

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): **August 7, 2018**

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: **+44 203 318 9709**

(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 x

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.

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2018, Myovant Sciences Ltd. (the “**Registrant**”) issued a press release providing a corporate update and announcing its financial results for the three months ended June 30, 2018, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Myovant Sciences Ltd., dated August 7, 2018, “Myovant Provides Corporate Update and Reports Financial Results for First Fiscal Quarter Ended June 30, 2018”

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Myovant Sciences Ltd.

Date: August 7, 2018

By: /s/ Frank Karbe

Name: Frank Karbe

Title: *Principal Financial and Accounting Officer*

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press Release of Myovant Sciences Ltd., dated August 7, 2018, "Myovant Provides Corporate Update and Reports Financial Results for First Fiscal Quarter Ended June 30, 2018"</u>



**Myovant Provides Corporate Update and Reports Financial Results
for First Fiscal Quarter Ended June 30, 2018**

- Completed patient screening for Phase 3 LIBERTY 1 Trial -

- On track to announce top-line results from all relugolix Phase 3 clinical trials during 2019 -

- Ended first fiscal quarter of 2018 with \$235.6 million in cash and committed financing -

- Raised approximately \$150.0 million in net proceeds from equity offerings in fiscal 2018 -

BASEL, Switzerland, August 7, 2018-- Myovant Sciences (NYSE: **MYOV**), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of women's health and endocrine diseases, today announced corporate updates and reported financial results for the first fiscal quarter ended June 30, 2018.

"We are off to an excellent start to the year, highlighted by the completion of patient screening for our Phase 3 LIBERTY 1 trial evaluating relugolix in women with heavy menstrual bleeding associated with uterine fibroids, and screening in the replicate LIBERTY 2 trial expected to be completed this quarter," said Lynn Seely, M.D., President and Chief Executive Officer of Myovant Sciences. "We are at an exciting stage in the evolution of the Company, with top-line safety and efficacy data expected for relugolix in 2019 in three distinct indications, each with large markets and wholly owned North American and European rights."

Recent Business Highlights and Upcoming Milestones

- On July 10, 2018, Myovant announced completion of patient screening for its LIBERTY 1 trial, the first of two Phase 3 replicate trials evaluating relugolix in women with heavy menstrual bleeding associated with uterine fibroids. Top-line safety and efficacy data from this trial are expected in the second quarter of 2019.
- Screening for the LIBERTY 2 trial is anticipated to be completed this quarter.
- Completion of enrollment and top-line safety and efficacy data from the two Phase 3 SPIRIT trials of relugolix in women with endometriosis-associated pain are expected in 2019.
- Enrollment is expected to be completed in 2018 for the Phase 3 HERO trial of relugolix in men with advanced prostate cancer, and top-line safety and efficacy data are expected in 2019.
- Myovant raised aggregate net proceeds of approximately \$150.0 million during fiscal 2018 from the issuance and sale of 3,333,334 common shares in an underwritten public offering in July 2018, 1,110,015 common shares in a private placement to the Company's controlling shareholder, Roivant Sciences, Ltd. in April 2018, and 2,767,129 common shares in an "at-the-market" equity offering program in April 2018.
- On May 30, 2018, Myovant entered into a Commercial Manufacturing and Supply Agreement with Takeda Pharmaceutical Company Ltd. pursuant to which Takeda will manufacture and supply Myovant with relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. Takeda has also agreed to assist with the transfer of technology and manufacturing know-how to a second contract manufacturing organization of Myovant.

- In May 2018, following the completion of a Phase 1 study, Myovant initiated a Phase 2a clinical trial in healthy female volunteers to characterize the dose-response curve in the controlled ovarian stimulation setting prior to studying MVT-602 in infertile woman seeking pregnancy.
- On April 20, 2018, Myovant announced a partnership with PERIOD, Inc., a youth-led non-profit organization focused on menstrual equity, to elevate the conversation around period health, including an *Ask Me About Periods* campaign on college campuses around the country.

