Risk Factor titled, "Relugolix combination therapy, relugolix monotherapy 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."

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 and adequacy of our marketing efforts, including direct-to-consumer advertising;
- the effectiveness of sales 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;
- 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 combination tablet, relugolix monotherapy tablet 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, market access, marketing, and distribution capabilities, either on our own or with third-party collaboration partners, we may not be successful in commercializing our product candidates, if approved.

To market any product that may be approved, we must develop our capabilities in sales, market access, marketing, distribution, and other commercial functions, either on our own or with third-party collaboration partners. We have made arrangements regarding some of these functions in certain markets with third-party collaboration partners. For example, on August 1,2020, we entered into a Market Access Services Agreement with Sunovion pursuant to which, among other things, Sunovion has agreed to provide to us certain market access services with respect to the distribution and sale of relugolix monotherapy for prostate cancer and relugolix combination tablet for uterine fibroids and endometriosis. As another example, on March 30, 2020, we entered into an exclusive license agreement with Richter pursuant to which, among other things, Richter will be responsible for all commercialization activities for relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S. If Richter or Sunovion, or any other collaboration partners we may engage in the future, fail to perform or satisfy its obligations under their respective agreements with us or terminate their relationship with us, the sales, market access, marketing and/or distribution of our product candidates would be delayed or may not occur. To the extent our financial returns depend on these collaboration partners' performance and capabilities, our business and prospects could be materially and adversely affected if our collaboration partner performing such functions fails to perform. We may pursue collaborative arrangements regarding these functions in certain markets with other collaboration partners in the future. However, it might be difficult for us to find third parties in markets that are willing to enter into such transactions on acceptable economic terms, or at all.

In addition to the third-party collaboration arrangements described above, we continue to build sales, market access, marketing, distribution and other commercial activities on our own. We may not have the resources in the foreseeable future to build our own sales, market access, marketing and distribution capabilities in all of the markets that we desire. Even if we are able to build such functions, there are significant expenses and risks involved with establishing such functions, including: (i) our inability to recruit, train, and retain adequate numbers of qualified and effective sales, market access and marketing personnel; (ii) our inability to attain access to adequate numbers of physicians to prescribe any drugs; (iii) the inability to negotiate with payors regarding reimbursement and formulary access for our products; and (iv) unforeseen costs and expenses associated with creating and sustaining internal sales, market access, marketing and distribution capabilities. The COVID-19 pandemic may negatively impact our ability to attract the human resources required to build out our own commercial capabilities and may

negatively impact our ability to rapidly and effectively educate potential prescribers and, if significant delays result, to commercialize our product candidates.

Any failure or delay in developing or maintaining our sales, market access, marketing and distribution capabilities, either on our own or with third-party collaboration partners, could delay any product launch, which would adversely impact its commercialization.

If we are unable to establish adequate sales, market access, marketing and distribution capabilities, either on our own or in collaboration with third parties, our product launch will be delayed and 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 sufficient support from an internal team or from third-party collaboration partners to perform these functions, we may be unable to compete successfully against these more established companies.

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, the federal false claims laws, the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the federal Physician Payments Sunshine Act and analogous state fraud and abuse, data privacy, and transparency laws.

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, 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 combination tablet, relugolix monotherapy tablet 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 combination tablet, relugolix monotherapy tablet or MVT-602, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration’s budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, President Trump previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs, that contained 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 solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020.This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional 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. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

Coverage 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 for these products 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 for products exists among third-party payors. Third-party payors decide which drugs they will pay for, what steps prescribers must take to obtain authorization for patients to fill their prescriptions, and how much patients must pay out of their own pocket. Payor decisions regarding the extent of coverage 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 for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an affordable out-of-pocket cost for patients will be established. 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 or prior authorizations. 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 may not use our products unless coverage is provided and out-of-pocket costs for them are affordable. Manufacturers have the ability to lower costs for patients with commercial insurance through various patients' saving offers such as co-pay cards or coupons. These types of consumer programs are not permissible for patients who participate in government health insurance programs such as Medicare or Medicaid.

Even if a payor places a product on its formulary, it may put in place procedures designed to control the utilization of our drugs, such as step-edits or prior-authorizations. Step edits require that a patient first try and fail to be adequately treated by one or more other prescription or over-the-counter medications. Prior authorizations require a physician to demonstrate with sufficient paperwork that a patient meets one or more criteria, such as having a formal diagnosis of the condition for which the drug is indicated, before the coverage for such drug can be provided. As a result, these additional requirements may deter physicians from prescribing our drugs.

