# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K
Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934
For the month of August 2017
Commission File Number 001-38079
UROGEN PHARMA LTD. (Translation of registrant's name into English)
9 Ha'Ta'asiya Street Ra'anana 4365007, Israel (Address of principal executive offices)
Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F ⊠ Form 40-F □
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): $\Box$
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): $\Box$

#### INCORPORATION BY REFERENCE

Exhibits 99.1 and 99.2 to this Report on Form 6-K shall be deemed to be incorporated by reference into the Registration Statement on Form S-8 (Registration Number 333-218992) of UroGen Pharma Ltd. (the "Company") and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit 99.3 to this Report on Form 6-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 (the "Securities Act") or the Exchange Act.

#### RISK FACTORS

The risk factors set forth under the caption "Risk Factors" in the Company's final prospectus for its initial public offering of ordinary shares filed on May 5, 2017 pursuant to Rule 424(b)(4) under the Securities Act shall be deemed to be incorporated by reference herein and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Additional risks and uncertainties not currently known to the Company, or that the Company currently deems to be immaterial, also may affect its business, financial condition and/or future operating results.

# **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, thereunto duly authorized.

# UROGEN PHARMA LTD.

August 14, 2017 By: /s/ Gary S. Titus

Gary S. Titus Chief Financial Officer

# EXHIBIT INDEX

Exhibit No.	<u>Description</u>
99.1	Unaudited Condensed Consolidated Interim Financial Statements as of and for the Six Months ended June 30, 2017
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations as of and for the Six Months ended June 30, 2017
99.3	Press Release, dated August 14, 2017

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
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

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

		Six months ended June 30,			Three months ende June 30			ded
		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	2,305,743

# CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (U.S. dollars in thousands, except share data) (Unaudited)

	Ordinary s Number of shares	s	Preferred s Number of shares	 ounts	Additional paid-in capital	_	ccumulated deficit Amounts	Total
BALANCE AS OF JANUARY 1, 2017	2,305,743	\$ 6	5,193,427	\$ 13	\$ 43,502	\$	(27,214)	\$16,307
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2017:								
Exercise of options into ordinary shares	1,920	*			4			4
Share-based compensation					1,873			1,873
Exercise of warrants into preferred shares			364,036	1	4,731			4,732
Conversion of preferred shares into ordinary shares	5,557,463	14	(5,557,463)	(14)				
Issuance of ordinary shares, net of issuance expenses	5,144,378	15			60,757			60,772
Net loss		 		 			(9,616)	(9,616)
BALANCE AS OF JUNE 30, 2017	13,009,504	\$ 35		_	\$110,867	\$	(36,830)	\$74,072
BALANCE AS OF JANUARY 1, 2016	2,300,959	\$ 6	5,193,427	\$ 13	\$ 41,535	\$	(25,273)	\$16,281
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2016:								
Exercise of options into ordinary shares	4,784	*			*			*
Share-based compensation					873			873
Net loss							(6,877)	(6,877)
BALANCE AS OF JUNE 30, 2016	2,305,743	\$ 6	5,193,427	\$ 13	\$ 42,408	\$	(32,150)	\$10,277

<sup>(\*)</sup> Represents less than one thousand

# CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (U.S. dollars in thousands, except share data) (Unaudited)

	Ordinary s	shares		Preferred s	shares		Additional paid-in	Ac	cumulated deficit	
	of shares	Am	ounts	of shares	Am	ounts	capital		Amounts	Total
BALANCE AS OF APRIL 1, 2017	2,307,663	\$	6	5,193,427	\$	13	\$ 43,803	\$	(30,631)	\$13,191
CHANGES DURING THE THREE MONTHS ENDED										
JUNE 30, 2017:										
Share-based compensation							1,576			1,576
Exercise of warrants into preferred shares				364,036		1	4,731			4,732
Conversion of preferred shares into ordinary shares	5,557,463		14	(5,557,463)		(14)				_
Issuance of ordinary shares, net of issuance expenses	5,144,378		15				60,757			60,772
Net loss									(6,199)	(6,199)
BALANCE AS OF JUNE 30, 2017	13,009,504	\$	35				\$110,867	\$	(36,830)	\$74,072
BALANCE AS OF APRIL 1, 2016	2,305,743	\$	6	5,193,427	\$	13	\$ 41,975	\$	(28,833)	\$13,161
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2016:										
Share-based compensation							433			433
Net loss								_	(3,317)	(3,317)
BALANCE AS OF JUNE 30, 2016	2,305,743	\$	6	5,193,427	\$	13	\$ 42,408	\$	(32,150)	\$10,277

