Urovant Sciences Reports 2019 Second Fiscal Quarter Financial Results

November 5, 2019

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Nov. 5, 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 second fiscal quarter ended September 30, 2019.

Recent Business Highlights

- Sumitomo Dainippon Pharma committed to provide Urovant with a $200 million, low-interest, interest-only, five-year term loan facility, access to enhanced commercial support, minority shareholder protection, and expected financial support through profitability.
- Reported positive data from the long-term extension of the phase 3 EMPOWUR study of vibegron in patients with overactive bladder, in which vibegron demonstrated a favorable long-term safety and tolerability profile and further improved treatment benefit on key overactive bladder symptoms over the 40-week extension period.
- Completed pharmacokinetic study to support administration of vibegron as a crushed tablet in soft food, which has the potential to be a significant benefit for elderly patients who have trouble swallowing.
- Initiated part 2 of the phase 3 COURAGE trial, which will assess both efficacy and safety of vibegron in men with OAB and BPH, a patient population for which no product is currently approved.

“Significant progress was made this quarter towards the filing of our New Drug Application for vibegron, with positive results reported from the long-term extension of the phase 3 EMPOWUR study and pharmacokinetic results to support administration of vibegron as a crushed tablet,” said Keith A. Katkin, chief executive officer of Urovant. “Now with additional financial and enhanced commercial support from Sumitomo Dainippon Pharma, we are well positioned for the potential launch of vibegron and developing Urovant into a leading specialty urology company.”

Second Fiscal Quarter 2019 Financial Summary

For the quarter ended September 30, 2019, research and development expenses were $17.8 million and general and administrative expenses were $7.4 million. Net loss for the quarter ended September 30, 2019 was $25.7 million, or $0.85 per share, and cash used in operations was $24.5 million. As of September 30, 2019, total cash and cash equivalents was $67.8 million.

Note to Investors

As previously announced, Urovant will hold a conference call to discuss 2019 second fiscal quarter ended September 30, 2019 financial results today, November 5, 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 5377353. 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 5377353. 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 long-term data for its lead product candidate, vibegron, an oral, once-daily small molecule beta-3 agonist being evaluated for overactive bladder (OAB). The extension of the 12-week pivotal phase 3 EMPOWUR study demonstrated a favorable long-term safety and tolerability profile for vibegron and further improved treatment benefit on key overactive bladder (OAB) symptoms over the 40-week extension period. 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 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; the Company’s pharmacokinetic crushed vibegron tablet study and its expectations regarding the inclusion of this in the product label; and the commitments of Sumitomo Dainippon Pharma with respect to financing, support for commercialization efforts, and minority shareholder protections and Urovant’s expectations regarding those commitments.

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 September 30,		Six Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development[1]	$ 17,796	$ 20,664	$ 39,810	$ 48,009
General and administrative[2]	7,435	3,664	12,900	7,788
Total operating expenses	25,231	24,328	52,710	55,797
Other income (expense):				
Interest expense, net	(581)	—	(1,094)	—
Loss on disposal of furniture and equipment	—	—	(236)	—
Other income (expense)	79	(309)	(111)	(80)
Loss before provision for income taxes	(25,733)	(24,637)	(54,151)	(55,877)
Provision for income taxes	8	5	75	60
Net loss	$ (25,741)	$ (24,642)	$ (54,226)	$ (55,937)
Net loss per common share—basic and diluted	$ (0.85)	$ (1.23)	$ (1.79)	$ (2.79)
Weighted average common shares outstanding—basic and diluted	30,355,874	20,025,098	30,340,603	20,025,098

(1) Includes $257 and $293 of share-based compensation expense during the three months ended September 30, 2019 and 2018, respectively, and $522 and $565 of share-based compensation during the six months ended September 30, 2019 and 2018.

(2) Includes $964 and $696 of share-based compensation expense during the three months ended September 30, 2019 and 2018, respectively, and $1,746 and $1,230 of share-based compensation during the six months ended September 30, 2019 and 2018.

Condensed Consolidated Balance Sheets
(*unaudited; in thousands*)

	September 30, 2019	March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 67,796	$ 85,353
Restricted cash	243	243
Prepaid expenses and other current assets	8,823	12,914
Total current assets	76,862	98,510
Furniture and equipment, net	1,226	923
Operating lease right-of-use assets	3,301	—
Restricted cash, net of current portion	623	600
Other assets	16	88
Total assets	$ 82,028	$ 100,121
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,567	$ 1,925
Accrued expenses	9,590	9,877
Due to Roivant Sciences Ltd.	133	15
Current portion of long-term debt	10	—

Current portion of operating lease liabilities.	265	—
Total current liabilities	11,565	11,817
Long-term debt, net of current portion	43,438	13,534
Operating lease liabilities, net of current portion	3,269	—
Total liabilities	58,272	25,351
Total shareholders' equity	23,756	74,770
Total liabilities and shareholders' equity	$ 82,028	$ 100,121

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Source: Urovant Sciences

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