

**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): February 12, 2021

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 February 12, 2021, Urovant Sciences Ltd., or the Company, issued a press release announcing its financial results for the third fiscal quarter ended December 31, 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 February 12, 2021.

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: February 12, 2021

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



5281 California Avenue
Suite 100
Irvine, California 92617

urovant.com

Urovant Sciences Provides Merger Update and Reports Third Quarter Fiscal Year 2020 Results

SEC reviewing preliminary proxy statement for the previously announced merger of the Company with Sumitovant Biopharma

Special General Meeting of Shareholders to approve the merger is expected to occur by the end of 1Q CY2021

U.S. commercial launch of GEMTESA® (vibegron) to treat OAB is on track for late-Q1 CY2021, following U.S. FDA approval in December 2020

IRVINE, Calif. and BASEL, Switzerland /February 12, 2021 /Business Wire – Urovant Sciences (Nasdaq: UROV) today reported financial results for its fiscal quarter ended December 31, 2020.

“The third quarter of fiscal 2020 was transformational for Urovant. In November, we announced the signing of a definitive merger agreement with Sumitovant Biopharma, the majority shareholder of Urovant. Under the terms of the definitive agreement, Urovant will be acquired by Sumitovant Biopharma at a 96% premium to the closing price of our shares prior to the agreement being announced. We look forward to obtaining shareholder approval for the merger at a special general meeting that we expect to take place at the end of 1Q CY2021,” said James Robinson, president and chief executive officer of Urovant Sciences.

“In December of 2020, Urovant also achieved a significant milestone with the FDA’s approval of GEMTESA for the treatment of patients suffering from overactive bladder, or OAB. We have recently completed the hiring of our sales force and look forward to launching GEMTESA in the coming weeks,” concluded Mr. Robinson.

Merger Update

The Urovant Board authorized and approved the definitive merger agreement with Sumitovant Biopharma and the management team is fully supportive of the transaction. The Board recommends that Urovant shareholders vote in favor of the merger at the upcoming special general meeting for shareholders, which is expected to be held next month. The Company requests that all shareholders carefully read the definitive proxy statement that will be mailed to shareholders, and then submit their proxy cards in time for the special general meeting of shareholders. If shareholders approve the merger, Urovant will become a wholly owned subsidiary of Sumitovant Biopharma.

Urovant Recent Business Highlights and Updates

- Received U.S. Food and Drug Administration (FDA) approval of GEMTESA® (vibegron) once daily 75 mg tablets for the treatment of patients with OAB
- Entered into a definitive agreement to be acquired by Sumitovant Biopharma for approximately \$584 million in total equity value on a fully diluted basis in an all-cash merger, or \$16.25 per share, a 96% premium to the closing price of Urovant's shares prior to the announcement (November 12, 2020)
- Completed commercial scale up, including the hiring of specialty and long-term care field sales team
- Commenced payor engagement regarding potential formulary access for GEMTESA
- Announced positive efficacy and safety data from the vibegron EMPOWUR long-term extension study, including patient data over a total exposure of 52 weeks, which demonstrate that vibegron improved quality of life (QoL) and incontinence efficacy endpoints
- Announced progression of URO-902 phase 2a trial following positive recommendation from the Data and Safety Monitoring board

Expected Upcoming Events

- Special General Meeting of Shareholders to approve the pending merger of the Company with Sumitovant Biopharma is expected to occur by the end of 1Q CY2021
- U.S. commercial launch of GEMTESA is targeted for late-Q1 CY2021

Details of the Previously Announced Definitive Merger Agreement with Sumitovant Biopharma

On November 12, 2020, Sumitovant Biopharma entered a definitive agreement to acquire all the outstanding shares of Urovant. Under the terms of the merger agreement, a wholly owned subsidiary of Sumitovant will merge with and into Urovant, with Urovant surviving the merger as a wholly owned subsidiary of Sumitovant Biopharma. In the merger all outstanding shares of Urovant stock (other than those held by Sumitovant Biopharma) will be cancelled and converted into the right to receive \$16.25 per share.

The closing of the merger is subject to certain limited customary conditions, including the approval of a majority of the minority shareholders. A special general meeting of shareholders to approve the pending merger of the Company with Sumitovant Biopharma is expected to occur by the end of 1Q CY2021. If approved by the shareholders, the transaction is expected to close shortly after the vote. Following the transaction, Urovant will become a wholly owned subsidiary of Sumitovant.

