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 14, 2023

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 NIS0.01 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 14, 2023, UroGen Pharma Ltd. (the "Company") announced its financial results for the quarter ended September 30, 2023 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

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 14, 2023
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 14, 2023

UROGEN PHARMA LTD.

By: /s/ Don Kim
Don Kim
Chief Financial Officer

Exhibit 99.1

UroGen Pharma Reports Third Quarter 2023 Financial Results

- *Continued strong growth with JELMYTO® net product revenues of $20.9 million in Q3 2023; an increase of ~30% from the same period last year*
- *Agreement with United States Food & Drug Administration (FDA) to proceed with rolling New Drug Application (NDA) for UGN-102 beginning in January 2024*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J. November 14, 2023 — UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced financial results for the third quarter ended September 30, 2023, and provided an overview of recent developments.

“During the third quarter, UroGen achieved several notable milestones, including announcement of unprecedented positive results from our ENVISION and ATLAS Phase 3 trials of UGN-102 in LG-IR-NMIBC,” said Liz Barrett, President, and Chief Executive Officer of UroGen. “Those seminal events paved the way for our recent pre-NDA meeting with the FDA where we aligned with the Agency on an efficient, rolling NDA review for UGN-102 starting in 2024. If approved, UGN-102 will be the first medicine approved for this patient population. The NDA will leverage the full strength of our clinical data with ENVISION as the pivotal trial and underscores our unwavering commitment to transforming the LG-IR-NMIBC treatment landscape, as we strive to reduce recurrence rates and minimize the need for multiple surgeries in this highly underserved patient population.”

Business Highlights:

UGN-102 (mitomycin) for intravesical solution:

- Announced agreement with the FDA that the current development plan evaluating duration of response at 12 months from the pivotal ENVISION trial will support submission of an NDA for the treatment of LG-IR-NMIBC. The FDA also agreed to a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls (CMC) sections of the NDA, presently slated for January 2024.

- Both ENVISION and ATLAS Phase 3 clinical trials met their primary endpoints in treating LG-IR-NMIBC.
    - ENVISION demonstrated an unprecedented 79.2% complete response rate (CRR) among 242 patients at three months after first instillation of UGN-102. Additional data evaluating the key secondary endpoint of duration of response is expected in Q2 2024.
    - The ATLAS trial met its primary endpoint of disease-free survival, with topline results demonstrating a reduced risk of recurrence, progression, or death by 55% for UGN-102 ± TURBT. ATLAS also demonstrated a 64.8% CRR at three months for patients who only received UGN-102, compared to 63.6% for those patients who only received TURBT. The estimated probability of remaining disease free 15-months after randomization was 72% for UGN-102 ± TURBT and 50% for TURBT monotherapy (hazard ratio 0.45).
- Accepted abstracts at the 2023 Society of Urologic Oncology Annual Meeting

    Late-Breaking Podium Presentation
    Urothelial Cancer Session I: Primary chemoablation for recurrent low grade intermediate risk (LG IR) NMIBC: The ENVISION trial
    Speaker: Sandip Prasad, M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Hospital/Atlantic Health System, NJ
    Date and Time: November 30, 2023 at 12:04-12:09 PM ET

    Digital Poster #: 132
    Session: Treatment of low-grade intermediate-risk non muscle invasive bladder cancer with UGN-102 ± transurethral resection of bladder cancer tumor (TURBT) monotherapy: the Phase 3 ATLAS trial
    Date and Time: November 30, 2023 at 2:15-3:15 PM ET

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

- Generated quarterly net product revenue of $20.9 million for the third quarter of 2023, representing ~30% growth over the third quarter of 2022.

- Activated sites on November 1, 2023 were 1,088, compared to 1,058 on August 1, 2023, while repeat accounts on November 1, 2023 were 296, compared to 267 on August 1, 2023.
- A retrospective study titled, The Ablative Effect of Mitomycin Reverse Thermal Gel: Expanding the Role for Nephron Preservation Therapy in Low Grade Upper Tract Urothelial Carcinoma, published in Urologic Oncology: Seminars and Original Investigations online aimed to explore alternatives to nephroureterectomy for kidney function preservation and assess JELMYTO's effectiveness in treating larger volume disease. Findings indicated that there were no significant differences in disease-free rates between complete ablation (78.6%), partial ablation (57.6%), or biopsy-only (66.7%) groups during the initial URS (p=0.15). Additionally, tumor size before JELMYTO induction did not significantly impact disease-free rates (p=0.09).

