Urovant Sciences Reports 2019 First Fiscal Quarter Financial Results

August 13, 2019

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Aug. 13, 2019-- Urovant Sciences (Nasdaq: UROV),a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions, today reported financial results for the 2019 first fiscal quarter ended June 30, 2019.

Recent Business Highlights

- Announced the ambulatory blood pressure study for vibegron achieved its primary endpoint demonstrating that vibegron does not have an effect on daytime systolic ambulatory blood pressure compared to placebo (where no effect was defined as a change from baseline of less than 3.5 mm Hg compared to placebo within a 90% confidence interval).
- Presented positive topline results from the Phase 3 EMPOWUR study of 75 mg vibegron for overactive bladder at the annual AUA meeting in May.
- Completed a productive pre-NDA meeting with the FDA in preparation for our anticipated New Drug Application (NDA) filing by early 2020.
- Completed enrollment in Part 1 of the two-part OAB/BPH study in men.
- Finalized Phase 2a protocol for URO-902, our novel gene therapy product for OAB and expect to start patient enrollment by the end of fourth quarter 2019.

“During the last quarter, Urovant Sciences continued to make excellent progress towards its vision of becoming a leading specialty urology company,” said Keith A. Katkin, chief executive officer of Urovant. “Today, we are very pleased to announce the successful completion of the vibegron ambulatory blood pressure study. This study will be an important component of our NDA and further supports the favorable safety profile of vibegron. We also remain on schedule to report results for the long-term extension portion of the phase 3 EMPOWUR study by the end of this quarter and are well underway in preparing to file the vibegron NDA by early 2020.”

First Fiscal Quarter 2019 Financial Summary

For the quarter ended June 30, 2019, research and development expenses were $22.0 million and general and administrative expenses were $5.5 million. Net loss for the quarter ended June 30, 2019 was $28.5 million, or $0.94 per share, and cash used in operations was $22.5 million. As of June 30, 2019, total cash and cash equivalents was $62.4 million or $92.4 million with the $30 million available to be drawn down from Hercules Capital by September 30, 2019.

Note to Investors

As previously announced, Urovant will hold a conference call to discuss 2019 first fiscal quarter ended June 30, 2019 financial results today, August 13, 2019, beginning at 1:30 p.m. Pacific Time. You can listen to this call by dialing (866) 470-1049 for domestic callers or (409) 217-8245 for international callers and entering conference ID 7747888. 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 7747888. 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. Urovant recently reported positive Phase 3 trial results for its lead product candidate, vibegron, an oral, once-daily small molecule beta-3 agonist being evaluated for overactive bladder (OAB). The international, pivotal trial achieved both co-primary endpoints and all seven key secondary endpoints. In addition, vibegron is being evaluated in a Phase 3 study for the treatment of OAB in men with benign prostatic hyperplasia and in a Phase 2a study for abdominal pain associated with irritable bowel syndrome. Urovant’s second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacological therapy. Urovant Sciences, a subsidiary of Roivant Sciences, Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at www.urovant.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; the Company’s expectations regarding its anticipated NDA filing for vibegron for OAB; the Company’s expectations regarding its Phase 3 study of vibegron in men with OAB and BPH; and the Company’s expectations regarding its Phase 2a study for URO-902.

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 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; the Company's ability to satisfy future funding needs on commercially reasonable terms and conditions if at all; 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*)

	Three Months Ended June 30,	
	2019	**2018**
Operating expenses:		
Research and development[1]	$ 22,014	$ 27,965
General and administrative[2]	5,465	3,504
Total operating expenses	27,479	31,469
Other income (expense):		
Interest expense, net	(513)	—
Loss on disposal of furniture and equipment	(236)	—
Other income (expense)	(190)	229
Loss before provision for income taxes	(28,418)	(31,240)
Provision for income taxes	67	55
Net loss	$ (28,485)	$ (31,295)
Net loss per common share—basic and diluted	$ (0.94)	$ (1.56)
Weighted average common shares outstanding—basic and diluted	30,325,169	20,025,098

(1) Includes $265 and $452 of share-based compensation expense during the three months ended June 30, 2019 and 2018, respectively.

(2) Includes $782 and $354 of share-based compensation expense during the three months ended June 30, 2019 and 2018, respectively.

Condensed Consolidated Balance Sheets

(*unaudited; in thousands*)

	June 30, 2019	**March 31, 2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 62,360	$ 85,353
Restricted cash	243	243
Prepaid expenses and other current assets	8,416	12,914
Total current assets	71,019	98,510
Furniture and equipment, net	1,203	923
Operating lease right-of-use assets	3,386	—
Restricted cash, net of current portion	623	600
Other assets	21	88
Total assets	$ 76,252	$ 100,121
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,971	$ 1,925
Accrued expenses	8,287	9,877

Due to Roivant Sciences Ltd.	97	15
Current portion of operating lease liabilities	92	—
Total current liabilities	11,447	11,817
Long-term debt	13,728	13,534
Operating lease liabilities, net of current portion	3,357	—
Total liabilities	28,532	25,351
Total shareholders' equity	47,720	74,770
Total liabilities and shareholders' equity	$ 76,252	$ 100,121

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