<sup>(\*)</sup> Represents less than one thousand

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands) (Unaudited)

	Six mont June	30,	Three months ended June 30,	
CASH FLOWS FROM OPERATING ACTIVITIES:	2017	2016	2017	2016
Net loss	\$ (9,616)	\$ (6,877)	\$ (6,199)	\$ (3,317)
Adjustments required to reconcile net loss to net cash used in operating activities:	\$ (3,010)	\$ (0,077)	\$ (0,133)	\$ (3,317)
Depreciation	132	75	87	38
Share-based compensation	1.873	873	1,576	433
Exchange rates differences	(2)	—	(1)	_
Fair value adjustment of warrants for preferred shares	168	(114)	277	(89)
Changes in operating asset and liabilities:		()		()
Increase in inventory	(293)	_	(167)	_
Decrease in accounts receivable	73	_	12	_
Decrease (increase) in prepaid expenses and other current assets	(308)	650	(150)	365
Increase (decrease) in accounts payable and accrued expenses	1,031	(327)	647	(460)
Deferred revenues	311		_	_
Increase in employee related accrued expenses	425	89	457	30
Net cash used in operating activities	(6,206)	(5,631)	(3,461)	(3,000)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property and equipment	(98)	(443)	(20)	(373)
Change in restricted deposit	(5)	(98)	(1)	(23)
Net cash used in investing activities	(103)	(541)	(21)	(396)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Exercise of options into ordinary shares	4	_	_	_
Issuance of ordinary shares, net of issuance expenses	61,654	_	61,766	_
Payment of deferred equity offering cost	_	(510)	_	(381)
Proceeds from exercise of warrants to preferred shares	382	192	382	192
Net cash provided by (used in) financing activities	62,040	(318)	62,148	(189)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	55,731	(6,490)	58,666	(3,585)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	21,362	17,975	18,427	15,070
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	\$77,093	\$11,485	\$77,093	\$11,485
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:				
Non cash purchase of property and equipment	_	_	_	\$ (146)
Non cash issuance cost	\$ 728	\$ 1,035	\$ 415	\$ 113
Exercise of warrants into preferred shares	\$ 4,732		\$ 4,732	

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

#### NOTE 1—NATURE OF OPERATIONS

a. UroGen Pharma Ltd. is an Israeli company incorporated in April 2004 ("UPL").

UroGen Pharma Inc. a subsidiary of UPL, was incorporated in Delaware in October 2015 and began operating in February 2016 ("UPI"). UPL and UPI are referred to herein together as the "Company."

The Company is a clinical stage biopharmaceutical company focused on developing novel therapies designed to change the standard of care for urological pathologies.

- b. In May 2017, the Company raised \$60.8 million, net of issuance costs and underwriting discounts, in an Initial Public Offering ("IPO") on the NASDAQ Stock Market (the "NASDAQ") (see Note 5a2).
- c. As of the date of approval of the consolidated financial statements, the Company has the ability to fund its planned operations for at least the next 12 months. However, the Company's product candidates may never achieve commercialization and it will continue to incur losses for the foreseeable future. Therefore, in order to fund the Company's research and development expenses, general and administrative expenses and capital expenditures until such time that the Company can generate substantial revenue, the Company may need to raise additional funds.
- d. As described in Note 5a1, in April 2017, the Company's board of directors and shareholders approved a 3.2-for-1 split of the Company's ordinary, Preferred A and Preferred A-1 shares. All of the share and per share amounts reflected in these financial statements and the notes thereto have been adjusted, on a retroactive basis, to reflect this share split.

# NOTE 2—BASIS OF PRESENTATION

The unaudited condensed consolidated interim financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial statements. Accordingly, they do not contain all information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's financial position as of June 30, 2017, the results of operations and cash flows for the six and three month periods ended June 30, 2017 and 2016.

These unaudited condensed consolidated interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2016 and notes thereto included in the Company's annual financial statements for the year ended December 31, 2016. The condensed balance sheet data as of December 31, 2016 included in these unaudited condensed consolidated financial statements was derived from the audited financial statements for the year ended December 31, 2016, but does not include all disclosures required by U.S. GAAP.

The results for the six and three months period ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017.

