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 October, 2018

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 October 30, 2018, 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 October 30, 2018: FDA Grants Breakthrough Therapy Designation (BTD) for UroGen Pharma's UGN-101 for the Treatment of Patients with Low-Grade Upper Tract Urothelial Cancer (LG 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.

October 31, 2018

By: /s/ Ron Bentsur
Ron Bentsur
Chief Executive Officer

Exhibit 99.1

FDA Grants Breakthrough Therapy Designation (BTD) for UroGen Pharma's UGN-101 for the Treatment of Patients with Low-Grade Upper Tract Urothelial Cancer (LG UTUC)

UGN-101 Joins Select Group of Urologic Oncology Product Candidates to Receive BTD

On Track to Initiate Rolling Submission of UGN-101 New Drug Application (NDA) in Q4 2018

RA'ANANA, Israel & NEW YORK—(BUSINESS WIRE)—Oct. 30, 2018—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 Breakthrough Therapy Designation status to the Company's lead product candidate, UGN-101, (mitomycin gel) for instillation. UGN-101 is currently in Phase 3 development for the treatment of patients with low-grade upper tract urothelial cancer (LG UTUC). Breakthrough Therapy Designation is designed to expedite the development and review of new drugs to treat serious or life-threatening conditions, so patients may have access to therapies through FDA approval as soon as possible. The FDA previously granted both Orphan Drug and Fast Track designations to UGN-101 for the treatment of LG UTUC.

"We are very excited about receiving the Breakthrough Therapy Designation for UGN-101 and the potential to deliver this far less invasive, organ-sparing therapy option to patients," said Ron Bentsur, Chief Executive Officer of UroGen. "We look forward to working with the FDA as we prepare to initiate a rolling submission of the UGN-101 New Drug Application (NDA) later this year, with the potential to become the first drug ever approved as frontline treatment of LG UTUC."

"UGN-101 was developed to provide an effective alternative to current treatment options, that avoids the risks of surgery, anesthesia, and the deleterious effects of kidney removal," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "The Breakthrough Therapy Designation confirms that UGN-101 represents a novel and effective approach to treat this devastating disease, and we look forward to close collaboration with the FDA as we bring this potentially transformative therapy to patients with LG UTUC as quickly as possible."

In the United States, approximately 6,000 to 8,000 patients present with new or recurrent LG UTUC every year[1], and nearly 14,500 people are currently living with low-grade LG UTUC. LG UTUC is a rare malignant tumor of the cells lining the urinary tract. It most commonly presents in the elderly who also suffer from comorbid conditions such as hypertension, diabetes, obesity and the metabolic syndrome. There is a clear unmet medical need to provide effective, organ-sparing therapy for these patients because the current standard of care imposes significant burdens on both patients and the healthcare system. Patients diagnosed with LG UTUC typically face either complete removal of the kidney and/or partial removal of the ureter. In selected patients who present with a limited tumor burden, repetitive endoscopic tumor resection is employed when feasible. These interventions are surgical in nature and require anesthesia; and these procedures are associated with the typical risks for this patient population, including bleeding, infection, injury to adjacent organs, and the potential long-term morbidity associated with kidney removal. Due to the anatomy and physiology of the upper urinary tract and renal pelvis, organ-sparing endoscopic tumor resection is often challenging, leading to high rates of recurrence. Although the administration of water-based drug solutions has been used following surgery to treat patients with LG UTUC, evidence of the therapeutic benefit of this approach is lacking and none of these products have been approved for frontline therapy. Continuous urine flow and the inability of the upper urinary tract to retain a liquid volume under normal circumstances results in limited exposure of target tissue to aqueous medications. No therapeutic agent has ever been approved to treat LG UTUC.

The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates that use of the drug may result in substantial improvement on at least one clinically significant endpoint over available therapy. The Breakthrough Therapy Designation for UGN-101 is supported by data from the ongoing Phase 3 OLYMPUS clinical trial of UGN-101 for the non-surgical treatment of LG UTUC. Results from an interim analysis presented in May, 2018 showed a complete response (CR) rate of 59 percent (20 out of the interim analysis intent to treat population of 34 patients) who were evaluated for primary disease evaluation (PDE, or the primary endpoint). In addition, 15 percent (five of 34 patients) achieved a partial response. At the time of the interim analysis presentation, of the 20 patients who achieved a CR, 13 patients had reached three-month follow-up, and all remained in CR. Four of these 13 patients had reached six-month follow-up and one of the 13 patients had reached nine-month follow-up, and all remained in CR. UGN-101 appeared to be well-tolerated with most treatment-emergent adverse events characterized as mild or moderate and transient.

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 (LG) upper tract urothelial cancer (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 the urinary tract tissue, thereby potentially enabling the treatment of tumors by non-surgical means. UGN-101 is delivered to patients using standard intravesical 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 New York, NY with offices in Ra'anana, Israel and Los Angeles, CA.

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 effect of Breakthrough Therapy Designation on the potential regulatory approval of UGN-101, timing and results of clinical development and commercial prospects of UGN-101, and results from the OLYMPUS trial, 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 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.

[1] Margulis 2009; Cutress 2010; Primary Market Research

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Source: UroGen Pharma Ltd.

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