Table of Contents

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, 2021

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 July 23, 2021 was 92,077,860.

MYOVANT SCIENCES LTD.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2021

TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements:	
Condensed Consolidated Balance Sheets as of June 30, 2021 and March 31, 2021 (Unaudited)	5
Condensed Consolidated Statements of Operations for the Three Months Ended June 30, 2021 and 2020 (Unaudited)	6
Condensed Consolidated Statements of Comprehensive Loss for the Three Months Ended June 30, 2021 and 2020 (Unaudited)	7
Condensed Consolidated Statements of Shareholders' Deficit for the Three Months Ended June 30, 2021 and 2020 (Unaudited)	8
Condensed Consolidated Statements of Cash Flows for the Three Months Ended June 30, 2021 and 2020 (Unaudited)	9
Notes to Condensed Consolidated Financial Statements (Unaudited)	10
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3. Quantitative and Qualitative Disclosures About Market Risk	39
Item 4. Controls and Procedures	39
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	39
Item 1A. Risk Factors	40
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	75
Item 3. Defaults Upon Senior Securities	75
Item 4. Mine Safety Disclosures	75
Item 5. Other Information	75
Item 6. Exhibits	76
Signatures	77

Risk Factor Summary

Below is a summary of the material factors that make an investment in our common shares speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under the heading "Risk Factors" in Item 1A of Part II of this Quarterly Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Item 1A of Part II of this Quarterly Report as part of your evaluation of an investment in our common shares.

Risks Related to Commercialization of Our Drug Products

- Our success depends in part on the successful commercialization of our drug products. To the extent our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed.
- Our drug products may fail to achieve the degree of market acceptance by physicians, patients, third-party payers or others in the medical community necessary for commercial success, which would negatively impact our business.
- If we and our collaboration partners are unable to effectively market and sell our drug products, the commercialization of our drug products will not be successful and our business will be harmed.
- Failure to successfully obtain coverage and reimbursement for ORGOVYX and MYFEMBREE in the United States, or the availability of coverage only at limited levels, would diminish our ability to generate net product revenue.
- We face substantial competition in the commercialization of ORGOVYX and MYFEMBREE, and our operating results will suffer if we fail to compete effectively.

Risks Related to Our Financial Position and Capital Requirements

- If we do not have adequate funds to cover our development and commercialization activities, we may have to raise additional capital or curtail or cease operations. 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.
- 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. Further, we may be obligated to repay the loans prior to their scheduled maturity date under certain circumstances.

Risks Related to Our Business Operations

- The terms of the Sumitomo Dainippon Pharma Loan Agreement place restrictions on our operating and financial flexibility.
- We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in delay in our ability to develop and commercialize our products.

Risks Related to Clinical Development and Regulatory Approval

- 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.
- 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.

- 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 for our product candidates, our ability to generate net product revenue will be materially impaired.

- Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval.

Risks Related to Our Dependence on Third Parties

- We are dependent upon our relationships with collaboration partners to further develop, fund, manufacture and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration partner terminates its collaboration agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration partner to perform its duties under its collaboration agreement with us (e.g. financial reporting or internal control compliance) may negatively affect us.

- 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.

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.

- 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.

Risks Related to Our Being a Controlled Company

- We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Dainippon Pharma, and their affiliates, including Sunovion, 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.

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, 2021	March 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 484,960	$ 674,493
Accounts receivable, net	10,608	3,570
Marketable securities	84,826	10,435
Inventory	4,172	2,611
Milestone receivable from Pfizer	100,000	—
Prepaid expenses and other current assets	17,569	13,536
Total current assets	702,135	704,645
Property and equipment, net	2,968	3,300
Operating lease right-of-use asset	9,252	9,655
Other assets	13,415	7,427
Total assets	$ 727,770	$ 725,027
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 9,122	$ 17,809
Accrued expenses and other current liabilities	42,938	44,612
Share-based compensation liabilities	21,151	21,636
Deferred revenue	117,231	100,564
Amounts due to Pfizer	11,025	1,954
Cost share advance from Pfizer	104,178	92,415
Operating lease liability	1,886	1,807
Amounts due to related parties	39	543
Total current liabilities	307,570	281,340
Deferred revenue, non-current	451,193	397,369
Cost share advance from Pfizer, non-current	—	29,447
Long-term operating lease liability	8,685	9,189
Long-term debt, less current maturities (related party)	358,700	358,700
Other liabilities	1,248	2,947
Total liabilities	1,127,396	1,078,992
Commitments and contingencies (Note 9)		
Shareholders' deficit:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 91,942,643 and 91,000,869 issued and outstanding at June 30, 2021 and March 31, 2021, respectively	2	2
Additional paid-in capital	725,465	709,466
Accumulated other comprehensive loss	(17,285)	(17,285)
Accumulated deficit	(1,107,808)	(1,046,148)
Total shareholders' deficit	(399,626)	(353,965)
Total liabilities and shareholders' deficit	$ 727,770	$ 725,027

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,	
	2021	2020
Revenues:		
Product revenue, net	$ 11,554	$ —
Pfizer collaboration revenue	29,509	—
Richter license and milestone revenue	—	33,333
Total revenues	41,063	33,333
Operating costs and expenses:		
Cost of product revenue	1,032	—
Collaboration expense to Pfizer	5,261	—
Research and development	30,880	44,186
Selling, general and administrative [(1)]	61,212	22,828
Total operating costs and expenses	98,385	67,014
Loss from operations	(57,322)	(33,681)
Interest expense [(2)]	3,505	2,184
Interest income	(78)	(108)
Foreign exchange gain	—	(3,569)
Loss before income taxes	(60,749)	(32,188)
Income tax expense	911	672
Net loss	$ (61,660)	$ (32,860)
Net loss per common share — basic and diluted	$ (0.67)	$ (0.37)
Weighted average common shares outstanding — basic and diluted	91,637,151	89,300,210

[(1)] Includes $1,323 and $114 of related party expense (inclusive of third-party pass-through costs) for the three months ended June 30, 2021 and 2020, respectively (see Note 5).

[(2)] Includes $2,904 and $2,184 of interest expense under the Sumitomo Dainippon Pharma Loan Agreement for the three months ended June 30, 2021 and 2020, respectively (see Note 5).

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,	
	2021	2020
Net loss	$ (61,660)	$ (32,860)
Other comprehensive loss:		
Foreign currency translation adjustment	—	(3,475)
Total other comprehensive loss	—	(3,475)
Comprehensive loss	$ (61,660)	$ (36,335)

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

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

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount				
Balance at March 31, 2021	91,000,869	$ 2	$ 709,466	$ (17,285)	$ (1,046,148)	$ (353,965)
Share-based compensation	—	—	11,262	—	—	11,262
Share-based compensation liabilities reclassified to equity upon settlement of awards	—	—	1,862	—	—	1,862
Share-based compensation reclassified to current liabilities	—	—	(1,377)	—	—	(1,377)
Issuance of shares upon exercise of stock options and vesting of restricted stock units	941,774	—	4,252	—	—	4,252
Net loss	—	—	—	—	(61,660)	(61,660)
Balance at June 30, 2021	91,942,643	$ 2	$ 725,465	$ (17,285)	$ (1,107,808)	$ (399,626)

	Common Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount				
Balance at March 31, 2020	89,833,998	$ 2	$ 684,381	$ (1,646)	$ (791,014)	$ (108,277)
Share-based compensation	—	—	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)

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,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (61,660)	$ (32,860)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	11,262	7,812
Depreciation and amortization [(1)]	724	551
Non-cash interest expense	601	—
Foreign currency transaction gain	—	(3,569)
Other	—	94
Changes in operating assets and liabilities:		
Accounts receivable	(7,038)	—
Inventory	(1,561)	—
Milestone receivable from Pfizer	(100,000)	—
Prepaid expenses and other current assets	(3,916)	(1,101)
Other assets	112	—
Accounts payable	(8,676)	(9,946)
Interest payable (related party)	—	9
Accrued expenses and other current liabilities	(1,674)	(254)
Deferred revenue	70,491	(23,333)
Amounts due to Pfizer	9,071	—
Cost share advance from Pfizer	(18,285)	—
Operating lease liabilities	(425)	(356)
Amounts due to related parties	(504)	114
Other liabilities	(1,699)	855
Net cash used in operating activities	(113,177)	(61,984)
Cash flows from investing activities:		
Purchases of marketable securities	(78,426)	(14,973)
Maturities of marketable securities	4,035	3,000
Purchases of property and equipment	—	(151)
Net cash used in investing activities	(74,391)	(12,124)
Cash flows from financing activities:		
Proceeds from related party debt financing	—	80,000
Proceeds from stock option exercises	4,135	2,190
Net cash provided by financing activities	4,135	82,190
Net change in cash, cash equivalents and restricted cash	(183,433)	8,082
Cash, cash equivalents and restricted cash, beginning of period	677,480	78,018
Cash, cash equivalents and restricted cash, end of period	$ 494,047	$ 86,100
Non-cash financing activities:		
Change in fair value of share-based awards recorded to additional paid-in capital	$ 1,377	$ —
Reclassification of share-based compensation liabilities to additional paid-in capital upon settlement of awards	$ 1,862	$ —
Stock options exercised receivable, included in prepaid expenses and other current assets	$ 117	$ —

[(1)] Includes amortization of operating lease right-of-use assets.

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—Organization and Summary of Significant Accounting Policies

Description of Business

Myovant Sciences Ltd. (together with its wholly-owned subsidiaries, the "Company") is a biopharmaceutical company focused on redefining care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, the Company has two FDA-approved products: (1) ORGOVYX® (relugolix 120 mg), which was approved in the U.S. by the U.S. Food and Drug Administration ("FDA") in December 2020 as the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for the treatment of adult patients with advanced prostate cancer; and (2) MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), which was approved in the U.S. by the FDA in May 2021 as the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, the European Commission approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in Europe for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In July 2021, Myovant Sciences GmbH ("MSG"), one of the Company's subsidiaries, submitted a supplemental New Drug Application ("sNDA") to the FDA for once-daily MYFEMBREE for the management of moderate to severe pain associated with endometriosis. MYFEMBREE is also being assessed for contraceptive efficacy in women ages 18-35 years who are at risk for pregnancy, pending FDA removal of a partial clinical hold. Relugolix (120 mg) is also under regulatory review in Europe for men with advanced prostate cancer. The Company is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as a part of assisted reproduction.

Since its inception, the Company has funded its operations primarily from the issuance and sale of its common shares, from debt financing arrangements, and more recently from the upfront and regulatory milestone payments it received from Pfizer Inc. ("Pfizer") and Gedeon Richter Plc. ("Richter"). The Company began generating product revenue from the sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively.

The Company's majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma"). As of June 30, 2021, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or approximately 52.9%, of the Company's outstanding common shares.

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, 2021, filed with the U.S. Securities and Exchange Commission (the "SEC") on May 11, 2021. The unaudited condensed consolidated balance sheet at March 31, 2021 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, 2021 are not necessarily indicative of the results that may be expected for the fiscal year ending March 31, 2022, for any other interim period or for any other future year.

Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification ("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.

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 contingencies 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, collaboration arrangements, revenue recognition, share-based compensation, research and development ("R&D") expenses and accruals, leases, and income taxes. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. 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.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 to the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the fiscal year ended March 31, 2021, filed with the SEC on May 11, 2021. There have been no significant changes in the Company's significant accounting policies from those disclosed in its Annual Report on Form 10-K for the fiscal year ended March 31, 2021.

Liquidity and Capital Resources

As of June 30, 2021, the Company had approximately $569.8 million in cash, cash equivalents, and marketable securities, which excludes $115.0 million of recently triggered regulatory milestone payments from Pfizer and Richter as discussed in Note 10, "Subsequent Events." The Company currently believes that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Quarterly Report on Form 10-Q.

In future periods, if the Company's cash, cash equivalents, marketable securities, and amounts that it expects to generate from product sales and/or third-party collaboration payments are not sufficient to enable the Company to fund its operations, the Company may need to raise additional funds in the form of equity, debt, or from other sources. There can be no assurances that such funding sources will be available at terms acceptable to the Company, or at all. If the Company has insufficient funding to meet its working capital needs, it could be required to delay, limit, reduce, or terminate its drug development programs, commercialization efforts, and/or limit or cease operations.

As of June 30, 2021, the Company had approximately $41.3 million of borrowing capacity available to it under the Sumitomo Dainippon Pharma Loan Agreement (see Note 5(A)). As of the date of issuance of this Quarterly Report on Form 10Q, the Company is also eligible to earn up to $3.6 billion and $122.5 million of additional milestone payments from Pfizer and Richter pursuant to the Pfizer Collaboration and License Agreement and the Richter Development and Commercialization Agreement, respectively, as well as potential royalty payments on net sales under each agreement. See Note 8 for additional information about the Pfizer Collaboration and License Agreement and the Richter Development and Commercialization Agreement. See Note 10 for additional information about regulatory milestone payments that were recently triggered under the Pfizer Collaboration and License Agreement and the Richter Development and Commercialization Agreement.

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 shares. 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, 2021 and 2020 potentially dilutive securities were as follows:

	June 30,	
	2021	2020
Stock options	8,613,006	8,648,078
Restricted stock awards (unvested)	—	564,111
Restricted stock units and performance stock units (unvested and unreleased)	5,170,442	3,603,201
Warrants	73,710	73,710
Total	13,857,158	12,889,100

Recently Adopted Accounting Standards

In December 2019, the FASB issued ASU 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. The Company adopted ASU 2019-12 on April 1, 2021, which did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Standards Not Yet Adopted

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 the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The amendments are effective prospectively for all entities as of March 12, 2020 through December 31, 2022. As of June 30, 2021, the Company has not modified its contract that will be impacted by reference rate reform (Sumitomo Dainippon Pharma Loan Agreement). The Company will continue to assess the impact the adoption of this standard will have on its consolidated financial statements and related disclosures when its contract impacted by reference rate reform is modified.

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 was effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption was 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 amended 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.

