# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 4, 2026**

# UROGEN PHARMA LTD.

**(Exact name of registrant as specified in its charter)**

| **Israel** | **001-38079** | **98-1460746** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| **400 Alexander Park Drive, 4th Floor Princeton, New Jersey** | **08540** |
|---|---|
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: +1 (646) 768-9780**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Ordinary Shares, par value NIS 0.01 per share | URGN | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02 Results of Operations and Financial Condition**

On November 4, 2026, UroGen Pharma Ltd. (the "Company") announced its financial results for the quarter ended September 30, 2026. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d)

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated November 4, 2026 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 4, 2026

**UROGEN PHARMA LTD.**

By: /s/ Chris Degnan
Chris Degnan
Chief Financial Officer

*Exhibit 99.1*

# UroGen Reports $68.0 Million of ZUSDURI Revenue and Provides Third Quarter 2026 Financial Results and Highlights

- *ZUSDURI® generated $68.0 million in revenue in the third quarter of 2026, representing 35% quarter-over-quarter growth*
- *The FDA accepted UroGen's NDA for UGN-103 (next-generation novel mitomycin-based formulation) for review; PDUFA goal date set for June 14, 2027*
- *Announced first patient dosed in the UGN-501 Phase 1 trial*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J., Nov. 4, 2026 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotechnology 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, 2026, and provided an overview of recent developments.

"We delivered another strong quarter of execution, with ZUSDURI continuing to scale as growing repeat utilization, expanding community adoption, and broader physician engagement reinforce our confidence in the long-term commercial opportunity," said Liz Barrett, President and Chief Executive Officer of UroGen. "At the same time, we are strengthening the durability of our business through the advancement of UGN-103, which aims to build on the success of ZUSDURI and create opportunities to expand into additional patient populations. The U.S. Food and Drug Administration's (FDA's) acceptance of the UGN-103 New Drug Application (NDA) in low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC), together with our newly issued patent providing coverage into July 2044, further reinforce the long-term revenue potential of our bladder cancer portfolio. Looking ahead, our planned expansion into high-grade NMIBC with UGN-103, advancement of UGN-501 into the clinic, and strategic collaboration with IntraGel provide multiple opportunities for future growth. Together, we believe these achievements position UroGen to build a sustainable growth company and create meaningful long-term shareholder value."

**Third Quarter 2026 and Recent Business Highlights:**

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

- ZUSDURI achieved net product revenue of $68.0 million in the third quarter of 2026, representing 35% growth over the second quarter of 2026. As of September 30, 2026, UroGen reported:
    - 1,538 activated sites of care, compared with 1,444 as of June 30, 2026
    - 662 unique ZUSDURI prescribers, compared with 452 as of June 30, 2026
    - 331 repeat ZUSDURI prescribers, compared with 204 as of June 20, 2026, representing approximately 50% of total prescribers, up from 45% as of June 30, 2026
    - These trends reflect continued growth in both the breadth and depth of ZUSDURI adoption, with increasing repeat utilization reinforcing physician confidence and integration into routine clinical practice.
- UroGen's new U.S. method-of-treatment patent covering the non-surgical treatment of recurrent LG-IR-NMIBC has been issued and listed in the FDA's Orange Book for ZUSDURI. The patent is expected to provide coverage into July 2044 for ZUSDURI and, if approved, UGN-103, reinforcing the long-term commercial opportunity for the franchise.

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

- Generated net product revenue of $21.0 million in the third quarter of 2026, compared with $25.7 million reported for the third quarter of 2025. Third-quarter 2026 results included a one-time unfavorable gross-to-net adjustment of approximately $1.5 million related to a Centers for Medicare and Medicaid Services (CMS) invoice for the discarded drug program that included a prior year true-up resulting in corresponding adjustments to the Company's reserves. Results also reflected ongoing competitive clinical trial enrollment activity affecting JELMTYO patient starts in low-grade upper tract urothelial cancer (LG-UTUC).

