UroGen Pharma Reports First Quarter 2025 Financial Results and Provides a Business Update

May 12, 2025

- *New Drug Application for UGN-102 on track for FDA-PDUFA target action date of June 13, 2025; assuming approval, commercial launch to immediately follow with product availability in July*
- *Oncologic Drugs Advisory Committee scheduled for May 21, 2025*
- *JELMYTO® achieved net product sales of $20.3 million in Q1 2025, compared with $18.8 million in Q1 2024, driven by underlying demand growth of 12%*
- *$200.4 million in cash, cash equivalents and marketable securities as of March 31, 2025*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J.--(BUSINESS WIRE)--May 12, 2025-- 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, 2025, and provided an overview of recent developments.

“We are entering a pivotal and exciting period for UroGen as we approach the anticipated FDA approval of our lead pipeline product, UGN-102, in June for recurrent low-grade intermediate-risk non-muscle invasive bladder cancer,” said Liz Barrett, President and Chief Executive Officer of UroGen. “This milestone has the potential to mark the first major advancement in treatment for this patient population in decades, delivering a much-needed novel and innovative treatment option that may offer meaningful disease and treatment-free intervals. With momentum building across the organization, we are entering the final phase of launch readiness. If approved, UGN-102 represents a significant commercial opportunity, with a total addressable market of over $5 billion. Backed by a strong balance sheet and a growing pipeline, we are well-positioned to build a long-term, sustainable growth company. We remain steadfast in our mission to transform the treatment paradigm in uro-oncology and see a great opportunity to advance patient care and deliver value for shareholders.”

Q1 2025 and Recent Business Highlights:

UGN-102 (mitomycin) for intravesical solution

- UroGen’s New Drug Application (NDA) for investigational drug UGN-102 (mitomycin) for intravesical solution as a treatment for recurrent low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC), is currently under review at the U.S. Food and Drug Administration (FDA). The FDA granted a Prescription Drug User Fee Act (PDUFA) target action date of June 13, 2025. The FDA has scheduled an Oncologic Drugs Advisory Committee (ODAC) meeting on May 21, 2025 to discuss the UGN-102 NDA.

- Updated 18-month Duration of Response (DOR) data from the Phase 3 ENVISION trial evaluating UGN-102 in patients with recurrent LG-IR-NMIBC were featured in a podium presentation by Dr. Sandip Prasad at the American Urological Association (AUA) 2025 Annual Meeting on April 26 in Las Vegas. The data are consistent with prior Kaplan-Meier estimates, with the probability of remaining in complete response (CR) of 80.6% (95% CI: 74.0, 85.7) at 18-months after achieving CR at 3 months (N=101) compared to 82.5% (95% CI: 76.1, 87.3) at 12-months after 3-month CR (N=146). Median follow-up time at 18 months was 18.7 months after the three-month CR.

- The results of a patient reported outcomes analysis from three UGN-102 studies (OPTIMA II, ATLAS and ENVISION) were presented in a poster at the AUA meeting. The results showed that UGN-102 did not have a negative impact on symptom burden, patient function, or quality of life.

- Long-term outcomes of the OPTIMA II LT study of UGN-102 were also presented at the meeting and demonstrated median DOR of 24.2 months (95% CI 9.72, 47.18) with a median follow-up time of 33.6 months (95% CI 10.78, 42.94) in the 41 patients who achieved a CR in the parent study.

- Results from a post-hoc sub-analysis of the ENVISION trial, showing that tumor burden and the number of tumors did not significantly affect the CR rate or durability of response for patients treated with UGN-102, were presented at the ASCO Genitourinary Cancers Symposium (ASCO-GU 2025) in February 2025.

- Results from the ENVISION trial were published in the February 2025 issue of *The Journal of Urology*.

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

- Generated net product revenue of $20.3 million in the quarter ended March 31, 2025, an increase of 8% over the $18.8 million reported for the same quarter in 2024. Underlying demand grew by 12% year-over-year.

- A poster featuring long-term outcomes of patients with recurrent and new-onset LG-UTUC who achieved CR in the Phase

3 trial of JELMYTO was presented at AUA 2025. As previously reported, the median DOR of all patients achieving CR in the JELMYTO Phase 3 study was 47.8 months, irrespective of whether their cancer was new onset or recurrent.