Third Quarter 2023 Financial Results:

JELMYTO Revenue: UroGen reported net product revenue of JELMYTO for the third quarter 2023 of $20.9 million, compared to $16.1 million in the third quarter of 2022.

R&D Expense: Research and development expenses for the third quarter 2023 were $10.2 million, including non-cash share-based compensation expense of $0.4 million as compared to $13.1 million, including non-cash share-based compensation expense of $0.6 million, for the same period in 2022.

SG&A Expense: Selling, general and administrative expenses for the third quarter 2023 were $21.8 million, including non-cash share-based compensation expense of $1.8 million. This compares to $19.1 million, including non-cash share-based compensation expense of $1.8 million, for the same period in 2022.

Financing on Prepaid Forward Obligation: UroGen reported non-cash financing expense related to the prepaid forward obligation to RTW Investments of $5.5 million for the third quarter 2023, compared to $4.8 million for the same period in 2022.

Interest Expense on Long-Term Debt: Interest expense related to the $100 million term loan facility with funds managed by Pharmakon Advisors was $3.8 million for the third quarter of 2023, compared to $2.7 million for the same period last year.

Net Loss: UroGen reported a net loss of $21.9 million, or basic and diluted net loss per ordinary share of $0.68, for the third quarter 2023 as compared to $25.8 million, or basic and diluted net loss per ordinary share of $1.13, for the same period in 2022.

Cash & Cash Equivalents: As of September 30, 2023, cash, cash equivalents and marketable securities totaled $153.9 million.

2023 Revenue, Operating Expense and RTW Expense Guidance: The Company reiterates anticipated full year 2023 net product revenues from JELMYTO to be in the range of $76 to $86 million. The Company also reiterates anticipated full year 2023 operating expenses in the range of $135 to $145 million, including non-cash share-based compensation expense of $6.0 to $11.0 million, subject to market conditions. The Company also reiterates anticipated full year 2023 non-cash financing expense related to the prepaid obligation to RTW Investments in the range of $21.0 to $26.0 million. Of this amount approximately $9.9 to $11.2 million is expected to be in cash.

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

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

UROGEN PHARMA LTD.

SELECTED CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands)

(Unaudited)

	September 30, 2023	December 31, 2022
Cash and cash equivalents and marketable securities	$ 153,926	$ 99,963
Total assets	$ 193,633	$ 135,619
Total liabilities	$ 235,626	$ 224,980
Total shareholders' deficit	$ (41,993)	$ (89,361)

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,	
	2023	2022	2023	2022
Revenue	$ 20,852	$ 16,097	$ 59,183	$ 46,265
Cost of revenue	2,367	2,020	7,075	5,391
Gross profit	18,485	14,077	52,108	40,874
Operating expenses:				
Research and development expenses	10,230	13,093	34,312	38,429
Selling, general and administrative expenses	21,755	19,071	68,723	61,204
Total operating expenses	31,985	32,164	103,035	99,633
Operating loss	(13,500)	(18,087)	(50,927)	(58,759)
Financing on prepaid forward obligation	(5,479)	(4,819)	(16,047)	(16,478)
Interest expense on long-term debt	(3,815)	(2,694)	(11,129)	(5,215)
Interest and other income, net	906	478	1,941	604
Loss before income taxes	$ (21,888)	$ (25,122)	$ (76,162)	$ (79,848)
Income tax expense	9	(709)	(66)	(1,066)
Net loss	$ (21,879)	$ (25,831)	$ (76,228)	$ (80,914)
Statements of Comprehensive Loss				
Net Loss	$ (21,879)	$ (25,831)	$ (76,228)	$ (80,914)
Other Comprehensive Income (Loss)				
Unrealized gain (loss) on investments	20	(99)	(27)	(130)
Comprehensive Loss	$ (21,859)	$ (25,930)	$ (76,255)	$ (81,044)
Net loss per ordinary share basic and diluted	$ (0.68)	$ (1.13)	$ (2.89)	$ (3.56)
Weighted average shares outstanding, basic and diluted	32,298,182	22,798,263	26,358,719	22,711,686

