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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 6-K**

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**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

**For the month of November 2018**

**Commission File Number 001-38079**

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**UROGEN PHARMA LTD.**

(Translation of registrant's name into English)

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**9 Ha'Ta'asiya Street  
Ra'anana 4365007, Israel**  
(Address of principal executive offices)

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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):

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):

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## 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 Statements on Form S-8 (Registration Numbers 333-218992, 333-221212, 333-222955 and 333-227812) and the Registration Statement on Form F-3 (Registration Number 333-227811) 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 (the “Company”) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act.

## RISK FACTORS

The risk factors set forth under the caption “Risk Factors” in the Company’s annual report on Form 20-F filed on March 15, 2018 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by reference herein and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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.

The following risk factor was added since the Company’s Annual Report on Form 20-F for the year ended December 31, 2017.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.***

We are currently an “emerging growth company” as defined in the U.S. federal securities laws. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the NASDAQ Global Market.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2018, we must perform system and process design evaluation and testing of the effectiveness of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. In addition, our internal controls over financial reporting will also be subject to testing by our independent registered public accounting firm. We have never been required to test our internal controls within a specified period, nor have our internal controls been subject to subsequent testing by our independent registered public accounting firm, and, as a result, we may experience difficulty in meeting these reporting and testing requirements in a timely manner.

We or our independent registered public accounting firm may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our shares could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

## PFIC STATUS

If we are a passive foreign investment company, or PFIC, we expect to provide investors, by annually posting a “PFIC Annual Information Statement” on our website, with the information required to allow investors to make a qualified electing fund, or QEF, election for United States federal income tax purposes.

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**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.

November 13, 2018

**UROGEN PHARMA LTD.**

By: /s/ Peter Pfreunds Schuh

Peter Pfreunds Schuh

Chief Financial Officer

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## EXHIBIT INDEX

Exhibit No.	Description
99.1	Unaudited Condensed Consolidated Interim Balance Sheets as of September 30, 2018 and December 31, 2017, Unaudited Condensed Consolidated Interim Statements of Operations for the nine and three months ended September 30, 2018 and 2017, Unaudited Condensed Consolidated Interim Statements of Changes in Shareholders' Equity and Statements of Cash Flows for the nine months ended September 30, 2018 and 2017 and Notes to the Condensed Consolidated Financial Statements.
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	Press Release dated November 12, 2018
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Changes in Shareholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements

**UROGEN PHARMA LTD.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(U.S. dollars in thousands, except share and per share data)  
(Unaudited)

<b>Assets</b>	<b>September 30, 2018</b>	<b>December 31, 2017</b>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 109,483	\$ 36,999
Short-term investments	—	36,001
Restricted deposit	197	198
Accounts receivable	112	—
Inventory	—	316
Prepaid expenses and other current assets	1,679	958
<b>TOTAL CURRENT ASSETS</b>	<b>111,471</b>	<b>74,472</b>
<b>NON-CURRENT ASSETS</b>		
Property and equipment, net	992	805
Restricted deposit	81	29
Other non-current assets	14	244
<b>TOTAL ASSETS</b>	<b>\$ 112,558</b>	<b>\$ 75,550</b>
<b>Liabilities and Shareholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 6,291	\$ 4,435
Employee related accrued expenses	2,684	1,950
Deferred revenues	—	650
<b>TOTAL CURRENT LIABILITIES</b>	<b>8,975</b>	<b>7,035</b>
<b>TOTAL LIABILITIES</b>	<b>8,975</b>	<b>7,035</b>
<b>COMMITMENTS AND CONTINGENCIES (NOTE 7)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Ordinary shares, NIS 0.01 par value; 100,000,000 shares authorized at September 30, 2018 and December 31, 2017; 16,102,257 and 13,751,390 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	44	37
Additional paid-in capital	202,693	115,692
Accumulated deficit	(99,154)	(47,214)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>103,583</b>	<b>68,515</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 112,558</b>	<b>\$ 75,550</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2018	2017	2018	2017
<b>REVENUES</b>	\$ 1,128	\$ 7,831	\$ 283	\$ 7,812
<b>COST OF REVENUES</b>	1,803	313	1,055	295
<b>GROSS PROFIT</b>	(675)	7,518	(772)	7,517
<b>OPERATING EXPENSES:</b>				
RESEARCH AND DEVELOPMENT EXPENSES	25,469	11,936	9,574	5,621
GENERAL AND ADMINISTRATIVE EXPENSES	27,019	5,374	10,743	2,199
<b>OPERATING LOSS</b>	53,163	9,792	21,089	303
<b>INTEREST AND OTHER (INCOME) EXPENSES, NET</b>	(1,323)	122	(556)	(5)
<b>REALIZED LOSS ON SALE OF SHORT-TERM INVESTMENT</b>	100	—	—	—
<b>NET LOSS</b>	\$ 51,940	\$ 9,914	\$ 20,533	\$ 298
<b>NET LOSS PER ORDINARY SHARE BASIC AND DILUTED</b>	\$ 3.30	\$ 1.31	\$ 1.28	\$ 0.02
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE</b>	15,721,445	8,223,124	16,092,583	13,051,117

