UroGen Pharma Meets Revenue Goal, Reports First Quarter 2023 Financial Results and Recent Corporate Developments

May 11, 2023

- *Reported JELMYTO® Q1 2023 net product revenues of $17.2 million, an increase of ~27% from Q1 2022*
- *Complete Response data from ENVISION pivotal trial and topline data readout from ATLAS trial on track for summer 2023*

PRINCETON, N.J.--(BUSINESS WIRE)--May 11, 2023-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced financial results for the first quarter ended March 31, 2023, and provided an overview of recent developments.

“2023 is off to a promising start as we reported double-digit year-over-year growth in worldwide JELMYTO net sales during the first quarter,” said Liz Barrett, President, and Chief Executive Officer of UroGen. “JELMYTO adoption continues to grow, attributable to the growing body of evidence supporting its benefits in a real-world setting, combined with key initiatives that have expanded access and improved logistical efficiencies for physicians and patients. As we look ahead to summer 2023, we have several key events to prepare for, primarily topline results from both the ENVISION and ATLAS clinical trials investigating the potential of UGN-102 for the treatment of LG-IR-NMIBC. With prospective favorable results, we will look to submit a New Drug Application (NDA) for UGN-102 in 2024 to the U.S. Food & Drug Administration (FDA), for which we are already actively preparing.”

Business Highlights:

UGN-102 (mitomycin) for intravesical solution:

- A topline data readout of the primary endpoint from the ENVISION Phase 3 pivotal study of UGN-102 evaluating the complete response (CR) rate of ~240 patients at 3-months after first instillation is expected this summer.
- Topline data from the ATLAS clinical trial, the predecessor to ENVISION, is expected summer 2023 and will evaluate complete response, duration of response and safety from ~280 patients that completed the trial.
- Announced preliminary results of a study to assess the feasibility of home instillation of UGN-102. In this study, UGN-102 was suitable to administer at home by a visiting nurse under the supervision of a treating physician and resulted in 75% (n=8) of patients achieving a complete response, defined as no detectable disease 3 months after starting treatment.

JELMYTO (mitomycin) for pyelocalyceal solution in low-grade upper tract urothelial cancer (LG-UTUC):

- Generated net product revenue of $17.2 million for the first quarter of 2023, representing ~27% growth over the first quarter of 2022.
- Activated sites on May 1, 2023 were 1,009, compared to 983 on March 1, 2023, while repeat accounts on May 1, 2023 were 235, compared to 214 on March 1, 2023.
- A positive American Urologic Association (AUA) meeting was headlined by the first ever AUA and Society of Urologic Oncology (SUO) treatment guideline for LG-UTUC, recommending use of JELMYTO in certain clinical scenarios. The guideline states that tumor ablation should be the initial management option for patients with low-risk favorable UTUC, for which JELMYTO can be a treatment option as part of a kidney sparing approach intended to prevent radical nephroureterectomies (RNU) in low-risk UTUC patients.
- New retrospective study presented at AUA 2023 reported on the use of JELMYTO in treating patients with UTUC after complete endoscopic ablation. Patients in this retrospective study who underwent complete endoscopic ablation followed by JELMYTO were more likely to be disease-free at first endoscopic evaluation than those who underwent chemoablation alone (69% vs. 40%). In the Phase 3 OLYMPUS study of JELMYTO, LG-UTUC patients in the primary chemoablation setting achieved a 58% complete response rate at first endoscopic evaluation.
- New retrospective study presented at AUA 2023 reported similar outcomes when utilizing Jelmyto in treating LG-UTUC of the ureter compared to renal pelvic cancers. In this analysis, 47 patients had UTUC tumors involving the ureter, with 12 cases of ureteral tumor only (8.8%) and 35 cases of ureteral plus renal pelvic tumors (25.7%). The investigators reported no difference in outcomes at first endoscopic evaluation based on tumor location (p=0.644). JELMYTO is approved for the chemoablation of low-grade upper tract urothelial cancer (LG-UTUC) involving the renal pelvis and calyces.

First Quarter 2022 Financial Results:

Jelmyto Revenue: UroGen reported net product revenue of Jelmyto for the first quarter 2023 of $17.2 million, compared to $13.6 million in the first quarter of 2022.

R&D Expense: Research and development expenses for the first quarter 2023 were $12.5 million, including non-cash share-based compensation expense of $0.5 million as compared to $12.7 million, including non-cash share-based compensation expense of $0.7 million, for the same period in 2022.

SG&A Expense: Selling, general and administrative expenses for the first quarter 2023 were $24.5 million, including non-cash share-based

compensation expense of $1.8 million. This compares to $21.3 million, including non-cash share-based compensation expense of $2.2 million, for the same period in 2022.

Financing on Prepaid Forward Obligation: UroGen reported non-cash financing expense related to the prepaid forward obligation to RTW Investments of $5.2 million for the first quarter 2023. The rate applied to cash payments incurred in 2023 is 13% based on global net product sales of JELMTYO in 2022.