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 that such a payor will pay for the product. Even if we do obtain adequate levels of formulary access, 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 affordable patient out-of-pocket costs will be available for any product that we commercialize. Inadequate coverage, patient affordability, and drug utilization controls 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

Regulatory requirements or manufacturing disruptions may make it difficult for us to be able to obtain materials or supplies necessary to conduct clinical studies 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 study needs and, if approved, to maintain sufficient commercial inventories of our products. 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 those suppliers are not approved or the qualification of a new supplier is required. For example, the receipt by Takeda of the warning letter described in the risk factor titled "We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of drug substance and drug product and, if they do not perform as we expect, could result in delay in our ability to develop and commercialize our products" has caused us to rely on our Commercial Manufacturing and Supply Agreement with Excella to a greater extent than we had intended, and may require us to remove the Hikari Facility from our regulatory filings until Takeda corrects the violations noted in the warning letter to the satisfaction of the regulatory authorities. We cannot predict if or when Takeda will correct the violations and deviations to the satisfaction of the FDA, EMA or any other regulatory agency or whether the regulatory agencies will be satisfied with Takeda's responses. The COVID-19 pandemic may also cause delays in the remediation and re-inspection process. 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 both prior to and 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, issue import restrictions or other cGMP or regulatory action that could affect our ability to obtain materials from such supplier. If the manufacturing operations of any single suppliers for any of our products are adversely affected or 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 studies. 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 or a pandemic, 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, manage, and monitor our clinical studies, 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 ("GLP") requirements. We also do not currently have the ability to independently conduct any clinical studies. We rely substantially on CROs and clinical study sites to ensure the proper and timely conduct of our clinical studies, 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 clinical study sponsors, principal investigators, and clinical study sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical studies, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical studies 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 studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical studies 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 studies, 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 studies, 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 studies 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 (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 combination therapy, relugolix monotherapy, 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 combination therapy, relugolix monotherapy, 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, market access, distribution 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

We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Dainippon Pharma, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Dainippon Pharma will not act in the best interests of all of our shareholders, may affect the price of our common shares and have other effects on our company.

There are a number of relationships that may give rise to certain conflicts of interest between Sumitovant and Sumitomo Dainippon Pharma, on the one hand, and the other investors of our common shares and us, on the other hand. We are party to a loan agreement with Sumitomo Dainippon Pharma that creates restrictions, including limiting or restricting our ability to take specific actions, such as raising additional capital, incurring additional debt, making capital expenditures, or declaring dividends. We are also a party to the 2020 Commitment Letter with Sumitomo Dainippon Pharma pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma has agreed to negotiate with us $200.0 million in unsecured revolving commitments to us. In addition, we are party to an Investor Rights Agreement with Sumitovant and Sumitomo Dainippon Pharma that, although designed in part to provide protections for our minority shareholders, also provides rights to Sumitovant and Sumitomo Dainippon Pharma, such as the ability of Sumitomo Dainippon Pharma to appoint directors on our board, to maintain their share ownership percentage in our company, and provide Sumitomo Dainippon Pharma with certain information and give them access to certain of our records. We may enter into additional agreements with Sumitovant or Sumitomo Dainippon Pharma in the future. Sumitovant and Sumitomo Dainippon Pharma may have interests which differ from our interests or those of the minority holders of our common shares. Any material transaction between us and Sumitomo Dainippon Pharma and its affiliates is subject to our related party transaction policy and the Investor Rights Agreement, which

requires prior approval of such transaction by our Audit Committee comprised of three independent directors. 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, and on the market price of our common shares. Further, our agreements with Sumitovant and Sumitomo Dainippon Pharma may result in unanticipated risks or other unintended consequences on our business and on investor perception that could have a significant impact on the market price of our common shares. Further, we are a party to a Market Access Services Agreement with Sunovion Pharmaceuticals Inc., a subsidiary of Sumitomo Dainippon Pharma, pursuant to which Sunovion provides certain market access services with respect to the distribution and sale of our product candidates.

