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): February 28, 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. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 28, 2019, UroGen Pharma Ltd. (the "Company") announced its financial results for the fourth quarter and year ended December 31, 2018 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 February 28, 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: February 28, 2019

UROGEN PHARMA LTD.

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

UroGen Pharma to Report Fourth Quarter and Full Year 2018 Financial Results

On Track to Complete UGN-101 Rolling NDA Submission to the FDA in 2H 2019

Acceleration of Pre-Commercial Activities and Infrastructure Buildout Underway to Support the Potential U.S. Approval and Launch of UGN-101 in 1H 2020

Initial Data from UGN-102 Trial Anticipated in 2019

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

NEW YORK, February 28, 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 fourth quarter and full year ended December 31, 2018 and provided an overview of the Company's recent developments.

"Our clinical and corporate execution in 2018 places UroGen in a position of strength as we prepare to potentially deliver UGN-101 as the first approved therapy for patients with low-grade upper tract urothelial cancer (LG UTUC)," said Liz Barrett, President and Chief Executive Officer of UroGen. "With this solid foundation, we remain intensely focused on finalizing our rolling New Drug Application (NDA) and accelerating commercial preparation to ensure a successful launch upon approval with seamless adoption of UGN-101. We believe UGN-101 is just the beginning of what may be possible with our proprietary RTGel™ technology platform."

"LG UTUC represents a clinical challenge as the current treatment of surgical intervention can put patients at risk for the well-known complications associated with repetitive surgical procedures and potential kidney removal," said Mark P. Schoenberg, M.D., Chief Medical Officer of UroGen. "If approved, UGN-101 could be a true breakthrough for patients by providing an option to avoid the risks and downstream consequences associated with surgery while arming urologists in general practice with a simple-to-use, kidney sparing approach to the management of their patient's disease."

Recent Highlights

- **UGN-101 Clinical Development:**
  - In the fourth quarter, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) for UGN-101 (mitomycin gel) for instillation, an investigational mitomycin formulation for the non-surgical treatment of patients with LG UTUC.
  - In January 2019, the Company announced positive topline results from the pivotal Phase 3 OLYMPUS clinical trial of UGN-101, in which 57 percent of patients achieved a complete response (CR) rate at their primary disease evaluation (PDE, or the primary endpoint) which was conducted four to six weeks after completion of UGN-101 treatment.
- **Pipeline Advancement:**
  - The Company continues to enroll patients as part of its Phase 2b OPTIMA II clinical trial of UGN-102 (mitomycin gel) for intravesical instillation as a potential first-line chemoablation agent in the treatment of intermediate risk patients with low-grade non-muscle invasive bladder cancer (LG NMIBC) at risk for recurrence.

- **Corporate Developments:**
    - UroGen strengthened its leadership team with the appointment of Liz Barrett as President and Chief Executive Officer. Ms. Barrett has over 30 years of industry experience spanning multiple areas including oncology, specialty care, surgical franchises, and consumer marketing in multiple geographic regions, most recently serving as CEO of Novartis Oncology and as a member of the Executive Committee of Novartis.
    - The Company enhanced its financial position with the completion of a successful public offering of ordinary shares in January 2019, resulting in net proceeds of approximately $162 million. These proceeds leave the company well-capitalized to execute on upcoming milestones, including preparation for potential commercialization of UGN-101, continued clinical development of our second product candidate (UGN-102), and advancement of our pipeline.

Upcoming Milestones:

- **UGN-101:** UroGen remains on track to complete its rolling NDA for UGN-101 in 2H 2019 and is planning for potential approval in 1H 2020. If approved, UGN-101 would be the first drug approved for the non-surgical treatment of LG UTUC.
    - The company continues to build out its commercial infrastructure and focus on scientific awareness to support adoption and seamless integration of UGN-101 into the urologist practice following potential regulatory approval.
- **UGN-102:** The Company intends to report initial data from the OPTIMA II trial of UGN-102 in 2019.
    - Similar to UGN-101, UGN-102 has the potential to transform the treatment paradigm for patients with LG NMIBC, as 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 with the potential to initially address up to approximately 80,000 patients for whom repetitive surgical resection via Transurethral Resection of Bladder Tumor (TURBT) remains the standard of care.
- **BotuGel:** Allergan continues to enroll patients in its Phase 2 trial of BotuGel, UroGen's RTGel in combination with BOTOX®[1], for the treatment of overactive bladder. Phase 2 data is expected in 2019.

