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): June 13, 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 Current Report on Form 8-K is a presentation of UroGen Pharma Ltd. (the "Company"), all or a portion of which will be presented by the Company beginning at 11:00 a.m. Eastern Time on June 13, 2024 at the Company's previously announced UGN-102 data event.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any filing the Company makes with the U.S. Securities and Exchange Commission ("SEC"), whether before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events

On June 13, 2024, the Company announced positive secondary endpoint duration of response ("DOR") data from the Phase 3 ENVISION trial investigating UGN-102 for intravesical solution in patients with low-grade intermediate risk non-muscle invasive bladder cancer ("LG-IR-NMIBC").

In the ENVISION trial, the 12-month DOR data by Kaplan-Meier ("KM") estimate for patients who achieved a complete response ("CR") at three months after the first instillation of UGN-102 was 82.3% (95% CI, 75.9%, 87.1%). This is in line with the 69.9% (51.8%, 82.3%) nine-month DOR data by KM estimate for patients who achieved a CR at three months after the first instillation of UGN-102 observed in the Company's Phase 2b OPTIMA II trial and the 79.6% (69.3%, 86.8%) 12-month DOR data by KM estimate for patients who achieved a CR at three months after the first instillation of UGN-102 alone observed in the Company's Phase 2 ATLAS trial.

The ENVISION trial met its primary endpoint with patients having a 79.6% (73.9%, 84.5%) CR rate at three months after the first instillation of UGN-102. This is in line with the CR rates at three months after the first instillation of UGN-102 of 65.1% (52.0%, 76.7%) and 64.8% (56.3%, 72.6%) observed in the OPTIMA II trial and ATLAS trial, respectively.

Among the patients in the ENVISION trial who achieved a CR at three months, 76.4% (69.8%, 82.3%) maintained a CR at 12 months. Among the 240 patients enrolled in the ENVISION trial, 60.8% (54.3%, 67.0%) were still in response at 12 months.

In the ENVISION trial, DOR KM estimates at 15 (n=43) and 18 (n=9) months were both 80.9% (95% CI, 73.9%, 86.2%). Although median DOR was not estimable due to the number of patients remaining in CR, the predicted median DOR is 40 months based on the Weibull Predicted Curve.

The ENVISION trial demonstrated a similar safety profile to that observed in the OPTIMA II and ATLAS trials, with treatment-emergent adverse events typically mild-to-moderate in severity.

In January 2024, the Company initiated the submission of a rolling New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for UGN-102 as a treatment for LG-IR-NMIBC. The latest DOR data are expected to support the UGN-102 NDA, which the Company plans to complete in the third quarter of 2024, with a potential FDA acceptance in the fourth quarter of 2024 and potential FDA approval in the first quarter of 2025 (assuming priority review) or the second quarter of 2025 (assuming standard review).

If approved, UGN-102 may become the first FDA-approved medicine for LG-IR-NMIBC. The Company estimates that the annual addressable U.S. patient population for LG-IR-NMIBC is approximately 82,000, of which approximately 23,000 are estimated to be newly diagnosed and 59,000 are estimated to be recurrent patients. The Company estimates that the total addressable market opportunity for UGN-102 in LG-IR-NMIBC is potentially over $5.0 billion, assuming an expected pricing range of $16,000 to $19,000 per dose.

UGN-102, if approved, may be an alternative to the current standard of care for LG-IR-NMIBC, trans-urethral resection of bladder tumor ("TURBT"). The Company estimates that approximately 68% of LG-IR-NMIBC patients have two or more recurrences, with approximately 23% having five or more recurrences. Repeated TURBT procedures to treat these recurrences can impact patients' physical health and quality of life. The Company estimates that around 35% of patients will experience an adverse event within 90 days of undergoing a TURBT, and patients who have had two to four procedures have an estimated 14% greater risk of death than patients who have only had one procedure.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although the Company believes that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, the Company can give no assurance that such expectations and assumptions will prove to be correct. Forward-looking statements include all statements that are not historical facts and can generally be identified by terms such as "could," "estimate," "expect," "intend," "may," "plan," "potentially," or "will" or similar expressions and the negatives of those terms. These statements include, but are not limited to, statements regarding the potential for the Company to transform bladder cancer treatment; the potential of JELMYTO® to change the treatment paradigm in low-grade upper tract urothelial cancer ("LG-UTUC"); the potential of UGN-102 to transform the treatment paradigm in LG-IR-NMIBC; the potential of UGN-301 to expand to Immuno-Oncology for high-grade non-muscle invasive bladder cancer ("HG-NMIBC"); the estimated patient population in bladder cancer and estimated addressable patient population for UGN-102 in LG-IR-NMIBC and UGN-301 in HG-NMIBC; the estimated total addressable market opportunity for UGN-102 in LG-IR-NMIBC; the expected price range per dose for UGN-102; the potential for UGN-102 to become the first FDA-approved medicine for LG-IR-NMIBC; the opportunity and potential benefits of UGN-102 for LG-IR-NMIBC and potential advantages over TURBT; the potential NDA completion and review timeline for UGN-102, including the FDA's potential acceptance thereof and approval of UGN-102 and the timing thereof; the potential of the Company's proprietary *RTGel*® technology platform to improve therapeutic profiles of existing drugs; and the Company's sustained release technology making local delivery potentially more effective as compared to other treatment options. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors relate to, among others: ENVISION DOR data may not be sufficient to support an NDA submission for UGN-102; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; 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; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities; the labeling for any approved product; competition in the Company's industry; the scope, progress and expansion of developing and commercializing the Company's product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; the Company's *RTGel* technology may not perform as expected and the Company may not successfully develop and receive regulatory approval of any product candidate beyond JELMYTO that incorporates *RTGel* technology; and the Company's ability to attract or retain key management, members of the board of directors and other personnel. These and other factors are described in greater detail under the "Risk Factors" heading of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, filed with the SEC on May 13, 2024. All information provided in this Current Report on Form 8-K is as of the date of this Current Report on Form 8-K, and any forward-looking statements contained herein are based on assumptions that the Company believes to be reasonable as of this date. Undue reliance should not be placed on the forward-looking statements in this report, which are based on information available to us on the date hereof. The Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits. (d) Exhibits.

