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): March 4, 2024

UROGEN PHARMA LTD.
(Exact name of registrant as specified in its charter)

Israel	**001-38079**	**98-1460746**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 7.01 Regulation FD Disclosure.

Furnished as Exhibit 99.1 to this report is a presentation of UroGen Pharma Ltd. (the "Company"), all or a portion of which is being presented by the Company at the TD Cowen 44th Annual Health Care Conference on March 4, 2024.

The information in this Item 7.01, including Exhibit 99.1, 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 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description
99.1	Company Presentation, dated March 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 4, 2024

UROGEN PHARMA LTD.

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

Exhibit 99.1

UroGen® Pharma

Developing Innovative Medicines to Treat Urothelial Cancers

March 2024

For investor audiences only. Not for promotional use with healthcare professionals.

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 estimated addressable patient population and market and revenue opportunity for *JELMYTO* in LG-UTUC, UGN-102 in LG-IR-NMIBC, and UGN-301 in HG-NMIBC; 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; the expectations regarding the annual and long-term growth of *JELMYTO* revenue; expected revenue trends for *JELMYTO*; UroGen's pipeline supporting long-term sustainable growth; the potential of *JELMYTO*®, UGN-102, and UGN-301 to transform the treatment paradigm in LG-UTUC, LG-IR-NMIBC, and HG-NMIBC, respectively; the clinical results from ATLAS and ENVISION providing optimism for potential FDA approval of UGN-102; the Company's pending patent applications, may not be successful and in such event the duration of our intellectual property protection would be more limited; the potential advantages of the antegrade administration of *JELMYTO*; the potential prescriber behavior, expected interest in prescribing as well as growing awareness and adoption of JELMYTO; the expectation that UGN-102 will be a significant driver of UroGen's future growth; the potential of UGN-102 to be the first non-surgical chemoablative therapy in LG-IR-NMIBC; the potential advantages of UGN-102 over TURBT; plans to submit an NDA for UGN-102 to the FDA in 2024; the expectation of ENVISION duration of response data in 2Q 2024; the expectation of safety and dosing data from the first arm evaluating UGN-301 as monotherapy in mid-2024; UroGen priorities including the advancement of pre-commercial activities for UGN-102, plans for capital preservation, use of sales strategy to accelerate *JELMYTO* adoption, a focus on urologic oncology expertise, and focus on UGN-301 as monotherapy and combination therapy to advance immune-oncology pipeline; the importance of and operational efficiencies created by the 2022 label update that extended the stability period for *JELMYTO* admixture and its potential to reduce operational hurdles to uptake upon launch of UGN-102; confidence in the future of JELYMYTO; the potential that *JELMYTO* is adopted as a standard of care; the interpretation and summary of results of OLYMPUS Phase 3, OPTIMA Phase 2b, ATLAS, and ENVISION trials; the size and importance of the shared *JELMYTO* and UGN-102 prescriber base; and the encouraging effects of combining UGN-301 with UGN-201 (UGN-302). 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 Securities and Exchange Commission (SEC) on November 14, 2023, and other filings that UroGen makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen'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.

UroGen is pioneering new therapies to meet the unique needs of patients with urothelial cancers by utilizing proprietary technology to potentially enhance proven and novel medicines and deliver them aligned with the way Urologists practice

Successful Commercial Product:

JELMYTO is the first and only FDA-approved non-surgical treatment for patients with LG-UTUC

Late-Stage Clinical Asset:

UGN-102 being developed as a minimally invasive, non-surgical option that has the potential to set the new standard of care for LG-IR-NMIBC. Clinical NDA submission planned for 2024. 10x larger potential patient population than LG-UTUC.

Immuno-Oncology Pipeline:

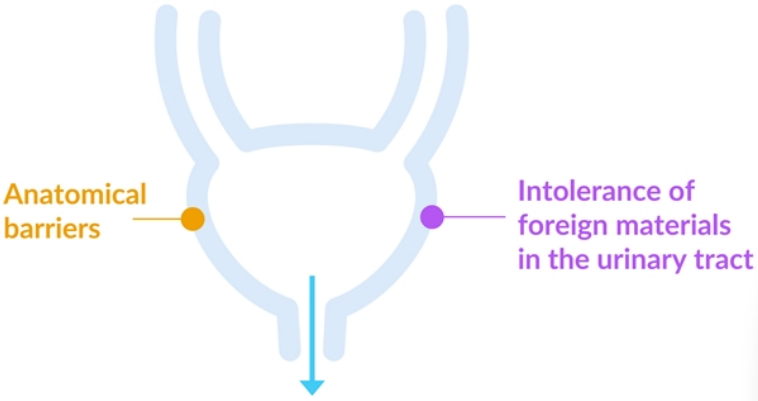
UGN-301 is an anti-CTLA 4 monoclonal antibody for monotherapy and combination intravesical solution for use in high grade NMIBC

Strong Balance Sheet:

$154 million in cash at September 30, 2023

Invasive and Radical Surgery is the Standard of Care in Urothelial Cancers

Urothelial cancers are challenging to treat:



The urinary tract is designed to void, which poses challenges including limited dwell time for chemotherapies and other therapies delivered to the bladder.

Resulting in:

- Repetitive risky surgeries
- Lost kidneys and organs
- Increased risk of morbidity in elderly patients

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 from 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**

UroGen Pharma

Unlocking A Strong Foundational Pipeline Supporting Long-Term Sustainable Growth

JELMYTO
(UGN-101)

Low-grade Upper Tract Urothelial Carcinoma (LG-UTUC)

UGN-102
Phase 3

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

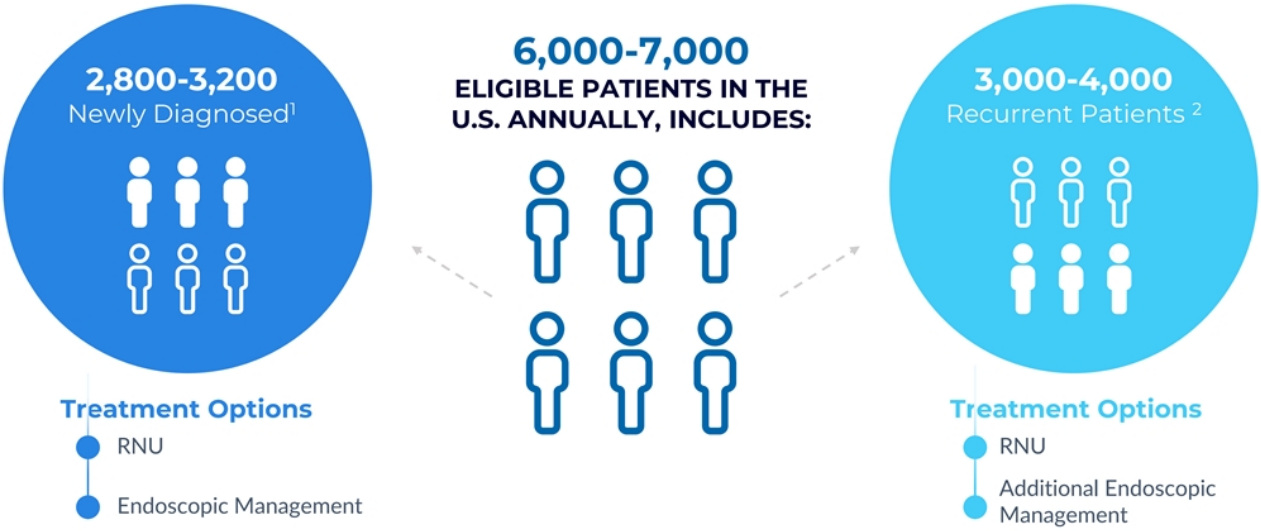
UGN-301
Phase 1

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

1. SEER*Stat Database (2019) Surveillance Research Program; Curr Urol Rep (2016) 17: 68; Ther Adv Urol. 2012 Feb; 4(1): 13–32; UroGen Market Research.

