



Myovant Provides Corporate Updates and Reports Financial Results for Second Fiscal Quarter Ended September 30, 2018

November 8, 2018

- Completed Patient Enrollment in Phase 3 LIBERTY 1 and HERO Trials -- Completed Screening in Phase 3 LIBERTY 2 Trial -- On Track to Announce Top-line Results from All Five Relugolix Phase 3 Clinical Trials in 2019 -

BASEL, Switzerland, Nov. 8, 2018 /PRNewswire/ -- 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 second fiscal quarter ended September 30, 2018.



"We continue to make significant progress in advancing our Phase 3 clinical trials and have achieved several important milestones," said Lynn Seely, M.D., President and Chief Executive Officer of Myovant Sciences. "We completed patient enrollment in both our Phase 3 LIBERTY 1 trial evaluating relugolix in combination with estradiol and a progestin in women with heavy menstrual bleeding associated with uterine fibroids and our Phase 3 HERO trial evaluating relugolix monotherapy in treating men with advanced prostate cancer. Screening has also been completed for our Phase 3 LIBERTY 2 trial. We remain on track to announce top-line safety and efficacy data for relugolix in 2019 in three distinct indications, each with wholly owned North American and European rights."

Recent Business Highlights and Upcoming Milestones

Relugolix Phase 3 Clinical Programs

- Completed enrollment in the Phase 3 LIBERTY 1 trial and completed patient screening for the Phase 3 LIBERTY 2 trial. Both trials are evaluating relugolix in combination with estradiol and a progestin in women with heavy menstrual bleeding associated with uterine fibroids. Top-line safety and efficacy data from the LIBERTY 1 trial are expected in the second quarter of 2019, and data from the LIBERTY 2 trial are expected in the third quarter of 2019, with a New Drug Application (NDA) filing expected in the fourth quarter of 2019.
- Continued enrolling patients in the Phase 3 SPIRIT 1 and SPIRIT 2 trials, which are evaluating relugolix in women with pain associated with endometriosis. Top-line results are expected in 2019.
- Completed patient enrollment in the pivotal Phase 3 HERO trial, which is evaluating the safety and efficacy of relugolix monotherapy for the treatment of men with advanced prostate cancer. Top-line safety and efficacy data are expected in the fourth quarter of 2019, with a NDA filing expected in early 2020.

MVT-602 Clinical Program

- Presented data at the American Society for Reproductive Medicine (ASRM) Annual Congress from a Phase 1 trial of MVT-602, a novel oligopeptide kisspeptin-1 receptor agonist in development as a potential treatment for female infertility in women as part of assisted reproduction.
- Completed enrollment in a Phase 2a clinical trial in approximately 70 fertile women undergoing a controlled ovarian stimulation. Top-line results are expected in the first half of 2019.

Corporate

- Appointed Kim Sablich, formerly Vice President of Primary Care Marketing in the United States for GlaxoSmithKline (GSK), as Chief Commercial Officer, and Jeff Nornhold, formerly Senior Vice President of Technical Operations for Impax Laboratories (now Amneal Pharmaceuticals, Inc.), as Senior Vice President of Pharmaceutical Operations & Development.
- Appointed industry veterans Myrtle Potter, Mark Guinan and Frank Torti, M.D., to the company's Board of Directors, and Ms. Potter to Chairman of the Board.
- Raised aggregate net proceeds of approximately \$74.4 million from the issuance and sale of 3,533,399 common shares in an underwritten secondary public equity offering.

Second Fiscal Quarter 2018 Financial Summary

Research and development (R&D) expenses for the quarter ended September 30, 2018, were \$53.8 million compared to \$24.2 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, as well as additional personnel-related expenses and MVT-602 clinical trial expenses.

General and administrative (G&A) expenses for the quarter ended September 30, 2018, were \$10.3 million compared to \$6.1 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 September 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 September 30, 2018, was \$65.8 million, compared to \$29.9 million for the comparable period in 2017. On a per common share basis, net loss was \$0.99 and \$0.50 for the quarters ended September 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 outlined above.

