Emerging growth company

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3 **REGISTRATION STATEMENT**

UNDER THE SECURITIES ACT OF 1933

UROGEN PHARMA LTD.

(Exact name of registrant as specified in its charter)

State of Israel (State or other jurisdiction of incorporation or organization)

standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. \Box

98-1460746 (I.R.S. Employer Identification Number)

400 Alexander Park Drive, 4th Floor Princeton, New Jersey 08540
Princeton, New Jersey 08540
Telephone: +1 (646) 768-9780
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

UroGen Pharma Ltd. **Jason Smith** General Counsel
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| 10265 Science Center Drive San Diego, California 92121 +1 (858) 550-6000 | |
|--|---|
| Approximate date of commencement of proposed sale to the public: From time to time after this Registration | n Statement becomes effective. |
| If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment | nt plans, please check the following box: \square |
| If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant only in connection with dividend or interest reinvestment plans, check the following box: \boxtimes | to Rule 415 under the Securities Act of 1933, other than securities offered |
| If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities a statement number of the earlier effective registration statement for the same offering. \Box | Act, please check the following box and list the Securities Act registration |
| If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the followerlier effective registration statement for the same offering. \Box | owing box and list the Securities Act registration statement number of the |
| If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment theret 462(e) under the Securities Act, check the following box. \Box | o that shall become effective upon filing with the Commission pursuant to Rule |
| If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. f to Rule 413(b) under the Securities Act, check the following box. \Box | iled to register additional securities or additional classes of securities pursuant |
| Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth of the company" and the company and the company are company and the company and the company and the company are company and the company are company and the company and the company and the company are company and the company and the company and the company and the company are company and the company and the company and the company are company and the company are company and the company are company and th | |
| Large accelerated filer \Box | Accelerated filer \Box |
| Non-accelerated filer | Smaller reporting company |

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting

The information in this prospectus is not complete and may be changed. The selling shareholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED SEPTEMBER 8, 2023

PROSPECTUS



12,579,156 Ordinary Shares

This prospectus covers the offer and resale by the selling shareholders identified in this prospectus of up to an aggregate of 12,579,156 of our ordinary shares, which includes 7,300,380 ordinary shares and 5,278,776 ordinary shares issuable upon the exercise of pre-funded warrants. An aggregate of 7,300,380 ordinary shares and pre-funded warrants to purchase 5,278,776 ordinary issuable were sold to the selling shareholders in a private placement that closed on July 28, 2023 and August 9, 2023, or the Private Placement.

We are not selling any ordinary shares under this prospectus and will not receive any proceeds from the sale by the selling shareholders of such shares.

Sales of the shares by the selling shareholders may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. The selling shareholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling shareholders, the purchasers of the shares, or both.

We are paying the cost of registering the ordinary shares covered by this prospectus as well as various related expenses. The selling shareholders are responsible for all selling commissions, fees and expenses of legal counsel, and other costs related to the offer and sale of their shares.

Our ordinary shares are listed on The Nasdaq Global Market under the symbol "URGN." On September 7, 2023, the last reported sale price of our ordinary shares was \$16.85 per share.

Investing in our ordinary shares involves a high degree of risk. Before making an investment decision, please read the information under "Risk Factors" on page 3 of this prospectus and under similar headings in any amendment or supplement to this prospectus or in any filing with the Securities and Exchange Commission that is incorporated by reference herein.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is September , 2023

TABLE OF CONTENTS

| ABOUT THIS PROSPECTUS | ii |
|---|-----|
| SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS | iii |
| PROSPECTUS SUMMARY | 1 |
| RISK FACTORS | 3 |
| <u>USE OF PROCEEDS</u> | 2 |
| SELLING SHAREHOLDERS | 5 |
| <u>PLAN OF DISTRIBUTION</u> | 7 |
| EXPERTS | g |
| <u>LEGAL MATTERS</u> | g |
| WHERE YOU CAN FIND ADDITIONAL INFORMATION | g |
| INCORPORATION OF CERTAIN INFORMATION BY REFERENCE | 10 |
| | |

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, using a "shelf" registration process. Under this registration statement, the selling shareholders may sell from time to time in one or more offerings the ordinary shares described in this prospectus.

