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): January 8, 2019

UROGEN PHARMA LTD.
(Exact name of registrant as specified in its charter)

Israel	**001-38079**	**Not applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

499 Park Avenue **New York, New York** **(Address of principal executive offices)**	**10014** **(Zip Code)**

Registrant's telephone number, including area code: (646) 768-9780

9 Ha'Ta'asiya Street
Ra'anana 4365007, Israel
(Former address)

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))

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 January 8, 2019, UroGen Pharma Ltd. issued a press release titled "UroGen Pharma Announces Positive Results of UGN-101 from Pivotal Phase 3 OLYMPUS Trial for the Non-Surgical Treatment of Patients with Low-Grade Upper Tract Urothelial Cancer (LG UTUC)" (the "Data Press Release"). A copy of the Data Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Data Press Release, issued by the Registrant on January 8, 2019.

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.

UROGEN PHARMA LTD.

Dated: January 9, 2019

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

UroGen Pharma Announces Positive Results of UGN-101 from Pivotal Phase 3 OLYMPUS Trial for the Non-Surgical Treatment of Patients with Low-Grade Upper Tract Urothelial Cancer (LG UTUC)

Data Demonstrates Complete Response (CR) Rate of 57 Percent in Patients with LG UTUC

All Evaluated Patients in CR Remain Disease Free at Six Months

Rolling Submission of New Drug Application (NDA) Initiated in December 2018

NEW YORK—(BUSINESS WIRE)—Jan. 8, 2019— UroGen Pharma Ltd. (Nasdaq:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, today announced topline results from the ongoing pivotal Phase 3 OLYMPUS clinical trial of UGN-101 (mitomycin gel) for instillation, an investigational mitomycin formulation for the non-surgical treatment of low-grade upper tract urothelial cancer (UTUC). This analysis showed that on an intent-to-treat basis, 57 percent of patients achieved a complete response (CR) rate at their primary disease evaluation (PDE, or the primary endpoint) which was conducted four to six weeks after completion of UGN-101 treatment. Importantly, all evaluated patients in CR remain disease free at six months.

This international, multi-center trial completed enrollment with 71 patients in December 2018. Of the 71 patients enrolled in the trial, 61 patients have been evaluated for the primary endpoint which was a CR as defined as a negative ureteroscopic evaluation and a negative wash cytology. The remaining 10 patients are awaiting PDE evaluation.

“We are pleased to report that the CR and durability data remain consistent with the Interim Analysis presented in May 2018. These results continue to validate the potential of UGN-101 to shift the surgical treatment paradigm and benefit patients whose only alternative would be repetitive endoscopic surgical intervention or complete loss of a kidney,” said Mark P. Schoenberg, M.D., Chief Medical Officer of UroGen. “The durability observed in the OLYMPUS study provides further evidence that the non-surgical treatment of LG UTUC with UGN-101 may result in clinically-meaningful, recurrence free survival. We are grateful to the patients, their families, and clinical investigators who have made this important study possible.”

Approximately 45 percent of tumors treated were categorized as unresectable by surgery at baseline. Of the patients who achieved CR, UroGen now has six-month durability on half of these patients. Durability is a key secondary endpoint for the trial.

The safety profile of UGN-101 continues to be acceptable with most treatment-emergent adverse events characterized as mild or moderate and transient and in line with ureteral procedures. These included ureteral narrowing and hydronephrosis, urinary tract infection, flank pain and creatinine elevation.

UroGen intends to seek regulatory approval of UGN-101 in LG UTUC based on data from all 71 patients and initiated its rolling submission of the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in December 2018. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of UTUC. If approved, UGN-101 would be the first drug approved for the non-surgical treatment of LG UTUC.

Seth Paul Lerner, M.D., FACS, Professor of Urology at Baylor College of Medicine in Houston, Texas served as Principal Investigator of the OLYMPUS trial.

About UGN-101

UGN-101 (mitomycin gel) for instillation is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade upper tract urothelial cancer (LG UTUC). Utilizing the RTGel™ technology platform, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-101 is designed to enable longer exposure of mitomycin to urinary tract tissue, thereby enabling the treatment of tumors by non-surgical means. UGN-101 is delivered to patients using standard ureteral catheters.

About UroGen Pharma Ltd.

UroGen Pharma Ltd. (Nasdaq:URGN) is a clinical-stage biopharmaceutical company developing advanced non-surgical treatments to address unmet needs in the field of urology, with a focus on uro-oncology. UroGen has developed RTGel™, a proprietary sustained release, hydrogel-based platform technology that has the potential to improve therapeutic profiles of existing drugs. UroGen's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. UroGen's lead product candidates, UGN-101 and UGN-102, are designed to potentially remove tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma and bladder cancer, respectively. UroGen is headquartered in New York, NY with operations in Los Angeles, CA and Israel.

Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to whether treatment with UGN-101 will result in clinically-meaningful, recurrence free survival and the potential of UGN-101 to be the first non-surgical therapy for LG UTUC and the first drug ever approved in this indication, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials, including the Olympus pivotal Phase 3 trial, and potential safety and other complications thereof; the ability to obtain and maintain regulatory approval; the labeling for any approved product; the scope, progress and expansion of developing and commercializing UroGen Pharma's product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; and UroGen Pharma's ability to attract or retain key management,

members of the board of directors and personnel. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen Pharma's Form 20-F filed with the SEC on March 15, 2018 and other filings that UroGen Pharma 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 UroGen Pharma'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 press release and are based on information available to UroGen Pharma as of the date of this release.

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Source: UroGen Pharma Ltd.

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