



Myovant Sciences Announces Financial Results for First Quarter of Fiscal Year 2021 and Corporate Updates

July 28, 2021

- *First fiscal quarter 2021 total revenues of \$41.1 million; net product revenue from U.S. sales of ORGOVYX® of \$10.5 million and MYFEMBREE® of \$1.1 million*
- *MYFEMBREE approved by the U.S. FDA in May 2021 as the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids; FDA approval triggered a \$100.0 million milestone payment from Pfizer received in July 2021*
- *RYEQO® approved by the European Commission in July 2021 for the treatment of women with uterine fibroids; Gedeon Richter will commercialize RYEQO in Europe; approval triggered a \$15.0 million milestone payment from Gedeon Richter, expected to be received in second fiscal quarter 2021*
- *Supplemental New Drug Application for MYFEMBREE for the management of moderate to severe pain associated with endometriosis submitted to FDA in July 2021*
- *Timeline for Pfizer's exclusive option to acquire development and commercialization rights to relugolix in oncology outside of U.S. and Canada extended through October 2021*
- *Myovant remains well-capitalized with cash, cash equivalents, marketable securities, and committed funding of \$611.1 million as of June 30, 2021, excluding \$115.0 million of recently-triggered milestone payments*

BASEL, Switzerland, July 28, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced corporate updates and financial results for the first quarter of fiscal year 2021.

"I am pleased with the significant progress Myovant has made toward delivering on our mission of redefining care for women and for men. MYFEMBREE was approved by the FDA in May for women with uterine fibroids and was launched by Myovant and Pfizer in mid-June. We are encouraged by our early progress and are excited to be bringing this important new treatment option to the millions of women suffering from the symptoms of uterine fibroids. In July, we submitted to the FDA a supplemental New Drug Application seeking to extend approval of MYFEMBREE to include women with endometriosis. Finally, RYEQO was approved in Europe as the first and only long-term, once-daily oral treatment for uterine fibroids. We look forward to RYEQO's launch later this year, to be executed by Gedeon Richter," said David Marek, Chief Executive Officer of Myovant Sciences, Inc.

Mr. Marek added, "ORGOVYX launch momentum continued to accelerate in first fiscal quarter 2021 with net product revenues of \$10.5 million, demonstrating substantial growth compared to the previous quarter. This performance reflects the overwhelmingly positive feedback we have received from patients and clinicians regarding the impact ORGOVYX has had on the advanced prostate cancer treatment experience. Providing patients and prescribers with an oral medication that is able to rapidly and profoundly reduce testosterone levels without an initial hormonal surge has positioned ORGOVYX to potentially become the new standard of care androgen deprivation therapy over time."

First Fiscal Quarter 2021 and Recent Corporate Updates

ORGOVYX (relugolix 120 mg)

- *First fiscal quarter 2021 net product revenues for ORGOVYX in the U.S. were \$10.5 million, driven by increased prescriber demand.*
- *Approximately 1,150 treatment centers have prescribed ORGOVYX to over 4,500 patients on free and commercial drug, estimated through June 30, 2021. The number of estimated patients initiating ORGOVYX therapy has steadily increased in each successive month since launch.*
- *As of July 1, 2021, Myovant achieved 63% commercial coverage and 78% Medicare Part D coverage for ORGOVYX. Myovant continues to engage in negotiations with payors yet to make 2021 coverage decisions and now expects to achieve broad coverage before its original calendar year-end 2021 goal.*

MYFEMBREE (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg)

- *On May 26, 2021, MYFEMBREE was approved by the U.S. Food and Drug Administration (FDA) as the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids.*
- *The FDA approval of MYFEMBREE triggered a \$100.0 million regulatory milestone payment from Pfizer, which Myovant*

received in July 2021 (Myovant's second fiscal quarter 2021).

- In mid-June 2021, Myovant and Pfizer launched MYFEMBREE in the U.S. First fiscal quarter 2021 net product revenues for MYFEMBREE in the U.S. were \$1.1 million, reflecting initial inventory stocking by distributors upon MYFEMBREE product availability.
- As of July 1, 2021, 37% of commercial lives were eligible for pre-review coverage for MYFEMBREE. Myovant continues to engage in coverage negotiations with key commercial payors and remains on track to achieve its goal of broad coverage within one year of launch.
- On July 6, 2021, Myovant 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. In April and June 2020 and January 2021, Myovant reported positive results from the two replicate Phase 3 SPIRIT studies and the SPIRIT long-term extension study.
- 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 May 18, 2021, the FDA informed Myovant 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, Myovant provided to the FDA an amended study protocol for the SERENE study. Following Myovant's discussions with the FDA, Myovant expects the partial clinical hold to be lifted in August 2021.