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

- In October 2026, the FDA accepted for review UroGen's NDA for UGN-103 and assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 14, 2027. The NDA is based on clinical data from the ongoing Phase 3 UTOPIA trial, a single-arm, multicenter trial evaluating the efficacy and safety of UGN-103 in adult patients with recurrent LG-IR-NMIBC. The three-month complete response (CR) rate, the six-month duration of response (DOR), and the safety results observed in UTOPIA were consistent with those observed in the pivotal ENVISION trial of ZUSDURI. UroGen plans to submit 12-month DOR data from the UTOPIA trial to the FDA during the NDA review.
- UroGen plans to initiate the Phase 3 LONGVIEW-HR randomized, multicenter trial in the fourth quarter of 2026 evaluating adjuvant UGN-103 versus intravesical gemcitabine in patients with recurrent, papillary-only high-risk NMIBC who previously received Bacillus Calmette-Guérin (BCG) therapy. Enrollment is planned for approximately 300 patients, and the primary endpoint will evaluate disease-free survival (DFS).
- The Company also plans to initiate a non-registrational trial in 2027 evaluating the use of UGN-103 as adjuvant therapy in the newly diagnosed intermediate-risk NMIBC population.
- The ongoing Phase 3 clinical trial evaluating UGN-104 in LG-UTUC is expected to complete enrollment by the end of 2026 or in early 2027.

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

- The FDA cleared UroGen's Investigational New Drug (IND) application for UGN-501 in July 2026. In November 2026, the Company announced that

the first patient began treatment with UGN-501 in the Phase 1 trial intended to evaluate the safety, tolerability, and feasibility of intravesical administration of UGN-501. The trial will initially evaluate UGN-501 in aqueous solution, with future development expected to explore delivery using UroGen's RTGel® technology.

**Strategic Collaboration with IntraGel Therapeutics:**

- In August 2026, UroGen entered into a strategic collaboration, licensing option and equity investment agreement with IntraGel Therapeutics. The agreement provides UroGen an exclusive option to evaluate and develop up to three future oncology products using IntraGel's proprietary SRGel platform, a biodegradable, sustained-release depot technology, as well as an exclusive option to acquire worldwide rights to IntraGel's Phase 2-ready investigational cisplatin therapy for locally advanced, inoperable head and neck cancer. UroGen also agreed to invest up to $7 million in IntraGel's equity securities, of which $4 million was invested in the third quarter of 2026.

**Third Quarter 2026 Financial Results**

**Revenue:** Total revenue was $89.0 million in the third quarter of 2026, compared with $27.5 million in the third quarter of 2025. The increase was driven by the continued commercial launch of ZUSDURI.

**Research and Development (R&D) Expenses:** R&D expenses were $26.0 million in the third quarter of 2026, including non-cash share-based compensation expense of $0.9 million. This compares to $14.0 million, including non-cash share-based compensation expense of $0.7 million, in the same period in 2025. The increase in R&D expenses was primarily attributable to an increase in UGN-103 and UGN-104 clinical development costs, the PDUFA fee related to the UGN-103 NDA submission, and increased development costs related to UGN-501.

**Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were $47.2 million in the third quarter of 2026, including non-cash share-based compensation expense of $5.3 million. This compares to $37.6 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 and an increase in overall commercial operations 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 third 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 $4.8 million in the third quarter of 2026, compared with $3.4 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 refinancing long-term debt with Pharmakon Advisors, LP, offset by the lower interest rate.

**Net Loss:** UroGen reported a net loss of $1.5 million, or $0.03 per basic and diluted share, in the quarter ended September 30, 2026, compared with a net loss of $33.3 million, or $0.69 per basic and diluted share, in the third quarter of 2025.

**Cash, Cash Equivalents and Marketable Securities:** As of September 30, 2026, cash, cash equivalents and marketable securities totaled $90.5 million.

**2026 JELMYTO Revenue and Company Operating Expense Guidance**

UroGen is updating its full-year 2026 net product revenue guidance for JELMYTO to approximately $90 million, compared with its prior guidance range of $97 million to $101 million. The revised outlook reflects a one-time unfavorable gross-to-net adjustment of approximately $1.5 million related to a CMS discard drug provision true-up, as well as ongoing competitive clinical trial enrollment activity in the United States that has affected JELMYTO patient starts in low-grade upper tract urothelial cancer. The Company continues to expect full-year 2026 operating expenses to be in the range of $260 million to $270 million, with expenses anticipated toward the upper end of the range, 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 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, 2026 | December 31, 2025 |
|---|---|---|
| Cash and cash equivalents and marketable securities | $ 90,549 | $ 120,456 |
| Total assets | $ 271,873 | $ 200,455 |
| Total liabilities | $ 397,090 | $ 305,929 |
| Total shareholders' deficit | $ (125,217) | $ (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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|
| 2026 | 2025 | 2026 | 2025 |

