



UroGen Pharma Reports Third Quarter 2017 Financial Results and Recent Corporate Developments

November 14, 2017

Conference Call Today at 8:30am Eastern Time

RAANANA, Israel and NEW YORK, Nov. 14, 2017 (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 the third quarter ended September 30, 2017 and provided an overview of the Company's recent developments.

"We believe that UroGen is on a trajectory to become a leading company in the field of uro-oncology, with the goal of providing new therapeutic options for the thousands of patients suffering from urothelial cancers," said Ron Bentsur, Chief Executive Officer of UroGen. "The past several months have been very productive for UroGen, highlighted by the progress of both our internal and partnered clinical programs as well as the recent expansion of our senior management team and board of directors. We look forward to the continued progress of the company as we diligently pursue the execution of our business objectives."

Recent Highlights and Upcoming Milestones

- Continue to enroll patients in the Phase 3 pivotal OLYMPUS clinical trial of MitoGel™ for the treatment of low-grade upper tract urothelial carcinoma (UTUC).
 - The OLYMPUS trial is a single-arm, open-label, pivotal study, that is anticipated to enroll approximately 70 patients at clinical sites across the United States and Europe.
 - Patients in the trial undergo six weekly instillations of MitoGel™. The primary efficacy endpoint is complete response (CR), evaluated approximately four weeks after the last instillation.
 - UroGen expects topline data from the trial to be available in the second quarter of 2018.
- Received Fast Track designation from the U.S. Food and Drug Administration (FDA) for MitoGel™ for the treatment of UTUC.
 - Through the FDA's Fast Track Program, a product candidate may be eligible for accelerated approval, priority review and for the submission of completed sections of the new drug application (NDA) on a rolling basis prior to completion of the full application.
- Announced the enrollment of the first patient by UroGen's partner, Allergan, in a Phase 2 clinical trial of RTGel™ in combination with BOTOX® for the treatment of overactive bladder (OAB).
- Expanded the Company's senior leadership team with the appointments of Paul Chu as Vice President of Business Development, Jeffrey Bova as Vice President of Commercial, and James Ottinger as Vice President of Regulatory Affairs.
- Strengthened the Company's board of directors with the appointment of Cynthia M. Butitta.
 - Most recently, Ms. Butitta served as Chief Operating Officer of Kite Pharma, where she played an instrumental role leading up to Kite's recent acquisition by Gilead Sciences for approximately \$11.9 billion in cash.

Third Quarter 2017 Financial Results

- As of September 30, 2017, cash and cash equivalents totaled \$79.2 million.
- Research and development expenses, net, for the nine months ended September 30, 2017 were \$11.9 million, including non-cash share based compensation expense of \$2.5 million. Research and development expenses, net, for the three months ended September 30, 2017 were \$5.6 million, including non-cash share based compensation expense of \$1.5 million.
- General and administrative expenses for the nine months ended September 30, 2017 were \$5.4 million, including non-cash share based compensation expense of \$1.5 million. General and administrative expenses for the three months ended September 30, 2017 were \$2.2 million, including non-cash share based compensation expense of \$0.7 million.
- The Company reported a net loss of \$(9.9 million), or basic and diluted net loss per ordinary share of \$(1.31), for the nine months ended September 30, 2017. The Company reported a net loss of \$(0.3 million), or basic and diluted net loss per ordinary share of \$(0.02), for the three months ended September 30, 2017.

Conference Call & Webcast Information

Members of UroGen Pharma's management team will host a live conference call and webcast today at 8:30am 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 (855) 765-5685 (U.S.) or (615) 247-5916 (international) to listen to the live conference call. The conference ID number for the live call will be 9197749. An archive of the webcast will be available until November 28, 2017 on the Company's website.

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 formulation for potentially improving therapeutic profiles of existing drugs. UroGen Pharma'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 Pharma's lead product candidates, MitoGel™ and VesiGel™, 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. UroGen Pharma is headquartered in Ra'anana, Israel and maintains a corporate office in New York City.

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 clinical development and commercial prospects of MitoGel™, BotuGel and the other product candidates in UroGen Pharma's pipeline, patient enrollment in the OLYMPUS trial, patient enrollment in Allergan's Phase 2 clinical trial of BotuGel, the scope and development of UroGen Pharma's product candidate pipeline, and the ability of UroGen Pharma 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 ability of the Company to maintain a strong management team and board of directors; the labeling for any approved product; the scope, progress and expansion of developing and commercializing UroGen Pharma's product candidates; and the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of the final prospectus for UroGen Pharma's initial public offering of securities in the United States filed with the SEC on May 5, 2017 and other filings that UroGen Pharma makes with the SEC from time to time (which are available at <https://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 PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	September 30, 2017	December 31, 2016
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 79,171	\$ 21,362
Restricted deposit	197	95
Accounts receivable	34	83
Inventory	137	105
Prepaid expenses and other current assets	910	396
TOTAL CURRENT ASSETS	80,449	22,041
NON-CURRENT ASSETS		
Property and equipment, net	710	741
Restricted deposit	29	24
Other non-current assets	-	250
TOTAL ASSETS	\$ 81,188	\$ 23,056
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 3,488	\$ 1,880
Employee related accrued expenses	1,139	687
Deferred revenues	300	-
Proceeds from exercise of warrants for preferred shares	-	570

TOTAL CURRENT LIABILITIES	4,927	3,137
NON-CURRENT LIABILITIES		
Warrants for preferred shares	-	3,612
TOTAL LIABILITIES	4,927	6,749
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.01 par value: 100,000,000 shares and 17,600,000 shares authorized at September 30, 2017 and December 31, 2016, respectively; 13,178,400 and 2,305,743 issued and outstanding at September 30, 2017 and December 31, 2016, respectively.	35	6
Preferred A and Preferred A-1 shares, NIS 0.01 par value: 14,400,000 shares authorized at December 31, 2016, 5,193,427 shares issued and outstanding at December 31, 2016.	-	13
Additional paid-in capital	113,354	43,502
Accumulated deficit	(37,128)	(27,214)
TOTAL SHAREHOLDERS' EQUITY	76,261	16,307
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 81,188</u>	<u>\$ 23,056</u>

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

	<u>Nine months ended</u>		<u>Three months ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
REVENUES	\$ 7,831	\$ -	\$ 7,812	\$ -
COST OF REVENUES	313	-	295	-
GROSS PROFIT	7,518	-	7,517	-
OPERATING EXPENSES:				
RESEARCH AND DEVELOPMENT EXPENSES, NET	11,936	7,915	5,621	2,873
GENERAL AND ADMINISTRATIVE EXPENSES	5,374	5,188	2,199	3,237
OPERATING LOSS	9,792	13,103	303	6,110
FINANCE EXPENSES (INCOME), net	122	1,761	(5)	1,877
NET LOSS	<u>\$ 9,914</u>	<u>\$ 14,864</u>	<u>\$ 298</u>	<u>\$ 7,987</u>
NET LOSS PER ORDINARY SHARE BASIC AND DILUTED	<u>\$ 1.31</u>	<u>\$ 7.25</u>	<u>\$ 0.02</u>	<u>\$ 3.73</u>
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING USED IN COMPUTATING BASIC AND DILUTED LOSS PER ORDINARY SHARE	<u>8,223,124</u>	<u>2,305,410</u>	<u>13,051,117</u>	<u>2,305,743</u>

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