RYEQO (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg)

- On July 16, 2021, the European Commission (EC) 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 Gedeon Richter (Richter), Myovant's commercialization partner for RYEQO in Europe and certain other international markets.
- The approval of RYEQO for the uterine fibroids indication by the EC triggered a \$15.0 million regulatory milestone payment due from Richter, which Myovant expects to receive and record as Richter license and milestone revenue in its second fiscal quarter of 2021. In addition to tiered milestones upon reaching certain net sales thresholds, Myovant is also eligible to receive tiered royalties on net sales.

Pfizer Collaboration

- In July 2021, Myovant 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

- 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. If Pfizer exercises this option, Myovant will receive a \$50.0 million payment and will be eligible to receive double-digit royalties on net sales in the Pfizer Territory.
- 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 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.

- EC decision on the advanced prostate cancer MAA is expected in calendar year 2022.

First Fiscal Quarter 2021 Financial Summary

Total revenues for the three months ended June 30, 2021 and 2020 were \$41.1 million and \$33.3 million, respectively.

- **Product revenue, net** from sales of ORGOVYX and MYFEMBREE in the U.S. for the three months ended June 30, 2021 were \$10.5 million and \$1.1 million, respectively. There were no such revenues recorded in the comparable prior year period.
- **Pfizer collaboration revenue** for the three months ended June 30, 2021 was \$29.5 million, reflecting the partial recognition of the upfront payment Myovant received from Pfizer in December 2020 and of the regulatory milestone payment 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 revenues recorded in the comparable prior year period.
- **Richter license and milestone revenue** for the three months ended June 30, 2020 was \$33.3 million, reflecting the partial recognition of the upfront payment Myovant received from Richter in March 2020 and the regulatory milestone payment Myovant received from Richter in April 2020. There were no such revenues in the three months ended June 30, 2021.

Cost of product revenue for the three months ended June 30, 2021 was \$1.0 million related to the cost of goods sold and royalty expense payable to Takeda pursuant to the Takeda License Agreement. There were no such amounts recognized in the comparable prior year period.

Collaboration expense to Pfizer for the three months ended June 30, 2021, was \$5.3 million, reflecting Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S., pursuant to the Pfizer Collaboration and License Agreement. There were no such amounts recognized in the comparable prior year period.

Research and development (R&D) expenses for the three months ended June 30, 2021, were \$30.9 million compared to \$44.2 million for the comparable prior year period. The decrease in R&D expenses reflects cost share reimbursements from Pfizer for certain R&D expenses and a reduction in clinical study costs as a result of the completion and wind down of Myovant's 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 Myovant's New Drug Applications 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.

Selling, general and administrative (SG&A) expenses for the three months ended June 30, 2021, were \$61.2 million compared to \$22.8 million for the comparable prior year period. The increase was primarily due to higher expenses related to commercial activities to support the ORGOVYX and MYFEMBREE U.S. launches, higher personnel-related costs primarily due to the hiring of Myovant's commercial operations, marketing, and market access teams, as well as the oncology and women's health sales forces, and higher general overhead expenses to support Myovant's organizational growth.

Interest expense was \$3.5 million for the three months ended June 30, 2021, compared to \$2.2 million for the comparable prior year period. The increase in interest expense was primarily driven by the higher balance under Myovant's loan agreement with Sumitomo Dainippon Pharma (Sumitomo Dainippon Pharma Loan Agreement) and \$0.6 million of accretion of the financing component of the cost share advance from Pfizer.

Foreign exchange gain for the three months ended June 30, 2020 was \$3.6 million, primarily the result of the increase in Myovant's 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 Myovant's wholly-owned subsidiary in Switzerland, Myovant Sciences GmbH, from the Swiss franc to the U.S. dollar in December 2020, Myovant is no longer exposed to significant foreign currency gains or losses.

Net loss for the three months ended June 30, 2021 was \$61.7 million compared to \$32.9 million for the comparable prior year period. On a per common share basis, net loss was \$0.67 and \$0.37 for the three months ended June 30, 2021 and 2020, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and amounts available under the Sumitomo Dainippon Pharma Loan Agreement totaled \$611.1 million as of June 30, 2021, and consisted of \$569.8 million of cash, cash equivalents, and marketable securities and \$41.3 million of available borrowing capacity under the Sumitomo Dainippon Pharma Loan Agreement. Subsequent to the end of the quarter, Myovant received a \$100.0 million milestone payment from Pfizer in July 2021 and expects to receive a \$15.0 million milestone payment from Richter in second fiscal quarter 2021.

Conference Call

As previously announced, Myovant will hold a webcast and conference call at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) today, July 28, 2021, to discuss financial results for its first fiscal quarter ended June 30, 2021 and corporate updates. Investors and the general public may access a live webcast of the call by visiting the investor relations page of Myovant's website at investors.myovant.com. Institutional investors and analysts may also participate in the conference call by dialing 1-800-532-3746 in the U.S. or +1-470-495-9166 from outside the U.S. The webcast will be archived on Myovant's Investor Relations website following the call.

