

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

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): July 26, 2023

**UROGEN PHARMA LTD.**

(Exact name of registrant as specified in its charter)

Israel  
(State or other jurisdiction  
of incorporation)

001-38079  
(Commission  
File Number)

98-1460746  
(IRS Employer  
Identification No.)

400 Alexander Park Drive, 4th Floor  
Princeton, New Jersey  
(Address of principal executive offices)

08540  
(Zip Code)

Registrant's telephone number, including area code: +1 (646) 768-9780

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value NIS0.01 per share	URGN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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 standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 1.01 Entry into a Material Definitive Agreement.**

On July 26, 2023, UroGen Pharma Ltd., an Israeli company (the “Company”), entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain institutional and other accredited investors (the “Purchasers”), pursuant to which the Company agreed to sell and issue to the Purchasers 12,579,156 ordinary shares of the Company (“Shares”) (or in lieu of Shares, pre-funded warrants to purchase ordinary shares of the Company) at a purchase price of \$9.54 per Share (or \$9.539 for each ordinary share underlying a pre-funded warrant), in a private placement transaction (the “Private Placement”). The aggregate gross proceeds from the Private Placement are expected to be \$120.0 million, before deducting fees to placement agents and financial advisors and before other expenses payable by the Company. Each pre-funded warrant will have an exercise price of \$0.001 per ordinary share, subject to customary adjustments, and will be exercisable at any time after original issuance 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.

Monograph Capital Partners I, L.P. (“Monograph”), a life sciences venture firm that is affiliated with Fred Cohen, M.D., a director of the Company, is purchasing 1,572,327 Shares in the Private Placement, for an aggregate purchase price of \$15.0 million. The closing for \$10.0 million of this amount is expected to occur on or about July 28, 2023 (the “Initial Closing”), concurrently with the closing for the Shares and pre-funded warrants being purchased by the other Purchasers. The closing for the remaining \$5.0 million of Shares being purchased by Monograph is expected to occur on or before August 14, 2023. Dr. Cohen is the Chair and Chief Investment Officer of Monograph.

BofA Securities, Inc. and H.C. Wainwright & Co., LLC are acting as joint placement agents for the Private Placement. Ladenburg Thalmann & Co. Inc. and Oppenheimer & Co. Inc. are acting as financial advisors for the Private Placement. The aggregate fee payable by the Company to the joint placement agents and financial advisors is \$3.6 million, plus the reimbursement of certain expenses.

Under the terms of the Purchase Agreement, the Company has agreed to prepare and file, within 45 days after the Initial Closing, one or more registration statements with the Securities and Exchange Commission (the “SEC”) to register for resale the Shares issued under the Purchase Agreement and the ordinary shares issuable upon exercise of the pre-funded warrants issued pursuant to the Purchase Agreement, and generally to cause the applicable registration statements to become effective as soon as practicable thereafter. Certain cash penalties will apply to the Company in the event of registration failures, as described in the Purchase Agreement.

The Purchase Agreement contains customary representations, warranties and covenants that were made solely for the benefit of the parties to the Purchase Agreement. Such representations, warranties and covenants (i) are intended as a way of allocating risk between the parties to the Purchase Agreement and not as statements of fact, and (ii) may apply standards of materiality in a way that is different from what may be viewed as material by stockholders of, or other investors in, the Company. Accordingly, the Purchase Agreement is included with this filing only to provide investors with information regarding the terms of the transaction and not to provide investors with any other factual information regarding the Company. Investors should not rely on the representations, warranties and covenants or any descriptions thereof as characterizations of the actual state of facts or condition of the Company or any of its subsidiaries or affiliates. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the Purchase Agreement, which subsequent information may or may not be fully reflected in public disclosures.

On July 27, 2023, the Company issued a press release announcing the Private Placement, a copy of which is filed with this report as Exhibit 99.1.

The foregoing descriptions of the Purchase Agreement and form of pre-funded warrant do not purport to be complete and are qualified in their entirety by reference to the Purchase Agreement and form of pre-funded warrant, copies of which are filed with this report as Exhibit 10.1 and Exhibit 4.1, respectively.

**Item 3.02 Unregistered Sales of Equity Securities.**

The information contained above in Item 1.01 relating to the Private Placement is incorporated by reference into this Item 3.02. Based in part upon the representations of the Purchasers in the Purchase Agreement, the offering and sale of the securities will be made in reliance on the exemption afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), and Regulation D promulgated thereunder. The Purchasers represented that they are accredited investors, as such term is defined in Rule 501(a) of Regulation D under the Securities Act, and that they are acquiring the securities for investment purposes only and not with a view to any resale, distribution or other disposition of the securities in violation of U.S. federal securities laws.

Neither this Current Report on Form 8-K nor any exhibit attached hereto is an offer to sell or the solicitation of an offer to buy any securities of the Company.

**Item 7.01 Regulation FD Disclosure.**

Furnished as Exhibit 99.2 to this report is a Company presentation, a subset of which is being presented by the Company beginning at 10:00 a.m. Eastern Time on July 27, 2023 at the Company's previously announced UGN-102 data event.

The information in this Item 7.01, including Exhibit 99.2, is being furnished and shall not be deemed "filed" for the 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 made by the Company under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.***ATLAS and ENVISION Phase 3 Trial Results*

On July 27, 2023, the Company announced topline data from its Phase 3 trials, ATLAS and ENVISION, studying UGN-102 (mitomycin) for intravesical solution in patients with low-grade, intermediate-risk non-muscle invasive bladder cancer.

In the ATLAS trial, UGN-102 met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55%. UGN-102 also showed a 64.8% complete response rate at three months for patients who only received UGN-102, compared to a 63.6% complete response rate at three months for patients who only received a trans-urethral resection of bladder tumor (TURBT).

The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.2% rate of complete response at 3-months following the initial treatment. Additional data evaluating the secondary endpoint of duration of response from ENVISION and the submission of a New Drug Application (NDA) (assuming additional positive findings) to the U.S. Food and Drug Administration (FDA) are anticipated in 2024.

In both trials, UGN-102 was generally well-tolerated, with a side effect profile similar to that of previous clinical trials of UGN-102.

For additional information regarding these results, refer to Exhibit 99.3 to this report, which is incorporated herein by reference.

**Forward-Looking Statements**

This report contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including without limitation statements regarding the timing, size, use of proceeds and closing of the Private Placement, the timing for additional data evaluating the secondary endpoint of duration of response from ENVISION, and the submission of an NDA to the FDA and the anticipated timing thereof. The words "anticipate," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including risks relating to the Company's inability, or the inability of the Purchasers, to satisfy the conditions to closing for the Private Placement; the closing of the Private Placement; the risk that results from a clinical trial may not be predictive of the final results of the trial or the results of future trials, or may not be sufficient to support approval of UGN-102 in any jurisdiction; the impacts of general macroeconomic and geopolitical conditions, high inflation, and uncertain credit and financial markets on the Company's business, clinical trials, and financial position; and other risks and uncertainties that are described in the Risk Factors section of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 11, 2023. The events and circumstances discussed in such forward-looking statements may not occur, and the Company's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements contained in this report speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise.

**Item 9.01 Financial Statements and Exhibits.**

(d)

<u>Exhibit No.</u>	<u>Description</u>
4.1	<a href="#">Form of July 2023 Pre-Funded Warrant</a>
10.1	<a href="#">Securities Purchase Agreement, dated July 26, 2023, by and among UroGen Pharma Ltd. and the Purchasers named therein</a>
99.1	<a href="#">Press release announcing Private Placement, dated July 27, 2023</a>
99.2	<a href="#">Company Presentation, dated July 27, 2023</a>
99.3	<a href="#">Trial Results Slides</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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 hereunto duly authorized.

Date: July 27, 2023

**UROGEN PHARMA LTD.**

By: /s/ Don Kim  
Don Kim  
Chief Financial Officer

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES. THE SECURITIES MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER APPLICABLE SECURITIES LAWS, OR UNLESS OFFERED, SOLD, PLEDGED, HYPOTHECATED OR TRANSFERRED PURSUANT TO AN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THOSE LAWS. THE COMPANY SHALL BE ENTITLED TO REQUIRE AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED TO THE EXTENT THAT SUCH OPINION IS REQUIRED PURSUANT TO THAT CERTAIN SECURITIES PURCHASE AGREEMENT UNDER WHICH THE SECURITIES WERE ISSUED.

**PRE-FUNDED ORDINARY SHARE PURCHASE WARRANT**

**UROGEN PHARMA LTD.**

Warrant Shares: [•]

Issue Date: July [•], 2023

THIS PRE-FUNDED ORDINARY SHARE PURCHASE WARRANT (the “**Warrant**”) certifies that, for value received, [•] or its assigns (the “**Holder**”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the “**Initial Exercise Date**”) until this Warrant is exercised in full (the “**Termination Date**”), to subscribe for and purchase from UroGen Pharma Ltd., a company organized under the laws of the State of Israel (the “**Company**”), up to [•] ordinary shares, par value NIS0.01 per share (the “**Ordinary Shares**”) (as subject to adjustment hereunder, the “**Warrant Shares**”). The purchase price of one Ordinary Share under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Securities Purchase Agreement (the “**Purchase Agreement**”), dated July 26, 2023, among the Company and the purchasers signatory thereto.

Section 2. Exercise.

(a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “**Notice of Exercise**”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

(b) **Exercise Price.** The aggregate exercise price of this Warrant, except for a nominal exercise price of \$0.001 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of \$0.001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever. The remaining unpaid exercise price per Ordinary Share under this Warrant shall be \$0.001, subject to adjustment hereunder (the “**Exercise Price**”).

(c) **Cashless Exercise.** This Warrant may also be exercised, in whole or in part, at such time by means of a “**cashless exercise**” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Ordinary Shares on the principal Trading Market as reported by Bloomberg L.P. (“**Bloomberg**”) as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the characteristics of the Warrants being exercised, and the holding period of this Warrant may be tacked on to the holding period of the Warrant Shares. The Company agrees not to take any position contrary to this Section 2(c).

“**Bid Price**” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Ordinary Shares are then listed or quoted on a Trading Market, the bid price of the Ordinary Shares for the time in question (or the nearest preceding date) on the Trading Market on which the Ordinary Shares are then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Ordinary Shares for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Ordinary Shares are not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Ordinary Shares are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per Ordinary Share so reported, or (d) in all other cases, the fair market value of an Ordinary Share as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“**VWAP**” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Ordinary Shares then listed or quoted on a Trading Market, the daily volume weighted average price of the Ordinary Shares for such date (or the nearest preceding date) on the Trading Market on which the Ordinary Shares are then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Ordinary Shares for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Ordinary Shares are not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Ordinary Shares are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per Ordinary Share so reported, or (d) in all other cases, the fair market value of an Ordinary Share as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

(d) Mechanics of Exercise.

(i) Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) the Warrant Shares are eligible for resale by the Holder pursuant to Rule 144 (assuming cashless exercise of the Warrants), and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the later of (i) the earlier of (a) two (2) Trading Days after the delivery to the Company of the Notice of Exercise and (b) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise, and (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company (providing the foregoing clause (ii) shall not apply in the event of a cashless exercise) (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Ordinary Shares on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Ordinary Shares as in effect on the date of delivery of the Notice of Exercise.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

(iii) Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

(iv) Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, Ordinary Shares to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the Ordinary Shares so purchased exceeds (y) the product of (1) the lesser of the (a) the number of Ordinary Shares so purchased and (b) the aggregate number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions). For example, if a Holder purchases Ordinary Shares having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of Ordinary Shares with an aggregate sale price giving rise to such purchase obligation of \$10,000, the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice after the occurrence of a Buy-In, indicating the amounts payable to the Holder in respect of the Buy-In together with applicable confirmations and other evidence reasonably requested by the Company. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver the Ordinary Shares upon exercise of the Warrant as required pursuant to the terms hereof.

(v) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

(vi) Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

(vii) Closing of Books. The Company will not close its shareholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with (i) the Holder's Affiliates, (ii) any other Persons acting as a group together with the Holder or any of the Holder's Affiliates and (iii) any other Persons whose beneficial ownership of Ordinary Shares would or could be aggregated with the Holder's for the purposes of Section 13(d) of the Exchange Act (such Persons, "**Attribution Parties**")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of Ordinary Shares beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of Ordinary Shares issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of Ordinary Shares which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding Ordinary Shares, a Holder may rely on the number of outstanding Ordinary Shares as reflected in (A) the Company's most recent periodic or annual report filed with the SEC, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of Ordinary Shares outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of Ordinary Shares then outstanding. In any case, the number of outstanding Ordinary Shares shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding Ordinary Shares was reported. The "**Beneficial Ownership Limitation**" shall be [4.9% / 9.99%] of the number of Ordinary Shares outstanding immediately after giving effect to the issuance of Ordinary Shares issuable upon exercise of this Warrant. The Holder,

upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds [4.9% / 9.99% / 19.99%] of the number of Ordinary Shares outstanding immediately after giving effect to the issuance of Ordinary Shares upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

(a) Share Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a share dividend or otherwise makes a distribution or distributions on Ordinary Shares or any other equity or equity equivalent securities payable in Ordinary Shares (which, for avoidance of doubt, shall not include any Ordinary Shares issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding Ordinary Shares into a larger number of shares, (iii) combines (including by way of reverse share split) outstanding Ordinary Shares into a smaller number of shares, or (iv) issues by reclassification of Ordinary Shares any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of Ordinary Shares (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of Ordinary Shares outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of shareholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any rights to purchase shares, warrants, securities or other property pro rata to the record holders of any class of Ordinary Shares (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of Ordinary Shares acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of Ordinary Shares are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such Ordinary Shares as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(c) Pro Rata Distributions. During such time as this Warrant is outstanding and except as covered by Section 3(d) below, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of Ordinary Shares, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of Ordinary Shares acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of Ordinary Shares are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any Ordinary Shares as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(d) **Fundamental Transaction.** If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (or any Subsidiary), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Ordinary Shares are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Ordinary Shares, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Ordinary Shares or any compulsory share exchange pursuant to which the Ordinary Shares are effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding Ordinary Shares (not including any Ordinary Shares held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "**Fundamental Transaction**"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of Ordinary Shares of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "**Alternate Consideration**") receivable as a result of such Fundamental Transaction by a holder of the number of Ordinary Shares for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one Ordinary Share in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Ordinary Shares are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "**Successor Entity**") to assume in writing all of the obligations of the Company under this Warrant prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the Ordinary Shares acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the Ordinary Shares pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

(e) **Calculations.** All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of Ordinary Shares deemed to be issued and outstanding as of a given date shall be the sum of the number of Ordinary Shares (excluding treasury shares, if any) issued and outstanding.

(f) **Notice to Holder.**

(i) **Adjustment to Exercise Price.** Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

(ii) Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Ordinary Shares, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Ordinary Shares, (C) the Company shall authorize the granting to all holders of the Ordinary Shares rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any shareholders of the Company shall be required in connection with any reclassification of the Ordinary Shares, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Ordinary Shares are converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 10 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Ordinary Shares of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Ordinary Shares of record shall be entitled to exchange their Ordinary Shares for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

#### Section 4. Transfer of Warrant.

(a) Transferability. Subject to compliance with any applicable securities laws and the conditions set forth in Section 4(d) hereof, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the original Issue Date and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

(c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

(d) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Miscellaneous.

(a) No Rights as Shareholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a shareholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a “*cashless exercise*” pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any share certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or share certificate, if mutilated, the Company will make and deliver a new Warrant or share certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or share certificate.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then such action may be taken, or such right may be exercised on the next succeeding Trading Day.

(d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Ordinary Shares a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Ordinary Shares may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its articles of association or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action that would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Purchase Agreement.

(f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

(g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant or the Purchase Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

(h) Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by email or facsimile if sent during normal business hours of the recipient, and if sent at a time other than during normal business hours of the recipient, then on the next Business Day (provided, with respect to notices sent by email so long as such sent email is kept on file by the sending party and the sending party does not receive an automatically generated message from the recipient's email server that such email could not be delivered to such recipient), (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one Business Day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. The addresses for such communications are:

If to the Company: UroGen Pharma Ltd.  
400 Alexander Park Drive  
Princeton, NJ 08540  
Attn: Jason Smith  
Email:

With a copy to: Cooley LLP  
10265 Science Center Drive  
San Diego, CA 92121  
Attn: Charles J. Bair  
Email: cbair@cooley.com

If to the Holder: To the address, email address or facsimile number set forth in the Warrant Register, or as otherwise provided by the Holder to the Company in accordance with this Section 5(h).

(i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Ordinary Share or as a shareholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

(l) Amendment. This Warrant may be modified or amended, or the provisions hereof waived with the written consent of the Company and the Holder.

(m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

*(Signature Page Follows)*

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IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

UROGEN PHARMA LTD.

By: \_\_\_\_\_

Name:

Title:

NOTICE OF EXERCISE

TO: UROGEN PHARMA LTD.

(1) The undersigned hereby elects to purchase \_\_\_\_\_ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

\_\_\_\_\_

(4) By its delivery of this Notice of Exercise, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of Ordinary Shares (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended) permitted to be owned under Section 2(e) of the Warrant to which this notice relates.

The Warrant Shares shall be delivered to the following DWAC Account Number:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

[SIGNATURE OF HOLDER]

Name of Investing Entity: \_\_\_\_\_

Signature of Authorized Signatory of Investing Entity: \_\_\_\_\_

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

Date: \_\_\_\_\_

**ASSIGNMENT FORM**

*(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)*

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:

(Please Print)

Address:

Phone Number:

(Please Print)

Email Address:

\_\_\_\_\_  
\_\_\_\_\_

Dated: \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_

Holder's Signature:

Holder's Address:

## SECURITIES PURCHASE AGREEMENT

This SECURITIES PURCHASE AGREEMENT (this “**Agreement**”), dated as of July 26, 2023, is made by and among UROGEN PHARMA LTD., a company organized under the laws of the State of Israel (the “**Company**”), and the Purchasers listed on **Exhibit A** hereto, together with their permitted transferees (each, a “**Purchaser**” and collectively, the “**Purchasers**”).

## RECITALS:

- A. The Company and the Purchasers are executing and delivering this Agreement in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act.
- B. The Purchasers, severally and not jointly, desire to purchase and the Company desires to sell, upon the terms and conditions stated in this Agreement, Ordinary Shares (the “**Shares**”) and Pre-Funded Warrants to purchase Ordinary Shares (the “**Pre-Funded Warrants**”), having an aggregate purchase price of up to \$120,000,000, as more fully described in this Agreement.
- C. The capitalized terms used herein and not otherwise defined have the meanings given them in Article 7.

## AGREEMENT

In consideration of the premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Purchasers (severally and not jointly) hereby agree as follows:

## ARTICLE 1

## PURCHASE AND SALE OF SECURITIES

## 1.1 Closing.

**(a) Purchase and Sale of Securities.** At the closing of the transaction contemplated by this Agreement (the “**Closing**”), the Company will sell and issue to each Purchaser, and each Purchaser will, severally and not jointly, purchase from the Company, the number of Shares equal to (x) the dollar amount set forth opposite such Purchaser’s name on **Exhibit A** hereto under the heading “Subscription Amount” divided by (y) the Per Share Purchase Price, rounded down to the nearest whole share; *provided, however*, in the event the number of Shares resulting from the foregoing calculation would result in such Purchaser, together with its Attribution Parties, beneficially owning in excess of the Beneficial Ownership Limitation of the outstanding Ordinary Shares immediately after the Closing, then (i) the number of Shares otherwise issuable to such Purchaser at the Closing will be reduced by the number (such number, the “**Overage Number**”) of Shares that would result in such Purchaser beneficially owning, together with its Attribution Parties, no more than the Beneficial Ownership Limitation of the outstanding Ordinary Shares immediately after the Closing, (ii) the Company will issue to such Purchaser at the Closing a Pre-Funded Warrant that is exercisable for a number of Warrant Shares that is equal to the Overage Number, and (iii) the Subscription Amount payable by such Purchaser at the Closing pursuant to Section 1.1(b) below shall be reduced by \$0.001 for each Warrant Share subject to the Pre-Funded Warrant being purchased by such Purchaser. The Pre-Funded Warrants shall have an exercise price of \$0.001 per Warrant Share. The applicable Purchaser’s name, Beneficial Ownership Limitation, Shares to be acquired, Warrant Shares underlying the Pre-Funded Warrant, aggregate Subscription Amount and aggregate amount of funds to be payable pursuant to this Section 1.1 are set forth on **Exhibit A**, provided the Warrant Shares underlying the Pre-Funded Warrant shall be increased, and the Shares correspondingly reduced, as necessary, a result of any purchase by such Purchaser (or its Attribution Parties) of Ordinary Shares (or securities exercisable or convertible into Ordinary Shares) following the execution of this Agreement and prior to the Closing (other than pursuant to this Agreement) to ensure that such Purchaser, together with its Attribution Parties, does not beneficially own in excess of the Beneficial Ownership Limitation of the outstanding Ordinary Shares immediately after the Closing.

**(b) Payment.** At the Closing, each Purchaser will pay to an account designated by the Company, by wire transfer of immediately available funds, the amount set forth opposite its name on **Exhibit A** hereto under the heading “Aggregate Purchase Price (Wire Amount)”. The Company will (i) instruct the Transfer Agent to credit each Purchaser the number of Shares purchased by the Purchaser pursuant to Section 1.1 hereof, (ii) if applicable, issue a certificate evidencing the Pre-Funded Warrants purchased by such Purchaser pursuant to Section 1.1 hereof and (iii) on the Closing Date (defined below) deliver written notice from the Company or the Transfer Agent evidencing the issuance to the Purchaser of the Shares and Pre-Funded Warrants on and as of the Closing Date.

(c) **Closing Date.** The Closing will take place as soon as reasonably practicable after the date hereof but no later than July 28, 2023 (the date on which the Closing actually occurs, the “**Closing Date**”) and the Closing will be held remotely via the exchange of documents and signatures, or at such other time and place as agreed upon by the Company and the Purchasers subscribing for a majority of the Shares and Pre-Funded Warrants to be sold and issued hereunder, based on the amounts set forth on **Exhibit A** hereto under the heading “Subscription Amount”. Solely with respect to the Purchaser denoted with an asterisk on **Exhibit A** hereto (the “**August Closing Purchaser**”), the Closing Date for the indicated portion of the August Closing Purchaser’s purchase of Shares hereunder will take place as soon as reasonably practicable after the date hereof but no later than August 14, 2023 and all references in this Agreement to the “Closing” shall refer, *mutatis mutandis*, to the closing of the indicated portion of the August Closing Purchaser’s purchase of Shares hereunder and all references in this Agreement to the “Closing Date” shall refer, *mutatis mutandis*, to the date on which the Closing actually occurs with respect to the indicated portion of the August Closing Purchaser’s purchase of Shares hereunder.

## ARTICLE 2

### REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except as specifically contemplated by this Agreement, the Company hereby represents and warrants to the Purchasers and the Placement Agents as of the date of this Agreement that:

**2.1 Good Standing of the Company.** The Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own its property and to conduct its business as described in the reports, schedules, forms, statements and other documents required to be filed by it with the SEC, pursuant to the reporting requirements of the Exchange Act (all of the foregoing filed prior to the date hereof and all exhibits included therein and financial statements and schedules thereto and documents (other than exhibits) incorporated by reference therein, the “**SEC Documents**”) and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a Material Adverse Effect. The Company has not been designated as a “breaching company” (within the meaning of the Companies Law) by the Registrar of Companies of the State of Israel. The certificate of incorporation, articles of association and other organizational documents of the Company comply with the requirements of applicable Israeli law and are in full force and effect.

**2.2 Authorization of Share Capital.** The authorized share capital of the Company consists of 100,000,000 Ordinary Shares. All of the issued and outstanding Ordinary Shares have been duly authorized and are validly issued, fully paid and non-assessable and were not issued in violation of the preemptive or similar rights of any security holder of the Company. The issuance and sale of the Securities will not obligate the Company to issue Ordinary Shares or other securities to any Person (other than the Purchasers or their permitted assignees/transferees). There are no outstanding securities or instruments of the Company with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company. There are no outstanding securities or instruments of the Company that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company is or may become bound to redeem a security of the Company.

**2.3 Authorization of Securities.** The Shares have been duly authorized and, when issued and delivered in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, and will not be subject to any preemptive or similar rights of shareholders of the Company. The Pre-Funded Warrants have been duly authorized by the Company and, when executed and delivered by the Company, will be valid and binding agreements of the Company, enforceable against the Company in accordance with their terms, except as the enforcement thereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles. The Warrant Shares have been duly authorized and validly reserved for issuance upon exercise of the Pre-Funded Warrants in a number sufficient to meet the current exercise requirements. The Warrant Shares, when issued and delivered upon exercise of the Pre-Funded Warrants in accordance therewith, will be validly issued, fully paid and nonassessable, and the issuance of the Warrant Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Warrant Shares.

**2.4 Private Placement.** Neither the Company nor any of its Affiliates, nor any Person acting on its or their behalf, has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under any circumstances that would require registration of the Shares, the Pre-Funded Warrants or the Warrants Shares (collectively, the “**Securities**”) under the Securities Act. Assuming the accuracy of the representations and warranties of the Purchasers contained in Article 3 hereof, the offer, sale and issuance of the Securities are exempt from registration under the Securities Act.

**2.5 No Integrated Offering.** Neither the Company nor its Affiliates nor any Person acting on their behalf has, directly or indirectly, made any offers or sales of any Company security or solicited any offers to buy any Company security, under circumstances that would adversely affect reliance by the Company on Section 4(a)(2) and Regulation D for the exemption from registration for the transactions contemplated hereby or would require registration of the Securities under the 1933 Act.

**2.6 No Directed Selling Efforts or General Solicitation.** Neither the Company nor any Person acting on its behalf has conducted any general solicitation or general advertising (as those terms are used in Regulation D promulgated under the 1933 Act) in connection with the offer or sale of any of the Securities.

**2.7 Authorization and Execution of Agreement.** This Agreement has been duly authorized, executed and delivered by the Company. The Company has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement.

**2.8 Absence of Defaults and Conflicts.** Neither the Company nor any of its subsidiaries is in violation of its articles of association or bylaws or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) (“**Default**”) under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which any of them may be bound, or to which any of their respective properties or assets are subject, including (A) any instrument of approval granted to any of them by the Israel Innovation Authority (formerly “Office of the Chief Scientist” of Israel’s Ministry of Commerce and Industry (currently known as the Ministry of Economy)) or (B) any instrument of approval granted to any of them by the Authority for Investment and Development of the Industry and the Economy (formerly the “Investment Center”) of the Israeli Ministry of Economy and Industry (each, an “**Existing Instrument**”), except for such Defaults as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company’s execution, delivery and performance of the Transaction Documents and consummation of the transactions contemplated hereby and thereby, including the issuance and sale of the Securities (i) have been duly authorized by all necessary corporate action, and will not result in any violation of the provisions of the articles of association or bylaws or similar organizational documents, as applicable, of the Company or any of its subsidiaries, (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument, except as would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries, except as would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. The Company is not required to publish a prospectus in the State of Israel under the laws of the State of Israel with respect to the offer or sale of the Securities. As used herein, a “**Debt Repayment Triggering Event**” means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder’s behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

**2.9 Absence of Further Requirements.** No filing with, or authorization, approval, consent, license, order, registration, exemption, qualification or decree of, any court or governmental authority or agency or any sub-division thereof is required for the performance by the Company of its obligations hereunder, in connection with the offering, issuance or sale of the Securities under this Agreement or the Pre-Funded Warrants (collectively, the “**Transaction Documents**”), as applicable, or the consummation of the transactions contemplated by the Transaction Documents, except such as have been already obtained or as may be required under the Securities Act or the rules and regulations of the SEC thereunder, state securities or blue sky laws, the rules and regulations of the Financial Industry Regulatory Authority, Inc. (“**FINRA**”) or Nasdaq.

