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): August 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))

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 2.02 Results of Operations and Financial Condition.

On August 9, 2019, UroGen Pharma Ltd. (the "Company") announced its financial results for the quarter ended June 30, 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 August 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: August 9, 2019

UROGEN PHARMA LTD.

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

Exhibit 99.1

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

UGN-101 Rolling NDA Submission on Track for Q4 2019 with Planned Launch in 1H 2020

Final Topline UGN-101 Phase 3 Data from OLYMPUS Trial to be Announced in Q3 2019

Company Investor Day Scheduled for September 24, 2019

Quarterly Conference Call and Webcast to be Held on Monday, August 12, 2019 at 8:30 AM ET

NEW YORK, August 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 second quarter ended June 30, 2019 and provided an overview of the Company's recent developments.

"Our team has continued to make significant progress on key initiatives during the second quarter, including the submission of the CMC modules to our rolling New Drug Application (NDA) for UGN-101. We have locked the database on our Phase 3 OLYMPUS study and are on track to complete the submission in Q4 as we prepare for a potential approval and launch in the first half of 2020," said Liz Barrett, President and Chief Executive Officer of UroGen. "We are confident that our account-based commercial strategy will allow for seamless adoption and integration into urology practices following anticipated approval. We look forward to sharing further details about UGN-101 commercial preparations, ongoing clinical programs, and new developments at our Investor Day on September 24, 2019."

Recent Highlights and Upcoming Milestones

- UGN-101 Clinical Development:
  - UroGen recently submitted the CMC modules to the rolling NDA for investigational agent UGN-101 for the treatment of patients with low-grade upper tract urothelial cancer (LG UTUC). Completion and acceptance of the Company's rolling NDA submission remains on track for 2H 2019. If approved, the Company expects to launch UGN-101 in the United States in 1H 2020. It would be the first medicine approved for this unique, orphan indication.
  - At the 114th American Urological Association (AUA) Annual Meeting in Chicago, a presentation in the plenary session highlighted findings from a secondary analysis from the pivotal Phase 3 OLYMPUS trial which demonstrated the unmet need and potential for UGN-101 to transform the treatment paradigm for patients with LG UTUC.
  - The Company expects to announce updated Phase 3 data from the OLYMPUS trial at its upcoming Investor Day on September 24, 2019.

- Pipeline Advancement:
  - **UGN-102:**
    - The Company continues to enroll patients in its Phase 2b OPTIMA II clinical trial of investigational agent 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. UGN-102 has the potential to address an unmet need for the approximately 80,000 patients with intermediate risk LG NMIBC.
    - The OPTIMA II trial is enrolling ahead of schedule, and the company plans to present early complete response data on a portion of patients at its upcoming Investor Day on September 24, 2019.
    - If approved, UGN-102 would represent a novel advance in the treatment of recurrent non-muscle invasive bladder cancer, as there are currently no drugs approved by the FDA as first-line treatment for LG NMIBC.
  - **UGN-201:**
    - The Company is developing investigational agent UGN-201, a TLR7/8 immunomodulatory agent for the treatment of high-grade bladder disease. UroGen is exploring the utility of UGN-201 in the context of novel combinatorial immunotherapy for NMIBC.
- Commercial Preparations:
  - UroGen has made considerable progress to accelerate educational initiatives to drive awareness of the significant unmet need for patients with LG UTUC where current SOC is kidney removal. Little education and support have previously been available for patients and stakeholders and UroGen is in a unique position to lead in this space. These pre-commercial activities and infrastructure build out will help to reinforce rapid adoption and seamless integration of UGN-101 into urology practices following anticipated regulatory approval.
  - In conjunction with the Company's educational efforts, UroGen is also engaging in a proactive market access strategy to define the cost burden to the system for LG UTUC via an HEOR study.
- Corporate:
  - Robert G. Uzzo, M.D., FACS, Chair of the Department of Surgical Oncology at Fox Chase Cancer Center in Philadelphia, PA, has joined UroGen as a special advisor working closely with UroGen's Medical Affairs team. Dr. Uzzo is well-known as a key opinion leader in the field of urological oncology and has made important clinical and scientific contributions to the field.
  - In the second quarter, UroGen 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.
  - The Company will host a live webcast in conjunction with its Investor Day taking place on Tuesday, September 24th at 10:00AM Eastern Time in New York, NY.

