Urovant Sciences Logo

Urovant Sciences Reports Financial Results for the Second Fiscal Quarter Ended September 30, 2018 and Provides Corporate Update

November 12, 2018

BASEL, Switzerland & IRVINE, Calif.--(BUSINESS WIRE)--Nov. 12, 2018-- Urovant Sciences Ltd. (Nasdaq: UROV),a clinical-stage biopharmaceutical company focused on developing therapies for urologic conditions, today reported financial results for the three and six months ended September 30, 2018 and announced corporate updates.

Recent Business Highlights

- Completed enrollment in international Phase 3 trial for vibegron in adults with symptoms of overactive bladder (OAB) as defined by urge urinary incontinence, urgency, and urinary frequency
- Positive results from the international Phase 2b study for vibegron in adults with OAB recently published in *European Urology*, the peer-reviewed medical journal of the European Association of Urology
- Expect to initiate U.S. clinical program for vibegron for pain associated with irritable bowel syndrome (IBS) in women before year end
- Submitted draft clinical trial protocol to the FDA to study vibegron in men with overactive bladder who have benign prostatic hyperplasia (BPH)
- Licensed hMaxi-K, a novel gene therapy for overactive bladder
- Completed initial public offering in October 2018 raising total gross proceeds of approximately $144.2 million

“Urovant Sciences advanced 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 successfully enrolled more than 1,500 patients into our robust international Phase 3 trial evaluating the safety and efficacy of vibegron as a treatment for adults with symptoms of overactive bladder. We expect to report top-line data from this phase 3 study by the end of March 2019. In addition, we plan to initiate a Phase 2a study of vibegron in women with IBS-associated pain by the end of 2018. And finally, we had productive discussions with the FDA that culminated in us submitting a proposed protocol to study vibegron for men with overactive bladder with BPH.”

“I am immensely proud of my team’s momentum with vibegron,” added Katkin. “We also continue to assess business development opportunities that support our longer-term vision of becoming a leading urology company. We were pleased to have recently added the gene therapy hMaxi-K to our clinical development portfolio.”

Second Quarter Financial Summary

For the quarter ended September 30, 2018, research and development expenses were $20.7 million and general and administrative expenses were $3.7 million. Cash used in operations was $23.6 million for the quarter ended September 30, 2018. Net loss for the quarter ended September 30, 2018 was $24.6 million, or $1.23 per share.

Six Months Financial Summary

For the six months ended September 30, 2018, research and development expenses were $48.0 million and general and administrative expenses were $7.8 million. Cash used in operations was $44.3 million for the six months ended September 30, 2018. Net loss for the six months ended September 30, 2018 was $55.9 million, or $2.79 per share.

Note to Investors

As previously announced, Urovant will hold a conference call to discuss fiscal 2018 second quarter financial results today, November 12, 2018, 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 7067348. 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 7067348. 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. Urovant has licensed global rights, excluding Japan and certain Asian territories, for the development and commercialization of vibegron. Urovant’s second product candidate, hMaxi-K, 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 study of vibegron in adults with symptoms of OAB by the end of March 2019; the Company's plan to initiate a Phase 2a study of vibegron in women with IBS-associated pain by the end of 2018; and the Company's expectations regarding its clinical programs for vibegron and gene therapy hMaxi-K.

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 vibergron and hMaxi-K 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 hMaxi-K 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 final prospectus dated September 26, 2018 filed with the SEC on September 27, 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 September 30,		Six Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development[(1)]	$ 20,664	$ 4,751	$ 48,009	$ 7,883
General and administrative[(2)]	3,664	219	7,788	553
Total operating expenses	24,328	4,970	55,797	8,436
Other income (expense):				
Other income (expense)	(309)	59	(80)	(88)
Loss before provision for income taxes	(24,637)	(4,911)	(55,877)	(8,524)
Provision for income taxes	5	2	60	4
Net loss	$ (24,642)	$ (4,913)	$ (55,937)	$ (8,528)
Net loss per common share—basic and diluted	$ (1.23)	$ (0.25)	$ (2.79)	$ (0.60)
Weighted average common shares outstanding—basic and diluted	20,025,098	20,025,098	20,025,098	14,240,070

(1) Includes $293 and $854 of share-based compensation during the three months ended September 30, 2018 and 2017, respectively, and $565 and $1,693 of share-based compensation expense during the six months ended September 30, 2018 and 2017, respectively.

(2) Includes $696 and $33 of share-based compensation during the three months ended September 30, 2018 and 2017, respectively, and $1,230 and $78 of share-based compensation expense during the six months ended September 30, 2018 and 2017, respectively.

UROVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets

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

	September 30, 2018	**March 31, 2018**
Assets		
Current assets:		
Cash	$ 1,659	$ 7,194
Prepaid expenses and other current assets	11,757	5,196
Deferred initial public offering costs	2,201	—
Total current assets	15,617	12,390

Property and equipment, net	587	510
Other assets	84	84
Total assets	$ 16,288	$ 12,984
Liabilities and Shareholder's Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,084	$ 833
Accrued expenses	9,875	3,595
Due to Roivant Sciences Ltd.	8,056	1,482
Total liabilities	23,015	5,910
Total shareholder's equity (deficit)	(6,727)	7,074
Total liabilities and shareholder's equity (deficit)	$ 16,288	$ 12,984

View source version on businesswire.com: https://www.businesswire.com/news/home/20181112005750/en/

Source: Urovant Sciences Ltd.

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