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, but not limited to, the following:

- inability to obtain additional funding, or investor perception that we may be unable to obtain additional funding or funding on desirable terms, such as a failure to successfully negotiate an agreement to effect the new debt facility transaction with Sumitomo Dainippon Pharma based on the terms described in the 2020 Commitment Letter with Sumitomo Dainippon Pharma;
- any delay in the commencement, enrollment, and ultimate completion of our clinical studies;
- actual or anticipated results of clinical studies of any of our product candidates or those of our competitors;
- any delay in submitting an NDA or similar application for any of our product candidates 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 any of our current or future product candidates;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to any of our current or future product candidates;
- adverse regulatory decisions or findings;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for any of our current or future product candidates, or the inability to do so at acceptable prices;
- inability to hire a qualified sales force in a timely fashion;
- inability to establish commercial capabilities and expertise including product marketing, sales, trade and distribution, pricing, market access, data analytics and insights, and other commercial operations functions;
- adverse developments or perceived adverse developments with respect to our third-party vendors on which we rely, including contract manufacturing organizations and contract research organizations;
- 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;
- adverse developments or perceived adverse developments with respect to our manufacturing, collaboration and alliance partners and affiliates, including Takeda, Excella, Sumitovant, Sumitomo Dainippon Pharma, Sunovion and/or Richter;

- 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 management or other key personnel;
- short sales of our common shares;
- sales or purchases of a substantial number of our common shares in the public market, by any of our larger shareholders, or the perception in the market that the holders of a large number of our common shares intend to sell or purchase 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;
- any changes in our relationships with Sumitomo Dainippon Pharma, Sumitovant, Sunovion and/or their respective affiliates, or actions taken or omission of actions with respect to the Sumitomo Dainippon Pharma Loan Agreement, the Investor Rights Agreement, the Market Access Services Agreement or under the other agreements we entered with Sumitomo Dainippon Pharma (such as the New Credit Facility), Sumitovant, Sunovion and their respective affiliates;
- 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, our business, and our majority shareholder;
- general political, economic, industry, and market conditions;
- effects of natural or man-made catastrophic events, including the COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

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

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.

Additionally, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

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

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

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 Sumitomo Dainippon Pharma Loan Agreement and, we expect, will be under the New Credit Facility. 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.

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, (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 in which 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, in which 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.

Legislation enacted in Bermuda as to economic substance may affect our operations.

Pursuant to the Economic Substance Act 2018 of Bermuda, as amended (the "Economic Substance Act") that came into force on January 1, 2019, a registered entity other than an entity which is resident for tax purposes in certain jurisdictions outside Bermuda (a "non-resident entity") that carries on as a business any one or more of the "relevant activities" referred to in the Economic Substance Act must comply with economic substance requirements. The Economic Substance Act may require in-scope Bermuda entities which are engaged in such "relevant activities" to be directed and managed in Bermuda, have an adequate level of qualified employees in Bermuda, incur an adequate level of annual expenditure in Bermuda, maintain physical offices and premises in Bermuda or perform core income-generating activities in Bermuda. The list of "relevant activities" includes carrying on any one or more of: banking, insurance, fund management, financing, leasing, headquarters, shipping, distribution and service centre, intellectual property and holding entities.

Based on the Economic Substance Act currently, for so long as we are a non-resident entity, we are not required to satisfy any such economic substance requirements other than providing the Bermuda Registrar of Companies annually information on the jurisdiction in which it claims to be resident for tax purposes together with sufficient evidence to support that tax residence. We currently do not anticipate material impact on our business or operations from the Economic Substance Act. However, since such legislation is new and remains subject to further clarification and interpretation, it is not currently possible to ascertain the precise impact of the Economic Substance Act on us. If we ceased to be a non-resident entity, we may be unable to comply with the Economic Substance Act or may have to restructure our business to comply with the Economic Substance Act, either of which may have a material adverse effect on our business.

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 when an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the U.K. could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could adversely affect our results of operations.

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

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

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

liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

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

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

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the U.K. and Switzerland), the U.S., Bermuda, and other jurisdictions, as well as being affected by certain changes resulting from 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 U.S. 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 our non-U.S. subsidiaries are expected to be characterized as "controlled foreign corporations" ("CFCs"), under Section 957(a) of the U.S. Internal Revenue Code of 1986, as amended (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 will be 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 ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares. In addition, special information reporting may be required.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile. With respect to the taxable year that ended on March 31, 2020, we believe that we were not a PFIC; however, with respect to the current taxable year and 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

None.

