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

August 14, 2017

Completed Initial Public Offering Raising $66.9 Million in Gross Proceeds

Continuing Enrollment of Patients in the Phase 3 OLYMPUS Clinical Trial of MitoGel ™ for the Treatment of Low-Grade Upper Tract Urothelial Carcinoma

RA'ANANA, Israel and NEW YORK, Aug. 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 second quarter ended June 30, 2017 and provided an overview of the Company's recent developments.

"UroGen has a clear vision and business strategy to become a leader in the treatment of urothelial cancers and other urological pathologies," said Ron Bentsur, Chief Executive Officer of UroGen. "This has been a highly productive period for the Company, highlighted by the recent closing of our initial public offering and commencement of patient enrolment in our open label Phase 3 OLYMPUS pivotal trial of MitoGel ™ for the treatment of UTUC, a condition for which there are no FDA approved drugs. We look forward to building upon our positive momentum throughout the rest of the year and into 2018."

Recent Highlights and Upcoming Milestones

- Successfully completed the Company's initial public offering (IPO), raising $66.9 million in gross proceeds.
- Continue to enroll patients in the Phase 3 OLYMPUS clinical trial of MitoGel ™ for treatment of low-grade upper tract urothelial carcinoma (UTUC).
  - The trial, designed to be a single, open-label, pivotal study for the potential approval of MitoGel ™ in low-grade UTUC, is anticipated to enroll approximately 70 patients at clinical sites across the U.S. and Europe.
  - Patients in the trial will undergo six weekly instillations of MitoGel ™. The primary efficacy endpoint is complete response (CR), approximately 4 weeks after the last instillation.
- In July 2017, we earned a milestone of $7.5 million under the Company's exclusive worldwide licensing agreement with Allergan plc resulting from Allergan's submission of an Investigational New Drug (IND) application for RTGel ™ in combination with BOTOX® for the treatment of overactive bladder to the FDA.
  - UroGen is eligible to receive up to $200 million in additional payments related to the achievement of certain development, regulatory, and commercial milestones, in addition to royalties on potential net sales.
- Strengthened the Company's Board of Directors with the appointments of Kate Falberg and Fred E. Cohen, MD, DPhil.

Second Quarter 2017 Financial Results

- As of June 30, 2017, cash and cash equivalents totaled $77.1 million. On May 9, 2017, the Company completed its IPO of 5,144,378 shares of common stock at a public offering price of $13.00 per share, raising gross proceeds of $66.9 million, prior to deducting the underwriting discount and estimated expenses of the offering.
- Research and development expenses, net, were $3.7 million for the second quarter of 2017, including non-cash share based compensation expense of $853,000.
- General and administrative expenses were $2.3 million for the second quarter of 2017, including non-cash share based compensation expenses of $723,000.
- The Company reported a net loss of $(6.2) million, or basic and diluted net loss per ordinary share of $(0.70), for the second quarter of 2017.

About UTUC

Non-muscle invasive upper tract urothelial carcinoma (UTUC) has an estimated annual incidence in the United States of up to 7,500 cases – about 5% to 10% of all new cases of urothelial cancer. There are approximately 2,500 new cases of low-grade UTUC in the U.S. with a prevalence of approximately 14,500. UTUC refers to cancer of the upper tract, which connects the bladder to the kidney, and the renal pelvis. The current standard of care for this cancer is complete or partial surgical removal of the involved kidney and upper tract. For patients with a bilateral disease, an anatomic or functionally solitary kidney, medical comorbidities or low-grade disease that present with a limited number of tumors, a kidney-conserving alternative is considered, if possible. However, due to the specific anatomy and physiology of the upper tract and renal pelvis, the performance of organ-sparing endoscopic resection and instillation of neoadjuvant or adjuvant chemotherapy are often challenging, leading to high rates of recurrence and risk for

progression. Difficulties in administering and maintaining Mitomycin C or any other drug in the upper tract due to low residual duration and short exposure time of the active agent in the treated area results in low treatment efficacy and limited use of chemoablative agents in patients with UTUC. Furthermore, there are currently no FDA-approved drugs for the treatment of UTUC.

