UroGen Reports ZUSDURI™ Revenue More Than Doubled Quarter-over-Quarter and Provides First Quarter 2026 Financial Results and Highlights

May 6, 2026

- *ZUSDURI™ generated revenue of$29.2 million in Q1 2026, representing 109% quarter-over-quarter growth, reflecting broader utilization with the permanent J Code effective January 1, 2026*
- *JELMYTO achieved $21.7 million in revenue in Q1 2026, representing year-over-year growth of 7%*
- *Continued advancement of next-generation pipeline, UGN-103 on track for NDA submission in the second half of 2026; six-month durability data expected in mid-2026*
- *UroGen to host Key Opinion Leader (KOL) panel highlighting real-world experience with ZUSDURI at the American Urological Association (AUA) annual meeting on May 17th at 8:30 AM ET*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J., May 06, 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 first quarter ended March 31, 2026, and provided an overview of recent developments.

“2026 is off to a strong start, with expanding usage of ZUSDURI™ (mitomycin) for intravesical solution and clear acceleration across key commercial indicators, including prescriber trial and adoption,” said Liz Barrett, President and Chief Executive Officer of UroGen. “These trends reflect growing clinical confidence in ZUSDURI as a primary, non-surgical therapy for adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The early launch momentum is now translating into meaningful revenue growth, providing early validation of our commercial model and reinforcing the blockbuster potential for ZUSDURI. In parallel, we continue to advance our broader pipeline, including next generation products UGN-103 in LG-IR-NMIBC and UGN-104 in low-grade upper tract urothelial carcinoma (LG-UTUC), as well as UGN-501, our investigational, potentially best-in-class, next-generation oncolytic virus. With this momentum, we are well positioned to execute our long-term growth strategy and continue to expand our leadership position in uro-oncology.”

Q1 2026 and Recent Business Highlights:

ZUSDURI (mitomycin) for intravesical solution:

- Commercial launch of ZUSDURI continues to accelerate, following its U.S. FDA-approval as the first and only FDA-approved medicine for adults with recurrent LG-IR-NMIBC.
- The permanent Healthcare Common Procedure Coding System Level II J Code (J9282) became effective on January 1, 2026 and has enabled broader adoption by improving reimbursement clarity and confidence across both hospital and community settings.
- ZUSDURI achieved net product revenue of $29.2 million in the first quarter of 2026, representing 109% quarter-over-quarter growth. The accelerating growth trend in prescribers, particularly repeat prescribers, reflects increasing health care provider confidence and successful integration of ZUSDURI into routine urology practice. As of March 31, 2026, UroGen reported:
  - 972 activated sites of care
  - 256 unique ZUSDURI prescribers
  - 103 repeat ZUSDURI prescribers
- Updated results from the Phase 3 ENVISION trial evaluating ZUSDURI were published online ahead of print in the Journal of Urology. The publication reported that patients who achieved a complete response (CR) three months after the first instillation of ZUSDURI had a 72.2% probability of remaining event-free 24 months after CR (95% CI: 64.1%, 78.8%) as determined by Kaplan-Meier analysis.

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

- Generated net product revenue of $21.7 million in the quarter ended March 31, 2026, an increase of approximately 7% over the $20.3 million reported for first quarter of 2025.

Next-generation novel mitomycin-based formulations for urothelial cancer

- UroGen plans to submit a New Drug Application (NDA) for UGN-103 (mitomycin) for recurrent LG-IR-NMIBC in the second

half of 2026 with potential FDA approval in 2027. The FDA has agreed with the Company's regulatory plan to submit the NDA based on the data from the Phase 3 UTOPIA trial. Top line results from UTOPIA were reported in November 2025, demonstrating a 77.8% three-month CR rate (95% CI, 68.3%, 85.5%). For more information on the UTOPIA trial, refer to clinicaltrials.gov/NCT06331299.

- UGN-103 is a next-generation mitomycin product designed to offer improvements over ZUSDURI, including a shorter manufacturing process and simplified reconstitution procedure. It combines UroGen's *RTGel*® technology with a novel mitomycin formulation licensed from medac. UroGen continues to evaluate 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 mitomycin product for LG-UTUC. For more information on the UGN-104 Phase 3 trial (UT002), refer to https://clinicaltrials.gov/study/NCT06774131.

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 being developed as a locally administered cancer treatment. Investigational New Drug (IND)-enabling studies are nearing completion, and UroGen plans to submit an IND in the second quarter of 2026 and initiate a Phase 1 clinical trial in NMIBC by year end. Nonclinical data to date demonstrate cytotoxic activity across a panel of bladder cancer cell lines representing a broad range of tumor stages and grades. The Phase 1 trial will initially evaluate aqueous intravesical administration of UGN-501, and UroGen plans to evaluate delivery using its proprietary *RTGel* technology, which may enable prolonged dwell time and enhanced local activity. The initial focus is bladder cancer with the potential to expand into additional tumor types beyond the genitourinary system.

Expanded Debt Facility with Pharmakon Advisors

- In February 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 second 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.