We have not authorized anyone to provide you with information other than the information that we have provided or incorporated by reference in this prospectus and your reliance on any unauthorized information or representation is at your own risk. This prospectus may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that the information appearing in this prospectus is accurate only as of the date of this prospectus and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, or any sale of our ordinary shares. Our business, financial condition and results of operations may have changed since those dates.

This prospectus and the information incorporated herein by reference contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading "Where You Can Find Additional Information."

Unless otherwise stated, all references in this prospectus to "we," "us," "our," "UroGen," "UroGen Pharma," the "Company" and similar designations refer to UroGen Pharma Ltd. and its wholly owned subsidiary, Urogen Pharma, Inc. UroGen, *RTGel* and *Jelmyto* are trademarks of ours that we use in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the [®] or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to our trademark and tradenames.

The terms "shekel," "Israeli shekel" and "NIS" refer to New Israeli Shekels, the lawful currency of the State of Israel, and the terms "dollar," "U.S. dollar" or "\$" refer to United States dollars, the lawful currency of the United States. All references to "ordinary shares" or "shares" in this prospectus refer to ordinary shares of UroGen Pharma Ltd., par value NIS 0.01 per share.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and any applicable prospectus supplement or free writing prospectus, including the documents that we incorporate by reference herein and therein, contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. As such, our actual results may differ significantly from those expressed in any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date they were made, and while we believe such information formed a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

We discuss many of these risks in greater detail under "Risk Factors" in this prospectus, in the "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections incorporated by reference from our most recent Annual Report on Form 10-K and in our Quarterly Reports on Form 10-Q for the quarterly periods ended subsequent to our filing of such Annual Report on Form 10-K, as well as any amendments thereto reflected in subsequent filings with the SEC.

Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should read this prospectus, any applicable prospectus supplement, together with the documents that we have filed with the SEC that are incorporated by reference and any free writing prospectus we have authorized for use in connection with this offering, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

PROSPECTUS SUMMARY

This summary highlights certain information about us, the Private Placement and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before making an investment decision. For a more complete understanding of our company, you should read and consider carefully the more detailed information included or incorporated by reference in this prospectus and any applicable prospectus supplement, including the factors described under the heading "Risk Factors" on page 3 of this prospectus, as well as the information incorporated herein by reference, before making an investment decision.

Company Overview

We are a biotechnology company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers. We have developed *RTGel* reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based technology that has the potential to improve therapeutic profiles of existing drugs. Our technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. Our approved product *Jelmyto* (mitomycin) for pyelocalyceal solution, and our investigational candidate, UGN-102 (mitomycin) for intravesical solution, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and low-grade intermediate risk non-muscle invasive bladder cancer, respectively. In addition, our immuno-uro-oncology pipeline includes UGN-301 (zalifrelimab), an anti-CTLA-4 antibody, which we intend to study as both monotherapy and in combination therapy.

Company Information

We were incorporated under the laws of the State of Israel in April 2004 under the name TheraCoat Ltd. In September 2015, we changed our name to UroGen Pharma Ltd. Our principal executive offices are located at 400 Alexander Park Drive, 4th Floor, Princeton, NJ 08540 and our telephone number is +1 (646) 768-9780. Our website address is http://www.urogen.com. The information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus. We have included our website address as an inactive textual reference only.

Urogen Pharma, Inc., our wholly owned subsidiary, was incorporated under the laws of the State of Delaware in October 2015 and is qualified to do business in New York and California.

Private Placement

On July 26, 2023, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with the selling shareholders named in this prospectus, pursuant to which we sold and issued 7,300,380 ordinary shares and pre-funded warrants, in lieu of ordinary shares, to purchase up to 5,278,776 ordinary shares, at closings held on July 28, 2023 and August 9, 2023. Each ordinary share was sold at a price of \$9.54 per share and each pre-funded warrant was sold at a price of \$9.539. The pre-funded warrants have a per share exercise price of \$0.001. The total purchase price paid by the selling shareholders was approximately \$120.0 million. The pre-funded warrants are exercisable at any time and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation.