Note 2—Revenue Components

The following table provides information about the Company's revenues (in thousands):

	Three Months Ended June 30,	
	2021	2020
Revenues:		
Product revenue, net:		
ORGOVYX	$ 10,479	$ —
MYFEMBREE	1,075	—
Total product revenue, net	11,554	—
Pfizer collaboration revenue:		
Amortization of upfront payment	20,974	—
Amortization of regulatory milestone	8,535	—
Total Pfizer collaboration revenue	29,509	—
Richter license and milestone revenue	—	33,333
Total revenues	$ 41,063	$ 33,333

The Company began generating product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively. The Company records product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions.

Pfizer collaboration revenue for the three months ended June 30, 2021 consists of the partial recognition of the upfront payment the Company received from Pfizer in December 2020 and of the regulatory milestone payment due from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. There were no such amounts recognized for the three months ended June 30, 2020.

There was no Richter license and milestone revenue for the three months ended June 30, 2021. Richter license and milestone revenue for the three months ended June 30, 2020 consists of the partial recognition of the upfront payment the Company received from Richter in March 2020 and the regulatory milestone payment the Company received from Richter in April 2020.

See Note 8 for additional information regarding collaboration revenue under the Pfizer Collaboration and License Agreement and license and milestone revenue under the Richter Development and Commercialization Agreement.

Note 3—Certain Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

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,	
	2021	2020
Cash and cash equivalents	$ 484,960	$ 84,726
Restricted cash	9,087	1,374
Total cash, cash equivalents and restricted cash	$ 494,047	$ 86,100

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash (maturity of three months or less at the time of purchase). Restricted cash consists of funds held or designated to satisfy the requirements of certain agreements that are restricted in their use and are included in other assets on the unaudited condensed consolidated balance sheets. As of June 30, 2021 and March 31, 2021, restricted cash includes approximately $7.1 million and $1.0 million, respectively, that is held in an escrow fund for use by Sunovion Pharmaceuticals Inc. ("Sunovion"), a subsidiary of Sumitomo Dainippon Pharma, to manage rebates, chargebacks, and similar fees pursuant to the Market Access Services Agreement (see Note 5(C)).

Inventory

As of June 30, 2021 and March 31, 2021, inventory consisted of the following (in thousands):

	June 30, 2021	March 31, 2021
Raw materials	$ 1,321	$ 1,390
Work in process	1,883	773
Finished goods	968	448
Total inventory	$ 4,172	$ 2,611

Accrued Expenses and Other Current Liabilities

As of June 30, 2021 and March 31, 2021, accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2021	March 31, 2021
Accrued R&D expenses	$ 7,894	$ 8,544
Accrued compensation-related expenses	17,936	20,571
Accrued commercial expenses	8,065	7,770
Accrued sales discounts, rebates, and allowances	4,737	1,315
Deferred net product revenue	—	162
Accrued professional service fees	1,075	935
Accrued other expenses and tax obligations	3,231	5,315
Total accrued expenses and other current liabilities	$ 42,938	$ 44,612

Note 4—Fair Value Measurements

The preparation of the Company's unaudited condensed consolidated financial statements in accordance with U.S. GAAP requires certain assets and liabilities to be reflected at their fair value. 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 measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed into one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- 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.

For a description of the methods and assumptions that are used to estimate the fair value and determine the fair value hierarchy classification of each class of the Company's financial instruments, see Note 2, "Summary of Significant Accounting Policies," and Note 3, "Fair Value Measurements," to the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the fiscal year ended March 31, 2021, filed with the SEC on May 11, 2021.

Financial Instruments Measured at Fair Value on a Recurring Basis

The following table summarizes the Company's financial assets and liabilities measured at fair value on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	Fair Value Measurement Using:			
	Level 1	Level 2	Level 3	Total
As of June 30, 2021				
Assets:				
Money market funds [1]	$ 4,871	$ —	$ —	$ 4,871
Commercial paper [2]	—	211,029	—	211,029
Corporate bonds [3]	—	4,002	—	4,002
Total assets	$ 4,871	$ 215,031	$ —	$ 219,902
Liabilities:				
Share-based compensation liabilities - stock options [4]	$ —	$ 10,615	$ —	$ 10,615
Share-based compensation liabilities - common shares [5]	10,536	—	—	10,536
Total liabilities	$ 10,536	$ 10,615	$ —	$ 21,151

	Fair Value Measurement Using:			
	Level 1	Level 2	Level 3	Total
As of March 31, 2021				
Assets:				
Money market funds [1]	$ 36,903	$ —	$ —	$ 36,903
Commercial paper [2]	—	21,689	—	21,689
U.S. agency securities [1]	—	10,000	—	10,000
Municipal bonds [3]	—	1,417	—	1,417
Total assets	$ 36,903	$ 33,106	$ —	$ 70,009
Liabilities:				
Share-based compensation liabilities - stock options [4]	$ —	$ 12,113	$ —	$ 12,113
Share-based compensation liabilities - common shares [5]	9,523	—	—	9,523
Total liabilities	$ 9,523	$ 12,113	$ —	$ 21,636

[1] Included in cash and cash equivalents.

[2] Includes $130.2 million in cash and cash equivalents and $80.8 million in marketable securities as of June 30, 2021. Includes $12.7 million in cash and cash equivalents and $9.0 million in marketable securities as of March 31, 2021.

[3] Included in marketable securities.

[4] Includes 1,081,803 and 1,281,803 outstanding stock options remeasured using the Black-Scholes option-pricing model as of June 30, 2021 and March 31, 2021, respectively. See Note 7(F).

[5] As of June 30, 2021, includes 462,705 common shares remeasured using the Company's June 30, 2021 closing market price of $22.77 per common share. As of March 31, 2021, includes 462,705 common shares remeasured using the Company's March 31, 2021 closing market price of $20.58 per common share. See Note 7(F).

The following table includes information regarding the Company's share-based compensation liabilities (a current liability) for the three months ended June 30, 2021 (in thousands):

March 31, 2021	$	21,636
Change in fair value		1,377
Settlements		(1,862)
June 30, 2021	$	21,151

The fair value of the share-based compensation liabilities related to outstanding stock options was estimated as of June 30, 2021 using the Black-Scholes option-pricing model and the following assumptions:

Expected common share price volatility	53.7 %
Expected risk free interest rate	0.06 %
Expected term, in years	0.5
Expected dividend yield	— %

Financial Instruments Not Measured at Fair Value on a Recurring Basis

The Company recorded the cost share advance from Pfizer, which is included in Level 2 of the fair value hierarchy, at its estimated fair value as of the transaction date. As discussed in Note 8(B), on the transaction date, the cost share advance from Pfizer was discounted to fair value using the Company's estimated incremental borrowing rate over the period in which the cost share advance is expected to be utilized. The recorded amount has been and will continue to be reduced each reporting period by the amount of Allowable Expenses applied to the cost share advance. There were no non-recurring fair value assets as of June 30, 2021 and March 31, 2021.

Note 5—Related Party Transactions

As of June 30, 2021, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or approximately 52.9%, of the Company's outstanding common shares. The Company has agreements with Sumitovant, Sumitomo Dainippon Pharma, and their affiliates, including Sunovion, a subsidiary of Sumitomo Dainippon Pharma. These agreements are described below.

(A) Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Loan Agreement

On December 27, 2019, the Company and one of its subsidiaries, 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. 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, and 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. LIBOR is currently expected to be phased out by the end of 2021, and if it becomes unavailable, the Company and Sumitomo Dainippon Pharma will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. 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, 2021, approximately $41.3 million of borrowing capacity remains available to the Company, subject to the terms of the Sumitomo Dainippon Pharma Loan Agreement and the outstanding loan balance of $358.7 million is classified as a long-term liability on the unaudited condensed consolidated balance sheets under the caption long-term debt, less current maturities (related party). Interest expense under the Sumitomo Dainippon Pharma Loan Agreement was $2.9 million and $2.2 million for the three months ended June 30, 2021 and 2020, respectively, and is included in interest expense in the unaudited condensed consolidated statements of operations.

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, as amended on November 9, 2020, pursuant to which Sumitovant provided 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, provided services to the Company on behalf of Sumitovant under this agreement. The term of the consulting agreement with Sumitovant expired on March 31, 2021. For the three months ended June 30, 2021 and 2020, the Company incurred less than $0.1 million and $0.1 million of expense under this consulting agreement, respectively, which are included in selling, general and administrative (“SG&A”) expenses in the unaudited condensed consolidated statements of operations. In addition, for the three months ended June 30, 2021, the Company agreed to

reimburse Sumitovant for certain other third-party pass-through expenses that it incurred on behalf of the Company. These expenses, totaling less than $0.1 million are included in R&D expenses in the unaudited condensed consolidated statements of operations.

The Company's outstanding obligations to Sumitovant were less than $0.1 million as of June 30, 2021 and $0.1 million as of March 31, 2021, and are included in amounts due to related parties on the unaudited condensed consolidated balance sheets.

(C) Sunovion Pharmaceuticals Inc.

Market Access Services Agreement

On August 1, 2020, one of the Company's subsidiaries, MSG, entered into a Market Access Services Agreement, as amended ("Market Access Services Agreement"), with Sunovion. Pursuant to the Market Access Services Agreement, among other things, Sunovion agreed to provide to MSG certain market access services with respect to the distribution and sale of ORGOVYX ("Prostate Cancer Product") and MYFEMBREE (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. Pursuant to this agreement, Sunovion will also provide certain services to the Company to enable the Company to comply with its obligations under the State Transparency Laws.

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 related, 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 has paid and will continue to 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 to manage rebates, chargebacks and similar fees (see Note 3). For the three months ended June 30, 2021, the Company incurred $1.3 million under this agreement (inclusive of third-party pass-through costs billed to the Company), which is included in SG&A expenses in the unaudited condensed consolidated statement of operations. No amounts were incurred in the three months ended June 30, 2020. As of each of June 30, 2021 and March 31, 2021, the Company's outstanding obligation pursuant to this agreement was $0.4 million and are included in accounts payable and amounts due to related parties, respectively, on the unaudited condensed consolidated balance sheets.

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.

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, 2021 and 2020 was (1.50)% and (2.09)%, 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 implemented certain provisions of the CARES Act, such as deferring employer payroll taxes through the end of calendar year 2020. As of June 30, 2021, the Company has deferred $1.8 million of employer payroll taxes, of which 50% are required to be deposited by December 2021 and the remaining 50% by December 2022. The current portion of the deferred payroll tax liability of $0.9 million is included in accrued expenses and other current liabilities and the non-current portion of the deferred payroll tax liability of $0.9 million is included in other liabilities on the unaudited condensed consolidated balance sheets.

Note 7—Share-Based Compensation

The Company has two share-based compensation plans, the Myovant Sciences Ltd. 2020 Inducement Plan and the Myovant Sciences Ltd. 2016 Equity Incentive Plan (collectively, the "Equity Plans").

(A) 2020 Inducement Plan

In November 2020, the compensation committee of the Company's board of directors adopted the Myovant Sciences Ltd. 2020 Inducement Plan (the "2020 Inducement Plan"), which, subject to the adjustment provisions thereof, reserved 1.0 million shares of the Company's common shares for issuance. The 2020 Inducement Plan was adopted without shareholder approval pursuant to the Listed Company Manual Rule 303A.08 ("Rule 303A.08") of the New York Stock Exchange (the "NYSE"). The 2020 Inducement Plan provides for the grant of restricted stock units and non-qualified stock options, and contains terms and conditions intended to comply with the inducement award exception under the NYSE rules. In accordance with Rule 303A.08, awards under the 2020 Inducement Plan may only be made to individuals not previously employees of the Company, or being rehired following a bona fide period of interruption of employment, as an inducement material to such individuals' entering into employment with the Company. An award is a right to receive the Company's common shares pursuant to the 2020 Inducement Plan pursuant to a restricted stock unit award or a non-qualified stock option award. As of June 30, 2021, there were less than 0.1 million common shares available for future issuance under the 2020 Inducement Plan.

(B) 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, 2021, the number of common shares authorized for issuance under the 2016 Plan increased automatically by 3.6 million shares in accordance with the evergreen provision. As of June 30, 2021, a total of 2.4 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.

(C) Stock Options

Activity for stock options for the three months ended June 30, 2021 is as follows:

	Number of Options
Options outstanding at March 31, 2021	8,293,331
Granted	892,157
Exercised	(436,573)
Forfeited	(135,909)
Options outstanding at June 30, 2021	8,613,006
Options vested and expected to vest at June 30, 2021	8,613,006
Options exercisable at June 30, 2021	5,308,419

(D) Restricted Stock and Performance Stock Units

Activity for restricted stock units and performance stock units for the three months ended June 30, 2021 is as follows:

	Number of Shares
Unvested balance at March 31, 2021	3,571,235
Granted	2,343,086
Vested	(540,760)
Forfeited	(238,678)
Unvested balance at June 30, 2021	5,134,883
Vested and unreleased	35,559
Outstanding balance at June 30, 2021	5,170,442

(E) Share-Based Compensation

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

	Three Months Ended June 30,	
	2021	2020
Share-based compensation recognized as:		
R&D expense	$ 3,957	$ 4,024
SG&A expense	7,155	3,788
Capitalized under inventory	150	—
Total	$ 11,262	$ 7,812

Total unrecognized share-based compensation was approximately $102.2 million as of June 30, 2021 and is expected to be recognized over a weighted-average period of approximately 3.3 years.

(F) Separation Agreement with Former Principal Executive Officer

In January 2021, the Company entered into a Separation and General Release Agreement with its former Principal Executive Officer. Pursuant to the terms of this agreement, all of the former Principal Executive Officer's then outstanding and unvested equity awards became fully vested. In addition, the post-termination period during which the former Principal Executive Officer may exercise her outstanding stock options was extended to 12 months. The former Principal Executive Officer has granted Sumitovant or any Sumitovant affiliate a right of first refusal to purchase her common shares of the Company under certain circumstances and provide the Company and its affiliates a general release of claims. Share-based compensation included in SG&A expense for the three months ended June 30, 2021 includes $1.4 million related to the settlement and remeasurement of these awards.