Third Quarter Fiscal Year 2020 Financial Summary

For the quarter ended December 31, 2020, total operating expenses were \$45.6 million, comprised of research and development expenses of \$15.6 million and general and administrative expenses of \$30.0 million. Net loss for the quarter ended December 31, 2020 was \$46.8 million, or \$1.46 per share. Cash used in operations was \$46.8 million. As of December 31, 2020, total cash was \$71.3 million.

No Conference Call

Due to the pending Sumitovant Biopharma merger, the company will not be holding a quarterly earnings call.

About Urovant Sciences

Urovant Sciences is a biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company's lead product, GEMTESA (vibegron), is an oral, once-daily (75 mg) small molecule beta-3 agonist approved by the U.S. FDA in December 2020 for the treatment of adult patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. GEMTESA is also being evaluated for the treatment of OAB in men with benign prostatic hyperplasia (OAB+BPH). The Company'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 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>.

Additional Information and Where to Find It

This communication is being made in respect of the proposed transaction involving Urovant and Sumitovant. Urovant intends to file with the Securities and Exchange Commission ("SEC") relevant materials, including a proxy statement on Schedule 14A in connection with the proposed transaction with Sumitovant, and Urovant and certain other persons, including Sumitovant, intend to file a Schedule 13E-3 transaction statement with the SEC. The definitive proxy statement and Schedule 13E-3 transaction statement will be sent or given to the shareholders of Urovant and will contain important information about the proposed transaction and related matters. UROVANT'S SECURITYHOLDERS ARE URGED TO READ THE PROXY STATEMENT REGARDING THE PROPOSED TRANSACTION, THE SCHEDULE 13E-3 AND ANY OTHER RELEVANT DOCUMENTS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED

TRANSACTION. The proxy statement, Schedule 13E-3 and other relevant materials (when they become available), and any other documents filed by Urovant with the SEC, may be obtained free of charge at the SEC's website, at www.sec.gov. In addition, securityholders of Urovant will be able to obtain free copies of the proxy statement and Schedule 13E-3 through the Investor Relations page of Urovant's website, www.urovant.com, or by contacting Urovant's Investor Relations Department by mail at Attention: Investor Relations, 5281 California Ave, Suite #100, Irvine, CA 92617, or by telephone at (949) 769-2706.

Participants in the Solicitation

Urovant, Sumitovant and their respective directors, executive officers, and other members of management and certain of their respective employees may be deemed to be participants in the solicitation of proxies in connection with the proposed merger. Information about Urovant's directors and executive officers is included in Urovant's Annual Report on Form 10-K for the year ended March 31, 2020 filed with the SEC on June 19, 2020, and the proxy statement for Urovant's annual meeting of shareholders for 2020, filed with the SEC on July 27, 2020. Additional information regarding these persons and their interests in the merger will be included in the proxy statement and Schedule 13E-3 relating to the proposed merger when they are filed with the SEC. These documents, when available, can be obtained free of charge from the sources indicated above.

Safe Harbor for Forward-looking Statements

This press release contains forward-looking statements. Forward-looking statements include all statements that are not historical statements of fact and statements regarding Urovant'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 expectations about the proposed transaction involving Urovant and Sumitovant, statements regarding Urovant's expectations for the commercialization of vibegron for the treatment of overactive bladder and plans and strategies for the clinical development of vibegron and other treatments for urologic diseases. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. Risks and uncertainties related to the proposed merger include, but are not limited to, the risk that the merger transaction does not close, due to the failure of one or more conditions to closing or otherwise; the risk that required Urovant shareholder approvals of the merger transaction will not be obtained or that such approvals will be delayed or conditioned beyond current expectations; risks related to the disruption of management time from ongoing business operations due to the proposed transaction and possible difficulties in maintaining customer, supplier, key personnel and other strategic relationships; and the possibility of unexpected costs, liabilities or litigation related to the proposed transaction. Additional risks and uncertainties related to Urovant and its business include, but are not limited to, Urovant's dependence on the success of its lead product candidate,

