

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

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 24, 2019

Myovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda
(State or other jurisdiction of
incorporation)

001-37929
(Commission File No.)

98-1343578
(I.R.S. Employer Identification No.)

Suite 1, 3rd Floor
11-12 St. James's Square
London SW1Y 4LB, United Kingdom
(Address of principal executive office)

Not Applicable
(Zip Code)

Registrant's telephone number, including area code: (441) 295-5950

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

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

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

Item 2.02 Results of Operations and Financial Condition.

On May 24, 2019, Myovant Sciences Ltd. (the “**Registrant**”) issued a press release providing corporate updates and announcing its financial results for the three months and the full fiscal year ended March 31, 2019, a copy of which is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

In accordance with General Instruction B.2. of Form 8-K, the information in this report furnished pursuant to Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liability of that section, or to the liabilities of Section 11 and 12(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, nor shall it be deemed incorporated by reference into any of the Registrant’s filings under the Exchange Act or the Securities Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Myovant Sciences Ltd., dated May 24, 2019, “Myovant Sciences Provides Corporate Updates and Reports Financial Results for Fourth Fiscal Quarter and Full Fiscal Year Ended March 31, 2019”

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 hereunto duly authorized.

Myovant Sciences Ltd.

Date: May 24, 2019

By: /s/ Frank Karbe

Name: Frank Karbe

Title: *Principal Financial and Accounting Officer*

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Myovant Sciences Ltd., dated May 24, 2019, "Myovant Sciences Provides Corporate Updates and Reports Financial Results for Fourth Fiscal Quarter and Full Fiscal Year Ended March 31, 2019"



**Myovant Sciences Provides Corporate Updates and Reports Financial Results
for Fourth Fiscal Quarter and Full Fiscal Year Ended March 31, 2019**

-Announced positive Phase 3 results from LIBERTY 1 study evaluating relugolix combination therapy in women with uterine fibroids-

-Data from four additional Phase 3 clinical studies expected over next three quarters-

BRISBANE, Calif. & BASEL, Switzerland - May 24, 2019 -- Myovant Sciences (NYSE: **MYOV**), a clinical-stage healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer, today announced corporate updates and reported financial results for the fourth fiscal quarter and full fiscal year ended March 31, 2019.

"Earlier this month, Myovant reached a significant milestone with the announcement of positive data from LIBERTY 1, the first of two Phase 3 studies of once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, which met its primary efficacy endpoint and six key secondary endpoints," said Lynn Seely, M.D., President and Chief Executive Officer of Myovant Sciences. "These positive results bring us one step closer to realizing the potential of relugolix combination as a new treatment option for the millions of women suffering from this debilitating disease. We look forward to reporting data from LIBERTY 2, the second Phase 3 study designed to confirm these results, next quarter and results from our Phase 3 studies in endometriosis and prostate cancer over the next three quarters."

Fourth Fiscal Quarter 2018 and Recent Business Highlights

Relugolix Phase 3 Clinical Programs

- On May 14, 2019, Myovant announced positive results from the LIBERTY 1 Phase 3 study evaluating relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) once daily in women with uterine fibroids and heavy menstrual bleeding. Results from the Phase 3 LIBERTY 2 study are expected in the third quarter of calendar year 2019, and, provided the LIBERTY 2 study is successful, Myovant plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the fourth quarter of calendar year 2019.

MVT-602 Clinical Program

- Myovant completed a dose-finding pharmacokinetic/pharmacodynamic Phase 2a study of MVT-602, a kisspeptin-1 receptor agonist, in healthy women undergoing a controlled ovarian stimulation protocol. Top-line results are expected to be presented at the European Society of Human Reproduction in Vienna, Austria in June.

Corporate

- In the fourth quarter of fiscal year 2018, Myovant issued and sold 1,203,000 common shares for aggregate net proceeds of \$26.7 million pursuant to its "at-the-market" equity offering program. In April 2019, Myovant issued and sold an additional 106,494 common shares for aggregate net proceeds of \$2.5 million pursuant to the "at-the-market" equity offering program.

