# UroGen Reports $50.4 Million of ZUSDURI Revenue and Provides Second Quarter 2026 Financial Results and Highlights

August 5, 2026

- *ZUSDURI® generated $50.4 million in revenue in the second quarter of 2026, representing 73% quarter-over-quarter growth*
- *Once issued, new U.S. patent is expected to provide protection into July 2044 for ZUSDURI and UGN-103*
- *Continued advancement of pipeline, with UGN-103 on track for NDA submission in the third quarter of 2026 and UGN-501 expected to begin a Phase 1 trial in the fourth quarter of 2026*
- *Conference call and webcast held today at 10:00 AM ET*

PRINCETON, N.J., Aug. 05, 2026 (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, 2026, and provided an overview of recent developments.

“The second quarter marked another important step in establishing ZUSDURI as a foundational therapy for adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer,” said Liz Barrett, President and Chief Executive Officer of UroGen. “The continued increase in utilization, expanding adoption across community practices, and growing repeat use reinforce our confidence we are building a durable commercial franchise with blockbuster potential. During the quarter, we strengthened the long-term sustainability of the franchise through a new U.S. patent allowance that, once the patent is issued, is expected to provide intellectual property coverage for both ZUSDURI and UGN-103 into July 2044. We believe this meaningfully enhances the long-term commercial opportunity for both products and further reinforces the sustainability of the franchise. Combined with the life-cycle expansion of UGN-103 and initiation of clinical development for UGN-501, we believe we are exceptionally well positioned to build a durable growth company and create long-term shareholder value.”

**Q2 2026 and Recent Business Highlights:**

**ZUSDURI (mitomycin) for intravesical solution:**

- ZUSDURI achieved net product revenue of $50.4 million in the second quarter of 2026, representing 73% growth over the first quarter of 2026. As of June 30, 2026, UroGen reported:
  - 1,444 activated sites of care
  - 452 unique ZUSDURI prescribers
  - 204 repeat ZUSDURI prescribers, representing approximately 45% of total prescribers, up from 40% in the first quarter of 2026
- Updated results from the Phase 3 ENVISION trial of ZUSDURI showed a 36-month duration of response (DOR) of 64.5% (95% CI: 54.6, 72.8) by Kaplan-Meier estimate among patients who achieved a complete response (CR) at three months (79.6%). At a median follow-up of 35.5 months, the median DOR had not been reached. ZUSDURI’s durability was achieved without maintenance therapy, supporting a treatment approach that can provide lasting disease control while reducing treatment burden for patients.
- UroGen received a Notice of Allowance from the U.S. Patent and Trademark Office for a new U.S. patent covering methods of treating patients with recurrent, low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) without transurethral resection of bladder tumor (TURBT). Once issued, the patent is expected to provide protection into July 2044, further strengthening the intellectual property supporting ZUSDURI and UGN-103 and reinforcing the long-term commercial opportunity for both products.

**American Urological Association (AUA) Key Opinion Leader Webinar:**

- On May 17, 2026, UroGen hosted a Key Opinion Leader webinar at the AUA Annual Meeting in Washington, D.C., focused on real-world experience with ZUSDURI. The discussion highlighted patient selection, workflow integration, treatment patterns, and physician experience across both hospital and community practices, reinforcing growing confidence in the use of ZUSDURI in routine clinical practice. A replay of the event is accessible through the Investors section of the Company’s website.

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

- Generated net product revenue of $22.0 million in the quarter ended June 30, 2026, compared with $24.2 million reported

for the second quarter of 2025. The Company continues to add new users and remains on track to deliver within its JELMYTO full-year 2026 guidance range of $97 million to $101 million.

- UroGen entered into a settlement and license agreement with Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals, USA, Inc. (collectively, "Teva") that resolves the patent litigation UroGen initiated in response to Teva's submission of an Abbreviated New Drug Application to the U.S. FDA for a generic version of JELMYTO prior to the expiration of the relevant UroGen patents. Under the terms of the agreement, UroGen granted Teva a non-exclusive license to sell its generic version of JELMYTO beginning on September 15, 2030, if approved by the FDA, unless certain limited circumstances customarily included in these types of agreements occur.

**Next-generation novel mitomycin-based formulations for urothelial cancer:**

- UGN-103 achieved a 94.5% (95% CI: 86.1, 97.9) DOR at six months by Kaplan-Meier estimate, in the ongoing Phase 3 UTOPIA trial in patients with LG-IR-NMIBC. The six-month results from UTOPIA are generally consistent with the 91.9% (95% CI: 86.9, 95.0) six-month DOR by Kaplan-Meier estimate observed with ZUSDURI in the pivotal ENVISION trial.
- UroGen remains on track to submit a New Drug Application (NDA) for UGN-103 in the third quarter of 2026, with potential FDA approval in 2027 and full launch anticipated following receipt of a unique J-Code. UGN-103 is designed to build on the clinical and commercial foundation of ZUSDURI. The benefits of UGN-103 include a more streamlined manufacturing process and simplified reconstitution, while preserving the innovative and proven *RTGel*® technology that enables sustained drug exposure at tumor sites in the bladder.
- The Company expects to initiate a randomized controlled Phase 3 trial evaluating UGN-103 in high-risk NMIBC in the second half of 2026, and a trial evaluating UGN-103 as adjuvant therapy in newly diagnosed intermediate-risk NMIBC patients in 2027.
- The Phase 3 clinical trial evaluating UGN-104 in low-grade upper tract urothelial cancer (LG-UTUC) remains on track to complete enrollment by the end of 2026.