Interest Expense on Long-Term Debt: Interest expense related to the $100 million term loan facility with funds managed by Pharmakon Advisors was $3.6 million for the first quarter of 2023, compared to $0.3 million for the same period last year due to the transaction closing in March 2022 and the final $25 million draw down under the term loan facility in December 2022.

Net Loss: UroGen reported a net loss of $30.2 million, or basic and diluted net loss per ordinary share of $1.30, for the first quarter 2023 as compared to $28.4 million, or basic and diluted net loss per ordinary share of $1.25, for the same period in 2022.

Cash & Cash Equivalents: As of March 31, 2023, cash, cash equivalents and marketable securities totaled $75.2 million.

2023 Revenue, Operating Expense and RTW Expense Guidance: The Company reiterates anticipated full year 2023 net product revenues from JELMYTO to be in the range of $76 to $86 million. The Company reiterates anticipated full year 2023 operating expenses in the range of $135 to $145 million, including non-cash share-based compensation expense of $6.0 to $11.0 million, subject to market conditions. The Company reiterates anticipated full year 2023 non-cash financing expense related to the prepaid obligation to RTW Investments in the range of $21.0 to $26.0 million. Of this amount approximately $9.9 to $11.2 million is expected to be in cash.

Conference Call & Webcast Information: Members of UroGen's management team will host a live conference call and webcast today at 10:00 AM Eastern Time to review UroGen's financial results and provide a general business update.

The live webcast can be accessed by visiting the Investors section of the Company's website at http://investors.urogen.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast.

UROGEN PHARMA LTD.
SELECTED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	March 31, 2023	December 31, 2022
Cash and cash equivalents and marketable securities	$ 75,218	$ 99,963
Total assets	$ 112,954	$ 135,619
Total liabilities	$ 229,508	$ 224,980
Total shareholders' deficit	$ (116,554)	$ (89,361)

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	Three months ended March 31,	
	2023	2022
Revenue	$ 17,192	$ 13,564
Cost of revenue	2,265	1,525
Gross profit	14,927	12,039
Operating expenses:		
Research and development expenses	12,498	12,696
Selling, general and administrative expenses	24,474	21,300
Total operating expenses	36,972	33,996
Operating loss	(22,045)	(21,957)
Financing on prepaid forward obligation	(5,224)	(5,826)
Interest expense on long-term debt	(3,553)	(282)
Interest and other income (expense), net	630	(2)
Loss before income taxes	$ (30,192)	$ (28,067)
Income tax expense	(21)	(325)
Net loss	$ (30,213)	$ (28,392)
Statements of Comprehensive Loss		
Net Loss	$ (30,213)	$ (28,392)
Other Comprehensive loss		
Unrealized gain (loss) on investments	62	(44)
Comprehensive Loss	$ (30,151)	$ (28,436)
Net loss per ordinary share, basic and diluted	$ (1.30)	$ (1.25)
Weighted average shares outstanding, basic and diluted	23,279,951	22,631,509

About *Jelmyto*®

JELMYTO® (mitomycin) for pyelocalyceal solution is a mitomycin-containing reverse thermal gel containing 4 mg mitomycin per mL gel indicated for

primary chemoablative treatment of LG-UTUC in adults. It is recommended for primary treatment of biopsy-proven LG-UTUC in patients deemed appropriate candidates for renal-sparing therapy. JELMYTO is a viscous liquid when cooled and becomes a semi-solid gel at body temperature. The drug slowly dissolves over four to six hours after instillation and is removed from the urinary tract by normal urine flow and voiding. It is approved for administration in a retrograde manner via ureteral catheter or antegrade through nephrostomy tube. The delivery system allows the initial liquid to coat and conform to the upper urinary tract anatomy. The eventual semisolid gel allows for chemoablative therapy to remain in the collecting system for four to six hours without immediately being diluted or washed away by urine flow.

APPROVED USE FOR JELMYTO

JELMYTO® is a prescription medicine used to treat adults with a type of cancer of the lining of the upper urinary tract including the kidney called low-grade Upper Tract Urothelial Cancer (LG-UTUC).

IMPORTANT SAFETY INFORMATION

You should not receive JELMYTO if you have a hole or tear (perforation) of your bladder or upper urinary tract.

Before receiving JELMYTO, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. JELMYTO can harm your unborn baby. You should not become pregnant during treatment with JELMYTO. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with JELMYTO. **Females who are able to become pregnant:** You should use effective birth control (contraception) during treatment with JELMYTO and for 6 months after the last dose. **Males being treated with JELMYTO:** If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with JELMYTO and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if JELMYTO passes into your breast milk. Do not breastfeed during treatment with JELMYTO and for 1 week after the last dose.
- **Tell your healthcare provider if you take water pills (diuretic).**

How will I receive JELMYTO?

