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): May 15, 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** **(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 May 15, 2020, UroGen Pharma Ltd. (the "Company") announced the presentation of positive interim data from the Phase 2b OPTIMA II trial evaluating the safety and efficacy of investigational agent UGN-102 (mitomycin) for intravesical solution in patients with low-grade intermediate risk non-muscle invasive bladder cancer ("LG IR-NMIBC"). The study was accepted for the 2020 American Urological Association ("AUA") Annual Meeting, published as a supplement to the April 2020 issue of *The Journal of Urology*® and presented as part of the AUA Virtual Experience.

Trial results showed that 65% (41/63) of patients treated with UGN-102 achieved a complete response ("CR") three months after the start of therapy. In this subset of patients, 97% (35/36) of patients (95% Confidence Interval), 86% (24/28) of patients and 85% (11/13) of patients who were present for evaluation at each timepoint, remained disease free at six, nine and 12 months following treatment initiation, respectively. Follow-up will continue until all patients have reached the 12-month time point.

In OPTIMA II, the most common adverse events (≥ 10%) were reported as mild to moderate and include dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection. Discussions for the planned Phase 3 clinical trial protocol for the study of UGN-102 in patients with LG IR-NMIBC are underway with the U.S. Food and Drug Administration.

OPTIMA II (OPTimized Instillation of Mitomycin for BlAdder Cancer Treatment) is an open-label, single-arm, multi-center Phase 2b clinical trial of UGN-102 for intravesical solution to evaluate its safety and efficacy in patients with low-grade non-muscle invasive bladder cancer ("LG NMIBC") at intermediate risk of recurrence. Intermediate risk is defined as one or two of the following: multiple tumors, solitary tumor >3 cm, or recurrence (≥ 1 occurrence of LG NMIBC within 1 year of the current diagnosis). The trial enrolled 63 patients at clinical sites across the United States and Israel. Study participants were treated with six weekly instillations of UGN-102 administered via a standard intravesical catheter. Four to six weeks following the last instillation, patients were evaluated for the purpose of evaluating the primary study endpoint, CR. The evaluation included cystoscopy and wash cytology, a standard microscopic test of cells obtained from the urine to detect cancer. Patients who achieve a CR were then followed quarterly, out to 12 months post treatment initiation, to determine the durability of disease control with UGN-102.

UGN-102 for intravesical solution is an investigational drug formulation of mitomycin in Phase 2b development for the treatment of LG IR-NMIBC. Utilizing the RTGel™ Technology Platform, the Company's proprietary sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using a standard urinary catheter. The Company completed enrollment in the Phase 2b OPTIMA II trial in September 2019 and intends to advance the program to a pivotal study to further investigate UGN-102 in the treatment of this condition.

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 benefits of UGN-102 and the potential advancement of UGN-102 to a pivotal study. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials and potential safety and other complications thereof; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on May 7, 2020, and other filings that UroGen 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: May 15, 2020

UROGEN PHARMA LTD.

By: /s/ Peter Pfreundschuh
Peter Pfreundschuh
Chief Financial Officer