**2.10 No Material Adverse Effect.** Except as otherwise disclosed in the SEC Documents, subsequent to the respective dates as of which information is given in the SEC Documents: (a) the Company and its subsidiaries (considered as one entity) has not sustained any material loss or material interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, (b) there has not been any change in the share capital or increase in short-term or long-term debt of the Company, other than a change in the number of outstanding Ordinary Shares due to the issuance of shares upon the exercise or settlement of outstanding options, warrants or restricted stock units as described in the SEC Documents, and (c) there has not occurred any Material Adverse Effect, or any development that would result, or would reasonably be expected to result, in a prospective Material Adverse Effect, in or affecting the condition, financial or otherwise, or in or affecting the revenues, business, assets, management, financial position, shareholders’ equity, operations or results of operations of the Company.

**2.11 Absence of Proceedings.** There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity (“*Action*”) now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by the Transaction Documents or the performance by the Company of its obligations hereunder and thereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to their business, if determined adversely to the Company or such subsidiary, would not reasonably be expected to have a Material Adverse Effect. Except as disclosed in the SEC Documents, there are no outstanding governmental orders and no unsatisfied judgments, penalties or awards against or affecting the Company or any of its properties or assets, except for any that are not required to be disclosed in the SEC Documents. No labor dispute with the employees of the Company or any of its subsidiaries, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent, which could reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect.

**2.12 Investment Company Act of 1940.** The Company is not, and after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described herein will not be, required to register as an “investment company” as such term is defined in the Investment Company Act of 1940, as amended.

**2.13 Registration Rights.** Except as described in the SEC Documents, there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company or to require the Company to include such securities with the Shares and Warrant Shares registered pursuant to a Registration Statement other than rights that have been validly waived.

**2.14 Title to Real and Personal Property.** The Company and its subsidiaries have good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in the consolidated financial statements of the Company included in the SEC Documents filed in calendar year 2023, in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except as do not materially interfere with the use made or proposed to be made of such property and other assets by the Company. Except as disclosed in the SEC Documents, the real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

**2.15 Intellectual Property Rights.** Except as disclosed in the SEC Documents, the Company and its subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property (1) described in the SEC Documents as being owned or licensed by them or (2) which are necessary for the conduct of their respective businesses as currently conducted or as currently proposed in the SEC Documents to be conducted (collectively, “*Intellectual Property*”) except in the case of clause (2) where the failure to own, possess or acquire such rights would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, to the Company’s knowledge: (i) there are no third parties who have rights to any Intellectual Property; and (ii) there is no infringement by third parties of any Intellectual Property. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company’s or its subsidiaries’ rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of any product or service described in the SEC Documents as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, the Company and its subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or its subsidiaries, and all such agreements are in full force and effect. The product candidates described in the SEC Documents as under development by the Company or its subsidiary fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company or any such subsidiary.

**2.16 Insurance.** Each of the Company and its subsidiaries are insured by recognized and reputable institutions with policies in such amounts and with such deductibles and covering such risks as the Company reasonably believes are generally deemed customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its subsidiaries for clinical trial liability claims. The Company has no reasonable basis to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any material insurance coverage which it has sought or for which it has applied.

**2.17 Licenses and Permits.** The Company and its subsidiaries possess such valid and current certificates, authorizations or permits required by state, federal or foreign, including Israeli, regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the SEC Documents ("**Permits**"), except where the failure to so possess would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or, to the knowledge of the Company, has been threatened with or received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any Permit, except as would not reasonably be expected to have a Material Adverse Effect.

**2.18 Accounting and Disclosure Controls.** The Company makes and keeps accurate books and records and maintains a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with United States generally accepted accounting principles ("**U.S. GAAP**") and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the SEC Documents fairly presents the information called for and is prepared, in each case in all material respects, in accordance with the Commission's rules and guidelines applicable thereto.

**2.19 Disclosure Controls.** The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which (i) are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter; and (iii) are effective, in all material respects, to perform the functions for which they were established. Since the end of the Company's most recent audited fiscal year, there have been no material weakness in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**2.20 Independent Accountants.** PricewaterhouseCoopers LLP, who have certified the financial statements and supporting schedules of the Company that are included in the SEC Documents and which will be included as a part of the Registration Statement, is an independent registered public accounting firm with respect to the Company as required by the Securities Act and the rules and regulations of the SEC thereunder.

**2.21 SEC Documents.** The Company has timely filed the SEC Documents required to be filed by it with the SEC, under the Securities Act and the Exchange Act, for the one year period preceding the date hereof. As of their respective dates, the SEC Documents complied in all material respects with the requirements of the Exchange Act or the Securities Act, as the case may be, and the rules and regulations of the SEC promulgated thereunder applicable to the SEC Documents, and none of the SEC Documents, at the time they were filed with the SEC, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. There are no material outstanding or unresolved comments in comment letters from the staff of the Division of Corporation Finance of the SEC with respect to any of the SEC Documents as of the date hereof. The Company meets the requirements for use of Form S-3 under the Securities Act.

**2.22 Financial Statements.** (a) The financial statements included in the SEC Documents since the end of the Company's most recent audited fiscal year, together with the related schedules and notes, present fairly, in all material respects, the financial position of the Company at the dates indicated and the statement of operations, shareholders' equity and cash flows of the Company for the periods specified; said financial statements have been prepared in conformity with U.S. GAAP applied on a consistent basis throughout the periods involved except, in the case of unaudited interim financial statements, for normal year-end audit adjustments and the exclusion of footnotes. The summary financial information included in the SEC Documents since the end of the Company's most recent audited fiscal year, if any, present fairly, in all material respects, the information shown therein and have been compiled on a basis consistent in all material respects with that of the audited financial statements included in the SEC Documents. (b) Except as set forth in the SEC Documents, there are no off-balance sheet arrangements, outstanding guarantees or other contingent obligations of the Company that would reasonably be expected to have a Material Adverse Effect. There are no transactions, arrangements or other relationships between and/or among the Company, any of its affiliates (as such term is defined in Rule 405 of the Securities Act) and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity, that would reasonably be expected to materially affect the Company's liquidity or the availability of or requirements for its capital resources required to be described in SEC Documents which have not been described as required. All disclosures contained in the SEC Documents regarding "non-GAAP financial measures" (as defined by the rules and regulations of the SEC) comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Securities Act, to the extent applicable. There are no financial statements (historical or pro forma) that are required to be included in the SEC Documents that are not so included as required. The interactive data in eXtensible Business Reporting Language ("**XBRL**") included or incorporated by reference in the SEC Documents fairly present the information called for in all material respects and have been prepared in accordance with the SEC's rules and guidelines applicable thereto. Except as would not, in the aggregate, reasonably be expected to have a Material Adverse Effect, since the date of the latest audited financial statements included in the SEC Documents, and, except as disclosed in a subsequent SEC Document filed prior to the date hereof, neither the Company has (i) sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, (ii) issued or granted any securities (other than pursuant to employee benefit plans, qualified stock option plans or other equity compensation plans or arrangements existing on the date hereof and disclosed in the SEC Documents), (iii) incurred any material liability or obligation, direct or contingent, other than liabilities and obligations that were incurred in the ordinary course of business, (iv) entered into any material transaction not in the ordinary course of business, or (v) declared or paid any dividend on its share capital.

**2.23 Tax Law Compliance.** The Company and its subsidiaries have filed all material United States (federal, state and local), Israeli and foreign (state and local) income and franchise tax returns or have properly requested extensions thereof and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings or except where the failure to pay such taxes could not reasonably be expected to result in a Material Adverse Effect. The Company has made adequate charges, accruals and reserves in the financial statements included in the SEC Documents since the end of the Company's most recent audited fiscal year in respect of all federal, state, Israeli and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its subsidiaries has not been finally determined.

**2.24 Related Party Transactions.** There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the SEC Documents that have not been described as required.

**2.25 Commission Agreements.** The Company is not a party to any contract, agreement or understanding with any person that would give rise to a valid claim against the Company or the Placement Agents for a brokerage commission, finder's fee or like payment in connection with any transaction contemplated by this Agreement, except for dealings with the Placement Agents, whose commissions and fees will be paid by the Company.

**2.26 Foreign Corrupt Practices Act.** Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic government official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "**FCPA**")) or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any applicable non-U.S. anti-bribery statute or regulation; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful

payment to any domestic government official, such foreign official or employee; and the Company and its subsidiaries and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith. The foregoing representation and warranty shall also be deemed given regarding laws of non-U.S. jurisdictions similar to the FCPA, including, without limitation, Sections 291 and 291A of the Israeli Penal Law, 5737- 1977, and the rules and regulations thereunder.

**2.27 Money Laundering Laws.** The operations of the Company and its subsidiaries are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

**2.28 OFAC.** Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, after due inquiry, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"), the United Nations Security Council ("**UNSC**"), the European Union, Her Majesty's Treasury ("**HMT**"), or other relevant sanctions authority (collectively, "**Sanctions**"), nor is the Company located, organized or resident in a country or territory that is the subject of Sanctions; and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, or any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or in any country or territory, that currently is the subject to any Sanctions, or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of such Sanctions.

**2.29 Use of Proceeds.** The Company will use the net proceeds of the sale of the Shares and Pre-Funded Warrants for non-clinical and clinical development activities for its product candidates, commercialization of any approved products and general corporate purposes.

**2.30 Acknowledgment Regarding Purchasers' Purchase of Shares and Pre-Funded Warrants.** The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to this Agreement and the transactions contemplated hereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity with respect to the Company) with respect to this Agreement and the transactions contemplated hereby and any advice given by any Purchaser or any of their respective representatives or agents to the Company in connection with this Agreement and the transactions contemplated hereby is merely incidental to such Purchaser's purchase of the Shares and Pre-Funded Warrants. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement has been based on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

**2.31 No Reliance.** The Company has not relied upon the Placement Agents or legal counsel for the Placement Agents for any legal, tax or accounting advice in connection with the offering and sale of the Securities.

**2.32 No Price Stabilization or Manipulation of Shares; Compliance with Regulation M.** The Company has not taken, directly or indirectly, any action designed to or that would be reasonably expected to cause or result in stabilization or manipulation of the price of the Ordinary Shares or any security of the Company whether to facilitate the sale or resale of any of the Securities or otherwise, and has taken no action which would directly or indirectly violate Regulation M under the Exchange Act. In addition, the Company has not engaged in any form of solicitation, advertising or other action constituting an offer or a sale under the Israeli Securities Law, 5728-1986, as amended (the "**Israeli Securities Law**"), and the regulations promulgated thereunder in connection with the transactions contemplated hereby which would require the Company to publish a prospectus in the State of Israel under the laws of the State of Israel.

**2.33 Never a Shell Company.** The Company has never been an issuer subject to Rule 144(i) under the Securities Act.

**2.34 Sarbanes-Oxley.** There is and has been no failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any provisions of the Sarbanes-Oxley Act that are applicable to the Company or its directors or officers in their capacities as directors or officers of the Company.

**2.35 Cybersecurity; Data Protection.** The Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are reasonably adequate for, and operate and perform in all material respects as required in connection with, the operation of the business of the Company and its subsidiaries as currently conducted, free and clear of all bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company and its subsidiaries have implemented and maintained commercially reasonable controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data (including all personal, personally identifiable, sensitive, confidential or regulated data ("**Personal Data**") used in connection with their businesses, and there have been no breaches, violations, outages or unauthorized uses of or accesses to same, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company and its subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

**2.36 Clinical Data and Regulatory Compliance.** The preclinical studies and clinical trials being conducted or sponsored by the Company, and, to the knowledge of the Company, other studies (collectively, "**studies**") that are described in, or the results of which are referred to in, the SEC Documents were and, if still pending, are being conducted, in all material respects, in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete, in all material respects, and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge as of the date hereof of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the SEC Documents; the Company and its subsidiaries have made all such filings and obtained all such approvals as may be required for the conduct of the studies by the Israeli Ministry of Health, the U.S. Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S., Israeli or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "**Regulatory Agencies**"), except where the failure to make such filing or obtain such approval would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect; neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring, and, to the knowledge of the Company, no Regulatory Agency has threatened to initiate, the termination, suspension or modification of any clinical trials that are described or referred to in the SEC Documents; and the Company and its subsidiaries have each operated and currently are in compliance, in all material respects, with all applicable rules, regulations and policies of the Regulatory Agencies.

**2.37 Contracts.** There are no contracts or other documents required to be described in the SEC Documents or filed as exhibits to the SEC Documents pursuant to Item 601 of Regulation S-K that are not described and filed as required. The statements made in the SEC Documents, insofar as they purport to constitute summaries of the terms of the contracts and other documents described and filed pursuant to Item 601 of Regulation S-K, constitute accurate summaries of the terms of such contracts and documents in all material respects. Except as disclosed in the SEC Documents, the Company does not have knowledge that any other party to any such contract or other document filed pursuant to Item 601 of Regulation S-K has any intention not to render full performance as contemplated by the terms thereof.

**2.38 Compliance with Israeli Law.** All corporate approvals on the part of the Company, including under Chapter 5 of Part VI of the Companies Law, for the offer or sale of Securities and the transactions contemplated under the Transaction Documents have been obtained.

**2.39 The Nasdaq Global Market.** The Ordinary Shares are listed on The Nasdaq Global Market, and to the Company's knowledge, there are no proceedings to revoke or suspend such listing. The Company is in material compliance with the requirements of Nasdaq for continued listing of the Ordinary Shares thereon and any other Nasdaq listing and maintenance requirements.

Any certificate signed by an authorized officer or representative of the Company and required to be delivered to the Placement Agents or to counsel for the Placement Agents in connection with this Agreement shall be deemed to be a representation and warranty by the Company to the Placement Agents as to the matters set forth therein.

**PURCHASER'S REPRESENTATIONS AND WARRANTIES**

Each Purchaser represents and warrants to the Company and the Placement Agents, severally and not jointly, with respect to itself and its purchase hereunder, that as of the Closing:

**3.1 Investment Purpose.** The Purchaser is purchasing the Securities for its own account and not with a present view toward the public sale or distribution thereof and has no intention of selling or distributing any of such Securities or any arrangement or understanding with any other Persons regarding the sale or distribution of such Securities except in accordance with the provisions of Article 6 and except as would not result in a violation of the Securities Act. The Purchaser will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the Securities except in accordance with the provisions of Article 6 or pursuant to and in accordance with the Securities Act.

**3.2 Information.** The Purchaser has been furnished with all relevant materials relating to the business, finances and operations of the Company necessary to make an investment decision, and materials relating to the offer and sale of the Securities, that have been requested by the Purchaser, including, without limitation, the SEC Documents, and the Purchaser has had the opportunity to review the SEC Documents. The Purchaser has been afforded the opportunity to ask questions of the Company. Neither such inquiries nor any other investigation conducted by or on behalf of such Purchaser or its representatives or counsel shall modify, amend or affect such Purchaser's right to rely on the truth, accuracy and completeness of the SEC Documents and the Company's representations and warranties contained in the Agreement. The Purchaser specifically understands and acknowledges that, on the date of this Agreement and on the Closing Date, the Company may have in its possession non-public information that could be material to the market price of the Securities, including with respect to the Company's financial results for the quarter ended June 30, 2023. The Purchaser hereby represents and warrants that, in entering into this Agreement and consummating the transactions contemplated hereby, it does not require the disclosure of such non-public information to it by the Company in order to make an investment in the Securities, and hereby waives all present or future claims arising out of or relating to the Company's failure to disclose such non-public information to the Purchaser. The Purchaser also specifically acknowledges that the Company would not enter into this Agreement or any related documents in the absence of such Purchaser's representations and acknowledgments set out in this Agreement, and that this Agreement, including such representations and acknowledgments, are a fundamental inducement to the Company, and a substantial portion of the consideration provided by such Purchaser, in this transaction, and that the Company would not enter into this transaction but for this inducement.

**3.3 Acknowledgement of Risk.**

(a) The Purchaser acknowledges and understands that its investment in the Securities involves a significant degree of risk, including, without limitation, (i) the Company has a limited operating history and may require substantial funds in addition to the proceeds from the sale of the Securities; (ii) an investment in the Company is speculative, and only Purchasers who can afford the loss of their entire investment should consider investing in the Company and the Securities; (iii) the Purchaser may not be able to liquidate its investment; (iv) transferability of the Securities is extremely limited; (v) in the event of a disposition of the Securities, the Purchaser could sustain the loss of its entire investment; and (vi) the Company has not paid any dividends on its Ordinary Shares since inception and does not anticipate the payment of dividends in the foreseeable future. Such risks are more fully set forth in the SEC Documents;

(b) The Purchaser is able to bear the economic risk of holding the Securities for an indefinite period, and has knowledge and experience in financial and business matters such that it is capable of evaluating the risks of the investment in the Securities; and

(c) The Purchaser has, in connection with the Purchaser's decision to purchase Securities, not relied upon any representations or other information (whether oral or written) other than as set forth in the representations and warranties of the Company contained herein and the information disclosed in the SEC Documents, and the Purchaser has, with respect to all matters relating to this Agreement and the offer and sale of the Securities, relied solely upon the advice of such Purchaser's own counsel and has not relied upon or consulted any counsel to the Placement Agents or counsel to the Company.

**3.4 Governmental Review.** The Purchaser understands that no United States federal or state agency or any other government or governmental agency has passed upon or made any recommendation or endorsement of the Securities or an investment therein.

**3.5 Transfer or Resale.** The Purchaser understands that:

(a) the Securities have not been and are not being registered under the Securities Act (other than as contemplated in Article 6) or any applicable state securities laws and, consequently, the Purchaser may have to bear the risk of owning the Securities for an indefinite period of time because the Securities may not be transferred unless (i) the resale of the Securities is registered pursuant to an effective registration statement under the Securities Act, as contemplated in Article 6; (ii) the Purchaser has delivered to the Company an opinion of counsel (in form, substance and scope customary for opinions of counsel in comparable transactions) to the effect that the Securities to be sold or transferred may be sold or transferred pursuant to an exemption from such registration; or (iii) the Securities are sold or transferred pursuant to Rule 144;

(b) any sale of the Securities made in reliance on Rule 144 may be made only in accordance with the terms of Rule 144 and, if Rule 144 is not applicable, any resale of the Securities under circumstances in which the seller (or the Person through whom the sale is made) may be deemed to be an underwriter (as that term is defined in the Securities Act) may require compliance with some other exemption under the Securities Act or the rules and regulations of the SEC thereunder; and

(c) except as set forth in Article 6, neither the Company nor any other Person is under any obligation to register the resale of the Securities under the Securities Act or any state securities laws or to comply with the terms and conditions of any exemption thereunder.

**3.6 Legends.**

(a) The Purchaser understands the book entries representing the Securities will bear a restrictive legend in substantially the following form, in addition to any other legend required by applicable state securities laws or as may be appropriate to legend any restrictions on transfer set forth in this Agreement (and a stop-transfer order may be placed against transfer of the book entries for such Securities):

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES. THE SECURITIES MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER APPLICABLE SECURITIES LAWS, OR UNLESS OFFERED, SOLD, PLEDGED, HYPOTHECATED OR TRANSFERRED PURSUANT TO AN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THOSE LAWS. THE COMPANY SHALL BE ENTITLED TO REQUIRE AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED TO THE EXTENT THAT SUCH OPINION IS REQUIRED PURSUANT TO THAT CERTAIN SECURITIES PURCHASE AGREEMENT UNDER WHICH THE SECURITIES WERE ISSUED.

(b) To the extent the resale of any issued Shares or Warrant Shares is registered under the Securities Act pursuant to an effective Registration Statement, the Company agrees to promptly (i) authorize the removal of the legend set forth in Section 3.6(a) and any other legend not required by applicable law from such Shares or Warrant Shares, (ii) cause the Transfer Agent to issue such Shares or Warrant Shares without such legends to the holders thereof by electronic delivery at the applicable balance account at the Depository Trust Company upon surrender of any share certificates evidencing such Shares or Warrant Shares and (iii) if required by the Transfer Agent, cause its counsel to issue a legal opinion to effect the removal of any restrictive legends and provide all other opinions as may be reasonably be required by the transfer agent in connection with the removal of legends (all such opinions, “**TA Legal Opinions**”). The Company’s obligation to remove legends under this Section 3.6(b) may be conditioned upon the Purchaser providing such representations and documentation as the Company or its legal counsel deems reasonably necessary in connection with the removal of restrictive legends, provided that the Company agrees to notify the Purchaser of any such necessary representations or documentation as soon as reasonably practicable (which shall generally be within one Business Day following a request by a Purchaser). With respect to any Shares or Warrant Shares for which restrictive legends are removed pursuant to this Section 3.6(b), the holder thereof agrees to only sell such Shares or Warrant Shares when and as permitted by the effective Registration Statement covering such resale and in accordance with applicable securities laws and regulations, or in accordance with Rule 144.

(c) The Purchaser may request that the Company remove, and the Company agrees to authorize, including through the issuance of TA Legal Opinions by the Company’s counsel, the removal of any legend from any Shares or Warrant Shares issued to such Purchaser (i) following any sale, or certification by a Purchaser of the expected sale, of such Shares or Warrant Shares pursuant to Rule 144, (ii) if such Shares or Warrant Shares are eligible for sale under Rule 144 following the expiration of the holding requirement under subparagraphs (b)(1)(i) and (d) thereof and the Purchaser is not an affiliate of the Company, in each case following receipt from the Purchaser of an appropriate certification to such effect, or (iii) following

the time that the Registration Statement is declared effective and while it remains effective. Following the time a legend is no longer required for the Shares or Warrant Shares under this Section 3.6(c), the Company will, no later than two Trading Days following the delivery by a Purchaser to the Company or the Transfer Agent of a legended certificate representing such securities (if any) (or a request for legend removal, in the case of Shares or Warrant Shares issued in book-entry form) and appropriate certifications that the applicable requirements have been satisfied (the “**Securities Delivery Date**”), deliver or cause to be delivered to such Purchaser evidence of book-entry position representing such securities that is free from all restrictive and other legends or, in the case of Shares or Warrant Shares, if requested by Purchaser, by crediting such Shares or Warrant Shares to the account of the Purchaser or its prime broker or other designee with The Depository Trust Company through its Deposit or Withdrawal at Custodian system (“**DWAC**”) if the Company is then a participant in such system (“**DWAC Delivery**”); if the Company fails for any reason to deliver Shares or Warrant Shares via DWAC Delivery (if the Company is then a participant in DWAC) to a Purchaser as required by this Section 3.6(c) (other than a failure caused by incorrect or incomplete information provided by Purchaser to the Company), and if after such Securities Delivery Date such Purchaser is required to or otherwise purchases (in an open market transaction or otherwise), Ordinary Shares to deliver in satisfaction of a sale by such Purchaser of the Shares or Warrant Shares which such Purchaser was entitled to receive relating to such Securities Delivery Date (a “**Buy-In**”), then the Company shall pay in cash to such Purchaser (in addition to any other remedies available to or elected by such Purchaser) the amount by which (x) such Purchaser’s total purchase price (including any brokerage commissions) for the Ordinary Shares so purchased exceeds (y) the product of (1) the lesser of the (a) the number of Ordinary Shares so purchased and (b) the aggregate number of Shares or Warrant Shares that such Purchaser was entitled to receive for the Securities Delivery Date multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions). For example, if a Purchaser purchases Ordinary Shares having a total purchase price of \$11,000 to cover a Buy-In with respect to Shares or Warrant Shares that were not delivered via DWAC Delivery by the Securities Delivery Date with respect to which the actual sale price (including any brokerage commissions) giving rise to such purchase obligation was a total of \$10,000, the Company shall be required to pay such Purchaser \$1,000. The Purchaser shall provide the Company written notice, within three (3) Business Days after the occurrence of a Buy-In, indicating the amounts payable to such Purchaser in respect of such Buy-In together with applicable confirmations and other evidence reasonably requested by the Company. Nothing herein shall limit a Purchaser’s right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company’s failure to timely deliver the Shares or Warrant Shares via DWAC Delivery as required pursuant to the terms hereof.

**3.7 Authorization; Enforcement.** The Purchaser has the requisite power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The Purchaser has taken all necessary action to authorize the execution, delivery and performance of this Agreement. Upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of the Purchaser enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors’ and contracting parties’ rights generally and except as enforceability may be subject to general principles of equity and except as rights to indemnity and contribution may be limited by state or federal securities laws or public policy underlying such laws.

**3.8 Residency.** Unless the Purchaser has otherwise notified the Company in writing, the Purchaser is a resident of the jurisdiction set forth immediately below such Purchaser’s name on the signature pages hereto.

**3.9 Short Sales and Confidentiality Prior to the Date Hereof.** Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including all “short sales” as defined in Rule 200 of Regulation SHO under the Exchange Act (“**Short Sales**”), of the securities of the Company during the period commencing as of the time that such Purchaser was first contacted by the Company, a Placement Agent or any other Person regarding the transactions contemplated hereby and ending immediately prior to the date hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser’s assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser’s assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities. Other than to other Persons party to this Agreement and other than to such Person’s affiliate or outside attorney, accountant, auditor or investment advisor only to the extent necessary to permit evaluation of the investment, and the performance of the necessary or required tax, accounting, financial, legal, regulatory or administrative tasks and services and other than as may be required by law or regulation, such Investor has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude or prohibit any actions, with respect to the identification of, the availability of, or securing of, available shares to borrow in order to effect Short Sales or similar transactions in the future.

### 3.10 Acknowledgements Regarding Placement Agents.

(a) The Purchaser acknowledges that each of the Placement Agents is acting as a placement agent on a “best efforts” basis for the Securities being offered hereby and will be compensated by the Company for acting in such capacity. The Purchaser represents that (i) the Purchaser was contacted regarding the sale of the Securities by a Placement Agent or the Company (or an authorized agent or representative thereof) with whom the Purchaser entered into a verbal or written confidentiality agreement and (ii) no Securities were offered or sold to it by means of any form of general solicitation or general advertising as such terms are used in Regulation D of the Securities Act.

(b) The Purchaser represents that it is making this investment based on the results of its own due diligence investigation of the Company, and has not relied on any information or advice furnished by or on behalf of either of the Placement Agents in connection with the transactions contemplated hereby. The Purchaser acknowledges that neither of the Placement Agents has made, and will not make, any representations and warranties with respect to the Company or the transactions contemplated hereby, and the Purchaser will not rely on any statements made by either of the Placement Agents, orally or in writing, to the contrary.

## ARTICLE 4

### COVENANTS

**4.1 Reporting Status.** The Ordinary Shares are registered under Section 12 of the Exchange Act. During the Registration Period, the Company will timely file all documents with the SEC, and the Company will not terminate its status as an issuer required to file reports under the Exchange Act even if the Exchange Act or the rules and regulations thereunder would permit such termination.

**4.2 Expenses.** The Company and each Purchaser shall be liable for, and will pay, its own expenses incurred in connection with the negotiation, preparation, execution and delivery of the Transaction Documents, including, without limitation, attorneys’ and consultants’ fees and expenses. Notwithstanding the foregoing, if the Closing is effected, the Company shall, at the Closing, reimburse the reasonable, documented fees and out-of-pocket expenses, including reasonable, documented outside counsel fees, of RA Capital Healthcare Fund, L.P., not to exceed \$50,000.

**4.3 Financial Information.** The financial statements of the Company to be included in any documents filed with the SEC have been or will be prepared in accordance with U.S. GAAP, consistently applied (except (i) as may be otherwise indicated in such financial statements or the notes thereto, or (ii) in the case of unaudited interim statements, to the extent they may not include footnotes, may be condensed or summary statements or may conform to the SEC’s rules and instructions for Reports on Form 10-Q), and fairly present or will fairly present in all material respects the financial position of the Company and results of its operations and cash flows as of, and for the periods covered by, such financial statements (subject, in the case of unaudited statements, to normal and recurring year-end audit adjustments).

**4.4 Securities Laws Disclosure; Publicity.** On or before the first Business Day following the date hereof, the Company shall file a Current Report on Form 8-K with the SEC describing the terms of the transactions contemplated by the Transaction Documents and including as exhibits to such Current Report on Form 8-K the Transaction Documents, in the forms required by the Exchange Act. From and after the filing of such Current Report on Form 8-K or, if sooner, upon the Company’s issuance of a press release describing the terms of the transactions contemplated by this Agreement, the Company represents to the Purchasers that it shall have publicly disclosed the material terms and conditions of the transactions contemplated by the Transaction Documents.

