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): May 9, 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**	**10014**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (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))

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. ☐

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**

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, UroGen Pharma Ltd. (the "Company") announced its financial results for the quarter ended March 31, 2019 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated May 9, 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.

Date: May 9, 2019

UROGEN PHARMA LTD.

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

Exhibit 99.1

UroGen Pharma Reports First Quarter 2019 Financial Results and Recent Corporate Developments

Recent Data Presentation Highlights Consistent Complete Response Rate and Strong Durability at Six-Months in Evaluable Patients with Low-Grade Upper Tract Urothelial Cancer (LG UTUC)

Completion of UGN-101 Rolling NDA Submission to the FDA On Track for 2H 2019

Pre-Commercial Activities and Infrastructure Build-out Accelerate Ahead of Planned U.S. Approval and Launch of UGN-101 in 1H 2020

Conference Call and Webcast to be Held Today at 8:30 AM ET

NEW YORK, May 9, 2019 - UroGen Pharma Ltd. (Nasdaq:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in uro-oncology, today announced financial results for the first quarter ended March 31, 2019 and provided an overview of the Company's recent developments.

"The accomplishments and performance of UroGen during the first quarter have set the stage for a pivotal and exciting year ahead as we prepare for the potential approval and commercialization of UGN-101, our first investigational candidate. Our top priority remains completion of our rolling New Drug Application (NDA) for UGN-101 for the treatment of patients with low-grade upper tract urothelial cancer (LG UTUC) and, with our commercial preparations well underway, we are confident in our readiness to deliver on a strong launch in the first half of 2020," said Liz Barrett, President and Chief Executive Officer of UroGen. "Our company sees great possibilities for the RTGel platform within uro-oncology, especially around new therapeutic modalities. Our goal is to leverage that and continue to build a company with sustainable growth via a robust pipeline as well as assessing opportunities via external partnerships."

Recent Highlights

- **UGN-101 Clinical Development:**
  - At the 114th American Urological Association (AUA) Annual Meeting in Chicago, Seth Lerner, M.D. delivered a presentation during the plenary session that highlighted the unmet need and potential for UGN-101 to change the treatment paradigm for patients with LG UTUC.
    - The updated analysis demonstrated that in the OLYMPUS intent-to-treat population, 71 patients had undergone primary disease evaluation (PDE) at the time of the analysis and 42 of the 71 patients (59 percent) achieved a complete response (CR). Forty-one patients entered follow-up. At the time of the analysis, 27 patients underwent a six-month evaluation, and 24 out of 27 patients (89 percent) have remained disease free at six months. The most common adverse events observed were urinary tract infection, ureteral narrowing and stricture formation. The majority of ureteral events were reported as mild to moderate and have resolved. Full Phase 3 data from the OLYMPUS trial is anticipated for 2H 2019.

- The Company remains on track to complete its rolling NDA for UGN-101 in 2H 2019 and is planning for approval in 1H 2020. If approved, UGN-101 would be the first drug approved for the non-surgical treatment of LG UTUC. Full data is planned for 2H 2019.

- **Pipeline Advancement:**
  - **UGN-102:**
    - The Company continues to enroll patients in its Phase 2b OPTIMA II clinical trial of UGN-102 (mitomycin gel) for intravesical instillation as a first-line chemoablation agent in the treatment of patients with intermediate risk low-grade non-muscle invasive bladder cancer (LG NMIBC), a form of disease associated with a high risk of recurrence.
    - Initial data from the OPTIMA II trial of UGN-102 is expected in 2H 2019.
    - There are currently no drugs approved by the FDA as first-line treatment for LG NMIBC. UGN-102 represents a substantial opportunity in UroGen's pipeline and has the potential to be a treatment option for up to approximately 80,000 patients for whom repetitive surgical resection via Transurethral Resection of Bladder Tumor (TURBT) remains the standard of care.
  - **UGN-201:**
    - UroGen is currently evaluating the optimal pathway to advance UGN-201, a TLR7/8 immunomodulatory agent for the treatment of high-grade bladder disease.

- **Commercial Preparations:**
  - The Company continues to accelerate its pre-commercial activities and infrastructure build-out to support the anticipated U.S. approval and launch of UGN-101 targeted for 1H 2020. The focus is on building awareness of our RTGel technology and unmet needs in UTUC to support rapid adoption and seamless integration of UGN-101 into the urologist practice following regulatory approval.
  - A strong team of seven medical science liaisons (MSLs) have been strategically deployed across the U.S. to engage in scientific exchange and clinical support.
  - The Company launched www.UTUC.com, the first resource designed to address a void in the urology space by educating patients about UTUC and available treatment options.

