UroGen Pharma Expands Commercial Portfolio with Launch of ZUSDURI™ and Reports Second Quarter 2025 Financial Results

August 7, 2025

- *ZUSDURI™ (mitomycin) for intravesical solution now available as the first and only FDA-approved medication for adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)*
- *JELMYTO® achieved net product sales of $24.2 million in Q2 2025, compared with $21.8 million in Q2 2024, representing 11% year-over-year growth*
- *$161.6 million in cash, cash equivalents and marketable securities as of June 30, 2025*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J., Aug. 07, 2025 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2025, and provided an overview of recent developments.

"The recent FDA approval of ZUSDURI for the treatment of adults with recurrent LG-IR-NMIBC represents a truly transformative milestone for patients and for UroGen, marking our evolution into a multi-product uro-oncology company and our leadership in the field," said Liz Barrett, President and Chief Executive Officer of UroGen. "Our commercial team is enthusiastically executing the ZUSDURI launch plan as we scale the organization to address the estimated $5 billion+ market opportunity. JELMYTO (mitomycin) for pyelocalyceal solution, our treatment for low-grade upper tract urothelial carcinoma (LG-UTUC), continues to grow with strong underlying demand in the second quarter reflecting continued interest in this important therapy for patients. We are equally excited about the continued progress across our pipeline, including our next-generation mitomycin formulations and immuno-oncology candidates. With a solid balance sheet, we are well positioned to fully support the launch of ZUSDURI while advancing strategic business initiatives to drive sustained growth and innovation."

Q2 2025 and Recent Business Highlights:

ZUSDURI (mitomycin) for intravesical solution:

- On June 12, 2025, the U.S. Food and Drug Administration (FDA) approved ZUSDURI (formerly UGN-102), the first and only FDA-approved medication for adults with recurrent LG-IR-NMIBC.
- Updated Duration of Response (DOR) data from the Phase 3 ENVISION trial evaluating ZUSDURI in patients with recurrent LG-IR-NMIBC demonstrate a probability of remaining in complete response (CR) of 72.2% (95% CI: 64.1%, 78.8%) by Kaplan-Meier estimate, at 24-months after achieving a CR at three-months. Median follow-up time at 24-months was 23.7 months after the three-month CR.
- Five-year results from the long-term extension study of the Phase 2b OPTIMA II trial evaluating ZUSDURI in patients with newly diagnosed or recurrent LG-IR-NMIBC were published in the Journal of Clinical Genitourinary Cancer. Among the 17 patients who achieved a CR and entered the long-term extension study, the median DOR was approximately 3.5 years by Kaplan-Meier estimate. A copy of the paper can be found here.

JELMYTO (mitomycin) for pyelocalyceal solution in LG-UTUC:

- Generated net product revenue of $24.2 million in the quarter ended June 30, 2025, an increase of 11% compared to the same quarter in 2024, driven by underlying demand growth of 7% and year-over-year price favorability.
- JELMYTO is being evaluated in the uTRACT Registry, details of which were presented at the 2025 American Society of Clinical Oncology annual meeting in June 2025. This single-arm, multicenter, prospective and retrospective study is looking at real-world use of JELMYTO for adult patients with UTUC across the United States. Comprehensive data over a three-year period will be collected, with the goal of providing insights into treatment patterns, long-term outcomes, and patient safety in real-world settings.

Next-generation novel mitomycin-based formulations for urothelial cancers

- Enrollment is now complete in the ongoing Phase 3 UTOPIA clinical trial of investigational drug UGN-103 (mitomycin) for intravesical solution in patients with recurrent LG-IR-NMIBC. UGN-103 is a next-generation product designed to offer improvements over ZUSDURI (mitomycin) for intravesical solution, including a shorter manufacturing process and simplified reconstitution procedure. It combines UroGen's *RTGel*® technology with a novel mitomycin formulation licensed from

medac GmbH. To learn more about the UTOPIA trial, refer to clinicaltrials.gov/NCT06331299.

- A Phase 3 study to explore the safety and efficacy of UGN-104 has been initiated. UGN-104 is a next generation product for LG-UTUC. To learn more about this trial, refer to https://clinicaltrials.gov/study/NCT06774131.

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

- Enrollment is complete in the dose escalation phase of UGN-301, alone and in combination with fixed dose UGN-201 or gemcitabine. The 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.

Second Quarter 2025 Financial Results

JELMYTO Revenue: JELMYTO net product revenues were $24.2 million for the three months ended June 30, 2025, compared with $21.8 million for the same quarter of 2024. Year-over-year revenue growth of 11% was driven by underlying demand growth of 7% and price favorability.

Research & Development Expenses (R&D): R&D expenses for the second quarter of 2025 were $18.9 million, including non-cash share-based compensation expense of $0.4 million as compared to $15.4 million, including non-cash share-based compensation expense of $0.6 million, for the same period in 2024. The increase in R&D expenses of $3.5 million was primarily driven by 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 ZUSDURI.

Selling, General and Administrative Expenses (SG&A): SG&A expenses for the second quarter of 2025 were $43.2 million, including non-cash share-based compensation expense of $2.3 million. This compares to $30.1 million, including non-cash share-based compensation expense of $3.0 million, for the same period in 2024. The increase in SG&A expenses of $13.1 million was primarily driven by ZUSDURI commercial preparation activities as well as an increase in overall commercial operation costs.

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 second quarter of 2025, compared to $5.8 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 second quarter of 2025, compared to $3.5 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 $49.9 million or ($1.05) per basic and diluted share in the second quarter of 2025 compared with a net loss of $33.4 million or ($0.82) per basic and diluted share in the same period in 2024.