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Ordinary Shares		Preferred Shares		Additional paid-in capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
<b>BALANCE AS OF JANUARY 1, 2018</b>	13,751,390	\$ 37	—	\$ —	\$ 115,692	\$ (47,214)	\$ 68,515
<b>CHANGES DURING THE NINE MONTHS ENDED SEPTEMBER 30, 2018:</b>							
Exercise of options into ordinary shares	667,941	2			1,048		1,050
Share-based compensation					21,765		21,765
Issuance of ordinary shares in public offering, net of issuance expenses	1,682,926	5			64,188		64,193
Net loss						(51,940)	(51,940)
<b>BALANCE AS OF SEPTEMBER 30, 2018</b>	<u>16,102,257</u>	<u>\$ 44</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 202,693</u>	<u>\$ (99,154)</u>	<u>\$ 103,583</u>
<b>BALANCE AS OF JANUARY 1, 2017</b>	2,305,743	\$ 6	5,193,427	\$ 13	\$ 43,502	\$ (27,214)	\$ 16,307
<b>CHANGES DURING THE NINE MONTHS ENDED SEPTEMBER 30, 2017:</b>							
Exercise of options into ordinary shares	170,816	*			333		333
Share-based compensation					4,031		4,031
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						(9,914)	(9,914)
<b>BALANCE AS OF SEPTEMBER 30, 2017</b>	<u>13,178,400</u>	<u>\$ 35</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 113,354</u>	<u>\$ (37,128)</u>	<u>\$ 76,261</u>

(\* ) Represents less than one thousand

The accompanying notes are an integral part of these condensed consolidated financial statements.

**UROGEN PHARMA LTD.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(U.S. dollars in thousands)  
(Unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (51,940)	\$ (9,914)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and disposals	349	149
Share-based compensation	21,765	4,031
Realized loss on sale of short-term investment	100	—
Exchange rates differences	1	(2)
Fair value adjustment of warrants for preferred shares	—	168
Changes in operating assets and liabilities:		
Decrease (increase) in inventory	316	(32)
(Increase) decrease in accounts receivable	(112)	49
Decrease (increase) in prepaid expenses and other current assets	329	(514)
Increase in accounts payable and accrued expenses	2,058	1,704
(Decrease) increase in deferred revenues	(650)	300
Increase in employee related accrued expenses	734	452
Net cash used in operating activities	<u>(27,050)</u>	<u>(3,609)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Change in restricted deposit	(52)	(105)
Sale of short-term investment	35,901	—
Purchase of property and equipment	(536)	(118)
Net cash provided by (used in) investing activities	<u>35,313</u>	<u>(223)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of options into ordinary shares	—	333
Issuance of ordinary shares in public offering, net of issuance expenses	64,221	60,926
Proceeds from exercise of warrants to preferred shares	—	382
Net cash provided by financing activities	<u>64,221</u>	<u>61,641</u>
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>72,484</b>	<b>57,809</b>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR</b>	<b>36,999</b>	<b>21,362</b>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE YEAR</b>	<b>\$ <u>109,483</u></b>	<b>\$ <u>79,171</u></b>
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Exercise of options	<u>\$ 1,050</u>	<u>\$ —</u>
Exercise of warrants into preferred shares	<u>\$ —</u>	<u>\$ 4,732</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.



**UROGEN PHARMA LTD.**  
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(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 (together 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.
- c. As described in Note 7a1, 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 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.
- d. In January 2018, the Company completed a follow-on public offering on Nasdaq of 1,682,926 ordinary shares, at a public offering price of \$41.00 per share, in consideration for approximately \$64.2 million net of underwriting discounts and commissions and issuance costs, including exercise of the underwriters' option to purchase an additional 219,512 ordinary shares at the public offering price.
- e. As of the date of issuance 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, the Company may need to raise additional funds to fund its research and development expenses, general and administrative expenses and capital expenditures until such time that it can generate substantial revenues.

**NOTE 2 - BASIS OF PRESENTATION**

The Company's unaudited condensed consolidated interim financial statements 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 September 30, 2018, and the results of operations for the nine and three months ended September 30, 2018 and 2017.

These unaudited condensed consolidated interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2017 and notes thereto included in the Company's annual financial statements for the year ended December 31, 2017. The condensed balance sheet data as of December 31, 2017 included in these unaudited condensed consolidated financial statements was derived from the audited financial statements for the year ended December 31, 2017 but does not include all disclosures required by U.S. GAAP.

The results for the nine and three months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018.

**UROGEN PHARMA LTD.**  
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands, except share data)  
(Unaudited)

**NOTE 3 - RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS:**

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" ("Topic 606", "ASU 2014-09", or "the New Revenue Standard"). ASU 2014-09 requires entities to recognize revenue that represents the transfer of promised goods or services to customers in an amount equivalent to the consideration to which the entity expects to be entitled in exchange for those goods or services. The following steps should be applied to determine this amount: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU 2014-09 supersedes the revenue recognition requirements in ASU 605, "Revenue Recognition," and most industry-specific guidance in the Accounting Standards Codification. The New Revenue Standard is effective for the Company for annual reporting periods, including interim periods therein, beginning January 1, 2018. The New Revenue Standard may be applied retrospectively with the cumulative effect recognized as of the date of adoption (modified retrospective method). The Company has adopted the New Revenue Standard using modified retrospective method. The Company has completed its assessment of the New Revenue Standard and identified two revenue streams; (1) licensing revenue and (2) revenue from clinical supply of RTGel per the license agreement with Allergan. The implementation of the New Revenue Standard did not have a material impact on the amount or timing of the Company's current revenue recognition related to these revenue streams.

In February 2016, the FASB issued ASU No. 2016-02, "Leases" ("Topic 842" or "ASU 2016-02"). ASU 2016-02 supersedes existing guidance in Leases (Topic 840). The revised standard requires lessees to recognize the assets and liabilities arising from leases with lease terms greater than twelve months on the balance sheet, including those currently classified as operating leases, and to disclose key information about leasing arrangements. Lessees will be required to recognize a lease liability and a right-of-use asset on their balance sheets, while lessor accounting will remain largely unchanged. The guidance is effective for annual periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact the adoption of ASU 2016-02 will have on its consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation" ("Topic 718" or "ASU 2018-07") to improve the usefulness of information provided to users of financial statements while reducing cost and complexity in financial reporting and provide guidance aligning the measurement and classification for share-based payments to nonemployees with the guidance for share-based payments to employees. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date. This standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently assessing the impact of ASU 2018-07.