- A long-term study on JELMYTO titled, "Durability of Response of UGN-101: Longitudinal Follow-Up of Multicenter Study," was published online in *Urologic Oncology: Seminars and Investigations* in January 2025. The results showed 68% recurrence-free survival rate at three years across a broad patient population with LG-UTUC.

UGN-301 (zalifrelimab) intravesical solution, an anti-CTLA4 antibody for use in high-grade non-muscle invasive bladder cancer (NMIBC)

- Enrollment is complete in the multi-arm dose escalation Phase 1 clinical study of UGN-301 in patients with high-grade NMIBC, alone and in combination with fixed dose UGN-201 or gemcitabine. The investigational treatments demonstrated an acceptable safety profile and were generally well tolerated across dose levels. Responses were observed in both monotherapy and combination therapy arms, and patient follow-up is ongoing to further assess the durability of these responses.

Next-generation investigational oncolytic virus UGN-501 (ICVB-1042)

- In February 2025, UroGen expanded its nonclinical oncology portfolio with the purchase of product candidate UGN-501 from IconOVir Bio, Inc (IconOVir). UGN-501 is a potent and fast-replicating investigational next generation oncolytic virus therapy, being developed as a locally administered treatment for bladder cancer and other specialty cancers. UroGen hosted a webinar to discuss UGN-501 (ICVB-1042) on February 20, 2025, and a replay can be accessed on the Company's website here.

Next-generation novel mitomycin-based formulation for urothelial cancers

- Enrollment is ongoing in the Phase 3 UTOPIA clinical trial of investigational drug UGN-103 (mitomycin) for intravesical solution in patients with LG-IR-NMIBC and enrollment is expected to be completed by mid-2025. UGN-103 is a next generation product that combines UroGen's RTGel ® technology with a novel mitomycin formulation licensed from medac GmbH. UGN-103 is planned to follow the potential FDA approval and launch of UGN-102 for recurrent LG-IR-NMIBC. To learn more about the UTOPIA trial, refer to clinicaltrials.gov/NCT06331299.

- UroGen plans to initiate a Phase 3 trial to explore the safety and efficacy of UGN-104 by mid-2025. UGN-104 is a next generation investigational product for LG-UTUC.

First quarter 2025 Financial Results

JELMYTO Revenue: JELMYTO net product revenues were $20.3 million for the three months ended March 31, 2025, compared with $18.8 million for the same quarter of 2024. Year-over-year revenue growth of 8% was driven by underlying demand growth of 12%, partially offset by higher 340B chargebacks.

R&D Expenses: R&D expenses for the first quarter of 2025 were $19.9 million, including non-cash share-based compensation expense of $0.6 million as compared to $15.5 million, including non-cash share-based compensation expense of $0.5 million, for the same period in 2024. The increase in R&D expenses of $4.4 million was primarily driven by the equity consideration issued to IconOVir for the acquisition of UGN-501 (ICVB-1042) which was expensed in the first quarter of 2025, higher manufacturing costs, and costs associated with the Phase 3 UTOPIA trial for UGN-103, partially offset by lower clinical trial costs and regulatory expenses in connection with UGN-102.

SG&A Expenses: SG&A expenses for the first quarter of 2025 were $35.0 million, including non-cash share-based compensation expense of $2.5 million. This compares to $27.3 million, including non-cash share-based compensation expense of $2.2 million, for the same period in 2024. The increase in SG&A expenses of $7.7 million was primarily driven by UGN-102 commercial preparation activities.

Financing on Prepaid Forward Obligation: UroGen reported non-cash financing expense related to the prepaid forward obligation to RTW Investments of $4.6 million in the first quarter of 2025, compared to $5.7 million in the same period in 2024. The decrease was primarily driven by changes in underlying assumptions for remeasuring the effective rate.

Interest Expense on Long-Term Debt: Interest expense related to the $125 million term loan facility with funds managed by Pharmakon Advisors was $4.1 million in the first quarter of 2025, compared to $2.4 million in the same period in 2024. The increase was primarily attributable to the interest expense on the third tranche of the loan that was funded in September 2024.

Net Loss: UroGen reported a net loss of $43.8 million or ($0.92) per basic and diluted share in the first quarter of 2025 compared with a net loss of $32.3 million or ($0.87) per basic and diluted share in the same period in 2024.