# NOTE 3—FAIR VALUE MEASUREMENT

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

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

#### NOTE 3—FAIR VALUE PRESENTATION (continued)

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The Company's assets and liabilities that are measured at fair value as of June 30, 2017 and December 31, 2016 are classified in the tables below in one of the three categories described above:

	June 30,	December 31,
	2017	2016
Warrants for preferred shares – Level 3		\$ 3,612

The fair value of the preferred share warrants as of December 31, 2016 was measured in accordance with the Hybrid Method. The Company utilized the Hybrid Method to combine the probability of an IPO scenario at such date, which was estimated at 20%, with the probability of a liquidation event at such date, which was estimated at 80%. As of December 31, 2016, the fair value of the warrants for preferred shares was determined mainly based on estimation of the Company's equity value derived from a discounted cash flow, or DCF, calculation and based on assumptions relating to the Company's revenue forecast, clinical success probabilities, relevant discount rates between 10.5%-19 % (10.5% for the cash flow expected to be derived from the license agreement with Allergan and 19% for the cash flow expected to be derived from the Company's internal development), and expected volatility at a rate of 73.93%.

The table below sets forth a summary of the changes in the fair value of the warrants for preferred shares classified as Level 3:

	Six month June		Three me ended Ju	
	2017	2016	2017	2016
Balance at the beginning of the period	\$ 3,612	\$ 872	\$ 3,503	\$847
Changes in fair value during the period	168	(114)	277	(89)
Exercise of warrants to preferred shares	(3,780)	_	(3,780)	
Balance at end of period	<u> </u>	\$ 758		\$758

In connection with the completion of the IPO, the Company converted all outstanding warrants into 364,036 Preferred A-1 shares of the Company and subsequently converted all of its preferred shares, including the Preferred A-1 shares, into ordinary shares.

#### NOTE 4—PROCEEDS FROM EXERCISE OF WARRANTS FOR PREFERRED A-1 SHARES

The Company's warrants outstanding prior to the IPO were exercisable for Series A-1 preferred shares at an exercise price of \$7.81 per share. Prior to the IPO, such warrants were exercisable for 728,312 Preferred A-1 shares.

During 2017 and 2016 the Company notified holders of these warrants that it was ready to accept an exercise notice that was conditioned on the price per share at which the Company's shares would be sold in an anticipated IPO. Prior to the IPO, the Company received a total amount of \$952 as consideration for the conditional cash exercise of these warrants. The cash received was recorded among current liabilities as proceeds from exercise of warrants for preferred shares. As of June 30, 2017, following the exercise of the warrants, the cash received was re-classified to additional paid in capital. See also note 5.

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

#### NOTE 5—SHARE CAPITAL

#### a. Share capital

- 1. On April 19, 2017, the Company's board of directors and shareholders approved an aggregate 3.2-for-1 share split of the Company's ordinary, Preferred A and Preferred A-1 shares. The share split was effected on April 19, 2017 by the issuance of 2.2 ordinary shares for each outstanding ordinary, Preferred A and Preferred A-1 share held immediately prior to the share split.
- 2. In May 2017, the Company completed an IPO on the NASDAQ Stock Market, in which it issued 5,144,378 ordinary shares in consideration for \$60.8 million, net of issuance costs and underwriting discounts. In addition, during the year ended December 31, 2016, the Company recorded \$1.7 million in general and administrative expenses related to IPO costs, in accordance with SEC staff Bulletin Topic 5A.

Upon the completion of the IPO, the Company converted all outstanding warrants for Preferred A-1 shares into 364,036 Preferred A-1 shares of the Company. Subsequently, the Company converted all outstanding Preferred A and Preferred A-1 shares into ordinary shares at a ratio of 1:1. As of June 30, 2017, the Company's share capital was composed entirely of ordinary shares.

#### b. Share-based compensation

1. The following table illustrates the effect of share-based compensation on the statements of operations:

	Six month June		Three n ended J	
	2017	2016	2017	2016
Research and development expenses	\$1,013	\$454	\$ 853	\$196
General and administrative expenses	860	419	723	237
	\$1,873	\$873	\$1576	\$433

#### 2. 2017 Equity Incentive Plan

In March 2017, the Company's board of directors adopted the 2017 Equity Incentive Plan, which was approved by the shareholders in April 2017. The 2017 Plan provides for the grant of incentive stock options to the Company's employees and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards, and other forms of stock awards to the Company's employees, directors and consultants.

The maximum number of ordinary shares that may initially be issued under the 2017 Plan is 1.4 million. In addition, the number of ordinary shares reserved for issuance under the 2017 Plan will automatically increase on January 1st of each calendar year, from January 1, 2018 through January 1, 2026, so that the number of such shares reserved for issuance will equal 12% of the total number of ordinary shares outstanding on the last day of the calendar month prior to the date of each automatic increase, or a lesser number of shares determined by our board of directors. The maximum number of ordinary shares that may be issued upon the exercise of incentive stock options under the 2017 Plan is 5,600,000.