**NOTE 4 – SHORT-TERM INVESTMENTS**

The Company sold its short-term investments during March 2018 and recorded a realized loss on sale of short-term investment of \$100 for the nine months ended September 30, 2018. The Company also recorded increased interest income for the same period related to the short-term investment. At September 30, 2018, all the Company's funds were in cash and cash equivalents.

**NOTE 5 - 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.

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.

**UROGEN PHARMA LTD.**  
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands, except share data)  
(Unaudited)

**NOTE 5 - FAIR VALUE MEASUREMENT (continued)**

The Company's assets and liabilities that are measured at fair value as of September 30, 2018 and December 31, 2017 are classified in the tables below in one of the three categories described above:

	September 30, 2018	December 31, 2017
Money market and mutual funds(1) - Level 1	\$ 89,486	\$ 26,127
Short-term investments - Level 2	—	36,001
Other - Level 3	—	—

(1) Included in cash and cash equivalents on the consolidated balance sheets. The carrying amount approximates fair value.

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

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2018	2017	2018	2017
Balance at the beginning of the period	\$ —	\$ 3,612	\$ —	\$ —
Changes in fair value during the period	—	168	—	—
Exercise of warrants to preferred shares	—	(3,780)	—	—
Balance at end of the period	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

**NOTE 6 - PREPAIDS AND OTHER CURRENT ASSETS**

- a. As of September 30, 2018, approximately \$1,050 was held at the Company's trustee for the exercise of 30,000 stock options by the Company's chairman of the board. The exercise date was September 26, 2018, and the funds were received by the Company in October 2018. Therefore, the amount was recorded as a receivable under other current assets on September 30, 2018.

**NOTE 7 - COMMITMENTS AND CONTINGENCIES**

- a. In September 2017, UPI entered into a new lease agreement for its New York headquarters. The lease agreement commenced in October 2017 and shall terminate in February 2021. The total contractual obligation for the duration of the lease is approximately \$2,130.
- b. In April 2018, UPI entered into a new lease agreement for an office in Los Angeles, CA. The lease commenced in July 2018 and shall terminate in March 2024. In order to make the space usable for its operations, substantial improvements were made. UPI's landlord agreed to pay approximately \$196 of the improvements, and the Company bore any additional costs incurred. As such, the Company determined that it is the owner of the improvements and account for these improvements as a lease incentive. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease. The total contractual obligation for the duration of the lease is approximately \$1,400.
- c. Through September 30, 2018, the Company has received grants of \$2,100 in the aggregate from the Israeli Innovation Authority, or IIA, for research and development funding. Pursuant to the terms of the grants, the Company is obligated to pay the IIA royalties of 3.0% to 5.0% 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. As of September 30, 2018, the Company has accrued \$800 in royalties due to the IIA, which has been recorded in cost of revenues in our results of operations for the nine and three months ended September 30, 2018.

**UROGEN PHARMA LTD.**  
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands, except share data)  
(Unaudited)

**NOTE 8 - 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 at a public offering price of \$13.00 per share in consideration for \$60.8 million, net of issuance costs and underwriting discounts.
3. In January 2018, the Company completed a follow-on public offering on Nasdaq of 1,682,926 ordinary shares, at a public offering price of \$41.00 per share, in consideration for approximately \$64.2 million net of underwriting discounts and commissions and issuance costs, including exercise of the underwriters' option to purchase an additional 219,512 ordinary shares at the public offering price.
4. In October 2018, the Company filed a shelf registration statement on Form F-3, which was declared effective by the U.S. Securities and Exchange Commission on October 26, 2018, registering a number of ordinary shares, warrants, rights and units with a maximum aggregate public offering price not to exceed \$250.0 million. Included in this amount is \$100.0 million of ordinary shares that may be offered, issued and sold under an Open Market Sales Agreement with Jeffries, LLC. To date, the Company has not issued any shares pursuant to this registration.
5. During the nine months ended September 30, 2018, the Company issued 667,941 ordinary shares with respect to the net exercise of stock options and restricted stock units (RSUs).

**b. Share-based compensation**

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

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses	\$ 9,056	\$ 2,513	\$ 3,795	\$ 1,499
General and administrative expenses	12,709	1,518	5,720	659
	<u>\$ 21,765</u>	<u>\$ 4,031</u>	<u>\$ 9,515</u>	<u>\$ 2,158</u>

2. 2017 Equity Incentive Plan

In March 2017, the Company's board of directors adopted the 2017 Equity Incentive Plan ("2017 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 1,400,000. 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, 2027, 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 3,550,167.

On January 1, 2018, the shares reserved for issuance under the 2017 Plan increased by 250,167 to 1,650,167.

**UROGEN PHARMA LTD.**  
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands, except share data)  
(Unaudited)

**NOTE 8 - SHARE CAPITAL (continued)**

On October 12, 2018, the Company filed a registration statement on Form S-8 increasing the amount of registered ordinary shares of the Company's 2017 Plan by 1,900,000.