**4.5 Non-Public Information.** Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information following the date of this Agreement that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser has consented to the receipt of such information and agreed with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company, provided that the Purchaser shall remain subject to applicable law. Upon the issuance of the Form 8-K described in Section 4.4, to the knowledge of the Company, no Purchaser shall be in possession of any material, non-public information received from the Company or any of its officers, directors, employees, agents or any other person acting at the direction of the Company.

**4.6 Sales by Purchasers.** Each Purchaser will sell any Securities held by it in compliance with applicable prospectus delivery requirements, if any, or otherwise in compliance with the requirements for an exemption from registration under the Securities Act and the rules and regulations promulgated thereunder. No Purchaser will make any sale, transfer or other disposition of the Securities in violation of federal or state securities laws.

**4.7 Reservation of Ordinary Shares.** The Company shall reserve and keep available at all times during which Pre-Funded Warrants remain exercisable, free of preemptive rights, a sufficient number of Ordinary Shares for the purpose of enabling the Company to issue the Warrant Shares.

**4.8 Non-Disclosure.** The Company shall not (and shall cause its officers, directors, employees and agents not to) publicly disclose the name of any Purchaser or any affiliate or investment adviser of any Purchaser, or include the name of such Purchaser or any affiliate or investment adviser of Purchaser without the prior written consent (including by e-mail) of such Purchaser (i) in any press release or marketing materials, or (ii) in any filing with the SEC or any regulatory agency or trading market, except (A) as required by the federal securities laws, rules or regulations, (B) to the extent such disclosure is required by other laws, rules or regulations, at the request of the staff of the SEC or regulatory agency or under regulations of any national securities exchange on which the Company's securities are listed for trading or (C) to the extent such announcements or other communications contain only information previously disclosed in a public statement, press release, or other communications previously approved in accordance with this Section 4.8.

**4.9 Tax Indemnity.** The Company will indemnify and hold harmless the Purchasers against any documentary, stamp or similar issue tax, including any interest and penalties, on the creation and issue of the Securities or in connection with the crediting of the Shares or the Warrant Shares to the account of the Purchasers or their respective designee with The Depository Trust Company through its Deposit or Withdrawal at Custodian system.

## ARTICLE 5

### CONDITIONS TO CLOSING

**5.1 Conditions to Obligations of the Company.** The Company's obligation to complete the purchase and sale of the Shares and Pre-Funded Warrants to each Purchaser at the Closing is subject to the waiver by the Company or fulfillment as of the Closing Date of the following conditions:

**(a) Receipt of Funds.** The Company shall have received immediately available funds in the full amount of the Aggregate Purchase Price (Wire Amount) for the Shares and Pre-Funded Warrants being purchased at the Closing as set forth opposite such Purchaser's name on **Exhibit A** hereto.

**(b) Representations and Warranties.** The representations and warranties made by each Purchaser in Article 3 shall be true and correct in all material respects as of the Closing Date.

**(c) Covenants.** All covenants, agreements and conditions contained in this Agreement to be performed by the Purchasers on or prior to the Closing Date shall have been performed or complied with in all material respects.

**(d) Blue Sky.** The Company shall have obtained all necessary blue sky law permits and qualifications, or secured exemptions therefrom, required by any state for the offer and sale of the Securities.

**(e) Nasdaq Qualification.** The Shares and the Warrant Shares shall be duly authorized for listing by Nasdaq, subject to official notice of issuance, to the extent required by the rules of Nasdaq.

**(f) Absence of Litigation.** No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, shall have been instituted or be pending before any court, arbitrator, governmental body, agency or official.

**(g) No Governmental Prohibition.** The sale of the Shares and Pre-Funded Warrants by the Company shall not be prohibited by any law or governmental order or regulation.

**5.2 Conditions to Purchasers' Obligations.** Each Purchaser's obligation to complete the purchase and sale of the Shares and Pre-Funded Warrants is subject to the waiver by such Purchaser or fulfillment as of the Closing Date of the following conditions:

- (a) **Representations and Warranties.** The representations and warranties made by the Company in Article 2 shall be true and correct in all material respects as of the Closing Date.
- (b) **Covenants.** All covenants, agreements and conditions contained in this Agreement to be performed by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.
- (c) **Blue Sky.** The Company shall have obtained all necessary blue sky law permits and qualifications, or secured exemptions therefrom, required by any state or foreign or other jurisdiction for the offer and sale of the Securities.
- (d) **Nasdaq Qualification.** The Shares and the Warrant Shares shall be duly authorized for listing by Nasdaq, subject to official notice of issuance, to the extent required by the rules of Nasdaq.
- (e) **No Governmental Prohibition.** The sale of the Shares and Pre-Funded Warrants by the Company shall not be prohibited by any law or governmental order or regulation.
- (f) **No Material Adverse Effect.** There shall not have occurred any Material Adverse Effect, or any development that could reasonably be expected to result in a Material Adverse Effect, as of the Closing.
- (g) **Transfer Agent Instructions.** The Company shall have delivered to the Transfer Agent irrevocable instructions to issue to such Purchaser or in such nominee name(s) as designated by such Purchaser in writing such number of Securities set forth opposite such Purchaser's name on Exhibit A hereto.
- (h) **Absence of Litigation.** No writ, order, stay, stipulation, determination, judgment or injunction (preliminary or permanent), award or decree of or by any court, or judge, justice or magistrate, including any bankruptcy court or judge, or any order, executive order, decree, statute, rule or regulation of or by any governmental authority, shall have been issued, and no action or proceeding shall have been instituted by any governmental authority, enjoining, preventing, or restraining, or seeking to enjoin, prevent or restrain, or which has effect of making the consummation of the transactions contemplated hereby illegal or otherwise prohibiting any of the transactions contemplated hereby, and no action or proceeding seeking to impose such injunction, prohibition or restrain shall have been, to the Company's knowledge, threatened against the Company.
- (i) **Authorizations and Consents.** The Company shall have obtained any and all authorizations, consents, permits, approvals, registrations and waivers necessary for the consummation of the purchase and sale of the Securities and the consummation of the other transactions contemplated by this Agreement, all of which shall be in full force and effect.
- (j) **No Stop Orders.** No stop order shall have been imposed by Nasdaq, the SEC or any other governmental or regulatory body with respect to public trading in the Ordinary Shares, other than stop orders imposed by Nasdaq that are only temporary.
- (k) **No Other Agreements.** The Company shall not have entered into any securities purchase agreement, subscription agreement, side letter or similar agreement or understanding with any other Purchaser or other person in connection with the transactions contemplated herein, and no Purchaser shall have received terms in respect of its purchase of any of the Securities that are more favorable than those of any other Purchaser.

## ARTICLE 6

### REGISTRATION RIGHTS

6.1 In no event later than 45 days after the Closing Date (the "**Filing Date**"), the Company shall file a registration statement covering the resale of the Registrable Securities with the SEC for an offering to be made on a continuous basis pursuant to Rule 415, or if Rule 415 is not available for offers and sales of the Registrable Securities, by such other means of distribution of Registrable Securities as the Holders of a majority of such Registrable Securities may reasonably specify (the "**Initial Registration Statement**"). The Initial Registration Statement shall be on Form S-3 (except if the Company is ineligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on Form S-1) and the Company shall have the Registration Statement declared effective, and any other qualifications or compliances (including, without limitation, the execution of any required undertaking to file post-effective amendments, appropriate qualifications or exemptions under applicable blue sky or other state securities laws and appropriate compliance with applicable securities laws, requirements or regulations) as promptly as possible after the filing thereof, but in any event prior to the date which is ten days after the receipt of a notification of no-review in the event of no review by the SEC, or 75 days after the Filing Date in the event of a review by the SEC (the "**Effectiveness Date**"). For purposes of clarification, any failure by the Company to file the Initial Registration Statement by the Filing Date or to have such Registration Statement declared

effective within such ten days after the notification of no-review or 75 days after the Filing Date, as applicable, shall not otherwise relieve the Company of its obligations to file or effect the Initial Registration Statement as set forth above in this Section 6.1. In the event the SEC informs the Company that all of the Registrable Securities cannot, as a result of the application of Rule 415, be registered for resale as a secondary offering on a single registration statement, the Company agrees to promptly (i) inform each of the Holders thereof, (ii) use its best efforts to file amendments to the Initial Registration Statement as required by the SEC and/or (iii) withdraw the Initial Registration Statement and file a new registration statement (a **"New Registration Statement"**), in either case covering the maximum number of Registrable Securities permitted to be registered by the SEC, on Form S-3 or, if the Company is ineligible to register for resale the Registrable Securities on Form S-3, Form S-1; *provided, however*, that prior to filing such amendment or New Registration Statement, the Company shall be obligated to use its best efforts to advocate with the SEC for the registration of all of the Registrable Securities. In the event the Company amends the Initial Registration Statement or files a New Registration Statement, as the case may be, under clauses (ii) or (iii) above, the Company will use its best efforts to file with the SEC, within 30 days following the date allowed by the SEC, one or more registration statements on Form S-3 or, if the Company is ineligible to register for resale the Registrable Securities on Form S-3, Form S-1, to register for resale those Registrable Securities that were not registered for resale on the Initial Registration Statement, as amended, or the New Registration Statement (the **"Remainder Registration Statements"**). If the SEC limits the number of Registrable Securities permitted to be registered on a particular Registration Statement (and notwithstanding that the Company used diligent efforts to advocate with the SEC for the registration of all or a greater number of Registrable Securities), any required cutback of Registrable Securities (such Registrable Securities so cut back, the **"Cut Back Securities"**) shall be applied to the Purchasers pro rata in accordance with the number of such Registrable Securities sought to be included in such Registration Statement by reference to the amount of Registrable Securities set forth opposite such Purchaser's name on **Exhibit A** (and in the case of a subsequent transfer, the initial Purchaser's transferee) relative to the aggregate amount of all Registrable Securities. In no event shall any Purchaser be identified as a statutory underwriter in the Registration Statement unless in response to a comment or request from the staff of the SEC or another regulatory agency; *provided*, that if the SEC requests that a Purchaser be identified as a statutory underwriter in the Registration Statement, such Purchaser will have an opportunity to withdraw from the Registration Statement.

**6.2** All Registration Expenses incurred in connection with any registration, qualification, exemption or compliance pursuant to Section 6.1 shall be borne by the Company. All Selling Expenses relating to the sale of securities registered by or on behalf of a Holder shall be borne by such Holder.

**6.3** The Company further agrees that, in the event that (i) the Initial Registration Statement has not been filed with the SEC by the Filing Date, (ii) the Initial Registration Statement or the New Registration Statement, as applicable, has not been declared effective by the SEC by the Effectiveness Date, or (iii) after such Registration Statement is declared effective by the SEC, is suspended by the Company or ceases to remain continuously effective as to all Registrable Securities for which it is required to be effective, other than, in each case, within the time period(s) permitted by Section 6.7(b) (each such event referred to in clauses (i), (ii) and (iii), (a **"Registration Default"**)), for more than 20 consecutive days or more than 40 days in any period of 365 days during which the Registration Default remains uncured, the Company shall pay to each Purchaser 1.0% of such Purchaser's Subscription Amount as set forth on **Exhibit A** hereto of such Purchaser's Registrable Securities for each 20-day period (a **"Penalty Period"**) (provided the payment amount shall increase by 1.0% of such Purchaser's Subscription Amount as set forth on **Exhibit A** hereto for each subsequent 20-day period following the initial 20-day period), or pro rata for any portion thereof, during which the Registration Default remains uncured; *provided, however*, that if a Purchaser fails to provide the Company with any information that is required to be provided in such Registration Statement with respect to such Purchaser as set forth herein, then the commencement of the Penalty Period described above shall be extended until two Business Days following the date of receipt by the Company of such required information; and provided, further, that in no event shall the Company be required hereunder to pay to any Purchaser pursuant to this Agreement more than 3.0% of such Purchaser's Subscription Amount of such Purchaser's Registrable Securities in any Penalty Period and in no event shall the Company be required hereunder to pay to any Purchaser pursuant to this Agreement an aggregate amount that exceeds 10.0% of the Subscription Amount paid by such Purchaser for such Purchaser's Securities. The Company shall deliver said cash payment to the Purchaser by the fifth Business Day after the end of such Penalty Period. Notwithstanding any other provision of this Section 6.3, no Registration Default as to the Cut Back Securities shall be deemed to have occurred until the date that is 30 days following the date on which the SEC permits the Cut Back Securities to be registered, and the payment of any penalty pursuant to this Section 6.3 shall be calculated to apply only to the percentage of Registrable Securities which are permitted by the SEC to be registered within the timeframes provided for in this Agreement.

6.4 In the case of the registration, qualification, exemption or compliance effected by the Company pursuant to this Agreement, the Company shall, upon reasonable request, inform each Holder as to the status of such registration, qualification, exemption and compliance. At its expense the Company shall:

(a) except for such times as the Company is permitted hereunder to suspend the use of the prospectus forming part of a Registration Statement, use its best efforts to keep such registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective with respect to a Holder, and to keep the applicable Registration Statement free of any material misstatements or omissions, until the earlier of the following: (i) the third anniversary of the Effectiveness Date or (ii) the date all Shares and Warrant Shares (assuming cashless exercise) held by or issuable to such Holder may be sold under Rule 144 without being subject to any volume, manner of sale or publicly available information requirements. The period of time during which the Company is required hereunder to keep a Registration Statement effective is referred to herein as the **"Registration Period."**

(b) advise the Holders within two Business Days:

(i) when a Registration Statement or any amendment thereto has been filed with the SEC and when such Registration Statement or any post-effective amendment thereto has become effective;

(ii) of any request by the SEC for amendments or supplements to any Registration Statement or the prospectus included therein or for additional information;

(iii) of the issuance by the SEC of any stop order suspending the effectiveness of any Registration Statement or the initiation of any proceedings for such purpose;

(iv) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Registrable Securities included therein for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; and

(v) of the occurrence of any event that requires the making of any changes in any Registration Statement or prospectus so that, as of such date, the statements therein are not misleading and do not omit to state a material fact required to be stated therein or necessary to make the statements therein (in the case of a prospectus, in the light of the circumstances under which they were made) not misleading;

(c) use its commercially reasonable efforts to obtain the withdrawal of any order suspending the effectiveness of any Registration Statement as soon as reasonably practicable;

(d) if a Holder so requests in writing, promptly furnish to each such Holder, without charge, at least one copy of each Registration Statement and each post-effective amendment thereto, including financial statements and schedules, and, if explicitly requested, all exhibits in the form filed with the SEC;

(e) during the Registration Period, promptly deliver to each such Holder, without charge, as many copies of each prospectus included in a Registration Statement and any amendment or supplement thereto as such Holder may reasonably request in writing; and the Company consents to the use, consistent with the provisions hereof, of the prospectus or any amendment or supplement thereto by each of the selling Holders of Registrable Securities in connection with the offering and sale of the Registrable Securities covered by a prospectus or any amendment or supplement thereto;

(f) during the Registration Period, if a Holder so requests in writing, deliver to each Holder, without charge, (i) one copy of the following documents, other than those documents available via EDGAR: (A) its annual report to its shareholders, if any (which annual report shall contain financial statements audited in accordance with generally accepted accounting principles in the United States by a firm of certified public accountants of recognized standing), (B) if not included in substance in its annual report to shareholders, its annual report on Form 10-K (or similar form), (C) its definitive proxy statement with respect to its annual meeting of shareholders, (D) each of its quarterly reports to its shareholders, and, if not included in substance in its quarterly reports to shareholders, its quarterly report on Form 10-Q (or similar form), and (E) a copy of each full Registration Statement (the foregoing, in each case, excluding exhibits); and (ii) if explicitly requested, all exhibits excluded by the parenthetical to the immediately preceding clause (E);

(g) prior to any public offering of Registrable Securities pursuant to any Registration Statement, promptly take such actions as may be necessary to register or qualify or obtain an exemption for offer and sale under the securities or blue sky laws of such United States jurisdictions as any such Holders reasonably request in writing, provided that the Company shall not for any such purpose be required to qualify generally to transact business as a foreign corporation in any jurisdiction where it is not so qualified or to consent to general service of process in any such jurisdiction, and do any and all other acts or things reasonably necessary or advisable to enable the offer and sale in such jurisdictions of the Registrable Securities covered by any such Registration Statement;

(h) upon the occurrence of any event contemplated by Section 6.4(b)(v) above, except for such times as the Company is permitted hereunder to suspend the use of a prospectus forming part of a Registration Statement, the Company shall use its best efforts to as soon as reasonably practicable prepare a post-effective amendment to such Registration Statement or a supplement to the related prospectus, or file any other required document so that, as thereafter delivered to purchasers of the Registrable Securities included therein, such prospectus will not include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(i) otherwise use its commercially reasonable efforts to comply in all material respects with all applicable rules and regulations of the SEC which could affect the sale of the Registrable Securities;

(j) use its commercially reasonable efforts to cause all Registrable Securities to be listed on each securities exchange or market, if any, on which equity securities issued by the Company have been listed;

(k) use its commercially reasonable efforts to take all other steps necessary to effect the registration of the Registrable Securities contemplated hereby and to enable the Holders to sell Registrable Securities under Rule 144;

(l) provide to each Purchaser and its representatives, if requested, the opportunity to conduct a reasonable inquiry of the Company's financial and other records during normal business hours and make available its officers, directors and employees for questions regarding information which such Purchaser may reasonably request in order to fulfill any due diligence obligation on its part; and

(m) permit a single counsel for the Purchasers to review any Registration Statement and all amendments and supplements thereto (other than supplements to a Registration Statement on Form S-1 solely for the purpose of incorporating other filings with the SEC into such Registration Statement and other than an amendment to a Registration Statement on Form S-1 for the purpose of converting such Registration Statement into a Registration Statement on Form S-3), within two Business Days prior to the filing thereof with the SEC; *provided* that each Purchaser shall have an opportunity to review all disclosures in which it is named prior to filing;

(n) permit each Purchaser to review the information contemplated to be included in the Selling Shareholder's section of any Registration Statement relating to such Purchaser within two Business Days prior to the filing thereof with the SEC;

*provided* that, in the case of clauses (l), (m) and (n) above, the Company shall not be required (A) to delay the filing of any Registration Statement or any amendment or supplement thereto as a result of any ongoing diligence inquiry by or on behalf of a Holder or to incorporate any comments to any Registration Statement or any amendment or supplement thereto by or on behalf of a Holder if such inquiry or comments would require a delay in the filing of such Registration Statement, amendment or supplement, as the case may be, or (B) to provide, and shall not provide, any Purchaser or its representatives with material, non-public information unless such Purchaser agrees to receive such information and enters into a written confidentiality agreement with the Company in a form reasonably acceptable to the Company.

6.5 The Holders shall have no right to take any action to restrain, enjoin or otherwise delay any registration pursuant to Section 6.1 hereof as a result of any controversy that may arise with respect to the interpretation or implementation of this Agreement.

6.6 (a) To the extent permitted by law, the Company shall indemnify each Holder and each Person controlling such Holder within the meaning of Section 15 of the Securities Act, with respect to which any registration that has been effected pursuant to this Agreement, against all claims, losses, damages and liabilities (or action in respect thereof), including any of the foregoing incurred in settlement of any litigation, commenced or threatened (subject to Section 6.6(c) below), arising out of or based on any untrue statement (or alleged untrue statement) of a material fact contained in any Registration Statement, prospectus, any amendment or supplement thereof, or other document incident to any such registration, qualification or compliance or based on any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in light of the circumstances in which they were made, or any violation by the Company of any rule or regulation promulgated by the Securities Act applicable to the Company and relating to any action or inaction required of the Company in connection with any such registration, qualification or compliance, and will reimburse each Holder and each Person controlling such Holder, for reasonable legal and other out-of-pocket expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability or action as incurred; *provided* that the Company will not be liable in any such case to the extent that any untrue statement or omission or allegation thereof is made in reliance upon and in conformity with written information furnished to the Company by or on behalf of such Holder for use in preparation of any Registration Statement, prospectus, amendment or supplement; *provided further*, that the Company will not be liable in any such case where the claim, loss, damage or liability arises out of or is related to the failure of such Holder to comply with the covenants and agreements contained in this Agreement respecting sales of Registrable Securities.

(b) Each Holder will severally, and not jointly, indemnify the Company, each of its directors and officers, and each Person who controls the Company within the meaning of Section 15 of the Securities Act, against all claims, losses, damages and liabilities (or actions in respect thereof), including any of the foregoing incurred in settlement of any litigation, commenced or threatened (subject to Section 6.6(c) below), arising out of or based on any untrue statement (or alleged untrue statement) of a material fact contained in any Registration Statement, prospectus, or any amendment or supplement thereof, incident to any such registration, or based on any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in light of the circumstances in which they were made, and will reimburse the Company, such directors and officers, and each Person controlling the Company for reasonable legal and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability or action as incurred, in each case to the extent, but only to the extent, that such untrue statement or omission or allegation thereof is made in reliance upon and in conformity with written information furnished to the Company by or on behalf of the Holder for use in preparation of any Registration Statement, prospectus, amendment or supplement. Notwithstanding the foregoing, a Holder's aggregate liability pursuant to this subsection (b) and subsection (d) shall be limited to the net amount actually received by the Holder from the sale of the Registrable Securities.

(c) Each party entitled to indemnification under this Section 6.6 (the "**Indemnified Party**") shall give notice to the party required to provide indemnification (the "**Indemnifying Party**") promptly after such Indemnified Party has actual knowledge of any claim as to which indemnity may be sought, and shall permit the Indemnifying Party (at its expense) to assume the defense of any such claim or any litigation resulting therefrom, provided that counsel for the Indemnifying Party, who shall conduct the defense of such claim or litigation, shall be approved by the Indemnified Party (whose approval shall not unreasonably be withheld, conditioned or delayed), and the Indemnified Party may participate in such defense at such Indemnified Party's expense, and provided further that the failure of any Indemnified Party to give notice as provided herein shall not relieve the Indemnifying Party of its obligations under this Agreement, unless such failure is materially prejudicial to the Indemnifying Party in defending such claim or litigation. An Indemnifying Party shall not be liable for any settlement of an action or claim effected without its written consent (which consent will not be unreasonably withheld, conditioned or delayed). No Indemnifying Party, in its defense of any such claim or litigation, shall, except with the consent of each Indemnified Party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect to such claim or litigation.

(d) If the indemnification provided for in this Section 6.6 is held by a court of competent jurisdiction to be unavailable to an Indemnified Party with respect to any loss, liability, claim, damage or expense referred to therein, then the Indemnifying Party, in lieu of indemnifying such Indemnified Party thereunder, shall contribute to the amount paid or payable by such Indemnified Party as a result of such loss, liability, claim, damage or expense in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party on the one hand and of the Indemnified Party on the other in connection with the statements or omissions which resulted in such loss, liability, claim, damage or expense as well as any other relevant equitable considerations. The relative fault of the Indemnifying Party and of the Indemnified Party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the Indemnifying Party or by the Indemnified Party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

**6.7 (a)** Each Holder agrees that, upon receipt of any notice from the Company of the happening of any event requiring the preparation of a supplement or amendment to a prospectus relating to Registrable Securities so that, as thereafter delivered to the Holders, such prospectus shall not contain an untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading, each Holder will forthwith discontinue disposition of Registrable Securities pursuant to a Registration Statement and prospectus contemplated by Section 6.1 until its receipt of copies of the supplemented or amended prospectus from the Company and, if so directed by the Company, each Holder shall deliver to the Company all copies, other than permanent file copies then in such Holder's possession, of the prospectus covering such Registrable Securities current at the time of receipt of such notice.

(b) Each Holder shall suspend, upon request of the Company, any disposition of Registrable Securities pursuant to any Registration Statement and prospectus contemplated by Section 6.1 during no more than two periods of no more than 30 consecutive calendar days each during any 12-month period to the extent that the Board of Directors of the Company determines in good faith that the sale of Registrable Securities under any such Registration Statement would be reasonably likely to cause a violation of the Securities Act or Exchange Act.

(c) As a condition to the inclusion of its Registrable Securities in a Registration Statement, each Holder shall furnish to the Company such information regarding such Holder and the distribution proposed by such Holder as the Company may reasonably request in writing, including completing a Registration Statement Questionnaire in the form provided by the Company, or as shall be required in connection with any registration referred to in this Article 6.

(d) Each Holder hereby covenants with the Company (i) not to make any sale of the Registrable Securities without effectively causing the prospectus delivery requirements under the Securities Act to be satisfied, and (ii) if such Registrable Securities are to be sold by any method or in any transaction other than on a national securities exchange or in the over-the-counter market, in privately negotiated transactions, or in a combination of such methods, to notify the Company at least five Business Days prior to the date on which the Holder first offers to sell any such Registrable Securities.

(e) At the end of the Registration Period the Holders shall discontinue sales of any Shares or Warrant Shares pursuant to any Registration Statement upon receipt of notice from the Company of its intention to remove from registration the Shares or Warrant Shares covered by any such Registration Statement which remain unsold, and such Holders shall notify the Company of the number of Shares or Warrant Shares registered which remain unsold immediately upon receipt of such notice from the Company.

6.8 With a view to making available to the Holders the benefits of certain rules and regulations of the SEC which at any time permit the sale of the Registrable Securities to the public without registration, so long as the Holders still own Registrable Securities, the Company shall use its best efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act, at all times;

(b) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act; and

(c) so long as a Holder owns any Registrable Securities, furnish to such Holder, upon any reasonable request, a written statement by the Company as to its compliance with Rule 144 under the Securities Act, and of the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other reports and documents of the Company as such Holder may reasonably request in availing itself of any rule or regulation of the SEC allowing a Holder to sell any such securities without registration.

6.9 The rights to cause the Company to register Registrable Securities granted to the Holders by the Company under Section 6.1 may be assigned by a Holder in connection with a transfer by such Holder of all or a portion of its Registrable Securities, *provided, however*, that such transfer must be made at least ten days prior to the Filing Date and that (i) such transfer may otherwise be effected in accordance with applicable securities laws; (ii) such Holder gives prior written notice to the Company at least ten days prior to the Filing Date; and (iii) such transferee agrees to comply with the terms and provisions of this Agreement, and such transfer is otherwise in compliance with this Agreement. Except as specifically permitted by this Section 6.9, the rights of a Holder with respect to Registrable Securities as set out herein shall not be transferable to any other Person, and any attempted transfer shall cause all rights of such Holder therein to be forfeited. The Company shall not enter into any agreement, take any action, or permit any change to occur, with respect to its securities that violates or subordinates the rights expressly granted to the Holders in this Agreement.

6.10 The rights of any Holder under any provision of this Article 6 may be waived (either generally or in a particular instance, either retroactively or prospectively and either for a specified period of time or indefinitely) or amended by an instrument in writing signed by such Holder.

## ARTICLE 7

### DEFINITIONS

7.1 “*Agreement*” has the meaning set forth in the preamble.

7.2 “*Affiliate*” means, with respect to any Person (as defined below), any other Person controlling, controlled by or under direct or indirect common control with such Person (for the purposes of this definition “*control*,” when used with respect to any specified Person, shall mean the power to direct the management and policies of such Person, directly or indirectly, whether through ownership of voting securities, by contract or otherwise; and the terms “*controlling*” and “*controlled*” shall have meanings correlative to the foregoing).

7.3 “**Attribution Parties**” means, with respect to any Person, such Person’s Affiliates and any other Person whose beneficial ownership of Ordinary Shares would be aggregated with such Person’s for purposes of Section 13(d) or Section 16 of the Exchange Act and the applicable regulations of the SEC, including any “group” of which such Person is a member.

7.4 “**Beneficial Ownership Limitation**” means the percentage set forth opposite such Purchaser’s name on **Exhibit A** hereto under the heading “Beneficial Ownership Limitation”.

7.5 “**Business Day**” means a day Monday through Friday on which banks are generally open for business in New York City.

7.6 “**Closing**” has the meaning set forth in Section 1.1(a).

