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): **December 18, 2020**

Myovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

001-37929

(Commission File No.)

Bermuda	**98-1343578**
(State or other jurisdiction of incorporation or organization)	(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 offices)	**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 8.01 Other Events.

On December 18, 2020, the U.S. Food and Drug Administration approved ORGOVYX™ (relugolix) as the first and only oral gonadotropin-releasing hormone (GnRH) therapy for the treatment of adult patients with advanced prostate cancer. Myovant expects ORGOVYX to be available in January 2021.

In the Phase 3 HERO study, ORGOVYX met the primary endpoint and achieved sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks in 96.7% (95% confidence interval (CI): 94.9-97.9) of men, compared with 88.8% (95% CI: 84.6-91.8) of men receiving leuprolide acetate injections, the current standard of care. ORGOVYX also achieved several key secondary endpoints compared to leuprolide acetate, including suppression of testosterone to castrate levels at Day 4 and Day 15 (56% versus 0% and 99% versus 12%, respectively) and profound suppression of testosterone (< 20 ng/dL) at Day 15 (78% versus 1%). ORGOVYX lowered prostate-specific antigen (PSA), on average, by 65% at Day 15 and by 83% at Day 29. In a substudy, 55% of men treated with ORGOVYX achieved normal testosterone levels (> 280 ng/dL) or returned to baseline within 90 days of treatment discontinuation. The most frequent adverse events reported in at least 10% of men in the ORGOVYX group were hot flush, musculoskeletal pain, fatigue, constipation, and mild to moderate diarrhea.

The wholesale acquisition cost for ORGOVYX in the United States will be $2,313 for a bottle containing thirty (30) 120 mg tablets. Myovant is committed to ensuring that men in the United States who are prescribed ORGOVYX can obtain access and receive the support they may need throughout their treatment journey. As part of this commitment, Myovant is launching the ORGOVYX Patient Support Program which provides insurance verifications, prior authorizations, copay support for commercially-insured patients, free trial for up to two (2) months of therapy, and patient assistance for qualifying uninsured patients.

Forward-Looking Statements

The statements above regarding Myovant's expectation that ORGOVYX will become available in January 2021, that the wholesale acquisition cost for ORGOVYX in the United States will be $2,313 for a bottle containing thirty (30) 120 mg tablets, Myovant's plans to offer a patient assistance program for patients and the expected features of such patient assistance program, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These 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, but not limited to: unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic; Myovant's ability to sustain a commercial field organization and distribution network; and Myovant's reliance on third parties for the manufacture of ORGOVYX. 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. You should not place undue reliance on these forward-looking statements, which speak only as of the date hereof, and, except as required by law, Myovant undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

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.

Myovant Sciences Ltd.

Date: December 18, 2020

By: /s/ Matthew Lang
Name: Matthew Lang
Title: *General Counsel and Corporate Secretary*