Fourth Fiscal Quarter and Full Fiscal Year 2018 Financial Summary

Research and development (R&D) expenses for the quarter ended March 31, 2019, were \$59.0 million compared to \$40.1 million for the comparable period in 2018. R&D expenses for the fiscal year ended March 31, 2019, were \$222.6 million, compared to \$116.8 million for the prior fiscal year. The increase for both the quarter and the year primarily reflects the progress of Myovant's Phase 3 clinical studies of relugolix, as well as additional personnel-related expenses and increased MVT-602 clinical trial expenses.

General and administrative (G&A) expenses for the quarter ended March 31, 2019, were \$12.5 million compared to \$7.3 million for the comparable period in 2018. G&A expenses for the fiscal year ended March 31, 2019, were \$42.2 million, compared to \$24.2 million for the prior fiscal year. The increase in G&A expenses for both the quarter and the year primarily reflects increases in personnel-related expenses, professional service fees, share-based compensation expense, and other administrative expenses to support Myovant's headcount growth and expanding operations.

Interest expense for the quarter ended March 31, 2019, was \$3.9 million compared to \$1.1 million in the comparable prior year period. Interest expense for the fiscal year ended March 31, 2019, was \$8.8 million, compared to \$2.0 million for the prior fiscal year. This consists of interest expense related to financing agreements with NovaQuest and Hercules Capital, Inc., as well as the associated non-cash amortization of debt discount and issuance costs. The increase for both the quarter and the year was primarily the result of higher outstanding debt balances under the financing agreements as compared to the prior year periods.

Interest income for the quarter and year ended March 31, 2019, was \$0.8 million and \$0.9 million, respectively. There was no interest income for the quarter and year ended March 31, 2018. During the year ended March 31, 2019, a portion of Myovant's cash was invested in a combination of money market funds and commercial paper. There were no such investments during the prior year periods.

Net loss for the quarter ended March 31, 2019, was \$75.0 million, compared to \$48.3 million for the comparable period in 2018. Net loss for the fiscal year ended March 31, 2019, was \$273.6 million, compared to \$143.3 million for the prior fiscal year. On a per common share basis, net loss was \$1.07 and \$0.81 for the quarters ended March 31, 2019, and 2018, respectively, and \$4.09 and \$2.41 for the fiscal years ended March 31, 2019 and 2018, respectively. The increases in the net loss and net loss per common share for both the quarter and the year were driven primarily by the increase in costs outlined above.

Capital resources: Cash and cash equivalents totaled \$156.1 million as of March 31, 2019. Currently, an additional \$10.4 million of capacity remains available under the "at-the-market" equity offering program that Myovant initiated in April 2018.

About Relugolix

Relugolix is a once daily oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces ovarian estradiol production, a hormone known to stimulate the growth of uterine fibroids. Myovant is studying relugolix combination therapy (relugolix 40 mg plus 1.0 mg estradiol with 0.5 mg norethindrone acetate) in two Phase 3 clinical studies (LIBERTY 1 and LIBERTY 2) in women with uterine fibroids and heavy menstrual bleeding, and in two Phase 3 clinical studies (SPIRIT 1 and SPIRIT 2) in women with endometriosis-associated pain. Myovant is studying whether the combination optimizes estradiol levels to maximize the benefit of relugolix on symptoms of uterine fibroids and endometriosis, while maintaining bone health and mitigating other side effects from a low-estrogen state such as vasomotor symptoms. Relugolix monotherapy, 120 mg once daily, is also being evaluated in the Phase 3 HERO study in men with advanced prostate cancer.

About MVT-602

MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin, the ligand, is a naturally-occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. A Phase 2a clinical study in healthy female volunteers to characterize the dose-response curve in the controlled ovarian stimulation setting has been completed. This study is intended to provide information for dose selection for a study of MVT-602 in infertile women seeking pregnancy.

About Myovant Sciences

Myovant Sciences aspires to be the leading healthcare company focused on innovative treatments for women's health and prostate cancer. Myovant's lead product candidate is relugolix, an oral, once daily small molecule that acts as a GnRH receptor antagonist. Myovant has three late-stage clinical programs for relugolix ongoing in uterine fibroids, endometriosis and prostate cancer. Myovant is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, that has completed a Phase 2a study for the treatment of female infertility as part of assisted reproduction. Myovant Sciences is the majority owner of Myovant. Takeda Pharmaceuticals International AG granted Myovant an exclusive, worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive license to develop and commercialize MVT-602 in all countries worldwide. Over time, Myovant intends to expand its development pipeline to include other potential treatments for women's health and prostate cancer. For more information, please visit Myovant's website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn (<https://www.linkedin.com/myovantsciences>).