Changing the Treatment Paradigm for Urothelial Cancers

LG-UTUC Is a Rare Disease that Recurs Often



UC is the costliest cancer in the U.S. healthcare system on a per-patient basis[4]

70%-80%
of LG-UTUC patients ultimately receive nephroureterectomies[3]

1. Upfill-Brown 2018, 2. Cutress 2012, 3. Grasso et al. (2012) BJU International, 4. Yeung et al. (2014) Pharmacoeconomics
RNU = radical nephroureterectomy

JELMYTO First & Only FDA-Approved Non-Surgical Treatment for Patients with LG-UTUC

Clinically Meaningful OLYMPUS Phase 3 Data[1]

58% Complete Response Rate at 3-months[2]

82% Durability of Response at 12-months by KM estimate[2]

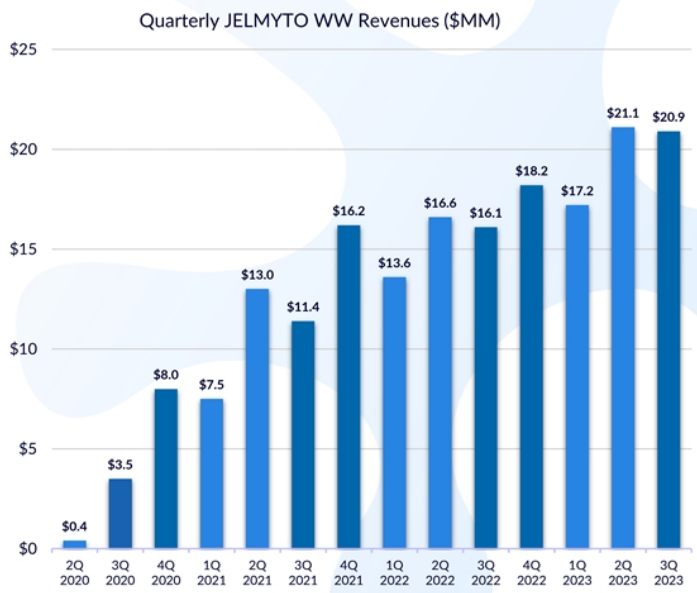
29 months Median Durability of Response (14.6 to 47.6 months) data from long-term follow-up study[3,4]

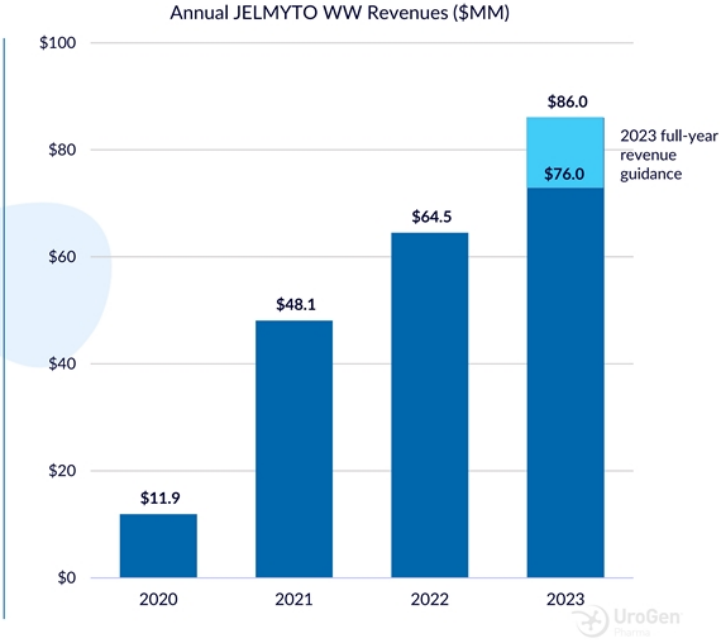
1. Important Safety Information and the full Prescribing Information available at https://www.urogen.com/download/pdf/jelmyto_prescribing.pdf
2. Matin, Surena F. J Urol. 2022 Apr;207(4):779-778
3. Pierorazio, Philip M. Long-term outcomes of treatment with UGN-101. SUO 2022, #158
4. Limitations of long-term follow-up study include N=16. Please refer to the referenced citations for disclosures of such limitations.

UroGen Pharma

JELMYTO Revenue Trend Reflects Long-term Growth

Observed QoQ Variability Is Expected with Summer/Holiday Seasonality





Changing the Urologic Cancer Landscape Post Launch

Growing Awareness and Adoption of JELMYTO Supports Use of RTGel®-based Therapies in Urology

Patient Identification & Adoption

- **1,088** practices/hospitals activated[1]
- 

Expected interest in prescribing JELMYTO over next 12 months[2]

Reimbursement

- Permanent J code effective January 1, 2021 to standardize and facilitate reimbursement; ASP +6% implemented
- Majority of large commercial plans have policies in place, covering over 150 million lives
- **≥96%** Positive reimbursement across all payer types[1]

Demonstration of Strong Support from Urologists

- **296 accounts** have treated more than one patient[1]
- High repeat use and awareness

1. Numbers as of November 1, 2023
2. UroGen market research, 91 urologists surveyed who are not currently prescribing JELMYTO (July 2022)

Growing Body of Real-World Evidence Supports Use Case for JELMYTO*

Data From 2+ Years In Market Reinforces JELMYTO Efficacy and Safety

- Independent Multicenter Reviews Support JELMYTO Real-World Effectiveness, Including as a Chemoablative Agent and Treatment of Residual Disease Following Endoscopic Resection
- Evaluated Outcomes in Range of Tumor Types; Evidence for Favorable Response in Patients with Low-Volume Residual Disease
- Varied Practice Patterns, with Antegrade Method of Administration via Nephrostomy Tube Shown as Viable

*Real world retrospective studies have inherent evidentiary limitations. Please refer to the referenced citations for disclosures of such limitations.

Select Results

69% CR

When JELMYTO treated residual disease following laser ablation (overall CR 59% in OLYMPUS)

23% Ureteric Stenosis

As compared to 44% in OLYMPUS. ~1/2 of patients were treated with antegrade administration.

Woldu, et al. Early Experience with UGN-101 for the Treatment of Upper Tract Urothelial Cancer – A MultiCenter Evaluation of Practice Patterns and Outcomes. *Urol Oncol*.

UGN-102: Anticipated Primary Driver of UroGen Future Growth

Potential to Transform the Treatment Paradigm in Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

UGN-102 Potential to be the First Non-Surgical Chemoablative Therapy in Low-Grade Intermediate Risk Disease

Low-grade IR NMIBC

Issue: chronic recurrence; rarely progresses to high-grade disease

SOC: repetitive TURBT

Newly diagnosed: ~22K/year

Recurrent: ~60K/year

Limited competition: UGN-102 is furthest along in clinical development as a non-surgical chemoablative therapy