Exhibit No.	Description
99.1	Company Presentation, dated June 13, 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 thereunto duly authorized.

Date: June 13, 2024

UROGEN PHARMA LTD.

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

Exhibit 99.1

New Horizons in Bladder Cancer: UGN-102 Duration of Response Results from the ENVISION Study

NASDAQ: URGN

June 13, 2024

UroGen Pharma

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 for UroGen to transform bladder cancer treatment; 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 potential of UGN-301 to expand to Immuno-Oncology for HG-NMIBC; the estimated patient population in bladder cancer and estimated addressable patient population for UGN-102 in LG-IR-NMIBC and UGN-301 in HG-NMIBC; the estimated total addressable market opportunity for UGN-102 in LG-IR-NMIBC; the potential for UGN-102 to become the first FDA approved medicine for LG-IR-NMIBC; the opportunity and potential benefits of UGN-102 for LG-IR-NMIBC and potential advantages over TURBT; the potential NDA completion and review timeline for UGN-102, including the expected completion of the NDA submission to the FDA and the FDA's potential acceptance thereof and the FDA's potential approval timing; and the potential of UroGen's proprietary RTGel® technology platform to improve therapeutic profiles of existing drugs. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: ENVISION duration of response data may not be sufficient to support an NDA submission for UGN-102; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; 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; 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; competition in UroGen's industry; 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 for the quarter ended March 31, 2024, filed with the Securities and Exchange Commission (SEC) on May 13, 2024, 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 UNIQUELY POSITIONED TO TRANSFORM BLADDER CANCER TREATMENT

LIZ BARRETT, PRESIDENT AND CEO

Today's Agenda

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

The Burden of LG-IR-NMIBC
- **Mark P. Schoenberg, M.D.**
  Chief Medical Officer, UroGen

UGN-102 Clinical Data
- **Sandip Prasad, M.D., M.Phil.**
  Morristown Hospital/Atlantic Health System, NJ

Patient Perspectives from ENVISION
- **Angela Stover, Ph.D.**
  UNC Gillings School of Global Public Health

Patient Interview
- **Julio Lago**
  Patient
- **Liz Barrett**
  President and CEO, UroGen

Panel Discussion
- **Moderator: Mark P. Schoenberg, M.D.**
  Chief Medical Officer, UroGen
- **Max Kates, M.D.**
  Johns Hopkins School Of Medicine
- **Jennifer Linehan, M.D.**
  Saint John's Cancer Institute
- **James McKiernan, M.D.**
  Columbia University Irving Medical Center, New York Presbyterian
- **Angela Stover, Ph.D.**
  UNC Gillings School of Global Public Health

What is Next?
- **Liz Barrett**
  President and CEO, UroGen

Q&A

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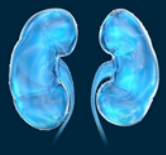
WE ASPIRE TO CHANGE THE TREATMENT PARADIGM

SURGICAL CARE

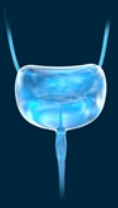
MINIMALLY INVASIVE, ORGAN-SPARING THERAPEUTIC OPTIONS

Because Patients Deserve Better



JELMYTO
(UGN-101)

Changing the Treatment Paradigm for Low-Grade Upper Tract Urothelial Cancer (LG-UTUC)



UGN-102

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

UGN-301

Expanding to Immuno-Oncology for High-Grade Non-Muscle Invasive Bladder Cancer (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 to active drugs

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

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

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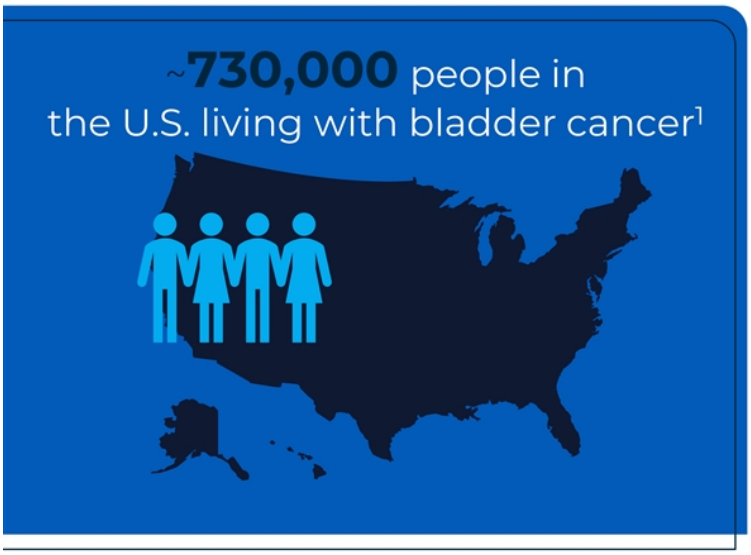
Bladder Cancer Affects Patients and Families Across The U.S.



