



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

January 26, 2022

- *Third fiscal quarter 2021 total revenues of \$54.4 million, including net product revenue of \$29.3 million*
- *Net product revenue from U.S. sales of ORGOVYX® of \$24.4 million, reflecting 40% sequential volume growth compared to second fiscal quarter 2021, partially offset by a lower net price*
- *Net product revenue from U.S. sales of MYFEMBREE® of \$2.4 million; New-to-brand prescription (NBRx) share among GnRH antagonist therapies FDA-approved for the treatment of uterine fibroids grew to 45% in December 2021, six months following launch*
- *Estimated 11,000 cumulative patients treated with ORGOVYX through December 2021; Approximately 1,800 treatment centers have prescribed ORGOVYX since launch*
- *Estimated 1,400 cumulative patients treated with MYFEMBREE through November 2021; Over 800 unique prescribers through December 2021 since launch*
- *FDA review of MYFEMBREE supplemental New Drug Application for the management of moderate to severe pain associated with endometriosis remains on track for a decision by May 6, 2022 target action date; U.S. launch planned for May 2022, if approved*
- *Myovant remains well-capitalized with cash, cash equivalents, and marketable securities of \$527.8 million as of December 31, 2021*

BASEL, Switzerland, Jan. 26, 2022 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced financial results for the third quarter of fiscal year 2021 and other corporate updates.

"Our third fiscal quarter 2021 financial results reflect the continued strong momentum for the ORGOVYX and MYFEMBREE launches. ORGOVYX volume grew 40% sequentially, reflecting steadily increasing patient and clinician demand for its differentiated clinical profile compared to other androgen deprivation therapy alternatives. By December 2021, MYFEMBREE had captured 45% new-to-brand prescription share among GnRH antagonist therapies FDA-approved for the treatment of uterine fibroids, significant progress only six months following launch. This notable performance for both brands reaffirms our belief that ORGOVYX and MYFEMBREE have the potential to become standard of care therapies in advanced prostate cancer and uterine fibroids, respectively, and represent significant commercial opportunities over time," said David Marek, Chief Executive Officer of Myovant Sciences, Inc.

Mr. Marek added, "We anticipate 2022 will be a significant growth year with several important milestones that will support our mission of redefining care and position Myovant for long-term success. In addition to executing commercially, we look forward to submitting for FDA review the results of the LIBERTY randomized withdrawal study in women with uterine fibroids, completing the two-year SPIRIT long-term extension study of MYFEMBREE in women with endometriosis-associated pain, and potentially launching MYFEMBREE in endometriosis in the U.S. pending FDA approval, while also expanding our pipeline by advancing relugolix lifecycle opportunities and pursuing business development."

Third Fiscal Quarter 2021 and Recent Corporate Updates

ORGOVYX (relugolix 120 mg)

- *Third fiscal quarter 2021 net product revenues for ORGOVYX in the U.S. were \$24.4 million, reflecting 40% sequential volume growth compared to second fiscal quarter 2021, partially offset by a lower net price due to higher gross-to-net discounts. There were no material changes in inventory for ORGOVYX over the course of third fiscal quarter 2021.*
- *Over 1,800 treatment centers prescribed ORGOVYX to approximately 11,000 patients on free and commercial drug, from launch through December 2021, excluding patients utilizing product samples. The cumulative number of estimated patients initiating ORGOVYX therapy has continued to increase steadily in each successive month since launch.*
- *As of January 2022, Myovant achieved 81% commercial coverage and 99% Medicare Part D coverage for ORGOVYX. Myovant continues to engage with key commercial and Part D payers to maintain coverage as well as to potentially expand coverage with payers yet to make a coverage decision.*

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

- *Third fiscal quarter 2021 net product revenues for MYFEMBREE in the U.S. were \$2.4 million. There were no material*

changes in inventory for MYFEMBREE over the course of third fiscal quarter 2021.