The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2017 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our Ordinary Shares on the date of grant. Options granted under the 2017 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

3. In April 2017, the Company's board of directors approved modifications of performance conditions for 67,200 RSU's and contingent options for executive management. The Company recorded an expense of \$527 under general and administrative expenses with respect to these modifications.

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

#### NOTE 5—SHARE CAPITAL (continued)

#### b. Share-based compensation (continued)

- 4. During the six months ended June 30, 2017, the Company's board of directors approved a grant of 80,000 options to directors of the Company. Each option is exercisable into one ordinary share of the Company at an exercise price between \$13.00 and \$16.99. The options vest in several installments over a three-year period. As of the grant date, the fair value of these options was estimated at \$953. The unexercised options expire ten years from the date of the grant.
- 5. During the six months ended June 30, 2017, the Company's board of directors approved a grant of 170,000 options to executive management of the Company. Each option is exercisable into one ordinary share of the Company at an exercise price of \$19.55. The options vest in several installments over a three-year period. As of the grant date, the fair value of these options was estimated at \$2,645. The unexercised options expire ten years after their grant date.

#### NOTE 6—RELATED PARTIES- TRANSACTIONS AND BALANCES:

Related parties include the Chairman and members of the Board of Directors and the Chief Executive Officer of the Company.

#### a. Transactions with related parties:

	Six month June		Three months ended June 30,		
	2017	2016	2017	2016	
Expenses:					
Payroll and related expenses	\$ 848	\$322	\$696	\$162	
Management fees	163	130	118	85	
Research grants	50	_	_	_	
	\$1,061	\$452	\$814	\$247	

# b. Balances with related parties:

	June	± 30,
	2017	2016
Accounts payable and accrued expenses	\$152	\$39

# c. Related parties:

UPI entered into a lease agreement in November 2015, which commenced in May 2016, for office space in New York, which serves as the headquarters for our U.S. subsidiary. UPI shares the office space equitably with Kite Pharma, Inc., a Delaware corporation that is a co-signatory to such lease. Arie Belldegrun, M.D., UPL's Chairman, serves as the Chairman and Chief Executive Officer of Kite Pharma.

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

#### NOTE 7—LOSS PER SHARE:

The following table sets forth the calculation of basic and diluted loss per share ("LPS") for the periods indicated:

	Six months er			Three months ended June 30,			
	2017	2016	2017	2016			
Basic and diluted:							
Loss attributable to equity holder of the Company	\$ 9,616	\$ 6,877	\$ 6,199	\$ 3,317			
Dividend accumulated on preferred shares during							
the period	\$ 824	\$ 1,223	\$ 216	\$ 608			
Loss attributable to equity holders of the Company, after reducing dividend accumulated on preferred	<del></del>	<del></del>	<del></del>				
shares	\$ 10,440	\$ 8,100	\$ 6,415	\$ 3,925			
Weighted average number of ordinary shares	5,755,714	2,305,241	9,204,405	2,305,743			
Loss per ordinary share	\$ 1.81	\$ 3.51	\$ 0.70	\$ 1.70			

For the six and three months periods ended June 30, 2017 and 2016, all ordinary shares underlying outstanding options, A-1 warrants and convertible preferred shares have been excluded from the calculation of the diluted loss per share since their effect was anti-dilutive.

The shares accounted for in diluted loss per ordinary share do not include 2,915,099 and 2,607,498 ordinary shares underlying outstanding options for the six- and three-month periods ended June 30, 2017 and 2016, respectively, and 728,312 shares issuable upon exercise of the Preferred A-1 warrants, which were converted to ordinary shares upon the IPO, for the six- and three-month periods ended June 30, 2017 and 2016.

#### NOTE 8—SUBSEQUENT EVENTS:

#### The Company has evaluated subsequent events through August 14, 2017

In July 2017, the Company announced that it had earned a milestone payment of \$7.5 million under its exclusive worldwide licensing agreement with Allergan Pharmaceuticals International Limited ("Allergan") resulting from Allergan's submission of an Investigational New Drug ("IND") application for the Company's RTGel in combination with Allergan's BOTOX for the treatment of overactive bladder to the U.S. Food and Drug Administration ("FDA"). As per the terms of the licensing agreement between the Company and Allergan for RTGel, the payment is expected to be received within 45 days after the achievement of this milestone.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations for the six and three months ended June 30, 2017 and 2016 should be read in conjunction with our unaudited condensed consolidated financial statements for such periods filed as Exhibit 99.1 to this Current Report on Form 6-K, as well as our annual financial statements for the years ended December 31, 2016 and 2015 and related discussion and analysis of our financial condition and results of operations for such periods, which were included in the final prospectus for our initial public offering, or IPO, filed with the U.S. Securities and Exchange Commission on May 5, 2017. All such financial statements were prepared in accordance with accounting principles generally accepted in the United States, or US GAAP. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors.