First Fiscal Quarter 2018 Financial Summary

Research and development (R&D) expenses for the quarter ended June 30, 2018, were \$51.3 million compared to \$17.7 million for the comparable period in 2017. The increase for the quarter primarily reflects the progress of Myovant's ongoing Phase 3 clinical trials of relugolix, which were initiated in 2017, and additional personnel-related expenses.

General and administrative (G&A) expenses for the quarter ended June 30, 2018, were \$8.7 million compared to \$4.2 million for the comparable period in 2017. The increase for the quarter primarily reflects increases in personnel-related expenses, professional service fees, and other administrative expenses to support Myovant's headcount growth and expanding operations.

Interest expense for the quarter ended June 30, 2018, was \$1.6 million compared to no interest expense in the comparable prior year period. Interest expense for the quarter consisted of interest expense related to financing agreements with NovaQuest Pharma Opportunities Fund IV L.P. and Hercules Capital, Inc., as well as the associated non-cash amortization of debt discount and issuance costs.

Net loss for the quarter ended June 30, 2018, was \$62.1 million, compared to \$23.3 million for the comparable period in 2017. On a per common share basis, net loss was \$0.98 and \$0.39 for the quarters ended June 30, 2018, and 2017, respectively. The increases in the net loss and net loss per common share for the quarter were driven primarily by the increase in costs associated with Myovant's ongoing Phase 3 clinical trials, which were initiated in 2017, as well as increased personnel-related expenses.

Capital resources: Cash and committed funding totaled \$235.6 million at June 30, 2018, consisting of \$143.6 million in cash and \$92.0 million in remaining financing commitments available from NovaQuest under the NovaQuest Securities Purchase Agreement and the NovaQuest Equity Purchase Agreement. In the second quarter of fiscal year 2018, Myovant further strengthened its balance sheet, raising net proceeds of approximately \$70.2 million from the issuance and sale of 3,333,334 common shares in an underwritten public offering. An additional \$40.6 million of capacity remains available under the "at-the-market" equity offering program that Myovant initiated in April 2018.

About Relugolix

Relugolix is an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist that has been evaluated in approximately 1,600 study participants in Phase 1, Phase 2 and Phase 3 clinical trials. In these trials, relugolix has been shown to be generally well tolerated and to suppress estrogen and progesterone levels in women and testosterone levels in men. Common side effects observed were consistent with suppression of these hormones. In the ongoing Phase 3 LIBERTY clinical trials in women with heavy menstrual bleeding associated with uterine fibroids and the ongoing Phase 3 SPIRIT clinical trials in women with endometriosis-associated pain, relugolix is undergoing evaluation alone as monotherapy and in combination with estradiol and norethindrone acetate, a progestin. Myovant is studying whether the combination decreases estradiol levels to the range required to treat signs and symptoms of endometriosis and uterine fibroids while minimizing the side effects such as bone mineral density loss and hot flashes, associated with low estrogen levels. The ongoing Phase 3 HERO study is evaluating relugolix alone in men with advanced prostate cancer.

About Myovant Sciences

Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of women's health and endocrine diseases. Myovant's goal is to be the leading global biopharmaceutical company focused on treating women's health and endocrine diseases in areas of high unmet medical need. Myovant's lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a GnRH receptor antagonist. Myovant has initiated three clinical programs for relugolix consisting of five international Phase 3 clinical trials, two in women with heavy menstrual bleeding associated with uterine fibroids (LIBERTY 1 and 2), two in women with endometriosis-associated pain (SPIRIT 1 and 2), and one in men with advanced prostate cancer (HERO). Myovant is also developing MVT-602, a kisspeptin agonist, for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG granted Myovant an exclusive, worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries where Takeda retains exclusive rights) 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 endocrine diseases. For more information, please visit the company's website at www.myovant.com.