Under the terms of the Purchase Agreement, we agreed to prepare and file, within 45 days after the initial closing, one or more registration statements with the SEC to register for resale the ordinary shares issued under the Purchase Agreement and the ordinary shares issuable upon exercise of the pre-funded warrants.

The Offering

Ordinary shares offered by the selling shareholders 12,579,156 shares⁽¹⁾

Terms of the offering Each selling shareholder will determine when and how it will sell the ordinary shares

offered in this prospectus, as described in "Plan of Distribution."

Use of proceeds We will not receive any proceeds from the sale of the ordinary shares covered by this

prospectus.

Risk factors See "Risk Factors" on page 3 for a discussion of factors you should carefully consider

before deciding to invest in our ordinary shares.

Nasdaq Global Market symbol URGN

(1) Includes 5,278,776 ordinary shares issuable upon the exercise of pre-funded warrants held by the selling shareholders named in this prospectus.

The selling shareholders named in this prospectus may offer and sell up to 12,579,156 ordinary shares. Our ordinary shares are currently listed on The Nasdaq Global Market under the symbol "URGN." Ordinary shares that may be offered under this prospectus will be fully paid and non-assessable. We will not receive any of the proceeds of sales by the selling shareholders of any of the ordinary shares covered by this prospectus. Throughout this prospectus, when we refer to the ordinary shares being registered on behalf of the selling shareholders for offer and resale, we are referring to the ordinary shares that have been issued to the selling shareholders and the ordinary shares issuable upon exercise of the pre-funded warrants issued in the Private Placement as described above. When we refer to the selling shareholders in this prospectus, we are referring to the selling shareholders identified in this prospectus and, as applicable, their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described in the sections entitled "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, as filed with the SEC, which are incorporated herein by reference in their entirety, as well any amendment or updates to our risk factors reflected in subsequent filings with the SEC, including any applicable prospectus supplement. Our business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment. This prospectus and the documents incorporated herein by reference also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned elsewhere in this prospectus. For more information, see the section entitled "Where You Can Find Additional Information." Please also read carefully the section entitled "Special Note Regarding Forward-Looking Statements."

USE OF PROCEEDS

We will not receive any of the proceeds from the sale or other disposition of our ordinary shares held by the selling shareholders pursuant to this prospectus.

We will bear the out-of-pocket costs, expenses and fees incurred in connection with the registration of the ordinary shares to be sold by the selling shareholders pursuant to this prospectus. Other than registration expenses, the selling shareholders will bear underwriting discounts, commissions, placement agent fees or other similar expenses payable with respect to sales of our ordinary shares.

SELLING SHAREHOLDERS

The selling shareholders may sell some, all or none of their shares. We do not know how long the selling shareholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling shareholders regarding the sale or other disposition of any of the shares. The shares covered hereby may be offered from time to time by the selling shareholders. As a result, we cannot estimate the number of ordinary shares each of the selling shareholders will beneficially own after termination of sales under this prospectus. In addition, each of the selling shareholders may have sold, transferred or otherwise disposed of all or a portion of its ordinary shares since the date on which it provided information for this table.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our ordinary shares. Generally, a person "beneficially owns" ordinary shares if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days.

The information in the table below and the footnotes thereto regarding ordinary shares to be beneficially owned after the offering assumes the sale of all shares being offered by the selling shareholders under this prospectus. The percentage of shares owned prior to the offering is based on 30,806,989 ordinary shares outstanding as of August 9, 2023. This information has been obtained from the selling shareholders or in Schedules 13G or 13D and other public documents filed with the SEC.

| Name of Selling Shareholder | Ordinary Shares Beneficially Owned Prior to Offering ⁽¹⁾ | Ordinary Shares <u>Being Offered⁽¹⁾</u> | Ordinary : Beneficially Ov Offerin Number | wned After |
|--|---|--|--|------------|
| RA Capital Healthcare Fund, L.P. | 6,289,808(3) | 6,289,808(3) | | |
| Entities affiliated with Acorn Bioventures | 1,983,608(4) | 1,939,244(5) | 44,364 | * |
| Entities affiliated with Great Point Partners, LLC | 2,620,545(6) | 2,620,545(6) | _ | _ |
| Monograph Capital Partners I, L.P. | 1,572,327(7) | 1,572,327(7) | _ | _ |
| Entities affiliated with Horton Capital Management, LLC | 976,958(8) | 157,232(9) | 819,726 | 2.7% |