7.7 “**Closing Date**” has the meaning set forth in Section 1.1(c).

7.8 “**Companies Law**” means the Israeli Companies Law, 5759-1999, as amended.

7.9 “**Company Intellectual Property**” has the meaning set forth in Section 2.13.

7.10 “**Cut Back Securities**” has the meaning set forth in Section 6.1.

7.11 “**Engagement Letters**” means the Engagement Letters by and between the Company and each of the Placement Agents, dated July 18, 2023.

7.12 “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

7.13 “**FDA**” means the United States Food and Drug Administration.

7.14 “**Filing Date**” has the meaning set forth in Section 6.1.

7.15 “**Holder**” means any Person holding Registrable Securities or any Person to whom the rights under Article 6 have been transferred in accordance with Section 6.9 hereof.

7.16 “**Indemnified Party**” has the meaning set forth in Section 6.6(c).

7.17 “**Indemnifying Party**” has the meaning set forth in Section 6.6(c).

7.18 “**Initial Registration Statement**” has the meaning set forth in Section 6.1.

7.19 “**Material Adverse Effect**” means a material adverse effect on (a) the business, operations, assets or condition (financial or otherwise) of the Company and its subsidiaries, taken as a whole, or (b) the ability of the Company to perform its obligations pursuant to the transactions contemplated by the Transaction Documents.

7.20 “**Nasdaq**” means The Nasdaq Stock Market LLC.

7.21 “**New Registration Statement**” has the meaning set forth in Section 6.1.

7.22 “**Ordinary Shares**” means the ordinary shares, par value NIS 0.01 per share, of the Company.

7.23 “**Penalty Period**” has the meaning set forth in Section 6.3.

7.24 “**Per Share Purchase Price**” means \$9.54.

7.25 “**Person**” means any person, individual, corporation, limited liability company, partnership, trust or other nongovernmental entity or any governmental agency, court, authority or other body (whether foreign, federal, state, local or otherwise).

7.26 “**Placement Agents**” means BofA Securities, Inc. and H.C. Wainwright & Co., LLC.

7.27 “**Warrant Shares**” means the Ordinary Shares issuable upon exercise of the Pre-Funded Warrants.

7.28 “**Pre-Funded Warrants**” has the meaning set forth in Recital B to this Agreement, in the form of **Exhibit B** attached hereto.

7.29 “**Purchasers**” has the meaning set forth in the preamble.

7.30 The terms “**register**,” “**registered**” and “**registration**” refer to the registration effected by preparing and filing a registration statement in compliance with the Securities Act, and the declaration or ordering of the effectiveness of such registration statement.

7.31 “**Registrable Securities**” means (i) the Shares and (ii) the Warrant Shares; *provided, however*, that Shares and Warrant Shares shall only be treated as Registrable Securities if and only for so long as they (A) have not been disposed of pursuant to a registration statement declared effective by the SEC, (B) have not been sold in a transaction exempt from the registration and prospectus delivery requirements of the Securities Act so that all transfer restrictions and restrictive legends with respect thereto are removed upon the consummation of such sale or (C) are held by a Holder or a permitted transferee pursuant to Section 6.9.

7.32 “**Registration Default**” has the meaning set forth in Section 6.3.

7.33 “**Registration Expenses**” means all expenses incurred by the Company in complying with Section 6.1 hereof, including, without limitation, all registration, qualification and filing fees, printing expenses, escrow fees, fees and expenses of counsel for the Company, blue sky fees and expenses and the expense of any special audits incident to or required by any such registration (but excluding the fees of legal counsel for any Holder).

7.34 “**Registration Statement**” means any one or more registration statements of the Company filed under the Securities Act that covers the resale of any of the Registrable Securities pursuant to the provisions of this Agreement (including without limitation any Initial Registration Statement, any New Registration Statement and any Remainder Registration Statements) and amendments and supplements to such Registration Statements, including post-effective amendments.

7.35 “**Registration Period**” has the meaning set forth in Section 6.4(a).

7.36 “**Remainder Registration Statement**” has the meaning set forth in Section 6.1.

7.37 “**Rule 144**” means Rule 144 promulgated under the Securities Act, or any successor rule.

7.38 “**Rule 415**” means Rule 415 promulgated under the Securities Act, or any successor rule.

7.39 “**SEC**” means the United States Securities and Exchange Commission.

7.40 “**SEC Documents**” has the meaning set forth in Section 2.1.

7.41 “**Securities Act**” means the Securities Act of 1933, as amended, and the rules and regulations thereunder, or any similar successor statute.

7.42 “**Selling Expenses**” means all selling commissions applicable to the sale of Registrable Securities and all fees and expenses of legal counsel for any Holder.

7.43 “**Securities**” has the meaning set forth in Section 2.4.

7.44 “**Shares**” has the meaning set forth in Recital B to this Agreement.

7.45 “**Subscription Amount**” has the meaning set forth in Section 1.1(a).

7.46 “**Trading Day**” means a day on which the principal Trading Market is open for trading.

7.47 “**Trading Market**” means any of the following markets or exchanges on which the Ordinary Shares are listed or quoted for trading on the date in question: the NYSE American, Nasdaq, or the New York Stock Exchange (or any successors to any of the foregoing).

7.48 “**Transfer Agent**” means Computershare Trust Company, N.A. or any successor transfer agent of the Company.

7.49 “**Transaction Documents**” has the meaning set forth in Section 2.7.

## GOVERNING LAW; MISCELLANEOUS

**8.1 Governing Law; Jurisdiction.** This Agreement will be governed by and interpreted in accordance with the laws of the State of New York without regard to the principles of conflict of laws (whether of the State of New York or any other jurisdiction) which would result in the application of the laws of any other jurisdiction. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby (“**Related Proceedings**”) may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the “**Specified Courts**”), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a “**Related Judgment**”), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party’s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum. The Company and each other party not located in the United States has irrevocably appointed UroGen Pharma, Inc., which currently maintains a New York City office at 689 Fifth Avenue, 14th Floor, New York, NY 10022, United States of America, as its agent to receive service of process or other legal summons for purposes of any such suit, action or proceeding that may be instituted in any state or federal court in the Borough of Manhattan in the City of New York, United States of America. With respect to any Related Proceeding, each party irrevocably waives, to the fullest extent permitted by applicable law, all immunity (whether on the basis of sovereignty or otherwise) from jurisdiction, service of process, attachment (both before and after judgment) and execution to which it might otherwise be entitled in the Specified Courts, and with respect to any Related Judgment, each party waives any such immunity in the Specified Courts or any other court of competent jurisdiction, and will not raise or claim or cause to be pleaded any such immunity at or in respect of any such Related Proceeding or Related Judgment, including, without limitation, any immunity pursuant to the United States Foreign Sovereign Immunities Act of 1976, as amended.

**8.2 Counterparts; Signatures by Facsimile.** This Agreement may be executed in counterparts, all of which are considered one and the same agreement and will become effective when counterparts have been signed by each party and delivered to the other parties. This Agreement may also be executed and delivered by facsimile signature, PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000 (e.g., [www.docuSign.com](http://www.docuSign.com)).

**8.3 Headings.** The headings of this Agreement are for convenience of reference only, are not part of this Agreement and do not affect its interpretation.

**8.4 Severability.** If any provision of this Agreement is invalid or unenforceable under any applicable statute or rule of law, then such provision will be deemed modified in order to conform with such statute or rule of law. Any provision hereof that may prove invalid or unenforceable under any law will not affect the validity or enforceability of any other provision hereof.

**8.5 Entire Agreement; Amendments.** The Transaction Documents (including all schedules and exhibits hereto and thereto) constitute the entire agreement among the parties hereto with respect to the subject matter hereof and thereof. There are no restrictions, promises, warranties or undertakings, other than those set forth or referred to herein or therein. The Transaction Documents supersede all prior agreements and understandings among the parties hereto with respect to the subject matter hereof and thereof. No waiver hereunder shall be effective unless in writing and signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Any amendment or waiver by a party effected in accordance with this Section 8.5 shall be binding upon such party, including with respect to any Securities purchased under the Transaction Documents at the time outstanding and held by such party and each future holder of all such Securities.

**8.6 Notices.** All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by email or facsimile if sent during normal business hours of the recipient, and if sent at a time other than during normal business hours of the recipient, then on the next Business Day (provided, with respect to notices sent by email so long as such sent email is kept on file by the sending party and the sending party does not receive an automatically generated message from the recipient's email server that such email could not be delivered to such recipient), (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one Business Day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. The addresses for such communications are:

If to the Company: UroGen Pharma Ltd.  
400 Alexander Park Drive  
Princeton, NJ 08540  
Attn: Jason Smith  
Email:

With a copy to: Cooley LLP  
10265 Science Center Drive  
San Diego, CA 92121  
Attn: Charles J. Bair  
Email: cbair@cooley.com

If to a Purchaser: To the address set forth immediately below such Purchaser's name on the signature pages hereto. Each party will provide ten days' advance written notice to the other parties of any change in its address.

**8.7 Successors and Assigns.** This Agreement is binding upon and inures to the benefit of the parties and their successors and assigns. The Company will not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Purchasers except in connection with a change of control of the Company pursuant to which the acquiror assumes the Company's obligations under Section 3.6 (if any) with respect to any Securities outstanding following such change of control. No Purchaser may assign this Agreement or any rights or obligations hereunder without the prior written consent of the Company, except to such Purchaser's Affiliates or as permitted in accordance with Section 6.9 hereof.

**8.8 Third Party Beneficiaries.** This Agreement is intended for the benefit of the parties hereto, their respective permitted successors and assigns and the Placement Agents, and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

**8.9 Further Assurances.** Each party will do and perform, or cause to be done and performed, all such further acts and things, and will execute and deliver all other agreements, certificates, instruments and documents, as another party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

**8.10 No Strict Construction.** The language used in this Agreement is deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

**8.11 Equitable Relief.** The Company recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to the Purchasers. The Company therefore agrees that the Purchasers are entitled to seek temporary and permanent injunctive relief in any such case. Each Purchaser also recognizes that, if it fails to perform or discharge any of its obligations under this Agreement, any remedy at law may prove to be inadequate relief to the Company. Each Purchaser therefore agrees that the Company is entitled to seek temporary and permanent injunctive relief in any such case.

**8.12 Survival of Representations and Warranties.** Notwithstanding any investigation made by any party to this Agreement, all representations and warranties made by the Company and the Purchasers herein shall survive for a period of one year following the Closing.

**8.13 Independent Nature of Purchasers' Obligations and Rights.** The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser under this Agreement. Nothing contained herein and no action taken by any Purchaser pursuant hereto shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group, or are deemed affiliates with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser shall be entitled to independently protect and enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose. The Company has elected to provide all Purchasers with the same terms of this Agreement for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers. Notwithstanding anything to the contrary in the foregoing, each of the Purchasers has been advised, and is being advised by this Agreement, to consult with an attorney before executing this Agreement, and each Purchaser has consulted (or had an opportunity to consult) with counsel of such Purchaser's choice concerning the terms and conditions of this Agreement for a reasonable period of time prior to the execution hereof and thereof.

**8.14 Exculpation of the Placement Agents.** Each party hereto agrees for the express benefit of the Placement Agents and their respective Affiliates and representatives that:

(a) The Placement Agents and their respective Affiliates and representatives (i) have no duties or obligations other than those specifically set forth herein or in their respective Engagement Letters; (ii) shall not be liable for any improper payment made in accordance with the information provided by the Company; (iii) make no representation or warranty, and have no responsibilities as to the validity, accuracy, value or genuineness of any information, certificates or documentation delivered by or on behalf of the Company pursuant to this Agreement or in connection with any of the transactions contemplated hereby; and (iv) shall not be liable (A) for any action taken, suffered or omitted by any of them in good faith and reasonably believed to be authorized or within the discretion or rights or powers conferred upon them by this Agreement, or (B) for anything which any of them may do or refrain from doing in connection with this Agreement, except in each case for such Person's own gross negligence, willful misconduct or bad faith.

(b) The Placement Agents and their respective Affiliates and representatives shall be entitled to (1) rely on, and shall be protected in acting upon, any certificate, instrument, notice, letter or any other document or security delivered to any of them by or on behalf of the Company, and (2) be indemnified by the Company for acting as a Placement Agent hereunder pursuant to the indemnification provisions set forth in their respective Engagement Letters.

**8.15 Waiver of Conflicts.** Each Purchaser acknowledges that Cooley LLP, outside general counsel to the Company, may have in the past performed and may now or in the future represent one or more Purchasers or their affiliates in matters unrelated to the transactions contemplated by this Agreement (the "**Financing**"), including representation of such Purchasers or their affiliates in matters of a similar nature to the Financing. The applicable rules of professional conduct require that Cooley LLP inform the Purchasers hereunder of this representation and obtain their consent. Cooley LLP has served as outside general counsel to the Company and has negotiated the terms of the Financing solely on behalf of the Company. Each Purchaser hereby (a) acknowledges that they have had an opportunity to ask for and have obtained information relevant to such representation, including disclosure of the reasonably foreseeable adverse consequences of such representation; (b) acknowledges that with respect to the Financing, Cooley LLP has represented solely the Company, and not any Purchaser or any shareholder, director or employee of the Company or any Purchaser; and (c) gives its informed consent to Cooley LLP's representation of the Company in the Financing.

[Signature Pages Follow]

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IN WITNESS WHEREOF, the undersigned has caused this Securities Purchase Agreement to be duly executed as of the date first above written.

**UROGEN PHARMA LTD.**

By: /s/ Elizabeth Barrett  
Name: Elizabeth Barrett  
Title: President and Chief Executive Officer

---

IN WITNESS WHEREOF, the undersigned has caused this Securities Purchase Agreement to be duly executed as of the date first above written.

**PURCHASER:** \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Attention: \_\_\_\_\_

Email: \_\_\_\_\_

**UroGen Announces \$120 Million Private Placement of Ordinary Shares**

PRINCETON, N.J.—July 27, 2023— UroGen Pharma Ltd. (Nasdaq: URGN) (UroGen), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that it has entered into a definitive securities purchase agreement in connection with a private placement (the Private Placement) to selected institutional and accredited investors. RA Capital Management L.P. and Great Point Partners LLC led the Private Placement, which also included Acorn Bioventures, Monograph Capital and Horton Capital Partners Fund, LP. UroGen expects to receive gross proceeds of approximately \$120 million, before deducting placement agent commissions and other offering expenses.

UroGen intends to use the net proceeds of the Private Placement for non-clinical and clinical development activities for its product candidates, commercialization expense and general corporate purposes.

Pursuant to the terms of the securities purchase agreement, UroGen will issue 12,579,156 ordinary shares, or pre-funded warrants in lieu thereof, at a purchase price of \$9.54 per share (less \$0.001 for each pre-funded warrant), which reflects a premium to the closing price on July 26, 2023. Each pre-funded warrant has an exercise price of \$0.001 per share and does not expire until exercised in full. The Private Placement is expected to close on or about July 28, 2023 subject to the satisfaction of customary closing conditions.

BofA Securities and H.C. Wainwright & Co. are acting as joint placement agents for the Private Placement. Ladenburg Thalmann & Co. Inc. acted as a financial advisor to UroGen for the Private Placement.

The securities described above are being offered and sold in a private placement and have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. UroGen has agreed to file a resale registration statement with the United States Securities and Exchange Commission (SEC), for purposes of registering the resale of the ordinary shares issued or issuable in connection with the Private Placement.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor may there be any sale of any securities in any state in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction.

**About UroGen Pharma Ltd.**

UroGen is a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers because patients deserve better options. UroGen has developed RTGel<sup>®</sup> reverse-thermal hydrogel, 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. JELMYTO<sup>®</sup> (mitomycin) for pyelocalyceal solution and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with low-grade non-muscle invasive bladder cancer are designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. Visit [www.urogen.com](http://www.urogen.com) to learn more or follow us on Twitter, @UroGenPharma.

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**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, without limitation, statements regarding the timing, size, use of proceeds and closing of the Private Placement. These statements may be identified by the words “expects,” “potential,” “will,” “would,” or other similar terms or expressions that concern UroGen’s expectations, strategy, plans, or intentions. The events and circumstances discussed in such forward-looking statements may not occur, and UroGen’s actual events or results may differ materially from those expressed or implied by any forward-looking statements contained herein, including, without limitation, as a result of market and other conditions; the risk that the conditions to the closing of the proposed Private Placement are not satisfied; as well as other risks and uncertainties that are described in the Risk Factors section of UroGen’s Form 10-Q filed with the SEC on May 11, 2023 and other filings that UroGen makes with the SEC from time to time (which are available at <http://www.sec.gov>). Any forward-looking statements speak only as of the date of this press release and are based on information available to UroGen as of the date of this release.

**INVESTOR CONTACT:**

Vincent Perrone  
Sr. Director, Investor Relations  
[vincent.perrone@urogen.com](mailto:vincent.perrone@urogen.com)  
609-460-3588 ext. 1093

**MEDIA CONTACT:**

Cindy Romano  
Director, Corporate Communications  
[cindy.romano@urogen.com](mailto:cindy.romano@urogen.com)  
609-460-3583 ext. 1083

Source: UroGen Pharma Ltd.

# New Horizons in Bladder Cancer: Insights from Top-Line Data of ATLAS & ENVISION Studies

July 27, 2023

NASDAQ: URGN



# Forward-looking Statements

This investor presentation contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation: the potential of JELMYTO® to change the treatment paradigm in LG-UTUC; the potential of UGN-102 to transform the treatment paradigm in LG-IR-NMIBC; the opportunity and potential benefits of UGN-102 for LG-IR-NMIBC and potential advantages over TURBT; the estimated patient population and market opportunity for UGN-102 in LG-IR-NMIBC; the potential of UGN-301 to expand to Immuno-Oncology for LG-IR and HG NMIBC and the estimated addressable patient population and market opportunity for UGN-301 in HG NMIBC; clinical results from ATLAS and ENVISION providing optimism for potential FDA approval of UGN-102; expected final data in the first half of 2024 and plans to submit an NDA for UGN-102 in 2024; potential prescriber behavior; the expectation that UGN-102 will be the primary driver of UroGen's future growth; and the potential of UroGen's proprietary RTGel® technology platform to improve therapeutic profiles of existing drugs to advance the treatment of specialty cancers and urologic disease. These 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 safety or other complications encountered therein; results from prior or ongoing clinical trials may not be indicative of results that may be observed in the future; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; potential prescriber behavior is based on preliminary feedback that may change as a result of new data, labeling limitations, or other factors; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with product development and commercialization activities; the labeling and packaging for any approved product; the scope, progress and expansion of developing and commercializing UroGen's product and 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; RTGel technology may not perform as expected and UroGen may not successfully develop and receive regulatory approval of any product candidate beyond JELMYTO that incorporates its RTGel technology; and UroGen'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's Form 10-Q filed with the SEC on May 11, 2023, and other filings that UroGen makes with the Securities and Exchange Commission (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'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 presentation and are based on information available to UroGen as of the date of this presentation.

# AGENDA

## **UroGen...Uniquely Positioned**

**Liz Barrett**, *President and CEO, UroGen*

## **The Burden of LG-IR-NMIBC**

**Karim Chamie**, *M.D., MSHS, Associate Professor of Urology, UCLA*

## **Top-Line Data Results: ATLAS and ENVISION**

**Sandip Prasad**, *M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Hospital/Atlantic Health System, NJ*

## **Impact on Clinical Practice: Panel Discussion**

Moderator, **Mark Schoenberg**, *M.D., Chief Medical Officer, UroGen*

**Trinity Bivalacqua**, *M.D., Ph.D., Director of Urologic Oncology and Co-Director Genitourinary Cancer Service Line, UPenn*

**Karim Chamie**, *M.D., MSHS, Associate Professor of Urology, UCLA*

**Katie Murray**, *D.O., Associate Professor of Urology, NYU*

**Sandip Prasad**, *M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Hospital/Atlantic Health System, NJ*

## **Q&A**

# UROGEN...UNIQUELY POSITIONED

LIZ BARRETT

**WE ASPIRE TO CHANGE THE TREATMENT PARADIGM**

SURGICAL CARE



**MINIMALLY INVASIVE,  
ORGAN-SPARING  
THERAPEUTIC OPTIONS**



**Because Patients Deserve Better**



**JELMYTO**

(UGN-101)

Changing the Treatment Paradigm for **LG-UTUC**



**UGN-102**

Potential to Transform the Treatment Paradigm in **LG-IR-NMIBC** Bladder Cancer



**UGN-301**

Expanding to Immuno-Oncology for **LG-IR and HG-NMIBC**

# RTGel® Proprietary Reverse-Thermal Hydrogel Technology Uniquely Designed to Allow for Local Delivery of Medicines



RTGel® exists as a **liquid** at lower temperatures and converts to gel form at body temperature.



**Increases dwell time** and exposure of active drugs

Potentially **improves the therapeutic effects of existing products**

Leverages physiologic flow of urine to provide **natural exit from the body**



# Bladder Cancer Affects Patients and Families Across the U.S.

~**726,000** people in  
the U.S. living with bladder cancer<sup>1</sup>



One of the

**most recurrent**

of **ALL** cancers<sup>2</sup>



7  
1. Cancer Stat Facts: Bladder Cancer. National Cancer Institute: Surveillance, Epidemiology, and End Results Program. Accessed July 10, 2023. <https://seer.cancer.gov/statfacts/html/urinb.html>  
2. MBA ASBP PhD. Cancer Recurrence Statistics. Cancer Therapy Advisor. Published November 30, 2018. <https://www.cancertherapyadvisor.com/home/tools/fact-sheets/cancer-recurrence-statistics/#:-:text=Some%20cancers%20are%20difficult%20to>

# NMIBC Patients Can Find Themselves in a Frustrating Cycle of Treatment

~**68%**

of recurrent patients  
have **2 or more**  
recurrences<sup>1</sup>

~**23%**

of recurrent  
patients **have 5 or**  
**more recurrences<sup>1</sup>**

~**82,000**

addressable LG-IR-  
NMIBC patients<sup>2-5</sup>

1. Babjuk et al. European Urology (2019), Simon (2019), UroGen projections based on SEER (2016 2. Cancer Stat Facts: Bladder Cancer. National Cancer Institute Surveillance, Epidemiology, and End Results Program. Accessed July 10, 2023. <https://seer.cancer.gov/statfacts/html/urinb.html> 3. Chevli KK, Shore ND, Trainer A, Smith AB, Saltzstein D, Ehrlich Y, Raman JD, Friedman B, D'Anna R, Morris D, Hu B, Tyson M, Sankin A, Kates M, Linehan J, Scherr D, Kester S, Verni M, Chamie K, Karsh L, Cinman A, Meads A, Lahiri S, Malinowski M, Gabai N, Raju S, Schoenberg M, Seltzer E, Huang WC. Primary Chemoablation of Low-Grade Intermediate-Risk Nonmuscle-Invasive Bladder Cancer Using UGN-102, a Mitomycin-Containing Reverse Thermal Gel (Optima II): A Phase 2b, Open-Label, Single-Arm Trial. J Urol. 2022 Jan;207(1):61-69. doi: 10.1097/JU.0000000000002186. Epub 2021 Aug 26. PMID: 34433303; PMCID: PMC8667793. 4. Babjuk et al. European Urology (2019), Simon (2019), 5. Simon M, Bosset PO, Rouanne M, et al. Multiple recurrences and risk of disease progression in patients with primary low-grade (TaG1) non-muscle-invasive bladder cancer and with low and intermediate EORTC-risk score. Real FX, ed. PLOS ONE. 2019;14(2):e0211721. doi:<https://doi.org/10.1371/journal.pone.0211721>

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# UGN-102: Leveraging Similarities

## JELMYTO® & UGN-102

- **RTGel®** method of delivery
- **Mitomycin RTGel®** combinations
- Similar diseases at a **genetic & mutational** driver level
- **Share a 95% prescriber base**



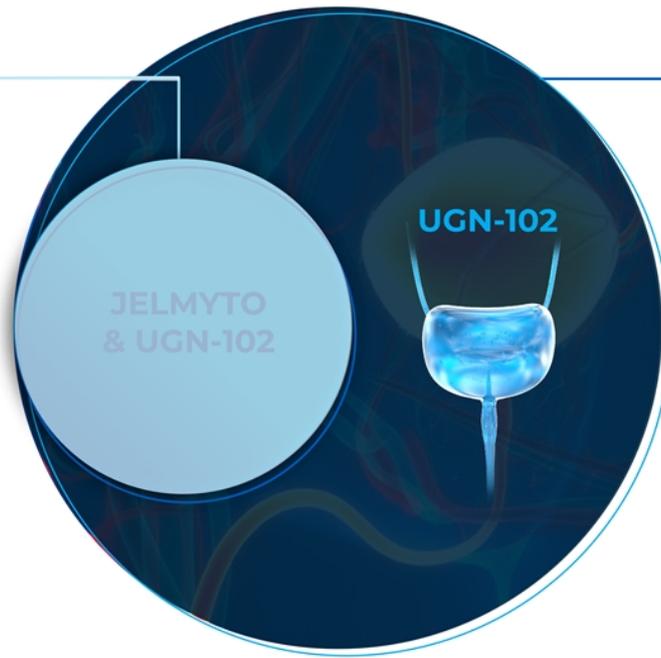
## UGN-102

- **10x larger** potential patient population
- **Simpler administration** to bladder than to upper tract
- **Routine procedure** in clinic that urology offices are very familiar with
- **No special equipment** like fluoroscopy

# UGN-102: With Distinct Advantages

## JELMYTO® & UGN-102

- RTGel® method of delivery
- Mitomycin RTGel® combinations
- Similar diseases at a **genetic & mutational** driver level
- **Share a 95% prescriber base**



## UGN-102

- **10x larger** potential patient population
- **Simpler administration** to bladder than to upper tract
- **Routine procedure** in clinic that urology offices are very familiar with
- **No special equipment** like fluoroscopy

# Potential to Unlock a Significant Market Opportunity in a Very Underserved Patient Population

**UGN-102**  
Phase 3

**UGN-301**  
Phase 1

**~82,000**

addressable U.S. population

**\$3B+** Market

Low-Grade Intermediate Risk  
Non-Muscle Invasive Bladder  
Cancer (LG-IR-NMIBC)

**\$5B+**  
combined TAM  
revenue opportunity  
in bladder cancer

**~18,700**

addressable U.S. population<sup>1</sup>

**\$2B+** Market

Immunotherapy Targeting High-  
Grade Non-Muscle Invasive  
Bladder Cancer (HG-NMIBC)

1. SEER\*Stat Database (2019) Surveillance Research Program; Curr Urol Rep (2015) 17: 68; Ther Adv Urol. 2012 Feb; 4(1): 13-32; UroGen Market Research



# UroGen is Poised to Transform the Way Bladder Cancer is Treated

## #1

UGN-102 may become the **first medicine** to treat LG-IR-NMIBC

## 95%

**shared prescriber base** with JELMYTO®

## \$3B+TAM

LG-IR-NMIBC market ripe for **innovation**

## \$120M

private placement with **experienced biotech investors**

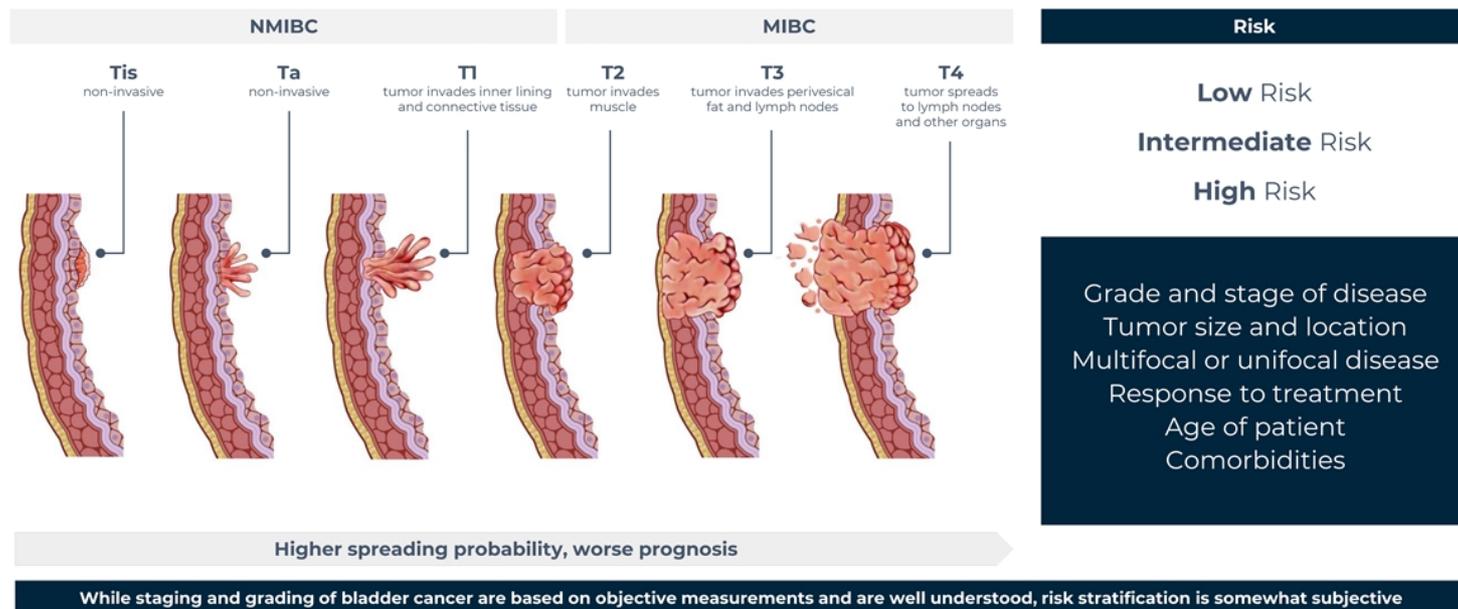


**Compelling clinical data** package from **3 trials** and **565 patients**

# THE BURDEN OF LG-IR-NMIBC

KARIM CHAMIE, M.D.

