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): March 14, 2024

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 March 14, 2024, UroGen Pharma Ltd. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2023. 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 March 14, 2024
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: March 14, 2024

UROGEN PHARMA LTD.

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

UroGen Pharma Delivers Double Digit JELMYTO® Growth and Prepares for the Next Phase of the Company with on Track Rolling Submission of UGN-102

- *Initiated submission of a rolling NDA to the FDA for UGN-102; 12-month duration of response data from ENVISION expected to support completion of NDA submission*
- *Announced next-generation novel mitomycin-based RTGel formulations for LG-IR-NMIBC and LG-UTUC programs from medac GmbH licensing agreement with potential IP protection until December 2041*
- *JELMYTO® achieved net product revenues of $82.7 million in 2023, an increase of ~28% compared with 2022*
- *Announced signing of a restructured agreement with Pharmakon Advisors that provides more favorable terms and provides UroGen up to an additional $100 million credit facility*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J. March 14, 2024— 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, 2023, and provided an overview of recent developments.

“In 2023, UroGen achieved important operational and clinical milestones, setting us up for further success in the coming years,” said Liz Barrett, President, and Chief Executive Officer of UroGen. “The Phase 3 ATLAS and ENVISION trials both produced meaningful and unprecedented results underscoring the potential of UGN-102 to fundamentally change the way patients with low-grade intermediate-risk non-muscle invasive bladder cancer are treated. We look forward to reporting the 12-month duration of response data from ENVISION in the second quarter of 2024 and to completing submission of an NDA in September of this year. UGN-102 has the potential to address a more than $3 billion market opportunity and, if approved, has the potential to be transformative for our company. JELMYTO continues to show double digit growth with patient and physician adoption expected to continue to increase.”

2023 and Recent Business Highlights:

UGN-102 (mitomycin) for intravesical solution:

- In January 2024, UroGen initiated submission of a rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for UGN-102 as a treatment of low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The first part of the submission was the Chemistry, Manufacturing and Controls (CMC) sections. The FDA indicated that evaluation of duration of complete response at 12-months from the pivotal ENVISION trial will be sufficient to support submission of the NDA. The company plans to complete the submission in September 2024 with a potential FDA decision as early as the first quarter of 2025.

- Positive top-line data from ATLAS Phase 3 clinical trial highlighting UGN-102 as non-surgical treatment option for LG-IR-NMIBC published in The Journal of Urology.

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

- Generated annual net product revenue of $82.7 million in 2023, compared with $64.4 million in 2022 in representing ~28% annual growth.
- Patient enrollment forms, new patient starts, and total doses each grew approximately 25% year-over-year. First-time writers, activated sites and repeat accounts also continue to grow.
- A retrospective study investigated whether patients with higher-volume low-grade disease could achieve disease-free status using partial ablation or biopsy before JELMYTO treatment during initial ureteroscopy. The study found no significant difference in disease-free rates between complete ablation (78.6), partial ablation (57.6%), or biopsy-only (66.7%) groups during initial ureteroscopy. Tumor size prior to JELMYTO induction also showed no significant impact on disease-free rates. The study aimed to find alternatives to nephroureterectomy for preserving kidney function and to assess JELMYTO's efficacy in managing larger volume disease. Findings from the study were published online in Urologic Oncology: Seminars and Original Investigations online.

Next-generation novel mitomycin-based formulation for urothelial cancers

- In January 2024, UroGen announced a license and supply agreement with medac GmbH to develop a next-generation novel mitomycin-based formulation for urothelial cancers. UGN-103 and UGN-104 combine UroGen's *RTGel*® technology with medac's licensed mitomycin formulation. The agreement and development program potentially allow UroGen to extend the patent protection on its urothelial cancer franchise. medac has intellectual property protection for its mitomycin formulation expected to last until June 2035 and UroGen has pending U.S. patent applications which may provide protection until December 2041.
- UroGen plans to initiate Phase 3 studies to explore the safety and efficacy of UGN-103 and UGN-104 in LG-IR-NMIBC and LG-UTUC, respectively, in 2024.

