UroGen Reports Third Quarter 2025 Financial Results as ZUSDURI™ Launch Gains Momentum

November 6, 2025

- *Reported three-month complete response rate of 77.8% from the Phase 3 UTOPIA trial of UGN-103, consistent with ENVISION results; FDA agreed to regulatory plan to submit an NDA based on data from the UTOPIA trial*
- *ZUSDURI received unique J-Code (J9282) in October 2025, effective January 1, 2026*
- *ZUSDURI achieved net product revenue of $1.8 million in Q3 2025; October 2025 preliminary demand revenue estimate of $4.5 million reflecting accelerating growth entering Q4 2025*
- *JELMYTO® achieved net product revenue of $25.7 million in Q3 2025, representing YoY underlying demand revenue growth of 13%*
- *$127.4 million in cash, cash equivalents and marketable securities as of September 30, 2025*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J., Nov. 06, 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 third quarter ended September 30, 2025, and provided an overview of recent developments.

“Our launch of ZUSDURI, the first and only FDA-approved medicine for adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer, continues to gain momentum,” said Liz Barrett, President and Chief Executive Officer of UroGen. “Despite slower than anticipated new patient starts, we are encouraged by the patient demand reflected in our patient enrollment forms. Strong enthusiasm and engagement from urologists, growing physician awareness, and broad reimbursement coverage are expanding patient access. Early launch indicators reflect robust interest and confidence in ZUSDURI’s clinical value, reinforcing our belief in the significant commercial opportunity ahead and our ability to fully capitalize on it. The strong complete-response rate for UGN-103 and the FDA’s agreement with our NDA submission plan supports our strategy for the next-generation medicines that are expected to enhance supply, improve manufacturing and preparation efficiencies and provide opportunity for lifecycle extensions. With a strong financial position, we are committed to driving a successful launch of ZUSDURI and advancing our pipeline in ways that deliver lasting impact for patients and long-term value for shareholders.”

Q3 2025 and Recent Business Highlights:

ZUSDURI (mitomycin) for intravesical solution:

- Following U.S. Food and Drug Administration (FDA) approval on June 12, 2025, UroGen launched ZUSDURI (formerly UGN-102), the first and only FDA-approved medicine for adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC), marking a major milestone in bladder cancer care.
- ZUSDURI was assigned a unique, permanent Healthcare Common Procedure Coding System J-code (J9282) by the Centers for Medicare & Medicaid Services. The J-code is expected to be effective January 1, 2026.
- ZUSDURI is now broadly accessible to patients through Commercial, Medicare, and Medicaid insurance programs, with open access for more than 95% of covered lives and approximately 296 million eligible patients.
- ZUSDURI achieved net product revenue of $1.8 million in Q3 2025; October 2025 preliminary demand revenue estimate of $4.5 million demonstrates accelerating commercial uptake and growing physician adoption.
- From launch on July 1, 2025 through October 31, 2025, UroGen reports:
    - 592 activated sites of care
    - 54 unique ZUSDURI prescribers
    - 16 repeat ZUSDURI prescribers
- The article “*Review of UGN-102: A Reverse Thermal Gel Containing Mitomycin for the Treatment of Recurrent, Low-Grade, Intermediate-Risk Non-Muscle Invasive Bladder Cancer*” was published in *Reviews in Urology* ™ and highlights durable efficacy and manageable safety profile of ZUSDURI in patients with recurrent LG-IR-NMIBC.

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

- Generated net product revenue of $25.7 million in the quarter ended September 30, 2025, compared to $25.2 million (which included CREATES Act sales of $2.6 million) reported for same quarter in 2024. Underlying demand revenue grew by approximately 13% year-over-year.

Next-generation novel mitomycin-based formulation for urothelial cancers

- Enrollment is complete in the ongoing Phase 3 UTOPIA clinical trial of investigational drug UGN-103 (mitomycin) for intravesical solution in patients with LG-IR-NMIBC. UroGen reported a three-month complete response rate (CRR) of

77.8% (95% CI, 68.3% to 85.5%), consistent with results from the ENVISION clinical trial.

- The FDA agreed with the regulatory plan to submit an NDA based on the data from the single-arm Phase 3 UTOPIA trial to support potential approval of UGN-103. UroGen anticipates submitting an NDA for UGN-103 in the second half of 2026 with potential approval anticipated in 2027.
- UGN-103 is a next generation product designed to offer certain improvements over ZUSDURI (mitomycin) for intravesical solution, including a shorter manufacturing process and simplified reconstitution procedure. UGN-103 combines UroGen's RTGel® technology with a novel mitomycin formulation licensed from medac GmbH. For more information on the UTOPIA trial, refer to clinicaltrials.gov/NCT06331299.
- The Phase 3 clinical trial to explore the safety and efficacy of UGN-104 is ongoing. UGN-104 is an investigational next-generation mitomycin product for LG-UTUC. Like UGN-103, UGN-104 combines UroGen's RTGel ® technology with a novel mitomycin formulation licensed from medac GmbH.

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

- UroGen has made the strategic decision to discontinue development of UGN-301 (zalifrelimab) following completion of its Phase 1 dose escalation study. While the study confirmed proof of concept for RTGel® as a viable platform for local delivery of complex immunotherapies, UGN-301's overall clinical profile did not meet UroGen's internal benchmarks for advancement to Phase 2. The program achieved key proof of concept objectives, including sustained bladder exposure with minimal systemic absorption and was generally well tolerated, demonstrating the ability to mitigate CTLA-4–related toxicities, and encouraging efficacy signals. These findings further reinforce the versatility and potential of RTGel technology to enable localized delivery of immunotherapy candidates.
- UroGen provided notice to Agenus Inc. of termination for convenience of the License Agreement between the parties. In accordance with the terms of the agreement, termination will become effective upon the later of (i) expiration of the 180-day notice period, or (ii) completion of all required wind-down activities, including the delivery of any Agenus Improvements as defined in the License Agreement.