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	Fifth Amended and Restated Bye-laws.	10-Q	001-37929	3.3	02/10/2020
10.1†	Consulting Agreement, dated May 18, 2020, by and between the Registrant and Sumitovant BioPharma Ltd.				
31.1†*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1††**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2††**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase				
104	Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				

† Filed herewith.

†† Furnished herewith.

* Confidential treatment has been granted for portions omitted from this exhibit (indicated by asterisks) and those portions have been separately filed with the SEC.

** These certifications are being furnished solely to accompany this 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 11, 2020

Exhibit 10.1

CERTAIN Information Identified by "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the "**Agreement**") is made and entered into as of May 18, 2020, effective as of May 11, 2020 ("**Effective Date**"), by and between **Myovant Sciences GmbH** ("**Myovant**") having a registered office at Viaduktstrasse 8, 4051 Basel, Switzerland and **Sumitovant Biopharma, INC. ("Sumitovant")**, having an office at 151 W. 42nd Street, 15th Floor, New York NY 10036 ("**Consultant**").

W I T N E S S E T H:

WHEREAS, Sumitovant Biopharma Ltd., an affiliate and beneficial owner of Consultant is the majority shareholder of Myovant Sciences Ltd. ("**MSL**"), Myovant's affiliate and beneficial owner;

WHEREAS, Myovant desires to engage Consultant to provide services to Myovant, and Consultant desires to accept engagement on the terms and conditions hereinafter stated;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties agree as follows:

1. Services.

1.1. Consultant shall provide the services set forth on Exhibit A (the "**Services**"). Adele Gulfo, Consultant's Chief Business and Commercial Development Officer and a member of MSL's Board of Directors, shall provide the Services to Myovant on behalf of Consultant under this Agreement ("**Individual Consultant**").

1.2. Consultant and Myovant acknowledge and agree that this Agreement is an independent contractor agreement and that Consultant is an independent contractor and that neither Consultant nor Individual Consultant is an agent or employee of Myovant. Myovant shall have no withholding obligations with respect to Consultant's or Individual Consultant's compensation and Consultant shall be solely responsible for payment of, and shall indemnify and hold Myovant harmless against, all taxes, including, without limitation, federal, state and local taxes arising out of Consultant's compensation under this Agreement and Individual Consultant's compensation from Consultant. With respect to the Services, Consultant and Individual Consultant shall not be covered by or have any rights to participate under any employee benefit plans of Myovant that are in existence or hereafter adopted or implemented and Myovant shall not be responsible for payment of workers' compensation, disability benefits or unemployment insurance. As an independent contractor, Consultant shall not have the power or authority to bind Myovant to any obligations whatsoever to third parties without the prior consent of Myovant.

1.3. Consultant represents and warrants to Myovant that this Agreement does not violate or breach, and Consultant's performance of Consultant's obligations hereunder will not violate or breach, any terms or provisions of any agreement or understanding to which Consultant is subject or bound. Consultant represents, warrants, covenants and agrees that it will not, during engagement by Myovant, improperly use or disclose any proprietary information or trade secrets of any other party, and will not share with Myovant any unpublished documents or any property belonging to any other party unless consented to in writing by said party.

1.4. Consultant represents and warrants that Consultant has not been debarred or received notice of any action or threat with respect to debarment under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) or any similar legislation applicable in the US or in any other

country where Myovant intends to develop its activities. Consultant agrees to promptly notify Myovant upon receipt of any such notice or similar notice and further agrees, upon Myovant's request, to provide a separate written certification, on a form provided by Myovant, to this effect.

2. Term of Engagement.

2.1. Subject to the terms and provisions set forth below in this Section 2, the term of Consultant's engagement will begin on May 11, 2020 and continue through November11, 2020 or such earlier time as Myovant hires a permanent Chief Commercial Officer. The Agreement may be renewed upon the mutual written consent of the parties.

2.2. Either Myovant or Consultant may terminate the engagement of Consultant under this Agreement at any time for any reason by giving not less than fifteen (15) days prior written notice thereof to the other party.

2.3. Upon termination of engagement pursuant to this Section 2, all obligations of Myovant under this Agreement shall terminate except with respect to payment for Services rendered prior to the date of termination, and reimbursement of expenses to which Consultant would have been entitled under this Agreement, it being agreed that such payment shall constitute full settlement of any and all claims of Consultant of every description. All of Consultant's obligations, including without limitation the provisions of this agreement relating to Confidential Information, Trade Secrets and Other Confidential Information under this Agreement shall survive any termination of this Agreement in accordance with its terms.