BCG is not widely used in low-grade disease

VS

High-grade NMIBC

Issue: progression, metastasis & death

SOC: TURBT, BCG, radical cystectomy, clinical trials

Incidence: ~25K

BCG-refractory: 18.7K

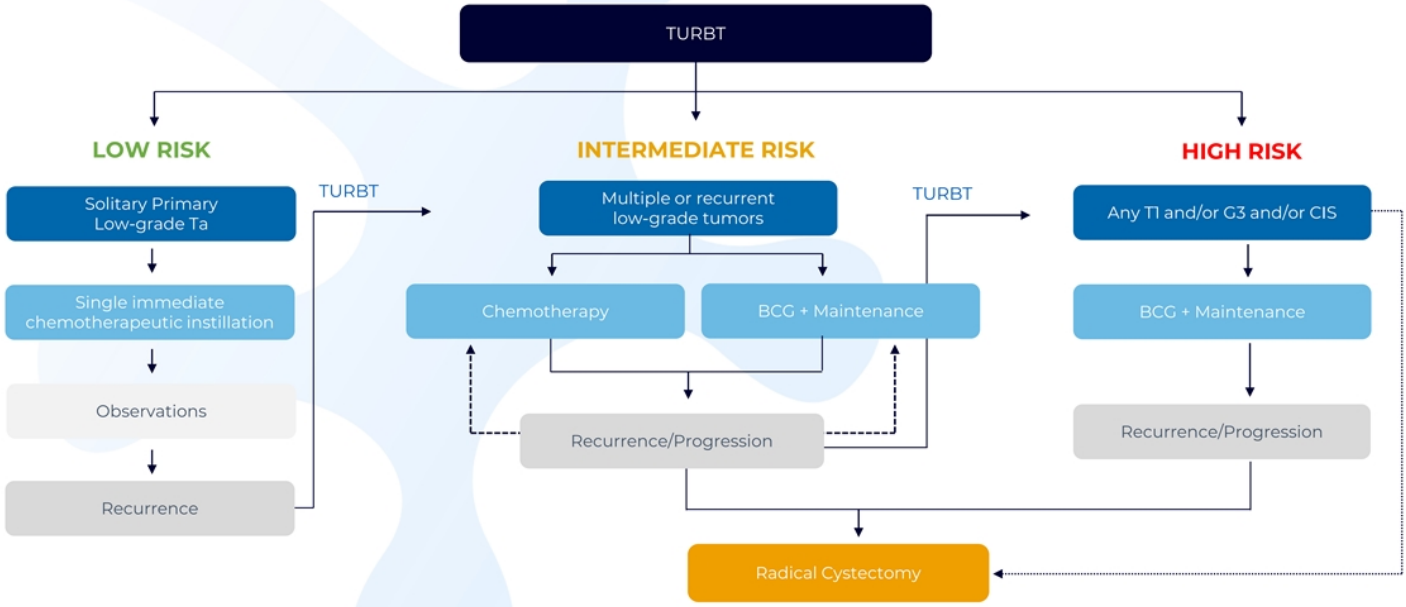
Clinical trials ongoing in BCG-refractory populations.

Significant unmet need given low response rates and durability

Goal is to avoid radical cystectomy

1. ACS Cancer Facts & Figures 2023 2. SEER, AUA/SUO joint guideline 3. Babjuk et al. European Urology (2019), Simon (2019),

Bladder Cancer Treatment Algorithm



Brausi et al. JUrol; December 2011. DOI:10.1016/j.juro.2011.07.076

UGN-102 Focus on Improving Patient Outcomes with Noninvasive, Durable Option for LG-IR-NMIBC

~82,000[1]
patients in the U.S. annually

60,000
Recurrent Patients[1,2,3]

22,000
New Patients[1,2,3]

INTERMEDIATE RISK (IR) PATIENTS ARE CHARACTERIZED BY 1-2 OF THE FOLLOWING[4]:

- Multiple tumors
- A low-grade solitary tumor >3 cm
- Recurrence of LG NMIBC within one year of the current diagnosis

1. ACS Cancer Facts & Figures 2023 2. SEER, AUA/SUO joint guideline 3. Babjuk et al. European Urology (2019), Simon (2019), 4. Tobert et al Urology (2019), Rhijn et al Nature Urology (2016), 4. Bryan et al Ann R Coll Surg Engl (2010)
*Adjuvant chemotherapy only used in 0-30% of U.S. eligible population
TURBT = trans urethral resection of bladder tumor

NMIBC Patients Can Find Themselves in a Frustrating Cycle of Treatment

~68%

of recurrent patients **have 2 or more recurrences**[1]

~23%

of recurrent patients **have 5 or more recurrences**[1]

~82,000

addressable LG-IR-NMIBC patients[2-5]

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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Patient Populations with Expected Rapid Adoption of UGN-102

- Multiple recurrences[1]
- Surgically ineligible[1]
- Early recurrences[2]

In a recent survey, **92%** of Urologists stated they would used UGN-102[3]

1. Areas of greatest unmet need, Qualitative in-depth interviews fielded September 2019 (N = 19 UROs, 8 patients)
2. Highest likelihood of use, Quantitative surveys fielded September 2023 (N = 111)
3. Based on survey conducted by UroGen in Q3 2023 of 111 board-certified urologists. Vendor IQVIA

ENVISION Patient Experience was Positive

Impact to Daily Life

TURBTs impacted daily activities for about one week

UGN-102 didn't affect daily responsibilities for most patients

Unmet Need

Nearly all patients felt strongly that a non-surgical treatment would be preferable to surgery

Patient Preference

The majority of patients reported they would recommend UGN-102 to other patients, citing:

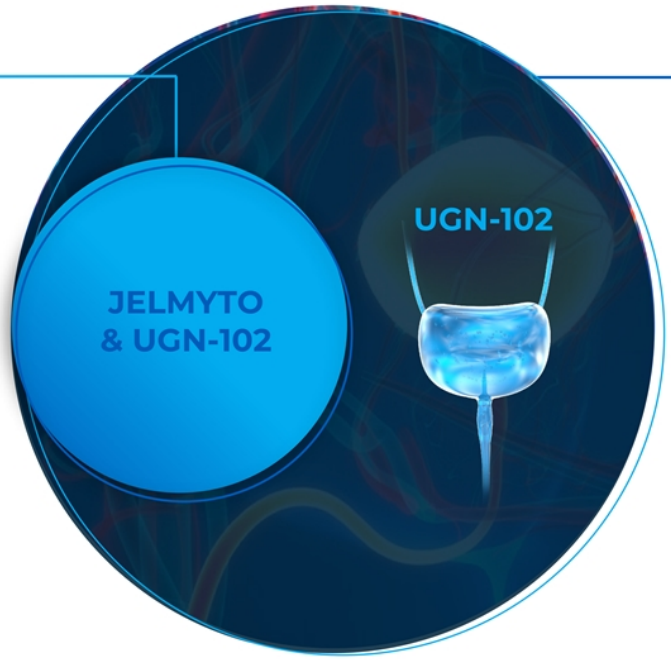
- Lack of disruption to daily life
- Less invasive
- Less painful
- Less time-consuming
- No post-op catheter

Work conducted by UNC-Chapel Hill faculty (Stover AM and Smith AB) who interviewed patients with NMIBC (N=31) participating in the Phase 3 ENVISION trial. . Paper in progress.

UGN-102: Leveraging Similarities with Distinct Advantages

JELMYTO® & UGN-102

- **RTGel® & mitomycin formulations**
- **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

