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): April 15, 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 **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 NIS 0.01 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.

FDA Approval of Jelmyto™ (mitomycin), formerly known as UGN-101

On April 15, 2020, the U.S. Food and Drug Administration ("FDA") granted expedited approval for Jelmyto (mitomycin), formerly known as UGN-101, for pyelocalyceal solution, a first-in-class treatment indicated for adults with low-grade upper tract urothelial cancer ("LG UTUC"). Jelmyto consists of mitomycin, an established chemotherapy, and sterile hydrogel, using our proprietary sustained release RTGel™ technology. It has been designed to enable longer exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means.

LG UTUC is a rare cancer that develops in the lining of the upper urinary tract, ureters and kidneys. In the U.S., there are approximately 6,000 - 7,000 new or recurrent LG UTUC patients annually. It is a challenging condition to treat due to the complex anatomy of the urinary tract system. The current standard of care includes multiple surgeries and most require a radical nephroureterectomy, which includes the removal of the renal pelvis, kidney, ureter and bladder cuff. Treatment is further complicated by the fact that LG UTUC is most commonly diagnosed in patients over 70 years of age, who may already have compromised kidney functionality and may suffer further complications as a result of major surgery.

The FDA approval is based on results from our Phase 3 OLYMPUS trial showing Jelmyto achieved clinically significant disease eradication in adults with LG UTUC. Findings include:

- Complete response ("CR") (primary endpoint) of 58% in the intent-to-treat population and in the sub-population of patients who were deemed not capable of surgical removal at diagnosis.
- At the 12-month time point for assessment of durability, 19 patients remained in CR, seven had experienced recurrence of disease and nine patients continued to be followed for the 12-month duration of response.
- Kaplan-Meier analysis estimated 12-month durability at 84% (based on interim data).
- The most commonly reported adverse events (≥ 20%) were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, fatigue, nausea, abdominal pain, dysuria, and vomiting. Most adverse events were mild to moderate and manageable using well established treatments. No treatment-related deaths occurred.

The FDA evaluated Jelmyto under Priority Review, which is reserved for medicines that may represent significant improvements in safety or efficacy in treating serious conditions. Jelmyto was also granted Breakthrough Therapy designation by the FDA, which was created to expedite the development and review of drugs developed for serious or life-threatening conditions with high unmet need.

Supplemental Risk Factor

In light of the continually evolving COVID-19 global pandemic and related government guidelines, we are supplementing the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 2, 2020 (the "Annual Report"), to include the following risk factor under the heading "Risks Related to Our Business and Strategy":

Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic.

The recent outbreak of the novel strain of coronavirus, SARS-CoV-2, causing COVID-19 disease, which has been declared by the World Health Organization to be a pandemic, has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, potential customers, and other partners may be prevented from conducting certain business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The continued spread of COVID-19 and the measures taken by various governments could disrupt the supply chain of material needed for our product candidates and our approved product, Jelmyto, interrupt healthcare services, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our product candidates and have a material adverse effect on our business, financial

condition and results of operations. In addition, as we are located in New Jersey, we are currently subject to a statewide stay-at-home order and many of our potential customers and partners worldwide are similarly impacted. While we, our clinical trials sites and certain of our vendors, including our third-party contract manufactures, are currently exempt from stay-at-home, shelter-in-place or similar orders for certain operations, any of the applicable exemptions may be curtailed or revoked, which would further adversely impact our business. In addition, our commercial launch of Jelmyto could be hindered by the COVID-19 pandemic, although we are currently not able to predict or quantify any such potential impact with any degree of certainty. However, the worldwide spread of the COVID-19 virus has resulted and may continue to result in a global slowdown of economic activity which is likely to decrease demand for a broad variety of goods and services, including potentially for Jelmyto, while also disrupting sales channels and marketing activities for an unknown period of time until the disease is contained. Moreover, the global outbreak of the COVID-19 coronavirus continues to rapidly evolve, and the extent to which the COVID-19 coronavirus may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in the “Risk Factors” section of the Annual Report.

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: April 15, 2020

UROGEN PHARMA LTD.

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