Capital resources: Cash and committed funding totaled \$246.3 million at September 30, 2018, consisting of \$154.3 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. 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. More than 2,150 study participants have received treatment with relugolix in Phase 1, Phase 2 and Phase 3 clinical trials. In completed trials, relugolix was generally well tolerated and suppressed 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 pain associated with endometriosis, relugolix is undergoing evaluation in combination with estradiol and norethindrone acetate, a progestin, and as monotherapy. 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 associated with low estrogen levels, which include bone mineral density loss and hot flashes. The ongoing Phase 3 HERO study is evaluating relugolix monotherapy 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 trial in healthy female volunteers is under way to characterize the dose-response curve in the controlled ovarian stimulation setting prior to studying MVT-602 in infertile women seeking pregnancy.

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 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 pain associated with endometriosis (SPIRIT 1 and 2), and one in men with advanced prostate cancer (HERO). Myovant is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, that is in Phase 2a development 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 Myovant'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; the statements and Dr. Seely's quotes regarding the expected timelines for announcing top-line safety and efficacy data for relugolix in 2019 in three distinct indications; other statements relating to the timing of reporting clinical trial results; and the remaining available financing commitments and funding status. Forward-looking statements 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. 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 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 November 8, 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. 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 September 30, Six Months Ended September 30,			
	2018	2017	2018	2017
Operating expenses:				
Research and development ⁽¹⁾	\$ 53,813	\$ 24,170	\$ 105,154	\$ 41,878
General and administrative ⁽¹⁾	10,310	6,141	19,052	10,323
Total operating expenses	64,123	30,311	124,206	52,201
Interest expense	1,580	—	3,197	—
Other (income) expense	(21)	(138)	268	204
Loss before income taxes	(65,682)	(30,173)	(127,671)	(52,405)
Income tax expense (benefit)	88	(265)	233	820
Net loss	\$ (65,770)	\$ (29,908)	\$ (127,904)	\$ (53,225)
Net loss per common share — basic and diluted	\$ (0.99)	\$ (0.50)	\$ (1.97)	\$ (0.90)
Weighted average common shares outstanding — basic and diluted	66,666,876	59,459,500	64,997,698	59,353,966

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

Research and development	\$ 1,846	\$ 679	\$ 3,407	\$ 1,539
General and administrative	\$ 2,879	\$ 2,070	\$ 5,562	\$ 3,411

MYOVANT SCIENCES LTD.

Condensed Consolidated Balance Sheets

(Unaudited, in thousands)

September 30, 2018 March 31, 2018

Assets

Current assets:

Cash	\$ 154,317	\$ 108,624
Prepaid expenses and other current assets	8,449	5,139
Income tax receivable	767	1,000
Total current assets	163,533	114,763
Furniture and equipment, net	1,472	1,273
Other assets	3,161	3,065
Total assets	\$ 168,166	\$ 119,101

Liabilities and Shareholders' Equity

Current liabilities:

Accounts payable	\$ 8,359	\$ 4,578
Interest payable	300	282
Accrued expenses	38,733	30,265
Due to Roivant Sciences Ltd., Roivant Sciences, Inc. and Roivant Sciences GmbH578		1,960
Total current liabilities	47,970	37,085
Deferred rent	975	408
Deferred interest payable	560	255
Long-term debt	44,560	43,624
Total liabilities	94,065	81,372
Total shareholders' equity	74,101	37,729
Total liabilities and shareholders' equity	\$ 168,166	\$ 119,101

Investor Contact:

Frank Karbe
Chief Financial Officer
Myovant Sciences
investors@myovant.com

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/myovant-provides-corporate-updates-and-reports-financial-results-for-second-fiscal-quarter-ended-september-30-2018-300747021.html>

SOURCE Myovant Sciences, Ltd.