Fourth Quarter and Full Year 2018 Financial Results; 2019 Guidance

- As of December 31, 2018, cash, cash equivalents, and short-term investments totaled $101.3 million. In addition, the Company raised net proceeds of approximately $162 million from an underwritten public offering in January 2019. Based on anticipated activities, the current cash balance is projected to carry the company for the next 24-36 months.
- Research and development expenses for the year ended December 31, 2018 were $36.9 million, including non-cash share-based compensation expense of $12.0 million. Research and development expenses for the three months ended December 31, 2018 were $11.5 million, including non-cash share-based compensation expense of $3.0 million.
- General and administrative expenses for the year ended December 31, 2018 were $39.6 million, including non-cash share-based compensation expense of $18.6 million. General and administrative expenses for the three months ended December 31, 2018 were $12.6 million, including non-cash share-based compensation expense of $5.9 million.
- The Company reported a net loss of $75.7 million, or basic and diluted net loss per ordinary share of $4.80, for the year ended December 31, 2018. The Company reported a net loss of $23.7

1 BOTOX® is a proprietary trademark of Allergan Pharmaceuticals

million, or basic and diluted net loss per ordinary share of $1.46, for the three months ended December 31, 2018.

- The Company anticipates a net loss in the range of $100 to $115 million for 2019, which is expected to include non-cash stock-based compensation expense in the range of $24 to $27 million subject to market conditions. The projected change in net loss for 2019 versus 2018 is expected to be largely attributable to the buildout of commercial infrastructure in anticipation of the potential launch of UGN-101. The Company has 20.4 million ordinary shares outstanding post the closing of our most recent financing in January.

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 48205742. 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)

	December 31, 2018	December 31, 2017
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 101,318	$ 36,999
Short-term investments	—	36,001
Restricted deposit	253	198
Inventory	—	316
Prepaid expenses and other current assets	672	958
TOTAL CURRENT ASSETS	102,243	74,472
NON-CURRENT ASSETS:		
Property and equipment, net	948	805
Restricted deposit	51	29
Other non-current assets	317	244
TOTAL ASSETS	$ 103,559	$ 75,550
Liabilities and Shareholders' equity		
LIABILITIES:		
Accounts payable and accrued expenses	$ 8,540	$ 4,435
Employee related accrued expenses	4,925	1,950
Deferred revenues	—	650
TOTAL LIABILITIES	13,465	7,035
TOTAL SHAREHOLDERS' EQUITY	90,094	68,515
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 103,559	$ 75,550

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

	Year ended December 31,		Three months ended December 31,	
	2018	2017	2018	2017
REVENUES	$ 1,128	$ 8,158	$ —	$ 327
COST OF REVENUES	1,803	600	—	287
GROSS PROFIT	(675)	7,558	—	40
OPERATING EXPENSES:				
Research and development expenses	36,934	18,697	11,465	6,761
General and administrative expenses	39,571	8,811	12,552	3,437
OPERATING LOSS	77,180	19,950	24,017	10,158
FINANCE (INCOME) EXPENSES, NET	(1,648)	31	(425)	(91)
LOSS BEFORE INCOME TAXES	75,532	19,981	23,592	10,067
INCOME TAX EXPENSE	125	19	125	—
NET LOSS	$ 75,657	$ 20,000	$ 23,717	$ 10,067
NET LOSS PER ORDINARY SHARE, BASIC AND DILUTED	$ 4.80	$ 2.14	$ 1.46	$ 0.74
WEIGHTED AVERAGE SHARES OUTSTANDING, BASIC AND DILUTED	15,754,193	9,716,790	16,212,274	13,612,814

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 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 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 with respect to the completion of the rolling NDA for UGN-101, approval, launch and adoption of UGN-101, the potential of UroGen's proprietary RTGel™ technology platform, timing with respect to data for UGN-102 and BotuGel, and the potential of UGN-102 and BotuGel, 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 10-K to be filed with the SEC on February 28, 2019 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.

UROGEN CONTACT:

Kate Bechtold
Director, Corporate Communications & Investor Relations
Kate.Bechtold@urogen.com
914-552-0456