# Bladder Cancer is a **HIGHLY** Heterogeneous Condition

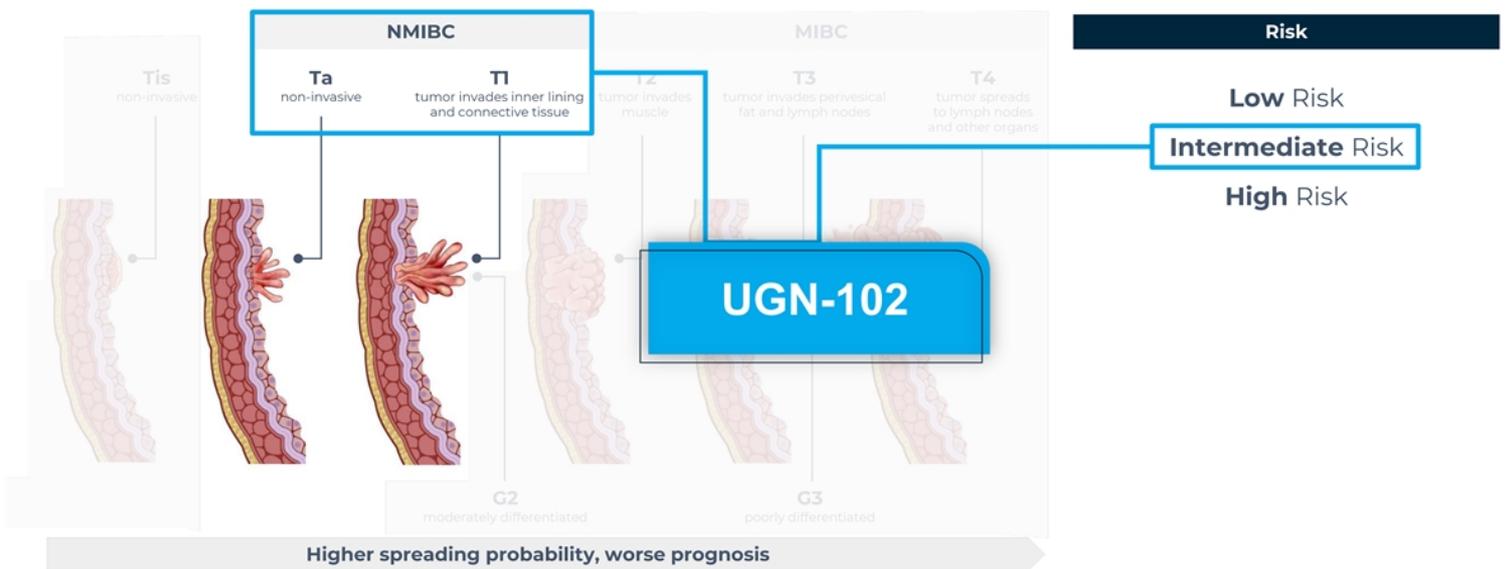


## AUA Risk Stratification for Non-Muscle Invasive Bladder Cancer

Low Risk	Intermediate Risk	High Risk
LG <sup>a</sup> solitary Ta ≤ 3cm PUNLMP <sup>b</sup>	Recurrence within 1 yr, LG Ta Solitary LG Ta > 3cm LG Ta, multifocal HG <sup>c</sup> Ta, ≤ 3cm LG T1	HG T1 Any recurrent, HG Ta HG Ta, > 3 cm (or multifocal) Any CIS <sup>d</sup> Any BCG failure in HG patient Any variant histology Any LVI <sup>e</sup> Any HG prostatic urethral involvement

<sup>a</sup>LG = low grade; <sup>b</sup>PUNLMP = papillary urothelial neoplasm of low malignant potential; <sup>c</sup>HG = high grade; <sup>d</sup>CIS = carcinoma *in situ*; <sup>e</sup>LVI = lymphovascular invasion

# UGN-102 Could Become the First Approved Non-Surgical Treatment for LG-IR-NMIBC



## Repeat Surgery Comes with Risks for this Patient Population

~**33%**

of patients will experience an **adverse event within 90 days** of undergoing a TURBT.<sup>1</sup>

Patients with LG-IR-NMIBC who have **multiple recurrences** carry a

**10-20%**

**risk of progression.**<sup>2</sup>

LG-IR-NMIBC patients who had **2-4 procedures** had a

**14%**

**greater risk of death** than patients who only had one procedure.<sup>3</sup>

1. Sharma V, Aaronson DS, Fero KE, et al. Adverse events after transurethral resection of intermediate-risk non-muscle invasive bladder cancer. *J Urol.* 2021;206(suppl 3):e122. doi:10.1097/JU.0000000000001977.08 2. Sharma V, Chamie K, Schoenberg M, et al. Natural history of multiple recurrences in intermediate-risk non-muscle invasive bladder cancer: lessons from a prospective cohort. *Urology.* 2023;173:134-141. doi:10.1016/j.urology.2022.12.009 3. Erikson MS, Petersen AC, Andersen KK, Jacobsen FK, Mogensen K, Hermann GG. Do repeated transurethral procedures under general anesthesia influence mortality in patients with non-invasive urothelial bladder cancer? A Danish national cohort study. *Scand J Urol.* 2020;54(4):281-289. doi:10.1080/21681805.2020.1782978

# OPTIMA II Phase 2b Trial Showed Significant Tumor Response and Long-Term Treatment Benefit



1. Chevli KK, Shore ND, Trainer A, et al. Primary chemoablation of low-grade intermediate-risk nonmuscle-invasive bladder cancer using UGN-102, a mitomycin-containing reverse thermal gel (Optima II): a phase 2b, open-label, single-arm trial. *J Urol*. 2022;207(1):61-69. doi:10.1097/JU.0000000000002186

2. Chevli KK, Shore ND, Trainer A, et al. Long-term outcomes of treatment with UGN-102 for primary chemoablation of low-grade intermediate risk non-muscle-invasive bladder cancer (LG IR NMIBC). Presented at: Society of Urologic Oncology 23rd Annual Meeting; November 30-December 2, 2022; San Diego, California. Poster 193. <https://suo-abstracts.secure-platform.com/gallery/rounds/15/details/2419>

<sup>a</sup> Continued durable CR beyond 12 months after treatment initiation observed in 7 of 15 evaluable patients who completed the OPTIMA II study and were eligible to participate in this rollover study.

<sup>a</sup>. Duration of complete response [0.1 – 30.7 months]; median range among 15 evaluable patients

<sup>b</sup>. Continued durable CR beyond 12 months after treatment initiation observed in 7 of 15 evaluable patients who completed the OPTIMA II study and were eligible to participate in this rollover study.



# Challenging the Future Standard of Care for LG-IR-NMIBC

## TURBT as the current standard of care



Requires **anesthesia**



Associated with **risk of complications**



Requires **lifelong surveillance** and **recurrent treatment**

## Key Unmet Needs for Patients and HCPs



**Additional** treatment options

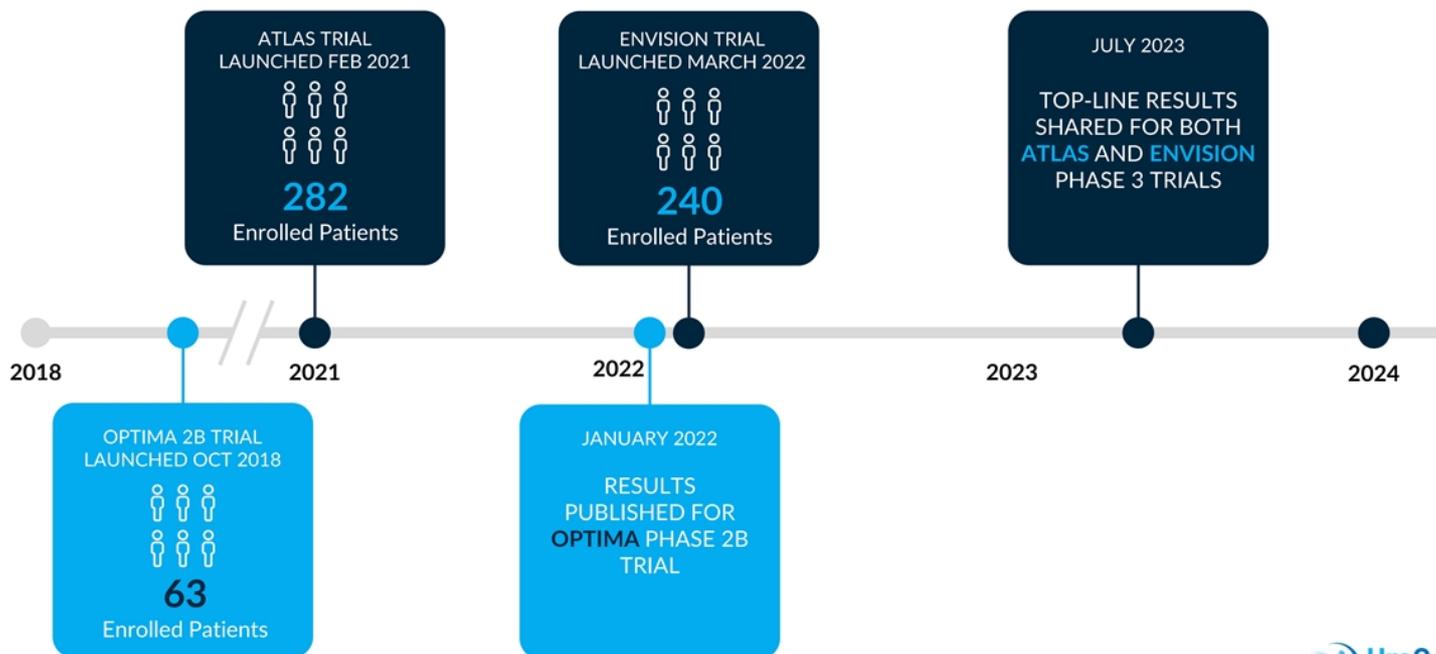


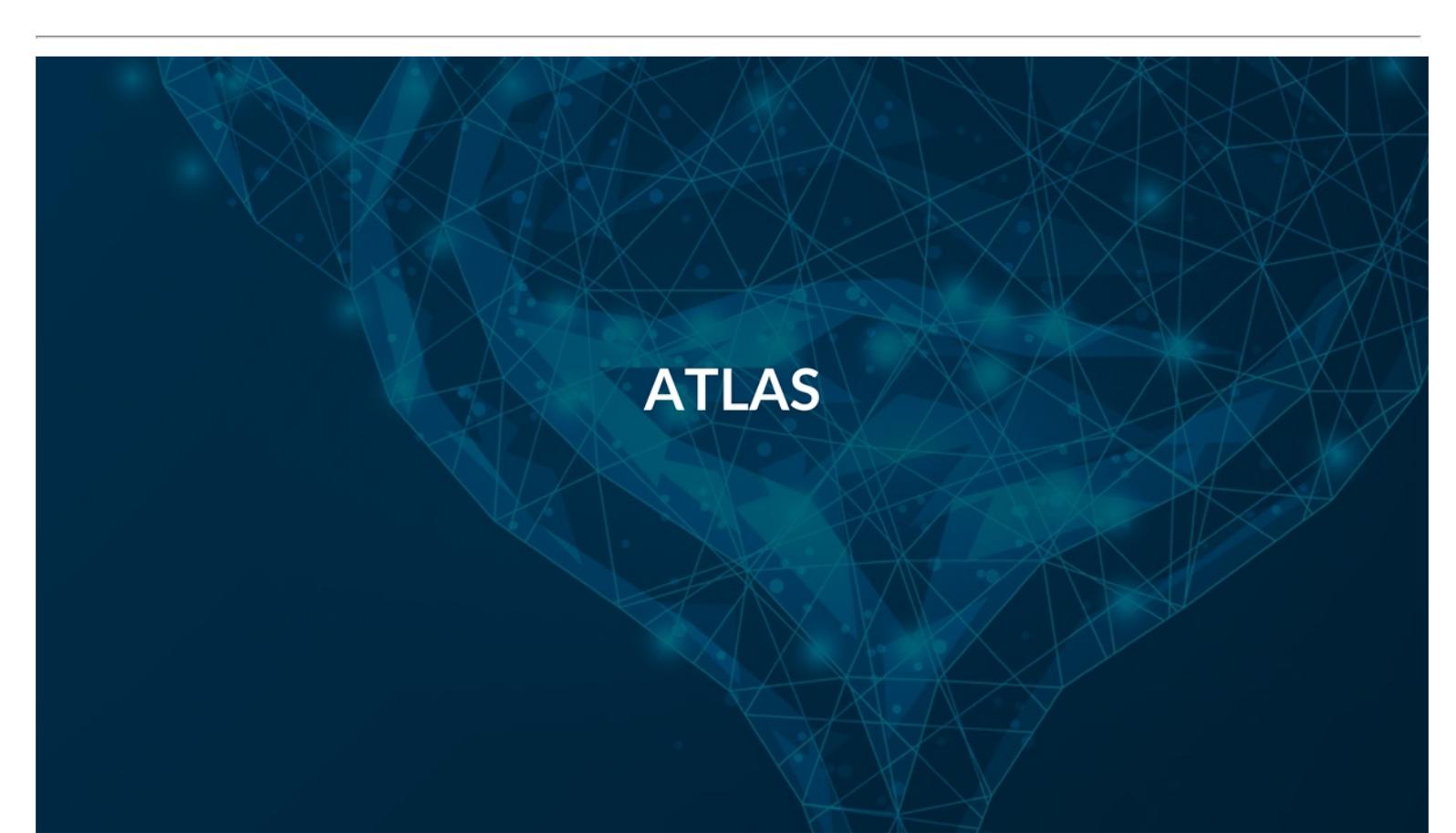
**Reduction** of recurrence

# TOP-LINE DATA RESULTS: ATLAS AND ENVISION

SANDIP PRASAD, M.D., M.PHIL.

# Overview of UGN-102 Program





**ATLAS**

# ATLAS Study Endpoints

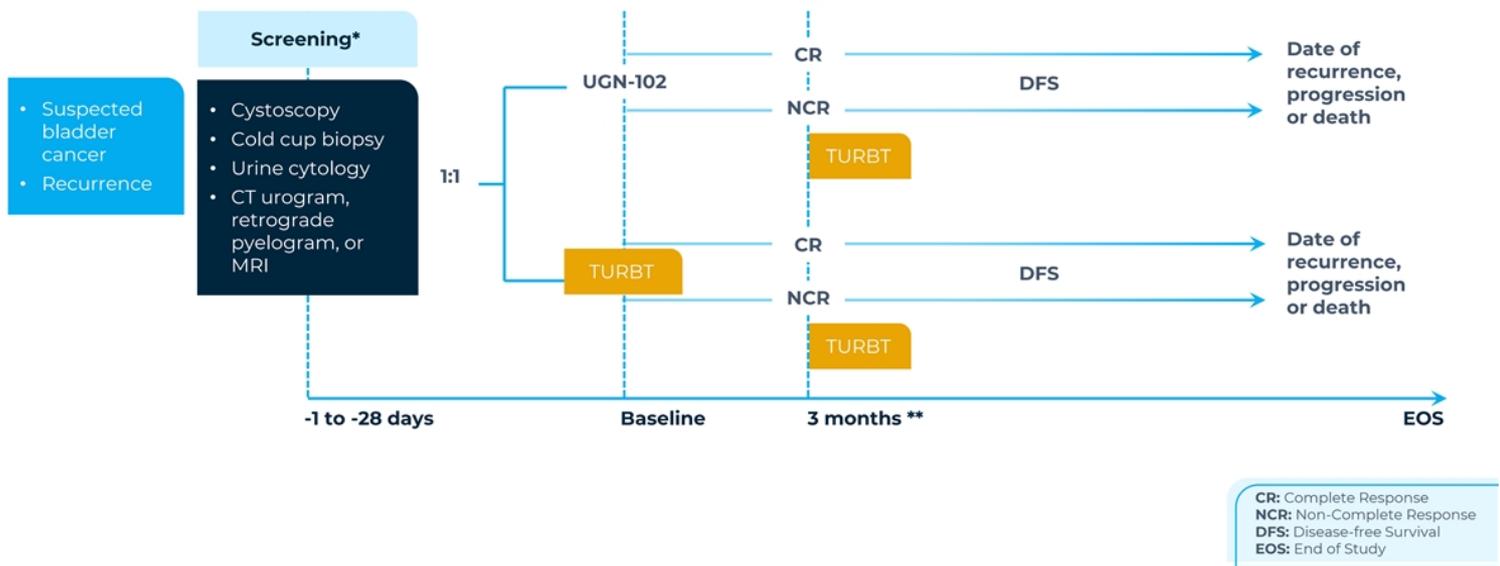
## Primary Endpoint (ITT):

- **Disease-free survival (DFS)**, defined as the time from randomization until the earliest date of any of the following events:
  - ✓ **Residual disease** at the 3-month assessment
  - ✓ **Recurrence**
  - ✓ **Progression**
  - ✓ **Death**

## Key Secondary Endpoints:

- **Complete response rate (CRR)** at 3-month visit
- **Duration of response (DOR)**, defined as the time from first documented CR until the earliest date of recurrence of low-grade disease, progression to high-grade disease, or death due to any cause (3-month CR analysis set)

# ATLAS Trial Design



# ATLAS Demographics and Safety Profile

Demographics and baseline characteristics were **well balanced** between treatment arms



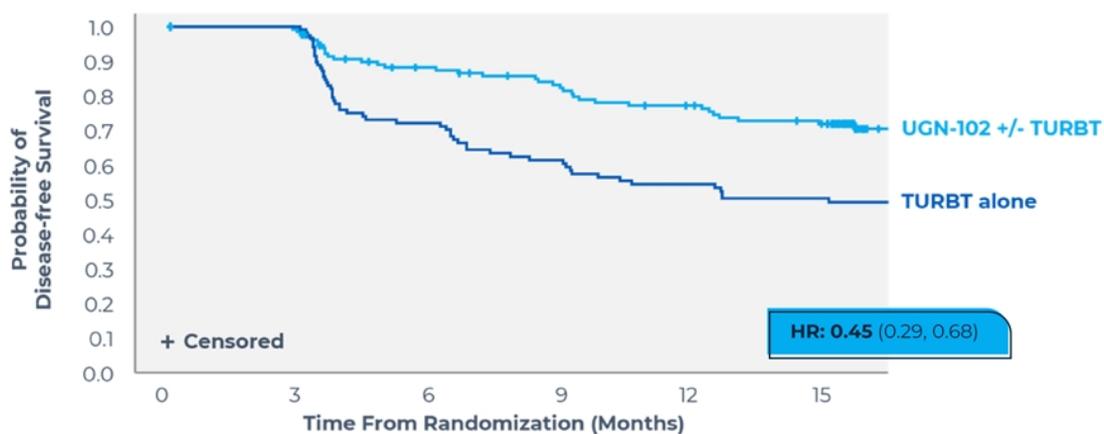
- Treatment-emergent AEs were generally **mild to moderate**
- **Similar safety profile** to other studies of UGN-102
- Any treatment or procedure related serious TEAEs were **comparable** across both arms
  - UGN-102 +/- TURBT: 1.4%
  - TURBT Alone: 0.8%

UroGen Data on File  
Overall summary of Demographics and AE's can be referenced in the Appendix

## Summary of Disease-Free Survival: Significantly More Total Recurrence and Progression in TURBT Alone Arm

	UGN-102 +/- TURBT (N = 142) / n (%)	TURBT Alone (N = 140) / n (%)
<b>Patients with Events, n (%)</b>	<b>37 (26.1)</b>	<b>55 (39.3)</b>
Recurrence of LG Disease	20 (14.1)	39 (27.9)
Progression to HG Disease	17 (12.0)	15 (10.7)
Death	0	1 (0.7)
<b>Patients Censored, n (%)</b>	<b>105 (73.9)</b>	<b>85 (60.7)</b>
<b>Hazard Ratio (95% CI)</b>	<b>0.45 (0.29, 0.68)</b>	

# DFS - 55% Reduction of Risk for Recurrence, Progression, or Death in the Intent to Treat Population



Number at Risk		0	3	6	9	12	15
<b>UGN-102 +/- TURBT</b>		142	128	108	96	87	73
<b>TURBT Alone</b>		140	119	76	60	54	42
Number Censored							
<b>UGN-102 +/- TURBT</b>		0	11	19	23	26	35
<b>TURBT Alone</b>		0	20	32	35	36	43

27 UroGen Data on File  
Source: Table 14.2.1.1a  
Kaplan-Meier Plot of Disease-Free Survival

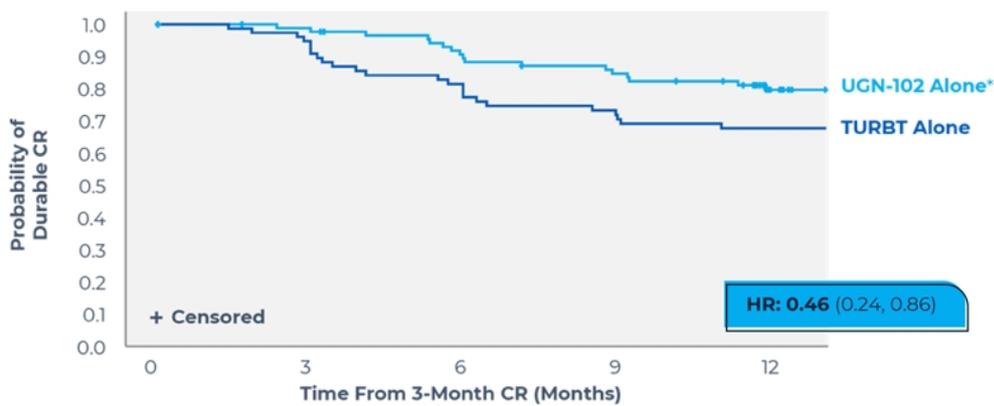
# Three-Month Complete Response Rates Were Similar Between Treatment Arms

Response	UGN-102 Alone (N = 142)		TURBT Alone (N = 140)	
	n (%)	CRR (95%CI)	n (%)	CRR (95% CI)
<b>Complete Response</b>	92 (64.8)	<b>64.8% (56.3, 72.6)</b>	89 (63.6)	<b>63.6% (55.0, 71.5)</b>
<b>Non-complete Response</b>	50 (35.2)		51 (36.4)	
Residual Disease	26 (18.3)		22 (15.7)	
Progression to HG Disease	12 (8.5)		9 (6.4)	
Indeterminate	3 (2.1)		0	
Missing	9 (6.3)		20 (14.3)	

## Summary of Duration of Response in Complete Responders: **Longer DOR with UGN-102 Alone**

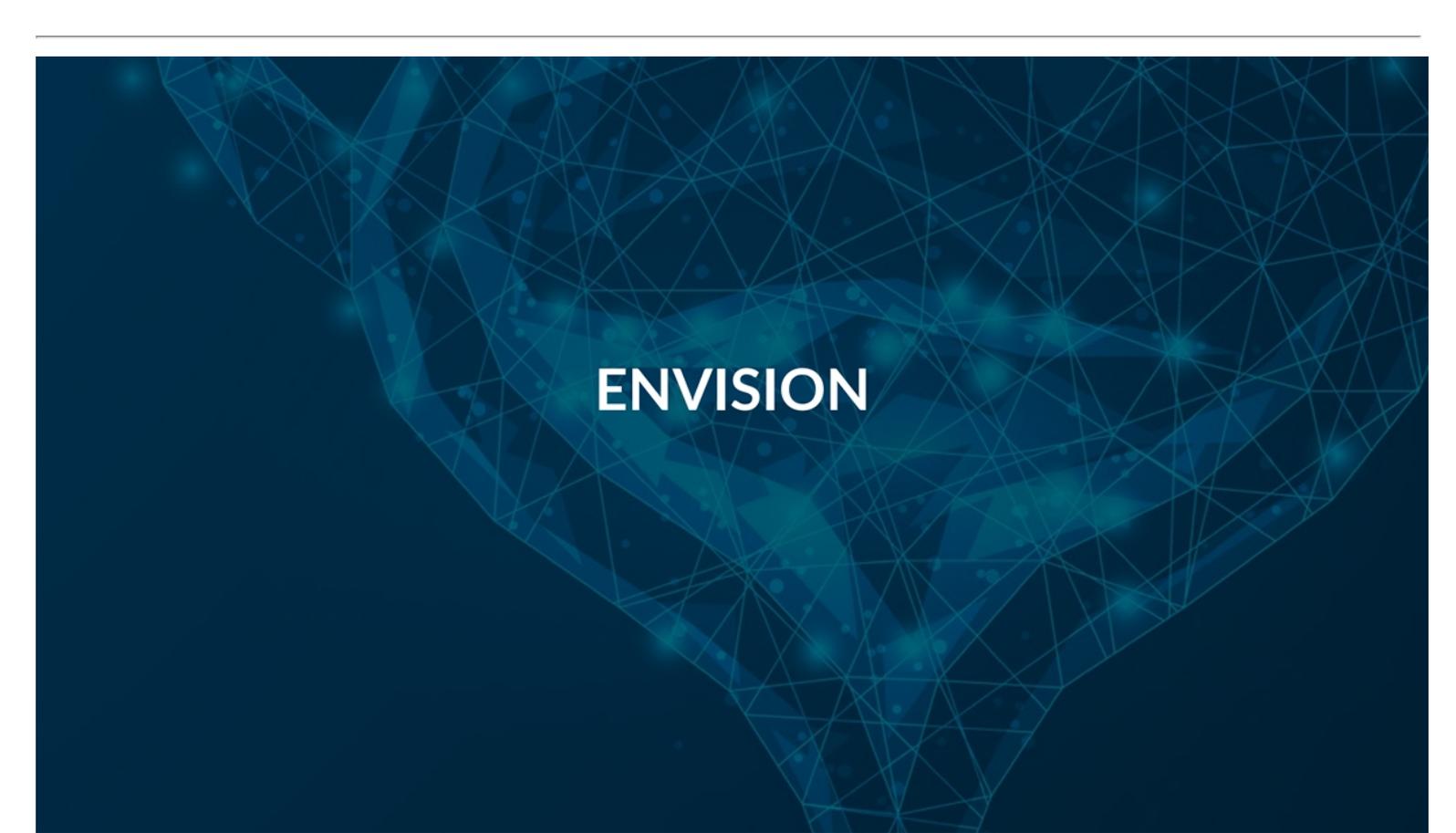
	<b>UGN-102 Alone</b> (N = 92) / n (%)	<b>TURBT Alone</b> (N = 89) / n (%)
<b>Patients with Events, n (%)</b>	<b>18 (19.6)</b>	<b>24 (27.0)</b>
Recurrence of LG Disease	15 (16.3)	17 (19.1)
Progression to HG Disease	3 ( 3.3)	6 ( 6.7)
Death	0	1 ( 1.1)
<b>Patients Censored, n (%)</b>	<b>74 (80.4)</b>	<b>65 (73.0)</b>
<b>Hazard Ratio (95% CI)</b>	<b>0.46 (0.24, 0.86)</b>	

