Urovant Sciences Reports Financial Results for the Fourth Fiscal Quarter and Full Fiscal Year Ended March 31, 2019

June 13, 2019

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Jun. 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 fourth fiscal quarter and full fiscal year ended March 31, 2019.

Recent Business Highlights

- Announced positive top-line data results from the pivotal Phase 3 EMPOWUR study of vibegron in patients with overactive bladder
- Presented EMPOWUR study results at the American Urological Association annual meeting in May
- Initiated enrollment into the pivotal Phase 3 study of vibegron in men with OAB and benign prostatic hyperplasia (BPH), for which there is currently no approved treatment
- Gained general alignment with U.S. Food and Drug Administration (FDA) on proposed Phase 2a protocol for URO-902, our novel gene therapy product for OAB
- Entered into a debt financing agreement with Hercules Capital for up to $100 million

“Urovant Sciences achieved key milestones for several clinical programs for vibegron, an investigational beta-3 adrenergic agonist, driving us closer toward the goal of developing a leading specialty urology company,” said Keith A. Katkin, chief executive officer of Urovant. “We were pleased to announce positive topline data from EMPOWUR, our robust Phase 3 trial of vibegron as a treatment for adults with symptoms of overactive bladder, which demonstrated significant clinical efficacy on both co-primary endpoints, as well as all seven key secondary endpoints.”

Mr. Katkin continued, “We achieved another important clinical milestone with enrollment into the pivotal Phase 3 study of vibegron in men with OAB and BPH, an important supplemental program for vibegron as there is currently no approved treatment for concomitant OAB and BPH. Furthermore, we gained general alignment with the FDA on the proposed Phase 2a protocol for URO-902, our novel gene therapy product for OAB.”

Fiscal 2018 Financial Summary

For the year ended March 31, 2019, research and development expenses were $92.2 million and general and administrative expenses were $18.6 million compared to research and development expenses of $32.4 million and general and administrative expenses of $4.6 million in the prior fiscal year. Cash used in operations increased by $75.0 million to $109.0 million for the year ended March 31, 2019 as compared to the prior fiscal year. Net loss for the year ended March 31, 2019 was $111.3 million, or $4.43 per share. As of March 31, 2019, total cash and cash equivalents balance was $85.4 million and the financing commitment available to be drawn down by the Company from Hercules Capital as of March 31, 2019 was $30.0 million.

Fourth Fiscal Quarter 2018 Financial Summary

For the quarter ended March 31, 2019, research and development expenses were $22.9 million and general and administrative expenses were $5.9 million compared to research and development expenses of $16.4 million and general and administrative expenses of $2.7 million in the prior quarter. Cash used in operations decreased by $16.7 million to $24.0 million for the quarter ended March 31, 2019 as compared to the prior quarter. Net loss for the quarter ended March 31, 2019 was $29.0 million, or $0.96 per share.

Note to Investors

As previously announced, Urovant will hold a conference call to discuss 2018 fourth fiscal quarter and full fiscal year ended March 31, 2019 financial results today, June 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 1883414. 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 1883414. 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 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 Phase 3 study of vibegron in men with OAB and BPH; and the Company’s expectations regarding its proposed Phase 2a protocol 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 Quarterly Report on Form 10-Q for the quarter ended December 31, 2018 filed with the SEC on February 14, 2019, as such risk factors may be amended, supplemented or superseded from time to time by other reports the Company files 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 March 31,		Year Ended March 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development[1]	$ 22,890	$ 16,430	$ 92,198	$ 32,359
General and administrative[2]	5,935	2,698	18,585	4,640
Total operating expenses	28,825	19,128	110,783	36,999
Other income (expense):				
Interest expense, net	(259)	—	(259)	—
Other income (expense)	42	44	(257)	(38)
Loss before provision for income taxes	(29,042)	(19,084)	(111,299)	(37,037)
Provision for (benefit from) income taxes	(74)	11	47	37
Net loss	$ (28,968)	$ (19,095)	$ (111,346)	$ (37,074)
Net loss per common share—basic and diluted	$ (0.96)	$ (0.95)	$ (4.43)	$ (2.16)
Weighted average common shares outstanding—basic and diluted	30,322,911	20,025,098	25,145,211	17,124,659

(1) Includes $409 and $367 of share-based compensation during the three months ended March 31, 2019 and 2018, respectively, and $1,296 and $2,477 of share-based compensation during the year ended March 31, 2019 and 2018.

(2) Includes $941 and $370 of share-based compensation during the three months ended March 31, 2019 and 2018, respectively, and $2,682 and $694 of share-based compensation during the year ended March 31, 2019 and 2018.

UROVANT SCIENCES LTD.

Condensed Consolidated Balance Sheets

(*unaudited; in thousands*)

	March 31, 2019	March 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 85,353	$ 7,194
Restricted cash	243	—
Prepaid expenses and other current assets	12,914	5,196
Total current assets	98,510	12,390
Furniture and equipment, net	923	510
Restricted cash, net of current portion	600	—
Other assets	88	84
Total assets	$ 100,121	$ 12,984
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,925	$ 833
Accrued expenses	9,877	3,595
Due to Roivant Sciences Ltd.	15	1,482
Total current liabilities	11,817	5,910
Long-term debt	13,534	—
Total liabilities	25,351	5,910
Total shareholders' equity	74,770	7,074
Total liabilities and shareholders' equity	$ 100,121	$ 12,984

View source version on businesswire.com: https://www.businesswire.com/news/home/20190613005014/en/

Source: Urovant Sciences

Investor inquiries: Investors@Urovant.com
Media inquiries: Media@Urovant.com