UroGen Pharma Reports First Quarter 2018 Financial Results and Recent Corporate Developments

May 15, 2018

Interim Analysis of Pivotal Phase 3 OLYMPUS Trial of UGN-101 (MitoGel™) for the Treatment of Low-Grade Upper Tract Urothelial Carcinoma (LG UTUC) to be Presented at American Urological Association (AUA) Annual Meeting on May 21, 2018

Submission of UGN-101 New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) Expected in Q1 2019

UGN-102 (VesiGel™) Investigational New Drug (IND) Application Planned for Mid-2018

Conference Call Today at 8:30 a.m. Eastern Time

RA'ANANA, Israel, and NEW YORK, May 15, 2018 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq:URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, with a focus on uro-oncology, today announced financial results for first quarter ended March 31, 2018 and provided an overview of the Company's recent developments.

"We are excited about the upcoming late-breaking presentation at AUA of the Interim Analysis of our pivotal Phase 3 OLYMPUS trial of UGN-101 (MitoGel™) for the treatment of LG UTUC. Our team remains intensely focused on our most important milestone - submitting an NDA to the FDA in Q1 2019, with the goal of UGN-101 potentially becoming the first-ever approved treatment for LG UTUC," said Ron Bentsur, Chief Executive Officer of UroGen. "In addition to UGN-101, we continue to advance our pipeline, as demonstrated by our planned IND submission in mid-2018 for UGN-102 (VesiGel™), as well as other development programs that have the potential to transform existing treatment paradigms across a number of urologic conditions."

Recent Highlights and Upcoming Milestones

- **Clinical Development Progress of UGN-101 (MitoGel™):**
  - The Company will present an interim analysis from the OLYMPUS pivotal trial of UGN-101 in patients with LG UTUC on Monday, May 21, 2018 during the Plenary Session of the 113th AUA Annual Meeting in San Francisco, CA.
    - Presentation details and the full text for the abstract are available online through the Journal of Urology website.
  - Top-line results from the completed OLYMPUS trial are expected in 2H 2018, with the Company planning to submit an NDA in Q1 2019 to the FDA for UGN-101 for the treatment of LG UTUC. Potential approval and commercial launch of UGN-101 in the United States is targeted for 2H 2019.

- **Advancing the Pipeline and Potential for the RTGel™ Platform:**
  - UGN-102 (VesiGel™): The Company intends to submit an IND Application to the FDA for UGN-102 as a potential first-line chemoablation treatment and alternative to the transurethral resection of bladder tumor (TURBT) surgical procedure for low-grade non-muscle invasive bladder (LG NMIBC) in mid-2018 and commence a single-arm, open-label Phase 2b trial shortly thereafter.
    - There are currently no drugs approved by the FDA as first-line treatment for non-muscle invasive disease, and only three drugs have been approved by the FDA, all as adjuvant treatments, following TURBT.
  - UGN-201 (Vesimune™): The Company continues to evaluate, in preclinical models, its novel imiquimod formulation for bladder instillation as a single agent and in combination with immune checkpoint inhibitors for the treatment of high-grade UTUC. A clinical trial of UGN-201 in this indication is expected to commence in 1H 2019.
  - BotuGel™: Enrollment of patients by Allergan in the Phase 2 trial of RTGel™ in combination with BOTOX® for the treatment of overactive bladder is ongoing. This clinical trial, if successful, has the potential to demonstrate the broad applicability of the RTGel platform beyond uro-oncology.

- **Corporate Developments**
  - The Company strengthened its financial position with the completion of a public offering of ordinary shares in January 2018, resulting in net proceeds of approximately $64.2 million.

First Quarter 2018 Financial Results

- As of March 31, 2018, cash and cash equivalents totaled $127.5 million. This includes net proceeds of approximately $64.2 million from a public offering of ordinary shares in January 2018.

- Research and development expenses for the three months ended March 31, 2018 were $7.6 million, including non-cash share-based compensation expense of $2.5 million.

- General and administrative expenses for the three months ended March 31, 2018 were $6.1 million, including non-cash

share-based compensation expense of $2.1 million.

- The Company reported a net loss of $13.4 million, or basic and diluted net loss per ordinary share of $0.88, for the three months ended March 31, 2018.

Conference Call & Webcast Information

Members of UroGen's management team will host a live conference call and webcast today at 8:30 a.m. 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 46778272. 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, 2018	December 31, 2017
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$127,460	$ 36,999
Short-term investments	-	36,001
Restricted deposit	197	198
Accounts receivable	4	-
Inventory	349	316
Prepaid expenses and other current assets	726	958
TOTAL CURRENT ASSETS	128,736	74,472
NON-CURRENT ASSETS:		
Property and equipment, net	637	805
Restricted deposit	29	29
Other non-current assets	-	244
TOTAL ASSETS	$129,402	$ 75,550
Liabilities and Shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 4,048	$ 4,435
Employee related accrued expenses	1,291	1,950
Deferred revenues	196	650
TOTAL CURRENT LIABILITIES	5,535	7,035
TOTAL LIABILITIES	5,535	7,035
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.01 par value: 100,000,000 shares authorized at March 31, 2018 and December 31, 2017; 15,473,981 and 13,751,390 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively.	42	37
Additional paid-in capital	184,421	115,692
Accumulated deficit	(60,596)	(47,214)
TOTAL SHAREHOLDERS' EQUITY	123,867	68,515
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$129,402	$ 75,550

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,	
	2018	2017
REVENUES	$ 481	$ 19
COST OF REVENUES	430	18
GROSS PROFIT	51	1
OPERATING EXPENSES:		
Research and Development Expenses	7,622	2,664
General and Administrative Expenses	6,069	875
OPERATING LOSS	13,640	3,538
INTEREST AND OTHER INCOME, NET	(358)	(121)
REALIZED LOSS ON SALE OF SHORT-TERM INVESTMENT	100	-
NET LOSS	$ 13,382	$ 3,417
NET LOSS PER ORDINARY SHARE BASIC AND DILUTED	$ 0.88	$ 1.74
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE	15,267,939	2,307,025

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. The Company 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 product candidates, UGN-101 (MitoGel™, also known as mitomycin urothelial gel) and UGN-102 (VesiGel™, also known as mitomycin intravesica gel), are designed to potentially remove tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma and bladder cancer, respectively. UroGen is headquartered in Ra'anana, Israel with U.S. headquarters in New York.

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 timing and results of clinical development and commercial prospects of the product candidates in UroGen's pipeline, including UGN-101 (MitoGel™) and UGN-102 (VesiGel™), the scope and development of UroGen's product candidate pipeline, results from the OLYMPUS trial, and Allergan's Phase 2 clinical trial of BotuGel, UroGen's expectations regarding its ability to fund its operations, and the ability of UroGen to become a leader in the field of uro-oncology, 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'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'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 annual report on From 20-F filed with the SEC on March 15, 2018 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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[1] BOTOX® is a proprietary trademark of Allergan Pharmaceuticals.

UroGen Pharma Ltd.