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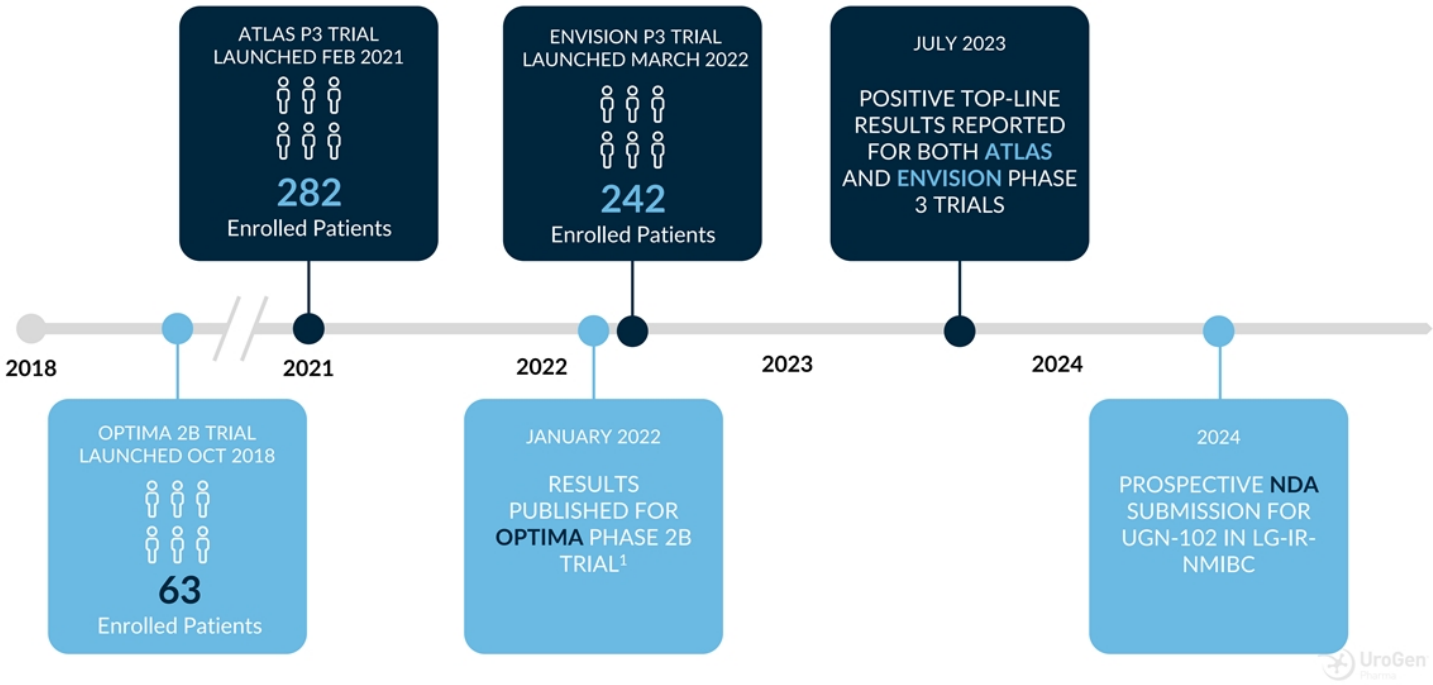
Overview of UGN-102 Program



1 J Urol. 2022 Jan; 207(1): 61–69.

ENVISION: Summary of Response Rate At 3-Month Disease Assessment

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

UroGen Data on File
Summary of Response Rate At 3-Month Disease Assessment

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UGN-102 Has Demonstrated Compelling Clinical Results in Both Phase 3 Clinical Trials

Endpoint	ENVISION Previously diagnosed with prior TURBT	ATLAS[4] Recurrent sub-group with prior TURBT	ATLAS ITT[4] Newly diagnosed and recurrent patients
Complete Response Rate[1] (CR) at 3-month disease assessment	**79%**	**74% vs. 53%**	**65% vs. 64%** Similar CRR; offers a less invasive option to patients
Duration of Response (DOR) at 12-months following CR	**TBD**	**66% vs. 40%**[2] HR = 0.34 (66% Risk Reduction)	**80% vs. 68%**[2] HR = 0.46 (54% Risk Reduction)
Disease-Free Survival[3] (DFS) at 12-months following randomization	**N/A**	**72% vs. 37%** HR=0.295 (70% Risk Reduction)	**72% vs. 50%**[3] HR= 0.45 (55% Risk Reduction)
Median Disease-Free Survival (DFS)	**TBD**	**Not reached vs. 7.2 months**	**Not reached vs. 14.8 months**

1. Complete Response defined as having no detectable disease (NDD) in the bladder at 3-month assessment following treatment
2. Probability of maintaining a durable response at 12-months post CR by Kaplan-Meier analysis (total of 15 months)
3. Defined as the time from randomization until the earliest date of an event (total of 12-months)
4. Patients in treatment arm received UGN-102 +/- TURBT vs. TURBT alone

Prasad et al. JURol, 7Aug2023,
UroGen Data on File, Source: Table 14.2.2.2.1a

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Looking Ahead

ENVISION DOR data expected in

2Q 2024

Planned NDA Submission by

4Q 2024

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UGN-103: Next-Generation Novel Mitomycin-Based Formulation

Licensing agreement with medac GmbH to commercialize a next-generation novel mitomycin-based formulation

Combines UroGen's RTGel® technology with medac's proprietary mitomycin

UroGen plans to initiate a Phase 3 study in 2024 to evaluate UGN-103 in LG-IR-NMIBC

Potential IP protection until 2041

POTENTIAL ADVANTAGES

- Production
- Supply
- Cost
- Product convenience

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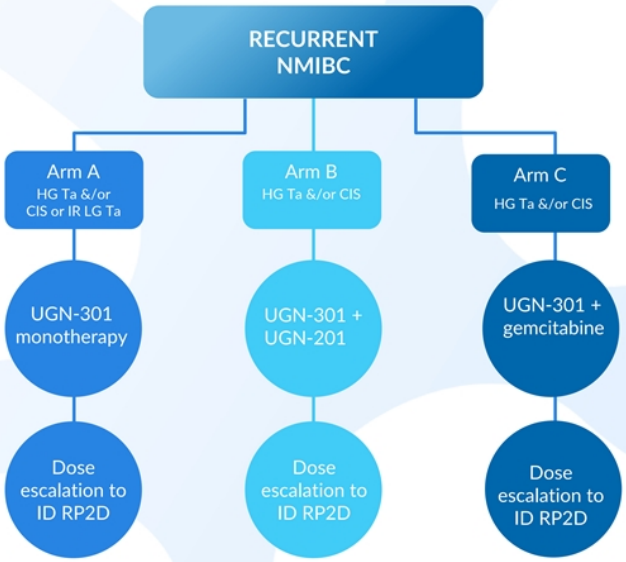
Expanding to Immuno-Oncology with Potential Monotherapy and Combination Therapy
JELMYTO
(UGN-101)
UGN-102
UGN-301

Ongoing Multi-arm Phase 1 Trial of UGN-301 (zalifrelimab)

Anti-CTLA4 Antibody for use in High-Grade Bladder Cancer



- Phase 1 clinical study **utilizes a Master Protocol, evaluates safety, tolerability and the potential Phase 2 dose** of UGN-301 as monotherapy and in combination with other agents, including UGN-201
- **Safety and dosing data from the first arm evaluating UGN-301** as monotherapy expected mid-2024
- **Initiated combination therapy arms** evaluating **UGN-301 + UGN-201**[1] and **UGN-301 + gemcitabine** in HG-NMIBC Patients