#### Overview

We are a clinical stage biopharmaceutical company focused on developing novel therapies designed to change the standard of care for urological pathologies. We have an innovative and broad pipeline of product candidates that we believe can overcome the deficiencies of current treatment options for a variety of urological conditions with a focus on uro-oncology. Our lead product candidates, MitoGel and VesiGel, are proprietary formulations of the chemotherapy drug Mitomycin C, or MMC, which is currently used for urothelial cancer treatment only in a water-based formulation as an adjuvant therapy. We are developing our product candidates as chemoablation agents, which means they are designed to remove tumors by non-surgical means, to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma, or UTUC, and low-grade bladder cancer. We believe that MitoGel and VesiGel, which are both local drug therapies, have the potential to significantly improve patients' quality of life by replacing costly, sub-optimal and burdensome tumor resection and kidney removal surgeries as the first-line standard of care. MitoGel and VesiGel may also reduce the need for bladder, kidney and upper urothelial tract removals, which are typically performed on patients whose cancer progresses despite undergoing tumor resection surgical procedures. Additionally, we believe that our product candidates, which are based on novel formulations of previously approved drugs, may qualify for streamlined regulatory pathways to market approval.

MitoGel and VesiGel are formulated using our proprietary RTGel technology. We believe that RTGel-based drug formulations, which provide for the sustained release of an active drug, may improve the efficacy of treatment of various types of urothelial cancer without compromising the safety of the patient or interfering with the natural flow of fluids from the urinary tract to the bladder. Our formulations are designed to achieve this by increasing the dwell time as well as the tissue coverage throughout the organ of the active drug. Consequently, we believe that RTGel-based drug formulations may enable us to overcome the anatomical and physiological challenges that have historically contributed to the lack of drug development for the treatment of urothelial cancer. No drugs have been approved by the FDA for the treatment of non-muscle invasive bladder cancer, or NMIBC, in more than 15 years.

Our clinical stage pipeline also includes Vesimune, our proprietary immunotherapy product candidate for the treatment of high-grade NMIBC. We acquired Vesimune from Telormedix SA, a private Swiss-based biotechnology company, in the fourth quarter of 2015.

We have incurred net losses in each period since our formation in 2004. We incurred net losses of \$9.7 million and \$1.9 million for the six months ended June 30, 2017 and the year ended December 31, 2016, respectively. As of June 30, 2017, and December 31, 2016, our accumulated deficit was \$36.9 million and \$27.2 million, respectively. We expect to continue to incur losses for the foreseeable future, and our losses may fluctuate significantly from year to year. We expect that our expenses will increase substantially in connection with our ongoing activities as we:

- conduct the single pivotal Phase 3 clinical trial for MitoGel, and plan to initiate a Phase 2b clinical trial for VesiGel, each pursuant to the FDA's 505(b)(2) regulatory pathway;
- initiate an additional clinical trial for Vesimune in combination with another agent;
- continue the preclinical development of our other product candidates;
- file an NDA seeking regulatory approval for any product candidates;
- establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we obtain regulatory approval;

- maintain, expand and protect our intellectual property portfolio;
- · add equipment and physical infrastructure to support our research and development;
- hire additional clinical development, quality control and manufacturing personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization.

We will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for, and if any of our product candidates are approved, proceed to commercialization. Adequate funding may not be available to us on acceptable terms, or at all.

#### **Allergan License Agreement**

We entered into an exclusive license agreement with Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc in October 2016, which we refer to as the Allergan Agreement. Allergan paid us a nonrefundable upfront license fee of \$17.5 million, and we are eligible to receive additional milestone payments upon the successful completion of certain development, regulatory and commercial milestones. Under the Allergan Agreement, Allergan is solely responsible, at its expense, for developing, obtaining regulatory approvals for and commercializing on a worldwide basis pharmaceutical products that contain RTGel and clostridial toxins (including BOTOX), alone or in combination with certain other active ingredients, which we refer to collectively as the Licensed Products. Allergan is obligated to pay us a tiered royalty in the low single digits based on worldwide annual net sales of Licensed Products, subject to certain reductions for the market entry of competing products and/or loss of our patent coverage of Licensed Products. We are responsible for payments to any third party under our existing agreement and certain future agreement for certain RTGel-related third party intellectual properties. In July 2017, Allergan notified us that they had submitted their Investigational New Drug, or IND, application for BotuGel, our proprietary novel RTGel-based formulation of BOTOX for the treatment of overactive bladder, to the FDA. The submission of the IND triggered the second milestone under our licensing agreement, pursuant to which we expect to receive a payment of \$7.5 million in the third quarter of 2017.