| | | | | |
|---|---|---|---|---|
| Revenue | $ 89,001 | $ 27,482 | $ 212,416 | $ 71,951 |
| Cost of revenue | 7,502 | 3,278 | 18,213 | 9,158 |
| Gross profit | 81,499 | 24,204 | 194,203 | 62,793 |
| Operating expenses: | | | | |
| Research and development expenses | 25,964 | 14,008 | 58,897 | 52,793 |
| Selling, general and administrative expenses | 47,206 | 37,582 | 147,129 | 115,748 |
| Total operating expenses | 73,170 | 51,590 | 206,026 | 168,541 |
| Operating income (loss) | 8,329 | (27,386) | (11,823) | (105,748) |
| Financing on prepaid forward obligation | (4,546) | (4,621) | (13,597) | (13,848) |
| Interest expense on long-term debt | (4,836) | (3,373) | (13,908) | (11,573) |
| Interest and other income, net | 607 | 979 | 1,814 | 4,392 |
| Loss before income taxes | $ (446) | $ (34,401) | $ (37,514) | $ (126,777) |
| Income tax (expense) benefit | (1,016) | 1,054 | (1,873) | (353) |
| Net loss | $ (1,462) | $ (33,347) | $ (39,387) | $ (127,130) |
| Net loss per ordinary share basic and diluted | $ (0.03) | $ (0.69) | $ (0.78) | $ (2.66) |
| Weighted average shares outstanding, basic and diluted | 50,558,200 | 48,057,386 | 50,375,299 | 47,742,305 |

**About UroGen Pharma Ltd.**

UroGen is a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers because patients deserve better options. UroGen has developed *RTGel* reverse-thermal hydrogel, a proprietary sustained-release, hydrogel-based platform technology that has the potential to improve the therapeutic profiles of existing drugs. UroGen's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. Our first product is approved to treat low-grade upper tract urothelial cancer (LG-UTUC), and our second product is approved for adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). Both products 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.

**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 (ZUSDURI)**

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, or are breastfeeding or plan to breastfeed. Females who are able to become pregnant should use effective birth control during treatment with ZUSDURI and for 6 months after the last dose. Males being treated with ZUSDURI should use effective birth control during treatment and for 3 months after the last dose.

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.

**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 (JELMYTO)**

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, are breastfeeding or plan to breastfeed, or take water pills (diuretic).

JELMYTO may cause serious side effects, including swelling and narrowing of the tube that carries urine from the kidney to the bladder (ureteric obstruction) and bone marrow problems. 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, and 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.

**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: confidence in the long-term commercial opportunity of ZUSDURI; the development plans for UGN-103, including to expand into additional patient populations, including high-grade NMIBC and as an adjuvant therapy in newly diagnosed intermediate-risk NMIBC patients and the timing, design and expected enrollment of planned clinical trials related thereto; the timing and outcome of the FDA's review of the UGN-103 NDA, including UroGen's planned submission of DOR data from the UTOPIA trial to the FDA and the expected PDUFA date; the expected scope and duration of patent protection for ZUSDURI and UGN-103; UroGen's ability to build a sustainable growth company and create meaningful long-term shareholder value; expected enrollment completion of the ongoing Phase 3 clinical trial evaluating UGN-104 in LG-UTUC; plans to evaluate UGN-501 in aqueous solution, as well as future development of UGN-501 formulated with *RTGel* technology; the opportunities for UroGen's future growth, including the expansion of UGN-103 into high-grade NMIBC, advancement of UGN-501 and the strategic collaboration with IntraGel; the long-term revenue potential of UroGen's bladder cancer portfolio; and UroGen's expected 2026 revenue and operating expenses. Words such as "anticipate," "believe," "could," "expect," "intend," "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: even though the NDA for UGN-103 has been accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-103 on the timeframe expected, or at all; the PDUFA target action date of June 14, 2027 may be delayed due to various factors outside UroGen's control; preliminary clinical results may not be indicative of results that may be observed in the future; potential safety and other complications related to UroGen's products and product candidates, including potential delays or difficulties in initiating, enrolling, conducting or completing clinical trials and submitting planned data; UroGen may not realize any benefits from the IntraGel collaboration; risks related to our and our licensors' ability to protect our respective patents and other intellectual property, including the fact 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 UroGen's products and product candidates may not perform as expected; new data relating to ZUSDURI may result in changes to the product label and may adversely affect sales, or result in withdrawal of ZUSDURI from the market; the potential for payors to delay, limit or deny coverage for ZUSDURI; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology; UroGen's ability to achieve its revenue and operating-expense guidance, which is based on estimates and assumptions that may prove inaccurate; and the impacts of general macroeconomic and geopolitical conditions on UroGen's business and financial position. These and other risks and uncertainties are described in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, filed with the U.S. Securities and Exchange Commission on November 4, 2026. In light of these risks and uncertainties, 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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Source: UroGen Pharma Ltd.