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 the Company's 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. During the nine months ended September 30, 2018, the Company's board of directors approved grants of 900,000 options to executive management and employees of the Company. Each option is exercisable into one ordinary share of the Company at an exercise price between \$38.64 to \$59.23. The options vest in several installments over a three-year period. As of the grant date, the fair value of these options was \$30,033. The options expire ten years after their grant date.
4. During the nine months ended September 30, 2018, the Company's board of directors approved grants of 111,493 restricted stock units, or RSUs, to executive management and employees of the Company. The RSUs vest in several installments over a three-year period. As of the grant date, the fair value of these RSUs was \$5,460. The RSUs expire ten years after their grant date.
5. In January 2018, the Company's board of directors approved a grant of 40,000 options to the Chairman of the board of directors of the Company. Each option is exercisable into one ordinary share of the Company at an exercise price of \$43.67. The options vest quarterly over a one-year period. As of the grant date, the fair value of these options was \$1,392. The options expire ten years after their grant date.
6. In January 2018, the Company's board of directors approved grants of 30,000 options to consultants of the Company. Each option is exercisable into one ordinary share of the Company at an exercise price of \$43.67. The options vest monthly over a one-year period. As of September 30, 2018, the fair value of the options remaining was estimated at \$95. The options expire ten years after their grant date.
7. In June 2018, the Company's board of directors approved a grant of 60,000 options to the board of directors of the Company. Each then current director, including the Chairman of the board, received 10,000 options. Each option is exercisable into one ordinary share of the Company at an exercise price of \$59.23. The options vest quarterly over a one-year period. As of the grant date, the fair value of these options was \$2,882. The options expire ten years after their grant date.
8. In June 2018, the Company's board of directors approved grants of 10,000 options to consultants of the Company. Each option is exercisable into one ordinary share of the Company at an exercise price of \$59.23. The options vest 50% six months from grant date and 50% nine months from grant date. As of September 30, 2018, the fair value of these options was estimated at \$367. The options expire ten years after their grant date.
9. In June 2018, the Company announced the resignation of its CFO, and in June 2018, the Company's board of directors approved a severance package including modifications to grants of his related option awards. The fair value of the modifications to these option awards was estimated at \$2,324 and was recorded in general and administrative expenses in the Company's Statements of Operations for the nine months ended September 30, 2018.
10. In July 2018, the Company's board of directors approved a grant of 50,000 options to a new member of the board of directors. Each option is exercisable into one ordinary share of the Company at an exercise price of \$49.40. The options vest quarterly over a three-year period. As of the grant date, the fair value of these options was \$2,000. The options expire ten years after their grant date.
11. In August and September 2018, the Company's board of directors approved severance packages for the President of Israeli Operations and two other members of senior management, which included modifications to their respective equity awards. The fair value of the modifications to these equity awards was estimated at \$4,657 and was recorded in research and development and general and administrative expenses, based on salary allocations respectively, in the Company's Statements of Operations for the nine and three months ended September 30, 2018.
12. In August 2018, in addition to the modifications, one senior executive was granted 10,466 RSUs in which no compensation expense was taken because the award vests upon a future performance condition that is not currently probable of occurring, this amount is included in total RSUs granted in Note 8b4.

**UROGEN PHARMA LTD.**  
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(U.S. dollars in thousands, except share data)  
(Unaudited)

**NOTE 9 - RELATED PARTIES**

UPI entered into a lease agreement, dated as of November 2015 and commencing as of May 2016, for office space located at 689 Fifth Avenue in New York. UPI shared the office space equitably with Kite Pharma, Inc., a Delaware corporation, which is a cosignatory to such lease agreement. Arie Beldegrun, M.D., UPL's chairman, served as the Chairman and Chief Executive Officer of Kite Pharma, Inc. until his resignation effective as of October 3, 2017, in connection with the acquisition of Kite Pharma, Inc. by Gilead Sciences, Inc.

In April 2018, the Company terminated its lease for offices at 689 Fifth Avenue in New York. The Company expects the office to be assumed by other tenants in the near future. However, until the assumption takes place, the Company has recorded an estimate of approximately \$291 in early termination expense on the lease for the nine months ended September 30, 2018. The Company also recorded a loss on disposal of fixed assets of \$183 for the nine months ended September 30, 2018, regarding the accelerated depreciation on the leasehold improvements associated with the lease.

**NOTE 10 - LOSS PER SHARE:**

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

	<u>Nine Months Ended September 30,</u>		<u>Three Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Basic and diluted:				
Net Loss attributable to equity holders of the Company	\$ 51,940	\$ 9,914	\$ 20,533	\$ 298
Dividend accumulated on preferred shares during the period	\$ —	\$ 825	\$ —	\$ —
Net Loss attributable to equity holders of the Company, after reducing dividend accumulated on preferred shares	\$ 51,940	\$ 10,739	\$ 20,533	\$ 298
Weighted average number of ordinary shares outstanding used in computing basic and diluted net loss per ordinary share	15,721,445	8,223,124	16,092,583	13,051,117
Basic and diluted net loss per ordinary share	\$ 3.30	\$ 1.31	\$ 1.28	\$ 0.02

For the nine and three months ended September 30, 2018 and 2017, 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.

**NOTE 11 - SUBSEQUENT EVENTS:**

The Company has evaluated and determined there were no subsequent events through November 12, 2018.