2.4. Consultant will, and will cause Individual Consultant to, provide Services hereunder in compliance with: 1) all applicable federal, state, and local laws and regulations including but not limited to the Federal Healthcare Programs Antikickback Statute and the Federal Food, Drug and Cosmetic Act; 2) the generally accepted standards of Consultant's profession; 3) relevant industry guidelines and codes of ethics to the extent that they are applicable to the Services hereunder, including the Pharmaceutical Research and Manufacturers of America's Code on Interactions With Health Care Professionals and 4) all of Consultant's policies and procedures, including any disclosure/transparency obligations regarding fees obtained for consultancy services.

3. Compensation.

3.1. In consideration of the Services provided by Consultant, Myovant shall provide Consultant with $[***]/hour (the "**Fee"**) not to exceed a total of $120,000 without prior written approval of Myovant.

3.2. All payments under this Agreement are contingent upon Consultant's completion, execution and sending to Myovant a completed Form W-9, Form W-8-BEN or other foreign withholding certificate, as applicable.

3.3. Consultant shall submit a detailed, itemized invoice for Services to Myovant on a monthly basis, and Myovant shall remit payment for properly performed Services within forty-five (45) days of receipt of the invoice and all supporting documentation.

3.4. Myovant and Consultant acknowledge and agree that the compensation herein represents the fair market value for the Services, is not influenced by the corporate relationship between Myovant and Consultant and has not been determined in a manner that takes into account the volume or value of any other business between Consultant and Myovant or any Myovant affiliate. Under no circumstance shall Consultant be entitled to receive any compensation or consideration beyond the Fee, as a result of or in connection with this Agreement or the Services or in connection with any Invention.

3.5. Myovant and Consultant acknowledge and agree that this Agreement is a "Related Person Transaction" pursuant to MSL's Related Person Transaction Policy and that MSL's board Audit Committee must approve this Agreement before it becomes effective. Consultant acknowledges that MSL is a public company listed on the New York Stock Exchange and agrees and acknowledges that Myovant may have reporting obligations under the securities laws and regulations applicable to US listed entities with respect to this Agreement and any compensation paid to Consultant.

4. Expense Reimbursements.

Consultant shall be reimbursed for all reasonable and necessary expenses incurred by Consultant when travel is undertaken at Myovant's request. Prior to receiving such reimbursement, Consultant shall submit documentation and receipts for such expenses in excess of $25.00 in sufficient detail for deduction by Myovant as an expense.

5. Confidential Information, Trade Secrets and Nonuse.

Myovant and Consultant acknowledge and agree that they have entered into a Nondisclosure and Common Interest Agreement ("**NDA**") as of April 8, 2020 and that the provisions in the NDA related to confidentiality, trade secrets and nonuse shall apply to this Agreement.

6. Inventions.

6.1. Disclosure of Inventions. Consultant shall promptly and fully disclose to Myovant any and all ideas, improvements, inventions, know-how, techniques and works of authorship learned, conceived or developed by Consultant or Individual Consultant pursuant to their performance of the Services for Myovant or of tasks assigned to them by Myovant hereunder (the "**Service Product**"). Consultant agrees to keep and maintain reasonable, adequate and current records (in the form of notes, sketches, drawings or in any other form that may be required by Myovant) of all Service Product, and such records, subject to any prior rights thereto held by Consultant shall be available to and remain the sole property of Myovant at all times.

6.2. Inventions Assigned to Myovant. Consultant agrees that, subject to any prior rights thereto held by Consultant, any and all Service Product shall be the sole and exclusive property of Myovant. Consultant hereby assigns to Myovant all its right, title and interest in and to any and all Service Product. Consultant explicitly acknowledges and agrees that all works of authorship contained in the Service Product are "works for hire" under the copyright laws of the United States, and that Myovant shall own the copyright in all such works of authorship.

6.3. Consultant further agrees that, except for any prior rights held by Consultant, Myovant is and shall be vested with all rights, title and interests, including patent, copyright, trade secret and trademark rights, in all of Consultant's Service Product under this Agreement. Notwithstanding anything in this Agreement to the contrary, nothing in this Agreement restricts or otherwise deprives Consultant of any of its rights or proprietary interests in any materials or intellectual property that existed prior to and independent of performance of any of the Services ("Pre-Existing Materials"). If Pre-Existing Materials are delivered in connection with or as part of the Service Product, Consultant hereby grants Myovant a non-exclusive, worldwide license to use, duplicate modify, sublicense, distribute, display and otherwise exploit such Pre-Existing Materials, but in each case, solely to enable Myovant to use and benefit from the Service Product.