- * Less than one percent.
- (1) Includes share issuable upon exercise of pre-funded warrants, with regard to any beneficial ownership limitations contained therein.
- (2) Assumes sale of all shares available for sale under this prospectus and no further acquisitions of shares by the selling shareholders.
- (3) Consists of 1,483,697 ordinary shares and 4,806,111 ordinary shares issuable upon the exercise of pre-funded warrants held by RA Capital Healthcare Fund, L.P. ("RACHF"). RA Capital Management, L.P. ("RA Capital") is the investment manager for RACHF. The general partner of RA Capital is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. Each of RA Capital, RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the securities held by RACHF. RA Capital, RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such securities, except to the extent of any pecuniary interest therein and except for the purpose of determining their obligations under Section 13(d) of the Securities Exchange Act of 1934, as amended ("Section 13(d)").
- (4) Consists of (i) 634,596 ordinary shares and 198,520 ordinary shares issuable upon exercise of pre-funded warrants held by Acorn Bioventures, L.P. and (ii) 876,347 ordinary shares and 274,145 ordinary shares issuable upon exercise of pre-funded warrants held by Acorn Bioventures 2, L.P. Acorn Capital Advisors,

- GP, LLC and Acorn Capital Advisors GP2, LLC are the sole general partners of Acorn Bioventures, L.P. and Acorn Bioventures 2, L.P., respectively. Anders Hove is the manager of Acorn Capital Advisors, GP, LLC and Acorn Capital Advisors GP2, LLC and may be deemed to have voting and dispositive power over the shares held by each of Acorn Bioventures, L.P. and Acorn Bioventures 2, L.P.
- (5) Consists of the shares described in footnote (4) above, less (i) 18,633 ordinary shares held by Acorn Bioventures, L.P. and (ii) 25,731 ordinary shares held by Acorn Bioventures 2, L.P.
- (6) Consists of (i) 1,467,505 ordinary shares held by Biomedical Value Fund, L.P. ("BMVF"), (ii) 969,602 ordinary shares held by Biomedical Offshore Value Fund, Ltd. ("BMOVF"), and (iii) 183,438 ordinary shares held by Cheyne Select Master Fund ICAV Cheyne Global Equity Fund ("Cheyne"). Great Point Partners, LLC is the investment manager for BMVF and BMOVF and the sub-advisor to Cheyne and, accordingly, may be deemed to beneficially own the securities held by BMVF, BMOVF and Cheyne. Each of Dr. Jeffrey R. Jay, M.D. and Mr. Ortav Yehudai, as Co-Portfolio Managers of Great Point, LLC, has voting and investment power with respect to the securities, and therefore may be deemed to be the beneficial owner of the securities for purposes of Section 13(d).
- (7) Consists of 1,572,327 ordinary shares held by Monograph Capital Partners I, L.P. ("Monograph I"). Monograph Capital Partners I GenPar, L.P. ("Monograph GenPar L.P.") is the general partner of Monograph I. Monograph Capital Holdings Advisors, LLC ("Monograph GovCo") is the general partner of Monograph GenPar L.P. Fred Cohen, M.D., one of our directors, and Charles Conn are managing members of Monograph GovCo and may be deemed beneficial owners for purposes of Section 13(d) of any of our securities beneficially owned by Monograph I.
- (8) Consists of 539,440 ordinary shares held by Horton Capital Partners Fund, LP ("HCPF") and (ii) 437,518 ordinary shares held by Horton Opportunity Partners Fund 2, LP ("HOF2"). Horton Capital Management, LLC ("HCM") maintains investment and voting power with respect to ordinary shares held by HCPF and HOF2. Horton Capital Partners, LLC ("HCP") and Horton Opportunity Partners 2, LLC ("HOP2") are the general partners of HCPF and HOF2, respectively. HCP and HOP2 may be deemed to be the beneficial owners of ordinary shares held by HCPF and HOF2, respectively, because HCP and HOP2 have the right to acquire investment and voting power through termination of investment management agreements with HCM. Joseph M. Manko, Jr. is the managing member of HCM, HCP and HOP2. Each of HCM, HCP, HOP2 and Mr. Manko disclaim beneficial ownership of such securities other than for the purpose of determining their obligations under Section 13(d).
- (9) Consists of 157,232 ordinary shares held by HCPF.

