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): November 24, 2020

Urovant Sciences Ltd.
(Exact name of Registrant as Specified in Its Charter)

Bermuda	**001-38667**	**98-1463899**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS 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)**

+44 (0) 207 400 3347
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(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 (see General Instructions A.2. below):

☐ 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(s)	Name of each exchange on which registered
Common Shares, $0.000037453 par value	**UROV**	**Nasdaq Global Select Market**

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 7.01. Regulation FD Disclosure

On November 24, 2020, Urovant Sciences Ltd. (the "Company") issued a press release announcing topline data from its Phase 2a study of vibegron, the Company's lead product candidate, for treatment of abdominal pain caused by irritable bowel syndrome. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information being furnished in this Item 7.01 of Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference into a filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated November 24, 2020

SIGNATURE

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.

UROVANT SCIENCES LTD.

Dated: November 24, 2020

By: /s/ Christine G. Ocampo
Christine G. Ocampo
Principal Accounting Officer

Exhibit 99.1

Urovant Sciences Announces Topline Data from Phase 2a Study of Vibegron for the Treatment of Irritable Bowel Syndrome (IBS) Pain Did Not Meet Primary Endpoint

Key secondary endpoint of Global Improvement Scale (GIS) showed numerical differences in favor of vibegron versus placebo, however data was not statistically significant

Vibegron was generally well-tolerated with safety profile comparable to placebo

IRVINE, Calif. and BASEL, Switzerland /November 24 2020 /Business Wire – Urovant Sciences (Nasdaq: UROV) today reported topline data from the Phase 2a randomized, double blind, placebo-controlled clinical trial evaluating once-daily vibegron 75 mg in women with abdominal pain due to irritable bowel syndrome (IBS) with IBS-D (diarrhea) and IBS-M (mixed IBS).

A total of 222 female IBS patients were enrolled at 35 sites in the United States, 189 of whom completed the 12-week study. In the primary efficacy analysis, the study did not meet the primary endpoint with 40.9 percent of vibegron IBS-D patients achieving at least a 30 percent improvement in average worst abdominal pain over the week 12 period, compared to 42.9 percent in the placebo group. A responder was defined as a subject with at least a 30 percent decrease in “worst abdominal pain in the past 24 hours” compared to the weekly baseline average over the 12-week period.

The most important secondary endpoint demonstrated 42.4 percent of Global Improvement Scale (GIS) responders at Week 12 for IBS-D patients in the vibegron group, compared with 33.3 percent for placebo but this was not statistically significant for the IBS-D, IBS-M or the overall IBS population. Urovant will continue to analyze the full data set of this study.

Vibegron was very well tolerated in the study and did not lead to any worsening of IBS symptoms. Discontinuation rates due to adverse events were 0 percent in the vibegron group and 2.7 percent in placebo. The frequency of serious adverse events was similar across treatment arms with 1 serious adverse effect in the placebo group and 2 in the vibegron treatment group which were not considered treatment related by the investigator. The adverse events reported for vibegron were in the placebo range (33.3 percent in both groups). In particular, the adverse events of worsening of IBS were 2.7 percent for both vibegron and placebo and the adverse event of diarrhea was 0 percent for vibegron 75mg and 1.8 percent for placebo respectively.

“While we are disappointed by the topline results from this Phase 2a trial, we want to sincerely thank the patients, investigators and their site staff who participated,” said Cornelia Haag-Molkenteller, M.D., Ph.D., chief medical officer of Urovant Sciences. “We look forward to advancing our Phase 3 program for vibegron in men with overactive bladder and benign prostatic hyperplasia (BPH), as well as our Phase 2a program for URO-902 in OAB and look forward to the U.S. Food and Drug Administration’s (FDA) upcoming assigned Prescription Drug User Fee Act (PDUFA) goal date of December 26, 2020 for the New Drug Application (NDA) for vibegron to treat overactive bladder (OAB).”

About Irritable Bowel Syndrome Related Pain

Irritable bowel syndrome (IBS) is characterized by recurrent abdominal pain associated with two or more of the following symptoms: defecation, change in stool frequency, and/or change in stool form or appearance. In the United States, approximately 30 million to 40 million have IBS symptoms, 30 percent of whom consult with a physician.[1] Approximately 80 percent of these patients identify pain as a symptom contributing to the severity of their IBS[2] and it is estimated 7.2 million to 9.6 million IBS patients suffer from IBS-associated pain.[1] While there are approved therapies for IBS with constipation and IBS with diarrhea, these therapies do not adequately address IBS-associated pain. Moreover, there are no currently marketed drugs indicated specifically for IBS-associated pain.[3]

About Vibegron

Vibegron is an oral, once-daily small molecule beta-3 agonist that is being evaluated for overactive bladder (OAB), OAB in men with benign prostatic hyperplasia (OAB+BPH) and for abdominal pain associated with irritable bowel syndrome (IBS).