vibegron, including uncertainties regarding FDA approval; the failure to achieve the market acceptance necessary for commercial success for vibegron or any other product candidate; the success and cost of Urovant's efforts to commercialize vibegron; the impact on Urovant's business, financial results, results of operations and ongoing clinical trials from the effects of the COVID-19 pandemic; risks related to clinical trials, including uncertainties relating to the success of Urovant'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; Urovant'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 Urovant's acquisition of the rights related to these product candidates; reliance on a single supplier for the enzyme used to manufacture vibegron; the ability to obtain, maintain, and enforce intellectual property protection for Urovant's technology and products; risks related to significant competition from other biotechnology and pharmaceutical companies; Urovant's ability to realize the anticipated benefits of the co-promotion agreement with Sunovion in the manner or timeline expected; and other risks and uncertainties listed in Urovant's filings with the SEC, including under the heading "Risk Factors" in Urovant's most recently filed Quarterly Report on Form 10-Q, as such risk factors may be amended, supplemented or superseded from time to time by other filings with the SEC. Given these risks and uncertainties, you should not place undue reliance on any forward-looking statements. These forward-looking statements are based on information available to Urovant as of the date of this press release and speak only as of the date of this release. Urovant disclaims any obligation to update these forward-looking statements, except as may be required by law.

UROVANT SCIENCES LTD.

Condensed Consolidated Statements of Operations

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

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development ⁽¹⁾	\$ 15,616	\$ 23,099	\$ 46,506	\$ 62,909
General and administrative ⁽²⁾	29,965	16,687	61,387	29,587
Total operating expenses	<u>45,581</u>	<u>39,786</u>	<u>107,893</u>	<u>92,496</u>
Other (expense) income:				
Interest expense, net	(1,615)	(1,401)	(4,522)	(2,495)
Loss on disposal of property and equipment	—	—	—	(236)
Other income (expense), net	271	(34)	(155)	(145)
Loss before (benefit from) provision for income taxes	<u>(46,925)</u>	<u>(41,221)</u>	<u>(112,570)</u>	<u>(95,372)</u>
(Benefit from) provision for income taxes	(128)	38	(123)	113
Net loss	<u>\$ (46,797)</u>	<u>\$ (41,259)</u>	<u>\$ (112,447)</u>	<u>\$ (95,485)</u>
Net loss per common share—basic and diluted	<u>\$ (1.46)</u>	<u>\$ (1.36)</u>	<u>\$ (3.59)</u>	<u>\$ (3.14)</u>
Weighted average common shares outstanding—basic and diluted	<u>32,101,832</u>	<u>30,413,946</u>	<u>31,355,190</u>	<u>30,365,142</u>

(1) Includes \$404 and \$1,192 and \$2,844 and \$3,366 of share-based compensation during the three and nine months ended December 31, 2020 and 2019, respectively.

(2) Includes \$5,516 and \$8,132 and \$9,685 and \$11,431 of share-based compensation during the three and nine months ended December 31, 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.

	December 31, 2020	March 31, 2020
Assets		
Current assets:		
Cash	\$ 71,295	\$ 51,414
Restricted cash	250	243
Prepaid expenses and other current assets	14,509	6,489
Due from Sumitovant Biopharma Ltd.	—	172
Total current assets	86,054	58,318
Property and equipment, net	2,020	1,210
Operating lease right-of-use assets	3,705	3,135
Intangible asset, net	14,000	—
Restricted cash, net of current portion	2,198	623
Other assets	910	9
Total assets	\$ 108,887	\$ 63,295
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 3,509	\$ 1,589
Accrued expenses	35,113	21,756
Due to Roivant Sciences Ltd.	—	31
Due to Sunovion Pharmaceuticals, Inc.	182	—
Current portion of share-based compensation liabilities	1,112	7,204
Current portion of operating lease liabilities	520	351
Total current liabilities	40,436	30,931
Share-based compensation liabilities, net of current portion	1,195	32
Related-party long-term debt	209,285	87,252
Operating lease liabilities, net of current portion	3,588	3,086
Total liabilities	254,504	121,301
Total shareholders' deficit	(145,617)	(58,006)
Total liabilities and shareholders' deficit	\$ 108,887	\$ 63,295

Contacts

Investor and Media inquiries:

Ryan Kubota
949.769.2706

ryan.kubota@urovant.com