# 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): September 13, 2021**

# 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**<br>**Princeton, New Jersey** | **08540** |
|---|---|
| **(Address of principal executive offices)** | **(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 September 13, 2021, UroGen Pharma Ltd. (the "Company") announced final data from two key trials, evaluating the safety and efficacy of investigational agent UGN-102 (mitomycin) for intravesical solution in adult patients with low-grade intermediate risk non-muscle invasive bladder cancer ("LG IR-NMIBC") and *Jelmyto*® (mitomycin) for pyelocalyceal solution in adult patients with low-grade upper tract urothelial cancer ("LG-UTUC"). The results were presented at the virtual 2021 American Urological Association (AUA) Annual Meeting and published as a supplement to the September 10, 2021 issue of *The Journal of Urology*®.

**Phase 2b OPTIMA II**

A podium presentation of the final OPTIMA II trial results showed that 65% (41/63) of patients receiving UGN-102 achieved a complete response ("CR") three months after the start of therapy. In this subset of patients, 95% (39/41) of patients, 73% (30/41) of patients and 61% (25/41) of patients who were present for evaluation at each timepoint, remained disease free at six, nine and 12 months following treatment initiation, respectively. Thirteen patients had documented recurrences. The probability of durable response nine months after CR (12 months after treatment initiation) was estimated to be 73% by Kaplan-Meier analysis.

The most common adverse events (³10%) were reported as mild to moderate and included dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection.

**Phase 3 OLYMPUS**

Results of 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 for adults with LG-UTUC, demonstrated clinically meaningful response in adults with LG-UTUC. Of 71 patients who initiated treatment, trial results showed 58% (41/71) achieved CR with durability of response at 12 months estimated to be 81.8% by Kaplan-Meier analysis. In this subset of patients, 56% (23/41) remained in CR after 12 months, including 50% (6/12) who did not receive any maintenance instillations and 59% (17/29) who received ³1 maintenance instillation. The most common adverse reactions (³20%) reported in the OLYMPUS trial were ureteric obstruction, urinary tract infection, hematuria, flank pain, nausea, dysuria, renal dysfunction, vomiting, fatigue, and abdominal pain.

Results from a separate, post-hoc analysis of female patients from the OLYMPUS trial, showed similar CR and durability of CR to male patients, with 65.2% of female patients achieving CR and 71.4% maintaining durable CR at 12 months compared to 81% for the entire patient population. The most common adverse events were urinary tract infection, hematuria, ureteric stenosis, flank pain, vomiting, hydronephrosis, dysuria, and nausea. Additional research is warranted to more clearly define gender-related outcomes for female patients with LG-UTUC.

**About the Phase 2b OPTIMA II Trial**

OPTIMA II (OPTimized Instillation of Mitomycin for Bladder Cancer Treatment) is an open-label, single-arm, multi-center Phase 2b clinical trial of investigational agent UGN-102 (mitomycin) 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, a low grade solitary tumor >3 cm, or recurrence of LG NMIBC within one year of the current diagnosis. Patients were to receive six weekly intravesical instillations of 75 mg UGN-102 in an office setting. The chemoablative effect of UGN-102 was assessed three months after initiation of study treatment with CR defined as a negative endoscopic examination, negative cytology, and when indicated, a negative for-cause biopsy. Patients achieving CR were followed quarterly to 12 months after initiation of study treatment to evaluate safety, efficacy, and durability.

**About the Phase 3 OLYMPUS Trial**

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 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 eligible for the maintenance phase of the trial, during which they could receive monthly maintenance instillations for up to 12 months and were assessed to determine the durability of response with *Jelmyto*.

**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: September 13, 2021

**UROGEN PHARMA LTD.**

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