

**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): **January 10, 2022**

Myovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

001-37929

(Commission File No.)

Bermuda

(State or other jurisdiction of
incorporation or organization)

Suite 1, 3rd Floor

11-12 St. James's Square

London

SW1Y 4LB

United Kingdom

(Address of principal executive offices)

98-1343578

(I.R.S. Employer
Identification No.)

Not Applicable

(Zip Code)

Registrant's telephone number, including area code: **+44 207 400 3351**

(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))

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

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

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.

Item 2.02 Results of Operations and Financial Condition.

On January 10, 2022, Myovant Sciences Ltd. (“Myovant”) issued a press release announcing its preliminary unaudited financial results for the fiscal quarter ended December 31, 2021, a copy of which is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto. The preliminary unaudited financial results contained in the press release do not present all information for an understanding of Myovant’s financial condition as of December 31, 2021 and its results of operations for the fiscal quarter ended December 31, 2021. The review of Myovant’s financial statements for the fiscal quarter ended December 31, 2021 is ongoing and could result in changes to the information in the press release.

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 (the “Securities Act”), nor shall it be deemed incorporated by reference into any of Myovant’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.

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Myovant Sciences Ltd., dated January 10, 2022, “Myovant Sciences Announces Preliminary Financial Results for Third Quarter of Fiscal Year 2021.”
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File - Formatted as Inline XBRL and contained in Exhibit 101

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.

Date: January 10, 2022

Myovant Sciences Ltd.

By: /s/ Uneek Mehra
Name: Uneek Mehra
Title: *Principal Financial Officer*



Myovant Sciences Announces Preliminary Financial Results for Third Quarter of Fiscal Year 2021

- *Estimated total revenue of \$54.0-\$55.0 million, including net product revenue of \$28.8-\$29.8 million*
- *Estimated ORGOVYX® net product revenue of \$24.2-\$24.6 million, reflecting 40% sequential volume growth compared to fiscal second quarter 2021, partially offset by a lower net price*
- *Estimated MYFEMBREE® net product revenue of \$2.3-\$2.6 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*
- *Myovant remains well-capitalized with cash, cash equivalents and marketable securities of approximately \$527.8 million as of December 31, 2021*
- *Myovant to present at 40th Annual J.P. Morgan Healthcare Conference on Wednesday, January 12, 2022 at 3:00 p.m. Eastern Time*

BASEL, Switzerland, January 10, 2022 -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced preliminary financial results for the third quarter of fiscal year 2021. The financial information presented in this press release may be adjusted at a later date following the completion of customary quarterly financial reviews and audit procedures.

“Myovant delivered on its mission of redefining care for women and for men over the course of calendar-year 2021 as momentum for ORGOVYX and MYFEMBREE launches continued to build, positioning the company for long-term success. Our strong quarterly performance continues to give us the confidence that ORGOVYX and MYFEMBREE have the potential to become standard of care therapies in advanced prostate cancer and uterine fibroids, respectively,” said David Marek, Chief Executive Officer of Myovant Sciences, Inc. “We believe we have set the stage for an important year in 2022 as we seek to drive significant revenue growth with continued ORGOVYX adoption and the potential launch of MYFEMBREE in endometriosis, pending FDA approval, while also expanding our pipeline by advancing relugolix lifecycle opportunities and pursuing business development.”

Unaudited preliminary revenue results:

Total revenue for the three months ended December 31, 2021 is estimated to be in the range of \$54.0-\$55.0 million. There was \$1.4 million of total revenue recorded in the three months ended December 31, 2020. Estimated total revenue consisted of the following:

- **Net product revenue** is estimated to be in the range of \$28.8-\$29.8 million in fiscal third quarter 2021. There was no such revenue recorded in the comparable prior year period. Estimated net product revenue consists of the following:
 - ORGOVYX net product revenue is estimated to be in the range of \$24.2-\$24.6 million for fiscal third quarter 2021, reflecting 40% sequential volume growth compared to fiscal second quarter 2021, partially offset by a lower net price due to higher gross-to-net discounts. There were no material changes in channel inventory for ORGOVYX over the course of fiscal third quarter 2021.

- MYFEMBREE net product revenue is estimated to be in the range of \$2.3-\$2.6 million for fiscal third quarter 2021. New-to-brand prescription (NBRx) share among GnRH antagonists FDA-approved 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. There were no material changes in channel inventory for MYFEMBREE over the course of fiscal third quarter 2021.
- RYEQO net product revenue related to product supply and royalties from Gedeon Richter, Myovant's commercialization partner for RYEQO in Europe and certain other international markets, is estimated to be in the range of \$2.3-\$2.6 million for fiscal third quarter 2021.
- **Pfizer collaboration revenue** in fiscal third quarter 2021 was \$25.2 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 in May 2021. Pfizer collaboration revenue for fiscal third quarter 2020 was \$1.4 million and represents the partial amortization of the upfront payment received from Pfizer.

Unaudited capital resources:

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

Myovant to present at 40th Annual J.P. Morgan Healthcare Conference on January 12, 2022

David Marek, Chief Executive Officer of Myovant Sciences, will present at the 40th Annual J.P. Morgan Healthcare Conference on Wednesday, January 12, 2022 at 3:00 p.m. Eastern Time. A live webcast of the presentation can be accessed by visiting the investor relations page of Myovant's website at investors.myovant.com. The webcast will be archived on Myovant's Investor Relations website following the presentation.

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 Sciences' 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 on Twitter and LinkedIn.

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 and Preliminary Financial Results

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 expected financial results for the fiscal quarter ended December 31, 2021; the statements regarding Myovant's aspiration to redefine care for women and for men; the statements regarding ORGOVYX's and MYFEMBREE's potential to become standard of care therapies in advanced prostate cancer and uterine fibroids, respectively; and the expectations to expand Myovant's pipeline by advancing relugolix lifecycle opportunities and pursuing business development.

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 the anticipated financial results are preliminary and may be adjusted at a later date following the completion of customary quarterly financial reviews and audit procedures. 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 filed on October 26, 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.

Furthermore, this press release includes information regarding Myovant Sciences' preliminary financial results for the third fiscal quarter ended December 31, 2021. Myovant Sciences is currently in the process of finalizing its

financial results for the third fiscal quarter ended December 31, 2021, and the preliminary financial results presented in this press release are based only on preliminary information available to Myovant Sciences as of January 10, 2022. These preliminary financial results should not be viewed as a substitute for audited consolidated financial statements prepared in accordance with U.S. GAAP, and undue reliance should not be placed on Myovant Sciences' preliminary financial results. Myovant Sciences' independent registered public accounting firm has not audited or reviewed the preliminary financial results included in this press release or expressed any opinion or other form of assurance on such preliminary financial results. In addition, items or events may be identified or occur after the date of this press release due to the completion of operational and financial closing procedures, final audit adjustments and other developments may arise that would require Myovant Sciences to make material adjustments to the preliminary financial results included in this press release. Therefore, the preliminary financial results included in this press release may differ, perhaps materially, from the consolidated financial results that will be reflected in Myovant Sciences' Quarterly Report on Form 10-Q expected to be filed on January 26, 2022.

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