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 Upper Tract Urothelial Cancer (UTUC)

Urothelial cancer is the ninth most common cancer globally and the eighth most lethal neoplasm in men in the U.S. Between five percent and ten percent of primary urothelial cancers originate in the ureter or renal pelvis and are collectively referred to as upper tract urothelial cancers (UTUC). In the U.S., there are approximately 6,000 - 7,000 new or recurrent low-grade UTUC patients annually. Most cases are diagnosed in patients over 70 years old, and these older patients often face comorbidities. There are limited treatment options for UTUC, with the most common being endoscopic surgery or nephroureterectomy (removal of the entire kidney and ureter). These treatments can lead to a high rate of recurrence and relapse.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade intermediate risk NMIBC. Utilizing the RTGel® Technology Platform, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby

enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using a standard urinary catheter. The Company presented positive results from the ENVISION and ATLAS Phase 3 trials with UGN-102 for the treatment of low-grade, intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) in July 2023 and assuming positive secondary endpoint data from the ENVISION study, is advancing a rolling NDA review anticipated to commence in January 2024.

About the Phase 3 ENVISION Trial

The Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 (mitomycin) for intravesical solution as primary chemoablative therapy in patients with low-grade, intermediate-risk NMIBC. The Phase 3 ENVISION trial completed target enrollment with approximately 240 patients across 56 sites. Study participants received six once-weekly intravesical instillations of UGN-102. The primary endpoint evaluated the complete response rate at the 3-month assessment after the first instillation, and the key secondary endpoint will evaluate durability over time in patients who achieved a complete response at the three-month assessment. Based on discussions with the FDA, and assuming positive secondary endpoint findings, UroGen anticipates submitting an NDA for UGN-102 in 2024. Learn more about the Phase 3 ENVISION trial at www.clinicaltrials.gov (NCT05243550)

About the Phase 3 ATLAS Trial

ATLAS was a global, open-label, randomized controlled Phase 3 trial designed to assess the efficacy and safety of UGN-102, with or without TURBT, vs. TURBT alone in patients diagnosed with LG-IR-NMIBC. The trial enrolled 282 patients in clinical sites in the U.S., Europe and Israel. Patients were randomized 1:1 to either UGN-102 + / - TURBT or TURBT. Patients in the UGN-102 arm were treated with six weekly intravesical instillations of UGN-102. At the 3-month time point, patients were assessed for response. Patients who demonstrated a complete response to either UGN-102 or TURBT, were assessed for long-term follow-up for evidence of recurrence. Patients who demonstrated presence of persistent disease at 3-months, in either arm, underwent a TURBT and continued for long-term follow-up for evidence of recurrence. The primary endpoint of the study is disease-free survival. Learn more about the ATLAS trial at www.clinicaltrials.gov http://www.clinicaltrials.gov/(NCT04688931)

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 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. JELMYTO® (mitomycin) for pyelocalyceal solution and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with low-grade non-muscle invasive bladder cancer 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 Twitter, @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: our plans for reporting the secondary endpoint of duration of response data from ENVISION and the timing thereof; the anticipated commencement of a rolling NDA for UGN-102 in January 2024; the potential approval of UGN-102; financial guidance for 2023; the potential of UroGen's proprietary RTGel technology to improve therapeutic profiles of existing drugs and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: preliminary results may not be indicative of results that may be observed in the future; the timing and success of clinical trials and potential safety and other complications thereof; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; there is no guarantee that the current clinical development plan for UGN-102 will ultimately support submission of an NDA, notwithstanding the current agreement with the FDA; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities; the labeling for any approved product; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's 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; UroGen's ability to attract or retain key management,

members of the board of directors and personnel; UroGen's RTGel technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; UroGen's financial condition and need for additional capital in the future. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC (available at http://www.sec.gov) on August 10, 2023, as well as in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, 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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