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): May 13, 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 May 13, 2024, UroGen Pharma Ltd. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024. 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 May 13, 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: May 13, 2024

UROGEN PHARMA LTD.

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

UroGen Pharma Announces Date for ENVISION Data, New Long-Term Jelmyto Durability Data, and Reports 2024 First Quarter Financial Results and Business Highlights

- *12-month duration of response data from ENVISION study of UGN-102 to be discussed during company sponsored virtual event on June 13, 2024*
- *ENVISION data expected to support completion of UGN-102 NDA in Q3 2024*
- *Post-hoc analysis of OLYMPUS study for JELMYTO shows disease-free periods more than 47.8 months in LG-UTUC*
- *JELMYTO® demonstrated continued growth with net product sales of $18.8 million in Q1, compared with $17.2 million in Q1 2023 representing ~10% YoY growth*
- *IND accepted for UGN-103, next-generation novel mitomycin-based formulation of UGN-102 to treat LG-IR-NMIBC*
- *Conference call and webcast to be held today at 10:00 AM ET*

PRINCETON, N.J. May 13, 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 first quarter ended March 31, 2024, and provided an overview of recent developments.

“In 2024 to date, UroGen has made excellent progress in both our commercial business and pipeline of innovative products designed to treat urothelial and specialty cancers,” said Liz Barrett, President, and Chief Executive Officer of UroGen. “The upcoming announcement of 12-month duration of response results from ENVISION will be a key clinical milestone and we expect the data to support completion of our NDA for UGN-102. Pre-launch activities are underway and we estimate that UGN-102 will address a more than $3 billion market opportunity. If approved, we believe this product will become the major growth driver for UroGen and could establish a new standard of care in LG-IR-NMIBC.”

Q1 2024 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 company plans to complete the submission in Q3 2024 with a potential FDA decision as early as the first quarter of 2025.
- In May 2024, a subgroup analysis from the UGN-102 ATLAS trial was featured in a podium presentation at the American Urological Association (AUA) 2024 Annual Meeting in San Antonio, Texas. The analysis showed that patients with new and recurrent LG-IR-NMIBC treated with UGN-102 ± TURBT (trans urethral resection of bladder tumor) had high probabilities of remaining event-free for disease free survival (DFS) and high probabilities of remaining in complete response.

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

- A soon-to-be-published post-hoc analysis of the OLYMPUS trial assessed the long-term effects in treating LG-UTUC with JELMYTO. Of the 71 patients who enrolled in OLYMPUS, 41 achieved a complete-response and their health outcomes were tracked for up to 12 months. 20 of these patients remaining in CR enrolled in a 5-year rollover study. All 41 patients with an initial CR indicated a promising median duration of response of 47.8 months, based on a median follow-up of 28.1 months. In the 5-year rollover trial, 75% (N=15) showed no disease recurrence, indicating potential for extended disease-free periods.
- JELMYTO was featured in three presentations at the AUA 2024 Annual Meeting. Independent long-term real-world analyses explored use of the product in broad patient types and with different methods of administration. The results show that JELMYTO treatment demonstrated favorable recurrence free survival rates for patients with LG-UTUC who respond to initial induction. The results were consistent regardless of JELMYTO administration, original tumor size, multifocality or tumor location.
- Continued strong demand for Jelmyto with record patient enrollments forms. Generated net product revenue of $18.8 million in the first quarter of 2024, compared with $17.2 million in the first quarter of 2023, representing ~10% annual growth.

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 offer both manufacturing efficiencies and IP protection for the Company's next-generation urothelial cancer franchise.
- In April 2024, the FDA accepted the Company's Investigational New Drug (IND) application for UGN-103. If approved, UGN-103 is expected to provide several advantages related to production, cost, supply, and product convenience.
- UroGen plans to initiate Phase 3 studies to explore the safety and efficacy of UGN-103 in LG-IR-NMIBC in 2024 and UGN-104 in LG-UTUC shortly thereafter.