Urovant has submitted a New Drug Application (NDA) for vibegron in OAB to the U.S. Food and Drug Administration's (FDA), which has an assigned Prescription Drug User Fee Act (PDUFA) goal date of December 26th. Data available to date on vibegron, which includes an international Phase 3 safety and efficacy study for OAB, indicate vibegron is well tolerated. If approved, vibegron would be the first new branded prescription drug for the treatment of OAB in nearly a decade and would offer these suffering patients another potential treatment option.

About Urovant Sciences

Urovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company's lead product candidate, vibegron is being evaluated for overactive bladder (OAB), OAB in men with benign prostatic hyperplasia (OAB+BPH), and for abdominal pain associated with irritable bowel syndrome (IBS). Urovant's second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacologic therapy.

Urovant Sciences, a subsidiary of Sumitovant Biopharma Ltd., which is a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at www.urovant.com.

About Sumitovant Biopharma Ltd.

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

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 Japan, the U.S., 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.

1. Canavan C., et al., Clinical Epidemiology 2014
2. Lovell RM, Ford AC, et al., Clin Gastroenterol Hepatol. 2012; Drossman DA, et al., J Clin Gastroenterol 2009
3. International Foundation for Gastrointestinal Disorders, accessed December 14, 2018; https://www.aboutibs.org/treating-ibs-pain.html

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical statements of fact and statements regarding the Company's intent, belief, or expectations, and 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," "strive," "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. In this press release, forward-looking statements include, but are not limited to, statements regarding the Company's plans and strategies for the development and commercialization of innovative therapies for the treatment of urological conditions; including expectations regarding the clinical development of vibegron in patients with overactive bladder (OAB), the clinical development of URO-902 in patients with OAB, the clinical development of vibegron in patients with OAB+BPH and IBS-pain, and the related status of FDA approval. The Company's forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks and uncertainties that could lead to actual results differing materially from those projected, forecasted, or expected. Although the Company believes that the assumptions underlying these forward-looking statements are reasonable, they are not guarantees and the Company can give no assurance that its expectations will be attained. Factors that could materially affect the Company's operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to: the Company's limited operating history and the fact that it has never generated any product revenue; the Company's ability

to achieve or maintain profitability in the future; the Company's dependence on the success of its lead product candidate, vibegron; the impact on the Company's business, financial results, results of operations and ongoing clinical trials from the effects of the COVID-19 pandemic; the Company's ability to satisfy future funding needs on commercially reasonable terms and conditions if at all; the Company's dependence on Sumitomo Dainippon Pharma and its affiliates to provide loan funding under the Company's loan agreement and commercial and operational support for the Company's product candidates and the significant control Sumitomo Dainippon Pharma Co., Ltd., through its wholly owned subsidiary, Sumitovant Biopharma Ltd., can assert over the Company through its ownership of the Company's common shares and control of the Company's board of directors; the Company's reliance on its key scientific, medical or management personnel, and on certain affiliates to provide certain services to the Company; risks related to clinical trials, including uncertainties relating to the success of the Company's clinical trials for vibegron and URO-902 and any future therapy or product candidates; uncertainties surrounding the regulatory landscape that governs gene therapy products; the Company's dependence on Merck Sharp & Dohme Corp. and Ion Channel Innovations, LLC to have accurately reported results and collected and interpreted data related to vibegron and URO-902 prior to the Company's acquisition of the rights related to these product candidates; reliance on third parties to conduct, supervise, and monitor the Company's clinical trials; reliance on a single supplier for the enzyme used to manufacture vibegron; the ability to obtain, maintain, and enforce intellectual property protection for the Company's technology and products; risks related to significant competition from other biotechnology and pharmaceutical companies; the failure to achieve the market acceptance necessary for commercial success for a product candidate; and other risks and uncertainties listed in the Company's filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's most recently filed Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q filed with the SEC, as such risk factors may be amended, supplemented, or superseded from time to time by other filings with the SEC. 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, the Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

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