**UROGEN PHARMA LTD.**  
**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 nine and three months ended September 30, 2018 and 2017 should be read in conjunction with our unaudited condensed consolidated financial statements for such periods filed as Exhibit 99.1 to this Report on Form 6-K, as well as our annual financial statements for the years ended December 31, 2017, 2016 and 2015 and related discussion and analysis of our financial condition and results of operations for such periods, which were included in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on March 15, 2018. Unless the context requires otherwise, references in this Report to "we," "us," "our" and "UroGen" refer to UroGen Pharma, Ltd. and its subsidiaries. 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, UGN-101 (mitomycin gel) for instillation, formerly known as MitoGel<sup>®</sup>, and UGN-102 (mitomycin gel) for intravesical instillation, are proprietary formulations of the chemotherapy drug mitomycin, a generic drug, which is currently used off-label for urothelial cancer treatment only in a water-based formulation as an adjuvant, or supplemental post-surgery, 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. No drugs have been approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of low-grade upper tract urothelial cancer. We believe that UGN-101 and UGN-102, 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. UGN-101 and UGN-102 may also reduce the need for bladder and upper urinary tract surgeries, including removal of the upper urinary tract and kidney, which are major surgical procedures typically performed when local endoscopic tumor resection fails to control the disease progression. Additionally, we believe that our product candidates, which are based on formulations of previously approved drugs, may qualify for streamlined regulatory pathways to market approval.

Our lead product candidates, UGN-101 and UGN-102, are formulated using our proprietary reverse thermally triggered hydrogel, or RTGel<sup>™</sup> 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 of the active drug throughout the organ. 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 the last 20 years.

Our clinical stage pipeline also includes UGN-201 (imiquimod), our immunotherapy product candidate for the treatment of high-grade NMIBC, which may include Carcinoma in Situ, or CIS. UGN-201 is a novel, liquid formulation of imiquimod, a generic toll-like receptor 7, or TLR7, agonist. Toll-like receptor agonists play a key role in initiating the innate immune response system. We believe that UGN-201 as a single agent or in combination with additional immunotherapy drugs, such as immune checkpoint inhibitors or chemotherapy drugs, could represent a valid alternative to the current standard of care for the post-transurethral resection of bladder tumor adjuvant treatment of high-grade NMIBC.

BotuGel is our proprietary novel RTGel-based formulation of BOTOX, a branded drug, that we believe can potentially serve as an effective treatment option for patients suffering from overactive bladder. In October 2016, we announced the licensing of the worldwide rights to RTGel in combination with neurotoxins, including BOTOX, to Allergan Pharmaceuticals International Limited, or Allergan. In August 2017, we announced that Allergan had submitted an Investigational New Drug, or IND, application to the FDA in order to be able to commence clinical trials in the United States using the RTGel in combination with BOTOX. In October 2017, Allergan commenced a Phase 2 clinical trial of BotuGel for the treatment of overactive bladder.

We have incurred net losses in each period since our formation in 2004. We incurred net losses of \$51.9 million and \$9.9 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, our accumulated deficit was \$99.2 million. 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:

- approach completion of the single pivotal Phase 3 clinical trial for UGN-101;
- conduct a Phase 2b clinical trial for UGN-102;
- initiate an additional clinical trial for UGN-201 as a single agent or in combination with another agent;
- continue the preclinical development of our other product candidates;
- submit a New Drug Application seeking regulatory approval for UGN-101, anticipated to be pursuant to the FDA's 505(b)(2) regulatory pathway, and additional product candidates;
- establish a sales, marketing and distribution infrastructure;
- 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, regulatory, commercial, quality control and manufacturing personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization.

We will need 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 in October 2016 (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 for certain RTGel-related third-party intellectual properties. In July 2017, Allergan notified us that they had submitted their IND 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 the Allergan Agreement, pursuant to which we received a payment of \$7.5 million in August 2017. Allergan commenced a Phase 2 clinical trial of BotuGel in October 2017.

### **Components of Results of Operations**

#### ***Revenues***

As of September 30, 2018, our revenue has been exclusively generated from our collaboration and license agreement with Allergan relating to milestones received and sales of RTGel to Allergan, per the Allergan Agreement. We do not currently have any products approved for sale and, to date, we have not recognized any revenues from sales of UGN-101, UGN-102 or UGN-201. 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 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***

Research and development expenses consist primarily of:

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

We expense all research and development costs as incurred. Our employees and internal resources may be engaged in projects for multiple programs at any time, and therefore our focus is on total research and development expenditures, and internal research and development expenses are not allocated by project.

Through September 30, 2018, we have received grants of \$2.1 million in the aggregate from the Israeli Innovation Authority, or 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 5.0% 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. As of September 30, 2018, we have accrued \$0.8 million in royalties due to the IIA, which has been recorded in cost of revenues in our results of operations for the nine and three months ended September 30, 2018.

In addition to paying any royalties due to the IIA, we must abide by other restrictions associated with receiving such grants under the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 5754-1984, or R&D Law, and the IIA rules for granting a right to use know-how developed from research and development that was conducted pursuant to a plan approved by the IIA outside of Israel, or the Licensing Rules. These rules will continue to apply to us following full repayment to the IIA. The IIA 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. 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 of the production process. We may not receive such approval. Even if we do receive such approval, we may be required to pay increased royalties to the IIA of up to 300% of the amount of the original grant received plus interest. If the IIA deems the license to Allergan to be a technology transfer, we may be required to pay up to 600% of the amount of the original grant plus interest. Such payment and its timing will be determined by various factors, including the consideration received by us and our R&D expenditure, and in accordance with the formulas set forth in the Licensing Rules.

We are 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, when such arrangements will be entered into, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

### ***General and administrative expenses***

General and administrative expenses consist primarily of personnel costs, including share-based compensation, related to directors, executive, commercial, investor relations, 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, manufacturing 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.

### **Interest and other income, net**

Interest and other income, net, for the nine and three months ended September 30, 2018 consisted primarily of interest income on our cash and short-term investments.