1. Cancer Stat Facts: Bladder Cancer. National Cancer Institute: Surveillance, Epidemiology, and End Results Program. Accessed June 5, 2024 (data as of 2021). 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

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High Recurrence Rate Leads to Frustrating Treatment Cycle

~68%

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

~23%

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

1. UroGen projections based on SEER (2016) Babjuk et al. European Urology (2019) and Simon (2019).

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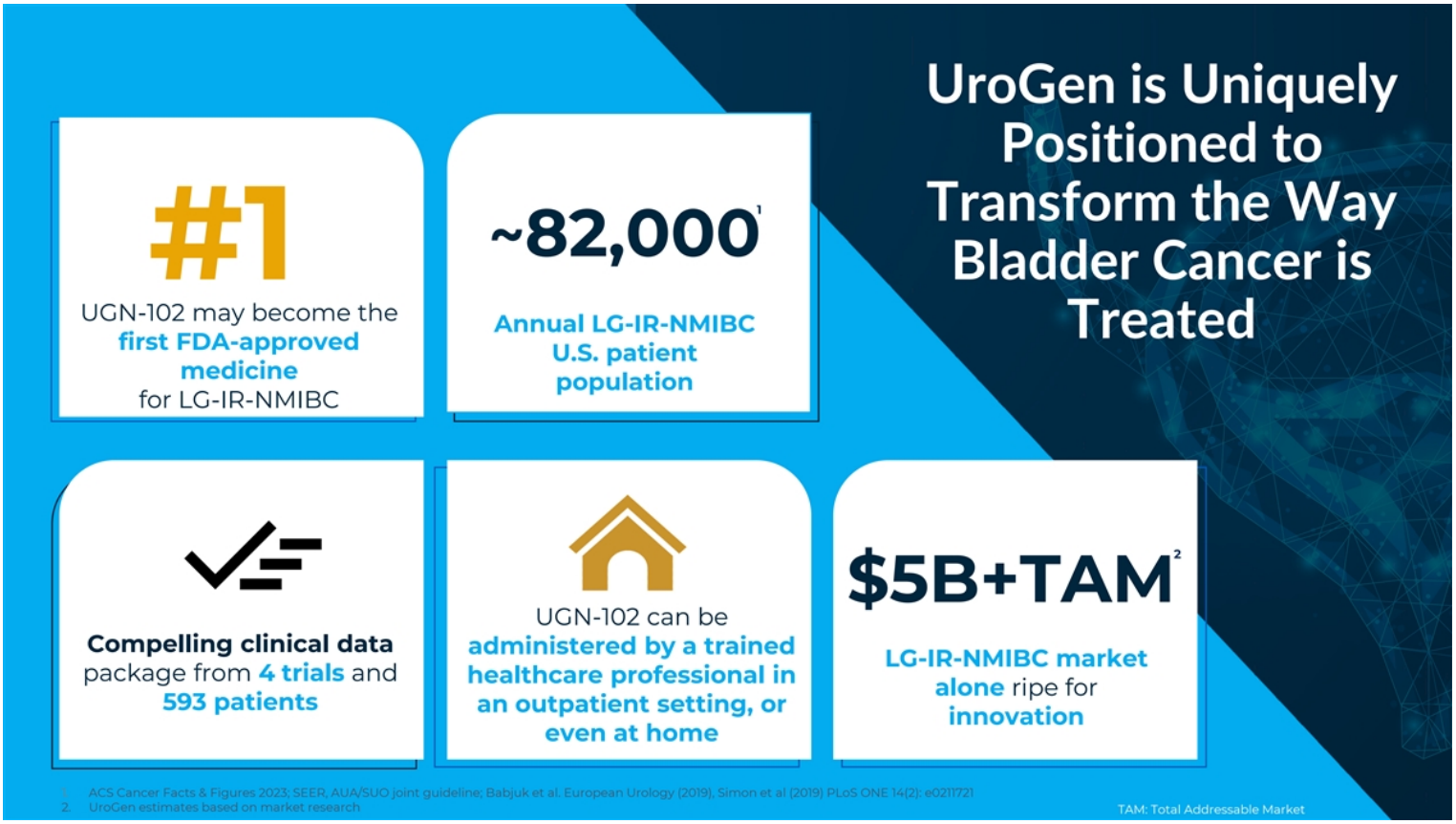
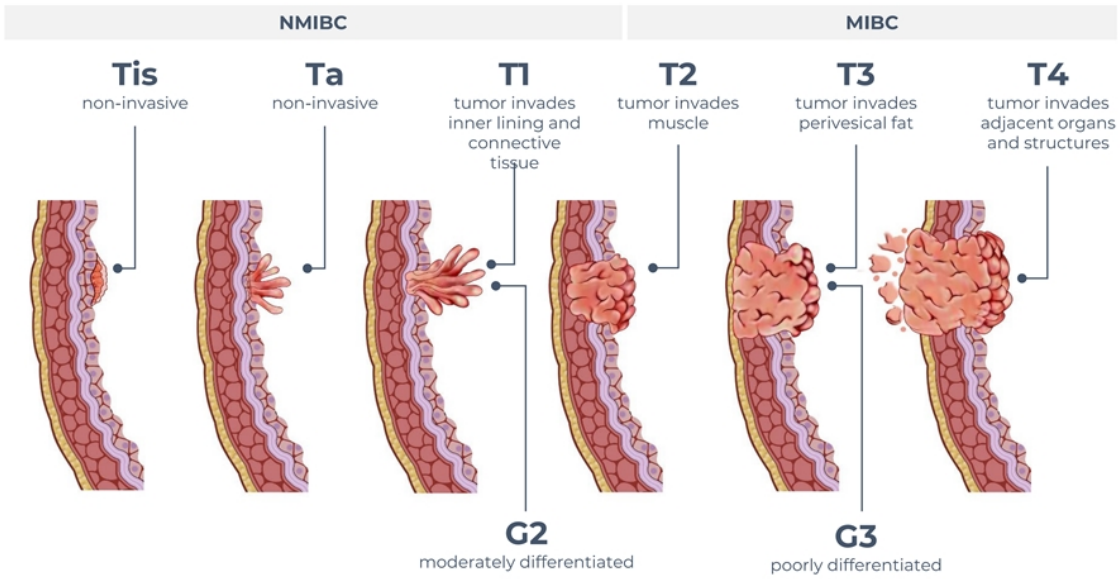