UGN-501 (investigational next-gen oncolytic virus) for use in high-grade non-muscle invasive bladder cancer (

- 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. Investigational New Drug (IND)-enabling studies are currently ongoing, with the goal of submitting an IND and initiating a Phase 1 trial in 2026.

Third quarter 2025 Financial Results

Revenue: Total revenues for the third quarter ended September 30, 2025 were $27.5 million. JELMYTO generated net product revenue of $25.7 million for the quarter ended September 30, 2025, compared to $25.2 million (which included $2.6 million of CREATES Act sales) in the same period of 2024, reflecting approximately 13% underlying year-over-year demand driven revenue growth. ZUSDURI achieved net product revenue of $1.8 million in its first quarter on the market, with October 2025 preliminary demand revenue estimate of $4.5 million demonstrating growing early commercial momentum.

R&D Expenses: Research and development (R&D) expenses for the third quarter of 2025 were $14.0 million, including non-cash share-based compensation expense of $0.7 million as compared to $11.4 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 $2.6 million was primarily driven by costs associated with the Phase 3 UTOPIA trial for UGN-103, partially offset by lower clinical trial costs, manufacturing costs, and regulatory expenses in connection with ZUSDURI.

SG&A Expenses: Selling, general and administrative expenses (SG&A) for the third quarter of 2025 were $37.6 million, including non-cash share-based compensation expense of $2.3 million. This compares to $28.9 million, including non-cash share-based compensation expense of $2.9 million, for the same period in 2024. The increase in SG&A expenses of $8.7 million was primarily driven by ZUSDURI commercial launch 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 third quarter of 2025, compared to $5.9 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 $3.4 million in the third quarter of 2025, compared to $2.7 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 $33.3 million or ($0.69) per basic and diluted share in the third quarter of 2025 compared with a net loss of $23.7 million or ($0.51) per basic and diluted share in the same period in 2024.

Cash and Equivalents: As of September 30, 2025, cash, cash equivalents and marketable securities totaled $127.4 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)

	September 30, 2025	December 31, 2024
Cash and cash equivalents and marketable securities	$ 127,413	$ 241,707
Total assets	$ 185,046	$ 285,711
Total liabilities	$ 300,454	$ 294,514
Total shareholders' deficit	$ (115,408)	$ (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 September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Revenue[1]	$ 27,482	$ 25,204	$ 71,951	$ 65,833
Cost of revenue	3,278	2,453	9,158	6,410
Gross profit	24,204	22,751	62,793	59,423
Operating expenses:				
Research and development expenses	14,008	11,355	52,793	42,251
Selling, general and administrative expenses	37,582	28,941	115,748	86,296
Total operating expenses	51,590	40,296	168,541	128,547
Operating loss	(27,386)	(17,545)	(105,748)	(69,124)
Financing on prepaid forward obligation	(4,621)	(5,915)	(13,848)	(17,348)
Interest expense on long-term debt	(3,373)	(2,721)	(11,573)	(8,629)
Interest and other income, net	979	2,599	4,392	5,922
Loss before income taxes	$ (34,401)	$ (23,582)	$ (126,777)	$ (89,179)
Income tax benefit (expense)	1,054	(91)	(353)	(183)
Net loss	$ (33,347)	$ (23,673)	$ (127,130)	$ (89,362)
Net loss per ordinary share basic and diluted	$ (0.69)	$ (0.51)	$ (2.66)	$ (2.15)
Weighted average shares outstanding, basic and diluted	48,057,386	46,779,637	47,742,305	41,476,892

1. Revenue includes $0.1 million and $2.6 million in JELMYTO CREATES Act sales during the three months ended September 30, 2025 and 2024, respectively.

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 in an out-patient procedure by a trained healthcare professional using a urinary catheter to enable 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 to treat LG-UTUC and second product (mitomycin) for intravesical solution for patients with recurrent LG-IR-NMIBC 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 preliminary demand revenue estimate for ZUSDURI in October and its demonstration of accelerating commercial uptake and growing physician adoption; early launch indicators reflecting robust interest and confidence in ZUSDURI's clinical value; the belief in the significant commercial opportunity ahead and UroGen's ability to fully capitalize on it; the expected effective date for the ZUSDURI J-code; the potential benefits and opportunities for UroGen's product candidates, including UGN-103, UGN-104 and UGN-501; UroGen's planned and ongoing clinical trials and non-clinical studies and the timing for regulatory submissions and potential regulatory approvals for its product candidates, including the ongoing UTOPIA clinical trial of UGN-103, the ongoing Phase 3 clinical trial of UGN-104 and the non-clinical studies of UGN-501, the planned NDA submission for UGN-103 and the potential regulatory approval thereof and the potential IND submission for UGN-501 and the potential Phase 1 trial thereof; the expectation that UroGen's next-generation medicines will enhance supply, improve manufacturing and preparation efficiencies and provide opportunity for lifecycle extensions; 2025 JELMYTO revenue and company operating expense guidance; the potential of UroGen's proprietary *RTGel* technology to improve therapeutic profiles of existing drugs other than mitomycin and as a viable platform for local delivery of complex immunotherapies; and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. Words such as "anticipate," "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, including that UroGen's or our licensors' pending patent applications may not be successful, and in such event, the duration of intellectual property protection would be more limited; 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; the data from the UTOPIA trial may not be sufficient to support approval of UGN-103; 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 June 30, 2025, filed with the SEC on August 7, 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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