Urovant Sciences Reports Fiscal Year and Fourth Quarter 2019 Results

June 18, 2020

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Jun. 18, 2020-- Urovant Sciences (Nasdaq: UROV) today reported financial results for the three months and 2019 fiscal year ended March 31, 2020.

The fiscal fourth quarter of 2019 marked achievement of key milestones for Urovant Sciences, including publication of results from the international EMPOWUR Phase 3 pivotal trial and acceptance of the Company's new drug application (NDA) for vibegron for the treatment of overactive bladder (OAB) by the U.S. Food and Drug Administration (FDA).

"The 2019 fiscal year and fourth quarter have been transformational for our company," said James Robinson, president and chief executive officer of Urovant Sciences. "With publication of data from the EMPOWUR study demonstrating that vibegron achieved statistical significance over placebo on both primary and all seven secondary endpoints, and FDA acceptance of our NDA, we look forward bringing to market a potentially best-in-class therapeutic option for the treatment of overactive bladder. Vibegron, if approved, could make a real difference in the lives of patients where there hasn't been a new branded oral therapy launched in nearly a decade and where patient dissatisfaction and unmet need remains high."

Urovant Fiscal 2019 and Recent Business Highlights

Clinical

- Reported positive long-term data from the double-blind extension of the Phase 3 EMPOWUR study of vibegron in patients with OAB.
- Initiated Part 2 of Phase 3 COURAGE study of vibegron for OAB in men with benign prostatic hyperplasia (BPH).
- Initiated enrollment in a Phase 2a study evaluating the efficacy and safety of URO-902, a novel gene therapy product, in patients with OAB suffering with urge urinary incontinence (UUI) not adequately managed with oral pharmacological therapy.
- Submitted NDA for vibegron for the treatment of OAB to the FDA.
- Received acceptance of NDA for vibegron for the treatment of patients with OAB by the FDA.

Financing

- Entered into a $300 million low interest, interest-only, five-year term loan facility with Sumitomo Dainippon Pharma.
- Fully repaid Hercules Capital debt facility.

Organization

- Named James Robinson as President and CEO. Mr. Robinson has deep experience in the urology and overactive bladder markets.
- Appointed James Hindman, former CFO of Allergan, to Urovant Board of Directors.
- Appointed Walt Johnston as Senior Vice President of Commercial, Kenton Stewart as Senior Vice President of Market Access. Mr. Johnston and Mr. Stewart, both seasoned industry veterans, have significant experience launching products in urology and OAB.

Operations

- Entered into an exclusive three-year agreement with Sunovion Pharmaceuticals for services related to wholesale trade and retail distribution, contract operations, and select account management activities.

Expected Upcoming Events

- Vibegron trial in IBS-associated pain top line results expected in Q4 2020.
- URO-902 data and safety monitoring board data review and decision to move from cohort 1 to cohort 2 in Phase 2a trial expected in 4Q 2020.
- Vibegron for OAB Prescription Drug User Fee Act (PDUFA) date – December 26, 2020.

Fourth Fiscal Quarter 2019 Financial Summary

For the quarter ended March 31, 2020, total operating expenses were $46.2 million, comprised of research and development (R&D) expenses of $29.5 million and general and administrative (G&A) expenses of $16.7 million. Net loss for the quarter ended March 31, 2020 was $51.3 million, or $1.68 per share. Cash used in operations was $31.6 million. As of March 31, 2020, total cash was $51.4 million.

Fiscal Year 2019 Financial Summary

For the fiscal year ended March 31, 2020, total operating expenses were $138.7 million, comprised of R&D expenses of $92.4 million and G&A expenses of $46.3 million. Net loss for fiscal year 2019 was $146.7 million, or $4.82 per share. Cash used in operations was $102.1 million.

Note to Investors

As previously announced, Urovant will hold a conference call today, June 18, 2020 to discuss financial results from the fourth quarter and full year fiscal 2019 ended March 31, 2020. The call will begin at 1:30 p.m. Pacific, 4:30 p.m. Eastern, and you may listen to this call by dialing (866) 470-1049 for domestic callers or (409) 217-8245 for international callers and entering conference ID 9106689. 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 9106689. 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 U.S. Food and Drug Administration 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 overactive bladder (OAB) and obtain U.S. Food and Drug Administration 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*)

Unless otherwise noted, the three months and fiscal year comparisons are to the prior fiscal year comparable period ended March 31, 2019.

	Three Months Ended March 31,		Year Ended March 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development[1]	$ 29,528	$ 22,890	$ 92,437	$ 92,198
General and administrative[2]	16,712	5,935	46,299	18,585
Total operating expenses	46,240	28,825	138,736	110,783
Other income (expense):				
Interest expense, net	(1,086)	(259)	(3,581)	(259)
Loss on extinguishment of long-term debt	(4,093)	—	(4,093)	—
Loss on disposal of property and equipment	—	—	(236)	—
Other income (expense), net	111	42	(34)	(257)
Loss before provision for (benefit from) income taxes	(51,308)	(29,042)	(146,680)	(111,299)
Provision for (benefit from) income taxes	(48)	(74)	65	47
Net loss	$ (51,260)	$ (28,968)	$ (146,745)	$ (111,346)
Net loss per common share—basic and diluted	$ (1.68)	$ (0.96)	$ (4.82)	$ (4.43)
Weighted average common shares outstanding—basic and diluted	30,572,272	30,322,911	30,416,641	25,145,211

(1) Includes $243 and $409 of share-based compensation during the three months ended March 31, 2020 and 2019, respectively, and $3,609 and $1,296 of share-based compensation during the year ended March 31, 2020 and 2019.

(2) Includes $5,443 and $941 of share-based compensation during the three months ended March 31, 2020 and 2019, respectively, and $16,874 and $2,682 of share-based compensation during the year ended March 31, 2020 and 2019.

Condensed Consolidated Balance Sheets

(*unaudited; in thousands*)

Unless otherwise noted, the three months and fiscal year comparisons are to the prior fiscal year comparable period ended March 31, 2019.

	March 31, 2020	March 31, 2019
Assets		
Current assets:		
Cash	$ 51,414	$ 85,353
Restricted cash	243	243
Due from Sumitovant Biopharma Ltd.	172	—
Prepaid expenses and other current assets	6,489	12,914
Total current assets	58,318	98,510
Property and equipment, net	1,210	923
Operating lease right-of-use assets	3,135	—
Restricted cash, net of current portion	623	600
Other assets	9	88
Total assets	$ 63,295	$ 100,121
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 1,589	$ 1,925
Accrued expenses	21,756	9,877
Due to Roivant Sciences Ltd.	31	15
Current portion of share-based compensation liabilities	7,204	—
Current portion of operating lease liabilities.	351	—
Total current liabilities	30,931	11,817
Share-based compensation liabilities, net of current portion	32	—
Related-party long-term debt	87,252	—
Long-term debt	—	13,534
Operating lease liabilities, net of current portion	3,086	—
Total liabilities	121,301	25,351
Total shareholders' (deficit) equity	(58,006)	74,770
Total liabilities and shareholders' (deficit) equity	$ 63,295	$ 100,121

View source version on businesswire.com: https://www.businesswire.com/news/home/20200618005101/en/

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