As a result of the repurchase feature described above, the outstanding awards were reclassified from additional paid-in capital to current liabilities. The share-based compensation liabilities have been and will continue to be remeasured at fair value each

reporting period end, with the change in fair value recorded as share-based compensation within SG&A until the stock options are exercised and the common shares are sold to Sumitovant, to the market, or otherwise settled, or the former Principal Executive Officer has held the common shares for a period of at least six months. As of June 30, 2021, a total of 1,081,803 outstanding stock options and a total of 462,705 common shares remain subject to the right of first refusal. The former Principal Executive Officer's outstanding stock options remain exercisable through January 11, 2022. As of June 30, 2021 and March 31, 2021, $21.2 million and $21.6 million, respectively, is included in share-based compensation liabilities on the unaudited condensed consolidated balance sheets.

Note 8—Collaboration and License Agreements

(A) Richter Development and Commercialization Agreement

On March 30, 2020, the Company entered into 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 "Richter Development and Commercialization Agreement"). Under the terms of the Richter Development and Commercialization 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. On July 16, 2021, the European Commission approved RYEQO as the first and only long-term, once-daily oral treatment in Europe for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. This approval triggered a $15.0 million regulatory milestone payment due from Richter, which the Company expects to receive and record as Richter license and milestone revenue in the three months ending September 30, 2021.

Under the terms of the Richter Development and Commercialization 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 CMOs to Richter to enable Richter to manufacture relugolix combination tablet. The Company has agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to the Company's agreements with its CMOs. 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 Richter 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. No other regulatory milestones, sales-related milestones, or royalties on net sales following regulatory approval were included 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, *Revenue from Contracts with Customers.* 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 tablet, 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 tablet. 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 delivered 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 Richter 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 tablet clinical and regulatory data packages to Richter, the Company concluded that during the three months ended June 30, 2020, it satisfied approximately two-thirds of the combined performance obligation and recognized $33.3 million of the transaction price as Richter license and milestone revenue during the three months ended June 30, 2020. The remaining $16.7 million of the transaction price is recorded as deferred revenue on the unaudited condensed consolidated balance sheet as of June 30, 2021 and is expected to be recognized as Richter license and milestone revenue during the three months ending September 30, 2021 when the Company expects to deliver the remaining substantive relugolix combination tablet data packages to Richter. No Richter license and milestone revenue was recorded in the three months ended June 30, 2021.

The term of the Richter Development and Commercialization Agreement shall expire on a country-by-country basis upon expiry of the Royalty Term for the Product in a country in the Richter Territory. The Richter Development and Commercialization Agreement may be terminated in its entirety or on a country-by-country basis by mutual consent of the

parties, or by either party for the uncured material breach of other party, for bankruptcy of the other party, and for certain other reasons in accordance with the terms of the Richter Development and Commercialization Agreement.

(B) Pfizer Collaboration and License Agreement

On December 26, 2020, one of the Company's subsidiaries, MSG, and Pfizer, entered into a collaboration and license agreement (the "Pfizer Collaboration and License Agreement"), pursuant to which the Company and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). In addition, Pfizer also received an option to acquire exclusive commercialization and development rights to relugolix in oncology outside the Co-Promotion Territory, excluding certain Asian countries (the "Pfizer Territory"). See Note 10, "Subsequent Events."

In the Co-Promotion Territory, the Company and Pfizer will equally share profits and certain expenses, including certain pre-launch inventory costs incurred by the Company prior to the effective date of the Pfizer Collaboration and License Agreement (the "Allowable Expenses"). The Company will remain responsible for regulatory interactions and drug supply and will continue to lead clinical development for MYFEMBREE in the women's health indications, while development for ORGOVYX will be shared equally among the parties.

In the Co-Promotion Territory, the Company will be the principal on all sales transactions with third parties and will recognize 100% of product sales to third parties as revenue from contracts with customers. The Company concluded that based on the principal vs. agent guidance in ASC 606, it has primary responsibility for fulfilling customer orders, controls inventory before it is sold to third party customers, assumes the risk of inventory loss, and maintains discretion in establishing product price.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, the Company received an upfront payment of $650.0 million in December 2020, and is eligible to receive up to $3.7 billion of milestone payments, including two regulatory milestones of $100.0 million upon each FDA approval for MYFEMBREE in uterine fibroids and endometriosis ($200.0 million in the aggregate), and tiered sales milestones of up to $3.5 billion upon reaching certain thresholds of annual net sales for oncology and the combined women's health indications in the Co-Promotion Territory. In July 2021, the Company received a $100.0 million regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. This regulatory milestone payment is included in the caption titled, milestone receivable from Pfizer, on the unaudited condensed consolidated balance sheet as of June 30, 2021.

If Pfizer exercises its option to acquire exclusive commercialization and development rights to relugolix in oncology in the Pfizer Territory, the Company will receive an option exercise fee of $50.0 million, will also be eligible to receive double-digit royalties on net sales of relugolix in the Pfizer Territory, and Pfizer will bear 100% of costs incurred in the Pfizer Territory.

Pursuant to the terms of the Pfizer Collaboration and License Agreement, the Company will bear Pfizer's share of Allowable Expenses, up to a maximum of $100.0 million for calendar year 2021 and up to a maximum of $50.0 million for calendar year 2022. Any unused portion will carry over into the subsequent calendar years until the Company has assumed in aggregate $150.0 million of Pfizer's share of the Allowable Expenses.

The term of the Pfizer Collaboration and License Agreement continues until no products are sold and all development activities have terminated in the Co-Promotion Territory and, in the case that Pfizer exercises its option for relugolix in the Pfizer Territory, on the last to expire royalty term with respect to a country in the Pfizer Territory. The Pfizer Collaboration and License Agreement may be terminated early by either party for the uncured material breach of the other party or for bankruptcy or other insolvency proceeding of the other party. In addition, Pfizer has certain other termination rights and may terminate the Pfizer Collaboration and License Agreement early upon providing written notice to the Company pursuant to the terms of the Pfizer Collaboration and License Agreement.

The Company assessed the Pfizer Collaboration and License Agreement and determined that it meets both criteria to be considered a collaborative agreement within the scope of ASC 808, *Collaborative Arrangements*: active participation by both parties and exposures to significant risks and rewards dependent on the commercial success of the activities. Although the Company is lead party and will perform many activities, both development and commercialization responsibilities are assigned between parties and both parties participate on joint steering and other committees overseeing the collaboration activities. Both parties are exposed to significant risks and rewards based on the economic outcomes of the collaboration through cost sharing and profit (loss) sharing provisions. Net payments to/from Pfizer for Pfizer's share of the net profits and Allowable Expenses will be disaggregated and presented in the Company's consolidated statements of operations according to the nature of the expense (e.g., collaboration expense, R&D expenses, or SG&A expenses).

As discussed above, the Company received a $650.0 million upfront payment from Pfizer in December 2020, of which $150.0 million is Pfizer's advanced reimbursement for Pfizer's share of Allowable Expenses (up to $100.0 million for calendar year 2021 and up to $50.0 million for calendar year 2022). The Company concluded that the prepayment by Pfizer of its share of Allowable Expenses represents a significant financing component since the Company received the cash flows at the outset of the arrangement, rather than over a two-year period. Accordingly, the Company reduced the amount of the advanced reimbursement by approximately $3.6 million, representing the implied financing costs based on the Company's incremental borrowing rate that was derived based on the Sumitomo Dainippon Pharma Loan Agreement, and recorded the discounted value on the consolidated balance sheet as a deposit liability (cost share advance from Pfizer) as of the transaction date, split between a current and a non-current portion, based on the expected timing of Allowable Expenses subject to cost share. The financing component has been and will continue to be accreted to interest expense utilizing a method that approximates the effective yield method over the period in which the cost share advance is expected to be used. The remainder of the upfront payment was recorded as deferred revenue and has been and will continue to be recognized as Pfizer collaboration revenue on a straight-line basis over the estimated term of the agreement of six years, which was estimated by the Company based upon the terms of the Pfizer Collaboration and License Agreement, including the termination provisions contained therein. The Company determined straight-line amortization to be appropriate because the upfront payment represents payment for Pfizer's right to participate in the collaboration activities, including both commercialization and development activities, which are expected to be realized evenly over this period.

The achievement of regulatory milestones is outside of the Company's control and therefore was not deemed probable at contract inception. Amounts associated with the regulatory milestones were not initially recognized. Upon achievement of the related regulatory milestone, cumulative catch-up revenue will be recorded as Pfizer collaboration revenue in the period in which the respective regulatory milestone is achieved, and the remainder will be recognized over the remaining contract term. The Company determined that, conceptually, the regulatory milestone payments represent payment for development activities that will continue to benefit the collaboration as the products move toward commercialization. Accordingly, the recognition of revenue associated with the regulatory milestones follows the same amortization model as the upfront payment described above.

Similar to the regulatory milestones, sales-based milestone payments will not initially be recognized due to the uncertainty associated with the future commercial outcomes of ORGOVYX and MYFEMBREE. Upon achievement, the sales-based milestones will be recognized as revenue immediately in the period when the annual sales thresholds are met as the payments represent consideration for past activities that are completed and culminated in the annual sales thresholds being met.

Amounts due to Pfizer as of June 30, 2021 totaling approximately $11.0 million consisted of $5.8 million payable to Pfizer for Pfizer's 50% share of net profits on sales of ORGOVYX and MYFEMBREE in the U.S. and approximately $5.2 million reimbursement of Allowable Expenses incurred by Pfizer (comprised of $0.4 million and $4.8 million in R&D and SG&A expenses, respectively). Amounts due to Pfizer as of March 31, 2021 totaling approximately $1.9 million consisted of $1.8 million payable to Pfizer for Pfizer's 50% share of net profits on sales of ORGOVYX in the U.S. and approximately $0.1 million reimbursement of Allowable Expenses incurred by Pfizer.

The Company determined that the $50.0 million option for an exclusive license in the Pfizer Territory does not give rise to a material right since the option fee, coupled with the net royalty payments, reflects its standalone selling price. As such, the option is not considered a unit of account under the present arrangement and will be assessed for accounting purposes if and when exercised.

(C) Contract Balances

The following table presents changes in the Company's contract assets and liabilities during the three months ended June 30, 2021 (in thousands):

	Balance at March 31, 2021	Additions	Imputed Interest	Deductions	Balance at June 30, 2021
Contract assets:					
Milestone receivable from Pfizer	$ —	$ 100,000	$ —	$ —	$ 100,000
Contract liabilities:					
Deferred revenue [1]	$ 497,933	$ 100,000	$ —	$ (29,509)	$ 568,424
Cost share advance from Pfizer [2]	$ 121,862	$ —	$ 601	$ (18,285)	$ 104,178

(1) Includes $117.2 million and $451.2 million presented as current and non-current, respectively, on the unaudited condensed consolidated balance sheet as of June 30, 2021. Includes $100.6 million and $397.4 million presented as current and non-current, respectively, on the unaudited condensed consolidated balance sheet as of March 31, 2021.

(2) Includes $104.2 million presented as current on the unaudited condensed consolidated balance sheet as of June 30, 2021. Includes $92.4 million and $29.4 million presented as current and non-current, respectively, on the unaudited condensed consolidated balance sheet as of March 31, 2021.

During the three months ended June 30, 2021, milestone receivable from Pfizer increased by $100.0 million as the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021 triggered a regulatory milestone payment due from Pfizer. The Company had no contract assets as of March 31, 2021.

During the three months ended June 30, 2021, deferred revenue increased by $70.5 million. The net increase was the result of a $100.0 million regulatory milestone receivable due from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021, partially offset by the recognition of $29.5 million of Pfizer collaboration revenue.

During the three months ended June 30, 2021, cost share advance from Pfizer decreased by $17.7 million. The decrease was the net result of the application of $18.3 million of shared Allowable Expenses incurred by the Company (comprised of $0.5 million, $7.6 million, and $10.2 million in reductions to collaboration expense, R&D expenses, and SG&A expenses, respectively), partially offset by accretion of the implied financing component of $0.6 million.

Note 9—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 also agreed to indemnify Sunovion against certain losses, claims, liabilities and related expenses incurred by Sunovion, subject to the terms of the Market Access Services 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

On April 29, 2016, 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. Pursuant to the license agreement (the "Takeda License Agreement"), Takeda granted to the Company an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize relugolix and MVT-602, and products containing these compounds for all human diseases and conditions. 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. As of June 30, 2021 and March 31, 2021, the Company recorded royalties payable to Takeda of $0.9 million and $0.3 million, respectively, which are included in the caption accrued expenses and other current liabilities on the unaudited condensed consolidated balance sheets. 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.

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.

In May 2018, the Company entered into a Commercial Manufacturing and Supply Agreement with Takeda (the "Takeda Commercial Supply Agreement") pursuant to which 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 10—Subsequent Events

(A) Richter Development and Commercialization Agreement

On July 16, 2021, the European Commission approved RYEQO as the first and only long-term, once-daily oral treatment in Europe for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. This approval triggered a $15.0 million regulatory milestone payment due from Richter, which the Company expects to receive and record as Richter license and milestone revenue in the three months ending September 30, 2021.

See Note 8(A) for additional information about the Richter Development and Commercialization Agreement.

(B) Pfizer Collaboration and License Agreement

In July 2021, the Company received a $100.0 million regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. This regulatory milestone is included in the caption titled, milestone receivable from Pfizer, on the unaudited condensed consolidated balance sheet as of June 30, 2021.

In July 2021, the Company and Pfizer agreed to extend the timeline for Pfizer's decision to exercise its exclusive option to develop and commercialize relugolix in oncology in the Pfizer Territory, through the end of October 2021.

See Note 8(B) for additional information about the Pfizer Collaboration and License Agreement.