- New-to-brand prescription share among gonadotropin-releasing hormone (GnRH) antagonists approved by the U.S. Food and Drug Administration (FDA) for the treatment of uterine fibroids was 45% in December 2021 compared to 20% in September 2021, reflecting steadily increasing demand for the differentiated clinical profile of MYFEMBREE while growing the class.
- Approximately 1,400 patients have been treated with MYFEMBREE from launch through November 2021, including patients on commercial drug and free drug programs, excluding patients utilizing product samples.
- From launch through December 2021, over 800 unique providers had prescribed MYFEMBREE, of which 58% had not previously prescribed a GnRH antagonist FDA-approved for the treatment of uterine fibroids.
- As of January 2022, Myovant achieved 83% commercial coverage for MYFEMBREE. Myovant continues to engage with key commercial payers to maintain coverage as well as to potentially expand coverage with payers yet to make a coverage decision.

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

- Since regulatory approvals for RYEQO by the European Commission (EC) in July 2021 and Medicines and Healthcare products Regulatory Agency in August 2021, Gedeon Richter (Richter), Myovant's commercialization partner in certain other international markets, has launched RYEQO in 12 countries.
- Third fiscal quarter 2021 net product revenues for RYEQO were \$2.4 million, composed of \$2.3 million related to product supply to Richter and \$0.1 million royalties on net sales of RYEQO in Richter's Territory.

Ex-U.S. Rights to Relugolix in Oncology

- Myovant is continuing to assess partnership opportunities with multiple interested parties for international commercialization and development rights (excluding Canada and certain Asian countries) to relugolix in oncology. Myovant's goal is to reach agreement with a partner by the anticipated EC approval of relugolix for prostate cancer, expected in mid-calendar year 2022.

Board of Director Appointment

- Effective on November 5, 2021, Dr. Nancy Valente, M.D. was appointed by Myovant's Board as an independent director following Ms. Kathleen Sebelius' retirement from Myovant's Board. Dr. Valente also became a member of the Audit Committee and the Chair of the Nominating and Corporate Governance Committee of Myovant's Board.

Expected Upcoming Milestones

- FDA submission of the Phase 3 LIBERTY randomized withdrawal study results for MYFEMBREE in women with uterine fibroids is expected in the first quarter of calendar year 2022.
- Two-year data from the SPIRIT long-term extension study of MYFEMBREE in women with endometriosis-associated pain is expected in the first quarter of calendar year 2022.
- FDA decision for the MYFEMBREE sNDA seeking approval for the management of moderate to severe pain associated with endometriosis is expected by its May 6, 2022 target action date. FDA approval of MYFEMBREE for this indication would trigger a \$100.0 million regulatory milestone payment from Pfizer. If approved by May 6, 2022, Myovant and Pfizer expect to launch MYFEMBREE in the U.S. for this indication in May 2022. If approved, this indication would utilize the same dosage, formulation, administration, and branding as MYFEMBREE, which was previously approved by the FDA in May 2021 for the management of heavy menstrual bleeding associated with uterine fibroids.
- EC decision on the advanced prostate cancer Marketing Authorisation Application is expected in mid-calendar year 2022.
- European Medicines Agency regulatory submission for RYEQO for the treatment of women with endometriosis-associated pain is expected in calendar year 2022. Richter will be the sponsor.

Third Fiscal Quarter 2021 Financial Summary

Total revenues for the three months ended December 31, 2021 were \$54.4 million compared to \$1.4 million for the three months ended December 31, 2020.

- **Product revenue, net** from sales of ORGOVYX and MYFEMBREE in the U.S. for the three months ended December 31, 2021 were \$24.4 million and \$2.4 million, respectively. For the three months ended December 31, 2021 product revenue,

net also includes revenues related to product supply to Richter of \$2.3 million, as well as royalties on net sales of RYEQO in Richter's Territory of \$0.1 million. There was no such revenue recorded in the comparable prior year period.

- **Pfizer collaboration revenue** for the three months ended December 31, 2021 was \$25.2 million, reflecting the partial recognition of the upfront payment Myovant received from Pfizer upon entering into the Pfizer Collaboration and License Agreement in December 2020 and of the 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 in May 2021. Pfizer collaboration revenue in the three months ended December 31, 2020 was \$1.4 million, reflecting the partial recognition of the upfront payment received from Pfizer.

Cost of product revenue for the three months ended December 31, 2021 was \$4.2 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 December 31, 2021, was \$12.1 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 December 31, 2021, were \$25.7 million compared to \$30.5 million for the comparable prior year period. The decrease in R&D expenses primarily reflects 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, as well as higher cost sharing with Pfizer for certain R&D expenses.