Up to $100 Million Letter of Credit Facility with Funds Managed by Pharmakon

- Announced signing of a restructured loan agreement with Pharmakon Advisors providing UroGen additional funding of up to $100 million. Under the terms of the restructured agreement, the interest rate on the previously funded $100 million loan is reduced, and the initiation of the payback period will be delayed following UGN-102 approval. The restructured agreement also includes a credit facility of up to $100 million. As part of the agreement, UroGen is required to draw down on the first tranche of $25 million of the credit facility by September 30, 2024, and will have the option to access as much as an additional $75 million following UGN-102 approval.

Fourth Quarter and Full Year 2023 Financial Results

JELMYTO Revenue: UroGen reported JELMYTO net product revenues of $23.5 million in the fourth quarter of 2023, compared to $18.1 million for the same period in 2023. Net JELMYTO product revenue for the full year 2023 was $82.7 million, compared to $64.4 million in 2022. Despite strong unit growth, full year 2023 net revenues were impacted by higher than forecast 340B chargebacks and first time estimated Medicare refunds for discarded drug, offset by non-patient purchases.

R&D Expense: Research and development expenses for the fourth quarter of 2023 were $11.3 million, including non-cash share-based compensation expense of $0.5 million as compared to $14.5 million, including non-cash share-based compensation expense of $0.6 million, for the same period in 2022. Research and development expenses for the full year 2023 were $45.6 million, including non-cash share-based compensation expense of $1.9 million as compared to $52.9 million, including non-cash share-based compensation expense of $2.6 million, in 2022.

SG&A Expense: Selling, general and administrative expenses for the fourth quarter of 2023 were $24.6 million, including non-cash share-based compensation expense of $2.1 million. This compares to $21.6 million, including non-cash share-based compensation expense of $1.8 million, for the same period in 2022. Selling, general and administrative expenses for the full year 2023 were $93.3 million, including non-cash share-based compensation expense of $7.4 million. This compares to $82.8 million, including non-cash share-based compensation expense of $8.0 million, 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 in the fourth quarter of 2023, compared to $5.1 million in the same period in 2022. Non-cash financing expense related to the RTW Investments obligation was $21.6 million for the full year 2023, compared to $21.6 million in 2022. The rate applied to cash payments incurred in 2023 is 13% based on global JELMTYO net product sales of $82.7 million in 2023.

Interest Expense on Long-Term Debt: Interest expense related to the $100 million term loan facility with funds managed by Pharmakon Advisors was $3.6 million and $14.7 million, respectively for the fourth quarter and full year 2023, compared to $3.2 million and $8.4 million in the same periods in 2022. The higher amount in 2023 was a result of interest expense for four full quarters in 2023, whereas the first and second tranches of the loan were funded in March 2022 and December 2022, respectively.

Net Loss: UroGen reported a net loss of $26.0 million or ($0.72) per basic and diluted share in the fourth quarter of 2023 compared with a net loss of $28.9 million or ($1.25) per basic and diluted share in the same period in 2022. Net loss was $102.2 million or ($3.55) per basic and diluted share in the full year 2023 compared with a net loss of $109.8 million or ($4.81) per basic and diluted share in 2022.

Cash & Cash Equivalents: As of December 31, 2023, cash, cash equivalents and marketable securities totaled $141.5 million.

2024 Revenue, Operating Expense and RTW Expense Guidance: The Company anticipates full year 2024 net product revenues from JELMYTO to be in the range of $95 to $102 million. Increased discounts related to Medicare refunds for discarded drugs and 340B purchases will further impact net revenues in 2024. The Company also expects full year 2024 operating

expenses in the range of $175 to $185 million, including non-cash share-based compensation expense of $6 to $11 million, subject to market conditions. The Company also reiterates anticipated full year 2024 non-cash financing expense related to the prepaid obligation to RTW Investments in the range of $21 to $26 million. Of this amount approximately $12.4 to $13.3 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)

	December 31, 2023	December 31, 2022
Cash and cash equivalents and marketable securities	$ 141,469	$ 99,963
Total assets	$ 178,311	$ 135,619
Total liabilities	$ 243,523	$ 224,980
Total shareholders' deficit	$ (65,212)	$ (89,361)