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, 2021 included in our Annual Report on Form 10-K, filed with the SEC on May 11, 2021. 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:

- our and our collaboration partners' ability to successfully plan for and commercialize ORGOVYX®, MYFEMBREE®, RYEQO®, as well as any product candidates, if approved;
- the success and anticipated timing of our clinical studies for our product candidates;
- 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 our product candidates;
- our ability to procure sufficient quantities of commercial relugolix drug substance and drug product from approved third party CMOs;
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain and maintain reimbursement and coverage from government and private payers 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 and third-party logistics providers;
- our ability to quickly and efficiently identify and develop new product candidates;
- the impact of pandemics, epidemics or outbreaks of infectious diseases, including the effect that the COVID-19 pandemic and related public health measures will have on our business operations, financial conditions and results of operations;
- our ability to hire and retain our management and other key personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our products and 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 expectations regarding potential future payments that we are eligible to receive from Pfizer under the Pfizer Collaboration and License Agreement and Richter under the Richter Development and Commercialization Agreement;
- our ability to borrow under the Sumitomo Dainippon Pharma Loan Agreement;
- third party collaboration partners' abilities to perform their obligations under our agreements with them;
- our ability to raise additional capital if needed, on acceptable terms to us;
- 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 biopharmaceutical company focused on redefining care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, we have two FDA-approved products: (1) ORGOVYX® (relugolix 120 mg), which was approved in the U.S. by the U.S. Food and Drug Administration ("FDA") in December 2020 as the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for the treatment of adult patients with advanced prostate cancer; and (2) MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), which was approved in the U.S. by the FDA in May 2021 as the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, the European Commission approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) as the first and only long-term, once-daily oral treatment in Europe for moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In July 2021, Myovant Sciences GmbH ("MSG"), one of our subsidiaries, submitted a supplemental New Drug Application ("sNDA") to the FDA for once-daily MYFEMBREE for the management of moderate to severe pain associated with endometriosis. MYFEMBREE is also being assessed for contraceptive efficacy in women ages 18-35 years who are at risk for pregnancy, pending FDA removal of a partial clinical hold. Relugolix (120 mg) is also under regulatory review in Europe for men with advanced prostate cancer. We are also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for the treatment of female infertility as a part of assisted reproduction.

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares, from debt financing arrangements, and more recently from the upfront and regulatory milestone payments we received from Pfizer Inc. ("Pfizer") and Gedeon Richter Plc. ("Richter"). We began generating product revenue from the sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively.

Our majority shareholder is Sumitovant Biopharma Ltd. ("Sumitovant"), a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma"). As of June 30, 2021, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,641,181, or approximately 52.9%, of our outstanding common shares.

First Fiscal Quarter Ended June 30, 2021 and Recent Business Updates

Below is a summary of certain events during our first fiscal quarter ended June 30, 2021 and recent business updates. Additional information about our business, our products, and our product candidates is included in Part I. Item 1., "Business," included in our Annual Report on Form 10-K, filed with the SEC on May 11, 2021.

Products and Product Candidates

- On May 26, 2021, the FDA approved MYFEMBREE as the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids. MYFEMBREE was launched in the U.S. by us and our collaboration partner, Pfizer, in mid-June 2021. Pursuant to the terms of the Pfizer Collaboration and License Agreement, this approval triggered a $100.0 million regulatory milestone payment due from Pfizer, which we received in July 2021.
- On June 15, 2021, the United States Patent and Trademark Office ("USPTO") granted U.S. Patent. No. 11,033,551 to Myovant. This patent covers the unique and innovative method of treating patients for heavy menstrual bleeding associated with uterine fibroids with MYFEMBREE. This patent will expire in September of 2037 and is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). This patent term matches that of two methods patents (U.S. Patent. Nos. 10,786,501 and 10,449,191) previously granted by the USPTO for ORGOVYX that cover methods of treating advanced prostate cancer with relugolix.
- On July 6, 2021, one of our subsidiaries, MSG, submitted an sNDA to the FDA for once-daily MYFEMBREE for the management of moderate to severe pain associated with endometriosis. In April and June 2020 and January 2021, we reported positive results from the two replicate Phase 3 SPIRIT studies and the SPIRIT long-term extension study.
- On July 16, 2021, the European Commission approved RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. RYEQO is the first and only long-term, once-daily oral treatment for uterine fibroids in Europe and has no limitation on its duration of use. The approval was based on safety and efficacy data from the Phase 3 LIBERTY program, which consisted of two replicate, 24-week, multinational clinical studies (LIBERTY 1 and LIBERTY 2), a one-year extension study, and supportive bone mineral density data from a randomized withdrawal study. The commercial launch of RYEQO is expected to begin in the second half of calendar year 2021 and will be executed by Richter, our commercialization partner for RYEQO in Europe and certain other international markets. This approval triggered a $15.0 million regulatory milestone payment due from Richter, which we expect to receive and record as Richter license and milestone revenue in the three months ending September 30, 2021.
- On May 18, 2021, the FDA informed us that they placed a partial clinical hold on the Phase 3 SERENE study evaluating MYFEMBREE for the prevention of pregnancy, pending certain study protocol modifications. In July 2021, we provided to the FDA an amended study protocol for the SERENE study. Following our discussions with the FDA, we expect the partial clinical hold to be lifted in August 2021.

Corporate

- For the three months ended June 30, 2021, we generated net product revenue from sales of ORGOVYX and MYFEMBREE of $10.5 million and $1.1 million, respectively.
- As of June 30, 2021, we had cash, cash equivalents and marketable securities of $569.8 million. We currently believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Quarterly Report on Form 10-Q. Our June 30, 2021 cash, cash equivalents, and marketable securities balance excludes $115.0 million of recently triggered regulatory milestone payments from Pfizer and Richter, of which $100.0 million was received from Pfizer in July 2021 and $15.0 million is expected to be received from Richter in the three months ending September 30, 2021.
- In July 2021, we and Pfizer agreed to extend the timeline for Pfizer's decision to exercise its exclusive option to develop and commercialize relugolix in oncology outside of the U.S. and Canada, excluding certain Asian countries (the "Pfizer Territory"), through the end of October 2021.

Expected Upcoming Milestones

The following is a summary of certain of our expected upcoming milestones.

- Pfizer's decision regarding its exclusive option to acquire development and commercialization rights to relugolix in oncology in the Pfizer Territory is expected by the end of October 2021.
- Commercial launch of RYEQO in Europe is expected to begin in the second half of calendar year 2021, to be executed by Richter.
- Marketing Authorization Application ("MAA") submission to the European Medicines Agency ("EMA") for RYEQO for the treatment of women with endometriosis-associated pain is expected in the second half of calendar year 2021. Richter will be the MAA sponsor.
- FDA submission of the Phase 3 LIBERTY randomized withdrawal study results for MYFEMBREE in women with uterine fibroids is expected by the end of calendar year 2021.
- European Commission decision on the advanced prostate cancer MAA is expected in calendar year 2022.

Effects of the COVID-19 Pandemic

In December 2019, an outbreak of a novel strain of coronavirus, or COVID-19, was identified. In March 2020, the World Health Organization categorized COVID-19 as a pandemic as it spread throughout the U.S. and other countries across the world. The COVID-19 pandemic and related public health measures, including orders to shelter-in-place, socially distance, close schools, restrict travel, and mandate business closures, adversely affected workforces, organizations, consumers and economies, which led to an economic downturn and which may cause market volatility and uncertainty in future periods. As vaccination rates against COVID-19 increase, many restrictions and public health guidelines have been recently eased. However new and potentially more virulent variants of the coronavirus have been recently identified, such as the delta variant, which may further impact the effects that the COVID-19 pandemic may have on us.

Our priorities during the COVID-19 pandemic have been to protect the health and safety of our employees and patients while continuing our mission to redefine care for women and for men. We believe the safety measures we have taken in response to the COVID-19 pandemic meet or exceed the guidelines established by 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 adopted remote working tools to minimize the disruption to our business activities. As vaccination rates against COVID-19 increase, we plan to ease restrictions to our facilities and allow our employees to return to work on-site. In June 2021, our oncology and women's health sales forces and our medical affairs team resumed in-person interactions with healthcare professionals.

To date, the impact of the COVID-19 pandemic on our ability to advance our clinical studies, our regulatory activities, and our U.S. commercial launch activities for ORGOVYX and MYFEMBREE have been limited. The FDA approved ORGOVYX for the treatment of adult patients with advanced prostate cancer on December 18, 2020 and MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. We and our collaboration partner, Pfizer, commercially launched ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively. 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, some physician's offices continue to have limited on-site access for pharmaceutical representatives to reduce exposure risk for their patients or staff. Conducting these interactions virtually could reduce the number of medical professionals we are able to present to, and these virtual meetings may not be as impactful as in-person meetings. The COVID-19 pandemic has presented challenges for our medical affairs team to present scientific data and for our regional medical advisors to engage potential prescribers in scientific exchange. Multiple medical conferences have been cancelled, postponed or moved to virtual formats, resulting in fewer opportunities to present our scientific data and our medical affairs team members have only begun to make in-person presentations to the medical community. Communications to the medical community virtually in many instances may make it less effective to educate and engage in scientific exchange. Reduced access to healthcare providers as a result of social distancing protocols may impact or require adjustments to our planned commercialization activities, including the manner in which our field teams engage with healthcare providers and facilities. At this time, we do not believe that the COVID-19 pandemic has disproportionately impacted us relative to other companies in our industry. To date, we have not experienced supply constraints, and we believe we have procured sufficient quantities of relugolix drug substance to meet our U.S. ORGOVYX and MYFEMBREE launch plans.

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 commercial launch activities for

ORGOVYX and MYFEMBREE, end user demand for our approved products, 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.

As vaccination rates against COVID-19 increase, we plan to ease restrictions to our facilities and allow our employees to return to work on-site during the third quarter of calendar year 2021. The safety protocols we implement as our employees return to work on-site may not prevent employees from contracting COVID-19. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to illness from COVID-19, we may not be able to execute on our business strategy and/or our operations may be negatively impacted. The magnitude of the adverse effect on our business operations will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Refer to the risk factor titled “Business interruptions resulting from effects of pandemics or epidemics, such as the COVID-19 pandemic, 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.

Components of our Results of Operations

Revenues

We currently have two FDA-approved products, ORGOVYX for the treatment of adult patients with advanced prostate cancer and MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids, which generate product revenue in the U.S. We record product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions.

Our Pfizer collaboration revenue consists of the partial recognition of the upfront payment we received from Pfizer in December 2020 and of the regulatory milestone payment due from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021 (see Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Our Richter license and milestone revenue consists of the recognition of previously deferred revenue associated with upfront and regulatory milestone payments we received from Richter pursuant to the terms of the Richter Development and Commercialization Agreement in March 2020 and April 2020, respectively (see Note 8(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). We recognize revenue as we satisfy our combined performance obligation to Richter.

Cost of Product Revenue

Our cost of product revenue is composed of the cost of goods sold and royalty expense. Our cost of goods sold consists of raw materials, third-party manufacturing costs to manufacture the raw materials into finished product, freight, and indirect overhead costs associated with sales of ORGOVYX and MYFEMBREE in the U.S. Our royalty expense consists of royalties on net sales of ORGOVYX and MYFEMBREE payable to Takeda pursuant to the terms of the Takeda License Agreement (see Note 9(D) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

In connection with the FDA approvals of ORGOVYX (on December 18, 2020) and MYFEMBREE (on May 26, 2021), we subsequently began capitalizing inventory manufactured or purchased for each product after its respective approval date. As a result, we expensed certain manufacturing costs of ORGOVYX and MYFEMBREE as research and development (“R&D”) expenses prior to FDA approval and, therefore, these costs are not included in cost of goods sold.

Collaboration Expense to Pfizer

Our collaboration expense to Pfizer consists of Pfizer’s 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S. (see Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Research and Development Expenses

Our R&D expenses to date have been primarily attributable 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.

Our program-specific costs primarily include third-party costs, which include expenses incurred under agreements with CROs and 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 pre-commercial manufacturing activities and regulatory submissions, and other third-party expenses directly attributable to the development of our product candidates.

Our unallocated R&D costs primarily include employee-related expenses, such as salaries, share-based compensation, fringe 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 and costs associated with nonclinical studies.

R&D activities have been, and will continue to be, central to our business model. We currently expect R&D expenses for the year ending March 31, 2022, to be modestly lower than the R&D expenses incurred in the year ended March 31, 2021, largely due to our sharing of certain expenses with Pfizer pursuant to the Pfizer Collaboration and License Agreement. Overall, we expect declining spend on our Phase 3 clinical programs that are winding down to be offset primarily by incremental spend on new relugolix development programs, such as the Phase 3 SERENE study, and certain other lifecycle opportunities to potentially expand the commercial opportunity for the relugolix franchise, as well as post-marketing requirements as agreed upon with the FDA.

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 commercial success for ORGOVYX and MYFEMBREE, or for any of our current or potential future 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 net 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.

We expect that certain R&D expenses will be shared equally with Pfizer pursuant to the Pfizer Collaboration and License Agreement.

Selling, General and Administrative Expenses

Our selling, general and administrative ("SG&A") expenses consist primarily of personnel costs, including salaries, sales incentive compensation, bonuses, fringe benefits, and share-based compensation for our executive, finance, human resources, legal, information technology, commercial operations, marketing, market access, sales, and other administrative functions. Our SG&A expenses also include marketing programs, advertising, conferences, congresses, travel expenses, professional fees for legal, accounting, auditing and tax services, and costs related to rent and facilities, insurance, information technology, commercial operations, and general overhead. Our SG&A expenses also include costs incurred under our Market Access Services Agreement with Sunovion.

We expect SG&A expenses to increase in future periods as we continue to expand our sales and marketing infrastructure and capabilities as well as general administrative functions to support multiple product launches and commercialization activities. We expect SG&A expenses in future periods to include certain expenses related to our patient support programs such as free drug and patient assistance for qualified uninsured patients. The timing of these increased expenditures and their magnitude are primarily dependent on our commercial success and sales growth of ORGOVYX and MYFEMBREE, as well as the timing of any new product launches and other potential business and operational activities.

We expect that certain SG&A expenses will be shared equally with Pfizer pursuant to the Pfizer Collaboration and License Agreement.

Interest Expense

Our interest expense consists of related party 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 and accretion of the financing component of the cost share advance from Pfizer (see Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Interest Income

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

Foreign Exchange Gain

Our foreign exchange gain in the three months ended June 30, 2020 consists of the impact of changes in foreign currency exchange rates on our foreign exchange denominated liabilities, relative to the U.S. dollar. The impact of foreign currency 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. Our primary foreign currency exposure has historically been the exchange rate between the Swiss franc and the U.S. dollar.