Forward-Looking Statements

This press-release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical statements of fact and statements regarding Myovant's intent, belief, or expectations and can be identified by 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 other similar expressions or variations, although not all forward-looking statements contain these identifying words. In this press release, forward-looking statements include, but are not limited to, statements regarding Myovant's intentions to expand its development pipeline to include other potential treatments for women's health and prostate cancer, Myovant's expected timelines for announcing and presenting additional top-line safety and efficacy data for relugolix and MVT-602 over the next three quarters, Myovant's plans to file for approval of relugolix, and the timing of such filing and the commercial potential for relugolix, including market size. Myovant's forward-looking statements are based on management's current expectations and beliefs and 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. Myovant 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. Factors that could materially affect Myovant's operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to the risks and uncertainties listed in Myovant's filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Myovant's Quarterly Report on Form 10-Q filed with the SEC on February 7, 2019, and in Myovant's future filings with the SEC including without limitation, Myovant's Annual Report on Form 10-K expected to be filed with the SEC on or about May 24, 2019, as such risk factors may be amended, supplemented or superseded from time to time by other reports Myovant files with the SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for Myovant's management to predict all risk factors, nor can Myovant assess the impact of all factors on its 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. You should not place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof, and, except as required by law, Myovant undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

MYOVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,		Years Ended March 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development ⁽¹⁾	\$ 59,019	\$ 40,079	\$ 222,607	\$ 116,832
General and administrative ⁽²⁾	12,481	7,268	42,219	24,231
Total operating expenses	<u>71,500</u>	<u>47,347</u>	<u>264,826</u>	<u>141,063</u>
Interest expense	3,913	1,142	8,821	2,046
Interest income	(804)	—	(881)	—
Other expense (income), net	162	158	309	(67)
Loss before income taxes	<u>(74,771)</u>	<u>(48,647)</u>	<u>(273,075)</u>	<u>(143,042)</u>
Income tax expense (benefit)	243	(394)	476	213
Net loss	<u>\$ (75,014)</u>	<u>\$ (48,253)</u>	<u>\$ (273,551)</u>	<u>\$ (143,255)</u>
Net loss per common share — basic and diluted	<u>\$ (1.07)</u>	<u>\$ (0.81)</u>	<u>\$ (4.09)</u>	<u>\$ (2.41)</u>
Weighted average common shares outstanding — basic and diluted	<u>70,076,475</u>	<u>59,748,711</u>	<u>66,910,060</u>	<u>59,520,747</u>

⁽¹⁾ Includes the following share-based compensation expenses:

Research and development	\$ 1,914	\$ 1,094	\$ 7,161	\$ 3,674
General and administrative	\$ 3,019	\$ 2,246	\$ 11,535	\$ 7,909

MYOVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands)

	March 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 156,074	\$ 108,624
Prepaid expenses and other current assets	10,194	5,139
Income tax receivable	524	1,000
Total current assets	<u>166,792</u>	<u>114,763</u>
Property and equipment, net	2,071	1,273
Other assets	4,114	3,065
Total assets	<u>\$ 172,977</u>	<u>\$ 119,101</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,019	\$ 4,578
Interest payable	1,077	282
Accrued expenses	53,614	30,265
Due to RSL, RSI and RSG	121	1,960
Current maturities of long-term debt	6,142	—
Total current liabilities	<u>71,973</u>	<u>37,085</u>
Deferred rent	1,157	408
Deferred interest payable	2,273	255
Long-term debt, less current maturities	93,240	43,624
Total liabilities	<u>168,643</u>	<u>81,372</u>
Total shareholders' equity	4,334	37,729
Total liabilities and shareholders' equity	<u>\$ 172,977</u>	<u>\$ 119,101</u>

Investor Contact:

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SOURCE: Myovant Sciences