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 1, 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 7.01 Regulation FD Disclosure.

Recently, UroGen Pharma Ltd. (the "Company," "UroGen," "we," "our," or "us") received a Paragraph IV Certification Notice Letter (the "Notice Letter") from Teva Pharmaceuticals, Inc. ("Teva"), providing notification to the Company that Teva has submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, use or sell a generic version of *Jelmyto*® (mitomycin) for pyelocaliceal solution.

In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069 each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission.

"We've known it was only a matter of time before others came to recognize what we've known for a very long time – UroGen is on the forefront of changing how urothelial cancers are treated," said Liz Barrett, President and Chief Executive Officer of UroGen. "We are only at the beginning of tapping into the market opportunity of what we've pioneered and clearly, others are now seeing the potential. Accordingly, we are prepared for such a filing and feel confident in the strength and breadth of our patent portfolio."

The information in this Item 7.01 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although the Company believes that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, the Company can give no assurance that such expectations and assumptions will prove to be correct. Forward-looking statements include all statements that are not historical facts and can generally be identified by terms such as "could," "estimate," "expect," "intend," "may," "plan," "potentially," or "will" or similar expressions and the negatives of those terms. These statements include, but are not limited to, statements regarding UroGen's potential to change how urothelial cancers are treated and tap into the market opportunity that it has pioneered; and UroGen's confidence in the strength and breadth of its patent portfolio. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors relate to, among others: the ability obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; the costs and outcome of legal proceedings to enforce such intellectual property rights; competition in UroGen's industry, including the approval and introduction of generic or branded products that compete with our product or product candidates; the ability to maintain regulatory approval; complications associated with commercialization activities; the scope, progress and expansion of developing and commercializing UroGen's product candidates; the timing and success of clinical trials and potential safety and other complications thereof; 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; and UroGen's financial condition and need for additional capital in the future. These and other factors are described in greater detail under the "Risk Factors" heading of the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, filed with the SEC on November 14, 2023. All information provided in this report is as of the date of this report, and any forward-looking statements contained herein are based on assumptions that the Company believes to be reasonable as of this date. Undue reliance should not be placed on the forward-looking statements in this report, which are based on information available to us on the date hereof. The Company undertakes no duty to update this information unless required by law.

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 1, 2024

UROGEN PHARMA LTD.

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