# Urovant Sciences Reports Second Quarter Fiscal Year 2020 Results

November 2, 2020

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Nov. 2, 2020-- Urovant Sciences (Nasdaq: UROV) today reported financial results for its fiscal quarter ended September 30, 2020.

During the second quarter of fiscal year 2020, the Company achieved a number of significant operational and commercial planning milestones in preparation for the U.S. Food and Drug Administration's (FDA) decision on the New Drug Application (NDA) for vibegron in overactive bladder (OAB) by the assigned Prescription Drug User Fee Act (PDUFA) goal date of December 26th. This includes the co-promotion agreement with Sunovion Pharmaceuticals that provides access to their multi-specialty sales force to bring vibegron to primary care physicians (PCP). This agreement significantly enhances the commercial reach of Urovant's direct sales approach that will target urology, long-term care and high prescribing PCPs following the launch of vibegron, if approved.

"We are pleased to have the key elements of our commercial strategy in place, including the Sunovion agreement, as we continue to prepare for the anticipated launch of vibegron in the first quarter of calendar year 2021. The Sunovion agreement and the completion of our sales and market access leadership teams are essential components to support the successful launch of vibegron," said James Robinson, president and chief executive officer of Urovant Sciences.

**Urovant Recent Business Highlights**

- Initiated the hiring process for the Company's front-line sales force that will be focused on urologists, long-term care, and high-prescribing PCPs.
- Entered into a five-year co-promotion agreement with Sunovion Pharmaceuticals that will supplement the Company's targeted sales and market access efforts in the launch of vibegron by expanding the outreach to primary care physicians.
- Engaged key payors on the clinical value of vibegron though pre-approval information exchange discussions.

**Expected Upcoming Events**

- The Company will be presenting at the upcoming International Continence Society (ICS) Annual meeting in November 2020.
- Topline results from vibegron trial in IBS-associated pain expected in late November 2020.
- The FDA PDUFA goal date for vibegron in OAB is December 26, 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 early 2021.

**Second Quarter Fiscal Year 2020 Financial Summary**

For the quarter ended September 30, 2020, total operating expenses were $33.5 million, comprised of research and development expenses of $14.5 million and general and administrative expenses of $18.9 million. Net loss for the quarter ended September 30, 2020 was $35.2 million, or $1.12 per share. Cash used in operations was $32.6 million.

As of September 30, 2020, total cash was $74.4 million.

**Conference Call**

As previously announced, Urovant will hold a conference call at 1:30 p.m. Pacific (4:30 p.m. Eastern) today, November 2, 2020, to discuss financial results from the second fiscal quarter ended September 30, 2020. Interested participants may listen to this call by dialing (866) 470-1049 for domestic callers or (409) 217-8245 for international callers and entering conference ID 8054049.

A replay of the call will be available approximately four hours after the call and accessible for seven days at (855) 859-2056, conference ID: 8054049. 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; including expectations regarding the clinical development of vibegron in patients with overactive bladder (OAB), the clinical development of URO-902 in patients with OAB, the clinical development of vibegron in patients with OAB+BPH and IBS-pain, the related status of FDA approval, and Urovant's planned commercial footprint for vibegron and Urovant's expectations regarding access to the market, including to primary care providers. 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 impact on the Company's business, financial results, results of operations and ongoing clinical trials from the effects of the COVID-19 pandemic; the Company's ability to satisfy future funding needs on commercially reasonable terms and conditions if at all; the Company's dependence on Sumitomo Dainippon Pharma and its affiliates to provide loan funding under the Company's loan agreement and commercial and operational support for the Company's product candidates and the significant control Sumitomo Dainippon Pharma Co., Ltd., through its wholly owned subsidiary, Sumitovant Biopharma Ltd., can assert over the Company through its ownership of the Company's common shares and control of the Company's board of directors; 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 success and cost of Urovant's efforts to commercialize vibegron; Urovant's ability to realize the anticipated benefits of the co-promotion agreement with Sunovion in the manner or timeline expected; Urovant's reliance on Sunovion for the co-promotion and distribution of vibegron and Urovant's ability to secure alternative access to commercial infrastructure or strategic collaborations for the commercialization or distribution of products if it is unable to continue the relationship with Sunovion; 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 and six months comparisons are to the prior fiscal year comparable period ended September 30, 2019.

| | Three Months Ended September 30, | | Six Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Operating expenses: | | | | |
| Research and development[1] | $ 14,536 | $ 17,796 | $ 30,890 | $ 39,810 |
| General and administrative[2] | 18,933 | 7,435 | 31,422 | 12,900 |
| Total operating expenses | 33,469 | 25,231 | 62,312 | 52,710 |
| Other (expense) income: | | | | |
| Interest expense, net | (1,464) | (581) | (2,907) | (1,094) |
| Loss on disposal of property and equipment | — | — | — | (236) |
| Other (expense) income, net | (308) | 79 | (426) | (111) |

| | | | | |
|---|---|---|---|---|
| Loss before (benefit from) provision for income taxes | (35,241) | (25,733) | (65,645) | (54,151) |
| (Benefit from) provision for income taxes | (85) | 8 | 5 | 75 |
| Net loss | $ (35,156) | $ (25,741) | $ (65,650) | $ (54,226) |
| Net loss per common share—basic and diluted | $ (1.12) | $ (0.85) | $ (2.12) | $ (1.79) |
| Weighted average common shares outstanding—basic and diluted | 31,251,351 | 30,355,874 | 30,979,833 | 30,340,603 |

(1) Includes $419 and $788 and $257 and $522 of share-based compensation during the three and six months ended September 30, 2020 and 2019, respectively.

(2) Includes $947 and $2,616 and $964 and $1,746 of share-based compensation during the three and six months ended September 30, 2020 and 2019, respectively.

**Condensed Consolidated Balance Sheets**

(*unaudited; in thousands*)

Unless otherwise noted, the three months comparisons are to the prior fiscal year comparable period ended March 31, 2020.

| | September 30, 2020 | March 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 74,401 | $ 51,414 |
| Restricted cash | 250 | 243 |
| Due from Sumitovant Biopharma Ltd. | — | 172 |
| Prepaid expenses and other current assets | 9,195 | 6,489 |
| Total current assets | 83,846 | 58,318 |
| Property and equipment, net | 1,492 | 1,210 |
| Operating lease right-of-use assets | 3,823 | 3,135 |
| Restricted cash, net of current portion | 2,198 | 623 |
| Other assets | 98 | 9 |
| Total assets | $ 91,457 | $ 63,295 |
| **Liabilities and Shareholders' Deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 493 | $ 1,589 |
| Accrued expenses | 23,747 | 21,756 |
| Due to Roivant Sciences Ltd. | — | 31 |
| Due to Sunovion Pharmaceuticals, Inc. | 173 | — |
| Current portion of share-based compensation liabilities | 3,934 | 7,204 |
| Current portion of operating lease liabilities | 497 | 351 |
| Total current liabilities | 28,844 | 30,931 |
| Share-based compensation liabilities, net of current portion | 658 | 32 |
| Related-party long-term debt | 171,278 | 87,252 |
| Operating lease liabilities, net of current portion | 3,727 | 3,086 |
| Total liabilities | 204,507 | 121,301 |
| Total shareholders' deficit | (113,050) | (58,006) |
| Total liabilities and shareholders' deficit | $ 91,457 | $ 63,295 |

View source version on businesswire.com: https://www.businesswire.com/news/home/20201102005164/en/

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