

**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): August 13, 2020

Urovant Sciences Ltd.

(Exact name of Registrant as Specified in Its Charter)

Bermuda
(State or Other Jurisdiction
of Incorporation)

001-38667
(Commission File Number)

98-1463899
(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 2.02. Results of Operations and Financial Condition.

On August 13, 2020, Urovant Sciences Ltd., or the Company, issued a press release announcing its financial results for the first fiscal quarter ended June 30, 2020. The press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Current Report shall not be incorporated by reference in any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release, dated August 13, 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: August 13, 2020

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



5281 California Avenue
Suite 100
Irvine, California 92617

urovant.com

Urovant Sciences Reports Fiscal First Quarter 2020 Results

IRVINE, Calif. and BASEL, Switzerland /August 13, 2020 /Business Wire – Urovant Sciences (Nasdaq: UROV) today reported financial results for the three months ended June 30, 2020.

The first quarter of fiscal 2020 saw the Company achieve a number of significant operational milestones as it embarked on the build out of both its commercial and market access teams and completed enrollment in the Phase 2a study of vibegron for irritable bowel syndrome (IBS) pain.

“We continued to make important progress in the first fiscal quarter of 2020. We significantly enhanced the commercial and market access capabilities we need to successfully launch vibegron,” said James Robinson, president and chief executive officer of Urovant Sciences. “In addition, we continue to maximize the value of vibegron and have completed enrollment in our Phase 2a study of vibegron for IBS pain, an indication for which there are no currently marketed drugs.”

Urovant Recent Business Highlights

- Completed enrollment in the Phase 2a study of vibegron for IBS pain.
- Made significant progress in the hiring of customer-facing personnel and are nearing completion of our sales leadership, market access, and medical science liaison teams.
- Initiated an unbranded campaign to help inform and support patients with overactive bladder (OAB), which included the launch of an OAB-focused community website called bladderchatter.com.

Expected Upcoming Events

- Topline results from vibegron trial in IBS-associated pain expected in Q4 2020.
- URO-902 Data and Safety Monitoring Board data review and decision to move from cohort 1 to cohort 2 in Phase 2a trial expected by early 2021.
- The U.S. Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) date for vibegron in OAB is December 26, 2020.

First Fiscal Quarter 2020 Financial Summary

For the quarter ended June 30, 2020, total operating expenses were \$28.8 million, comprised of research and development expenses of \$16.3 million and general and administrative expenses of \$12.5 million. Net loss for the quarter ended June 30, 2020 was \$30.5 million, or \$0.99 per share. Cash used in operations was \$30.8 million. As of June 30, 2020, total cash was \$63.0 million.

Note to Investors

As previously announced, Urovant will hold a conference call today, August 13, 2020, to discuss financial results from the first fiscal quarter ended June 30, 2020. The call will begin at 1:30 p.m. Pacific, 4:30 p.m. Eastern, and you may listen to this call by dialing (866) 470-1049 for domestic callers or (409) 217-8245 for international callers and entering conference ID 7356668. A replay of the call will be available approximately four hours after the call and accessible for 7 days at (855) 859-2056, conference ID 7356668. A webcast will be archived on the Investor Relations page of the Urovant Sciences website immediately after the call and available for at least 30 days.

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 an oral, once-daily small molecule beta-3 agonist that is being evaluated for overactive bladder (OAB). Urovant Sciences reported positive data from the vibegron 12-week, Phase 3 pivotal EMPOWUR study and demonstrated favorable longer-term efficacy, safety, and tolerability in a 40-week extension study. The Company submitted a New Drug Application to the U.S. Food and Drug Administration seeking approval of vibegron for the treatment of patients with OAB in December 2019. Vibegron is also being evaluated for treatment of 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 and Urovant, and wholly owns Enzyvant, Spirovant, and Altavant. 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>.

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.

UROVANT SCIENCES LTD.

Condensed Consolidated Statements of Operations

(unaudited; in thousands, except share and per share data)

Unless otherwise noted, the three months comparisons are to the prior fiscal year comparable period ended June 30, 2019.

	Three Months Ended June 30,	
	2020	2019
Operating expenses:		
Research and development ⁽¹⁾	\$ 16,354	\$ 22,014
General and administrative ⁽²⁾	12,489	5,465
Total operating expenses	<u>28,843</u>	<u>27,479</u>
Other expense:		
Interest expense, net	(1,443)	(513)
Loss on disposal of property and equipment	—	(236)
Other expense, net	<u>(118)</u>	<u>(190)</u>
Loss before provision for income taxes	<u>(30,404)</u>	<u>(28,418)</u>
Provision for income taxes	90	67
Net loss	<u>\$ (30,494)</u>	<u>\$ (28,485)</u>
Net loss per common share—basic and diluted	<u>\$ (0.99)</u>	<u>\$ (0.94)</u>
Weighted average common shares outstanding—basic and diluted	<u>30,705,334</u>	<u>30,325,169</u>

(1) Includes \$369 and \$265 of share-based compensation during the three months ended June 30, 2020 and 2019, respectively.

(2) Includes \$1,669 and \$782 of share-based compensation during the three months ended June 30, 2020 and 2019, respectively.

UROVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets

(unaudited; in thousands)

Unless otherwise noted, the three months comparisons are to the prior fiscal year comparable period ended March 31, 2020.

	June 30, 2020	March 31, 2020
Assets		
Current assets:		
Cash	\$ 63,039	\$ 51,414
Restricted cash	250	243
Due from Sumitovant Biopharma Ltd.	—	172
Prepaid expenses and other current assets	8,980	6,489
Total current assets	72,269	58,318
Property and equipment, net	1,237	1,210
Operating lease right-of-use assets	3,939	3,135
Restricted cash, net of current portion	623	623
Other assets	69	9
Total assets	\$ 78,137	\$ 63,295
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 130	\$ 1,589
Accrued expenses	23,098	21,756
Due to Roivant Sciences Ltd.	2	31
Current portion of share-based compensation liabilities	6,919	7,204
Current portion of operating lease liabilities	422	351
Total current liabilities	30,571	30,931
Share-based compensation liabilities, net of current portion	370	32
Related-party long-term debt	128,270	87,252
Operating lease liabilities, net of current portion	3,862	3,086
Total liabilities	163,073	121,301
Total shareholders' deficit	(84,936)	(58,006)
Total liabilities and shareholders' deficit	\$ 78,137	\$ 63,295

Contacts

Investor and Media inquiries:

Ryan Kubota
949.769.2706
ryan.kubota@urovant.com