In December 2020, we changed the functional currency of our wholly-owned subsidiary in Switzerland, MSG, from the Swiss franc to the U.S. dollar. This change in functional currency was accounted for prospectively. As a result of this change, we currently expect that future impacts of changes in foreign currency exchange rates on our results of operations will not be significant. See Note 2 to our audited consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2021, filed with the SEC on May 11, 2021.

Results of Operations

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,	
	2021	**2020**
Revenues:		
Product revenue, net	$ 11,554	$ —
Pfizer collaboration revenue	29,509	—
Richter license and milestone revenue	—	33,333
Total revenues	41,063	33,333
Operating costs and expenses:		
Cost of product revenue	1,032	—
Collaboration expense to Pfizer	5,261	—
Research and development	30,880	44,186
Selling, general and administrative	61,212	22,828
Total operating costs and expenses	98,385	67,014
Loss from operations	(57,322)	(33,681)
Interest expense	3,505	2,184
Interest income	(78)	(108)
Foreign exchange gain	—	(3,569)
Loss before income taxes	(60,749)	(32,188)
Income tax expense	911	672
Net loss	$ (61,660)	$ (32,860)

Revenues

The following table provides information about our revenues (in thousands):

	Three Months Ended June 30,	
	2021	2020
Revenues:		
Product revenue, net:		
ORGOVYX	$ 10,479	$ —
MYFEMBREE	1,075	—
Total product revenue, net	11,554	—
Pfizer collaboration revenue:		
Amortization of upfront payment	20,974	—
Amortization of regulatory milestone	8,535	—
Total Pfizer collaboration revenue	29,509	—
Richter license and milestone revenue	—	33,333
Total revenues	$ 41,063	$ 33,333

We began generating product revenue from sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively. We record product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions.

Pfizer collaboration revenue for the three months ended June 30, 2021, consists of the partial recognition of the upfront payment we received from Pfizer in December 2020 and of the regulatory milestone payment due from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the treatment for heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. There were no such amounts recognized for the three months ended June 30, 2020.

There was no Richter license and milestone revenue for the three months ended June 30, 2021. Richter license and milestone revenue for the three months ended June 30, 2020 consists of the partial recognition of the upfront payment we received from Richter in March 2020 and the regulatory milestone payment we received from Richter in April 2020.

See Note 8 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information regarding collaboration revenue under the Pfizer Collaboration and License Agreement and license and milestone revenue under the Richter Development and Commercialization Agreement.

Cost of Product Revenue

For the three months ended June 30, 2021, our cost of product revenue was $1.0 million, which includes the cost of goods sold and royalty expense payable to Takeda pursuant to the Takeda License Agreement (see Note 9(D) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). There were no such amounts recognized for the three months ended June 30, 2020.

In connection with the FDA approvals of ORGOVYX for adult patients with advanced prostate cancer (on December 18, 2020) and MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids (on May 26, 2021), we subsequently began capitalizing inventory manufactured or purchased for each product after its respective approval date. Previously, costs to manufacture ORGOVYX and MYFEMBREE were expensed as incurred as R&D expenses. As a result, minimal cost of goods sold has been recorded during the three months ended June 30, 2021 and the costs for quantities of ORGOVYX and MYFEMBREE sold during the three months ended June 30, 2021 were previously recorded as R&D expenses prior to FDA approval. We expect our cost of goods sold to increase in future periods as quantities of previously expensed ORGOVYX and MYFEMBREE inventory are depleted from our inventory stock.

Collaboration Expense to Pfizer

For the three months ended June 30, 2021, our collaboration expense to Pfizer was $5.3 million and represents Pfizer’s 50% share of net profits from the sales of ORGOVYX and MYFEMBREE in the U.S. pursuant to the terms of the Pfizer Collaboration and License Agreement (see Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). There were no such amounts recognized for the three months ended June 30, 2020.

Research and Development Expenses

For the three months ended June 30, 2021 and 2020, our R&D expenses consisted of the following (in thousands):

	Three Months Ended June 30,		
	2021	2020	Change
Program-specific costs:			
Relugolix	$ 7,191	$ 25,893	$ (18,702)
MVT-602	63	224	(161)
Unallocated costs:			
Share-based compensation	3,957	4,024	(67)
Personnel expense	14,764	11,836	2,928
Other expense	4,905	2,209	2,696
Total R&D expenses	$ 30,880	$ 44,186	$ (13,306)

R&D expenses decreased by $13.3 million, to $30.9 million, in the three months ended June 30, 2021 compared to $44.2 million in the three months ended June 30, 2020. The decrease in R&D expenses reflects cost share reimbursements from Pfizer for certain R&D expenses during three months ended June 30, 2021 (See Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q) and a reduction in clinical study costs as a result of the completion and wind down of our Phase 3 LIBERTY, HERO, and SPIRIT studies. The decrease also reflects lower regulatory expenses during the three months ended June 30, 2021, as the prior year period included submission fees for our NDAs for ORGOVYX for advanced prostate cancer and MYFEMBREE for the uterine fibroids indication. This decrease was partially offset by an increase in medical affairs personnel expenses to support the U.S. commercial launches of ORGOVYX and MYFEMBREE.

R&D expenses for the three months ended June 30, 2021 consisted primarily of personnel expenses of $14.8 million, program-specific costs composed of CRO, drug supply and other study, regulatory, and manufacturing related costs of $7.3 million (including regulatory submission fees of $0.5 million), share-based compensation of $4.0 million, and other R&D costs of $4.9 million, which primarily includes contractors, consultants, and information technology costs. R&D expenses for relugolix for the three months ended June 30, 2021 are presented net of approximately $7.2 million of costs shared with Pfizer pursuant to the terms of the Pfizer Collaboration and License Agreement.

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 $26.1 million (including fees related to our NDA submissions for MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids and ORGOVYX for adult patients with advanced prostate cancer of $5.8 million), personnel expenses of $11.8 million, share-based compensation of $4.0 million, and other R&D costs of $2.2 million, which primarily includes contractors, consultants, and information technology costs.

Selling, General and Administrative Expenses

SG&A expenses increased by $38.4 million, to $61.2 million, in the three months ended June 30, 2021 compared to $22.8 million in the three months ended June 30, 2020, primarily due to higher expenses related to commercial activities to support the U.S commercial launches of ORGOVYX and MYFEMBREE as well as higher personnel expenses primarily related to the hiring of our commercial operations, marketing, and market access teams, and our oncology and women’s health sales forces, and other general overhead, administrative, and information technology expenses to support our organizational growth.

SG&A expenses in the three months ended June 30, 2021 consisted primarily of personnel expenses of $27.5 million, commercial expenses of $12.7 million, general overhead, administrative and information technology expenses of $9.9 million, share-based compensation of $7.2 million, professional service fees of $1.8 million, and rent and other facilities-related costs of $0.9 million. SG&A expenses for the three months ended June 30, 2021 are presented net of approximately $5.4 million of costs shared with Pfizer. Share-based compensation includes approximately $1.4 million related to the settlement and remeasurement of our former Principal Executive Officer’s outstanding stock options and common shares as discussed further in Note 7(F) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

SG&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 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.

Interest Expense

Interest expense was $3.5 million in the three months ended June 30, 2021 compared to $2.2 million in the three months ended June 30, 2020, and was primarily related to the Sumitomo Dainippon Pharma Loan Agreement. The increase in interest expense related to the Sumitomo Dainippon Pharma Loan Agreement was primarily driven by a higher balance in the current period. Interest expense in the three months ended June 30, 2021 also includes $0.6 million of accretion of the financing component of the cost share advance from Pfizer (see Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). There was no such accretion for the three months ended June 30, 2020.

Interest Income

Interest income was $0.1 million for both the three months ended June 30, 2021 and 2020.

Foreign Exchange Gain

For the three months ended June 30, 2020 we recorded a foreign exchange gain of $3.6 million, primarily as the result of the increase in our outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement and the impact of fluctuations in the foreign currency exchange rate between the Swiss franc and the U.S. dollar. As a result of a change in the functional currency of our wholly-owned subsidiary in Switzerland, MSG, from the Swiss franc to the U.S. dollar in December 2020, we are no longer exposed to significant foreign currency gains or losses.

Income Tax Expense

Our income tax expense was $0.9 million and $0.7 million for the three months ended June 30, 2021 and 2020, respectively. Our effective tax rate for the three months ended June 30, 2021 and 2020 was (1.50)% and (2.09)%, 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, from debt financing arrangements, and more recently from upfront and milestone payments we received from Pfizer and Richter. We began generating net product revenue from the sales of ORGOVYX and MYFEMBREE in the U.S. in January 2021 and June 2021, respectively.

As of June 30, 2021, we had cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement of $611.1 million, consisting of $569.8 million of cash, cash equivalents, and marketable securities and $41.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement, as compared to cash, cash equivalents, marketable securities, and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement of $726.2 million, consisting of $684.9 million of cash, cash equivalents, and marketable securities and $41.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement, as of March 31, 2021. 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. Our June 30, 2021 cash, cash equivalents, and marketable securities balance excludes $115.0 million of recently triggered regulatory milestone payments from Pfizer and Richter of which we received $100.0 million from Pfizer in July 2021, and of which we expect to receive $15.0 million from Richter in the three months ending September 30, 2021.

Pursuant to the Pfizer Collaboration and License Agreement, we are eligible to receive up to $3.6 billion of additional milestone payments, including a regulatory milestone of $100.0 million upon the FDA approval for MYFEMBREE in endometriosis, and tiered sales milestones of up to $3.5 billion upon reaching certain thresholds of annual net sales for oncology and the combined women’s health indications in the Co-Promotion Territory. We and Pfizer equally share profits and certain expenses in the Co-Promotion Territory. In addition, if Pfizer exercises its option to acquire exclusive commercialization and development rights to relugolix in oncology in the Pfizer Territory, we will receive an option exercise fee of $50.0 million and will also be eligible to receive double-digit royalties on net sales of relugolix in the Pfizer Territory.

Pursuant to the Richter Development and Commercialization Agreement, we are eligible to receive up to $122.5 million of additional milestone payments, including regulatory milestones of up to $15.0 million and tiered sales milestones of up to $107.5 million upon reaching certain thresholds of annual net sales in Richter's territory, and tiered royalties on net sales in Richter's territory.

Capital Requirements

We currently believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our anticipated operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Quarterly Report on Form 10-Q. This estimate is based on our current assumptions, including assumptions related to our ability to manage our spend, that might prove to be wrong, and we could use our available capital resources sooner than we currently expect. In future periods, if our cash, cash equivalents, marketable securities, and amounts that we expect to generate from product sales and/or third-party collaboration payments, are not sufficient to enable us to fund our operations, we may need to raise additional funds in the form of equity, debt, or from other sources. In addition, we may choose to raise additional funds in the form of equity, debt, or from other sources due to market conditions or strategic considerations even if we believe we have sufficient funds for our current and future operating plans. 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.

We expect our operating expenses, net of costs that are expected to be shared with Pfizer pursuant to the Pfizer Collaboration and License Agreement, to increase as we continue to commercialize ORGOVYX and MYFEMBREE in the U.S., prepare for additional potential regulatory approvals, initiate life cycle management activities as well as conduct post-marketing requirements as agreed upon with the FDA for our relugolix franchise, and potentially further develop our product candidates and expand our pipeline. However, while we expect our future capital requirements and operating expenses to continue to be significant, we expect our net cash burn to gradually decrease as our net revenues increase. Our operating expenses and operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year and our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the price, level of demand and net product revenues generated from commercial sales of ORGOVYX, MYFEMBREE, and from any product candidates that may receive marketing approval in the future;
- the achievement of regulatory milestones, sales milestones, and/or royalties that we are eligible to earn pursuant to our collaboration agreements;
- the timing, shared costs, and level of investment in our and our collaboration partners' activities related to sales, marketing, market access, manufacturing, and distribution for ORGOVYX, MYFEMBREE, and for any product candidates that may receive marketing approval in the future;
- the timing, shared costs, and level of investment in our and our collaboration partners' research and development activities involving ORGOVYX, MYFEMBREE, and any product candidates;
- costs, timing, and outcomes of regulatory submissions and regulatory reviews of our product candidates;
- costs to expand our chemistry, manufacturing, and control and other manufacturing related activities;
- costs to identify, acquire, develop, and commercialize additional product candidates;
- costs to integrate acquired technologies into a comprehensive regulatory and product development strategy;
- costs to maintain, expand, and protect our intellectual property portfolio;
- costs to hire additional commercial operations, sales and marketing, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, sales and marketing, regulatory, and clinical development efforts;
- costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems;
- costs to service our debt obligations and associated interest payments; and
- costs to operate as a public company.

Until such time, if ever, as we can generate substantial net product revenue from sales of ORGOVYX, MYFEMBREE, or any product candidate, we expect to fund our operations through a combination of cash, cash equivalents, and marketable securities currently on hand and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement, subject to the consent of our board of directors, as well as potential payments we are eligible to receive from Pfizer and Richter pursuant to the terms of our agreements with them.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (113,177)	$ (61,984)
Net cash used in investing activities	$ (74,391)	$ (12,124)
Net cash provided by financing activities	$ 4,135	$ 82,190

Operating Activities

For the three months ended June 30, 2021, we used $113.2 million in operating activities primarily due to activities related to our preparation for potential regulatory approvals and commercialization of our product candidates and the expansion of our company, including our oncology and women's health sales forces.

The primary drivers of the net cash used in operating activities during the three months ended June 30, 2021 were attributable to the following:

- net loss for the period of $61.7 million (see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations" for information regarding the components of our net loss);
- an increase in milestone receivable from Pfizer of $100.0 million that was triggered upon the FDA approval of MYFEMBREE for the uterine fibroids indication;
- a decrease of $18.3 million in cost share advance from Pfizer due to the application of shared Allowable Expenses (see Note 8(B) and 8(C) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10Q);
- a decrease of $8.7 million in accounts payable due to the timing of vendor invoice payments; and
- an increase in accounts receivable of $7.0 million as a result of an increase in net product revenues.

These items were partially offset by:

- a net increase in deferred revenue of $70.5 million (see Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10Q);
- non-cash share-based compensation of $11.3 million; and
- an increase of $9.1 million in amounts due to Pfizer (see Note 8(B) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10Q).

