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 3, 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

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 December 3, 2020, UroGen Pharma Ltd. announced final data from the UGN-101 Jelmyto® (mitomycin) for pyelocalyceal solution Phase 3 OLYMPUS trial in patients with low-grade upper tract urothelial cancer (LG-UTUC).

Final results from the Phase 3 OLYMPUS trial of Jelmyto, the first and only non-surgical kidney-sparing treatment approved by the U.S. Food and Drug Administration (FDA) for adults with LG-UTUC, show that Jelmyto demonstrated clinically meaningful response in adults with LG-UTUC. In both the OLYMPUS intent-to-treat population and in the sub-population of patients who were deemed to have unresectable disease at study entry, 58% of patients achieved a complete response with durability of response at 12-months estimated to be 81.8% by Kaplan-Meier analysis. Median time to recurrence was not reached.

The safety profile in the final OLYMPUS data was consistent with previously reported results. The most common adverse events were uretic stenosis, urinary tract infection, hematuria, flank pain, nausea, dysuria, renal dysfunction, abdominal pain and vomiting.

OLYMPUS (Optimized DeLiverY of Mitomycin for Primary UTUC Study) is an open-label, single-arm Phase 3 clinical trial of UGN-101, Jelmyto (mitomycin) for pyelocalyceal solution, to evaluate the safety, tolerability and tumor ablative effect of Jelmyto in patients with low-grade UTUC. Seventy-one patients were treated at clinical sites across the United States and Israel. Study participants were treated with six weekly instillations of Jelmyto administered via a standard catheter. Four to six weeks following the last instillation, patients underwent a Primary Disease Evaluation (PDE) to determine Complete Response (CR), the primary endpoint of the study. PDE involved a ureteroscopy and wash cytology, a standard microscopic test of cells obtained from the urine to detect cancer and for cause biopsy. Patients who achieved a CR at the PDE timepoint were continued onto the maintenance phase of the trial, during which they were to receive monthly maintenance instillations for up to 12 months to determine the durability of response with Jelmyto.

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: December 3, 2020

UROGEN PHARMA LTD.

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