1. UGN-201 is UroGen's proprietary formulation of imiquimod, a toll-like receptor 7 (TLR 7) agonist

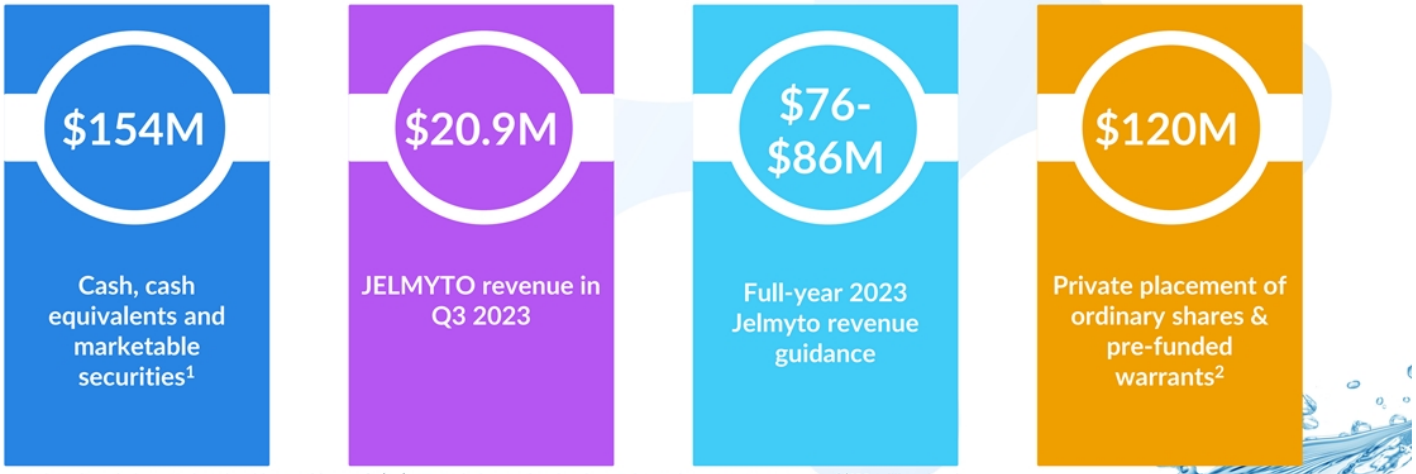
Looking Ahead

UroGen Priorities

- Advance pre-commercial activities for UGN-102 in LG-IR-NMIBC; Data from 12-month durability of response data anticipated in 2Q 2024; prospective NDA submission by 4Q 2024
- Accelerate JELMYTO U.S. adoption leveraging adjusted sales strategy
- Support balance sheet with focus on strategic and efficient capital deployment, including prioritization of UGN-102 pre-commercialization and launch plan
- Evaluate growth-minded business development opportunities with focus on leveraging urologic oncology expertise
- Advance immuno-oncology pipeline, focusing on UGN-301 as monotherapy and combination therapy

Q3 2023 Financial Snapshot

Strengthened balance sheet to focus on maximizing shareholder value through disciplined investment supporting clinical and commercial execution



1. Cash, cash equivalents, and marketable securities as of 9/30/2023. Excludes restricted cash on Balance Sheet; 2. Gross proceeds of $120 million via private placement of ordinary shares and pre-funded warrants before deducting fees to placement agents and financial advisors and before other expenses paid by UroGen.

UroGen® Pharma

Thank You

March 2024

APPENDIX

Extended 96-hour Shelf-Life Increases Operational Efficiencies

September 2022 Label Update Extended Stability Period for JELMYTO Admixture from 8 Hours to 96 Hours

Increased flexibility

- Provides pharmacists more flexibility in handling chilling block and printed product labels
- Flexible scheduling for instillation times benefits both patients and providers
- Rx partners can mix and deliver the prior day

Reduced gaps in treatment availability

- Longer shelf life allows for more drive-time, extending geographic coverage of mixing partners
- Optimizes Territory Business Managers' (TBM) time in field

Expanded future opportunities

- Opportunity to re-engage with prospective customers who have expressed hesitancy due to logistical challenges
- Potentially reduces operational hurdles to uptake upon launch of UGN-102

Confident in JELMYTO's Future Outlook

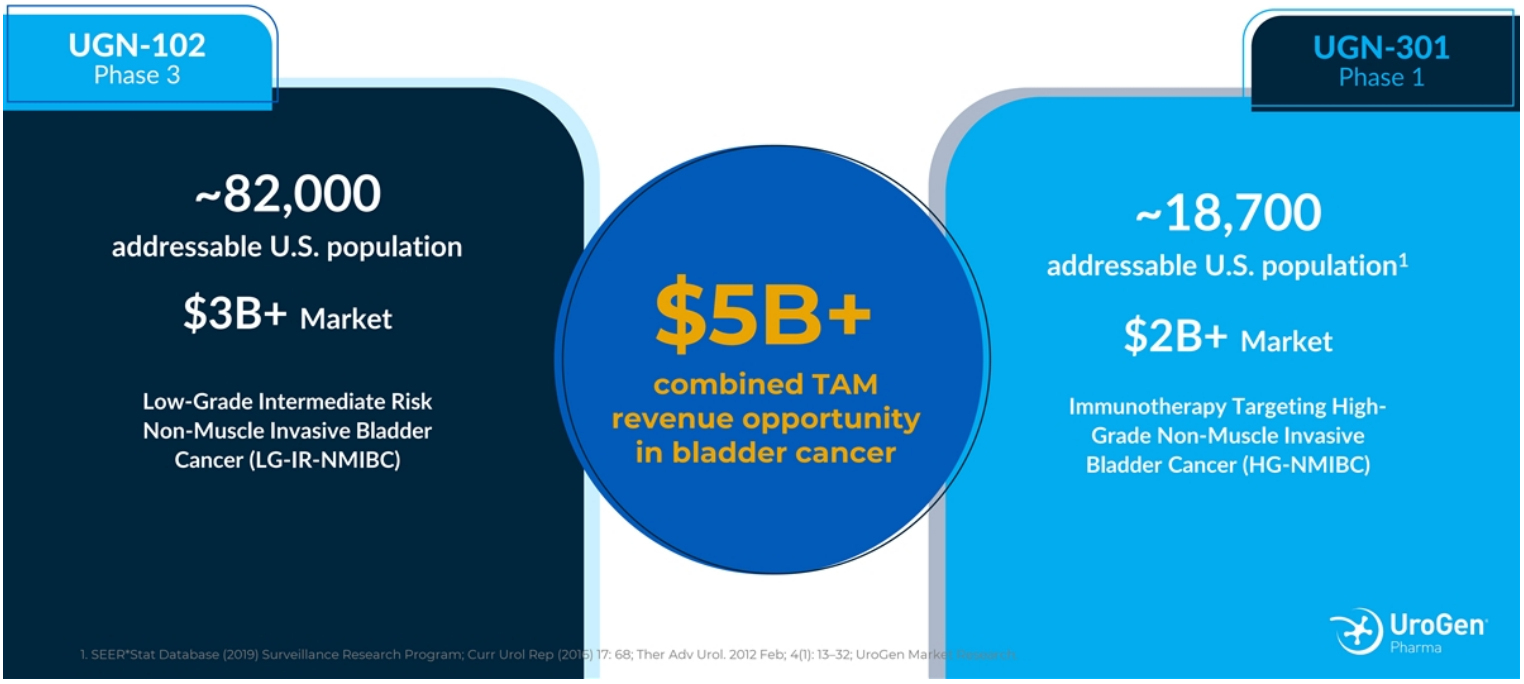
High Performing and Growth in Developing Territories Reflect Potential to Adopt **JELMYTO as SOC**

Growing Body of Multicenter **Real-World and Long-Term Follow-up Data** Support Use Case for JELMYTO

Antegrade Administration Offers Efficient Mode of Administration and a Favorable Safety Profile

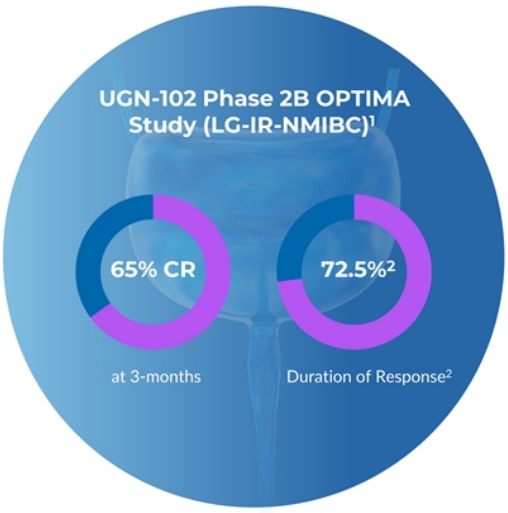
JELMYTO 2022 Label Update with **Extended Shelf Life Increases Operational Efficiencies** and Potentially Reduces Barriers to Uptake

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

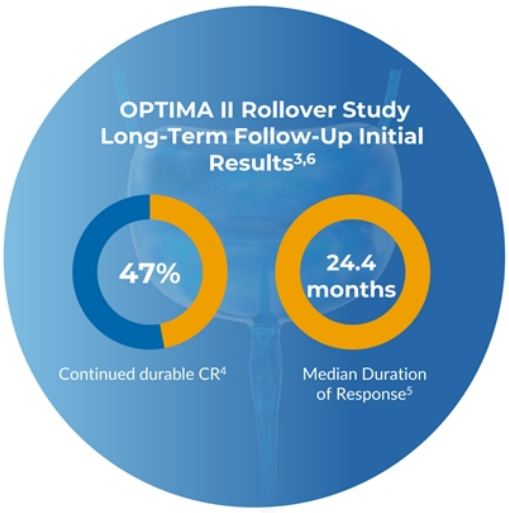


1. SEER*Stat Database (2019) Surveillance Research Program; Curr Urol Rep (2015) 17: 68; Ther Adv Urol. 2012 Feb; 4(1): 13–32; UroGen Market Research