# DOR - 54% Reduction of Risk for Recurrence, Progression, or Death in Patients Who had a 3-Month CR



Number at Risk		0	3	6	9	12
UGN-102 Alone		92	86	77	71	49
TURBT Alone		89	73	60	53	34
Number Censored		0	3	6	9	12
UGN-102 Alone		0	5	7	8	26
TURBT Alone		0	12	15	16	31

\*UGN Alone Subgroup of the UGN 102 +/- TURBT arm in ATLAS  
 UroGen Data on File  
 Source: Table 14.2.1.1a  
 Kaplan-Meier Plot of Duration of Response in Complete Responders



**ENVISION**

# ENVISION Single-Arm Study Description

## Primary endpoint:

- **Complete response rate (CRR)** at 3-month visit

## Key Secondary endpoint:

- **Duration of Response (DOR)**, defined as time from first documented CR until the earliest date of:
  - ✓ **Recurrence** of low-grade disease at the 3-month assessment
  - ✓ **Progression**
  - ✓ **Death**

## Patient Population:

- **Previously diagnosed**

# ENVISION Demographics and Safety Profile

Demographics and baseline characteristics were **reflective of typical LG-IR-NMIBC patient population**



- Treatment-emergent AEs were generally **mild to moderate**
- **Similar safety profile** to other studies of UGN-102

# Summary of Response Rate At 3-Month Disease Assessment: **CRR of 79.2%**

UGN-102 (N = 240)		
	n (%)	CRR (95% CI)
<b>Complete Response</b>	<b>190 (79.2)</b>	<b>79.2 (73.5, 84.1)</b>
<b>Non-Complete Response</b>	<b>50 (20.8)</b>	
Residual Disease	35 (14.6)	
Progression to HG Disease	6 (2.5)	
Indeterminate	4 (1.7)	
Missing	5 (2.1)	



## Next for ENVISION

DOR data expected in

**1H, 2024**



Planned NDA Submission

**2024**



# IMPACT ON CLINICAL PRACTICE

## PANEL DISCUSSION



**Dr. Mark Schoenberg**

**Moderator**

*M.D., Chief Medical Officer, UroGen*



**Dr. Trinity Bivalacqua**

*M.D., Ph.D., Director of Urologic Oncology and Co-Director Genitourinary Cancer Service Line with the Abramson Cancer Center, Hospital of the University of Pennsylvania, PA*



**Dr. Karim Chamie**

*M.D., MSHS, Associate Professor of Urology at UCLA, CA*



**Dr. Katie Murray**

*DO, Associate Professor of Urology, New York University Langone and Chief of Urology, Bellevue Hospital, NYC*



**Dr. Sandip Prasad**

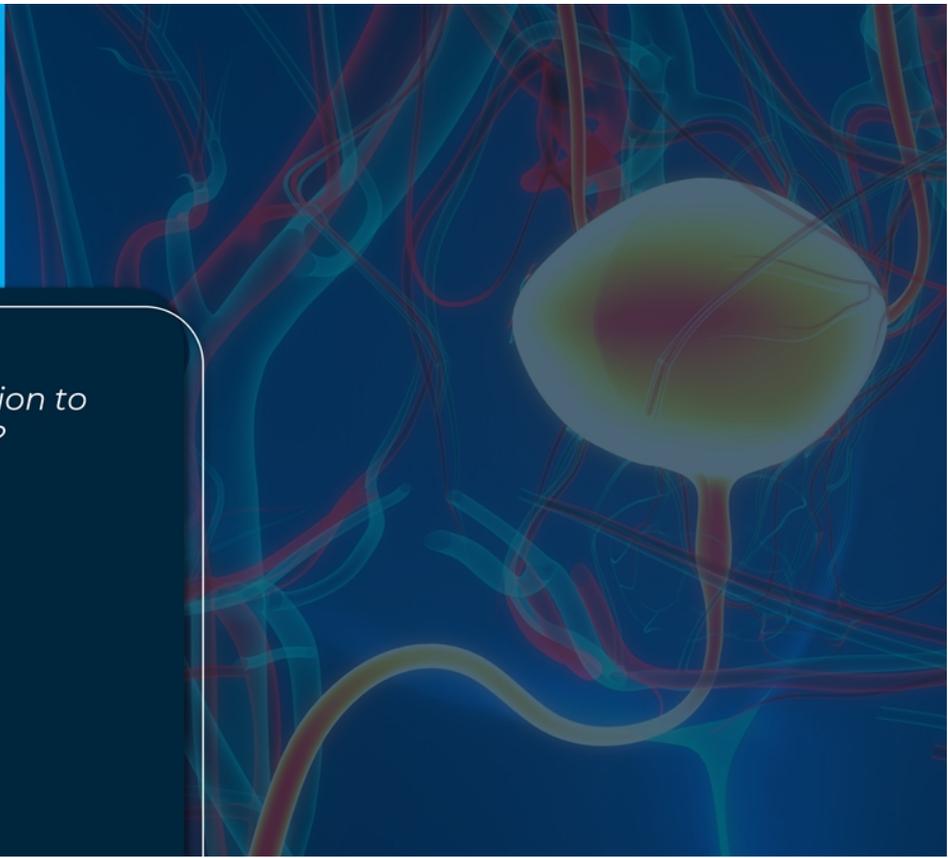
*M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Medical Center/Atlantic Health System, NJ*

The views expressed by the healthcare professionals on this panel are their own and do not necessarily represent the views of their employers or affiliated institutions. Additionally, these healthcare professionals are consultants for UroGen and are being compensated for their participation in today's event.

TOPIC

1

*What 's your initial reaction to the data presented?*

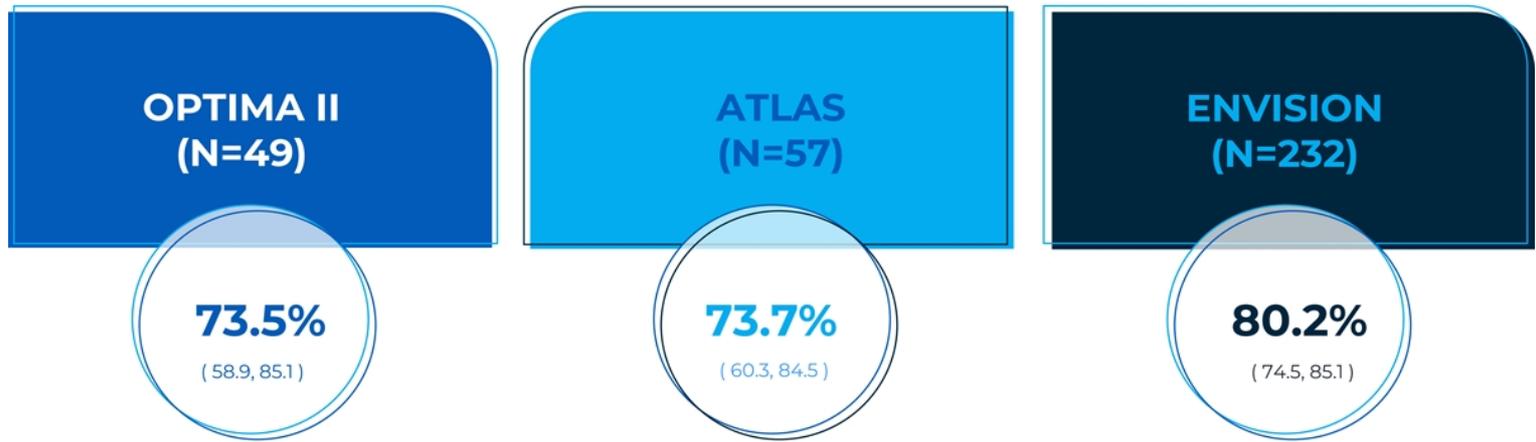


TOPIC

# 2

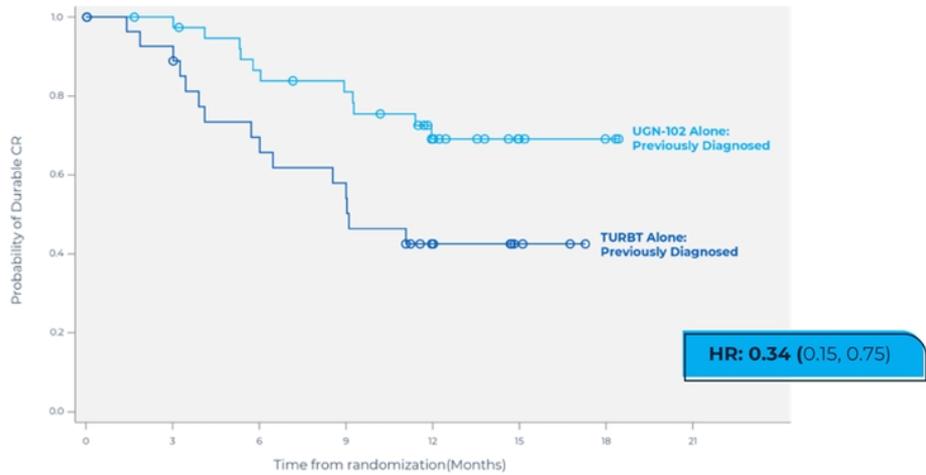
*Discussing the CR rate across  
the OPTIMA II, ATLAS and  
ENVISION trials.*

# Complete Response Rate for Recurrent Patients Within the UGN-102 Trials



UroGen Data on File  
Total OPTIMA II population n=63, recurrent population n=49  
Total ATLAS population n=282, recurrent population n=57  
Total ENVISION population n=240, recurrent population n=232

# DOR - 66% Reduction of Risk for Recurrence, Progression, or Death in Recurrent Patients Who Received UGN-102 Alone in the ATLAS Trial



UGN-102 Alone: Previously Diagnosed	42	38	32	29	16	4	2	0
TURBT Alone: Previously Diagnosed	35	25	18	15	7	3	0	0

41 \*UGN Alone Subgroup of the UGN 102 +/- TURBT arm in ATLAS  
UroGen Data on File  
Kaplan-Meier Plot of DOR in Complete Responders in the Recurrent Subgroup (ATLAS)



## UGN-102 Shows **Substantial Reduction of Risk** of Recurrence, Progression, or Death Across Multiple Patient Populations in ATLAS

**ITT – All Patients**  
DFS

**0.45** (0.29, 0.68)

**CR Duration – UGN-102 Alone**  
DOR

**0.46** (0.24, 0.86)

**Recurrent – UGN-102 Alone**  
DOR

**0.34** (0.15, 0.75)

TOPIC

3

*How does the fact that UGN-102, if approved, can be given by an APP in the office impact how you might view adoption?*

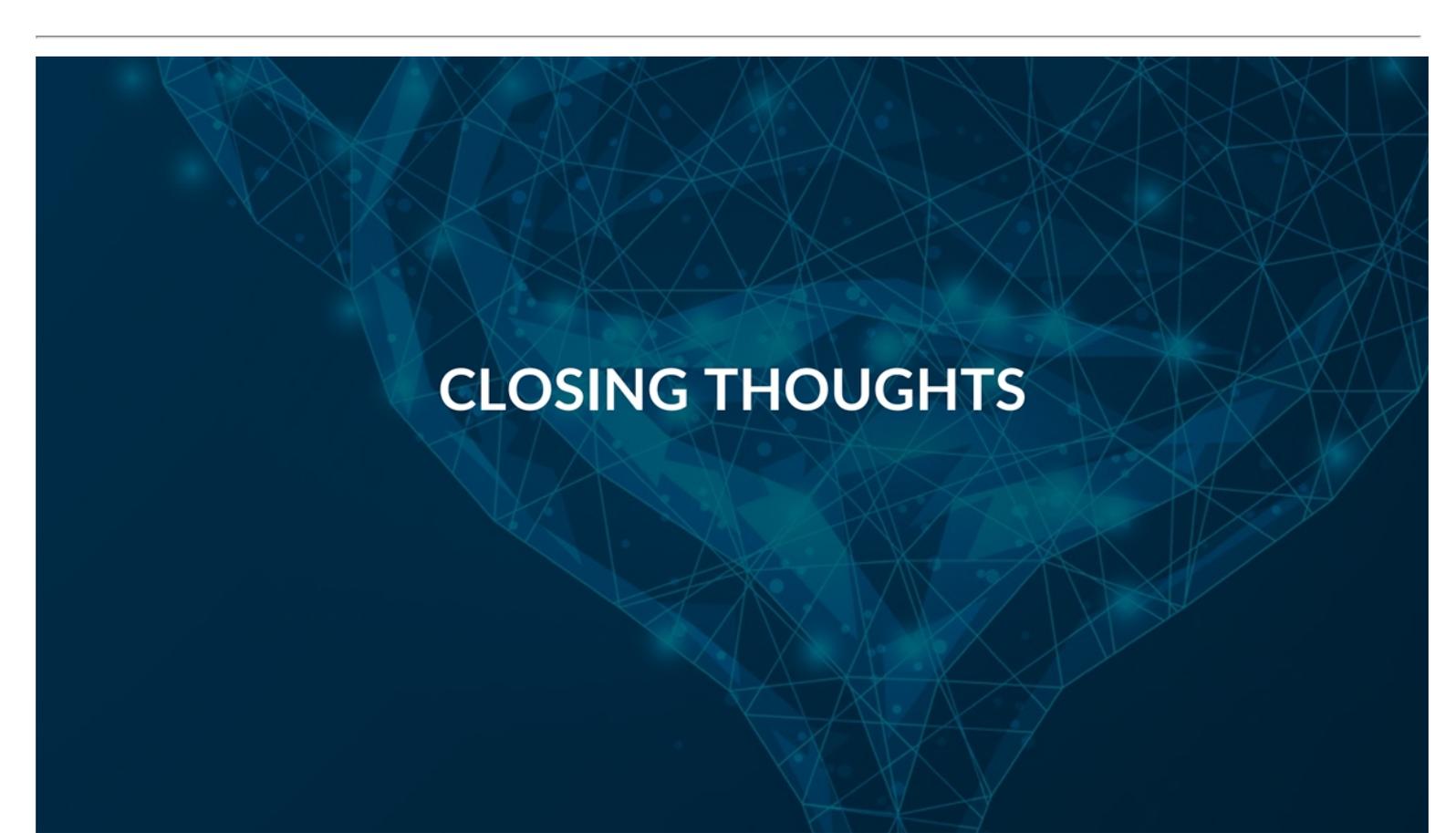


TOPIC

# 4

*Given that urologists are familiar with neoadjuvant chemotherapy use in the context of treating MIBC, do you think it will be a big leap for them to adopt neoadjuvant therapy for NMIBC?*





# CLOSING THOUGHTS

## UGN-102 Shows **Substantial Reduction of Risk** of Recurrence, Progression, or Death Across Multiple Patient Populations in ATLAS

**ITT – All Patients**  
DFS

**0.45** (0.29, 0.68)

**CR Duration – UGN-102 Alone**  
DOR

**0.46** (0.24, 0.86)

**Recurrent – UGN-102 Alone**  
DOR

**0.34** (0.15, 0.75)

# Q&A

Moderated by LIZ BARRETT



UGN-102 shows **substantial risk reduction** across patient populations



**Compelling clinical data** package from **3 trials** and **565 patients**

# UroGen is Poised to Transform the Way Bladder Cancer is Treated

# #1

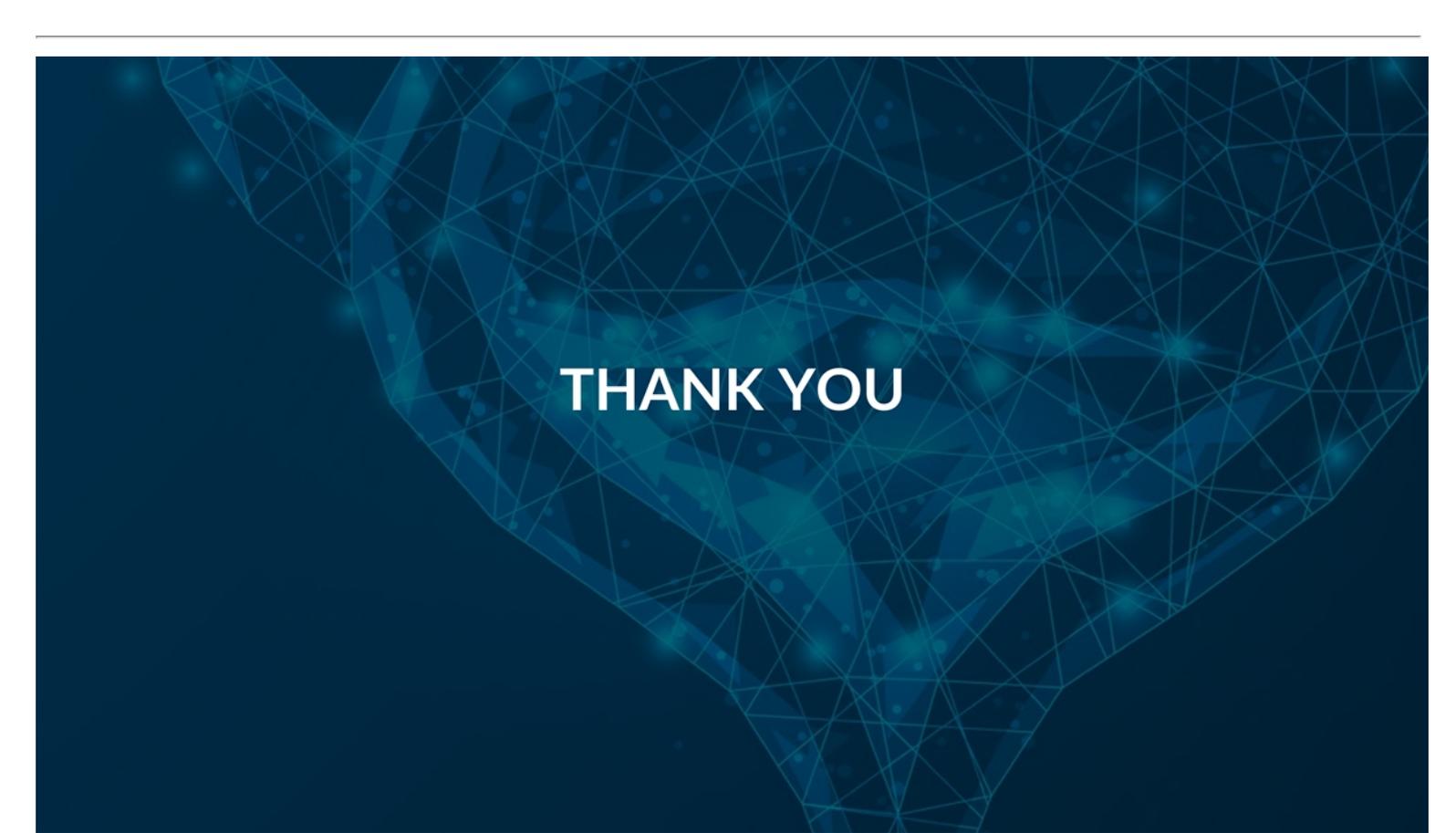
UGN-102 may become the **first medicine** to treat LG-IR-NMIBC

# \$3B+TAM

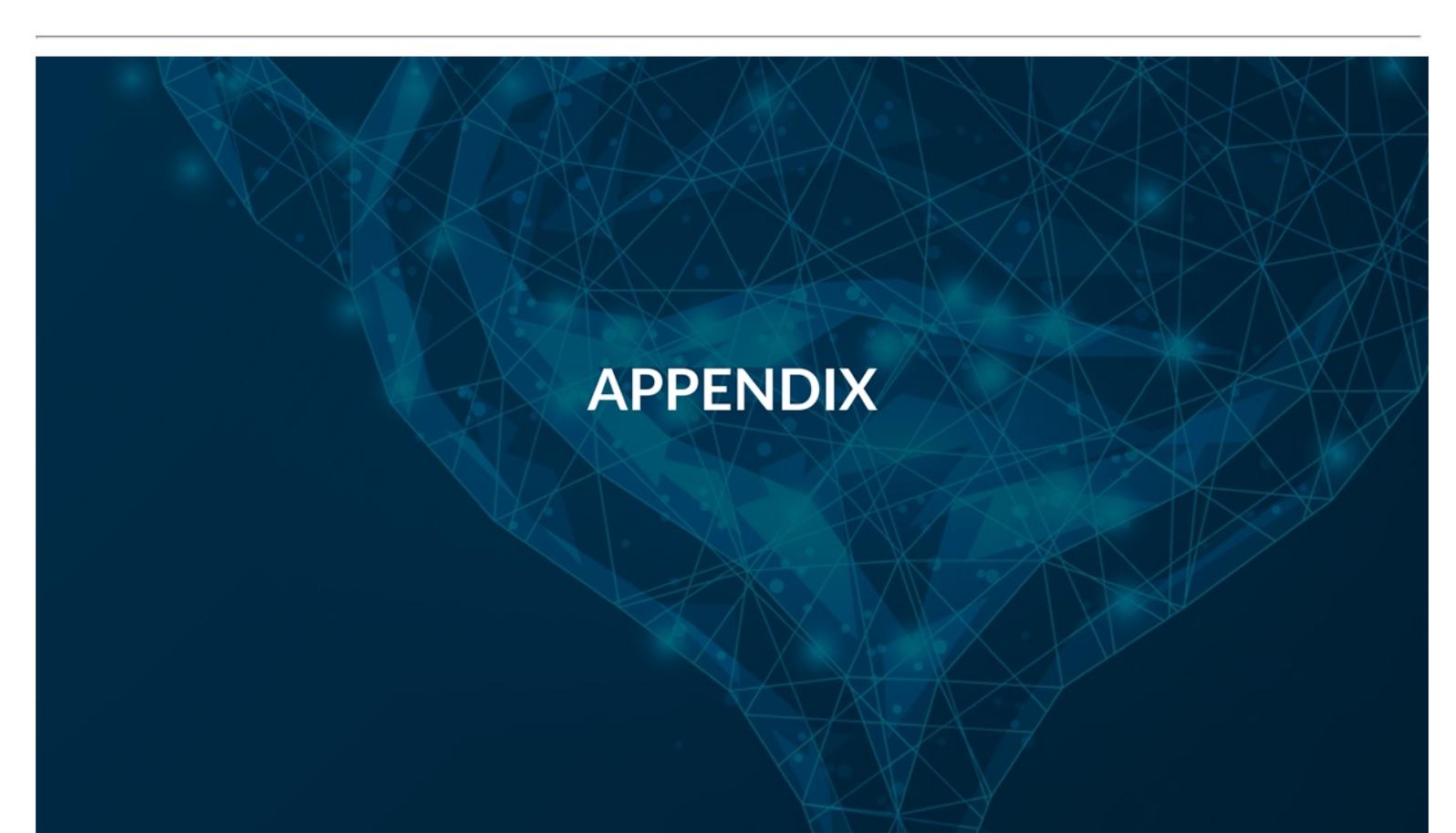
LG-IR-NMIBC market ripe for **innovation**

# \$120M

private placement with **experienced biotech investors**



**THANK YOU**



# APPENDIX

## Demographics and Baseline Characteristics **Were Well Balanced** Between Treatment Arms

<b>Characteristic</b>	<b>UGN-102 +/- TURBT</b> (N = 142) / n (%)	<b>TURBT Alone</b> (N = 140) / n (%)
<b>Median age</b> (range), years	<b>68.0</b> (23, 85)	<b>67.0</b> (29, 88)
<b>Age ≥ 65 years, n (%)</b>	<b>91</b> (64.1)	<b>77</b> (55.0)
<b>Sex, n (%)</b>		
Male	<b>105</b> (73.9)	<b>93</b> (66.4)
Female	<b>37</b> (26.1)	<b>47</b> (33.6)
<b>Any prior NMIBC episode, n (%)</b>	<b>57</b> (40.1)	<b>66</b> (47.1)
<b>Prior TURBT, n (%)</b>	<b>55</b> (38.7)	<b>63</b> (45.0)

## Overall Summary of Adverse Events in ATLAS: Safety Profile Similar to Other Studies of UGN-102

	UGN-102 ± TURBT (N = 138)		TURBT Alone (N = 132)	
	Events	n (%)	Events	n (%)
<b>Any Adverse Events</b>	442	108 (78.3)	249	81 (61.4)
Any Serious Adverse Events	13	12 (8.7)	11	7 (5.3)
<b>Any TEAEs</b>	402	104 (75.4)	166	63 (47.7)
Any Treatment or Procedure Related TEAEs	211	65 (47.1)	21	15 (11.4)
Any Treatment Related TEAEs	186	54 (39.1)	19	15 (11.4)
Any Procedure Related TEAEs	65	31 (22.5)	2	2 (1.5)
Any TEAEs Leading to Treatment Discontinuation	19	5 (3.6)	NA	NA
Any TEAEs Leading to Study Discontinuation	7	4 (2.9)	2	2 (1.5)
<b>Any Serious TEAEs</b>	13	12 (8.7)	11	7 (5.3)
Any Treatment or Procedure Related Serious TEAEs	2	2 (1.4)	1	1 (0.8)
Any Treatment Related Serious TEAEs	0	0	1	1 (0.8)
Any Procedure Related Serious TEAEs	2	2 (1.4)	0	0
Any TEAEs Leading to Death	0	0	1	1 (0.8)
Any TEAEs of Special Interest	213	78 (56.5)	59	36 (27.3)

# Most Commonly Reported AEs and Serious TEAEs

## Incidence of Treatment-Emergent Adverse Events (≥ 5% in Either Group)

	<b>UGN-102 ± TURBT</b> (N = 138) / n (%)	<b>TURBT Alone</b> (N = 132) / n (%)
<b>Patients With Any TEAE</b>	<b>104 (75.4)</b>	<b>63 (47.7)</b>
Dysuria	42 (30.4)	6 (4.5)
Micturition urgency	25 (18.1)	10 (7.6)
Nocturia	25 (18.1)	9 (6.8)
Pollakiuria	22 (15.9)	8 (6.1)
Flatulence	13 (9.4)	4 (3.0)
COVID-19	11 (8.0)	8 (6.1)
Erectile dysfunction	9 (6.5)	4 (3.0)
Haematuria	9 (6.5)	6 (4.5)
Malaise	8 (5.8)	2 (1.5)

## Incidence of Serious TEAEs (≥ 1% in Either Group)

	<b>UGN-102 ± TURBT</b> (N = 138) / n (%)	<b>TURBT Alone</b> (N = 132) / n (%)
<b>Patients With Any Serious TEAE</b>	<b>12 (8.7)</b>	<b>7 (5.3)</b>
COVID-19	4 (2.9)	2 (1.5)
Sepsis	1 (0.7)	2 (1.5)
Haematuria	0	2 (1.5)