Second Quarter 2019 Financial Results; 2019 Guidance

- As of June 30, 2019, cash, cash equivalents and marketable securities totaled $233.3 million.
- Research and development expenses for the three months ended June 30, 2019 were $10.0 million, including non-cash share-based compensation expense of $2.0 million. Research and development expenses for the six months ended June 30, 2019 were $19.7 million, including non-cash share-based compensation expense of $4.3 million.
- General and administrative expenses for the three months ended June 30, 2019 were $13.8 million, including non-cash share-based compensation expense of $5.2 million. General and administrative expenses for the six months ended June 30, 2019 were $26.5 million, including non-cash share-based compensation expense of $10.3 million.

- The Company reported a net loss of $22.5 million, or basic and diluted net loss per ordinary share of $1.08, for the three months ended June 30, 2019. The Company reported a net loss of $43.9 million, or basic and diluted net loss per ordinary share of $2.19, for the six months ended June 30, 2019.
- The 2019 financial guidance set forth during the Company's year-end earnings call on February 28, 2019 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 on Monday, August 12, 2019 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 48773603. 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)

	June 30, 2019	December 31, 2018
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 90,424	$ 101,318
Marketable Securities	98,739	—
Restricted deposit	307	253
Prepaid expenses and other current assets	1,724	672
TOTAL CURRENT ASSETS	191,194	102,243
NON-CURRENT ASSETS:		
Property and equipment, net	909	948
Restricted deposit	55	51
Marketable Securities	43,851	—
Other non-current assets	2,557	317
TOTAL ASSETS	$238,566	$ 103,559
Liabilities and Shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 7,071	$ 8,540
Employee related accrued expenses	3,706	4,925
Other current liabilities	1,067	—
TOTAL CURRENT LIABILITIES	11,844	13,465
NON-CURRENT LIABILITIES:		
Long-term lease liability	1,943	—
TOTAL NON-CURRENT LIABILITIES	1,943	—
TOTAL LIABILITIES	13,787	13,465
TOTAL SHAREHOLDERS' EQUITY	224,779	90,094
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$238,566	$ 103,559

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

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
REVENUES	18	$ 364	18	$ 845
COST OF REVENUES	—	318	—	748
GROSS PROFIT	18	46	18	97
OPERATING EXPENSES:				
Research and development expenses	9,996	8,273	19,722	15,895
General and administrative expenses	13,775	10,207	26,482	16,276
OPERATING LOSS	(23,753)	(18,434)	(46,186)	(32,074)
FINANCE INCOME, NET	1,276	408	2,265	766
REALIZED LOSS ON SALE OF SHORT-TERM INVESTMENT	—	—	—	(100)
NET LOSS	$ (22,477)	$ (18,026)	$ (43,921)	$ (31,408)
NET LOSS PER ORDINARY SHARE, BASIC AND DILUTED	$ (1.08)	$ (1.14)	$ (2.19)	$ (2.02)
WEIGHTED AVERAGE SHARES OUTSTANDING, BASIC AND DILUTED	20,833,671	15,784,393	20,095,174	15,528,826
STATEMENT OF COMPREHENSIVE LOSS				
NET LOSS	$ (22,477)	$ (18,026)	$ (43,921)	$ (31,408)
OTHER COMPREHENSIVE INCOME:				
UNREALIZED GAIN ON MARKETABLE SECURITIES	281	—	281	—
COMPREHENSIVE LOSS	$ (22,196)	$ (18,026)	$ (43,640)	$ (31,408)

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 with Janssen to conduct an early stage feasibility evaluation in an area of mutual interest; 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 in 1H 2020 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 enrollment and initial data from the OPTIMA II trial; the opportunity and potential of UGN-102 for LG NMIBC; and UroGen's 2019 financial 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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