- Your healthcare provider will tell you to take a medicine called sodium bicarbonate before each JELMYTO treatment.
- You will receive your JELMYTO dose from your healthcare provider 1 time a week for 6 weeks. It is important that you receive all 6 doses of JELMYTO according to your healthcare provider's instructions. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. Your healthcare provider may recommend up to an additional 11 monthly doses.
- JELMYTO is given to your kidney through a tube called a catheter.
- During treatment with JELMYTO, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

After receiving JELMYTO:

- JELMYTO may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at least 6 hours.
- To urinate, **males and females should sit** on a toilet and flush the toilet several times after you use it. After going to the bathroom, wash your hands, your inner thighs, and genital area well with soap and water.
- Clothing that comes in contact with urine should be washed right away and washed separately from other clothing.

JELMYTO may cause serious side effects, including:

- **Swelling and narrowing of the tube that carries urine from the kidney to the bladder (ureteric obstruction).** If you develop swelling and narrowing, and to protect your kidney from damage, your healthcare provider may recommend the placement of a small plastic tube (stent) in the ureter to help the kidney drain. Tell your healthcare provider right away if you develop side pain or fever during treatment with JELMYTO.
- ***Bone* marrow problems.** JELMYTO can affect your bone marrow and can cause a decrease in your white blood cell, red blood cell, and platelet counts. Your healthcare provider will do blood tests prior to each treatment to check your blood cell counts during treatment with JELMYTO. Your healthcare provider may need to temporarily or permanently stop JELMYTO if you develop bone marrow problems during treatment with JELMYTO.
- **The most common side effects of JELMYTO include:** urinary tract infection, blood in your urine, side pain, nausea, trouble with urination, kidney problems, vomiting, tiredness, stomach (abdomen) pain.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to **UroGen Pharma** at 1-855-987-6436.

Please see JELMYTO Full Prescribing Information, including the Patient Information, for additional information.

About Upper Tract Urothelial Cancer (UTUC)

Urothelial cancer is the ninth most common cancer globally and the eighth most lethal neoplasm in men in the U.S. Between five percent and ten percent of primary urothelial cancers originate in the ureter or renal pelvis and are collectively referred to as upper tract urothelial cancers (UTUC). In the U.S., there are approximately 6,000 - 7,000 new or recurrent low-grade UTUC patients annually. Most cases are diagnosed in patients over 70 years old, and these older patients often face comorbidities. There are limited treatment options for UTUC, with the most common being endoscopic surgery or nephroureterectomy (removal of the entire kidney and ureter). These treatments can lead to a high rate of recurrence and relapse.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade intermediate risk NMIBC. Utilizing the RTGel® Technology Platform, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using a standard urinary catheter. The Company presented results from the Phase 2b OPTIMA II trial in September 2021.

About the Phase 3 ENVISION Trial

The Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 (mitomycin) as primary chemoablative therapy in patients with low-grade, intermediate-risk NMIBC. The Phase 3 ENVISION trial completed target enrollment with approximately 240 patients across 90 sites. Study participants will receive six once-weekly intravesical instillations of UGN-102. The planned primary endpoint will evaluate the complete response rate at three months after the first installation, and the key secondary endpoint will evaluate durability over time in patients who achieve complete response at the three-month assessment. Based on discussions with the FDA, and assuming positive findings, UroGen anticipates submitting an NDA for UGN-102 in 2024. Learn more about the Phase 3 ENVISION trial at www.clinicaltrials.gov (NCT05243550)

About UroGen Pharma Ltd.

UroGen is a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers because patients deserve better options. UroGen has developed RTGel® reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based platform technology that has the potential to improve therapeutic profiles of existing drugs. UroGen's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. JELMYTO® (mitomycin) for pyelocalyceal solution and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with low-grade non-muscle invasive bladder cancer are designed to ablate tumors by non-surgical means. UroGen is headquartered in *Princeton, NJ* with operations in *Israel*. Visit www.urogen.com to learn more or follow us on Twitter, @UroGenPharma.

Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding: the number of patients expected to be enrolled and the timing for completion of enrollment with respect to our ongoing Phase 3 ENVISION trial; our plans for reporting complete response data from ENVISION and topline data from ATLAS and the timing thereof; plans with respect to a regulatory submission for UGN-102 and the timing thereof; financial guidance for 2023; the potential of UroGen's proprietary RTGel technology to improve therapeutic profiles of existing drugs and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: preliminary results may not be indicative of results that may be observed in the future; the timing and success of clinical trials and potential safety and other complications thereof; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities; the labeling for any approved product; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; UroGen's ability to attract or retain key management, members of the board of directors and personnel; UroGen's RTGel technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; UroGen's financial condition and need for additional capital in the future. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Form 10-K filed with the SEC on March 24, 2023, as well as in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q being filed with the SEC later today (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to UroGen as of the date of this release.

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