# **Components of Results of Operations**

#### Revenues

We do not currently have any products approved for sale and, to date, we have not recognized any revenues from sales of MitoGel, VesiGel or Vesimune. During the year ended December 31, 2016, we recognized revenues of \$17.5 million from a payment received under the Allergan Agreement. We did not recognize any revenues under the Allergan Agreement for the six months ended June 30, 2017. However, we expect to receive additional revenues of \$7.5 million under the Allergan Agreement in the third quarter of 2017 pursuant to a previously achieved milestone. In the future, we may generate revenue from a combination of product sales, reimbursements, up-front payments, milestone payments and royalties in connection with the Allergan Agreement and future collaborations. If we fail to achieve clinical success and/or to obtain regulatory approval of any of our product candidates in a timely manner, our ability to generate future revenue will be impaired.

#### Research and development expenses, net

The largest component of our total operating expenses has historically been, and we expect will continue to be, research and development. Research and development expenses consist primarily of:

- salaries and related costs, including share-based compensation expense, for our personnel in research and development functions;
- expenses incurred under agreements with third parties, including CROs, subcontractors, suppliers and consultants, preclinical studies and clinical trials:
- · expenses incurred to acquire, develop and manufacture preclinical study and clinical trial materials;
- · facility and equipment costs, including depreciation expense, maintenance and allocated direct and indirect overhead costs;

We expense all research and development costs as incurred. In light of the fact that our employees and internal resources may be engaged in projects for multiple programs at any time, our focus is on total research and development expenditures, and we do not allocate our internal research and development expenses by project.

Through June 30, 2017, we had received grants of \$2.1 million in the aggregate from the Israeli Innovation Authority, ("IIA"), for research and development funding. Pursuant to the terms of the grants, we are obligated to pay the IIA royalties of 3.0% to 4.5% on revenues from sales of products developed from a project financed in whole or in part by IIA grants, up to a limit of 100% of the amount of the grant received, plus annual interest calculated at a rate based on 12-month LIBOR.

In addition to paying any royalties due, we must abide by other restrictions associated with receiving such grants under the R&D Law, which will continue to apply to us following full repayment to the IIA. For example, under the Allergan Agreement, Allergan has the option to manufacture products developed with IIA-funded technology outside of Israel, which would require approval from the IIA. Although Allergan has not yet exercised this option, we have requested approval from the IIA for a possible transfer. We may not receive such approval. Even if we do receive such approval, we may be required to pay increased royalties of up to 300% of the amount of the original grant and other amounts. The Israeli government grants we have received for research and development activities restrict our ability to manufacture products and transfer technologies outside of Israel and require us, in addition to the payment of royalties, to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received and incur financial penalties.

We are currently focused on advancing our product candidates, and our future research and development expenses will depend on their clinical success. Research and development expenses will continue to be significant and will increase over at least the next several years as we continue to develop our product candidates and conduct preclinical studies and clinical trials of our product candidates.

We do not believe that it is possible at this time to accurately project total expenses required for us to reach commercialization of our product candidates. Due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with certainty the costs we will incur and the timelines that will be required in the continued development and approval of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, if and when such arrangements will be entered into, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Under applicable accounting rules, we deduct the IIA grants from research and development expenses as the applicable costs are incurred. We also had a preclinical collaboration for BotuGel with Allergan into which we initially entered into in February 2014. We deduct amounts received from the preclinical collaboration with Allergan from our research and development expenses as the applicable costs are incurred. As a result, our research and development expenses are shown on our financial statements net of the IIA grants and amounts received from the preclinical collaboration.

#### General and administrative expenses

General and administrative expenses consist primarily of personnel costs, including share-based compensation, related to directors, executive, finance, and human resource functions, facility costs and external professional service costs, including legal, accounting and audit services and other consulting fees.

We anticipate that our general and administrative expenses will increase in the future as we increase our administrative headcount and infrastructure to support our continued research and development programs and the potential approval and commercialization of our product candidates. We also anticipate that we will incur increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with NASDAQ and SEC requirements, director and officer insurance premiums, executive compensation, and other costs associated with being a public company.

In addition, if any of our product candidates receives regulatory approval and if we invest in building a commercial infrastructure to support the marketing of our products, we expect to incur greater expenses.

#### Finance expenses, net

Finance expenses, net, consist primarily of finance expenses on warrants.

# Income taxes

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately \$14.2 million as of December 31, 2016. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We have provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses.