Forward-Looking Statements

This press-release contains forward-looking statements, including without limitation, statements related to: Myovant's focus on developing and commercializing innovative therapies for the treatment of women's health and endocrine diseases; Dr. Seely's quotes regarding the expected timeline of completing patient screening for LIBERTY 2 and the timeline of the reporting of top-line efficacy and safety data for relugolix in 2019 in three distinct indications; the expectation for top-line safety and efficacy data from the LIBERTY 1 trial in the second quarter of 2019; the expectation for completion of screening for the LIBERTY 2 trial this quarter; the expectation for completion of enrollment and top-line safety and efficacy data from the two Phase 3 SPIRIT trials of relugolix in women with endometriosis-associated pain in 2019; the expectation for completion of enrollment for the Phase 3 HERO trial of relugolix in men with advanced prostate cancer in 2018 and that for top-line safety and efficacy data in 2019; and the remaining available financing commitments and funding status. Forward-looking statements can be identified by the words "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. 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. 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, risks relating to: the success of Myovant's clinical trials for relugolix and MVT-602; future regulatory submissions and the timing of, and Myovant's ability to, obtain and maintain regulatory approvals for relugolix, MVT-602 and any future product candidates; Myovant's ability to hire and retain its key scientific or management personnel; Myovant's ability to obtain, maintain and enforce intellectual property rights for its product candidates; the anticipated receipt of the remaining funding available to Myovant under its agreements with NovaQuest; Myovant's need for future funding; and those discussed in the section titled "Risk Factors" set forth in Part I, Item 1A of Myovant's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission, or the SEC, on June 7, 2018, and in Myovant's future filings with the SEC including without limitation, Myovant's Quarterly Report on Form 10-Q expected to be filed with the SEC on or about August 7, 2018, and other filings that Myovant makes with the SEC from time to time. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for its 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. In addition, statements that "we believe," "Myovant believes," and similar statements reflect its beliefs and opinions on the relevant subject. These statements are based upon information available to Myovant as of the date of this press release, and while Myovant believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and its statements should not be read to indicate that it has 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, Myovant undertakes no obligation to update any 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 June 30,	
	2018	2017
Operating expenses:		
Research and development ⁽¹⁾	\$ 51,341	\$ 17,708
General and administrative ⁽¹⁾	8,742	4,182
Total operating expenses	60,083	21,890
Interest expense	1,617	—
Other expense	289	342
Loss before income taxes	(61,989)	(22,232)
Income tax expense	145	1,085
Net loss	\$ (62,134)	\$ (23,317)
Net loss per common share — basic and diluted	\$ (0.98)	\$ (0.39)
Weighted average common shares outstanding — basic and diluted	63,310,177	59,247,273

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

Research and development	\$ 1,561	\$ 860
General and administrative	\$ 2,683	\$ 1,341

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

	<u>June 30, 2018</u>	<u>March 31, 2018</u>
Assets		
Current assets:		
Cash	\$ 143,635	\$ 108,624
Prepaid expenses and other current assets	5,702	5,139
Income tax receivable	855	1,000
Total current assets	<u>150,192</u>	<u>114,763</u>
Furniture and equipment, net	1,379	1,273
Other assets	2,777	3,065
Total assets	<u>\$ 154,348</u>	<u>\$ 119,101</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,039	\$ 4,578
Interest payable	372	282
Accrued expenses	38,305	30,265
Due to Roivant Sciences Ltd., Roivant Sciences, Inc. and Roivant Sciences GmbH	5,207	1,960
Total current liabilities	<u>48,923</u>	<u>37,085</u>
Deferred rent	732	408
Deferred interest payable	407	255
Long-term debt	44,131	43,624
Total liabilities	<u>94,193</u>	<u>81,372</u>
Total shareholders' equity	<u>60,155</u>	<u>37,729</u>
Total liabilities and shareholders' equity	<u>\$ 154,348</u>	<u>\$ 119,101</u>

Investor Contact:

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SOURCE: Myovant Sciences