UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the month of August, 2017

Commission File Number 001-38079

UROGEN PHARMA LTD.
(Translation of registrant's name into English)

9 Ha'Ta'asiya Street
Ra'anana 4365007, Israel
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

On August 29, 2017, UroGen Pharma Ltd. issued a press release, a copy of which is furnished as Exhibit 99.1 to this Form 6-K.

Exhibit

99.1	Press Release, dated August 29, 2017: UroGen Pharma Receives FDA Fast Track Designation for MitoGel™ for the Treatment of Upper Tract Urothelial Carcinoma (UTUC).

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, thereunto duly authorized.

UROGEN PHARMA LTD.

August 29, 2017

By: /s/ Gary S. Titus
Gary S. Titus
Chief Financial Officer

UroGen Pharma Receives FDA Fast Track Designation for MitoGel™ for the Treatment of Upper Tract Urothelial Carcinoma (UTUC)

Ra'anana, Israel, and New York, NY, August 29, 2017: UroGen Pharma Ltd. (NASDAQ: URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, with a focus on uro-oncology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the Company's lead product candidate, MitoGel™, for the treatment of patients with low-grade upper tract urothelial carcinoma (UTUC) not amendable to endoscopic resection or with contraindication to nephroureterectomy (removal of kidney and upper tract), including impaired renal function. MitoGel is currently being evaluated in the ongoing, single-arm, open-label, pivotal Phase 3 OLYMPUS clinical trial in patients with low-grade UTUC.

There are currently no drugs approved by the FDA for the treatment of UTUC. The current treatment of UTUC involves endoscopic surgical resection of visible cancer or complete removal of the affected kidney and ureter. However, endoscopic surgical resection of upper tract tumors is associated with a high rate of disease recurrence. Moreover, many patients are not amenable to endoscopic resection due to the anatomic complexity of the upper urinary tract, which often presents significant challenges to the resection of urothelial tumors. In such cases, patients frequently undergo complete removal of the affected kidney and ureter, which involves risks of major surgery and the long-term consequences of decreased renal function in this typically elderly population. MitoGel is designed to enable the potential treatment of patients with low-grade UTUC by non-surgical means.

"Uro-oncology is an area that has seen limited therapeutic innovation over the last several decades," said Arie Belldegrun, MD, Chairman of UroGen. "UroGen's broad product pipeline, including MitoGel for UTUC, aims to overcome the limitations and deficiencies of currently available treatment options for these cancers. Importantly, Fast Track designation will help potentially expedite the future regulatory review of MitoGel so we can execute on our goal of bringing this innovative product candidate to market as rapidly as possible."

The FDA's Fast Track Program is designed to facilitate the development and expedite the review of new drugs to treat serious conditions and fill an unmet medical need. The designation enables early and frequent communication between the FDA and a product sponsor throughout the drug development and review process. Through the Fast Track Program a product candidate may be eligible for accelerated approval, priority review and for the submission of completed sections of the new drug application (NDA) on a rolling basis prior to completion of the full application.

"MitoGel has the potential to become a first-line treatment for low-grade UTUC, sparing patients from invasive surgery as well as the potential risks and complications of kidney removal," said Ron Bentsur, Chief Executive Officer of UroGen. "We believe that the FDA's Fast Track designation for MitoGel underscores the significant unmet medical need facing UTUC patients and our goal is to bring MitoGel to this underserved patient population as quickly and efficiently as possible."

About UTUC

Non-muscle invasive upper tract urothelial carcinoma (UTUC) has an estimated annual incidence in the United States of up to 7,500 cases – about 5% to 10% of all new cases of urothelial cancer. There are approximately 2,500 new cases of low-grade UTUC in the U.S. with a prevalence of approximately 14,500. UTUC refers to cancer of the upper tract, which connects the bladder to the kidney, and the renal pelvis. The current standard of care for this cancer is complete or partial surgical removal of the involved

kidney and upper tract. For patients with a bilateral disease, an anatomic or functionally solitary kidney, medical comorbidities or low-grade disease that present with a limited number of tumors, a kidney-conserving alternative is considered, if possible. However, due to the specific anatomy and physiology of the upper tract and renal pelvis, the performance of organ-sparing endoscopic resection and instillation of neoadjuvant or adjuvant chemotherapy are often challenging, leading to high rates of recurrence. Continuous urine flow, the inability of the upper tract to retain a liquid volume under normal circumstances and the effects of systemic peristalsis result in short exposure time of active agents in the target area. This leads to poor efficacy and limited use of standard chemoablative agents in patients with UTUC. No drugs are currently FDA-approved for the treatment of UTUC.

About MitoGel™

Utilizing RTGel™, UroGen's proprietary sustained release, hydrogel-based formulation, MitoGel is designed to enable longer exposure of Mitomycin C to the urinary tract tissue, thereby potentially enabling the treatment of tumors by non-surgical means. MitoGel is administered to patients using standard intravesical catheters. The U.S. Food and Drug Administration (FDA) has granted both Orphan Drug and Fast Track designations to MitoGel for the treatment of low-grade UTUC.

About the OLYMPUS Trial

OLYMPUS (**O**ptimized De**L**ivery of **M**itomycin for **P**rimary **U**TUC **S**tudy) is an open-label, single-arm Phase 3 clinical trial of MitoGel to evaluate the safety, tolerability and tumor ablative effect of MitoGel in low grade UTUC patients. The trial, designed to be a single pivotal study for the approval of MitoGel in low-grade UTUC, is anticipated to enroll approximately 70 patients in clinical sites in the U.S. and Europe. The trial will also evaluate the durability of the tumor ablative effect of MitoGel.

About UroGen Pharma Ltd.

UroGen Pharma (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. The Company has developed RTGel, a proprietary sustained release, hydrogel-based formulation for potentially improving therapeutic profiles of existing drugs. UroGen Pharma'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 Pharma's lead product candidates, MitoGel and VesiGel, are designed to potentially remove tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade UTUC and bladder cancer. UroGen Pharma has offices located in both Ra'anana, Israel and New York, NY, USA.

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 the clinical development of MitoGel™ and other product candidates in UroGen Pharma's pipeline, the OLYMPUS pivotal Phase 3 clinical trial, the Fast Track Designation, which 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 complications thereof; the fact that the grant of Fast Track designation does not guarantee that we will experience a faster development process, review or approval of MitoGel compared to conventional FDA procedures, the possibility that the FDA could withdraw Fast Track designation if it believes that it is no longer supported by data from the MitoGel clinical development program; the ability to obtain and maintain regulatory approval; the labeling for any approved product; the scope, progress and expansion of developing and commercializing a product candidate, the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; and the maintenance of any

applicable collaborations. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of the final prospectus for UroGen Pharma's initial public offering of securities in the United States filed with the SEC on May 5, 2017 and other filings that UroGen Pharma makes with the SEC from time to time (which are available at http://www.edgar.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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