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 our product candidates, and the expansion of our company.

The primarily drivers of the net cash used in operating activities during the three months ended June 30, 2020 were attributable to the following:

- net loss for the period of $32.9 million (see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations" for information regarding the components of our net loss);

- a net decrease of $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 (see Note 8(A) to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10Q);
- a decrease of $9.9 million in accounts payable due to the timing of vendor invoice payments; 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 and $0.6 million of total depreciation and amortization expense.

Investing Activities

For the three months ended June 30, 2021, we used $74.4 million in investing activities, which was for the purchase of marketable securities, net of maturities.

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.

Financing Activities

For the three months ended June 30, 2021, $4.1 million was provided by financing activities, which was from proceeds from the exercise of stock options under our 2016 Equity Incentive Plan.

For the three months ended June 30, 2020, $82.2 million was provided by financing activities. This was 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.

Contractual Obligations

During the three months ended June 30, 2021, 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, 2021.

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 ("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 contingencies as of the dates of the unaudited condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. 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, 2021, filed with the SEC on May 11, 2021. 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 1 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, as a "smaller reporting company," we are not required to provide the information otherwise required by this item in this Quarterly Report on Form 10-Q.

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. In the fourth quarter of our fiscal year ended March 31, 2021 and in the three months ended June 30, 2021, we began to generate net product revenue from sales of ORGOVYX and MYFEMBREE, respectively. Commensurate with the evolution of our business operations, we have implemented and continue to optimize new procedures and controls pertaining to the order to cash, including net revenue and inventory accounting processes. No other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2021 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 Commercialization of Our Drug Products.

Our success depends in part on the successful commercialization of our drug products. To the extent our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed.

We received approval for ORGOVYX (relugolix 120 mg) in December 2020 from the FDA for the treatment of adult patients with advanced prostate cancer, and received approval for MYFEMBREE (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in May 2021 for the management of heavy menstrual bleeding associated with uterine fibroids. We have started commercialization and continue to invest a significant portion of our efforts and financial resources in the commercialization of these drug products in the U.S. The ability for us and/or our collaboration partner, Pfizer, to generate net product revenues from our drug products will depend upon the size of the markets, the number of competitors in such markets and numerous other factors, including:

- successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which our drug products are approved for sale;
- successfully establishing and maintaining commercial third-party manufacturers and having adequate commercial quantities of our drug products manufactured at acceptable cost and quality levels, including maintaining current good manufacturing practice ("cGMP") and quality systems regulation standards required by various regulatory agencies;
- broad acceptance of our drug products by physicians, patients and the healthcare community;
- the acceptance of pricing and placement of our drug products on payers' formularies and the associated tiers;
- effectively competing with other approved or used medicines and future compounds in development;
- continued demonstration of safety and efficacy of our drug products in comparison to competing products, including through differentiated approved product labeling; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we and/or Pfizer do not achieve one or more of these factors in a timely manner or at all, we and/or Pfizer could experience significant delays or an inability to successfully commercialize any of our drug products, which would materially harm our business.

Our drug products may fail to achieve the degree of market acceptance by physicians, patients, third-party payers or others in the medical community necessary for commercial success, which would negatively impact our business.

Our drug products may fail to gain sufficient market acceptance by physicians, patients, third-party payers, or others in the medical community. If any of our drug products do not achieve an adequate level of acceptance, we may not generate significant net product revenue or become profitable. The degree of market acceptance of our drug products is dependent 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 acceptability of the price of our drug products relative to other treatments;
- the content of the approved product labels and our ability to make compelling product claims;

- the effectiveness and adequacy of our and our collaboration partner's sales and marketing efforts;
- the patient out-of-pocket costs in relation to alternative treatments;
- 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 effectiveness of our patient assistance and support programs;
- the availability of third-party payer coverage and adequate reimbursement;
- whether diagnosis and treatment rates change in advanced prostate cancer and heavy menstrual bleeding associated with uterine fibroids or other indications for which the drug products were approved; and
- any restrictions on the use of our drug products together with other medications.

The degree of market acceptance of ORGOVYX will also depend on the acceptance and degree of adoption by institutional treatment pathways and institutional, local, and national clinical guidelines such as the National Comprehensive Cancer Networks® Clinical Practice Guidelines in Oncology, or the NCCN Guidelines, the American Urological Association ("AUA") guidelines, American Society of Clinical Oncology ("ASCO") Clinical Practice Guidelines, or other country-specific guidelines. This could also be the case for MYFEMBREE in terms of inclusion in practice guidelines such as those from the American College of Gynecology ("ACOG"), American Society for Reproductive Medicine ("ASRM"), American Association of Gynecologic Laparoscopists ("AAGL"), or other country-specific guidelines. In the U.S., healthcare providers may refer to these guidelines related to patient treatment decisions. To the extent that our current or any future approved products are not included or positioned favorably in such treatment guidelines and pathways, the full utilization potential of our products may not be reached, which may harm our ability to successfully commercialize our current or any future approved products.

If we and our collaboration partners are unable to effectively market and sell our drug products, the commercialization of our drug products will not be successful and our business will be harmed.

To market our drug products successfully, we must continue to develop and maintain our capabilities in sales, market access, marketing, distribution, and other commercial functions, either on our own or with our 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, as amended, 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 ORGOVYX and MYFEMBREE in the U.S. On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the U.S. and Canada (the "Co-Promotion Territory"). In addition, Pfizer also received an option to acquire exclusive commercialization and development rights to relugolix in oncology outside the Co-Promotion Territory, excluding certain Asian countries (the "Pfizer Territory"). If Sunovion or Pfizer, 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 drug products would be delayed or may not occur. In addition to the third-party collaboration arrangements described above, we continue to develop and maintain our own sales, market access, marketing, distribution and other commercial capabilities. There are significant expenses and risks involved with maintaining our own sales, market access, marketing, distribution, and other commercial capabilities, including: (i) our ability to recruit, train, and retain adequate numbers of qualified and effective sales, market access and marketing personnel; (ii) our ability to attain access to adequate numbers of physicians to prescribe any approved drugs; (iii) our ability to negotiate coverage and reimbursement for our products with payers at reasonable rebate or discount levels; (iv) our ability to negotiate competitive provider contracts to ensure access in in-office dispensing pharmacies; and (v) unforeseen costs and expenses associated with establishing and maintaining our own sales, market access, marketing, distribution, and other commercial capabilities. The COVID-19 pandemic may negatively impact our and our collaboration partners' ability to maintain commercial capabilities and may negatively impact our ability to rapidly and effectively educate potential prescribers and, if significant delays result, to commercialize our drug products.

ORGOVYX and MYFEMBREE are both newly approved and marketed drugs in the U.S. ORGOVYX is the first and only oral gonadotropin-releasing hormone ("GnRH") receptor antagonist for adult patients with advanced prostate cancer. MYFEMBREE is the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women. Therefore, we and our collaboration partner, Pfizer, have only recently begun to promote these drug products in the U.S. In addition, we have only recently established our distribution and reimbursement capabilities in the U.S. together with Sunovion, all of which are necessary to successfully commercialize these drug products.

As a result, we and/or our collaboration partners will be required to expend significant time and resources to market, sell, and distribute these drug products to physicians and the medical community in a credible, persuasive, and compliant manner consistent with applicable laws. There is no guarantee that the strategies, tactics and marketing messages, or the distribution and reimbursement capabilities, that we or our collaboration partners have developed will be successful. Specifically, for distribution of these drug products, we are heavily dependent on third-party logistics, pharmacy and distribution partners. If we or our collaboration partners are unable to perform effectively, our ability to realize the return on our investment in developing these drug products will suffer.

Failure to successfully obtain coverage and reimbursement for ORGOVYX and MYFEMBREE in the United States, or the availability of coverage only at limited levels, would diminish our ability to generate net product revenue.

Our and Pfizer's ability to commercialize ORGOVYX and MYFEMBREE successfully in the U.S. will depend in part on the extent to which coverage and reimbursement for ORGOVYX and MYFEMBREE will be available from third-party payers, including government health administration authorities, Medicare Part D plan sponsors and private health insurers, such as pharmacy benefit managers, health plans, and self-insured organizations. In the U.S., no uniform policy for coverage for products exists among third-party payers. Third-party payers 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. Payer decisions regarding the extent of coverage to be provided for any of our product candidates that obtain marketing approval will be made on a plan-by-plan basis. Additionally, a third-party payer's decision to provide coverage for a drug does not imply that an affordable out-of-pocket cost for patients will be established. Each third-party payer determines whether or not it will provide coverage for a drug, what amount it will reimburse 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 out-of-pocket costs that a patient will pay 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 payers to reimburse all or part of the associated healthcare costs. Coverage from both governmental healthcare programs, such as Medicare Part D and Medicaid, and coverage by private commercial payers are critical to ORGOVYX's and MYFEMBREE's commercial success. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system that may impact drug coverage, reimbursement for drugs, and patient out-of-pocket costs in the U.S. and in some foreign jurisdictions that could affect our ability to successfully commercialize ORGOVYX and MYFEMBREE. These legislative and regulatory changes may negatively impact the coverage, reimbursement, and patient out-of-pocket costs for ORGOVYX, MYFEMBREE and any future drugs, if approved.

We face substantial competition in the commercialization of ORGOVYX and MYFEMBREE, and our operating results will suffer if we fail to compete effectively.

The commercialization of new pharmaceutical products is highly competitive, and we face substantial competition with respect to ORGOVYX and MYFEMBREE. For example, although ORGOVYX is the first and only oral GnRH receptor antagonist for adult patients with advanced prostate cancer approved by the FDA in the U.S., we may face competition from various drugs approved for the treatment of prostate cancer, such as Lupron Depot® (AbbVie Inc.), Eligard® (Tolmar Pharmaceuticals) and Firmagon® (Ferring Pharmaceuticals). In addition, although MYFEMBREE is the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women approved by the FDA in the U.S., with a treatment duration of up to 24 months, we expect to face competition from ORIAHNN™, an oral GnRH receptor antagonist combination therapy (one capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening), which was approved by the FDA and launched by AbbVie in June 2020 for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Many of our current and potential future competitors may have significantly more resources that they can deploy to commercialize drugs and may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than our drug products or any product candidate that we may obtain approval or 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. The availability and pricing of our competitors' products could limit the demand and the price we are able to charge for our drug products or our product candidate that we may obtain approval or 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.

If manufacturers obtain approval for generic versions of ORGOVYX, MYFEMBREE, or of products with which they compete, our business may suffer.

Under the U.S. Food, Drug and Cosmetic Act ("FDCA"), the FDA can approve an Abbreviated New Drug Application ("ANDA"), for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the branded product.

The FDCA requires that an applicant seeking approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the Orange Book or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon notice of a paragraph IV challenge, a patent owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

The ANDA process can result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. If this were to occur with respect to ORGOVYX, MYFEMBREE, or products with which they compete, our business would be materially harmed.

If patient safety issues were to arise for any of our drug products, our future sales of our drug products may be reduced, adversely affecting our results of operations.

The data supporting the marketing approvals in the U.S. for ORGOVYX and MYFEMBREE and forming the basis for our product labels for ORGOVYX and MYFEMBREE were obtained in controlled clinical studies of limited duration. As ORGOVYX and MYFEMBREE are used over a longer period of time by patients, including those taking other medicines, we may continue to identify new issues such as safety concerns, resistance or drug interactions of these drug products, which may require us to provide additional warnings or contraindications on our product labels or narrow the approved indications, each of which could reduce the market acceptance of our drug products.

Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand-alone safety information directly available to the public through websites and other means, e.g., periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to misperception or legal action which may potentially negatively impact sales of our drug products. Further, if serious safety, resistance or drug interaction issues arise with any of our drug products, sales could be limited or halted by us or by regulatory authorities and our results of operations would be adversely affected. In addition, problems with other drugs marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as any of our drug products could adversely affect commercialization of our drug products.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, patients or payers. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by our insurance. If we cannot successfully defend ourselves against claims that our drug products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug products;
- the inability to commercialize our drug products;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of clinical studies of our product candidates;
- significant costs to defend the related litigation;

- substantial monetary awards to patients; and
- loss of net product revenue.

Our product liability insurance coverage may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to obtain insurance coverage at a reasonable cost or in amounts adequate to satisfy any liability or associated costs that may arise in the future. These events could harm our business and results of operations and cause our common share price to decline.

If we or our collaboration partner, Pfizer, are found to have improperly promoted unapproved uses of our drug products, we may be subject to restrictions on the sale or marketing of our drug products and significant fines, penalties, sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies, including regulatory authorities outside the U.S., strictly regulate the marketing and promotional claims that are made about drug products, such as ORGOVYX and MYFEMBREE. In particular, promotion for a product must be consistent with its labeling approved by the FDA or by regulatory agencies in other countries. For example, in the case of ORGOVYX and MYFEMBREE, physicians may prescribe ORGOVYX or MYFEMBREE for indications or uses that are inconsistent with the approved label while we and our collaboration partner, Pfizer, may not market or promote such off-label uses. If we or our collaboration partner, Pfizer, are found to have promoted such unapproved uses, we may, among other consequences, receive untitled or warning letters and become subject to significant liability, which would materially harm our business. Furthermore, the use of our products for indications other than those approved by the FDA or regulatory authorities outside the U.S. may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Both the U.S. federal government and foreign regulatory authorities have levied significant civil and criminal fines against companies and individuals for alleged improper promotion and have entered into settlement agreements with pharmaceutical companies to limit inappropriate promotional activities. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged.

Physicians' prescribing our products for unapproved uses may also subject us to product liability claims, to the extent such uses lead to adverse events, side effects, or injuries. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Any of these events could harm our business and results of operations and cause our common share price to decline.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by the Centers for Medicare and Medicaid Services ("CMS") and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional enforcement and administrative bodies have increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price ("AMP"), and best price ("BP"), for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

Our drug products are complex to manufacture, and manufacturing disruptions may occur that could cause us to experience disruptions in the supply of our drug products.