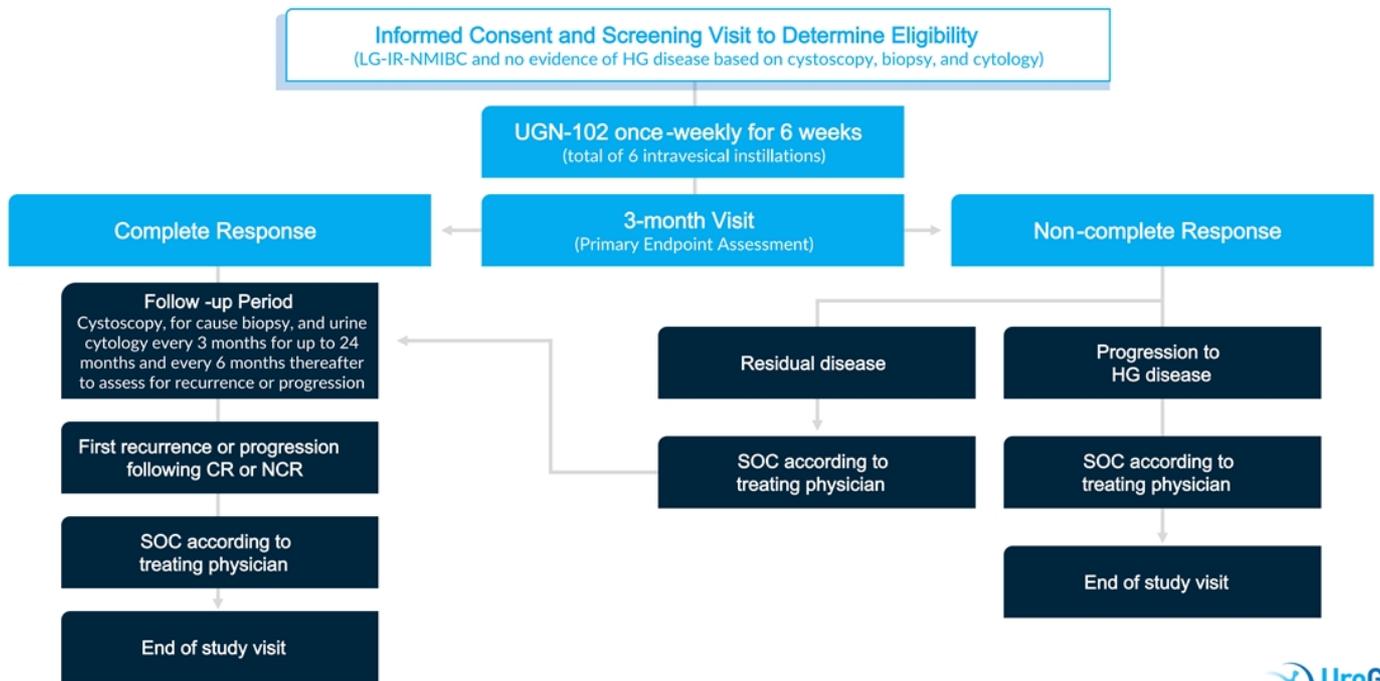
## Summary of Disease-Free Survival: Significantly More Total Progressions and Recurrences in TURBT Alone Arm

	UGN-102 +/- TURBT (N = 142) / n (%)	TURBT Alone (N = 140) / n (%)
<b>Patients with Events, n (%)</b>	<b>37 (26.1)</b>	<b>55 (39.3)</b>
Recurrence of LG Disease	20 (14.1)	39 (27.9)
Progression to HG Disease	17 (12.0)	15 (10.7)
Death	0	1 (0.7)
<b>Patients Censored, n (%)</b>	<b>105 (73.9)</b>	<b>85 (60.7)</b>
No Post-baseline Disease Assessment	10 (7.0)	20 (14.3)
Received Non-protocol Therapy	7 (4.9)	4 (2.9)
Early Termination	6 (4.2)	12 (8.6)
Disease-free at End of Study	81 (57.0)	49 (35.0)
Extended Lost to Follow-up	1 (0.7)	0
<b>Hazard Ratio (95% CI)</b>	<b>0.45 (0.29, 0.68)</b>	

## Summary of Duration of Response in Complete Responders: **Longer DOR with UGN-102**

	<b>UGN-102 Alone</b> (N = 92) / n (%)	<b>TURBT Alone</b> (N = 89) / n (%)
<b>Patients with Events, n (%)</b>	<b>18 (19.6)</b>	<b>24 (27.0)</b>
Recurrence of LG Disease	15 (16.3)	17 (19.1)
Progression to HG Disease	3 (3.3)	6 (6.7)
Death	0	1 (1.1)
<b>Patients Censored, n (%)</b>	<b>74 (80.4)</b>	<b>65 (73.0)</b>
No Follow-up	1 (1.1)	10 (11.2)
Received Non-protocol Therapy	5 (5.4)	4 (4.5)
Early Termination	1 (1.1)	2 (2.2)
Disease-free at End of Study	67 (72.8)	49 (55.1)
Extended Lost to Follow-up	0	0
<b>Hazard Ratio (95% CI)</b>	<b>0.46 (0.24, 0.86)</b>	

# ENVISION Trial Design



## Summary of Demographics and Baseline Characteristics

Characteristic Statistic	UGN-102 (N = 240) / n (%)
<b>Age</b>	
Median Age (Min, Max)	70.0 (30, 92)
<b>Age Group 2 (Years), n (%)</b>	
>= 65	162 (67.5)
<b>Sex, n (%)</b>	
Male	147 (61.3)
Female	93 (38.8)
<b>Prior TURBT, n (%)</b>	
Yes	231 (96.3)
No	9 (3.8)
<b>Previous LG NMIBC Episodes, n (%)</b>	
Yes	224 (93.3)
No	16 (6.7)
<b>Treatment Course, n (%)</b>	
6 instillations	228 (95.0)
< 6 instillations	12 (5.0)

## Overall Summary of Adverse Events in ENVISION: **Safety Profile Similar to Other Studies of UGN-102**

	<b>UGN-102</b> (N = 240)	
	<b>Events</b>	<b>n (%)</b>
<b>Any Adverse Events</b>	<b>563</b>	<b>129 (53.8)</b>
Any Serious Adverse Events	26	19 (7.9)
<b>Any TEAEs</b>	<b>523</b>	<b>127 (52.9)</b>
Any Treatment or Procedure Related TEAEs	283	96 (40.0)
Any Treatment Related TEAEs	242	80 (33.3)
Any Procedure Related TEAEs	121	62 (25.8)
Any TEAEs Leading to Treatment Discontinuation	7	6 (2.5)
Any TEAEs Leading to Study Discontinuation	3	3 (1.3)
<b>Any Serious TEAEs</b>	<b>25</b>	<b>18 (7.5)</b>
Any Treatment or Procedure Related Serious TEAEs	4	4 (1.7)
Any Treatment Related Serious TEAEs	2	2 (0.8)
Any Procedure Related Serious TEAEs	3	3 (1.3)
Any TEAEs Leading to Death	2	2 (0.8)
Any TEAEs of Special Interest	241	96 (40.0)

# Treatment-Related AEs were Generally Mild to Moderate and in line with expectations in the field

## Incidence of Treatment-emergent Adverse Events (≥ 5%)

	UGN-102 (N = 240) / n (%)					
	Mild	Moderate	Severe or Medically Significant	Life-threatening	Death	Total
<b>Patients With Any TEAEs</b>	<b>60 (25.0)</b>	<b>47 (19.6)</b>	<b>16 (6.7)</b>	<b>2 (0.8)</b>	<b>2 (0.8)</b>	<b>127 (52.9)</b>
Dysuria	43 (17.9)	9 (3.8)	1 (0.4)	0	0	53 (22.1)
Haematuria	15 (6.3)	5 (2.1)	0	0	0	20 (8.3)
Pollakiuria	13 (5.4)	2 (0.8)	0	0	0	15 (6.3)
Urinary tract infection	4 (1.7)	10 (4.2)	0	0	0	14 (5.8)
Fatigue	9 (3.8)	4 (1.7)	0	0	0	13 (5.4)

## Incidence of Treatment Related Serious TEAEs

	UGN-102 (N = 240) / n (%)
<b>Patients With Any Serious TEAEs</b>	<b>2 (0.8)</b>
Urethral stenosis	1 (0.4)
Urinary retention	1 (0.4)

## Clinical Results Propel Us Towards FDA Submission

**OPTIMA II**

**CR: 65.1%**

**12-month DOR: 72.5%**

**Safety: AEs mostly mild to moderate**

**ATLAS**

**CR: 64.8%**

**12-month DOR: 79.7%**

**Safety: AEs mostly mild to moderate**

**ENVISION**

**CR: 79.2%**

**Safety: AEs mostly mild to moderate**



UGN-102 shows **substantial risk reduction** across patient populations



**Compelling clinical data** package from **3 trials** and **565 patients**

# UroGen is Poised to Transform the Way Bladder Cancer is Treated

# #1

UGN-102 may become the **first medicine** to treat LG-IR-NMIBC

# \$3B+TAM

LG-IR-NMIBC market ripe for **innovation**

# \$120M

private placement with **experienced biotech investors**

**ATLAS Summary of Response Rate at Scheduled Disease Assessments (3-month CR Analysis Set)**

Visit	Response	UGN-102 ± TURBT (N = 92)		TURBT Alone (N = 89)	
		n (%)	CRR (95% CI)	n (%)	CRR (95% CI)
Month 6	Complete Response	85 (92.4)	92.4 (84.9, 96.9)	64 (71.9)	71.9 (61.4, 80.9)
	Recurrence	5 (5.4)		14 (15.7)	
	Indeterminate	0		1 (1.1)	
Month 9	Complete Response	74 (80.4)	80.4 (70.9, 88.0)	56 (62.9)	62.9 (52.0, 72.9)
	Recurrence	9 (9.8)		5 (5.6)	
	Indeterminate	0		1 (1.1)	
Month 12	Complete Response	69 (75.0)	75.0 (64.9, 83.4)	51 (57.3)	57.3 (46.4, 67.7)
	Recurrence	4 (4.3)		5 (5.6)	
	Indeterminate	0		0	
Month 15	Complete Response	66 (71.7)	71.7 (61.4, 80.6)	49 (55.1)	55.1 (44.1, 65.6)
	Recurrence	2 (2.2)		1 (1.1)	
	Indeterminate	0		1 (1.1)	
Month 18	Complete Response	32 (34.8)	34.8 (25.1, 45.4)	23 (25.8)	25.8 (17.1, 36.2)
	Recurrence	1 (1.1)		1 (1.1)	
	Indeterminate	2 (2.2)		0	
Month 21	Complete Response	7 (7.6)	7.6 (3.1, 15.1)	4 (4.5)	4.5 (1.2, 11.1)
	Recurrence	0		0	
	Indeterminate	0		0	

Source: Table 14.2.2.2.2a

Table 14.1.6.2  
Summary of Baseline Prognostic Factors  
ITT Analysis Set

Characteristic	UGN-102 + TURBT (N=142) n (%)	TURBT Alone (N=140) n (%)
Age Group (Years), n (%)		
< 65	51 (35.9)	62 (45.0)
>= 65	91 (64.1)	77 (55.0)
Age Group (Years), n (%)		
< 75	110 (77.5)	110 (78.6)
>= 75	32 (22.5)	30 (21.4)
BMI (kg/m <sup>2</sup> ) category, n (%)		
< 30	104 (73.2)	96 (68.6)
>= 30	34 (23.9)	35 (25.0)
Missing	4 (2.8)	9 (6.4)
Tumor Size (cm), n (%)		
<= 3	69 (48.6)	73 (52.1)
> 3	67 (47.2)	59 (42.1)
Missing	6 (4.2)	8 (5.7)
Tumor Count, n (%)		
Multiple	82 (57.7)	94 (67.1)
Single	54 (38.0)	40 (28.6)
Missing	6 (4.2)	6 (4.3)

BMI = Body Mass Index; LG = Low Grade; NMIBC = Non-muscle Invasive Bladder Cancer; TURBT = Transurethral Resection of Bladder Tumor.  
Smoker category includes both former and current smokers. Non-smoker category includes "Never".  
Percentages are based on the number of patients in each treatment group.  
1. Based on the randomisation strata determined on IRT.  
2. At least 1 prior episode of LG NMIBC was treated with TURBT.

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Table 14.1.6.2  
Summary of Baseline Prognostic Factors  
ITT Analysis Set

Characteristic	UGN-102 + TURBT (N=142) n (%)	TURBT Alone (N=140) n (%)
Previous LG NMIBC Episodes within 1 Year <sup>1</sup> , n (%)		
Yes	41 (28.9)	40 (28.6)
No	101 (71.1)	100 (71.4)
Number of Previous LG NMIBC Episodes, n (%)		
≤ 2	129 (90.8)	123 (87.9)
> 2	13 (9.2)	17 (12.1)
Previous LG NMIBC Episodes, n (%)		
Yes	54 (38.0)	65 (46.4)
No	88 (62.0)	75 (53.6)
Prior TURBT, n (%)		
Yes	52 (36.6)	64 (45.7)
No	90 (63.4)	76 (54.3)
Smoking History, n (%)		
Non-Smoker	63 (44.4)	73 (52.1)
Smoker	79 (55.6)	67 (47.9)

BMI = Body Mass Index; LG = Low Grade; NMIBC = Non-muscle Invasive Bladder Cancer; TURBT = Transurethral Resection of Bladder Tumor.

Smoker category includes both former and current smokers. Non-smoker category includes "Never". Percentages are based on the number of patients in each treatment group.

1. Based on the randomisation strata determined on IRF.

2. At least 1 prior episode of LG NMIBC was treated with TURBT.

Generated from v0progofact.sas on 30JUN2023 at 12:25:41. Date of data extraction: 17MAY2023.

Table 14.1.8.2  
 Summary of Prior NMIBC Episodes and Prior TURBT  
 ITT Analysis Set

	UGN-102 + TURBT (N=142)	TURBT Alone (N=140)
Patients with Any Prior NMIBC episode, n (%)		
Yes	57 (40.1)	66 (47.1)
No	85 (59.9)	74 (52.9)
Number of Prior NMIBC Episode(s)		
n	142	140
Mean	0.8	1.1
Median (Min, Max)	0.0 (0, 12)	0.0 (0, 18)
Time to Recurrence of Baseline NMIBC (months) [1]		
n	57	66
Mean (SD)	19.4 (22.50)	22.1 (25.43)
Median (Q1, Q3)	9.0 (5.3, 22.2)	9.7 (5.9, 18.0)
Min, Max	1.6, 96.4	0.6, 188.4

NMIBC = Non-muscle Invasive Bladder Cancer; Q1 = Lower Quartile; Q3 = Upper Quartile; SD = Standard Deviation; TURBT =  
 Transurethral Resection of Bladder Tumor.  
 [1] Time to recurrence of Baseline NMIBC (months) is calculated as (start date of current episode - end date of previous  
 episode + 1)/30.4375.  
 [2] For treatment of NMIBC.

Generated from t0nmibc0turbt.sas on 30JUN2023 at 12:25:28. Date of data extraction: 17MAY2023.

Table 14.1.8.2  
 Summary of Prior NMIBC Episodes and Prior TURBT  
 ITT Analysis Set

	UGN-102 + TURBT (N=142)	TURBT Alone (N=140)
Number of Prior TURBT [2]		
n	142	140
Mean	0.8	1.0
Median (Min, Max)	0.0 (0, 12)	0.0 (0, 10)
Prior TURBT, n (%) [2]		
Yes	55 (38.7)	63 (45.0)
No	87 (61.3)	77 (55.0)
Number of Prior TURBT Group, n (%) [2]		
0	87 (61.3)	77 (55.0)
1	30 (21.1)	30 (21.4)
2	12 ( 8.5)	16 (11.4)
>= 3	13 ( 9.2)	17 (12.1)

NMIBC = Non-muscle Invasive Bladder Cancer; Q1 = Lower Quartile; Q3 = Upper Quartile; SD = Standard Deviation; TURBT = Transurethral Resection of Bladder Tumor.  
 (1) Time to recurrence of Baseline NMIBC (months) is calculated as (start date of current episode - end date of previous episode + 1)/30.4375.  
 (2) For treatment of NMIBC.

Generated from t0nmibc0turbt.sas on 30JUN2023 at 12:25:28. Date of data extraction: 17MAY2023.

Table 14.1.8.2  
Summary of Prior NMIBC Episodes and Prior TURBT  
ITT Analysis Set

	UGN-102 + TURBT (N=142)	TURBT Alone (N=140)
Days since last TURBT at the time of randomisation, n (%) [2]		
<= 365	31 (21.8)	32 (22.9)
> 365	24 (16.9)	31 (22.1)
Time since last TURBT at the time of randomisation (months)		
n	55	63
Mean (SD)	21.0 (24.06)	29.0 (43.18)
Median (Q1, Q3)	9.8 (8.5, 26.6)	11.7 (6.7, 29.5)
Min, Max	1.2, 98.0	0.5, 198.9

NMIBC = Non-muscle Invasive Bladder Cancer; Q1 = Lower Quartile; Q3 = Upper Quartile; SD = Standard Deviation; TURBT = Transurethral Resection of Bladder Tumor.  
 [1] Time to recurrence of Baseline NMIBC (months) is calculated as (start date of current episode - end date of previous episode + 1)/30.4375.  
 [2] For treatment of NMIBC.

Generated from t0nmibc0turbt.sas on 30JUN2023 at 12:25:28. Date of data extraction: 17MAY2023.

## ATLAS SUMMARY DEMOGRAPHICS/BASELINE DATA BY (TURBT NAÏVE VS. >=1 PRIOR TURBT)

	TURBT Naïve (N=164)		>=1 prior TURBT (N=118)	
	UGN-102 ± TURBT (N=87)	TURBT Alone (N=77)	UGN-102 ± TURBT (N=55)	TURBT Alone (N=63)
Median age (range), years	66 (23,85)	65 (29,83)	69 (35,85)	69 (47,88)
Sex, n (%)				
Male	64(73.6)	51(66.2)	41(74.5)	42(66.7)
Female	23(26.4)	26(33.8)	14(25.5)	21(33.3)
Age Group (Years), n (%)				
< 65	33(37.9)	38(49.4)	18(32.7)	25(39.7)
>= 65	54(62.1)	39(50.6)	37(67.3)	38(60.3)
Age Group (Years), n (%)				
< 75	67(77.0)	66(85.7)	43(78.2)	44(69.8)
>= 75	20(23.0)	11(14.3)	12(21.8)	19(30.2)
BMI (kg/m) category, n (%)				
<30 (kg/m2)	69(79.3)	50(64.9)	35(63.6)	46(73.0)
>=30 (kg/m2)	14(16.1)	19(24.7)	20(36.4)	16(25.4)

## ATLAS SUMMARY DEMOGRAPHICS/BASELINE DATA BY (TURBT NAÏVE VS. >=1 PRIOR TURBT)

	TURBT Naïve (N=164)		>=1 prior TURBT (N=118)	
	UGN-102 ± TURBT (N=87)	TURBT Alone (N=77)	UGN-102 ± TURBT (N=55)	TURBT Alone (N=63)
<b>Tumor Size (cm), n (%)</b>				
<=3 cm	30(34.5)	33(42.9)	39(70.9)	40(63.5)
>3 cm	54(62.1)	42(54.5)	13(23.6)	17(27.0)
<b>Tumor Count, n (%)</b>				
Single	37(42.5)	23(29.9)	17(30.9)	17(27.0)
Multiple	46(52.9)	53(68.8)	36(65.5)	41(65.1)
Missing	4(4.6)	1(1.3)	2(3.6)	5(7.9)
<b>Previous LG NMIBC Episodes within 1 Year, n (%)</b>				
Yes	9(10.3)	5(6.5)	32(58.2)	35(55.6)
No	78(89.7)	72(93.5)	23(41.8)	28(44.4)

## ATLAS SUMMARY DEMOGRAPHICS/BASELINE DATA BY (TURBT NAÏVE VS. >=1 PRIOR TURBT)

	TURBT Naïve (N=164)		>=1 prior TURBT (N=118)	
	UGN-102 ± TURBT (N=87)	TURBT Alone (N=77)	UGN-102 ± TURBT (N=55)	TURBT Alone (N=63)
<b>Number of Previous LG NMIBC Episodes, n (%)</b>				
Yes	2(2.3)	3(3.9)	52(94.5)	62(98.4)
No	85(97.7)	74(96.1)	3(5.5)	1(1.6)
<b>Previous LG NMIBC Episodes, n (%)</b>				
<=2	87(100.0)	77(100.0)	42(76.4)	46(73.0)
>2	0(0.0)	0(0.0)	13(23.6)	17(27.0)
<b>Prior TURBT, n (%)</b>				
Yes	0(0.0)	3(3.9)	52(94.5)	61(96.8)
No	87(100.0)	74(96.1)	3(5.5)	2(3.2)
<b>Smoking History, n (%)</b>				
Non-Smoker	39(44.8)	37(48.1)	24(43.6)	36(57.1)
Smoker	48(55.2)	40(51.9)	31(56.4)	27(42.9)

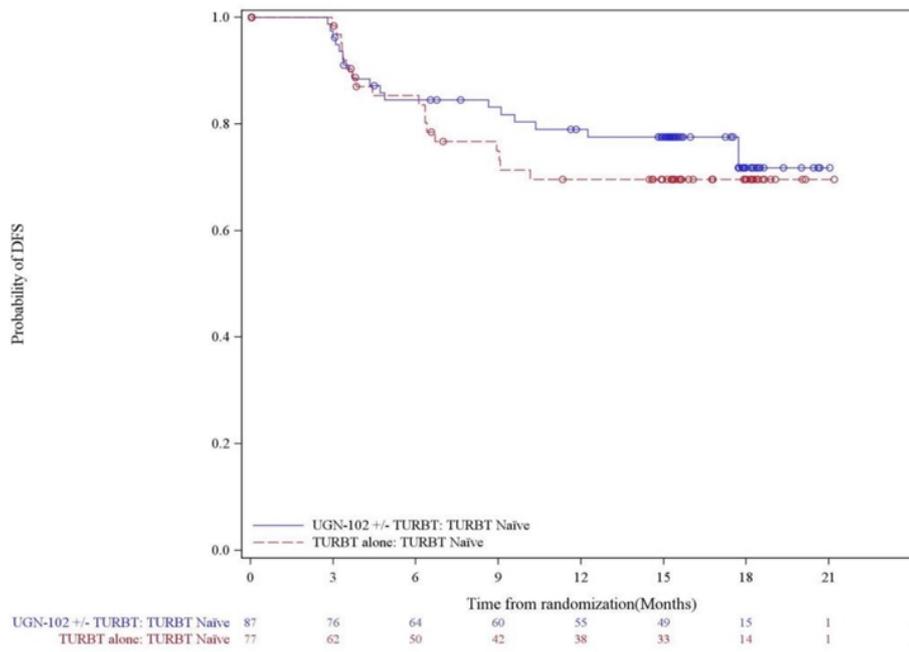
## ATLAS SUMMARY OF COMPLETE RESPONSE RATE (CRR) BY SUBGROUP (NAÏVE TURBT VS. >1 TURBT)

	TURBT Naive (N=164)				>= 1 TURBT (N=118)			
	UGN-102 ± TURBT (N=87)		TURBT Alone (N=77)		UGN-102 ± TURBT (N=55)		TURBT Alone (N=63)	
	n(%)	CRR (95% CI)	n(%)	CRR (95% CI)	n(%)	CRR (95% CI)	n(%)	CRR (95% CI)
Complete Response	51( <b>58.6</b> )	58.6 (47.6,69.1)	54( <b>70.1</b> )	70.1 (58.6,80.0)	41( <b>74.5</b> )	74.5 (61.0,85.3)	35( <b>55.6</b> )	55.6 (42.5,68.1)
Non-Complete Response	36(41.4)		23(29.9)		14(25.5)		28(44.4)	
Residual disease	19(21.8)		5(6.5)		7(12.7)		17(27.0)	
Progression to HG disease	9(10.3)		4(5.2)		3(5.5)		5(7.9)	
Indeterminate	1(1.1)		0		2(3.6)		0	
Missing	7(8.0)		14(18.2)		2(3.6)		6(9.5)	

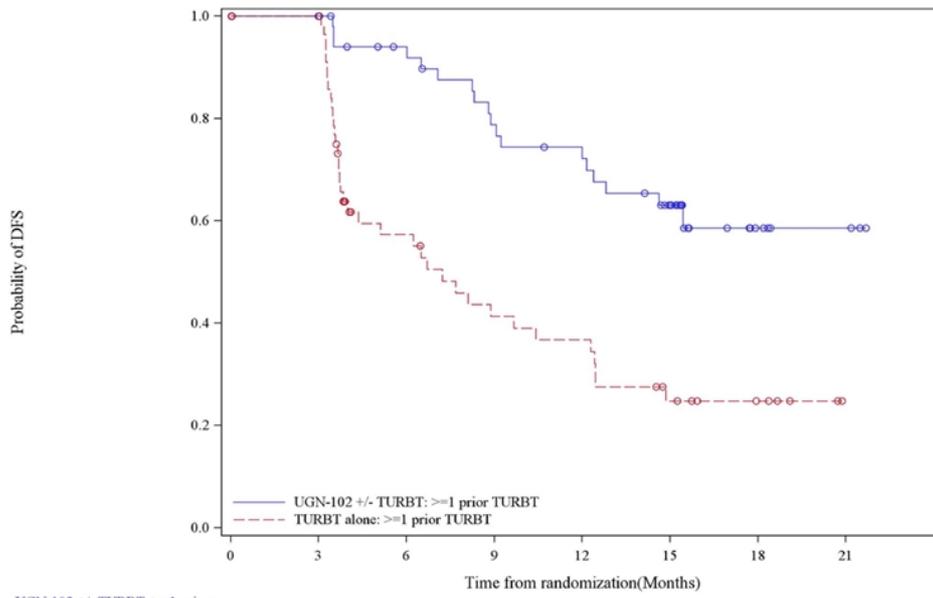
**ATLAS SUMMARY OF CRR BY MONTH BY (TURBT NAÏVE VS. >=1 PRIOR TURBT) (3-MONTH CRR ANALYSIS SET)**

		TURBT Naïve (N=105)				>=1 prior TURBT (N=76)			
		UGN-102 ± TURBT (N=51)		TURBT Alone (N=54)		UGN-102 ± TURBT (N=41)		TURBT Alone (N=35)	
Visit	Response	n(%)	CRR (95% CI)	n(%)	CRR (95% CI)	n(%)	CRR (95% CI)	n(%)	CRR (95% CI)
Month 6	Complete Response	49(96.1)	96.1 (86.5,99.5)	44(81.5)	81.5 (68.6,90.7)	36(87.8)	87.8 (73.8,95.9)	20(57.1)	57.1 (39.4,73.7)
	Recurrence	1(2.0)		6(11.1)		4(9.8)		8(22.9)	
	Indeterminate	0(0.0)		0(0.0)		0(0.0)		1(2.9)	
Month 9	Complete Response	43(84.3)	84.3 (71.4,93.0)	40(74.1)	74.1 (60.3,85.0)	31(75.6)	75.6 (59.7,87.6)	16(45.7)	45.7 (28.8,63.4)
	Recurrence	5(9.8)		3(5.6)		4(9.8)		2(5.7)	
	Indeterminate	0(0.0)		1(1.9)		0(0.0)		0(0.0)	
Month 12	Complete Response	42(82.4)	82.4 (69.1,91.6)	39(72.2)	72.2 (58.4,83.5)	27(65.9)	65.9 (49.4,79.9)	12(34.3)	34.3 (19.1,52.2)
	Recurrence	1(2.0)		1(1.9)		3(7.3)		4(11.4)	
Month 15	Complete Response	42(82.4)	82.4 (69.1,91.6)	38(70.4)	70.4 (56.4,82.0)	24(58.5)	58.5 (42.1,73.7)	11(31.4)	31.4 (16.9,49.3)
	Recurrence	0(0.0)		0(0.0)		2(4.9)		1(2.9)	
	Indeterminate	0(0.0)		1(1.9)		0(0.0)		0(0.0)	
Month 18	Complete Response	24(47.1)	47.1 (32.9,61.5)	17(31.5)	31.5 (19.5,45.6)	8(19.5)	19.5 (8.8,34.9)	6(17.1)	17.1 (6.6,33.6)
	Recurrence	1(2.0)		0(0.0)		0(0.0)		1(2.9)	
	Indeterminate	1(2.0)		0(0.0)		1(2.4)		0(0.0)	
Month 21	Complete Response	4(7.8)	7.8 (2.2,18.9)	2(3.7)	3.7 (0.5,12.7)	3(7.3)	7.3 (1.5,19.9)	2(5.7)	5.7 (0.7,19.2)

## ATLAS SUMMARY OF DISEASE-FREE SURVIVAL (DFS) BY SUBGROUP (NAÏVE TURBT VS. >1 TURBT)



## ATLAS SUMMARY OF DISEASE-FREE SURVIVAL (DFS) BY SUBGROUP (NAÏVE TURBT VS. >1 TURBT)



	0	3	6	9	12	15	18	21
UGN-102 +/- TURBT: $\geq 1$ prior TURBT	55	52	44	36	32	24	6	3
TURBT alone: $\geq 1$ prior TURBT	63	57	26	18	16	9	5	0

**ATLAS % Patients who received TURBT at 3 months**

At the 3-Month Assessment	UGN-102 ± TURBT (N=138) n (%)	TURBT Alone (N=132) n (%)
TURBT	24 (17.4%)	18 (13.6%)

Reference: 14.2.2.4

**ATLAS: Summary of Patients who received TURBT at 3 months with a history of > 1 prior TURBT (ITT Analysis Set)**

	<b>UGN-102 ± TURBT (N=55)</b>	<b>TURBT Alone (N=63)</b>
Follow-on treatment with TURBT at Month-3 Assessment Visit	8 (14.5)	17 (27.0)

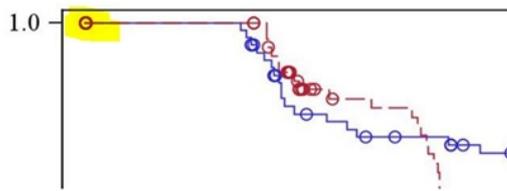
### ATLAS CENSORING IN MONTHS 0-3

Number of patients by treatment arm who were censored prior to a DFS of 3.0 months:

- UGN Arm: 11 patients
- TURBT Arm: 20 patients

Many censored observations (n=31) take place near time zero due to patients being randomized but without additional assessments (e.g. at month 3). As such, all of these are censored at the highlighted circle in the below graph.

