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 17, 2020

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

N/A
(Former name or former address, if changed since last report.)

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 17, 2020, UroGen Pharma Ltd. (the "Company") announced final topline results from its single-arm, open-label OPTIMA II Phase 2b trial evaluating the efficacy and safety of investigational UGN-102 (mitomycin) for intravesical solution in patients with low-grade intermediate risk non-muscle invasive bladder cancer ("LG IR-NMIBC").

As previously reported, 65% (41/63) of patients receiving UGN-102 achieved a complete response ("CR") three months after the start of therapy. In this subset of patients, duration of response at nine months (12-months from start of therapy) was estimated by Kaplan-Meier analysis to be 72.5%. Median duration of response was not reached. The Company expects to initiate a Phase 3 study evaluating UGN-102 versus current standard of care by the end of the year.

The majority of the most common adverse events (³ 10%) were reported as mild to moderate in severity and include dysuria, urinary frequency, hematuria, urinary urgency, urinary tract infection and fatigue.

The Company anticipates submitting the final topline data from this trial for presentation at an upcoming medical meeting as well as potential publication in a peer-reviewed journal.

OPTIMA II (OPTimized Instillation of Mitomycin for Bladder Cancer Treatment) is an open-label, single-arm, multi-center Phase 2b clinical trial of investigational agent UGN-102 for intravesical solution to evaluate its safety and efficacy in patients with low-grade non-muscle invasive bladder ("LG NMIBC") cancer at intermediate risk of recurrence. Intermediate risk is defined as one or two of the following: multiple tumors, solitary tumor >3 cm, or recurrence (³ 1 occurrence of LG NMIBC within one year of the current diagnosis). Patients were to receive six weekly intravesical instillations of 75 mg UGN-102 in an office setting. The chemoablative effect of UGN-102 was assessed three months after initiation of study treatment with CR defined as a negative endoscopic examination, negative cytology, and when indicated, a negative for-cause biopsy. Patients achieving CR were followed quarterly to 12 months after initiation of study treatment to evaluate safety, efficacy, and durability.

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: the expected initiation of the Phase 3 trial of UGN-102 in LG IR-NMIBC by the end of 2020; and the submission of UGN-102 data for presentation at an upcoming medical meeting as well as potential publication in a peer-reviewed journal. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to risks associated with clinical development. 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 Securities and Exchange Commission ("SEC") on November 9, 2020, 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 release and the Company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
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: November 17, 2020

UROGEN PHARMA LTD.

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