Our drug products are complex to manufacture. Notwithstanding the fact that our third-party manufacturers have validated our processes, manufacturing disruptions may occur. Such problems may prevent the production of lots that meet the specifications required for sale of the product and may be difficult and expensive to resolve. If any such issues were to arise with respect to our drug products or any future products, our business, financial results, or common share price could be adversely affected. Also, see the Risk Factor titled, "We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may result in delay in our ability to develop and commercialize our products."

Risks Related to Commercialization of our Drug Products Outside the U.S. and for Product Candidates

Our success relies on the successful commercialization of drug products outside the U.S. or the development or commercialization of our product candidates. If we are successful in obtaining regulatory approval for the drug products in jurisdictions outside the U.S. or for the product candidates, we will be subject to the same or similar commercialization risks as described above for our approved drug products.

On July 16, 2021, the European Commission approved our marketing authorization application for RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for duration of use. We expect that our collaboration partner, Gedeon Richter Plc. ("Richter"), will begin commercializing RYEQO in Europe during the second half of calendar year 2021. In addition, in July 2021, we submitted a supplemental New Drug Application to the FDA for MYFEMBREE for the management of moderate to severe pain associated with endometriosis. We also expect to seek other regulatory approvals for our drug products in jurisdictions outside the U.S. or for our product candidates in the U.S. When our collaboration partner, Richter, commercializes RYEQO in Europe or if we receive regulatory approval for any of those drug products in other jurisdictions or for our product candidates in the U.S., we will be subject to the same or similar risks we currently face with the commercialization of ORGOVYX and MYFEMBREE, as described under "Risks Related to Commercialization of Our Drug Products" above.

Risks Related to Our Financial Position and Capital Requirements

If we do not have adequate funds to cover our development and commercialization activities, we may have to raise additional capital or curtail or cease operations. 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.

In the U.S., we began to commercialize ORGOVYX for the treatment of adult patients with advanced prostate cancer in January 2021 and MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in June 2021. We also seek to advance additional product candidates through research and clinical development to regulatory approval and commercialization. These activities will require substantial financial resources.

As of June 30, 2021, we had cash, cash equivalents and marketable securities of $569.8 million. Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of this Quarterly Report on Form 10-Q. 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. In future periods, if our cash, cash equivalents, marketable securities, and amounts that we expect to generate from product sales and/or third-party collaboration payments are not sufficient to enable us to fund our operations, we may need to raise additional funds in the form of equity, debt, or from other sources. In addition, we may choose to raise additional funds in the form of equity, debt, or from other sources due to market conditions or strategic considerations even if we believe we have sufficient funds for our current and future operating plans.

We expect our operating expenses, net of costs that are expected to be shared with Pfizer pursuant to the Pfizer Collaboration and License Agreement, to increase and our future capital requirements are expected to be significant. Our operating expenses and operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year and our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the price, level of demand and net product revenues generated from commercial sales of our drug products, and for any product candidates that may receive marketing approval in the future;

- the achievement of regulatory milestones, sales milestones, and/or royalties that we are eligible to earn pursuant to our collaboration agreements;
- the timing, shared costs, and level of investment in our and our collaboration partners' activities related to sales, marketing, market access, manufacturing, and distribution for our drug products and for any product candidates that may receive marketing approval;
- the timing, shared costs, and level of investment in our and our collaboration partners' research and development activities involving ORGOVYX, MYFEMBREE, and any product candidates;
- 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 to maintain, expand, and protect our patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the cost of raw materials and manufacture of our drug products, including packaging;
- the costs to hire additional commercial operations, sales and marketing, scientific, clinical, regulatory, quality, and other personnel to support our commercialization, sales and marketing, regulatory, and clinical development efforts; and
- the costs to implement or enhance operational, accounting, finance, quality, commercial, and management information systems.

Under the terms of the Sumitomo Dainippon Pharma Loan Agreement, we may not raise additional capital without obtaining the consent of Sumitomo Dainippon Pharma. If we do not have sufficient funds to complete the development of, seek regulatory approvals for our product candidates and commercialize our drug products and, if approved, our product candidates, 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 to support our current operating plan. 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.

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. Further, we may be obligated to repay the loans prior to their scheduled maturity date under certain circumstances.

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, 2021, approximately $41.3 million of borrowing capacity remained available to us under the Sumitomo Dainippon Pharma Loan 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. We may not be able to meet such terms and conditions in the future and may not be able to secure additional funds. The maturity date of the loans under the Sumitomo Dainippon Pharma Loan Agreement is December 27, 2024 or the date the outstanding principal of the loans is declared due and payable due to an event of default pursuant to the terms of the agreement. 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, and 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 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 may 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 expenses as we continue commercialization of ORGOVYX and MYFEMBREE in the U.S.,

continue to develop our product candidates and prepare for potential regulatory approval and commercialization of our drug products in the U.S. and other jurisdictions. The timing and magnitude of our net income (loss) will depend on the commercial success of our drug products, as well as the timing and commercial success of any product launches, as well as other potential business and operational activities. Likewise, any potential future milestone or royalty payments that we are eligible to earn under the Pfizer Collaboration and License Agreement and the Richter Development and Commercialization Agreement will depend on the regulatory and commercial success of our drug products and product candidates, if approved. As a result, we may never achieve or maintain profitability.

Risks Related to Our Business Operations

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 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, investment 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, which may limit our growth potential.

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 novel product candidates may prove to be unsuccessful and may not be effective in treating their targeted diseases.

In addition, 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 for future growth.

We do not have our own manufacturing capabilities and rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may 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 drug substance and drug product manufacturing, storage and distribution, or testing and are subject to the risk that our contract manufacturers become subject to negative circumstances. For example, 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. 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 GmbH & Co. KG ("Excella") pursuant to which Excella agreed to manufacture and supply us with certain commercial relugolix drug substance quantities.

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 may 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 may not be able to secure or maintain regulatory approvals 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. For example, 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 manufacturing facility located at Takeda 4720, Mitsui, Hikari, Yamaguchi ("Hikari Facility"). We initially listed both Takeda and Excella as contract manufacturing organizations ("CMOs") in our regulatory filings for the manufacture of relugolix drug substance. We are now procuring the commercial relugolix drug substance for U.S. ORGOVYX and MYFEMBREE solely from Excella. We have removed the Hikari Facility as a manufacturing site from our NDA submissions and may remove it from other regulatory filings if 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 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 CMOs 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 CMOs fail

to fulfill their obligations to manufacture and supply relugolix drug substance and drug product needed for ORGOVYX, MYFEMBREE and our other potential launches, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections, process validation delays, or other reasons, our development plans and commercialization of ORGOVYX, MYFEMBREE and any of our product candidates 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 various risks, including:

- delay or inability to manufacture our drug products;
- 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 our drug products or product candidates (if approved) 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 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, independent 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 payers, 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 COVID-19 pandemic, may materially and adversely affect our business and financial condition.

The COVID-19 pandemic may materially and adversely affect our business and financial condition. For example, the majority of our employees continue to work from home as a result of the COVID-19 pandemic. 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 or expect to procure will be sufficient to support our ongoing clinical studies, our commercial launches for our approved drug products, including ORGOVYX, MYFEMBREE and RYEQO, our supply chain for raw materials, drug substance and drug product is worldwide, and the duration of the COVID-19 pandemic and its impact on the ability of our suppliers to operate could negatively impact our manufacturing supply chain for our approved drug products and for our product candidates that may receive regulatory approval, or for clinical study materials. 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. New and potentially more virulent variants of the coronavirus have been recently identified, such as the delta variant, which may further impact the effects that the COVID-19 pandemic may have on us.

The COVID-19 pandemic has presented challenges for our medical affairs team to present scientific data and for our regional medical advisors to engage potential prescribers in scientific exchange. Multiple medical conferences have been canceled, postponed or moved to virtual formats, resulting in fewer opportunities to present our scientific data and our medical affairs team members have only begun to make in-person presentations to the medical community. Communications to the medical community virtually in many instances may make it less effective to educate and engage in scientific exchange.

In addition, the COVID-19 pandemic may impact the FDA's review process and timing of potential approval of our product candidates. Regulatory agency pre-approval inspections are now limited, and it is not clear if virtual inspections will be required and acceptable.

The COVID-19 pandemic may negatively impact our ability to rapidly and effectively educate potential prescribers and payers and, successfully commercialize our approved drug products and our product candidates, if approved. We launched

ORGOVYX in the U.S. in January 2021, MYFEMBREE in the U.S. in June 2021 and we and our collaboration partners may launch other approved products in the COVID-19 environment, including Richter's launch of RYEQO in Europe during the second half of calendar year 2021. 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, some physician's offices continue to have limited on-site access for pharmaceutical representatives to reduce exposure risk for their patients or staff. Conducting these interactions virtually could reduce the number of medical professionals we are able to present to, and these virtual meetings may not be as impactful as in-person meetings. Reduced access to healthcare providers as a result of social distancing protocols may impact or require adjustment to our planned commercialization activities, including the way our field teams engage with healthcare providers and facilities. Travel restrictions may make it more difficult for us and our collaboration partners, such as Sunovion, Pfizer, and Richter, to maximize the effectiveness of third-party market access, marketing, sales and distribution capabilities.

The COVID-19 pandemic may negatively impact our ability to attract and retain the human resources required to maintain and build out our commercial capabilities. 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.

The extent to which the COVID-19 pandemic and global efforts to address the COVID-19 pandemic 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 COVID-19 pandemic may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

As vaccination rates against COVID-19 increase, we plan to ease restrictions to our facilities and allow our employees to return to work on-site during the third quarter of calendar year 2021. The safety protocols we implement as our employees return to work on-site may not prevent employees from contracting COVID-19. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to illness from COVID-19, we may not be able to execute on our business strategy and/or our operations may be negatively impacted. The magnitude of the adverse effect on our business operations will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

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, payers, 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 and maintain 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 payer-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 European Union (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.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules continued to apply. A trade and cooperation agreement (the "Trade and Cooperation Agreement") that outlines the future trading relationship between the U.K. and the EU was agreed to in December 2020. 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 has had, and may continue to have, a material impact upon 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, the U.K is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidates in the U.K. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency ("MHRA") in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. 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.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the U.K. and the EU there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the U.K. diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) 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 those of our third-party collaborators, consultants or contractors, may fail or suffer cybersecurity breaches and data leakage, which could result in a material disruption of our business and operations or liabilities that adversely affect our financial performance.

Our computer systems, as well as those of our contract research organizations ("CROs"), CMOs, third-party logistics providers, 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 the commercialization of our drug products and our drug development programs. For example, the loss of commercialization information, nonclinical or clinical study data from completed, ongoing or planned clinical studies could result in delays in our commercialization, 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, California enacted the California Consumer Privacy Act (“CCPA”), which became effective 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 Health Insurance Portability and Accountability Act (“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 expand and maintain our enterprise resource planning ("ERP") system and other information technology systems could adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

During our fiscal year 2019, we began the implementation of a company-wide ERP system pertaining to certain business, operational, and finance processes. We have continued to optimize and expand this ERP system and have implemented and continue to optimize other systems as a part of our ongoing technology and process improvement initiatives. ERP and other information technology system implementations are complex, expensive 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.

Any disruptions, delays, or deficiencies in the design or the ongoing maintenance and optimization of the ERP system and other information technology systems 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 and other information technology systems do not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected and could cause us to fail to comply with SEC obligations related to 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 or other information technology systems, 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 an alternative reference rate, may adversely affect interest rates on our outstanding variable rate indebtedness with Sumitomo Dainippon Pharma.

On July 27, 2017, the United Kingdom's Financial Conduct Authority (the authority that regulates LIBOR) announced that after 2021, it would no longer compel banks to submit the rates required to calculate LIBOR. This announcement indicates that the continuation of LIBOR on its current basis cannot and will not be guaranteed after 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 calculated based on LIBOR and, when LIBOR is phased out, we will need to agree with Sumitomo Dainippon Pharma to a new method of calculating the interest rate under the Sumitomo Dainippon Pharma Loan Agreement. 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.

Risks Related to Clinical Development and Regulatory Approval

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. The FDA or other regulatory authorities may not agree with our proposed plans for any clinical studies of our product candidates, or any other potential future product candidates, which may delay or prevent the approval of an NDA or similar application. For example, on May 18, 2021, the FDA informed us by teleconference that it placed a partial clinical hold on the Phase 3 SERENE study (MVT-601-050) evaluating relugolix combination tablet for the prevention of pregnancy pending amendment of the study protocol. We cannot predict when the FDA may lift the clinical hold on the SERENE study, nor what requirements the FDA may impose on how the clinical study is conducted. The clinical study process is also very time-consuming. The commencement and completion of clinical studies may be delayed or prevented by several factors, including:

- failure to obtain regulatory approval to commence a study or regulatory actions requiring a hold on any of our clinical studies;
- 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;
- our determination that the cost of completing the clinical trial and obtaining regulatory approval does not warrant the expense and investment of time by management and our other personnel;
- 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 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 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 or other similar application for regulatory approval. Further, we may determine to terminate a clinical trial if we determine that the cost and time of management and our other personnel does not warrant further investment in the clinical trial. 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 net 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 net product 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. If Takeda did not conduct this research and development in compliance with applicable requirements, it 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 not comply with the protocol or 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 or certain collaboration partners 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 or positive results reported by our competitors about their products or product 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 recruitment, 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 primary endpoints would likely cause us to abandon a product candidate and may delay development of a product candidate. Any delay in, or termination of, our clinical studies will delay the submission of our NDAs to the FDA or other similar applications to other foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate net product revenue.

Reported data or other clinical development announcements by Takeda, its partners or sublicensees, or by our collaboration partners, including Pfizer and Richter may adversely affect our commercialization of our drug products and our clinical development plans.

Takeda, its partners and sublicensees and our collaboration partners, Pfizer and Richter, may be involved in the further clinical development of relugolix. Favorable announcements by Takeda, Pfizer or Richter do not guarantee that the results of our clinical studies will also be favorable as the designs of our clinical studies may differ from those of Takeda, Pfizer or Richter. Further, if clinical study or post-marketing adverse events regarding relugolix are reported, or subsequent announcements by our partners regarding relugolix are unfavorable, it could negatively impact our commercialization of drug products, and our clinical development plans for or opinions of the FDA or other regulatory authorities with respect to relugolix. For example, 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. 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.