### **Income taxes**

We have yet to generate taxable income in Israel. We have historically incurred operating losses resulting in carry forward tax losses totaling approximately \$24.8 million as of December 31, 2017. 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 nine and three months ended September 30, 2018 and 2017**

The following table summarizes our results of operations for the nine and three months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited in thousands)		(Unaudited in thousands)	
Revenues	\$ 1,128	\$ 7,831	\$ 283	\$ 7,812
Cost of revenues	1,803	313	1,055	295
Gross profit	(675)	7,518	(772)	7,517
Research and development expenses (1)	25,469	11,936	9,574	5,621
General and administrative expenses (1)	27,019	5,374	10,743	2,199
Operating loss	53,163	9,792	21,089	303
Interest and other (income) expenses, net	(1,323)	122	(556)	(5)
Realized loss on sale of short-term investment	100	—	—	—
Net loss	<u>\$ 51,940</u>	<u>\$ 9,914</u>	<u>\$ 20,533</u>	<u>\$ 298</u>

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

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited in thousands)		(Unaudited in thousands)	
Research and development expenses	\$ 9,056	\$ 2,513	\$ 3,795	\$ 1,499
General and administrative expenses	12,709	1,518	5,720	659
Total share-based compensation	<u>\$ 21,765</u>	<u>\$ 4,031</u>	<u>\$ 9,515</u>	<u>\$ 2,158</u>

### **Revenues**

Our total revenues decreased by \$6.7 million from \$7.8 million in the nine months ended September 30, 2017 to \$1.1 million in the nine months ended September 30, 2018. The decrease is due to a \$7.5 million milestone payment received from Allergan in the third quarter of 2017. The balance of revenues is primarily related to sales of RTGel to Allergan, per the Allergan Agreement.

Our total revenues decreased by \$7.5 million from \$7.8 million in the three months ended September 30, 2017 to \$0.3 million in the three months ended September 30, 2018 and is primarily related to a \$7.5 million milestone payment received from Allergan in the third quarter of 2017.

### *Research and development expenses*

Research and development expenses increased by \$13.6 million to \$25.5 million in the nine months ended September 30, 2018 from \$11.9 million in the nine months ended September 30, 2017. The increase was attributable mainly to an increase of approximately \$6.5 million of share-based compensation, as a result of new grants to executive management and employees and modifications costs relating to senior management severance packages, and an increase of approximately \$3.4 million in headcount and related costs to support increased clinical trial activities. The remaining increase of \$3.7 million is mainly comprised of \$1.3 million direct costs associated with the UGN-101 Phase 3 clinical trial, \$1.3 million due to increased clinical activity of the UGN-102 Phase 2b clinical trial, \$0.4 million relating to activity in preclinical studies for our UGN-201 product candidate, and approximately \$0.4 million in allocated overhead costs to support the growth of our U.S. operations.

Research and development expenses increased by \$4.0 million to \$9.6 million in the three months ended September 30, 2018 from \$5.6 million in the three months ended September 30, 2017. The increase was attributable mainly to an increase of \$2.3 million of share-based compensation and an increase of \$1.7 million in headcount and related costs to support increased clinical trial activities.

### *General and administrative expenses*

General and administrative expenses increased by \$21.6 million to \$27.0 million in the nine months ended September 30, 2018 from \$5.4 million in the nine months ended September 30, 2017. The increase in general and administrative expenses resulted primarily from an increase in share-based compensation expense of \$11.2 million, including \$5.4 million in modification costs relating to senior management severance packages and \$5.8 million in new grants to executive management and employees. The remaining increase resulted primarily from a \$3.4 million increase in payroll and recruitment costs due to headcount and related costs to support our growing business, an increase of \$2.8 million in commercial services, an increase of \$2.5 million in consultant and directors fees and an increase of \$1.5 million to support the growth of our U.S. operations.

General and administrative expenses increased by \$8.5 million to \$10.7 million in the three months ended September 30, 2018 from \$2.2 million in the three months ended September 30, 2017. The increase in general and administrative expenses resulted primarily from an increase in share-based compensation expense of \$5.1 million, including \$3.0 million in modification costs relating to senior management severance packages and \$2.1 million in new grants to executive management and employees, an increase of \$1.2 million in payroll and recruitment costs due to headcount and related costs to support our growing business, an increase of \$1.0 million in commercial services, an increase of approximately \$0.8 million in consultant and directors fees and an increase of \$0.5 million to support the growth of our U.S. operations.

### *Interest and other income, net*

Interest and other income, net, increased by \$1.4 million to \$1.3 million in income for the nine months ended September 30, 2018 from \$0.1 million in expense for the nine months ended September 30, 2017. The change in income was primarily due to interest received on increased cash and cash equivalent balances received from our initial public offering, or IPO, and follow-on offering.

Interest and other income, net, increased by \$0.6 million to \$0.6 million in income for the three months ended September 30, 2018 from \$5,000 in expense for the three months ended September 30, 2017. The change in income was primarily due to interest received on increased cash and cash equivalent balances received from our IPO and follow-on offering.

### *Realized loss on sale of short-term investment*

We recorded a realized loss of \$0.1 million on sale of short-term investment for the nine months ended September 30, 2018.

## **Liquidity and Capital Resources**

### ***Liquidity***

Since our inception, we have incurred losses and negative cash flows from our operations. For the nine months ended September 30, 2018, we incurred a net loss of \$51.9 million and used net cash of \$27.1 million in our operating activities. As of September 30, 2018, we had working capital of \$102.5 million, and an accumulated deficit of \$99.2 million. Our principal source of liquidity as of September 30, 2018 consisted of cash and cash equivalents of \$109.5 million.