UroGen is Uniquely Positioned to Transform the Way Bladder Cancer is Treated
#1
UGN-102 may become the first FDA-approved medicine for LG-IR-NMIBC
~82,000[1]
Annual LG-IR-NMIBC U.S. patient population
Compelling clinical data package from 4 trials and 593 patients
UGN-102 can be administered by a trained healthcare professional in an outpatient setting, or even at home
$5B+TAM[2]
LG-IR-NMIBC market alone ripe for innovation
1. ACS Cancer Facts & Figures 2023; SEER, AUA/SUO joint guideline; Babjuk et al. European Urology (2019), Simon et al (2019) PLoS ONE 14(2): e0211721
2. UroGen estimates based on market research
TAM: Total Addressable Market

THE BURDEN OF LGR-NMIBC

MARK SCHOENBERG, M.D.,
CHIEF MEDICAL OFFICER

NMIBC Has Multiple Stages Before Becoming Muscle Invasive



[11] American Joint Committee on Cancer. AJCC Cancer Staging Manual. Urinary Bladder. 7th edn. New York, NY: Springer; 2010: 497-502.

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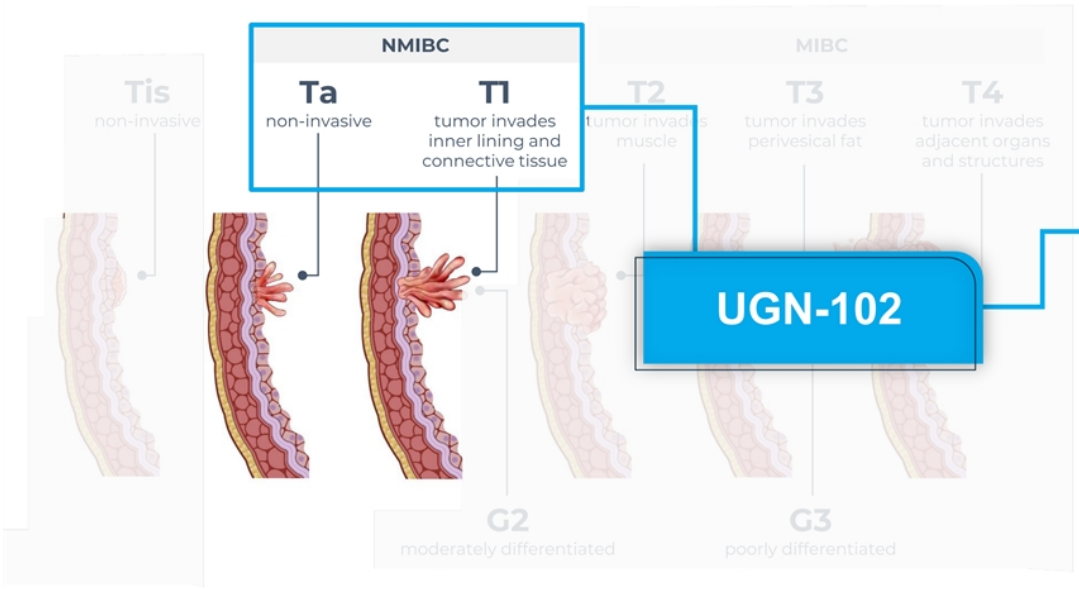
UGN-102's Proposed Indication: For Treatment of LG-IR-NMIBC



Low Grade

- ~70% of all bladder cancers
- High risk of recurrence
- Low risk of progression