Relationship with Selling Shareholders

As discussed in greater detail above under the section "Prospectus Summary—Private Placement," on July 26, 2023, we entered into the Purchase Agreement with the selling shareholders pursuant to which we sold ordinary shares and pre-funded warrants to the selling shareholders and agreed with the selling shareholders to file a registration statement to enable the resale of the ordinary shares covered by this prospectus. Fred Cohen, M.D., who is a member of our Board of Directors, is the Chair and Chief Investment Officer of Monograph Capital Partners I, L.P., a life sciences venture firm and selling shareholder named above. Other than Dr. Cohen's affiliation with Monograph Capital Partners I, L.P., none of the selling shareholders or any persons having control over such selling shareholders has held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years, other than as a result of the ownership of our shares or other securities.

PLAN OF DISTRIBUTION

We are registering the ordinary shares issued to the selling shareholders in the Private Placement and the ordinary shares issuable to the selling shareholders upon the exercise of pre-funded warrants purchased in the Private Placement to permit the resale of such ordinary shares by such holders from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling shareholders of the ordinary shares. We will bear all fees and expenses incident to our obligation to register such ordinary shares.

Each selling shareholder, which may include donees, pledgees, transferees or other successors-in-interest selling ordinary shares or interests in ordinary shares received after the date of this prospectus from a selling shareholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of its ordinary shares or interests in ordinary shares on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at privately negotiated prices.

A selling shareholder may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its own account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- through agreements between broker-dealers and the selling shareholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

The selling shareholders may, from time to time, pledge or grant a security interest in some or all of the ordinary shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the ordinary shares, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b) or other applicable provision of the Securities Act amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus. The selling shareholders also may transfer the ordinary shares in other circumstances, in which case the pledgees, transferees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our ordinary shares or interests therein, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the ordinary shares in the course of hedging the positions they assume. The selling shareholders may also sell ordinary shares short and deliver these securities to close out their short positions, or loan or pledge the ordinary shares to broker-dealers that in turn may sell these securities. The selling shareholders may also enter into options or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to each such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling shareholders from the sale of the ordinary shares offered by them will be the purchase price of the ordinary shares less discounts or commissions, if any. Each of the selling shareholders reserves the right to accept and, together with its agents from time to time, to reject, in whole or in part, any proposed purchase of ordinary shares to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling shareholders also may resell all or a portion of the shares in open market transactions, rather than under this prospectus, in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling shareholders and any underwriters, broker-dealers or agents that participate in the sale of the ordinary shares or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling shareholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the ordinary shares to be sold, the names of the selling shareholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

If underwriters are used in the sale, the ordinary shares will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. In connection with any such underwritten sale of ordinary shares, underwriters may receive compensation from the selling shareholders, for whom they may act as agents, in the form of discounts, concessions or commissions. If the selling shareholders use an underwriter or underwriters to effectuate the sale of ordinary shares, we and/or they will execute an underwriting agreement with those underwriters at the time of sale of those ordinary shares. To the extent required by law, the names of the underwriters will be set forth in a prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes the prospectus supplement and the accompanying prospectus used by the underwriters to sell those securities. The obligations of the underwriters to purchase those ordinary shares will be subject to certain conditions precedent, and unless otherwise specified in a prospectus supplement, the underwriters will be obligated to purchase all the ordinary shares offered by such prospectus supplement if any of such ordinary shares are purchased. Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

We have advised the selling shareholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling shareholders and their affiliates. The selling shareholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We are required to pay certain fees and expenses incurred by us incident to the registration of the ordinary shares of the selling shareholders. We have agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act, and the selling shareholders may be entitled to contribution. We may be indemnified by the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the selling shareholders specifically for use in this prospectus, or we may be entitled to contribution.

