



## UroGen Announces ZUSDURI™ Launch is On-Track and Reports Fourth Quarter and Full Year 2025 Financial Results

March 2, 2026

- *Commercial launch is on-track for ZUSDURI™, the first and only FDA-approved medication for adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC); net sales in 2025 were \$15.8 million, reflecting the initial launch period ahead of the permanent J Code*
- *Permanent J Code for ZUSDURI became effective on January 1, 2026, streamlining reimbursement procedures and supporting broader patient access*
- *JELMYTO® achieved net product sales of \$94 million in 2025, representing year-over-year underlying demand sales growth of 7%*
- *Announced refinancing of existing term loan with Pharmakon Advisors that provides additional non-dilutive capital at more favorable terms*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J., March 02, 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 fourth quarter and full year ended December 31, 2025, and provided an overview of recent developments.

"2025 was a tremendously successful and transformative year for UroGen, highlighted by the FDA approval and commercial launch of ZUSDURI, the first and only approved medicine for adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer," said Liz Barrett, President and Chief Executive Officer of UroGen. "2026 is a pivotal year for the ZUSDURI launch, and we are encouraged by the early post-J Code trajectory. As expected, we are seeing an acceleration across key launch indicators, including physician uptake and adoption. We believe ZUSDURI is well positioned to address a significant unmet need and represents a greater than \$1 billion peak sales opportunity."

Ms. Barrett continued, "We are advancing our pipeline with meaningful momentum across our next-generation clinical programs, UGN-103 and UGN-104. The UTOPIA trial evaluating UGN-103 demonstrated compelling complete response results consistent with the ENVISION trial, and we remain on-track to submit an NDA in the second half of 2026. We also plan to explore label expansion opportunities for UGN-103, including in high-grade NMIBC settings and as an adjuvant to TURBT in IR-NMIBC patients. Following the refinancing of our term loan agreement with Pharmakon, we have further strengthened our balance sheet, and believe we are well-positioned to execute on our long-term growth strategy and build upon our leadership in uro-oncology."

### **Q4 2025 and Recent Business Highlights:**

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

- Commercial launch is progressing as expected for ZUSDURI, the first and only FDA-approved medication for adults with recurrent LG-IR-NMIBC. ZUSDURI was approved by the U.S. Food and Drug Administration (FDA) on June 12, 2025. The Company's expanded field team is scaled and actively supporting the ZUSDURI launch.
- On January 1, 2026, the permanent Healthcare Common Procedure Coding System Level II J Code (J9282) became effective, building buy-and-bill reimbursement confidence across hospital and community urology practices, removing a key barrier and supporting broader uptake.
- ZUSDURI achieved net product sales of \$15.8 million in 2025. As of December 31, 2025, UroGen reports:
  - 838 activated sites of care
  - 102 unique ZUSDURI prescribers
  - 32 repeat ZUSDURI prescribers

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

- Generated net product sales of \$94.0 million in the year ended December 31, 2025, compared to \$90.4 million reported in 2024 (which included CREATES Act sales of \$0.2 million in 2025 and \$3.0 million in 2024). Underlying demand revenue grew by 7% year-over-year.

#### **Next-generation novel mitomycin-based formulation for urothelial cancers**

- UroGen announced robust results from its ongoing Phase 3 UTOPIA trial evaluating UGN-103 (mitomycin) for intravesical

solution in recurrent LG-IR-NMIBC. UGN-103 demonstrated a 77.8% three-month complete response (CR) rate (95% CI, 68.3%, 85.5%). For more information on the UTOPIA trial, refer to [clinicaltrials.gov/NCT06331299](https://clinicaltrials.gov/NCT06331299).