Cash and Equivalents: As of June 30, 2025, cash, cash equivalents and marketable securities totaled $161.6 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)

	June 30, 2025	December 31, 2024
Cash and cash equivalents and marketable securities	$ 161,586	$ 241,707
Total assets	$ 208,717	$ 285,711
Total liabilities	$ 302,093	$ 294,514
Total shareholders' deficit	$ (93,376)	$ (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 June 30,		Six months ended June 30,	
2025	2024	2025	2024

Revenue	$ 24,215	$ 21,848	$ 44,469	$ 40,629
Cost of revenue	3,550	2,229	5,880	3,957
Gross profit	20,665	19,619	38,589	36,672
Operating expenses:				
Research and development expenses	18,914	15,402	38,785	30,896
Selling, general and administrative expenses	43,199	30,056	78,166	57,355
Total operating expenses	62,113	45,458	116,951	88,251
Operating loss	(41,448)	(25,839)	(78,362)	(51,579)
Financing on prepaid forward obligation	(4,644)	(5,773)	(9,227)	(11,433)
Interest expense on long-term debt	(4,132)	(3,461)	(8,200)	(5,908)
Interest and other income, net	1,299	1,708	3,413	3,323
Loss before income taxes	$ (48,925)	$ (33,365)	$ (92,376)	$ (65,597)
Income tax expense	(1,015)	(38)	(1,407)	(92)
Net loss	$ (49,940)	$ (33,403)	$ (93,783)	$ (65,689)
Net loss per ordinary share basic and diluted	$ (1.05)	$ (0.82)	$ (1.97)	$ (1.69)
Weighted average shares outstanding, basic and diluted	47,739,816	40,501,315	47,582,610	38,785,924

About ZUSDURI

ZUSDURI (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, approved for the treatment of adults with recurrent LG-IR-NMIBC. Utilizing UroGen's proprietary *RTGel*® technology (a sustained release, hydrogel-based formulation) ZUSDURI is delivered directly into the bladder by a trained healthcare professional using a urinary catheter in an outpatient setting, thereby enabling the treatment of tumors by non-surgical means.

APPROVED USE FOR ZUSDURI

ZUSDURI (mitomycin) for intravesical solution is a prescription medicine used to treat adults with a type of cancer of the lining of the bladder called low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC) after previously receiving bladder surgery to remove tumor that did not work or is no longer working.

IMPORTANT SAFETY INFORMATION

You should not receive ZUSDURI if you have a hole or tear (perforation) of your bladder or if you have had an allergic reaction to mitomycin or to any of the ingredients in ZUSDURI.

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

- have kidney problems
- are pregnant or plan to become pregnant. ZUSDURI can harm your unborn baby. You should not become pregnant during treatment with ZUSDURI. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ZUSDURI.

  Females who are able to become pregnant: You should use effective birth control (contraception) during treatment with ZUSDURI and for 6 months after the last dose.

  Males being treated with ZUSDURI: You should use effective birth control (contraception) during treatment with ZUSDURI and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if ZUSDURI passes into your breast milk. Do not breastfeed during treatment with ZUSDURI and for 1 week after the last dose.

How will I receive ZUSDURI?

- You will receive your ZUSDURI dose from your healthcare provider 1 time a week for 6 weeks into your bladder through a tube called a urinary catheter. It is important that you receive all 6 doses of ZUSDURI according to your healthcare provider's instructions.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.
- During treatment with ZUSDURI, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

After receiving ZUSDURI:

- ZUSDURI may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at

least 24 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.

The most common side effects of ZUSDURI include: increased blood creatinine levels, increased blood potassium levels, trouble with urination, decreased red blood cell counts, increase in certain blood liver tests, increased or decreased white blood cell counts, urinary tract infection, and blood in your urine.

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 ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.

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 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 is approved to treat low-grade upper tract urothelial cancer, and our second product is the first and only FDA-approved medication for recurrent low-grade intermediate-risk non-muscle invasive bladder cancer. Both medicines 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, @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 estimated market opportunity for ZUSDURI; UroGen's optimism regarding the progress of its pipeline; the belief that UroGen is well-positioned to support the launch of ZUSDURI and for sustained growth; the potential benefits of the uTRACT Registry study, including the nature of the expected data and its ability to help optimize the use of JELMYTO with insights into treatment patterns, long-term outcomes, and patient safety in real-world settings; the belief that UGN-103, if approved, will offer several improvements over ZUSDURI, including a shorter manufacturing process and simplified reconstitution procedure; 2025 financial guidance the potential of UroGen's proprietary *RTGel* technology to improve therapeutic profiles of existing drugs other than mitomycin; and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. Words such as "can," "continue," "estimate," "expect," "may," "plan," "potential," "will," or other words that convey uncertainty of future events or outcomes are used to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: clinical results may not be indicative of results that may be observed in the future, including in larger populations; potential safety and other complications related to UroGen's products; risks related to our and our licensors' ability to protect our respective patents and other intellectual property; the ability to maintain regulatory approval; complications associated with commercialization activities; labeling limitations; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's products and 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 or procedures, such as surgery; UroGen's ability to attract or retain key management, members of the board of directors and other personnel; UroGen's *RTGel* technology and ZUSDURI may not perform as expected; new data relating to ZUSDURI, including from spontaneous adverse event reports and from the ongoing ENVISION trial, may result in changes to the product label and may adversely affect sales, or result in withdrawal of ZUSDURI from the market; the potential for payors to delay, limit or deny coverage for ZUSDURI; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology; and the impacts of general macroeconomic and geopolitical conditions on UroGen's business and financial position. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 12, 2025, as well as 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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