We have agreed with the selling shareholders to keep the registration statement of which this prospectus forms a part effective until the earlier of (i) the third anniversary of the date this registration statement becomes effective and (ii) the date all the shares and shares issuable upon exercise of the pre-funded warrants (assuming cashless exercise) held by or issuable to such selling shareholder may be sold under Rule 144 without being subject to any volume, manner of sale or publicly available information requirements.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2022 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to our ability to continue as a going concern as described in Note 2 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

LEGAL MATTERS

The validity of the ordinary shares being offered by this prospectus will be passed upon for us by Erdinast, Ben Nathan, Toledano & Co. with Hamburger Evron, Tel Aviv, Israel.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We must comply with the informational requirements of the Exchange Act, and we are required to file reports and proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information on the SEC's website at http://www.sec.gov, which contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC. We maintain a website at www.urogen.com. The information contained in, or that can be accessed through, our website is not incorporated by reference herein and is not part of this prospectus.

Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance we refer you to the copy of the contract or document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We also incorporate by reference into this prospectus the documents listed below and any future filings made by us with the SEC (other than current reports or portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items and other portions of documents that are furnished, but not filed, or are otherwise not incorporated into registration statements, pursuant to applicable rules promulgated by the SEC) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of the registration statement, and (ii) after the effectiveness of the registration statement but prior to the termination of the offering of the securities covered by this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 24, 2023;
- our Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2022, filed with the SEC on May 1, 2023;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023, filed with the SEC on May 11, 2023, and August 10, 2023;
- our Current Reports on Form 8-K filed on <u>July 25, 2023</u> and <u>July 27, 2023</u>; and
- the description of our ordinary shares in our registration statement on <u>Form 8-A</u> filed with the SEC on May 1, 2017, including any amendments or reports filed for the purpose of updating such description.

We will furnish without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, a copy of any document incorporated by reference. Requests should be addressed to UroGen Pharma Ltd., Attn: Chief Financial Officer, 400 Alexander Park Drive, 4th Floor, Princeton, New Jersey 08540, or may be made telephonically at +1 (646) 768-9780.

In accordance with Rule 412 of the Securities Act, any statement contained in a document incorporated by reference herein shall be deemed modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following is a statement of the estimated expenses to be incurred by us in connection with the registration of the securities under this registration statement, all of which will be borne by us.

| Securities and Exchange Commission Registration Fee | \$ 24,051 |
|---|-----------|
| Legal Fees and Expenses | \$ 50,000 |
| Accounting Fees and Expenses | \$ 10,000 |
| Miscellaneous | \$ 5,949 |
| Total | \$ 90,000 |

Item 15. Indemnification of Officers and Directors.

Under the Israeli Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care, but only if a provision authorizing such exculpation is included in its articles of association. Our amended and restated articles of association include such a provision. A company may not exculpate in advance a director from liability arising out of a breach of the duty of care with respect to a distribution.

Under the Israeli Companies Law, a company may indemnify an office holder with respect to the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award
 approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then
 such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's
 activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as
 reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted
 against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder
 was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Israeli Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder, if and to the extent provided in the company's articles of association:

• a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;

- a breach of the duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor of a third party.

Under the Israeli Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder:
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, monetary sanction or forfeit levied against the office holder.

The Israeli Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the tables under "Executive Officers of the Company" and "Proposal 1 — Election of Directors — Nominees for Election" in our definitive proxy statement on Schedule 14A dated August 1, 2023 is an office holder under the Israeli Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty includes an obligation that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to any such action.

The duty of loyalty includes a duty to:

- refrain from any conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- · refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his
 or her position as an office holder.

Our amended and restated articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Israeli Companies Law.

We maintain directors and officers liability insurance for the benefit of our office holders to the fullest extent permitted by the Israeli Companies Law. In addition, we have entered into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our amended and restated articles of association and Israeli law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance.

