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): January 16, 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 1.01 Entry into a Material Definitive Agreement.

On January 16, 2024, UroGen Pharma Ltd. (the "Company") entered into a license and supply agreement (the "Agreement") with Medac Gesellschaft für klinische Spezialpräparate m.b.H. ("medac"), pursuant to which medac granted to the Company an exclusive, worldwide, royalty-free, sublicensable license under medac's intellectual property rights to develop, commercialize, import, export, use, distribute and register the pharmaceutical lyophilized product—a specific 80 mg formulation of mitomycin and 640 mg urea, manufactured according to medac's proprietary lyophilization process (the "Product")—as an integrated part of a pharmaceutical product that includes the Product and a reverse thermal gel, including the Company's RTGel® reverse thermal hydrogels (the "Combined Product"). The Product was developed pursuant to a Development Agreement between the Company and medac dated August 18, 2019, as amended.

Pursuant to the Agreement, medac has agreed to manufacture and supply the Company's requirements for Product for commercial use at an agreed upon price, which may be renegotiated on an annual basis upon request of one of the parties. The Company is responsible for development, commercialization, and regulatory approval activities, and medac agreed to use commercially reasonable efforts to provide reasonable and timely assistance for information and documents regarding the Product for use in obtaining and maintaining regulatory approvals. Pursuant to the Agreement, the Company retains the unlimited right to source from a party other than medac any lyophilized mitomycin for use in any Company product, including Jelmyto® (mitomycin) for pyelocalyceal solution and UGN-102, that: a) includes mannitol as an excipient; and b) is not manufactured according to the medac patents listed in the Agreement.

Unless earlier terminated in accordance with the terms of the Agreement, the Agreement (a) will remain in effect for the United States until the expiration of the last to expire licensed patent; and (b) will remain in effect for countries other than the United States, for 10 years after the date of the Agreement, automatically renewing for successive two year terms unless the Company or medac provides written notice to the other at least 180 days in advance of the end of the then existing term that it does not wish to renew the term of the Agreement for such country. medac has the right to terminate the Agreement if the Company does not progress development or suspends commercialization of a Combined Product in accordance with the terms of the Agreement or if a Combined Product is not approved in the United States by June 30, 2029. If a marketing authorization of the Combined Product is not approved in a country in the territory or such approval is withdrawn or cancelled in such country, medac has the right to terminate the Agreement with respect to such country upon 60 days' advance notice to the Company. If the Company suspends commercialization of a Combined Product in any country and fails to resume commercialization 18 months following delivery to medac of a written plan of action to resume commercialization, medac may terminate the Agreement with respect to such country upon 30 days' advance notice to the Company. Furthermore, either party may terminate the License Agreement in the event of an uncured material breach of the other party.

Item 8.01 Other Events.

On January 17, 2024, the Company announced its plan to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-103 in low-grade, intermediate risk, non-muscle invasive bladder cancer. UGN-103 is intended to be a next-generation version of UGN-102 that combines medac's mitomycin formulation (i.e., the Product) with the Company's RTGel technology, which the Company believes will provide advantages related to production, cost, supply and product convenience. With medac's intellectual property protection for its mitomycin formulation expected to last until June 2035 and the Company's pending U.S. patent applications, the Company projects potential intellectual property protection on UGN-103 until December 2041.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including without limitation statements regarding activities to be performed under the Agreement, the timing for the planned Phase 3 trial of UGN-103, the potential advantages of UGN-103 and anticipated intellectual property protection. The words "estimate," "may," "plan," "project," "potential," "will," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations

disclosed in these forward-looking statements as a result of various factors, including risks relating to the 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, reporting data and initiating product launches; 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, our 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 our NDA for UGN-102 will be sufficient to support approval of UGN-102 on 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 the Company's industry; the scope, progress and expansion of developing and commercializing the Company's product candidates; the Company's pending patent applications may not be successful and in such event the duration of our intellectual property protection would be more limited; we and our third-party licensors may be subject to claims that we or they infringe, misappropriate or otherwise violate the intellectual property rights of third parties; licensors or collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; risks related to our and our licensors' ability to protect our respective patents and other intellectual property; 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; the Company's ability to attract or retain key management, members of the board of directors and personnel; the Company's RTGel technology may not perform as expected; the Company may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; and the Company'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 the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the SEC on November 14, 2023, the events and circumstances discussed in such forward-looking statements may not occur, and the Company'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 report and are based on information available to the Company as of the date of this report.

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: January 17, 2024

UROGEN PHARMA LTD.

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