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

- UroGen's Investigational New Drug application for UGN-501 has been accepted by the FDA, and the Company plans to initiate its Phase 1 clinical trial in NMIBC in the fourth quarter of 2026.

**Second Quarter 2026 Financial Results**

**Revenue:** Total revenue was $72.5 million in the second quarter of 2026, compared with $24.2 million in the second quarter of 2025. The increase was driven by the continued commercial launch of ZUSDURI.

**Research and Development (R&D) Expenses:** R&D expenses were $17.3 million in the second quarter of 2026, including non-cash share-based compensation expense of $0.9 million. This compares to $18.9 million, including non-cash share-based compensation expense of $0.4 million, in the same period in 2025. The decrease in R&D expenses was primarily attributable to ZUSDURI manufacturing costs, which were recognized as an R&D expense in the second quarter of 2025 prior to receiving FDA approval.

**Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were $48.4 million in the second quarter of 2026, including non-cash share-based compensation expense of $4.4 million. This compares to $43.2 million, including non-cash share-based compensation expense of $2.3 million, in the same period in 2025. The increase in SG&A expenses was primarily attributable to ZUSDURI commercial activities, including the sales force expansion following ZUSDURI approval and higher brand marketing expenses, and 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 $4.5 million in the second quarter of 2026, compared with $4.6 million in the same period in 2025.

**Interest Expense on Long-term Debt:** Interest expense related to long-term debt was $4.9 million in the second quarter of 2026, compared with $4.1 million in the same period in 2025. The increase in interest expense was primarily attributable to the additional borrowings of $75.0 million in the first quarter of 2026 in connection with the Pharmakon refinancing of long-term debt, offset by the lower interest rate.

**Net Loss:** UroGen reported a net loss of $14.4 million, or $0.28 per basic and diluted share, in the quarter ended June 30, 2026, compared with a net loss of $49.9 million, or ($1.05) per basic and diluted share, in the second quarter of 2025.

**Cash, Cash Equivalents and Marketable Securities:** As of June 30, 2026, cash, cash equivalents and marketable securities totaled $108.0 million.

**2026 JELMYTO Revenue and Updated Company Operating Expense Guidance:** The Company continues to expect 2026 net product revenue for JELMYTO to be in the range of $97 million to $101 million. This implies a year-over-year growth rate of approximately 3% to 7% over the $94 million of JELMYTO revenue reported in 2025. The Company is not providing full-year 2026 revenue guidance for ZUSDURI at this time, as the product remains in the early stages of its commercial launch. The Company is increasing its full-year 2026 operating expenses guidance to be in the range of $260 million to $270 million, including non-cash share-based compensation expense of $20 million to $24 million. The increase reflects the decision to accelerate investment behind the business in response to the continued strength of the ZUSDURI launch. Specifically, the Company plans to increase investment in ZUSDURI peer-to-peer promotional education and patient awareness initiatives to support long-term commercial adoption, and also accelerate start-up activities for the UGN-103 high-grade NMIBC trial and development activities of UGN-501 with *RTGel*®.

**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 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, 2026 | December 31, 2025 |
|---|---|---|
| Cash and cash equivalents and marketable securities | $ 107,976 | $ 120,456 |
| Total assets | $ 252,590 | $ 200,455 |
| Total liabilities | $ 384,986 | $ 305,929 |
| Total shareholders' deficit | $ (132,396) | $ (105,474) |

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, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Revenue | $ 72,456 | $ 24,215 | $ 123,415 | $ 44,469 |
| Cost of revenue | 6,572 | 3,550 | 10,711 | 5,880 |
| Gross profit | 65,884 | 20,665 | 112,704 | 38,589 |
| Operating expenses: | | | | |
| Research and development expenses | 17,336 | 18,914 | 32,933 | 38,785 |
| Selling, general and administrative expenses | 48,437 | 43,199 | 99,923 | 78,166 |
| Total operating expenses | 65,773 | 62,113 | 132,856 | 116,951 |
| Operating income (loss) | 111 | (41,448) | (20,152) | (78,362) |
| Financing on prepaid forward obligation | (4,545) | (4,644) | (9,051) | (9,227) |
| Interest expense on long-term debt | (4,887) | (4,132) | (9,072) | (8,200) |
| Interest and other income, net | 599 | 1,299 | 1,207 | 3,413 |
| Loss before income taxes | $ (8,722) | $ (48,925) | $ (37,068) | $ (92,376) |
| Income tax expense | (5,629) | (1,015) | (857) | (1,407) |
| Net loss | $ (14,351) | $ (49,940) | $ (37,925) | $ (93,783) |
| Net loss per ordinary share basic and diluted | $ (0.28) | $ (1.05) | $ (0.75) | $ (1.97) |
| Weighted average shares outstanding, basic and diluted | 50,380,112 | 47,739,816 | 50,282,221 | 47,582,610 |

**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 a 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 approved for the treatment of adult patients with LG-UTUC. 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 a 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 chemo-ablative 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. UroGen's 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 potential benefits and expected length of patent protection for ZUSDURI and UGN-103; 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 UGN-103, UGN-104, and UGN-501; the belief in the significant commercial opportunity ahead and UroGen's ability to fully capitalize on it; 2026 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 UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. Words such as "anticipate," "believe," "can," "continue," "estimate," "expect," "may," "on track," "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 UroGen’s and its licensors’ ability to protect their respective patents and other intellectual property, including that UroGen’s or its 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 March 31, 2026, filed with the SEC on May 6, 2026, 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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