Urovant Sciences Reports 2019 Third Fiscal Quarter Financial Results

February 13, 2020

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Feb. 13, 2020-- Urovant Sciences (Nasdaq: UROV) today reported financial results for the 2019 third fiscal quarter ended December 31, 2019.

Recent Business Highlights

- Submitted a New Drug Application for vibegron for the treatment of patients with overactive bladder to the U.S. Food and Drug Administration (FDA) in December 2019.
- Initiated a Phase 2a study of URO-902, a novel gene therapy product for patients with overactive bladder that have failed oral pharmacologic therapy.
- Entered into a $300 million low interest, interest-only, five-year term loan facility with Sumitomo Dainippon Pharma.

“This has been an exciting and transformational quarter for our company, marked by key milestones across all aspects of our business,” said Keith A. Katkin, chief executive officer of Urovant Sciences. “We submitted our New Drug Application for vibegron for the treatment of patients with overactive bladder to the FDA ahead of schedule, initiated a Phase 2a study of our novel gene therapy product, URO-902 and entered into a transformative relationship with Sumitomo Dainippon Pharma. We now look forward to our interactions with the FDA as we prepare to bring to market a potentially best in class therapeutic option for the treatment of patients suffering from overactive bladder.”

Third Fiscal Quarter 2019 Financial Summary

For the quarter ended December 31, 2019, total operating expenses were $39.8 million, comprised of research and development expenses of $23.1 million and general and administrative expenses of $16.7 million. Total operating expenses for the quarter include a $10.3 million non-cash, stock-based compensation charge due to the accelerated vesting of certain options and restricted stock units upon the change in control triggered by the closing of the Sumitomo Dainippon Pharma transaction with Roivant Sciences. Net loss for the quarter ended December 31, 2019 was $41.3 million, or $1.36 per share. Cash used in operations was $23.6 million. As of December 31, 2019, total cash and cash equivalents was $131.9 million.

Note to Investors

As previously announced, Urovant will hold a conference call to discuss 2019 third fiscal quarter ended December 31, 2019 financial results today, February 13, 2020, 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 9699592. 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 9699592. 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. The Company’s lead product candidate, vibegron, is an oral, once-daily small molecule beta-3 agonist that is being evaluated for overactive bladder (OAB). Urovant Sciences reported positive data from the vibegron 12-week, Phase 3 pivotal EMPOWUR study and demonstrated favorable longer-term efficacy, safety, and tolerability in a 40-week extension study. The Company submitted a New Drug Application to the FDA seeking approval of vibegron for the treatment of patients with OAB in December 2019. Vibegron is also being evaluated for treatment of OAB in men with benign prostatic hyperplasia (OAB+BPH) and for abdominal pain associated with irritable bowel syndrome (IBS). Urovant’s second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacologic therapy. Urovant Sciences, a subsidiary of Sumitovant Biopharma Ltd., which is a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at www.urovant.com.

About Sumitovant Biopharma Ltd.

Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma. Sumitovant is the majority shareholder of Myovant and Urovant, and wholly owns Enzyvant, Spirovant and Altavant. Sumitovant's promising pipeline is comprised of early-through late-stage investigational medicines across a range of disease areas targeting high unmet need. For further information about Sumitovant, please visit https://www.sumitovant.com.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China and the European Union. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has more than 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.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; Urovant's plans to advance the clinical development of vibegron in patients with OAB and obtain FDA approval; the Company's plans to advance the clinical development of URO-902 in patients with OAB; the clinical development of vibegron in patients with OAB+BPH and IBS-pain; and continued commitments of Sumitomo Dainippon Pharma with respect to financing and support for commercialization efforts. 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 December 31,		Nine Months Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development[1]	$ 23,099	$ 21,299	$ 62,909	$ 69,308
General and administrative[2]	16,687	4,862	29,587	12,650
Total operating expenses	39,786	26,161	92,496	81,958
Other income (expense):				
Interest expense, net	(1,401)	—	(2,495)	—
Loss on disposal of furniture and equipment	—	—	(236)	—
Other income (expense)	(34)	(219)	(145)	(299)
Loss before provision for income taxes	(41,221)	(26,380)	(95,372)	(82,257)
Provision for income taxes	38	61	113	121
Net loss	$ (41,259)	$ (26,441)	$ (95,485)	$ (82,378)
Net loss per common share—basic and diluted	$ (1.36)	$ (0.87)	$ (3.14)	$ (3.51)
Weighted average common shares outstanding—basic and diluted	30,413,946	30,264,643	30,365,142	23,450,692

(1) Includes $2,844 and $322 of share-based compensation expense during the three months ended December 31, 2019 and 2018, respectively, and $3,366 and $887 of share-based compensation during the nine months ended December 31, 2019 and 2018.

(2) Includes $9,685 and $511 of share-based compensation expense during the three months ended December 31, 2019 and 2018, respectively, and $11,431 and $1,741 of share-based compensation during the nine months ended December 31, 2019 and 2018.

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

	December 31, 2019	March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 131,921	$ 85,353
Restricted cash	243	243
Due from Sumitovant Pharma Ltd.	111	—
Prepaid expenses and other current assets	10,182	12,914
Total current assets	142,457	98,510

Furniture and equipment, net	1,241	923
Operating lease right-of-use assets	3,219	—
Restricted cash, net of current portion	623	600
Other assets	11	88
Total assets	$ 147,551	$ 100,121
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,388	$ 1,925
Accrued expenses	14,701	9,877
Due to Roivant Sciences Ltd.	7	15
Interest payable	343	—
Current portion of long-term debt	43,760	—
Current portion of operating lease liabilities.	335	—
Total current liabilities	61,534	11,817
Long-term debt, net of current portion	87,287	13,534
Operating lease liabilities, net of current portion	3,179	—
Total liabilities	152,000	25,351
Total shareholders' equity (deficit)	(4,449)	74,770
Total liabilities and shareholders' equity (deficit)	$ 147,551	$ 100,121

View source version on businesswire.com: https://www.businesswire.com/news/home/20200213005891/en/

Source: Urovant Sciences

Investor inquiries:
Ryan Kubota
949.769.2706
ryan.kubota@urovant.com

Media inquiries:
media@urovant.com