- The FDA has agreed with the regulatory plan to submit a New Drug Application (NDA) based on the data from the Phase 3 UTOPIA trial to support potential approval of UGN-103 for recurrent LG-IR-NMIBC. UroGen plans to submit the NDA in the second half of 2026 with potential FDA approval in 2027.
- UGN-103 is a next generation product designed to offer improvements over ZUSDURI, including a shorter manufacturing process and simplified reconstitution procedure. It combines UroGen's RTGel<sup>®</sup> technology with a novel mitomycin formulation licensed from medac GmbH. UroGen plans to continue evaluating lifecycle management and pipeline expansion opportunities, including potential applications in high-grade NMIBC settings and adjuvant use of UGN-103 in IR-NMIBC patients.
- The Phase 3 clinical trial to explore the safety and efficacy of UGN-104 is ongoing and is expected to be fully enrolled by the end of 2026. UGN-104 is a next generation product for LG-UTUC. For more information on the UGN-104 Phase 3 trial, refer to <https://clinicaltrials.gov/study/NCT06774131>.

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

- UGN-501 is a potent and fast-replicating investigational next generation oncolytic virus therapy being developed as a locally administered cancer treatment. Investigational New Drug-enabling studies are currently ongoing, with the goal of submitting an IND and initiating a Phase 1 trial by the end of 2026. UroGen intends to evaluate several modes of administration, including delivery using its proprietary RTGel technology. The initial focus will be bladder cancer, and UroGen also intends to explore UGN-501's potential in a broader range of cancers beyond the genitourinary system.

#### **Expanded Debt Facility with Pharmakon Advisors**

- On February 26, 2026, UroGen entered into an amended and restated loan agreement with Pharmakon Advisors for two additional tranches of senior secured term loans. The first tranche of \$200 million was funded at closing to refinance the existing \$125 million loan facility and provide additional non-dilutive capital. A second tranche of \$50 million may be drawn at the Company's option no later than June 30, 2027, subject to customary conditions. All outstanding loans with Pharmakon Advisors will accrue interest at a fixed rate of 8.25% and be repaid in four equal quarterly payments commencing in the first quarter of 2030. All outstanding loans with Pharmakon Advisors can be prepaid in whole at UroGen's discretion at any time, subject to prepayment premiums, make-whole amounts, as applicable, and fees.

#### **Full Year 2025 Financial Results**

**Revenue:** Total revenue was \$109.8 million for the full year ended December 31, 2025, compared to \$90.4 million for the full year ended December 31, 2024. The 21% year-over-year increase was primarily driven by the commercial launch of ZUSDURI in 2025 and JELMYTO revenue growth.

**R&D Expenses:** Research and development (R&D) expenses were \$67.1 million for the full year ended December 31, 2025, including non-cash shared-based compensation expense of \$2.3 million. This compares to \$57.1 million, including non-cash shared-based compensation expense of \$2.2 million, for the full year ended December 31, 2024. The increase in R&D expenses was primarily driven by higher ZUSDURI manufacturing costs, which are recognized as R&D expenses prior to receiving FDA approval, costs associated with the Phase 3 trials for UGN-103 and UGN-104, and the acquisition of UGN-501, partially offset by lower clinical trial costs and regulatory expenses in connection with ZUSDURI.

**SG&A Expenses:** Selling, general and administrative (SG&A) expenses were \$155.1 million for the full year ended December 31, 2025, including non-cash shared-based compensation expense of \$9.6 million. This compares to \$121.2 million, including non-cash shared-based compensation expense of \$10.9 million, for the full year ended December 31, 2024. The increase in SG&A expenses was primarily driven by ZUSDURI commercial activities, including the sales force expansion following ZUSDURI approval in 2025, 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 \$18.5 million and \$23.4 million for the years ended December 31, 2025 and 2024, respectively. The decrease was driven primarily by changes in underlying assumptions for remeasuring the effective interest rate.

**Interest Expense on Long-term Debt:** Interest expense related to the prior \$125 million term loan facility with funds managed by Pharmakon Advisors was \$15.3 million and \$12.5 million for the years ended December 31, 2025 and 2024, respectively. The increase was primarily attributed to the interest expense on the \$25 million third tranche of the loan that was funded in September 2024.

**Net Loss:** UroGen reported a net loss of \$153.5 million or (\$3.19) per basic and diluted share for the year ended December 31, 2025, compared with a net loss of \$126.9 million or (\$2.96) per basic and diluted share for the year ended December 31, 2024.

**Cash, Cash Equivalents and Marketable Securities:** As of December 31, 2025, cash, cash equivalents and marketable securities totaled \$120.5 million.