Insofar as the indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or persons controlling the registrant, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits.

| Exhibit Number | Description of Document |
|-------------------|---|
| 4.1 | Articles of Association of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Report on Form 6-K (File No. 001-38079), filed with the SEC on May 18, 2017). |
| 4.2 | Form of July 2023 Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38079), filed with the SEC on July 27, 2023). |
| 5.1 | Opinion of Erdinast, Ben Nathan, Toledano & Co. with Hamburger Evron, Israeli counsel to the Registrant, as to the validity of the Registrant's Ordinary Shares. |
| 23.1 | Consent of Independent Registered Public Accounting Firm. |
| 23.2 | Consent of Erdinast, Ben Nathan, Toledano & Co. with Hamburger Evron (included in Exhibit 5.1). |
| 24.1 | Power of Attorney (included on signature page). |
| 107 | Filing Fee Table. |

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (a)(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
- (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
- (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
 - (4) That, for the purpose of determining liability under the Securities Act to any purchaser:
- (i) each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
- (ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(b)The undersigned registrant undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c)Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person of the registrant in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Princeton, State of New Jersey, on September 8, 2023.

UROGEN PHARMA LTD.

By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer and Authorized United States
Representative

POWERS OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Elizabeth Barrett and Don Kim, and each or of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign, and file with the SEC any and all amendments (including post- effective amendments) to this registration statement together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | <u>Title</u> | <u>Date</u> |
|---|---|-------------------|
| /s/ Elizabeth Barrett Elizabeth Barrett | Chief Executive Officer and Director (Principal Executive Officer) | September 8, 2023 |
| /s/ Don Kim Don Kim | Chief Financial Officer (Principal Financial and Accounting Officer) | September 8, 2023 |
| /s/ Arie Belldegrun, M.D. Arie Belldegrun, M.D. | Chair | September 8, 2023 |
| /s/ Cynthia Butitta Cynthia Butitta | Director | September 8, 2023 |
| /s/ Fred E. Cohen Fred E. Cohen | Director | September 8, 2023 |
| /s/ Leana Wen Leana Wen | Director | September 8, 2023 |

| Signature | <u>Title</u> | <u>Date</u> | |
|--------------------------------------|--------------|-------------------|--|
| /s/ Stuart Holden Stuart Holden | Director | September 8, 2023 | |
| /s/ James Robinson James Robinson | Director | September 8, 2023 | |
| /s/ Dan Wildman Dan Wildman | Director | September 8, 2023 | |

EBNECO | Erdinast, Ben Nathan, Toledano & Co.

Museum Tower, 4 Berkowitz St.

Tel Aviv 6423806, Israel

T.+972 3 7770111 F.+972 3 7770101

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September 8, 2023

UroGen Pharma Ltd. 9 Ha'Ta'asiya Street Ra'anana 4365007 Israel

Ladies and Gentlemen:

You have requested our opinion, as Israeli counsel to UroGen Pharma Ltd., an Israeli company (the "Company"), with respect to certain matters in connection with the filing by the Company of a Registration Statement on Form S-3 (the "Registration Statement") with the Securities and Exchange Commission (the "Commission"), including a related prospectus included in the Registration Statement (the "Prospectus"), covering the registration for resale of up to 12,579,156 ordinary shares, par value NIS 0.01 per share ("Ordinary Shares"), of the Company on behalf of certain selling shareholders, including 7,300,380 currently outstanding Ordinary Shares (the "Shares") and 5,278,776 Ordinary Shares (the "Warrant Shares" and together with the Shares, the "Securities") issuable upon exercise of certain pre-funded warrants (the "Pre-Funded Warrants") issued by the Company pursuant to that certain Securities Purchase Agreement, dated July 26, 2023, by and among the Company and the purchasers named therein (the "Purchase Agreement").

In connection herewith, we have examined the originals, or photocopies or copies, certified or otherwise identified to our satisfaction, of: (i) the Registration Statement and the Prospectus; (ii) the articles of association of the Company (the "Articles"); (iii) the Purchase Agreement; (iv) the Pre-Funded Warrants; (v) certain resolutions adopted by the board of directors of the Company (the "Board"); and (vi) such other corporate records, agreements, documents and other instruments, and such certificates or comparable documents of public officials and of officers and representatives of the Company as we have deemed relevant and necessary as a basis for the opinions hereafter set forth. We have assumed the genuineness of all signatures, the legal capacity of all-natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, confirmed as photostatic copies and the authenticity of the originals of such latter documents. As to all questions of fact material to these opinions that have not been independently established, we have relied upon certificates or comparable documents of officers and representatives of the Company.