- **Business Development:**
  - UroGen recently entered into an agreement with Janssen Research & Development, LLC (Janssen) to conduct an early-stage feasibility evaluation in a therapeutic area of mutual interest. UroGen and Janssen will each conduct certain activities under the terms of the agreement.

First Quarter 2019 Financial Results; 2019 Guidance

- As of March 31, 2019, cash and cash equivalents totaled $246.7 million. This includes net proceeds of approximately $161.4 million from a public offering of ordinary shares in January 2019.
- Research and development expenses for the three months ended March 31, 2019 were $9.7 million, including non-cash share-based compensation expense of $2.3 million.
- General and administrative expenses for the three months ended March 31, 2019 were $12.7 million, including non-cash share-based compensation expense of $5.1 million.

- The Company reported a net loss of $21.4 million, or basic and diluted net loss per ordinary share of $1.11, for the three months ended March 31, 2019.
- The 2019 financial guidance set forth during the Company's year-end earnings call on February 28th remains the same based on current business goals and anticipated activities.

Conference Call & Webcast Information

Members of UroGen's management team will host a live conference call and webcast today at 8:30 am Eastern Time to review the Company's financial results and provide a general business update.

The live webcast can be accessed by visiting the Investors section of the Company's website at http://investors.urogen.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (888) 771-4371 (U.S.) or (847) 585-4405 (International) to listen to the live conference call. The conference ID number for the live call will be 48486174. An archive of the webcast will be available for two weeks on the Company's website.

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	March 31, 2019	December 31, 2018
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$246,692	$ 101,318
Restricted deposit	407	253
Prepaid expenses and other current assets	1,196	672
TOTAL CURRENT ASSETS	248,295	102,243
NON-CURRENT ASSETS:		
Property and equipment, net	929	948
Restricted deposit	51	51
Other non-current assets	2,777	317
TOTAL ASSETS	$252,052	$ 103,559
Liabilities and Shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 5,942	$ 8,540
Employee related accrued expenses	3,334	4,925
Other current liabilities	1,001	—
TOTAL CURRENT LIABILITIES	10,277	13,465
NON-CURRENT LIABILITIES:		
Long-term lease liability	2,184	—
TOTAL NON-CURRENT LIABILITIES	2,184	—
TOTAL LIABILITIES	12,461	13,465
TOTAL SHAREHOLDERS' EQUITY	239,591	90,094
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$252,052	$ 103,559

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	Three months ended March 31,	
	2019	2018
REVENUES	$ —	$ 481
COST OF REVENUES	—	430
GROSS PROFIT	—	51
OPERATING EXPENSES:		
Research and development expenses, net	9,726	7,622
General and administrative expenses	12,707	6,069
OPERATING LOSS	22,433	13,640
FINANCE INCOME, NET	(989)	(258)
NET LOSS	$ 21,444	$ 13,382
NET LOSS PER ORDINARY SHARE, BASIC AND DILUTED	$ 1.11	$ 0.88
WEIGHTED AVERAGE SHARES OUTSTANDING, BASIC AND DILUTED	19,340,082	15,267,939

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™ reverse-thermal hydrogel, 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 investigational candidates, UGN-101 (mitomycin gel) for instillation, and UGN-102 (mitomycin gel) for intravesical instillation, are designed to potentially ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and low-grade non-muscle invasive 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, without limitation: plans to conduct an early stage feasibility evaluation; the potential of UGN-101 for LG UTUC; the timing for completion of the rolling NDA for UGN-101; the anticipated timing for full Phase 3 data from the OLYMPUS trial; the potential approval of UGN-101 and the timing thereof; the expectation that UGN-101, if approved, will be the first drug approved for the non-surgical treatment of LG UTUC; the timing for completion of pre-commercial activities and infrastructure build-out in anticipation of a potential commercial launch of UGN-101; the expected readiness of UroGen for a potential commercial launch of UGN-101 and the strength and timing of the potential commercial launch of UGN-101; the potential of UroGen's proprietary RTGel™ technology platform to improve therapeutic profiles of existing drugs; the anticipated timing for initial data from the OPTIMA II trial; the opportunity and potential of UGN-102 for LG NMIBC; and UroGen's 2019 guidance. These 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 Phase 3 trial and the OPTIMA II Phase 2b trial and potential safety and

other complications thereof; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with achieving commercial readiness for the launch of a new product; the labeling for any approved product; the scope, progress and expansion of developing and commercializing UroGen'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; risks that UroGen's net loss for 2019 may differ materially from the anticipated range previously provided by UroGen and affirmed in this press release due to changes in UroGen's operating plans and/or due to estimates that may prove to be incorrect; and UroGen'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's Form 10-Q filed with the SEC on the date hereof and other filings that UroGen 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'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 as of the date of this release.

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