If the circles were proportional, the highlighted circle would be much larger than what it is.



## ENVISION: Summary of Baseline Prognostic Factors (ITT Analysis Set)

Characteristic	UGN-102 (N=240) n (%)
Age Group (Years), n (%)	
< 65	78 (32.5)
>= 65	162 (67.5)
Age Group (Years), n (%)	
< 75	151 (62.9)
>= 75	89 (37.1)
BMI (kg/m <sup>2</sup> ) category, n (%)	
< 30	183 (76.3)
>= 30	55 (22.9)
Missing	2 (0.8)
Sex, n (%)	
Male	147 (61.3)
Female	93 (38.8)

## ENVISION: Summary of Baseline Prognostic Factors (ITT Analysis Set)

Characteristic	UGN-102 (N=240) n (%)
Tumor Size (cm), n (%)	
<= 3	164 (68.3)
> 3	40 (16.7)
Missing	36 (15.0)
Tumor Count, n (%)	
Single	45 (18.8)
Multiple	193 (80.4)
Missing	2 (0.8)
Previous LG NMIBC Episodes within 1 Year of the Current Diagnosis, n (%)	
Yes	113 (47.1)
No	127 (52.9)
Number of Previous LG NMIBC Episodes, n (%)	
0	16 (6.7)
>= 1 to <= 2	179 (74.6)
> 2	45 (18.8)

**Incidence of Treatment Related Serious TEAEs (ENVISION Safety Analysis Set)**

Preferred Term	UGN-102 (N=240) n (%)
Patients with Any Treatment Related Serious TEAE	2 (0.8)
Urethral stenosis	1 (0.4)
Urinary retention	1 (0.4)

## Incidence of Deaths (ENVISION Safety Analysis Set)

	UGN-102 (N=240) n (%)
Total Deaths anytime after first installation	2 (0.8)
Pneumonia	1 (0.4)
Cardiac failure	1 (0.4)

Notes: Reported deaths were unrelated to treatment

**Incidence of Serious TEAEs (ENVISION Safety Analysis Set)**

Preferred Term	UGN-102 (N=240) n (%)
Patients with Any Serious TEAE	18 (7.5)
Acetabulum fracture	1 (0.4)
Adenocarcinoma pancreas	1 (0.4)
Atrioventricular block second degree	1 (0.4)
Blood creatinine increased	1 (0.4)
COVID-19	1 (0.4)
Cardiac failure	1 (0.4)
Cardiac failure acute	1 (0.4)
Carotid artery disease	1 (0.4)
Carpal tunnel syndrome	1 (0.4)
Dyspnoea	1 (0.4)
Femur fracture	1 (0.4)
Fournier's gangrene	1 (0.4)
Gallbladder polyp	1 (0.4)

Incidence of Serious TEAEs (ENVISION Safety Analysis Set)

Preferred Term	UGN-102 (N=240) n (%)
Headache	1 (0.4)
Hyponatraemia	1 (0.4)
Incarcerated inguinal hernia	1 (0.4)
Jaundice	1 (0.4)
Lung cancer metastatic	1 (0.4)
Nausea	1 (0.4)
Pneumonia	1 (0.4)
Transient ischaemic attack	1 (0.4)
Urethral stenosis	1 (0.4)
Urinary retention	1 (0.4)
Urosepsis	1 (0.4)

## Summary of Study Discontinuation by Study and Arm

Study	Treatment	0-3 Months	3 -6 Months	6 - 9 Months	>9 Months
ATLAS	UGN-102 +/- TURBT (N=142)	8 (5.6)	5 (3.5)	3 (2.1)	3 (2.1)
	TURBT alone (N=140)	16 (11.4)	6 (4.3)	7 (5.0)	5 (3.6)
ENVISION	UGN-102 (N=240)	2 (0.8)	2 (0.8)		1 (0.4)
OLYMPUS II	UGN-102 75 mg MMC (n=63)		1 (1.6)		2 (3.2)

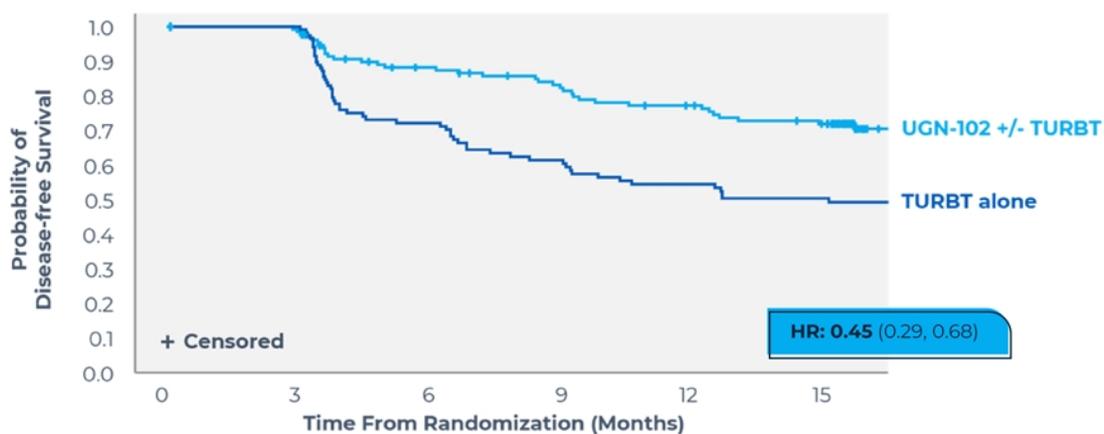
Preliminary Data



## Summary of Disease-Free Survival: Significantly More Total Recurrence and Progression in TURBT Alone Arm

	UGN-102 +/- TURBT (N = 142) / n (%)	TURBT Alone (N = 140) / n (%)
<b>Patients with Events, n (%)</b>	<b>37 (26.1)</b>	<b>55 (39.3)</b>
Recurrence of LG Disease	20 (14.1)	39 (27.9)
Progression to HG Disease	17 (12.0)	15 (10.7)
Death	0	1 (0.7)
<b>Patients Censored, n (%)</b>	<b>105 (73.9)</b>	<b>85 (60.7)</b>
<b>Hazard Ratio (95% CI)</b>	<b>0.45 (0.29, 0.68)</b>	

# DFS - 55% Reduction of Risk for Recurrence, Progression, or Death in the Intent to Treat Population



Number at Risk		0	3	6	9	12	15
<b>UGN-102 +/- TURBT</b>		142	128	108	96	87	73
<b>TURBT Alone</b>		140	119	76	60	54	42
Number Censored							
<b>UGN-102 +/- TURBT</b>		0	11	19	23	26	35
<b>TURBT Alone</b>		0	20	32	35	36	43

27 UroGen Data on File  
Source: Table 14.2.1.1a  
Kaplan-Meier Plot of Disease-Free Survival

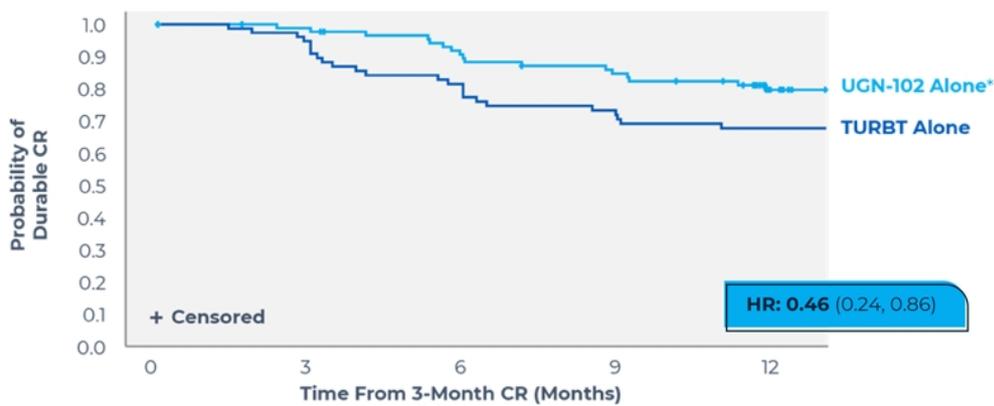
# Three-Month Complete Response Rates Were Similar Between Treatment Arms

Response	UGN-102 Alone (N = 142)		TURBT Alone (N = 140)	
	n (%)	CRR (95%CI)	n (%)	CRR (95% CI)
<b>Complete Response</b>	92 (64.8)	<b>64.8% (56.3, 72.6)</b>	89 (63.6)	<b>63.6% (55.0, 71.5)</b>
<b>Non-complete Response</b>	50 (35.2)		51 (36.4)	
Residual Disease	26 (18.3)		22 (15.7)	
Progression to HG Disease	12 (8.5)		9 (6.4)	
Indeterminate	3 (2.1)		0	
Missing	9 (6.3)		20 (14.3)	

## Summary of Duration of Response in Complete Responders: **Longer DOR with UGN-102 Alone**

	<b>UGN-102 Alone</b> (N = 92) / n (%)	<b>TURBT Alone</b> (N = 89) / n (%)
<b>Patients with Events, n (%)</b>	<b>18 (19.6)</b>	<b>24 (27.0)</b>
Recurrence of LG Disease	15 (16.3)	17 (19.1)
Progression to HG Disease	3 ( 3.3)	6 ( 6.7)
Death	0	1 ( 1.1)
<b>Patients Censored, n (%)</b>	<b>74 (80.4)</b>	<b>65 (73.0)</b>
<b>Hazard Ratio (95% CI)</b>	<b>0.46 (0.24, 0.86)</b>	

# DOR - 54% Reduction of Risk for Recurrence, Progression, or Death in Patients Who had a 3-Month CR



Number at Risk		0	3	6	9	12
UGN-102 Alone		92	86	77	71	49
TURBT Alone		89	73	60	53	34
Number Censored		0	3	6	9	12
UGN-102 Alone		0	5	7	8	26
TURBT Alone		0	12	15	16	31

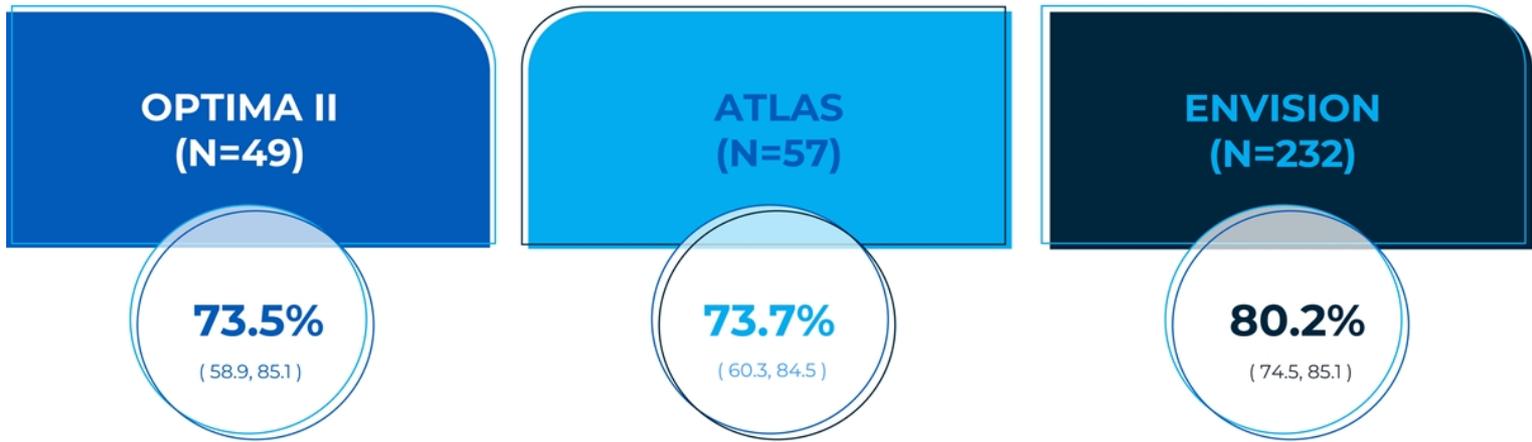
\*UGN Alone Subgroup of the UGN 102 +/- TURBT arm in ATLAS  
 UroGen Data on File  
 Source: Table 14.2.1.1a  
 Kaplan-Meier Plot of Duration of Response in Complete Responders

# Summary of Response Rate At 3-Month Disease Assessment: **CRR of 79.2%**

UGN-102 (N = 240)		
	n (%)	CRR (95% CI)
<b>Complete Response</b>	<b>190 (79.2)</b>	<b>79.2 (73.5, 84.1)</b>
<b>Non-Complete Response</b>	<b>50 (20.8)</b>	
Residual Disease	35 (14.6)	
Progression to HG Disease	6 (2.5)	
Indeterminate	4 (1.7)	
Missing	5 (2.1)	

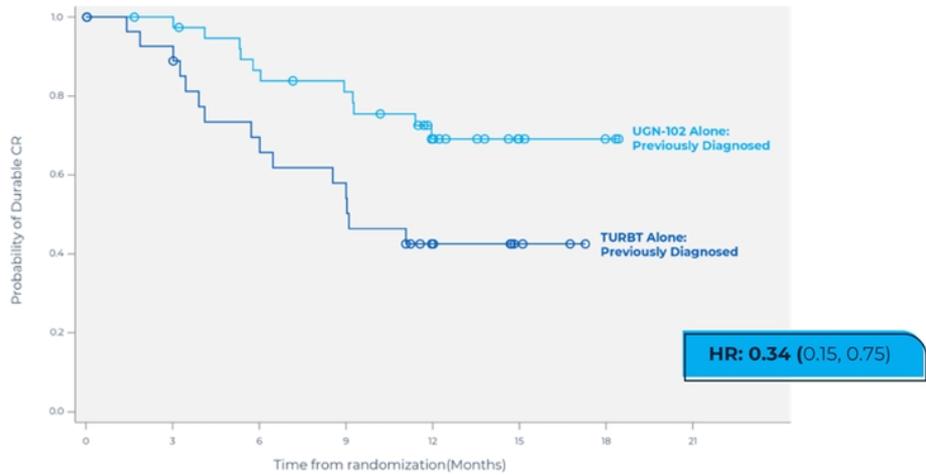


# Complete Response Rate for Recurrent Patients Within the UGN-102 Trials



UroGen Data on File  
Total OPTIMA II population n=63, recurrent population n=49  
Total ATLAS population n=282, recurrent population n=57  
Total ENVISION population n=240, recurrent population n=232

# DOR - 66% Reduction of Risk for Recurrence, Progression, or Death in Recurrent Patients Who Received UGN-102 Alone in the ATLAS Trial



UGN-102 Alone: Previously Diagnosed	42	38	32	29	16	4	2	0
TURBT Alone: Previously Diagnosed	35	25	18	15	7	3	0	0

41 \*UGN Alone Subgroup of the UGN 102 +/- TURBT arm in ATLAS  
UroGen Data on File  
Kaplan-Meier Plot of DOR in Complete Responders in the Recurrent Subgroup (ATLAS)



## UGN-102 Shows **Substantial Reduction of Risk** of Recurrence, Progression, or Death Across Multiple Patient Populations in ATLAS

**ITT – All Patients**  
DFS

**0.45** (0.29, 0.68)

**CR Duration – UGN-102 Alone**  
DOR

**0.46** (0.24, 0.86)

**Recurrent – UGN-102 Alone**  
DOR

**0.34** (0.15, 0.75)

## Demographics and Baseline Characteristics **Were Well Balanced** Between Treatment Arms

Characteristic	UGN-102 +/- TURBT (N = 142) / n (%)	TURBT Alone (N = 140) / n (%)
Median age (range), years	<b>68.0</b> (23, 85)	<b>67.0</b> (29, 88)
Age ≥ 65 years, n (%)	<b>91</b> (64.1)	<b>77</b> (55.0)
Sex, n (%)		
Male	<b>105</b> (73.9)	<b>93</b> (66.4)
Female	<b>37</b> (26.1)	<b>47</b> (33.6)
Any prior NMIBC episode, n (%)	<b>57</b> (40.1)	<b>66</b> (47.1)
Prior TURBT, n (%)	<b>55</b> (38.7)	<b>63</b> (45.0)

## Overall Summary of Adverse Events in ATLAS: Safety Profile Similar to Other Studies of UGN-102

	UGN-102 ± TURBT (N = 138)		TURBT Alone (N = 132)	
	Events	n (%)	Events	n (%)
<b>Any Adverse Events</b>	442	108 (78.3)	249	81 (61.4)
Any Serious Adverse Events	13	12 (8.7)	11	7 (5.3)
<b>Any TEAEs</b>	402	104 (75.4)	166	63 (47.7)
Any Treatment or Procedure Related TEAEs	211	65 (47.1)	21	15 (11.4)
Any Treatment Related TEAEs	186	54 (39.1)	19	15 (11.4)
Any Procedure Related TEAEs	65	31 (22.5)	2	2 (1.5)
Any TEAEs Leading to Treatment Discontinuation	19	5 (3.6)	NA	NA
Any TEAEs Leading to Study Discontinuation	7	4 (2.9)	2	2 (1.5)
<b>Any Serious TEAEs</b>	13	12 (8.7)	11	7 (5.3)
Any Treatment or Procedure Related Serious TEAEs	2	2 (1.4)	1	1 (0.8)
Any Treatment Related Serious TEAEs	0	0	1	1 (0.8)
Any Procedure Related Serious TEAEs	2	2 (1.4)	0	0
Any TEAEs Leading to Death	0	0	1	1 (0.8)
Any TEAEs of Special Interest	213	78 (56.5)	59	36 (27.3)

# Most Commonly Reported AEs and Serious TEAEs

## Incidence of Treatment-Emergent Adverse Events (≥ 5% in Either Group)

	UGN-102 ± TURBT (N = 138) / n (%)	TURBT Alone (N = 132) / n (%)
<b>Patients With Any TEAE</b>	<b>104 (75.4)</b>	<b>63 (47.7)</b>
Dysuria	42 (30.4)	6 (4.5)
Micturition urgency	25 (18.1)	10 (7.6)
Nocturia	25 (18.1)	9 (6.8)
Pollakiuria	22 (15.9)	8 (6.1)
Flatulence	13 (9.4)	4 (3.0)
COVID-19	11 (8.0)	8 (6.1)
Erectile dysfunction	9 (6.5)	4 (3.0)
Haematuria	9 (6.5)	6 (4.5)
Malaise	8 (5.8)	2 (1.5)

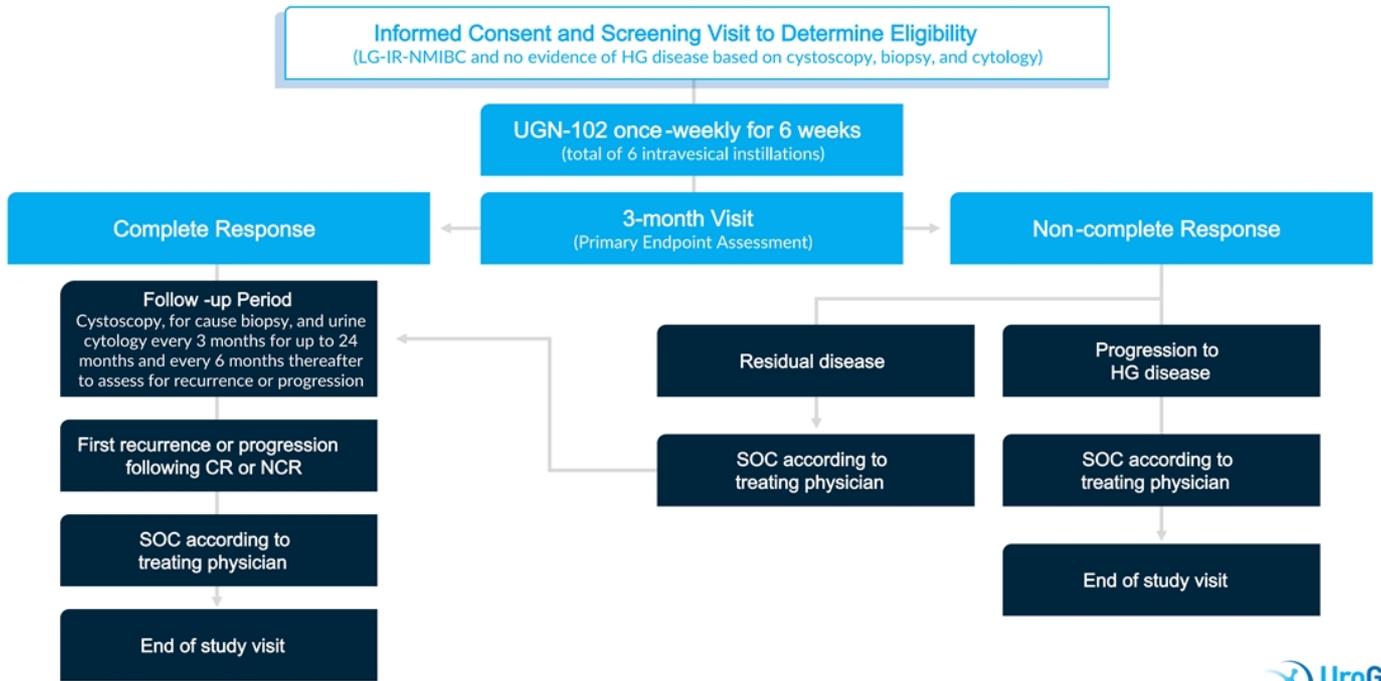
## Incidence of Serious TEAEs (≥ 1% in Either Group)

	UGN-102 ± TURBT (N = 138) / n (%)	TURBT Alone (N = 132) / n (%)
<b>Patients With Any Serious TEAE</b>	<b>12 (8.7)</b>	<b>7 (5.3)</b>
COVID-19	4 (2.9)	2 (1.5)
Sepsis	1 (0.7)	2 (1.5)
Haematuria	0	2 (1.5)

## Summary of Disease-Free Survival: Significantly More Total Progressions and Recurrences in TURBT Alone Arm

	UGN-102 +/- TURBT (N = 142) / n (%)	TURBT Alone (N = 140) / n (%)
<b>Patients with Events, n (%)</b>	<b>37 (26.1)</b>	<b>55 (39.3)</b>
Recurrence of LG Disease	20 (14.1)	39 (27.9)
Progression to HG Disease	17 (12.0)	15 (10.7)
Death	0	1 (0.7)
<b>Patients Censored, n (%)</b>	<b>105 (73.9)</b>	<b>85 (60.7)</b>
No Post-baseline Disease Assessment	10 (7.0)	20 (14.3)
Received Non-protocol Therapy	7 (4.9)	4 (2.9)
Early Termination	6 (4.2)	12 (8.6)
Disease-free at End of Study	81 (57.0)	49 (35.0)
Extended Lost to Follow-up	1 (0.7)	0
<b>Hazard Ratio (95% CI)</b>	<b>0.45 (0.29, 0.68)</b>	

# ENVISION Trial Design



## Summary of Demographics and Baseline Characteristics

Characteristic Statistic	UGN-102 (N = 240) / n (%)
<b>Age</b>	
Median Age (Min, Max)	70.0 (30, 92)
<b>Age Group 2 (Years), n (%)</b>	
>= 65	162 (67.5)
<b>Sex, n (%)</b>	
Male	147 (61.3)
Female	93 (38.8)
<b>Prior TURBT, n (%)</b>	
Yes	231 (96.3)
No	9 (3.8)
<b>Previous LG NMIBC Episodes, n (%)</b>	
Yes	224 (93.3)
No	16 (6.7)
<b>Treatment Course, n (%)</b>	
6 instillations	228 (95.0)
< 6 instillations	12 (5.0)

## Overall Summary of Adverse Events in ENVISION: **Safety Profile Similar to Other Studies of UGN-102**

	<b>UGN-102</b> (N = 240)	
	<b>Events</b>	<b>n (%)</b>
<b>Any Adverse Events</b>	<b>563</b>	<b>129 (53.8)</b>
Any Serious Adverse Events	26	19 (7.9)
<b>Any TEAEs</b>	<b>523</b>	<b>127 (52.9)</b>
Any Treatment or Procedure Related TEAEs	283	96 (40.0)
Any Treatment Related TEAEs	242	80 (33.3)
Any Procedure Related TEAEs	121	62 (25.8)
Any TEAEs Leading to Treatment Discontinuation	7	6 (2.5)
Any TEAEs Leading to Study Discontinuation	3	3 (1.3)
<b>Any Serious TEAEs</b>	<b>25</b>	<b>18 (7.5)</b>
Any Treatment or Procedure Related Serious TEAEs	4	4 (1.7)
Any Treatment Related Serious TEAEs	2	2 (0.8)
Any Procedure Related Serious TEAEs	3	3 (1.3)
Any TEAEs Leading to Death	2	2 (0.8)
Any TEAEs of Special Interest	241	96 (40.0)

# Treatment-Related AEs were Generally Mild to Moderate and in line with expectations in the field

## Incidence of Treatment-emergent Adverse Events (≥ 5%)

	UGN-102 (N = 240) / n (%)					
	Mild	Moderate	Severe or Medically Significant	Life-threatening	Death	Total
<b>Patients With Any TEAEs</b>	<b>60 (25.0)</b>	<b>47 (19.6)</b>	<b>16 (6.7)</b>	<b>2 (0.8)</b>	<b>2 (0.8)</b>	<b>127 (52.9)</b>
Dysuria	43 (17.9)	9 (3.8)	1 (0.4)	0	0	53 (22.1)
Haematuria	15 (6.3)	5 (2.1)	0	0	0	20 (8.3)
Pollakiuria	13 (5.4)	2 (0.8)	0	0	0	15 (6.3)
Urinary tract infection	4 (1.7)	10 (4.2)	0	0	0	14 (5.8)
Fatigue	9 (3.8)	4 (1.7)	0	0	0	13 (5.4)

## Incidence of Treatment Related Serious TEAEs

	UGN-102 (N = 240) / n (%)
<b>Patients With Any Serious TEAEs</b>	<b>2 (0.8)</b>
Urethral stenosis	1 (0.4)
Urinary retention	1 (0.4)