#### **Analysis of Results of Operations**

# Comparison of the six months and three months ended June 30, 2017 and 2016

The following table summarizes our results of operations for six months and three months ended June 30, 2017 and 2016:

	Six months ended June 30,		Three months ended June 30,	
	2017	2016	2017	2016
	(Unaudited in thousands)			
Revenues	\$ 19	\$ —	\$ —	\$ —
Cost of revenues	18			
Gross profit	1		_	_
Research and development expenses, net (1)	6,315	5,042	3,651	2,351
General and administrative expenses (1)	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

(1) Includes share-based compensation expense as follows:

	Six months ended June 30,		Three months ended June 30,	
	2017	2016	2017	2016
	(Unaudited in thousands)			]
Research and development, net	\$1,013	\$ 454	\$ 853	\$ 196
General and administrative expenses	860	419	723	237
Total share-based compensation	\$1,873	\$ 873	\$ 1,576	\$ 433

#### Revenues

Our total revenues increased by \$19,000 from \$0 in the six months ended June 30, 2017 to \$19,000 in the six months ended June 30, 2017 due to revenues from the supply of RTGel vials under the Allergan Agreement.

#### Research and development expenses

Research and development expenses increased by \$1.3 million, to \$6.3 million in the six months ended June 30, 2017 from \$5.0 million in the six months ended June 30, 2016. The increase was primarily attributable to an increase in share-based compensation of approximately \$559,000, and an increase of \$325,000 in headcount and related costs, to support increased clinical trial activities including clinical manufacturing.

Research and development expenses increased by \$1.3 million, to \$3.7 million in the three months ended June 30, 2017 from \$2.4 million in the three months ended June 30, 2016. The increase was primarily attribute to an increase in share-based compensation of approximately \$657,000 and an increase of \$220,000 in in headcount and related costs, to support increased clinical trial activities including clinical manufacturing. The remaining increase is primarily related to direct costs associated with the MitoGel Phase 3 clinical trial.

#### General and administrative expenses

General and administrative expenses increased by \$1.2 million, to \$3.2 million in the six months ended June 30, 2017 from \$2.0 million in the six months ended June 30, 2016. The increase in general and administrative expenses resulted primarily from an increase in share-based compensation expenses of approximately \$440,000, an increase of \$366,000 in payroll primarily due to headcount and related costs, to support our growing business and an increase of \$266,000 in professional service expenses for consultants hired by us in preparation for the IPO, director and officer insurance premiums, and other costs associated with being a public company.

General and administrative expenses increased by \$1.3 million, to \$2.3 million in the three months ended June 30, 2017 from \$1.0 million in the three months ended June 30, 2016. The increase in general and administrative expenses resulted primarily from an increase in share-based compensation expenses of \$486,000, an increase of \$360,000 in headcount and related costs, to support our growing business and an increase of \$282,000 in professional services expenses for consultants hired by us in preparation for the IPO, director and officer insurance premiums, and other costs associated with being a public company.

#### Finance expenses

Finance expenses, net, increased by \$243,000, to \$127,000 expenses in the six months ended June 30, 2017 from \$116,000 income in the six months ended June 30, 2016. The change in finance expense was primarily due to the increased fair value of the warrants converted to Preferred A-1 shares.

Finance expenses, net, increased by \$326,000, to \$248,000 expenses in the three months ended June 30, 2017 from \$78,000 income in the three months ended June 30, 2016. The change in finance expense was primarily due to the increased fair value of the warrants converted to Preferred A-1 shares.

#### **Liquidity and Capital Resources**

#### Liauidity

Since our inception, we have incurred losses and negative cash flows from our operations. For the six months ended June 30, 2017, we incurred a net loss of \$9.6 million and used net cash of \$6.2 million in our operating activities. As of June 30, 2017, we had working capital of \$73. 3million, and an accumulated deficit of \$36.8 million. Our principal source of liquidity as June 30, 2017 consisted of cash and cash equivalents of \$77.0 million.