Intermediate Risk

- LG Ta Tumors that are large (> 3cm), multifocal, or recurrent
- LG T1 Tumors
- SOC: Repeated Transurethral Resection of Bladder Tumor (TURBT)

American Joint Committee on Cancer. AJCC Cancer Staging Manual. Urinary Bladder. 7th edn. New York, NY: Springer; 2010: 497-502. Apollo et al. PLOS ONE (2019)

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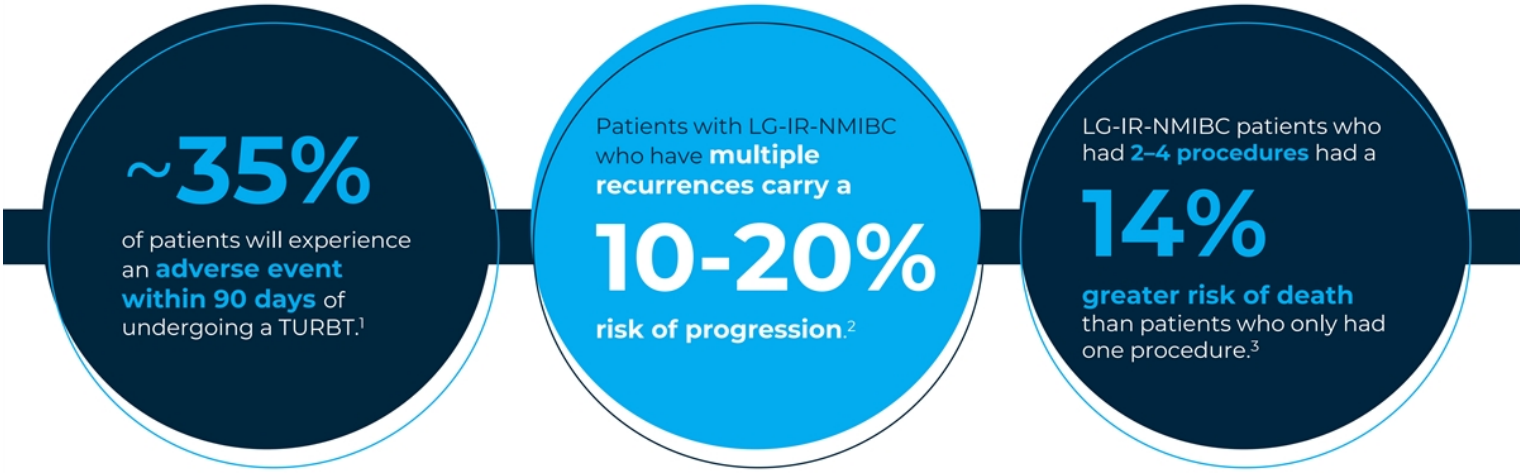
Repeat Surgery for LG-IR NMIBC Comes with Risks for Patients



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

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LG-IR-NMIBC Market: Key Differences Compared to HG-NMIBC Market

Low-Grade IR-NMIBC		High-Grade NMIBC
Issues: Chronic recurrence; rarely progresses to high-grade disease		**Issues**: Progression, metastasis & death
SOC: Repetitive TURBT	VS	**SOC**: TURBT, BCG, radical cystectomy, clinical trials
Newly diagnosed: ~23K/year[1,2,3] **Recurrent**: ~59K/year[1,2,3]		**Incidence**: ~25K/year[4] **BCG-refractory**: 18.7K/year[4]
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**		**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),
4. 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.

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Positioning UGN-102 for Success

Low-Grade IR NMIBC

Issues: Chronic recurrence; rarely progresses to high-grade disease

SOC: Repetitive TURBT

Newly diagnosed: ~23K/year[1,2,3]
Recurrent: ~59K/year[1,2,3]

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

Issues: Progression, metastasis & death

SOC: TURBT, BCG, radical cystectomy, clinical trials

Incidence: ~25K/year[4]
BCG-refractory: 18.7K/year[4]

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),
4. 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.

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UGN-102: ROBUST AND CONSISTENT CLINICAL RESULTS

About Dr. Sandip Prasad

Sandip Prasad, M.D., M.Phil.

- Garden State Urology
- Director of Genitourinary Surgical Oncology
- Vice-Chair of Urology at Morristown Medical Center/Atlantic Health System in New Jersey
- Clinical Associate Professor at Rutgers NJMS
- Clinical Assistant Professor at Thomas Jefferson University
- Completed residency at the Harvard Program in Urology and an SUO fellowship at the University of Chicago
- 60 peer-reviewed journal articles and book chapters
- Associate editor or editorial reviewer for nine specialty journals in Urology

