Urovant Sciences Reports Financial Results for the Third Fiscal Quarter Ended December 31, 2018

February 13, 2019

BASEL, Switzerland & IRVINE, Calif.--(BUSINESS WIRE)--Feb. 13, 2019-- Urovant Sciences Ltd. (Nasdaq: UROV),a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions, today reported financial results for the three months ended December 31, 2018.

Recent Business Highlights

- Announced plans to report topline data from international Phase 3 trial for vibegron in adults with symptoms of overactive bladder (OAB) by the end of March 2019.
- Initiated U.S. clinical program for vibegron for abdominal pain associated with irritable bowel syndrome (IBS) in women.
- Gained alignment with U.S. Food and Drug Administration (FDA) on clinical trial protocol for pivotal Phase 3 trial for vibegron in men with OAB who have benign prostatic hyperplasia (BPH).

“Urovant Sciences continued to make progress on several clinical programs for vibegron, an investigational beta-3 adrenergic agonist, demonstrating our commitment to urology,” said Keith A. Katkin, chief executive officer of Urovant. “We remain on schedule to report topline data from EMPOWUR, our robust international Phase 3 trial evaluating the safety and efficacy of vibegron as a treatment for adults with symptoms of overactive bladder by the end of March 2019.”

Mr. Katkin continued, “Furthermore, we initiated a Phase 2a study of vibegron in women with IBS-associated abdominal pain in December 2018. And we recently received a response from the FDA to our proposed protocol for our pivotal Phase 3 study of vibegron in men with overactive bladder and benign prostatic hyperplasia. This is an important supplemental program for vibegron as there is currently no treatment for men with concomitant OAB and BPH.”

Third Quarter Financial Summary

For the quarter ended December 31, 2018, research and development expenses were $21.3 million and general and administrative expenses were $4.9 million. Cash used in operations increased by $17.2 million to $40.7 million for the quarter ended December 31, 2018 as compared to the prior quarter. The increase in cash used is attributed to a decrease of $8.0 million in amounts due to Roivant Sciences, an increase of $3.4 million in prepaid expenses associated with our ongoing clinical studies, a decrease of $4.0 million in accounts payable and accrued expenses, and an increase of $1.8 million in operating expenses. Net loss for the quarter ended December 31, 2018 was $26.4 million, or $0.87 per share. As of December 31, 2018, total cash balance was $95.6 million.

Note to Investors

As previously announced, Urovant will hold a conference call to discuss fiscal 2018 third quarter financial results today, February 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 passcode 3197868. 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 3197868. 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’s lead product candidate, vibegron, is an oral, once-daily, small molecule beta-3 agonist being evaluated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency; for OAB in men with benign prostatic hyperplasia; and for abdominal pain associated with irritable bowel syndrome. Urovant has licensed global rights, excluding Japan and certain Asian territories, for the development and commercialization of vibegron. 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 intends to develop treatments for additional urologic diseases. For more information, please visit 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 reporting of top-line data from its Phase 3 trial for vibegron in adults with symptoms of OAB by the end of March 2019; the Company’s expectations regarding its Phase 2a trial for vibegron in women with IBS-associated abdominal pain; and the Company’s expectations regarding its Phase 3 trial for vibegron for the treatment of OAB in men with BPH.

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 September 30, 2018 filed with the SEC on November 13, 2018, 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 December 31,		Nine Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development[(1)]	$ 21,299	$ 8,046	$ 69,308	$ 15,929
General and administrative[(2)]	4,862	1,389	12,650	1,942
Total operating expenses	26,161	9,435	81,958	17,871
Other income (expense):				
Other income (expense)	(219)	6	(299)	(82)
Loss before provision for income taxes	(26,380)	(9,429)	(82,257)	(17,953)
Provision for income taxes	61	22	121	26
Net loss	$ (26,441)	$ (9,451)	$ (82,378)	$ (17,979)
Net loss per common share—basic and diluted	$ (0.87)	$ (0.47)	$ (3.51)	$ (1.11)
Weighted average common shares outstanding—basic and diluted	30,264,643	20,025,098	23,450,692	16,175,425

(1) Includes $322 and $417 of share-based compensation during the three months ended December 31, 2018 and 2017, respectively, and $887 and $2,110 of share-based compensation during the nine months ended December 31, 2018 and 2017.

(2) Includes $511 and $246 of share-based compensation during the three months ended December 31, 2018 and 2017, respectively, and $1,741 and $324 of share-based compensation during the nine months ended December 31, 2018 and 2017.

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Condensed Consolidated Balance Sheets

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

	December 31, 2018	**March 31, 2018**
Assets		
Current assets:		
Cash	$ 95,613	$ 7,194
Restricted cash	244	—
Prepaid expenses and other current assets	15,140	5,196
Total current assets	110,997	12,390

Furniture and equipment, net	571	510
Restricted cash, net of current portion	600	—
Other assets	84	84
Total assets	$ 112,252	$ 12,984
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,696	$ 833
Accrued expenses	6,365	3,595
Due to Roivant Sciences Ltd.	33	1,482
Total liabilities	10,094	5,910
Total shareholders' equity	102,158	7,074
Total liabilities and shareholders' equity	$ 112,252	$ 12,984

View source version on businesswire.com: https://www.businesswire.com/news/home/20190213005779/en/

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