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

	Three months ended December 31, (Unaudited)		Year ended December 31,	
	2023	2022	2023	2022
Revenue[1]	$ 23,530	$ 18,092	$ 82,713	$ 64,357
Cost of revenue	2,286	2,263	9,361	7,654
Gross profit	21,244	15,829	73,352	56,703
Operating expenses:				
Research and development expenses	11,302	14,477	45,614	52,906
Selling, general and administrative expenses	24,551	21,634	93,274	82,838
Total operating expenses	35,853	36,111	138,888	135,744
Operating loss	(14,609)	(20,282)	(65,536)	(79,041)
Financing on prepaid forward obligation	(5,505)	(5,081)	(21,552)	(21,559)
Interest expense on long-term debt	(3,586)	(3,223)	(14,715)	(8,438)
Interest and other income, net	1,538	406	3,479	1,010
Loss before income taxes	$ (22,162)	$ (28,180)	$ (98,324)	$ (108,028)
Income tax expense	(3,854)	(689)	(3,920)	(1,775)
Net loss	$ (26,016)	$ (28,869)	$ (102,244)	$ (109,783)
Net loss per ordinary share basic and diluted	$ (0.72)	$ (1.25)	$ (3.55)	$ (4.81)
Weighted average shares outstanding, basic and diluted	36,153,634	23,088,891	28,834,303	22,806,812

1. 2023 full-year Jelmyto net revenues include gross-to-net unfavorability driven by higher 340b chargebacks and estimated Medicare refunds for discarded drugs, offset by $4.4 million in CREATES Act sales, of which $2.4 million was realized in Q4 2023.

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 innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of low-grade, intermediate-risk, non-muscle invasive bladder cancer (LG-IR-NMIBC). Utilizing UroGen's proprietary *RTGel*® technology, a 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 in an outpatient setting. Assuming positive findings from the durability of response endpoint from the ENVISION Phase 3 study, UroGen anticipates completing its NDA submission for UGN-102 in September with a potential FDA decision as early as the first quarter of 2025.

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 low-grade upper tract urothelial cancer 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 X (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: operational and clinical milestones achieved in 2023 will set the Company up for further success in the coming years; the potential of UGN-102 to fundamentally change the way patients with LG-IR-NMIBC are treated; the expected timing for the release of 12-month duration of response data from ENVISION in the second quarter of 2024 and that such data will be sufficient to support the submission of an NDA for UGN-102; the expected timing for completing a submission of an NDA to the FDA for UGN-102 and the potential FDA decision; the potential of UGN-102 to address more than $3 billion in market opportunity and to be transformative to the Company; expectations that JELMYTO patient and physician adoption is expected to continue to increase; the potential of the license and supply agreement with medac GmbH to allow UroGen to extend patent protection on its urothelial cancer franchise; UroGen's pending U.S. patent applications potentially providing protection for UGN-103 and UGN-104 until December 2041; UroGen's plans to initiate Phase 3 studies to explore the safety and efficacy of UGN-103 and UGN-104 in 2024; UroGen's ability to access an additional $75 million under the amended credit facility with Pharmakon Advisors, in addition to the required $25 million draw; UroGen's 2024 financial guidance; 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. Words and phrases such as "anticipate," "assume," "believe," "expected," "if," "indicate," "look forward to," "potential," "will," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. 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; the ability to obtain regulatory approval within the timeframe expected, or at all; the findings from the durability of response endpoint from the ENVISION Phase 3 study may not be positive, and in such event, UroGen's NDA pathway could be negatively impacted; even if the durability of response endpoint data from the ENVISION Phase 3 study are positive 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; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; UroGen's ability to access the additional $75 million under the amended credit facility with Pharmakon Advisers (in addition to the required $25 million draw) is subject to certain drawdown conditions; the ability to maintain regulatory approval; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; 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) for our product and product candidates 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; and 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 September 30, 2023, filed with the SEC on November 14, 2023, and in UroGen's Annual Report on Form 10-K for the year ended December 31, 2023, being filed with the SEC today (available at www.sec.gov), 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240124917135/en/

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