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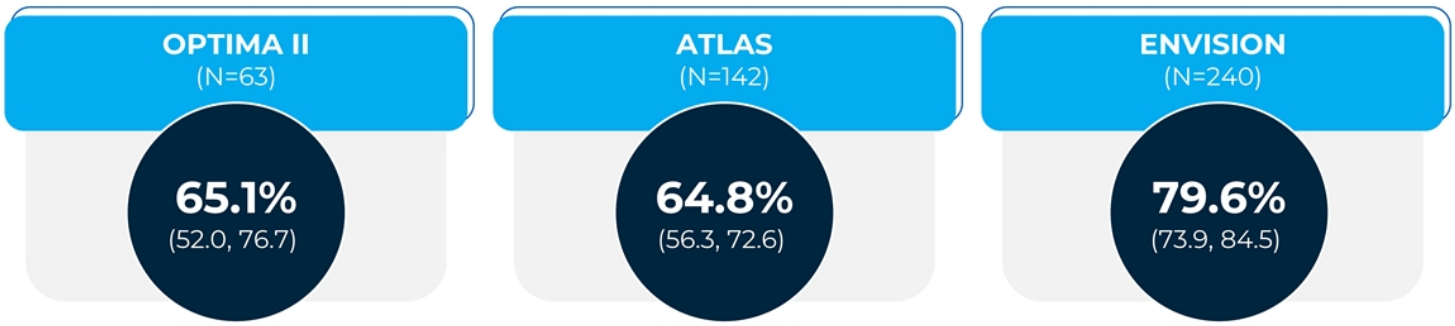
ENVISION DURATION OF
RESPONSE RESULTS

Strong, Consistent Complete Response Rate At 3 Months



UroGen Data on File

OPTIMA II was a Phase 2B, single-arm, open-label study in patients with newly diagnosed and recurrent LG-IR-NMIBC.

ATLAS was a Phase 3, randomized, controlled trial of UGN-102 +/- TURBT vs TURBT alone in patients with newly diagnosed and recurrent LG-IR-NMIBC. ATLAS complete response is based on treatment with UGN-102 alone.

ENVISION is a Phase 3, single-arm, open-label study in patients with LG-IR-NMIBC.

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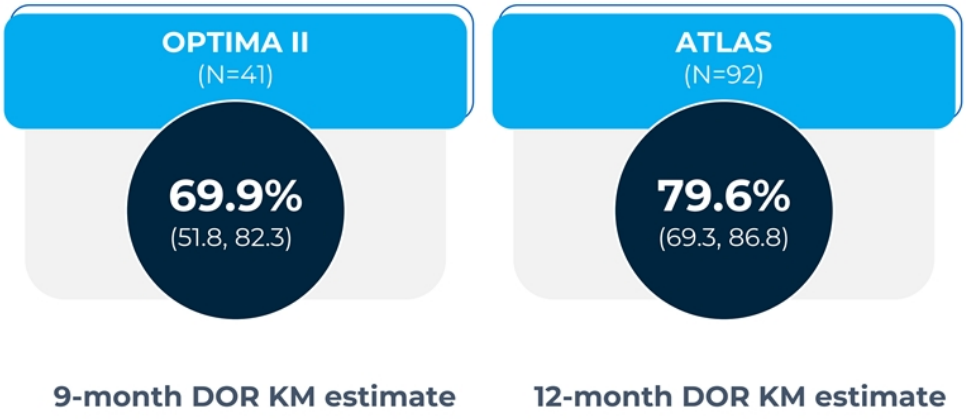
Robust Duration of Response (DOR) Observed in Multiple Trials



UroGen Data on File
ATLAS DOR estimates based on treatment with UGN-102 alone
Based on Kaplan-Meier (KM) Estimates.

UroGen Pharma

ENVISION Single-Arm Pivotal Study Description

Patient Population:

- Demographics and baseline characteristics reflective of general LG-IR-NMIBC patient population
- All patients followed for a minimum of 15 months

Primary Endpoint:

- **Complete response rate (CRR)** at 3-month visit, as defined by cystoscopy, for cause biopsy, and urine cytology

Key Secondary Endpoint:

- **Duration of response (DOR)**, defined as time from first documented CR until the earliest date of:
  - ✓**Recurrence**
  - ✓**Progression**
  - ✓**Death**

UroGen Data on File
Overall Summary of Demographics in the Appendix

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Robust Complete Response Rate At 3 Months

	UGN-102 (N = 240)	
	n (%)	**CRR** (95% CI)
Complete Response	**191 (79.6)**	**79.6 (73.9, 84.5)**
Non-Complete Response	**49 (20.4)**	
Residual Disease	35 (14.6)	
Progression to HG Disease	7 (2.9)	
Indeterminate	2 (0.8)	
Missing	5 (2.1)	

UroGen Data on File

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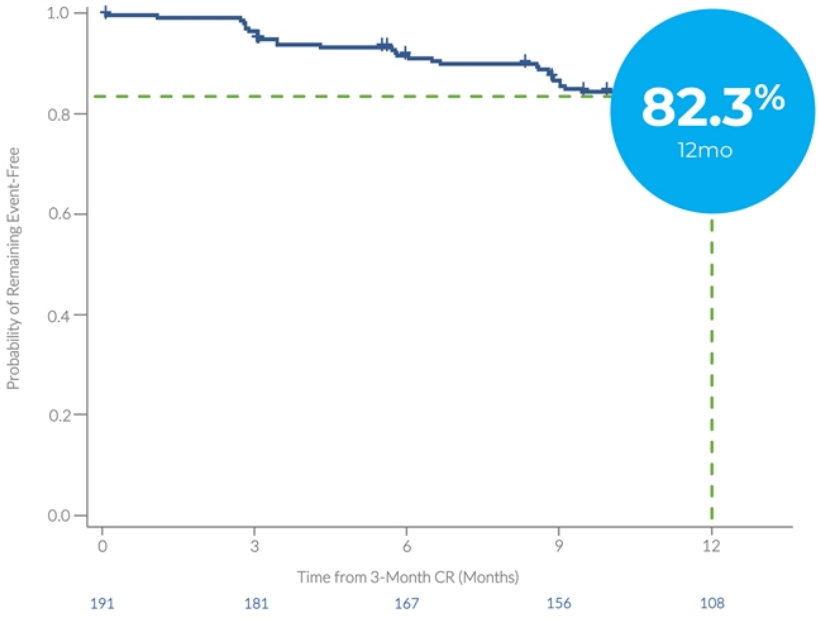
DOR: 82.3% at 12 Months, Overwhelming Majority Remain Disease Free