6.4. Obtaining Intellectual Property Protection. Consultant agrees to assist Myovant in every proper way to obtain and enforce United States and foreign proprietary rights relating to the Service Product in any and all countries. To that end, Consultant agrees to execute, verify and deliver such documents and perform such other acts (including appearing as a witness) as Myovant may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such proprietary rights and the assignment thereof. In addition, Consultant agrees to

execute, verify and deliver assignments of such proprietary rights in the Service Product to Myovant or its designee. Consultant's obligation to assist Myovant with respect to such proprietary rights in the Service Products in any and all countries shall continue beyond the termination of its engagement, but Myovant shall compensate Consultant at a reasonable rate after such termination for the time actually spent by Consultant at Myovant's request on such assistance.

6.5. In the event Myovant is unable for any reason, after reasonable effort, to secure Consultant's signature on any document needed in connection with the actions specified in the preceding paragraph, Consultant hereby irrevocably designates and appoints Myovant and its duly authorized officers and agents as his agent and attorney in fact, to act for and on it behalf to execute, verify and file, with the same legal force and effect as if executed by him, any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph. Consultant hereby waives and quitclaims to Myovant any and all claims of any nature whatsoever which Consultant now or may hereafter have for infringement of any proprietary rights assigned to Myovant in accordance with this Section 6

7. Remedies and Special Severability.

7.1. Consultant acknowledges and agrees that by virtue of the duties and responsibilities attendant to Consultant's engagement by Myovant and the special knowledge of Myovant's affairs, business, clients, and operations, that Consultant will have as a consequence of such engagement, Myovant will suffer irreparable loss and damage if Consultant should breach or violate any of the covenants and agreements contained in Sections 5, and/or 6 hereof. Consultant further acknowledges and agrees that each of such covenants is reasonably necessary to protect and preserve the business and the assets of Myovant. Consultant acknowledges and agrees that Myovant will have no adequate remedy at law and would be irreparably harmed, if Consultant actually breaches or threatens to breach any of the provisions of Sections 5, and/or 6hereof. Consultant agrees that Myovant shall be entitled to equitable and/or injunctive relief to prevent any actual breach or contemplated breach of Sections 5, and/or 6 hereof, and to specific performance of each of the terms of such Section in addition to any other legal or equitable remedies that Myovant may have. Consultant further agrees that it shall not, in any equity proceeding relating to the enforcement of the terms of Sections 5, 6, 7 and/or 8 hereof, raise the defense that Myovant has an adequate remedy at law.

7.2. Nothing contained in this Agreement shall limit, abridge, or modify the rights of Myovant under applicable trade secret, trademark, copyright, or patent law or under the laws of unfair competition.

7.3. The terms and provisions of Sections 5, 6, and/or 7 hereof are intended to be separate and divisible provisions and if, for any reason, any one or more of them is held to be invalid or unenforceable, neither the validity nor the enforceability of any other provision of this Agreement shall thereby be affected. It is the intention of the parties to this Agreement that the potential restrictions on Consultant's conduct are reasonable in both duration and geographic scope and in all other respects. If for any reason any court of competent jurisdiction shall find any provisions of Sections 5, 6, and/or 7 unreasonable in duration or geographic scope or otherwise, the restrictions and prohibitions contained therein shall be effective to the fullest extent allowed under applicable law in such jurisdiction.

8. Notices.

All notices, requests, consents, and other communications hereunder to any party shall be deemed to be sufficient if contained in a written instrument delivered in person (including delivery by overnight or express courier) or duly sent by certified mail, return receipt requested, proper postage prepaid, addressed to such party at the address set forth below or such other addresses as may hereafter be designated in writing by the addressee to the addressor listing all parties:

Myovant:	Myovant Sciences GmbH c/o Myovant Sciences, Inc. 2000 Sierra Point Parkway 9th Floor Brisbane, CA 94005 Attn: Legal Department
Consultant:	Sumitovant Biopharma, Inc. 151 W. 42nd Street, 15th Floor New York, NY 10036 Attn: Legal Department

All such notices, advices, and communications shall be deemed to have been received (a) in the case of personal delivery, on the date of actual personal receipt, and (b) in the case of mailing, on the third day after the posting by certified mail, return receipt requested.