First Quarter 2024 Financial Results

JELMYTO Revenue: JELMYTO net product revenues were $18.8 million and $17.2 million for the three months ended March 31, 2024 and 2023, respectively.

R&D Expense: Research and development expenses for the first quarter of 2024 were $15.5 million, including non-cash share-based compensation expense of $0.5 million as compared to $12.5 million, including non-cash share-based compensation expense of $0.5 million, for the same period in 2023.

SG&A Expense: Selling, general and administrative expenses for the first quarter of 2024 were $27.3 million, including non-cash share-based compensation expense of $2.2 million. This compares to $24.5 million, including non-cash share-based compensation expense of $1.8 million, for the same period in 2023.

Financing on Prepaid Forward Obligation: UroGen reported non-cash financing expense related to the prepaid forward obligation to RTW Investments of $5.7 million in the first quarter of 2024, compared to $5.2 million in the same period 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 $2.4 million in the first quarter of 2024, compared to $3.6 million in the same period in 2023.

Net Loss: UroGen reported a net loss of $32.3 million or ($0.97) per basic and diluted share in the first quarter of 2024 compared with a net loss of $30.2 million or ($1.30) per basic and diluted share in the same period in 2023.

Cash & Cash Equivalents: As of March 31, 2024, cash, cash equivalents and marketable securities totaled $164.5 million.

2024 Revenue, Operating Expense and RTW Expense Guidance: The Company is reiterating full year 2024 net product revenues guidance from JELMYTO 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 the 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)

	March 31, 2024	December 31, 2023
Cash and cash equivalents and marketable securities	$ 164,525	$ 141,470
Total assets	$ 200,574	$ 178,311
Total liabilities	$ 240,708	$ 243,523
Total shareholders' deficit	$ (40,134)	$ (65,212)

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,	
	2024	2023
Revenue	$ 18,781	$ 17,192
Cost of revenue	1,728	2,265
Gross profit	17,053	14,927
Operating expenses:		
Research and development expenses	15,494	12,498
Selling, general and administrative expenses	27,299	24,474
Total operating expenses	42,793	36,972
Operating loss	(25,740)	(22,045)
Financing on prepaid forward obligation	(5,660)	(5,224)
Interest expense on long-term debt	(2,447)	(3,553)
Interest and other income, net	1,615	630
Loss before income taxes	$ (32,232)	$ (30,192)
Income tax expense	(54)	(21)
Net loss	$ (32,286)	$ (30,213)
Net loss per ordinary share, basic and diluted	$ (0.97)	$ (1.30)
Weighted average shares outstanding, basic and diluted	33,379,786	23,279,951

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. 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: the Phase 3 ENVISION trial, including the expected release of data in June 2024; the estimated addressable patient population and market and revenue opportunity for UGN-102; the expectation UGN-102 will be a significant driver of UroGen's future growth; potential for UGN-102 to establish a new standard of care in LG-IR-NMIBC; UroGen's plans to complete its NDA submission for UGN-102 in the third quarter of 2024, with a potential FDA decision as early as the first quarter of 2025; the potential advantages of treatment with UGN-102 ± TURBT over TURBT alone; publication of the post-hoc analysis of the OLYMPUS trial that assessed the long-term effects in treating LG-UTUC with JELMYTO; the interpretation and summary of results of ENVISION, OLYMPUS, and ATLAS trials; potential for the license and supply agreement with medac to offer both manufacturing efficiencies and IP protection; the timing for the planned Phase 3 trial of UGN-103 and the potential approval of UGN-103; the timing of the planned Phase 3 trial of UGN-104; the potential of UroGen's proprietary RTGel technology to improve therapeutic profiles of existing drugs; and the potential of UroGen's sustained release technology to make local delivery more effective as compared to other treatment options. Words such as "anticipate," "could," "may," "plan," "potential," "soon-to-be," "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; findings from the durability of response endpoint from the ENVISION Phase 3 study may not be sufficient to support UroGen's NDA; 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; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; 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) for UroGen's 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 14, 2024, 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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