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 for our product candidates, our ability to generate net product revenue will be materially impaired.

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. 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 and our collaboration partners 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 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 future for our anticipated regulatory submissions, 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 our product candidates for the specified indication. The process of responding to the FDA or other regulatory authorities' information requests in the review process, potentially preparing for and appearing at a public advisory committee or oral hearing and preparing our manufacturers and investigators to successfully complete inspections by the FDA or other regulatory authorities during the approval process requires significant human and financial resources. If the information from our completed clinical studies is insufficient to support regulatory approvals, we may have to complete ongoing or additional clinical studies.

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 net product revenue. 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 the Hikari Facility. The Hikari Facility is one of two CMOs included in our initial 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 are now procuring the commercial relugolix drug substance for U.S. ORGOVYX and MYFEMBREE solely from Excella, pursuant to the Commercial Manufacturing and Supply Agreement we have with Excella. Due to the warning letter, we have removed the Hikari Facility as a manufacturing site from our NDA submissions and may remove it from other regulatory filings if 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 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 CMOs 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 CMOs fail to fulfill their obligations to manufacture and supply relugolix drug substance and drug product needed for our commercialization, or if any of the materials cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections, process validation, or other reasons, our development plans and commercialization of our product candidates could be significantly delayed or otherwise adversely affected.

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 certain drug products in the licensed territories and are completely reliant on Richter to generate net product revenue in the licensed territories to Richter. For example, we obtained approval of RYEQO in Europe in July 2021 and will rely on Richter to successfully commercialize it in Europe. 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.

Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval.

Adverse events associated with our product candidates, including relugolix combination tablet for endometriosis or MVT-602 could cause us, regulatory authorities, other reviewing entities or clinical study sites 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 our 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.

We are required to monitor the safety and efficacy of ORGOVYX and MYFEMBREE and any other products candidates that are approved by the FDA or other regulatory authorities. We will be subject to ongoing regulatory requirements to submit safety and other post-marketing information and reports, including adverse event reporting. If post-marketing adverse events related to ORGOVYX and MYFEMBREE are reported, it could negatively impact our commercialization plans for these products and could negatively impact the clinical development of our product candidates.

If any of our approved drug products causes, or any of our product candidates is approved and then causes, 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 ORGOVYX, MYFEMBREE, and any of our product candidates, if approved.

Even though we have obtained regulatory approval for ORGOVYX and MYFEMBREE in the U.S. and RYEQO in Europe, or even if we obtain regulatory approval for any of our product candidates, we face or will still face extensive regulatory requirements and our products may face future development risks and regulatory difficulties.

Our drug products and 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, are and 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 any product candidate 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, regulatory authorities, including the FDA, impose stringent restrictions on manufacturers' communications regarding off-label use of their products, 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, "Adverse events associated with our product candidates could cause us, regulatory authorities, other reviewing entities or clinical study sites to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval."

Our current and future relationships with investigators, healthcare professionals, consultants, third-party payers, 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 payers, patient support service providers, 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, HIPAA, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, 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 Part D, 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 our drug products or product candidates 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 our drug products in other jurisdictions or product candidates in the U.S. and other jurisdictions, 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 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 in response to the COVID-19 pandemic.

Risks Related to Our Dependence on Third Parties

We are dependent upon our relationships with collaboration partners to further develop, fund, manufacture and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration partner terminates its collaboration agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration partner to perform its duties under its collaboration agreement with us (e.g. financial reporting or internal control compliance) may negatively affect us.

On December 26, 2020, we entered into the Pfizer Collaboration and License Agreement, pursuant to which we and Pfizer will collaborate to jointly develop and commercialize relugolix in oncology and women's health in the Co-Promotion Territory. In addition to the Pfizer Collaboration and License Agreement, we have entered into collaboration arrangements with other collaboration partners. On August 1, 2020, we entered into a Market Access Services Agreement, as amended, 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 ORGOVYX for prostate cancer, MYFEMBREE for uterine fibroids, and relugolix combination tablet for endometriosis, if approved. On March 30, 2020, we entered into the Richter Development and Commercialization Agreement pursuant to which, among other things, Richter will be responsible for all commercialization activities for RYEQO for the treatment of women with uterine fibroids and relugolix combination tablet for endometriosis (if approved) in certain territories outside of the U.S.

We are subject to a number of risks associated with our dependence on our relationships with our collaboration partners, including:

- our collaboration partners may terminate their collaboration agreements with us for reasons specified in the collaboration agreements, including our breach;
- the need for us to identify and secure on commercially reasonable terms the services of third parties to perform key activities, including development and commercialization activities, currently performed by our collaboration partners in the event that a collaboration partner was to terminate its collaboration with us;
- adverse decisions by a collaboration partner regarding the amount and timing of resource expenditures for the commercialization, distribution and sale of our drug products
- failure by a collaboration partner to perform its duties under its collaboration agreement with us (e.g., its failure to comply with regulatory requirements which may disrupt its performance of its obligations under the collaboration agreement with us);
- failure by a collaboration partner to timely deliver accurate and complete financial information to us or to maintain adequate and effective internal control over its financial reporting may negatively affect our ability to meet our financial reporting obligations as required by the SEC;
- decisions by a collaboration partner to prioritize other of its current or future products more highly than our drug products or our product candidates when it performs its duties;
- possible disagreements with a collaboration partner as to the timing, nature and extent of our development plans or distribution and sales and marketing plans; and
- the financial returns to us, if any, under our collaboration agreements with Pfizer and Richter, depend in large part on the achievement of milestones and generation of product sales, and if Pfizer or Richter fail to perform or satisfy their obligations under the collaboration agreements, the development and commercialization of our drug products could be delayed, hindered or may not occur and our business and prospects could be materially and adversely affected.

Due to these factors and other possible disagreements with our collaboration partners, we may be delayed or prevented from further developing, manufacturing or commercializing our drug products or our product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

If any collaboration partner were to terminate our collaborative relationship with it unilaterally, we would need to undertake development, commercialization or distribution or sale activities for our drug products and product candidates solely at our own expense and/or seek one or more other partners for some or all of these activities in the U.S. or worldwide. If we pursued these activities on our own, it would significantly increase our capital and infrastructure requirements, might limit the indications we are able to pursue for our drug products and our product candidates and could prevent us from effectively commercializing our drug products and our product candidates. If we sought to find one or more other pharmaceutical company partners for some or all of these activities, we may not be successful in such efforts, or they may result in collaborations that have us expending greater funds and efforts than our relationships with our current collaboration partners.

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 rely on third parties to produce clinical and commercial supplies of drug substance and drug product. If these third parties do not perform as we expect, do not maintain their regulatory approvals, or become subject to other negative circumstances, it may 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 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 cGMP. 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 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 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 of our product candidates and commercialization of our drug products 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 our drug products and other clinical study materials, 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.

Risks Related to Our Being a Controlled Company

We have agreements with Sumitovant, our majority shareholder, and with Sumitovant's parent, Sumitomo Dainippon Pharma, and their affiliates, including Sunovion, 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, and their affiliates, 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. 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. Further, we are a party to a Market Access Services Agreement with Sunovion, 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. We may enter into additional agreements with Sumitovant or Sumitomo Dainippon Pharma or their affiliates in the future. Sumitovant and Sumitomo Dainippon Pharma and its affiliates 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 composed 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, Sumitomo Dainippon Pharma and Sunovion 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, a subsidiary of Sumitomo Dainippon Pharma, pursuant to which Sunovion has agreed to provide certain market access services to us with respect to the distribution and sale of certain of our drug products.

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, our shareholders 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.

Risks Related to Us and Our Shareholders Related to Our Being a Foreign Corporation

We are an exempted company limited by shares incorporated under the laws of Bermuda and it may be difficult for our shareholders 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 as well as their other initiatives. 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 as a result of certain constructive ownership rules. For any U.S. holders who hold 10% or more of the vote or value of our common shares directly or indirectly, 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, 2021, we believe that we were not a PFIC. However, we cannot predict whether we will or will not be classified as a PFIC in 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. 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.

General Risk Factors

Raising additional funds may cause dilution to existing shareholders and/or may restrict our operations.

To the extent that we raise additional funds 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.

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

We expect to hire additional employees. The market for talent in our industry is very competitive. Many of the other pharmaceutical companies we compete against for qualified personnel 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 than what we have to offer. It is particularly difficult to recruit and 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 continue 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 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 net product revenue could be adversely affected, and we may not be able to implement our business strategies. 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.

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 or product candidates. 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 liabilities and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- inability to commercialize our products or any future products;
- 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;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our products or any future products, if approved for commercial sale; and
- loss of net product 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 commercially reasonable terms or in adequate amounts to protect us against losses due to liability. 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 or 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, our products, or our product candidates on any social media platform. 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.

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.

Our operating results may fluctuate significantly and our future operating results could fall below expectations. 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. Our quarterly and annual operating results may fluctuate significantly in the future. Any future net product revenue will depend on the successful commercialization and sales of our drug products and product candidates that receive marketing approval. Any future regulatory milestones, sales milestones and royalty payments we are eligible to earn from Pfizer under terms of the Pfizer Collaboration and License Agreement and from Richter under the terms of the Richter Development and Commercialization Agreement, or any potential future collaboration and license agreements, if any, will depend on the achievement of the underlying milestone event or level of sales activity. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including:

- the price, level of demand, and net revenues for our products, which may vary significantly as they are launched and compete for position in the marketplace;
- the extent to which coverage and adequate reimbursement is available from government and private payers such as Medicare Part D, Medicaid, pharmacy benefit managers, health plans, self-insured organizations, insurance companies and other plan administrators with respect to our drug products and product candidates, if approved, and the competitive response from existing and potential future therapeutic approaches that compete with our approved products and our product candidates;
- inability to obtain additional funding, or investor perception that we may be unable to obtain additional funding, if needed, or funding on desirable terms;
- 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 products or 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 products or current or future product candidates, or the inability to do so at acceptable prices;
- inability to maintain a qualified sales force;

- inability to establish and maintain 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 vendors on which we rely, including CMOs, CROs and third-party logistics providers;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may 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 on us or our competitors;
- 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, Pfizer, 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 our 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 significant 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 or members of our board of directors;
- issuance of additional shares of our common shares, or the perception that such issuances may occur;
- negative coverage in the media or securities 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, 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.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or securities analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the public, or if the forecasts we provide to the public are below the expectations of securities analysts or investors, the price of our common shares could decline substantially. Such a share price decline could occur even when we have met any previously publicly stated operating results and/or earnings guidance that we may provide.

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.

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. 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.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit No.		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		Employment Agreement, effective as of April 5, 2021, by and between Lauren Merendino and Myovant Sciences, Inc.	10-K	001-37929	10.27	05/11/2021
10.2	†*	Letter Agreement, dated May 4, 2021, by and between Myovant Sciences GmbH and Pfizer Inc.				
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.

* Portions of this exhibit have been omitted from this exhibit (indicated by asterisks) as such portions are both (a) not material and (b) is the type of information that the Registrant treats as private or confidential.

** 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: July 28, 2021

Exhibit 10.2

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

May 4, 2021

Re: Collaboration License Agreement by and between MYOVANT SCIENCES GMBH ("**Myovant**") and PFIZER INC. ("**Pfizer**"), dated as December 26, 2020 (the "**Myovant/Pfizer Agreement**")

This side letter agreement (the "**Side Letter Agreement**") relates to the Myovant/Pfizer Agreement, under which Myovant and Pfizer have agreed for Pfizer to have an exclusive option to obtain exclusive commercialization and promotion rights and related development rights for the Oncology Product(s) in the Oncology Field in the Pfizer Territory (each as defined therein), among other activities, in accordance with the terms of the Myovant/Pfizer Agreement. The Parties now wish to enter into this Side Letter Agreement to extend the time period within which Pfizer may exercise such exclusive option under Section 10.5 of the Agreement.

Unless otherwise noted, capitalized terms used, but not defined herein, shall have the respective meanings ascribed to them in the Myovant/Pfizer Agreement, as the context requires.

Myovant and Pfizer hereby agree as follows:

1. Section 1.185 is hereby deleted in its entirety and replaced as follows:

"Option Period" means the time period beginning on the date when a Drug Approval Application is filed with the EMA with respect to the Oncology Product for prostate cancer and ending on [***].

2. Termination. This Side Letter Agreement shall terminate automatically upon any expiration or termination of the Myovant/Pfizer Agreement in its entirety.

3. Miscellaneous. The provisions of Sections 18.7 (Amendment), 18.8 (Notices), 18.11 (Severability), 18.12 (Waivers) and 18.15 (Counterparts) of the Myovant/Pfizer Agreement are hereby incorporated by reference as though set out in full in this Side Letter Agreement, provided that each reference to "this Agreement" in such incorporated provisions shall be construed as a reference to this Side Letter Agreement.

4. Entire Agreement. This Side Letter Agreement and the Myovant/Pfizer Agreement set forth and constitute the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby and thereby.

5. Governing Law. This Agreement shall be governed by and construed and enforced under the substantive laws of the State of New York, without giving effect to any choice of law rules that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods (1980) shall not apply to this Agreement.

6. Disputes. Any controversy or claim arising out of or relating to this Side Letter Agreement shall constitute a "Dispute" under the Myovant/Pfizer Agreement, and Section 17.2 of the Myovant/Pfizer Agreement shall apply to any such Dispute accordingly.

[Signature page follows]

This Side Letter Agreement is signed below by authorized representatives of Myovant and Pfizer, respectively indicating the Parties' acceptance of the terms and conditions of this Side Letter Agreement.

MYOVANT SCIENCES GMBH		**PFIZER INC.**	
By:	/s/ Elke Hunsche	By:	/s/ John DeYoung
Name:	Elke Hunsche	Name:	John DeYoung
Title:	VP, Global Market Access & HEOR	Title:	Vice President

Exhibit 31.1

CERTIFICATION

I, David Marek, 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: July 28, 2021

By: /s/ David Marek
David Marek
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: July 28, 2021

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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David Marek, 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 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: July 28, 2021

By: /s/ David Marek
David Marek
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, 2021 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: July 28, 2021

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.