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



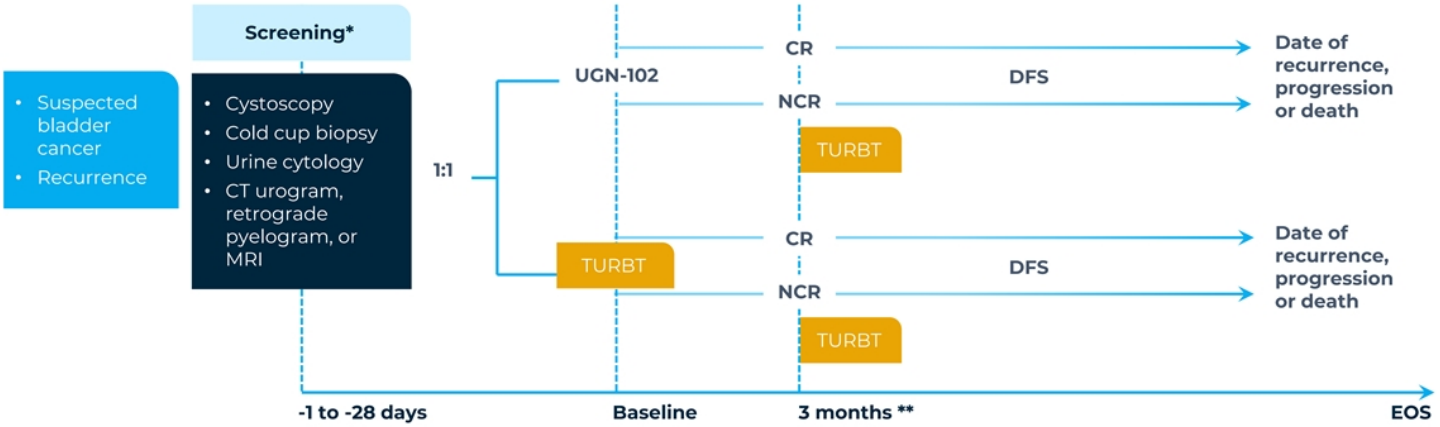
These data suggest continued durability in patients treated with UGN-102



1. Chevli et al. JUrol Jan2022
2. Estimated probability by Kaplan-Meier analysis that a patient will remain in CR at 9-months post CR (12 months after treatment initiation).
3. Chevli et al. Long-Term Outcomes of Treatment with UGN-102 for Primary Chemoablation of LG-IR-NMIBC. Poster presented at: 23rd Annual Society of Urological Oncology (SUO); December 2, 2022; San Diego, CA
4. 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 participatee in this rollover study.
5. Duration of complete response (10.1 – 30.7 months); median range among 15 evaluable patients
6. Limitations of long-term follow-up study include N=15. Please refer to the referenced citations for disclosures of such limitations.


ATLAS

ATLAS Trial Design



CR: Complete Response
NCR: Non-Complete Response
DFS: Disease-free Survival
EOS: End of Study

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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)

A limitation of this study is that enrollment was halted early to pursue an alternative development strategy after fewer than half of the planned number of patients had been enrolled rendering the trial underpowered to determine whether primary chemoablation with UGN-102 is statistically superior to TURBT monotherapy

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

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ATLAS Scorecard Highlights Clinically Meaningful, Durable Results for UGN-102 Overall and Relative to TURBT

Analysis	Assessment	UGN-102 +/- TURBT vs TURBT Alone
Primary Endpoint of Disease-Free Survival (DFS)	✓	**72% vs. 50%** Probability of Disease-Free Survival (KM) at 15 months HR = 0.45 (55% Risk Reduction)
Complete Response Rate (CRR) at 3-months	✓	**65% vs. 64%** Similar CRR; offers a less invasive option to patients Reponses are durable
Duration of Response (DOR)	✓	**80% vs. 68%** Probability of Maintaining a Durable Response at 12 months post-CR (KM) HR=0.46 (54% Risk Reduction)
DOR in Recurrent Sub-group with 1-prior TURBT	✓	**66% vs. 40%** Probability of Maintaining a Durable Response at 12 months post-CR (KM) HR=0.34 (66% Risk Reduction)
Median Time of DFS	✓	**Not Reached vs 14.8 months**
Safety	✓	Comparable to profile observed in other studies

DFS: Disease-free survival; DOR: Duration of response; CRR: complete response rate; KM: Kaplan Meier; HR: Hazard Ratio; TURBT: trans urethral resection of bladder tumor

Prasad et al. JURol, 7Aug2023
UroGen Data on File
Source: Table 14.2.2.2.1a

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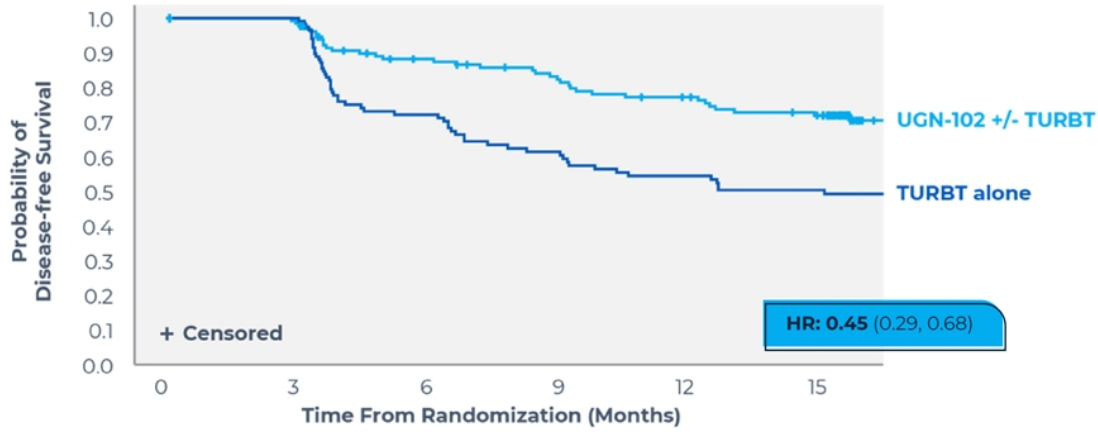
ATLAS DFS - 55% Reduction of Risk for Recurrence, Progression, or Death in the Intent to Treat Population in ATLAS

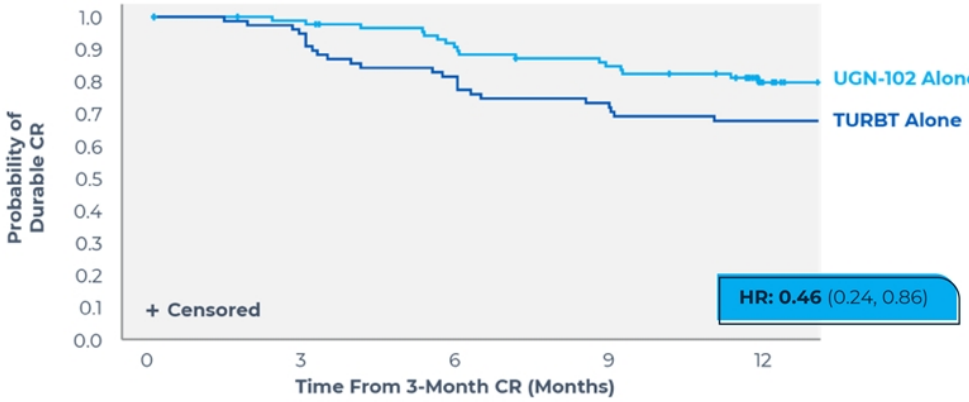


Number at Risk						
UGN-102 +/- TURBT	142	128	108	96	87	73
TURBT Alone	140	119	76	60	54	42
Number Censored						
UGN-102 +/- TURBT	0	11	19	23	26	35
TURBT Alone	0	20	32	35	36	43