About the OLYMPUS Trial

OLYMPUS (**O**ptimized De**L**ivery of **M**itomycin for **P**rimary **U**TUC **S**tudy) is an open-label, single-arm Phase 3 clinical trial of MitoGel ™ to evaluate the safety, tolerability and tumor ablative effect of MitoGel ™ in low grade UTUC patients. The trial, designed to be a single pivotal study for the potential approval of MitoGel ™ in low-grade UTUC, is anticipated to enroll approximately 70 patients in clinical sites in the U.S. and Europe. The trial will also evaluate the durability of the tumor ablative effect of MitoGel ™.

About MitoGel ™

Utilizing RTGel ™, UroGen's proprietary sustained release, hydrogel-based formulation, MitoGel ™ is designed to enable longer exposure of Mitomycin C to the urinary tract tissue, thereby potentially enabling the treatment of tumors by non-surgical means. MitoGel ™ is administered to patients using standard intravesical catheters.

About UroGen Pharma Ltd.

UroGen Pharma (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 UTUC and bladder cancer. UroGen Pharma is headquartered in Israel and also 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 of RTGel/BOTOX® and other product candidates in UroGen Pharma's pipeline, patient enrolment in the Olympus clinical trial, and the prospective receipt of milestone payments and royalties under the Allergan Agreement, including with respect to the development potential of RTGel/BOTOX®, 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 a product candidate, the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; and the maintenance of any applicable collaborations. 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 http://www.edgar.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)

	June 30, 2017	December 31, 2016
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 77,093	$ 21,362
Restricted deposit	97	95
Accounts receivable	10	83
Inventory	398	105
Prepaid expenses and other current assets	704	396
TOTAL CURRENT ASSETS	78,302	22,041
NON-CURRENT ASSETS		
Property and equipment, net	707	741
Restricted deposit	29	24
Other non-current assets	-	250
TOTAL ASSETS	$ 79,038	$ 23,056
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		

Accounts payable and accrued expenses	$ 3,543	$ 1,880
Employee related accrued expenses	1,112	687
Deferred revenues	311	-
Proceeds from exercise of warrants for preferred shares	-	570
TOTAL CURRENT LIABILITIES	4,966	3,137
NON-CURRENT LIABILITIES		
Warrants for preferred shares	-	3,612
COMMITMENTS AND CONTINGENCIES		
TOTAL LIABILITIES	4,966	6,749
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.01 par value: 100,000,000 shares and 17,600,000 shares authorized at June 30, 2017 and December 31, 2016, respectively; 13,009,504 and 2,305,743 issued and outstanding at June 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	110,867	43,502
Accumulated deficit	(36,830)	(27,214)
TOTAL SHAREHOLDERS' EQUITY	74,072	16,307
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 79,038	$ 23,056

UROGEN PHARMA LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Six months ended June 30,		Three months ended June 30,	
	2017	**2016**	**2017**	**2016**
REVENUES	$ 19	-	-	-
COST OF REVENUES	18	-	-	-
GROSS PROFIT	1	-	-	-
OPERATING EXPENSES:				
RESEARCH AND DEVELOPMENT EXPENSES, NET	6,315	5,042	3,651	2,351
GENERAL AND ADMINISTRATIVE EXPENSES	3,175	1,951	2,300	1,044
OPERATING LOSS	9,489	6,993	5,951	3,395
FINANCE EXPENSES (INCOME), net	127	(116)	248	(78)
NET LOSS	$ 9,616	$ 6,877	$ 6,199	$ 3,317
LOSS PER ORDINARY SHARE BASIC AND DILUTED	$ 1.81	$ 3.51	$ 0.70	$ 1.70
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING USED IN COMPUTATING BASIC AND DILUTED LOSS PER ORDINARY SHARE	5,755,714	2,305,241	9,204,405	2,305,743

CONTACTS:

UroGen Pharma Ltd.
Gary Titus
Chief Financial Officer
garyt@urogen.com
646-768-9531

Or

Burns McClellan, Inc.
Steve Klass
sklass@burnsmc.com
212-213-0006

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