We express no opinion to the extent that, notwithstanding its current reservation of Ordinary Shares, future issuances of securities of the Company, including the Warrant Shares, and/or antidilution adjustments to outstanding securities of the Company, including the Pre-Funded Warrants, cause the Pre-Funded Warrants to be exercisable for more Ordinary Shares than the number that then remain authorized but unissued. We have assumed that the per share exercise price of the Pre-Funded Warrants (inclusive of the pre-funded portion of such per share exercise price) will at least equal the par value of the Ordinary Shares.

EBN⊕CO | Erdinast, Ben Nathan, Toledano & Co.

In addition to the assumptions, comments, qualifications, limitations and exceptions set forth above, the opinions set forth herein are further limited by, subject to and based upon the following assumptions, comments, qualifications, limitations and exceptions:

• We are members of the Israel Bar, and we express no opinion as to any matter relating to the laws of any jurisdiction other than the laws of the State of Israel and have not, for the purpose of giving this opinion, made any investigation of the laws of any other jurisdiction than the State of Israel. The opinions set forth herein are made as of the date hereof and are subject to, and may be limited by, future changes in the factual matters set forth herein, which hereafter may be brought to our attention and which may alter, affect or modify the opinion expressed herein, and we disclaim and undertake no duty to advise you of the same. The opinions expressed herein are based upon the law in effect (and published or otherwise generally available) on the date hereof, and we disclaim and assume no obligation to revise or supplement these opinions should such law be changed by legislative action, judicial decision or otherwise. In rendering our opinions, we have not considered, and hereby disclaim any opinion as to, the application or impact of any laws, cases, decisions, rules or regulations of any other jurisdiction, court or administrative agency. This opinion is expressly limited to the matters set forth above, and we render no opinion, whether by implication or otherwise, as to any other matters relating to the Company or the Securities, except as set forth above.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that (i) the Shares have been validly issued and are fully paid and nonassessable and (ii) the Warrant Shares, when issued in accordance with the terms of the Pre-Funded Warrants, will be validly issued, fully paid and nonassessable.

We consent to the filing of this opinion as an exhibit to the Registration Statement to be filed with the Commission for incorporation by reference into the Registration Statement and to the reference to our firm appearing under the captions "Legal Matters" in the Prospectus. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended (the "Securities Act"), the rules and regulations of the Commission promulgated thereunder or Item 509 of the Commission's Regulation S-K under the Securities Act.

This opinion letter is rendered as of the date hereof and we disclaim any obligation to advise you of facts, circumstances, events or developments that may be brought to our attention after the date hereof that may alter, affect or modify the opinions expressed herein.

Erdinast, Ben Nathan, Toledano & Co.
with Hamburger Evron

By: /s/Yaron Sobol
Yaron Sobol, Adv.

Very truly yours,

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of UroGen Pharma Ltd. of our report dated March 24, 2023 relating to the financial statements, which appears in UroGen Pharma Ltd.'s Annual Report on Form 10-K for the year ended December 31, 2022. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP Florham Park, New Jersey September 8, 2023

Calculation of Filing Fee Tables

FORM S-3 (Form Type)

UroGen Pharma Ltd.

(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

| | Security Type | Security Class Title | Fee Calculation or Carry Forward Rule | Amount Registered (1) | Proposed Maximum Offering Price Per Share (2) | Maximum Aggregate Offering Price (2) | Fee Rate | Amount of Registration Fee |
|--------------------|------------------|---|---|--------------------------|---|---|-------------|----------------------------------|
| Fees to Be Paid | Equity | Ordinary Shares, par value NIS 0.01 per share | 457(c) | 12,579,156 | \$17.35 | \$218,248,357 | 0.00011020 | \$24,051 |

- (1) Consists of an aggregate of 12,579,156 ordinary shares of UroGen Pharma Ltd., which includes 5,278,776 ordinary shares issuable upon the exercise of pre-funded warrants, all of which were acquired by the selling shareholders in a private placement. Pursuant to Rule 416 under the Securities Act of 1933, as amended, the ordinary shares being registered hereunder include such indeterminate number of ordinary shares as may be issuable with respect to the ordinary shares being registered hereunder as a result of splits, dividends or similar transactions.
- (2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices per ordinary share reported on The Nasdaq Global Market on September 7, 2023.