Selling, general and administrative (SG&A) expenses for the three months ended December 31, 2021, were \$72.1 million compared to \$49.2 million for the comparable prior year period. The increase was primarily due to higher expenses to support the ORGOVYX and MYFEMBREE U.S. launches, including 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.

Interest expense was \$3.5 million for the three months ended December 31, 2021, compared to \$2.6 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 December 31, 2020 was \$5.9 million, primarily the result of the impact of fluctuations in the foreign currency exchange rate between the Swiss franc and the U.S. dollar on Myovant's outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement. 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 December 31, 2021 was \$63.4 million compared to \$73.8 million for the comparable prior year period. On a per common share basis, net loss was \$0.68 and \$0.82 for the three months ended December 31, 2021 and 2020, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and amounts available under the Sumitomo Dainippon Pharma Loan Agreement totaled \$569.1 million as of December 31, 2021, and consisted of \$527.8 million of cash, cash equivalents, and marketable securities and \$41.3 million of available borrowing capacity under the Sumitomo Dainippon Pharma Loan Agreement.

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, January 26, 2022, to discuss financial results for its third fiscal quarter ended December 31, 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 in premenopausal women, with a treatment duration of up to 24 months, and by the European Commission and the Medicines and Healthcare products Regulatory Agency in July 2021 and August 2021, respectively, as RYEQO[®] for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for duration of use. In September 2021, the FDA accepted Myovant's supplemental New Drug Application for MYFEMBREE for the management of moderate to severe pain associated with endometriosis, setting a target action date of May 6, 2022. MYFEMBREE is also being assessed for contraceptive efficacy in women with endometriosis or uterine fibroids who are 18 to 50 years of age and at risk for pregnancy.

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, Myovant has executed five successful Phase 3 clinical trials across oncology and women's health leading to two regulatory approvals by the U.S. Food and Drug Administration for men with advanced prostate cancer and women with heavy menstrual bleeding associated with uterine fibroids, respectively, as well as regulatory approvals by the European Commission and the Medicines and Healthcare products Regulatory Agency for women with symptomatic uterine fibroids. Additionally, Myovant has two regulatory submissions under review, a Marketing Authorization Application in advanced prostate cancer and a supplemental New Drug Application in endometriosis-associated pain. Myovant is conducting a Phase 3 study to evaluate the prevention of pregnancy in women with uterine fibroids or endometriosis. Myovant is also developing MVT-602, an investigational 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 Myovant's majority shareholder. For more information, please visit 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 other Asian countries. 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 7,000 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 leveraging data-driven insights to rapidly accelerate development of new potential therapies for unmet patient conditions. Through its unique portfolio of companies—wholly-owned Urovant, Enzyvant, Spirovant, Altavant, plus majority-owned Myovant Sciences (NYSE: MYOV)—and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported the development of FDA-approved products and advanced a promising pipeline of early-through late-stage investigational assets for other serious conditions. Sumitovant is a wholly-owned subsidiary of Sumitomo Dainippon Pharma. For more information, please visit Sumitovant's website at www.sumitovant.com or follow Sumitovant on [Twitter](https://twitter.com/Sumitovant) and [LinkedIn](https://www.linkedin.com/company/sumitovant).