## Capital Resources

### Overview

In May 2017, we completed an IPO, which raised \$60.8 million, net of issuance costs and underwriting discounts and commissions, on the Nasdaq Stock Market. In January 2018, we completed a follow-on public offering which raised approximately \$64.2 million net of underwriting discounts and commissions and issuance costs. Through December 31, 2016, we had financed our operations primarily through private placements of equity securities and through the upfront payment received under the Allergan Agreement.

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 12 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 UGN-101 and UGN-102;
- preclinical studies and clinical trials for UGN-201 or any of our other product candidates;
- the costs related to obtaining regulatory approval for UGN-101, UGN-102 and UGN-201 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 UGN-101 and UGN-102 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 UGN-101, UGN-102, UGN-201, BotuGel and any other product candidates, or from other potential licenses of our technology platform.

Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain 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.

In October 2018, we filed a shelf registration statement on Form F-3, which was declared effective by the U.S. Securities and Exchange Commission on October 26, 2018, registering a number of ordinary shares, warrants, rights and units with a maximum aggregate public offering price not to exceed \$250.0 million. Included in this amount is \$100.0 million of ordinary shares that may be offered, issued and sold under an Open Market Sales Agreement with Jeffries, LLC. To date, we have not issued any shares pursuant to this registration.

## Cash flows

The following table summarizes our statement of cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(In thousands)	
Net cash provided by (used in):		
Operating activities	\$ (27,050)	\$ (3,609)
Investing activities	35,313	(223)
Financing activities	64,221	61,641
Increase in cash and cash equivalents:	\$ 72,484	\$ 57,809

### *Net cash used in operating activities*

Net cash used in operating activities during the nine months ended September 30, 2018 was approximately \$27.1 million compared to \$3.6 million for the nine months ended September 30, 2017. The \$23.5 million increase was attributable primarily to the increase of \$42.1 million in the net loss for the nine-month period, partly offset by an increase of \$17.7 million in share-based compensation expense.

### *Net cash provided by (used in) investing activities*

Net cash provided by investing activities was \$35.3 million for the nine months ended September 30, 2018 compared to \$0.2 million used in investing activities for the nine months ended September 30, 2017. The increase of \$35.5 million is related to the sale of short-term investments.

### *Net cash provided by financing activities*

Net cash provided by financing activities was \$64.2 million during the nine months ended September 30, 2018 compared to \$61.6 million during the nine months ended September 30, 2017. The increase of approximately \$2.6 million is primarily related to our follow-on public offering.

**UroGen Pharma Reports Third Quarter 2018 Financial Results and Completed UGN-101 OLYMPUS Trial Enrollment**

*Following a Recent Pre-New Drug Application (NDA) Meeting with the FDA for UGN-101, the Company Has Concluded Patient Enrollment in the OLYMPUS Phase 3 Trial for Low-Grade Upper Tract Urothelial Cancer (LG UTUC)*

*Breakthrough Therapy Designation (BTD) Previously Granted by the FDA for UGN-101 for the Treatment of LG UTUC*

*Company On Track to Initiate UGN-101 Rolling NDA Submission to the FDA in Q4 2018 with Completed Submission in Q2 2019 and Potential Approval in 2019*

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

**Ra'anana, Israel and New York, NY**, November 12, 2018 - 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 third quarter ended September 30, 2018 and that it has completed enrollment of the UGN-101 OLYMPUS Phase 3 Trial in patients with low-grade upper tract urothelial cancer (LG UTUC) following a recent pre-New Drug Application (NDA) meeting held with the U.S. Food and Drug Administration (FDA).

At the pre-NDA meeting, the company presented updated data from this open-label, single arm Phase 3 study. The meeting resulted in agreement on the required information for the NDA submission and suitability for NDA submission of primary endpoint (Complete Response) data for the approximately 65 patients enrolled to date.

UroGen plans to present the topline data in January 2019, with the full dataset expected at a medical meeting in the second quarter of 2019.

"We are pleased by the FDA's support for UGN-101 and recognition of the potential clinical benefit that UGN-101 presents for LG UTUC as a potentially organ-sparing, non-invasive therapy for this disease.", said Ron Bentsur, Chief Executive Officer of UroGen. "We are excited about the progress that we continue to make across our clinical pipeline and look forward to collaborating with the FDA to bring this potentially transformative therapy to patients with LG UTUC."

Breakthrough Therapy Designation (BTD) was granted by the FDA for UGN-101 for the treatment of LG UTUC in October 2018. UroGen remains on track to initiate the UGN-101 Rolling NDA Submission to the FDA in Q4 2018 and complete the submission in Q2 2019, with potential approval expected in 2019.

**Additional Highlights and Upcoming Milestones**

- **UGN-102 Clinical Development:**
  - UroGen is enrolling patients as part of its Phase 2b single-arm, open-label, multi-center trial designed to assess the efficacy and safety of UGN-102 (mitomycin gel) for intravesical instillation as a potential first-line chemoablation agent in the treatment of patients with LG Non-Muscle Invasive Bladder Cancer (NMIBC) at risk for recurrence.
  - Initial data from the trial is expected in 1H 2019.
  - Similar to LG UTUC, there are currently no drugs approved by the FDA as first-line treatment for NMIBC, and only three drugs have been approved by the FDA, all as adjuvant treatments, following TURBT (transurethral resection of bladder tumor).