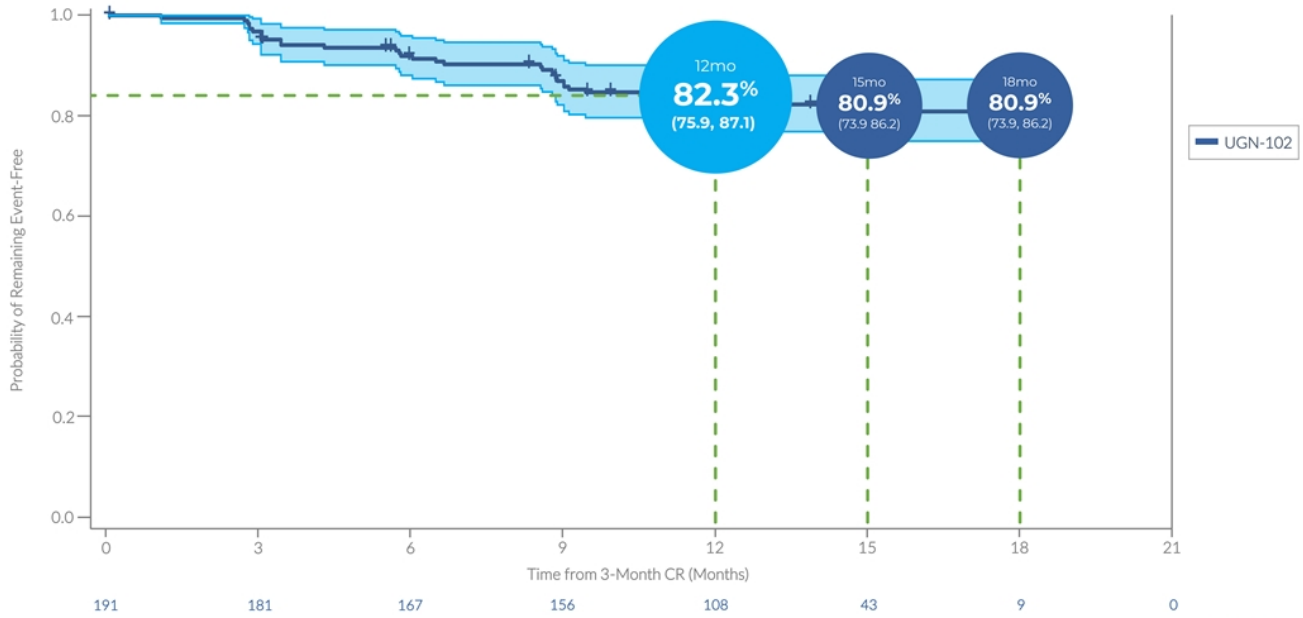
	UGN-102 (N = 191)
Number (%) of Patients with Events	**33** (17.3%)
Median (Months) Estimate:	**NE** (NE, NE)
KM Estimates at*:	
3 months	**96.8%**
6 months	**91.9%**
9 months	**86.9%**
12 months	**82.3%** (75.9, 87.1)
15 months	**80.9%** (73.9, 86.2)
18 months	**80.9%** (73.9, 86.2)

*Time from 3-Month CR

UroGen Pharma

UroGen Data on File

Large Sample Size Resulted In Tight DOR Confidence Intervals



UroGen Data on File

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Median DOR Not Estimable Due to Patients Remaining in CR

	UGN-102 (N=191)
Kaplan-Meier Estimates of Duration of Response (Months)	
1st Quartile (95% CI)	Not Estimable (14.7, Not Estimable)
Median (95% CI)	**Not Estimable**
3rd Quartile (95% CI)	Not Estimable
Median Follow-Up Time, Months (95% CI)	**13.8 (12.2, 14.5)**