Prasad et al. JURol 7Aug2023
UroGen Data on File
Source: Table 14.2.1.1a
Kaplan-Meier Plot of Disease-Free Survival

UroGen Pharma

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

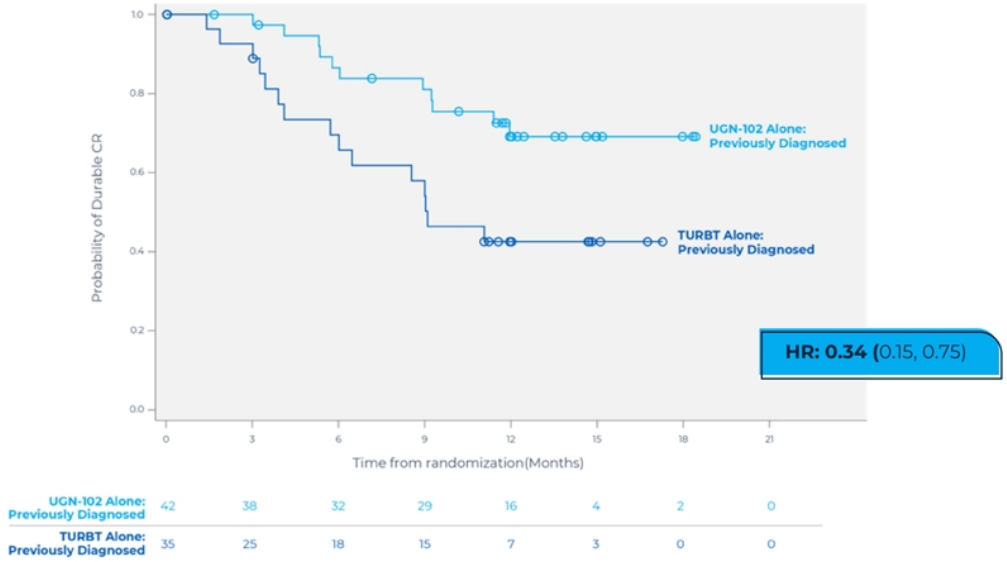


Number at Risk					
UGN-102 Alone	92	86	77	71	49
TURBT Alone	89	73	60	53	34
Number Censored					
UGN-102 Alone	0	5	7	8	26
TURBT Alone	0	12	15	16	31

*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

UroGen Pharma

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



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

*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)

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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** (%)
Patients with Events, n (%)	**37 (26.1)**	**55 (39.3)**
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)
Patients Censored, n (%)	**105 (73.9)**	**85 (60.7)**
Hazard Ratio (95% CI)	**0.45 (0.29, 0.68)**	

UroGen Data on File
Source: Table 14.2.1.1
Full table in Appendix

UroGen Pharma

Three-Month Complete Response Rates Were Similar Between Treatment Arms in ATLAS

Response	UGN-102 Alone (N = 142) n (%)	UGN-102 Alone (N = 142) CRR (95%CI)	TURBT Alone (N = 140) n (%)	TURBT Alone (N = 140) CRR (95% CI)
Complete Response	92 (64.8)	**64.8% (56.3, 72.6)**	89 (63.6)	**63.6% (55.0, 71.5)**
Non-complete Response	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)	

Prasad et al. JURol, 7Aug2023
UroGen Data on File
Source: Table 14.2.2.2.1a

UroGen Pharma

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

	UGN-102 Alone (N = 92) / **n** (%)	TURBT Alone (N = 89) / **n** (%)
Patients with Events, n (%)	**18 (19.6)**	**24 (27.0)**
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)
Patients Censored, n (%)	**74 (80.4)**	**65 (73.0)**
Hazard Ratio (95% CI)	**0.46 (0.24, 0.86)**	

UroGen Data on File
Source: Table 14.2.2.3.1a
Full table in Appendix

UroGen Pharma

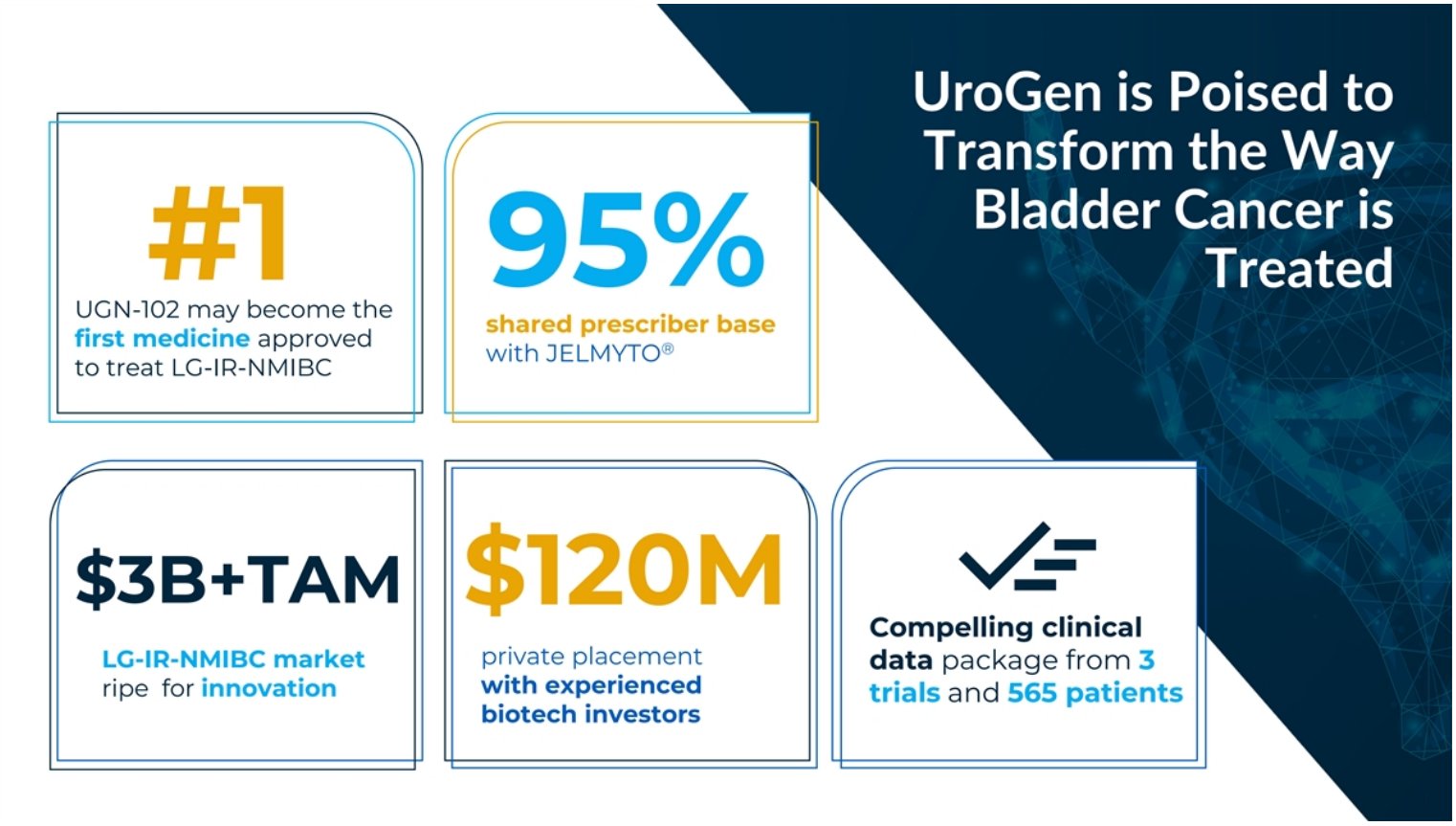
UGN-102 Shows Substantial Reduction of Risk of Recurrence, Progression, or Death Across Multiple Patient Populations in ATLAS