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 but not limited to: Myovant's belief that ORGOVYX and MYFEMBREE have the potential to become standard of care therapies in advanced prostate cancer and uterine fibroids, respectively; Myovant's anticipation that 2022 will be a significant growth year with several important milestones that will support its mission of redefining care and position Myovant for long-term success; statements regarding Myovant's intention to submit for FDA review the results of the LIBERTY randomized withdrawal study in women with uterine fibroids, completing the two-year SPIRIT long-term extension study of MYFEMBREE in women with endometriosis-associated pain, and potentially launching MYFEMBREE in endometriosis in the U.S. pending FDA approval, while also expanding its pipeline by advancing relugolix lifecycle opportunities and pursuing business development; the statement about Myovant's goal to reach agreement with a partner by the anticipated EC approval of relugolix for prostate cancer and the expected timeline; and the 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 January 26, 2022, 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 December		Nine Months Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Product revenue, net	\$ 29,268	\$ —	\$ 61,885	\$ —
Pfizer collaboration revenue	25,172	1,379	79,853	1,379
Richter license and milestone revenue	—	—	31,667	33,333
Total revenues	<u>54,440</u>	<u>1,379</u>	<u>173,405</u>	<u>34,712</u>
Operating costs and expenses:				
Cost of product revenue	4,243	—	7,897	—
Collaboration expense to Pfizer	12,086	—	25,912	—
Research and development ⁽¹⁾	25,726	30,453	82,886	115,160
Selling, general and administrative ⁽¹⁾	72,125	49,243	192,118	103,387
Total operating costs and expenses	<u>114,180</u>	<u>79,696</u>	<u>308,813</u>	<u>218,547</u>
Loss from operations	(59,740)	(78,317)	(135,408)	(183,835)
Interest expense	3,479	2,609	10,478	6,908
Interest income	(70)	(32)	(248)	(178)
Foreign exchange gain	—	(5,891)	—	(16,178)
Loss before income taxes	(63,149)	(75,003)	(145,638)	(174,387)
Income tax expense (benefit)	<u>296</u>	<u>(1,154)</u>	<u>1,058</u>	<u>(616)</u>

Net loss	\$ (63,445)	\$ (73,849)	\$ (146,696)	\$ (173,771)
Net loss per common share — basic and diluted	\$ (0.68)	\$ (0.82)	\$ (1.59)	\$ (1.94)
Weighted average common shares outstanding — basic and diluted	93,474,985	90,096,557	92,514,657	89,715,160

(1) Includes the following share-based compensation:

Selling, general and administrative	\$ 4,173	\$ 3,699	\$ 18,131	\$ 10,686
Research and development	3,026	3,311	12,193	11,060
Total share-based compensation	\$ 7,199	\$ 7,010	\$ 30,324	\$ 21,746

Revenue components are as follows:

Product revenue, net:				
ORGOVYX	\$ 24,393	\$ —	\$ 53,535	\$ —
MYFEMBREE	2,429	—	4,133	—
Richter product supply and royalties	2,446	—	4,217	—
Total product revenue, net	29,268	—	61,885	—
Pfizer collaboration revenue:				
Amortization of upfront payment	20,974	1,379	62,922	1,379
Amortization of regulatory milestone	4,198	—	16,931	—
Total Pfizer collaboration revenue	25,172	1,379	79,853	1,379
Richter license and milestone revenue	—	—	31,667	33,333
Total revenues	\$ 54,440	\$ 1,379	\$ 173,405	\$ 34,712

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

	<u>December 31, 2021</u>	<u>March 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 457,742	\$ 674,493
Accounts receivable, net	18,910	3,570
Marketable securities	70,020	10,435
Inventories	6,737	2,611
Prepaid expenses and other current assets	20,795	13,536
Amount due from related party	550	—
Total current assets	<u>574,754</u>	<u>704,645</u>
Property and equipment, net	2,952	3,300
Operating lease right-of-use asset	8,405	9,655
Other assets	18,181	7,427
Total assets	<u>\$ 604,292</u>	<u>\$ 725,027</u>
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 12,130	\$ 17,809
Accrued expenses and other current liabilities	58,423	44,612
Share-based compensation liabilities	2,724	21,636
Deferred revenue	100,564	100,564
Amounts due to Pfizer	37,727	1,954
Cost share advance from Pfizer	55,026	92,415
Operating lease liability	2,052	1,807
Amounts due to related parties	391	543
Total current liabilities	<u>269,037</u>	<u>281,340</u>
Deferred revenue, non-current	400,849	397,369
Cost share advance from Pfizer, non-current	—	29,447
Long-term operating lease liability	7,618	9,189
Long-term debt, less current maturities (related party)	358,700	358,700
Other liabilities	371	2,947
Total liabilities	<u>1,036,575</u>	<u>1,078,992</u>
Total shareholders' deficit	<u>(432,283)</u>	<u>(353,965)</u>
Total liabilities and shareholders' deficit	<u>\$ 604,292</u>	<u>\$ 725,027</u>

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