American Urological Association Key Opinion Leader Panel to Showcase Real-World Experience with ZUSDURI

- UroGen will host a KOL panel at the upcoming AUA Annual Meeting focused on real-world experience with ZUSDURI, including patient selection, workflow integration, treatment patterns, and patient outcomes. The event will feature leading urologists highlighting the role of ZUSDURI as a primary, non-surgical treatment option in recurrent low-grade intermediate-risk NMIBC and will be webcast and accessible through the Company's website. To register click here.

First quarter 2026 Financial Results

Revenue: Total revenue was $51.0 million in the first quarter ended March 31, 2026, compared with $20.3 million in the first quarter of 2025. Year-over-year revenue growth of 152% was primarily driven by the commercial launch of ZUSDURI and JELMYTO revenue growth.

Research and Development (R&D) Expenses: R&D expenses were $15.6 million in the first quarter of 2026, including non-cash share-based compensation expense of $0.8 million. This compares to $19.9 million, including non-cash share-based compensation expense of $0.6 million, for the same period in 2025. The decrease in R&D expenses was primarily attributable to the acquisition of UGN-501 in the first quarter of 2025 and ZUSDURI manufacturing costs, which were recognized as R&D expense in the first quarter of 2025 prior to receiving FDA approval.

Selling, General and Administrative (SG&A) Expenses: SG&A expenses were $51.5 million in the first quarter of 2026, including non-cash share-based compensation expense of $3.9 million. This compares to $35.0 million, including non-cash share-based compensation expense of $2.5 million, for 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, an increase in overall commercial operation costs, and higher advisory costs, including fees associated with the Pharmakon Advisors debt refinancing in the first quarter of 2026.

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 first 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 $4.2 million in the first quarter of 2026, compared to $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 $23.6 million or ($0.47) per basic and diluted share in the quarter ended March 31, 2026, compared with a net loss of $43.8 million or ($0.92) per basic and diluted share in the first quarter of 2025.

Cash, Cash Equivalents and Marketable Securities: As of March 31, 2026, cash, cash equivalents and marketable securities totaled $140.3 million.

2026 JELMYTO Revenue and 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 continues to expect full-year 2026 operating expenses to be in the range of $240 million to $250 million, including non-cash share-based compensation expense of $20 million to $24 million.

Conference Call & Webcast Information: Members of UroGen's management team will host a live conference call and webcast today at 10:00 AM Eastern Time to review UroGen's financial results and provide a general business update.

The live webcast can be accessed by visiting the Investors section of the Company's website at http://investors.UroGen.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast.

UROGEN PHARMA LTD.
SELECTED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	March 31, 2026	December 31, 2025
Cash and cash equivalents and marketable securities	$ 140,274	$ 120,456
Total assets	$ 253,690	$ 200,455
Total liabilities	$ 377,943	$ 305,929
Total shareholders' deficit	$ (124,253)	$ (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 March 31,	
	2026	2025
Revenue	$ 50,959	$ 20,254
Cost of revenue	4,139	2,330
Gross profit	46,820	17,924
Operating expenses:		
Research and development expenses	15,597	19,871
Selling, general and administrative expenses	51,486	34,967
Total operating expenses	67,083	54,838
Operating loss	(20,263)	(36,914)
Financing on prepaid forward obligation	(4,506)	(4,583)
Interest expense on long-term debt	(4,185)	(4,068)
Interest and other income, net	608	2,114
Loss before income taxes	$ (28,346)	$ (43,451)
Income tax benefit (expense)	4,772	(392)
Net loss	$ (23,574)	$ (43,843)
Net loss per ordinary share, basic and diluted	$ (0.47)	$ (0.92)
Weighted average shares outstanding, basic and diluted	50,182,758	47,422,119

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 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. UroGen's 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 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 for ZUSDURI as a primary, non-surgical therapy for adults with recurrent LG-IR-NMIBC; ZUSDURI's accelerating commercial uptake and growing rates of prescriber trial and adoption; the belief that growing clinical confidence in ZUSDURI will continue to drive commercial momentum and that the early launch trajectory provides validation of UroGen's commercial model; the belief in the significant commercial opportunity for ZUSDURI and UroGen's ability to fully capitalize on it; 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 IND-enabling studies and the timing for regulatory submissions and potential regulatory approvals for its product candidates, including the ongoing Phase 3 UTOPIA clinical trial of UGN-103, the ongoing Phase 3 clinical trial of UGN-104 and the IND-enabling studies of UGN-501, the planned NDA submission for UGN-103 and the

potential regulatory approval thereof and the planned IND submission for UGN-501 and the potential Phase 1 trial thereof; the potential of UGN-501 to expand into additional tumor types beyond the genitourinary system; the expectation that UroGen's next-generation medicines will enhance supply, improve manufacturing and preparation efficiencies and provide opportunity for lifecycle extensions; 2026 JELMYTO revenue and company operating expense guidance; the expected timeline of UroGen's expanded debt facility with Pharmakon Advisors; 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 "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 Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 2, 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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