ITT[1] – All Patients	**0.45** (0.29, 0.68)
Complete Responders – UGN-102 Alone	**0.46** (0.24, 0.86)
Recurrent Complete Responders[2] – UGN-102 Alone	**0.34** (0.15, 0.75)

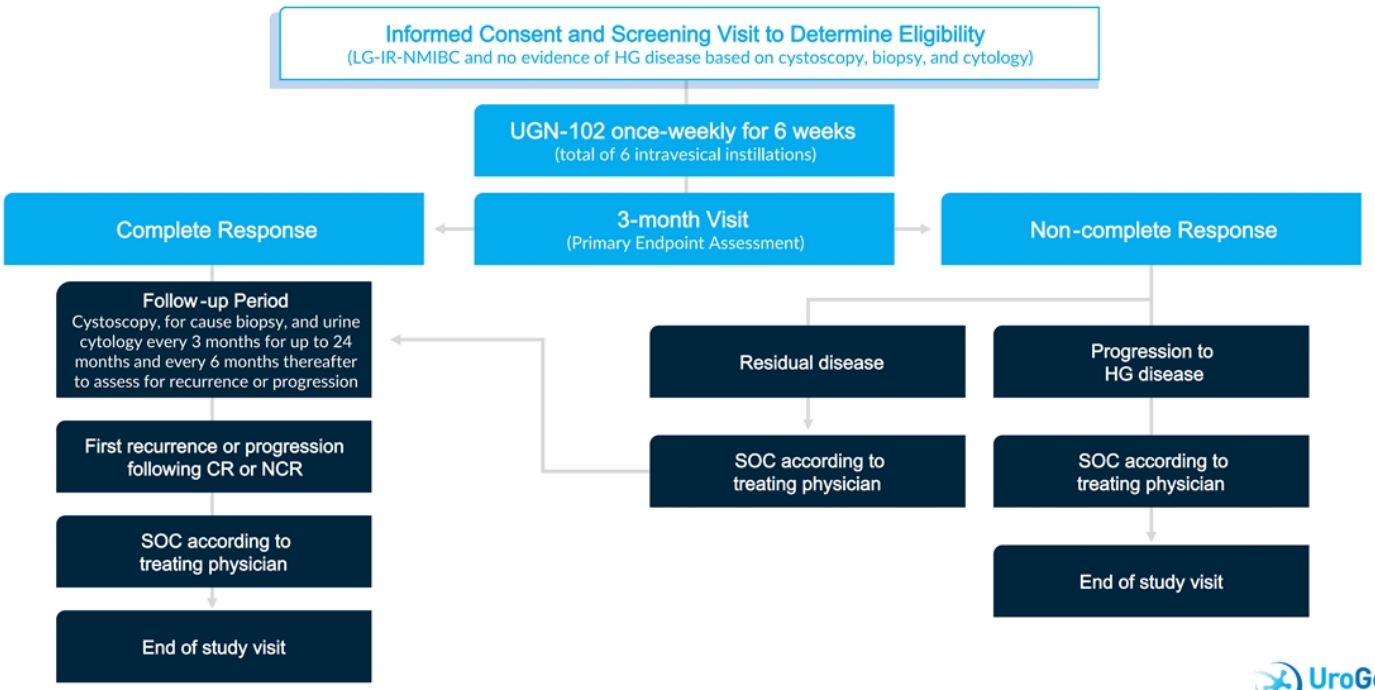
1. Intent to Treat population (all comers)
2. Recurrent subgroup with prior TURBT (comparable to ENVISION patient population)

UroGen Data on File
Various ATLAS 3-Month CR Rate Cohorts

UroGen Pharma


UroGen is Poised to Transform the Way Bladder Cancer is Treated
#1
UGN-102 may become the first medicine approved 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

ENVISION Trial Design



SOC: Standard of Care

UroGen Pharma

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**
  - ✓**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

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

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Standard of Care for HG-NMIBC

CURRENT TREATMENT

TURBT, BCG, Clinical trials, Radical Cystectomy

ANNUAL U.S. PATIENTS*

~18,700

BCG Unresponsive

CLINICAL TRIALS ONGOING IN BCG-REFRACTORY POPULATIONS

- Significant unmet need given low response rates and durability
- Goal is to avoid radical cystectomy (bladder removal)

*SEER, AUA/SUO Joint Guidelines, Babjuk et al. European Urology (2019), Simon 2019, UGN-301 initial target patient population

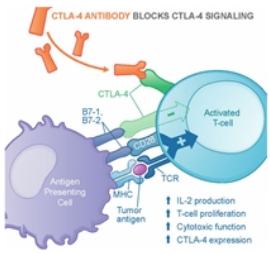
UroGen Pharma

Combining UGN-301 with UGN-201 (UGN-302) Shows Encouraging Activity as a Novel Agonist / Antagonist Immunotherapy Combination

TLR 7 (UGN-201): stimulates cytokines and T & B cells

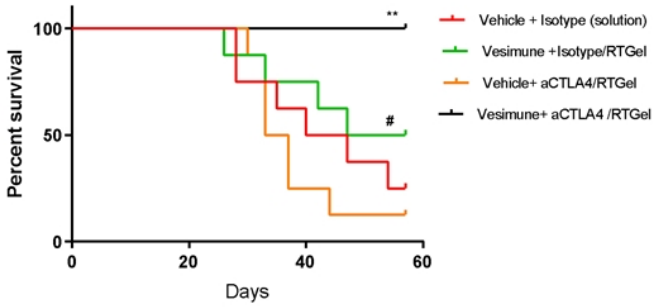
Phase 1 & 2 human data suggest UGN-201 activity in human bladder cancer

Anti-CTLA4 (UGN-301): blocks "cancer masking" action of CTLA4



HG-NMIBC is responsive to immunomodulation as evident from experience with BCG

UGN-201 + UGN-301 = UGN-302: Non-clinical data suggest improved survival (murine) and decreased tumor size when **201** and a **CTLA4** inhibitor are combined



Patinote (2020); Falke (2013), Arends (2015), Donin (2017); Donin (2016)

UroGen has made Significant Progress

KEY ACCOMPLISHMENTS

- JELMYTO FDA approval and U.S. launch
- Strengthened balance sheet via $120 million private placement
- Announced next-generation novel mitomycin-based formulation UGN-103 and medac GmbH licensing agreement with potential IP protection until 2041
- Announced positive topline data from Phase 3 Trials & held successful pre-NDA meeting with FDA for UGN-102 in LG-IR-NIMBC
- Advanced Immuno-Oncology program resulting in multi-arm Phase I clinical trial

UroGen Pharma

Growing Body of Evidence that Nephrostomy Tube Administration of JELMYTO is Efficient for Doctors and Favorable Safety Profile

ANTEGRADE ADMINISTRATION

Minimizes manipulation of the ureter during treatment which may limit stricture formation associated with repeated instrumentation of the upper urinary tract

May be performed by trained nursing professionals under clean rather than sterile conditions

Does not require fluoroscopy after a nephrostogram confirms placement at the first instillation

Retrospective analyses of real-world data support benefits of antegrade administration, making it an attractive alternative to retrograde administration[1,2,3]

1. Murray K, et al. J Urol. 2022 Feb 7;101097JU;
2. Rose K, et al. J Urol. 2022 May 1; doi.org/10.1097/JU.0000000000002643.06
3. Rose K, et al. BJUI. 2022 Oct 26; DOI: 10.1111/bju.15925