About Relugolix

Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone, a hormone known to stimulate the growth of prostate cancer, and ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis. ORGOVYX[®] (relugolix 120 mg) was approved in the U.S. by the FDA in December 2020 as the first and only oral GnRH receptor antagonist for the treatment of adult patients with advanced prostate cancer, and relugolix (120 mg) is also under regulatory review in Europe for men with advanced prostate cancer. MYFEMBREE[®] (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) 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. On July 16, 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. On July 6, 2021, Myovant Sciences GmbH, a subsidiary of Myovant Sciences Ltd., submitted a supplemental New Drug Application 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.

About Myovant Sciences

Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, we have two FDA-approved products. ORGOVYX[®] (relugolix) was approved by the U.S. Food and Drug Administration in 2020 as the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of adult patients with advanced prostate cancer, and relugolix is also under regulatory review in Europe for men with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) was approved in 2021 in the EU as RYEQO[®] for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, and in the U.S. as MYFEMBREE[®] as the first once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women. The therapy has also completed Phase 3 registration-enabling studies for women with endometriosis, and is being assessed for contraceptive efficacy in healthy women ages 18-35 years who are at risk for pregnancy. We are also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is our majority shareholder. For more information, please visit our website at www.myovant.com. Follow [@Myovant](https://twitter.com/Myovant) on Twitter and [Linkedin](https://www.linkedin.com/company/myovant).

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including the U.S., Japan, China, and the European Union. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has more than 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at <https://www.ds-pharma.com>.

About Sumitovant Biopharma Ltd.

Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is the majority shareholder of Myovant, and wholly owns Urovant Sciences, Enzyvant Therapeutics, Spirovant Sciences, and Altavant Sciences. Sumitovant's pipeline is comprised of commercialized and investigational medicines across a range of disease areas targeting high unmet need. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma. For further information about Sumitovant, please visit <https://www.sumitovant.com>.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In this press release, forward-looking statements include, but are not limited to, all statements reflecting Myovant Sciences' expectations, including: statements regarding Myovant's aspiration to redefine care for women and for men; certain statements with respect to expectations of Myovant's approved drug products in Mr. Marek's quote; Myovant's expectations of the commercialization of RYEQO by Gedeon Richter in Europe; Myovant's expectations regarding status of its publicly announced milestones and expectations of milestone revenue; Myovant's expectations of payor coverage decisions; the timing of Myovant's regulatory submissions and anticipated regulatory review results; any expectation of the regulatory review results relating to the lifting of the partial clinical hold of the SERENE study; timeline for Pfizer's decision to exercise its exclusive option to acquire rights to relugolix in oncology in the Pfizer Territory; and those statements under the caption "Expected Upcoming Milestones."

Myovant Sciences' 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, including unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic. Myovant Sciences 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 Sciences' 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 Sciences' filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Myovant Sciences' Quarterly Report on Form 10-Q to be filed on July 28, 2021, as such risk factors may be amended, supplemented, or superseded from time to time. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for Myovant Sciences' management to predict all risk factors, nor can Myovant Sciences 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 Sciences 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 June 30,	
	2021	2020
Revenues:		
Product revenue, net	\$ 11,554	\$ —
Pfizer collaboration revenue	29,509	—
Richter license and milestone revenue	—	33,333
Total revenues	<u>41,063</u>	<u>33,333</u>
Operating costs and expenses:		
Cost of product revenue	1,032	—
Collaboration expense to Pfizer	5,261	—

Research and development ⁽¹⁾	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	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	<u>\$ (61,660)</u>	<u>\$ (32,860)</u>
Net loss per common share — basic and diluted	<u>\$ (0.67)</u>	<u>\$ (0.37)</u>
Weighted average common shares outstanding — basic and diluted	91,637,151	89,300,210

⁽¹⁾ Includes the following share-based compensation:

Research and development	\$ 3,957	\$ 4,024
Selling, general and administrative	\$ 7,155	\$ 3,788

Revenue components are as follows:

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	<u>\$ 41,063</u>	<u>\$ 33,333</u>

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

	<u>June 30, 2021</u>	<u>March 31, 2021</u>
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	<u>\$ 727,770</u>	<u>\$ 725,027</u>
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	<u>1,127,396</u>	<u>1,078,992</u>
Total shareholders' deficit	<u>(399,626)</u>	<u>(353,965)</u>
Total liabilities and shareholders' deficit	\$ 727,770	\$ 725,027

Investor Contact:

Ryan Crowe
Vice President, Investor Relations
Myovant Sciences, Inc.
+1 (650) 781-9106
investors@myovant.com

Media Contact:

Albert Liao
Director, Corporate Communications
Myovant Sciences, Inc.
+1 (650) 410-3055
media@myovant.com



Source: Myovant Sciences, Inc.