**2026 JELMYTO Sales and Company Operating Expense Guidance:** Guidance for full-year 2026 net product sales for JELMYTO are expected 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 sales reported in 2025. The Company is not providing full-year 2026 sales guidance for ZUSDURI at this time, as the product remains in the early stages of its commercial launch. Full-year 2026 operating expenses are expected to be in the range of \$240 million to \$250 million, including non-cash share-based compensation expense of \$20 million to \$24 million.

For further details on the Company's financials, refer to our Annual Report on Form 10-K, being filed with the SEC today.

**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](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)

	December 31, 2025	December 31, 2024
Cash and cash equivalents and marketable securities	\$ 120,456	\$ 241,707
Total assets	\$ 200,455	\$ 285,711
Total liabilities	\$ 305,929	\$ 294,514
Total shareholders' deficit	\$ (105,474)	\$ (8,803)

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

	Three months ended December 31,		Year ended December 31,	
	2025	2024	2025	2024
Revenue	\$ 37,837	\$ 24,565	\$ 109,788	\$ 90,398
Cost of revenue	3,289	2,471	12,447	8,881
Gross profit	34,548	22,094	97,341	81,517
Operating expenses:				
Research and development expenses	14,314	14,894	67,107	57,145
Selling, general and administrative expenses	39,349	34,858	155,097	121,154
Total operating expenses	53,663	49,752	222,204	178,299
Operating loss	(19,115)	(27,658)	(124,863)	(96,782)
Financing on prepaid forward obligation	(4,655)	(6,063)	(18,503)	(23,411)
Interest expense on long-term debt	(3,772)	(3,892)	(15,345)	(12,521)
Interest and other income, net	903	2,750	5,295	8,672
Loss before income taxes	(26,639)	(34,863)	(153,416)	(124,042)
Income tax benefit (expense)	275	(2,649)	(78)	(2,832)
<b>Net loss</b>	<b>\$ (26,364)</b>	<b>\$ (37,512)</b>	<b>\$ (153,494)</b>	<b>\$ (126,874)</b>
Net loss per ordinary share basic and diluted	\$ (0.54)	\$ (0.80)	\$ (3.19)	\$ (2.96)
Weighted average shares outstanding, basic and diluted	49,230,277	47,030,820	48,116,098	42,876,737

**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 *RTGeI* 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](http://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](http://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 adults 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](http://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: ZUSDURI's rate of market acceptance and growing rates of physician uptake and adoption; the expected benefits of the permanent J Code for ZUSDURI, including building buy-and-bill reimbursement confidence across hospital and community urology practices, removing key adoption barriers and supporting broader uptake; early post-J Code trajectory providing optimism for ZUSDURI sales; 2026 being a pivotal year for the ZUSDURI launch; the belief ZUSDURI is well positioned to address a significant unmet patient need; the belief there is significant ZUSDURI sales opportunity ahead and UroGen's ability to fully capitalize on it, including the estimated peak sales opportunity; 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 expectation that enrollment will be completed by the end of 2026, the IND-enabling studies of UGN-501, the planned NDA submission for UGN-103 in the second half of 2026 and the potential regulatory approval thereof in 2027, the potential IND submission for UGN-501 and the potential initiation of a Phase 1 trial thereof by the end of 2026; UroGen's

plans to explore label and pipeline expansion opportunities for UGN-103 and continue evaluating lifecycle management opportunities; UroGen's plans to evaluate several modes of administration for UGN-501; the potential benefits of UGN-103 and UGN-104 as compared to ZUSDURI and JELMYTO, respectively, including the expectation that these next-generation medicines will enhance supply, improve manufacturing and preparation efficiencies and provide opportunity for lifecycle extensions; the expected benefits of the new term loan with Pharmakon Advisors; the belief that UroGen is well-positioned to execute on its long-term growth strategy and build upon its leadership in uro-oncology; 2026 JELMYTO revenue and company operating expense guidance; the potential of UroGen's proprietary *RTGeI* 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 "believe," "can," "continue," "estimate," "expect," "intend," "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 *RTGeI* 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 *RTGeI* 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 September 30, 2025, filed with the SEC on November 6, 2025, as updated by the Risk Factors section of UroGen's Annual Report on Form 10-K being filed with the SEC 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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