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): December 28, 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 1.01 Entry into a Material Definitive Agreement.

On December 28, 2023, UroGen Pharma Ltd. (the "Company") entered into Amendment No. 2 (the "Amendment") to its Manufacturing & Supply Agreement with Cenexi-Laboratoires Thissen S.A. ("Cenexi"), dated as of April 24, 2020 and amended as of March 2, 2022 (as amended by the Amendment, the "Agreement"). Pursuant to the Amendment, and in anticipation of the potential approval and subsequent launch of UGN-102, (i) the parties extended the initial term of the Agreement through April 1, 2027, (ii) the Company revised its minimum annual quantity (MAQ) forecast of bulk product (mitomycin) purchases under the Agreement, (iii) the parties agreed to certain terms, and agreed to a schedule to negotiate other terms of conditions, related to Cenexi's purchase, installation, validation and qualification of certain capital equipment for use exclusively in the manufacture of mitomycin product to be supplied to the Company under the Agreement (the "Dedicated Equipment"), and the performance of refurbishment activities, and (iv) the Company agreed to reimburse Cenexi for up to approximately €4.4 million in connection with the purchase and other activities described in the foregoing clause (iii), to be expensed in accordance with a budget and payment timeline to be negotiated by the parties.

Forward-Looking Statements

This report contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding: the potential approval and subsequent launch of UGN-102; the future negotiation of the terms and conditions of the purchase, installation, validation and qualification of the Dedicated Equipment and the performance of refurbishment activities. 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, reporting data and initiating product launches; the findings from the durability of response endpoint from the ENVISION Phase 3 study may not be positive, and in such event, the Company's NDA pathway for UGN-102 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 NDA for UGN-102 will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; the Company and Cenexi may not be able to successfully agree upon the terms and conditions related to the Dedicated Equipment; and third-party performance. 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 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 2, 2024

UROGEN PHARMA LTD.

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