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): November 10, 2021

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** **(Address of principal executive offices)**	**08540** **(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 8.01 Other Events.

On November 10, 2021, UroGen Pharma Ltd. (the "Company") announced that, following recent discussions with the U.S. Food and Drug Administration, it plans to conduct a new, single-arm Phase 3 pivotal study of UGN-102 for the treatment of low-grade, intermediate-risk, non-muscle invasive bladder cancer. This new study, which is expected to initiate in early 2022, is expected to enroll approximately 220 patients across 90 sites. The Company believes this new study increases the probability of regulatory success for UGN-102 given its design, in addition to the encouraging results observed in the Company's Phase 2 OPTIMA II study. In light of the new planned Phase 3 study, the Company will stop enrollment in its ATLAS trial. Patients already enrolled in ATLAS will have the option to remain in the study until completion. The Company believes the data generated from the ATLAS study will represent an important component of the Company's planned NDA submission for UGN-102, which remains on track for 2024.

The Company is also currently conducting non-human primate toxicity studies to facilitate the initiation of a multi-arm Phase 1 study of UGN-301 in early 2022 to be followed by UGN-301 in combination with other agents. This approach leverages the Company's unique platform for drug delivery and provides an opportunity to evaluate intravesical delivery of its anti-CTLA4 monoclonal antibody in combination with other immuno-modulators, chemotherapies, gene therapy and innate immune stimulators.

Forward-Looking Statements

This report contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including statements regarding the new single-arm Phase 3 study for UGN-102 and the timing thereof, the timing of the planned NDA for UGN-102, and the planned Phase 1 studies of UGN-301 and the timing thereof. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: clinical trial enrollment challenges that may impact the expected timing of our planned clinical trials, including challenges related to the ongoing COVID-19 pandemic; the timing and success of clinical trials and potential complications thereof; the Company's ability to attract or retain key management, members of the board of directors and personnel; and any negative effects on the Company's business, commercialization and product development plans caused by or associated with COVID-19. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of the Company's Form 10-Q filed with the SEC on August 4, 2021 and other filings that the Company makes with the SEC from time to time (which are available at http://www.sec.gov), 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: November 10, 2021

UROGEN PHARMA LTD.

By: /s/ Molly Henderson
Molly Henderson
Chief Financial Officer