- UGN-102 represents a very substantial opportunity in UroGen's pipeline with the potential to initially address up to approximately 85,000 patients for whom TURBT is no longer effective.<sup>1</sup>
- **Advancing the Potential of the RTGel Platform:**
  - Allergan continues to enroll patients in its Phase 2 trial of BotuGel, UroGen's RTGel in combination with BOTOX®<sup>2</sup>, for the treatment of overactive bladder. This clinical trial, if successful, has the potential to demonstrate the broad applicability of the RTGel platform beyond uro-oncology. Phase 2 data is expected in 2019.
- **Corporate Developments:**
  - UroGen strengthened its leadership team with the appointment of Jones "Woody" Bryan, Ph.D., as Senior Vice President, Business Development. Dr. Bryan is a seasoned industry veteran who brings over 25 years of industry experience. He is focused on the integration of corporate strategy and business development to assess potential partnerships, both inbound and outbound, and bolster UroGen's product portfolio.

### **Third Quarter 2018 Financial Results**

- As of September 30, 2018, cash and cash equivalents totaled \$109.5 million.
- Research and development expenses for the nine months ended September 30, 2018 were \$25.5 million, including non-cash share-based compensation expense of \$9.1 million. Research and development expenses for the three months ended September 30, 2018 were \$9.6 million, including non-cash share-based compensation expense of \$3.8 million.
- General and administrative expenses for the nine months ended September 30, 2018 were \$27.0 million, including non-cash share-based compensation expense of \$12.7 million. General and administrative expenses for the three months ended September 30, 2018 were \$10.7 million, including non-cash share-based compensation expense of \$5.7 million.
- The Company reported a net loss of \$51.9 million, or basic and diluted net loss per ordinary share of \$3.30, for the nine months ended September 30, 2018. The Company reported a net loss of \$20.5 million, or basic and diluted net loss per ordinary share of \$1.28, for the three months ended September 30, 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. Due to observance of the Veteran's Day holiday in the United States on November 12, 2018, UroGen's corresponding 6-K will be filed with the Securities and Exchange Commission (SEC) before market on November 13, 2018.

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 47697839. An archive of the webcast will be available for two weeks on the Company's website.

<sup>1</sup> Cutress, 2012; NIH SEER Stat; UroGen Market Research

<sup>2</sup> BOTOX® is a proprietary trademark of Allergan Pharmaceuticals

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**UROGEN PHARMA LTD.**  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(U.S. dollars in thousands, except share and per share data)  
(Unaudited)

	September 30, 2018	December 31, 2017
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 109,483	\$ 36,999
Short-term investments	—	36,001
Restricted deposit	197	198
Accounts receivable	112	—
Inventory	—	316
Prepaid expenses and other current assets	1,679	958
<b>TOTAL CURRENT ASSETS</b>	<b>111,471</b>	<b>74,472</b>
<b>NON-CURRENT ASSETS</b>		
Property and equipment, net	992	805
Restricted deposit	81	29
Other non-current assets	14	244
<b>TOTAL ASSETS</b>	<b>\$ 112,558</b>	<b>\$ 75,550</b>
<b>Liabilities and Shareholders' equity</b>		
<b>LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 6,291	\$ 4,435
Employee related accrued expenses	2,684	1,950
Deferred revenues	—	650
<b>TOTAL LIABILITIES</b>	<b>8,975</b>	<b>7,035</b>
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>103,583</b>	<b>68,515</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 112,558</b>	<b>\$ 75,550</b>



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

	Nine Months Ended September 30,		Three Months Ended
	2018	2017	2018
<b>REVENUES</b>	\$ 1,128	\$ 7,831	\$ 283
<b>COST OF REVENUES</b>	1,803	313	1,055
<b>GROSS PROFIT</b>	(675)	7,518	(772)
<b>OPERATING EXPENSES:</b>			
Research and development expenses	25,469	11,936	9,574
General and administrative expenses	27,019	5,374	10,743
<b>OPERATING LOSS</b>	53,163	9,792	21,089
<b>INTEREST AND OTHER (INCOME) EXPENSES, NET</b>	(1,323)	122	(556)
<b>REALIZED LOSS ON SALE OF SHORT-TERM INVESTMENT</b>	100	—	—
<b>NET LOSS</b>	\$ 51,940	\$ 9,914	\$ 20,533
<b>NET LOSS PER ORDINARY SHARE, BASIC AND DILUTED</b>	\$ 3.30	\$ 1.31	\$ 1.28
<b>WEIGHTED AVERAGE SHARES OUTSTANDING, BASIC AND DILUTED</b>	15,721,445	8,223,124	16,092,583

**About UroGen Pharma Ltd.**

UroGen Pharma Ltd. (Nasdaq:URGN) is a clinical-stage biopharmaceutical company developing advanced non-surgical treatments to address unmet needs in the field of urology, with a focus on uro-oncology. UroGen has developed RTGel™, a proprietary sustained release, hydrogel-based platform technology that has the potential to improve therapeutic profiles of existing drugs. UroGen's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. UroGen's lead product candidates, UGN-101 and UGN-102, 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, NY and an office in Los Angeles, CA.

**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 effect of Breakthrough Therapy Designation on the potential regulatory approval of UGN-101, timing and results of clinical development and commercial prospects of UGN-101, and submission of a rolling NDA for UGN-101, the timing and results of clinical development of UGN-102, and the timing and clinical application of RTGel including with respect to BotuGel, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials and potential complications thereof; the ability to obtain and maintain regulatory approval; the labeling for any approved product; the scope, progress and expansion of developing and commercializing UroGen Pharma's product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; and UroGen Pharma's ability to attract or retain key management, members of the board of directors and personnel. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen Pharma's Form 20-F filed with the SEC on March 15, 2018 and other filings that UroGen Pharma makes with the SEC from time to time (which are available at <http://www.sec.gov>), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen Pharma's actual results could differ materially and adversely from those anticipated or

implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to UroGen Pharma as of the date of this release.

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