#### Capital resources

#### Overview

Through December 31, 2016, we have financed our operations primarily through private placements of equity securities and through the upfront payment received under the Allergan Agreement. In May 2017, we raised \$60.8 million, net of issuance costs and underwriting discounts and commissions in our IPO on the NASDAQ Stock Market. In addition, during the year ended December 31, 2016, we recorded \$1.7 million in general and administrative expenses related to IPO costs, in accordance with SEC staff Bulletin Topic 5A. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our present and future funding requirements will depend on many factors, including, among other things:

- the progress, timing and completion of clinical trials for MitoGel and VesiGel;
- preclinical studies and clinical trials for Vesimune or any of our other product candidates;
- the costs related to obtaining regulatory approval for MitoGel, VesiGel and Vesimune and any of our other product candidates, and any delays we may encounter as a result of regulatory requirements or adverse clinical trial results with respect to any of these product candidates;
- selling, marketing and patent-related activities undertaken in connection with the commercialization of MitoGel and VesiGel and any of our other product candidates, and costs involved in the development of an effective sales and marketing organization;

- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents or defending against claims or infringements raised by third parties, and license royalties or other amounts we may be required to pay to obtain rights to third party intellectual property rights;
- potential new product candidates we identify and attempt to develop; and
- revenues we may derive either directly or in the form of royalty payments from future sales of MitoGel, VesiGel, Vesimune, BotuGel and any other
  product candidates.

Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

#### Cash flows

The following table summarizes our statement of cash flows for the six months ended June 30, 2017 and 2016, and for three months ended June 30, 2017 and 2016:

	Six months ended June 30,		Three months ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Net cash provided by (used in):				
Operating activities	\$ (6,206)	\$(5,631)	\$ (3,461)	\$(3,000)
Investing activities	\$ (103)	\$ (541)	\$ (21)	\$ (396)
Financing activities	\$62,040	\$ (318)	\$62,148	\$ (189)
Net cash provided by (used in):	\$55,731	\$(6,490)	\$58,666	\$(3,585)

#### Net cash provided by (used in) operating activities

The cash used in operating activities during the aforementioned periods resulted primarily from our net losses incurred during such periods, as adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net losses for non-cash items mainly included depreciation and amortization, fair value adjustment of the Preferred A-1 warrants and share-based compensation.

Net cash used in operating activities was \$6.2 million in the six months ended June 30, 2017, compared to \$5.6 million used in operating activities the six months ended June 30, 2016. The \$600,000 increase was attributable primarily to the increase of \$2.8 million in the loss for the year, partly offset by an increase of \$1.0 million in share-based compensation expenses and increase of \$1.4 million in accounts payable and accrued expenses.

Net cash used in operating activities was \$3.5 million in the three months ended June 30, 2017, compared to \$3.0 million used in operating activities in the three months ended June 30, 2016. The \$500,000 increase was attributable primarily to the increase of \$2.8 million in the loss for the year, partly offset by an increase of \$1.1 million in share-based compensation expenses and increase of \$1.1 million in accounts payable and accrued expenses.

#### Net cash used in investing activities

The use of cash in investing activities relates primarily to the purchase of property and equipment and changes in restricted deposits.

Net cash used in investing activities was \$103,000 in the six months ended June 30, 2017, compared to \$541,000 in the six months ended June 30, 2016. The decrease of \$438,000 in use of cash in investing activities mainly related to leasehold improvements in the Israel and our U.S. offices performed during the six months ended June 30, 2016, which costs did not recur in the six months ended June 30, 2017.

Net cash used in investing activities was \$21,000 in the three months ended June 30, 2017, compared to \$396,000 in the three months ended June 30, 2016. The decrease of \$375,000 in use of cash in investing activities mainly related to the leasehold improvements in the Israel and our U.S. offices performed during the three months ended June 30, 2017, which costs did not recur in the three months ended June 30, 2017.

# Net cash provided by (used in) financing activities

Net cash provided by financing activities was \$62.0 million in the six months ended June 30, 2017, compared to \$318,000 used in financing activities in the six months ended June 30, 2016, the difference of which primarily reflected the net proceeds received by us in the IPO.

Net cash provided by financing activities was \$62.0 million in the three months ended June 30, 2017, compared to \$189,000 provided by financing activities in the six months ended June 30, 2016, the difference of which is primarily derived by net proceeds received by us in the IPO.

# Contractual obligations and commitments

# **Off-balance Sheet Arrangements**

As of the date of this discussion and analysis, we do not have any off- balance sheet arrangements.



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

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, NY**, August 14, 2017: 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<sup>TM</sup> to evaluate the safety, tolerability and tumor ablative effect of MitoGel<sup>TM</sup> in low grade UTUC patients. The trial, designed to be a single pivotal study for the potential approval of MitoGel<sup>TM</sup> 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<sup>TM</sup>.

#### About MitoGel™

Utilizing RTGel<sup>TM</sup>, UroGen's proprietary sustained release, hydrogel-based formulation, MitoGel<sup>TM</sup> 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<sup>TM</sup> 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.

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

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	F 755 74 A	2 205 244	0.204.405	2 205 742
LOSS PER ORDINARY SHARE	5,755,714	2,305,241	9,204,405	2,305,743

# CONTACTS:

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Or

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