Cash and Equivalents: As of March 31, 2025, cash, cash equivalents and marketable securities totaled $200.4 million.

For further details on the Company's financials, refer to Form 10-Q, filed with the SEC.

2025 JELMYTO Revenue and Company Operating Expense Guidance: Guidance for full-year 2025 net product revenues for JELMYTO remains unchanged and is expected to be in the range of $94 to $98 million. This implies a year-over-year growth rate of approximately 8% to 12% over the $87.4 million in demand driven JELMYTO sales in 2024, which excludes the $3.0 million in CREATES Act sales reported in 2024. Continue to expect full-year 2025 operating expenses to be in the range of $215 to $225 million, including non-cash share-based compensation expense of $11 million to $14 million.

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, 2025	December 31, 2024
Cash and cash equivalents and marketable securities	$ 200,405	$ 241,707
Total assets	$ 247,618	$ 285,711
Total liabilities	$ 294,076	$ 294,514
Total shareholders' deficit	$ (46,458)	$ (8,803)

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,	
	2025	2024
Revenue	$ 20,254	$ 18,781
Cost of revenue	2,330	1,728
Gross profit	17,924	17,053
Operating expenses:		
Research and development expenses	19,871	15,494
Selling, general and administrative expenses	34,967	27,299
Total operating expenses	54,838	42,793
Operating loss	(36,914)	(25,740)
Financing on prepaid forward obligation	(4,583)	(5,660)
Interest expense on long-term debt	(4,068)	(2,447)
Interest and other income, net	2,114	1,615
Loss before income taxes	$ (43,451)	$ (32,232)
Income tax expense	(392)	(54)
Net loss	$ (43,843)	$ (32,286)
Net loss per ordinary share, basic and diluted	$ (0.92)	$ (0.87)
Weighted average shares outstanding, basic and diluted	47,422,119	37,059,186

About JELMYTO

JELMYTO® (mitomycin) for pyelocalyceal solution is a mitomycin-containing reverse thermal gel containing 4 mg mitomycin per mL gel indicated for the treatment of adult patients with LG-UTUC. 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 UTUC. In the U.S., there are approximately 6,000 - 7,000 new or recurrent LG-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). Treatment with endoscopic surgery can be associated with a high rate of recurrence and relapse.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of recurrent LG-IR-NMIBC. Utilizing UroGen's proprietary RTGel® technology, a 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 in an outpatient setting by a trained healthcare professional. UroGen completed the submission of a rolling NDA in August 2024, ahead of schedule. The FDA accepted the NDA for UGN-102 and assigned a PDUFA goal date of June 13, 2025.

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 the 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. Our first product to treat LG-UTUC and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with recurrent 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 X (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: UroGen's UGN-102 NDA submission, scheduled ODAC meeting, and expected PDUFA goal date; the potential for UGN-102 to be the first major advancement in treatment recurrent LG-IR-NMIBC in decades; the estimated patient population, demographics, and market opportunities for LG-IR-NMIBC and UTUC; the belief that UroGen is well-positioned for sustained growth; conclusions from the ENVISION data; the potential applications of UGN-501 in treating bladder cancer as well as other types of cancers; the timing for enrollment completion in the Phase 3 UTOPIA clinical trial of UGN-103; plans for UGN-103 to follow the potential FDA approval and launch of UGN-102; the timing for the planned Phase 3 trial to explore the safety and efficacy of UGN-104 in the first half of 2025; 2025 financial guidance; 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. Words such as "anticipate," "assume," "can," "expect," "if," "imply," "may," "plan," "potential," "remain," "will," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

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 outcome of the ODAC meeting is uncertain and it is possible that the ODAC meeting will have an adverse or split recommendation with respect to UGN-102; even if the ODAC recommends the approval of UGN-102, the FDA is not bound by the ODAC's recommendation; the PDUFA goal date may be delayed due to various factors outside UroGen's control; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; the ability to obtain and maintain regulatory approval within the timeframe expected, or at all; 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 and product candidates; the size and growth of the market(s) for UroGen's product and product candidates and the rate and degree of market acceptance thereof vis-à-vis alternative therapies or procedures, such as surgery; 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; and 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 Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 10, 2025, as well as in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q being filed with the SEC later today. 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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