9. Binding Agreement.

The rights and obligations of Myovant under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of Myovant. This Agreement is a personal service agreement and may not be assigned in whole or in part by Consultant.

10. Severable Provisions.

The provisions of this Agreement are severable and if any one or more provisions may be determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions, and any partial enforceable provision to the extent enforceable in any jurisdiction, shall nevertheless be binding and enforceable.

11. Waiver.

The waiver by one party of a breach of any provision of this Agreement by the other party shall not operate or be construed as a waiver of any subsequent breach of the same or any other provision by the other party.

12. Entire Agreement.

This Agreement constitutes the entire agreement of the parties hereto with respect to the engagement of Consultant by Myovant and supersedes all prior agreements, understandings, discussions, negotiations and undertakings, whether written or oral, between the parties with respect thereto and may not be changed orally, but only by an agreement in writing signed by the party against whom the enforcement of any waiver, change, modification, extension, or discharge is sought.

13. Counterparts.

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all which together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, by electronic mail in “portable document format” (“.pdf”), or by any other electronic means which preserves the original graphic and pictorial appearance of the Agreement, shall have the same effect as physical delivery of the paper document bearing the original signature.

14. Applicable Law.

This Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to its conflict of laws principles. For all matters relating to or arising directly or indirectly from this Agreement in connection with any legal action, lawsuit, arbitration, mediation, or other legal or quasi legal proceeding, the parties hereby irrevocably consent and submit to the sole exclusive jurisdiction of the United States District Court for the Southern District of New York and any state court in the State of New York that is located in the county of New York (and the appropriate appellate courts of any of the foregoing).

15. Reporting.

It is understood by Consultant that if required by applicable law, rule or regulation, Myovant will report all payments and may be required to report other value transferred to Consultant under this Agreement. Consultant understands that information about payments or other value transferred to Consultant may be made publicly available. The obligations of this section shall survive the expiration or earlier termination of this Agreement.

16. Dispute Resolution.

Any dispute, claim or controversy arising out of or in connection with this Agreement, including any dispute regarding its existence, validity or termination (the "**Dispute**"), except to the extent that Myovant is seeking injunctive relief pursuant to Sections 5, 6, and/or 7 hereunder (which are governed by Section 14), shall be finally resolved through arbitration under the Commercial Arbitration Rules of the American Arbitration Association in force as of the date of this Agreement (the "**Rules**"). The Dispute shall be resolved by a sole arbitrator appointed in accordance with the Rules. The place of arbitration shall be New York, New York. The arbitration shall be conducted in the English language. The award issued by the sole arbitrator shall be final and binding upon the parties and shall not be subject to appeal.

17. Captions.

The captions of this Agreement are not part of the provisions hereof and shall have no force or effect.

Signature Page to Follow

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have caused this Agreement to be duly executed as of the date set forth.

Myovant Sciences GmbH (“Myovant”)		**Sumitovant Biopharma, Inc. (“Consultant”)**	
By:	/s/ Elke Hunsche	By:	/s/ Tara Soni
Name:	Elke Hunsche	Name:	Tara Soni
Title:	VP, Global Market Access & HEOR	Title:	Head of Legal

EXHIBIT A

Description of Consultant's Services

- **Project Name or Services Reference:** Adele Gulfo, Interim Chief Commercial Officer for Myovant.
- **Objective**: Support Myovant in commercial planning, commercial launch activities and implementation.
- **Scope of Work**: Adele Gulfo to serve as Myovant's interim Chief Commercial Officer with all associated responsibilities of this role provided that Myovant shall remain responsible for all administrative duties related to this role, including but not limited to, annual performance review of team members, training programs, replacement candidate search and so forth. The primary focus of this role relates to commercial launch preparation and implementation.
- **Anticipated Timeframe to Completion**: Until permanent Chief Commercial Officer has been hired and onboarded by Myovant.
- **Deliverable(s)**: to be mutually agreed in writing based on individual projects.
- **Contact information**:

  Individual Consultant's name
  Adele Gulfo
  151 W 42nd Street, 15th Floor, New York NY 10036
  Email: [***]

  Myovant contact
  Lynn Seely
  2000 Sierra Point Parkway, 9th Floor
  Brisbane, CA 94005 USA
  Email: [***]

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 11, 2020

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 11, 2020

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, 2020 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 11, 2020

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, 2020 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 11, 2020

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.