UroGen Data on File

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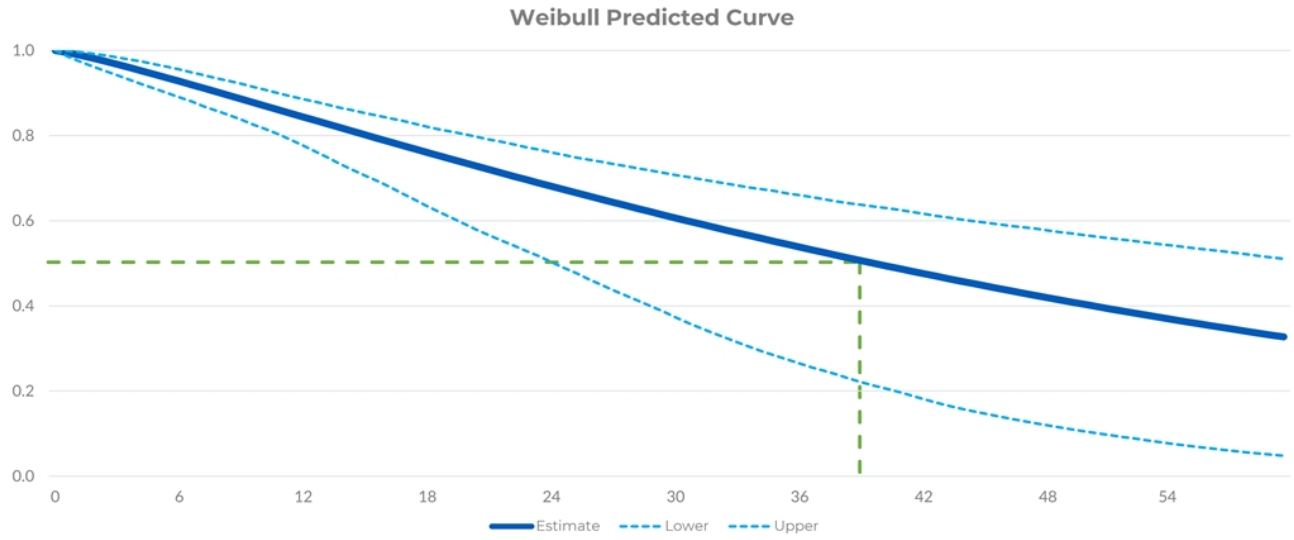
Predicted Median Duration Of Response (DOR) is 40.0 Months



Predicted Median (95% CI): 40.0 months (23.9, 63.9)

UroGen Data on File

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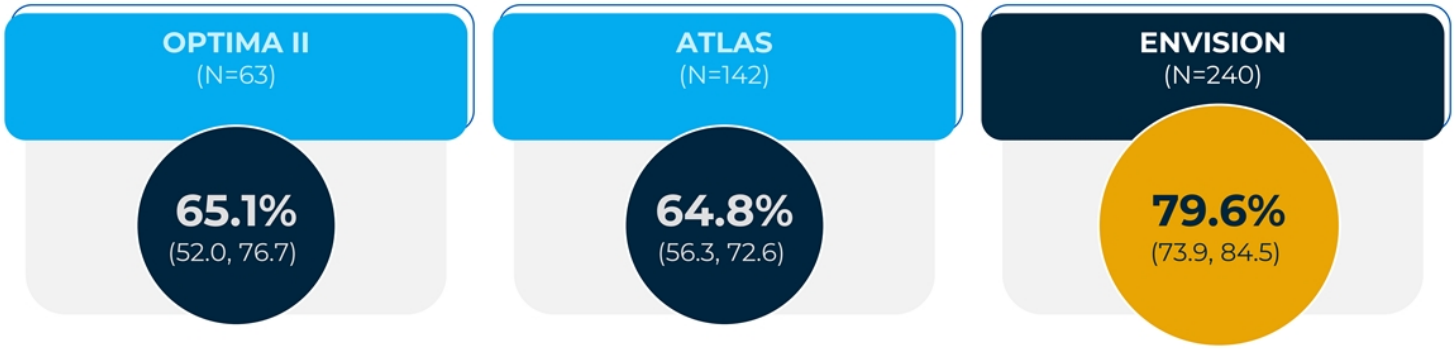
AEs Generally Mild to Moderate in Severity

	UGN-102 (N=240) n (% incidence)
Any Adverse Events	140 (58.3)
Any Serious Adverse Events	30 (12.5)
Any TEAEs	137 (57.1)
Any Grade ≥3 TEAEs	33 (13.8)
Any Treatment or Procedure Related TEAEs	97 (40.4)
Any Treatment Related TEAEs	81 (33.8)
Any Procedure Related TEAEs	64 (26.7)
Any TEAEs Leading to Treatment Discontinuation	7 (2.9)
Any TEAEs Leading to Study Discontinuation	6 (2.5)
Any Serious TEAEs	29 (12.1)
Any Treatment or Procedure Related Serious TEAEs	4 (1.7)
Any Treatment Related Serious TEAEs	2 (0.8)
Any Procedure Related Serious TEAEs	3 (1.3)
Any TEAEs Leading to Death	3 (1.3)
Any TEAEs of Special Interest	100 (41.7)

- AEs mainly related to lower urinary tract symptoms
- The 2 treatment-related SAEs were urethral stenosis and urinary retention (both resolved)
- The 3 deaths were unrelated to treatment: (cardiac event, pneumonia, and not reported)

UroGen Data on File
Overall summary of AEs in the Appendix

Consistently High Complete Response Rate At 3 Months



UroGen Data on File

OPTIMA II was a Phase 2B, single-arm, open-label study in patients with newly diagnosed and recurrent LG-IR-NMIBC.
ATLAS was a Phase 3, randomized, controlled trial of UGN-102 +/- TURBT vs TURBT alone in patients with newly diagnosed and recurrent LG-IR-NMIBC. ATLAS complete response is based on treatment with UGN-102 alone.
ENVISION is a Phase 3, single-arm, open-label study in patients with LG-IR-NMIBC.

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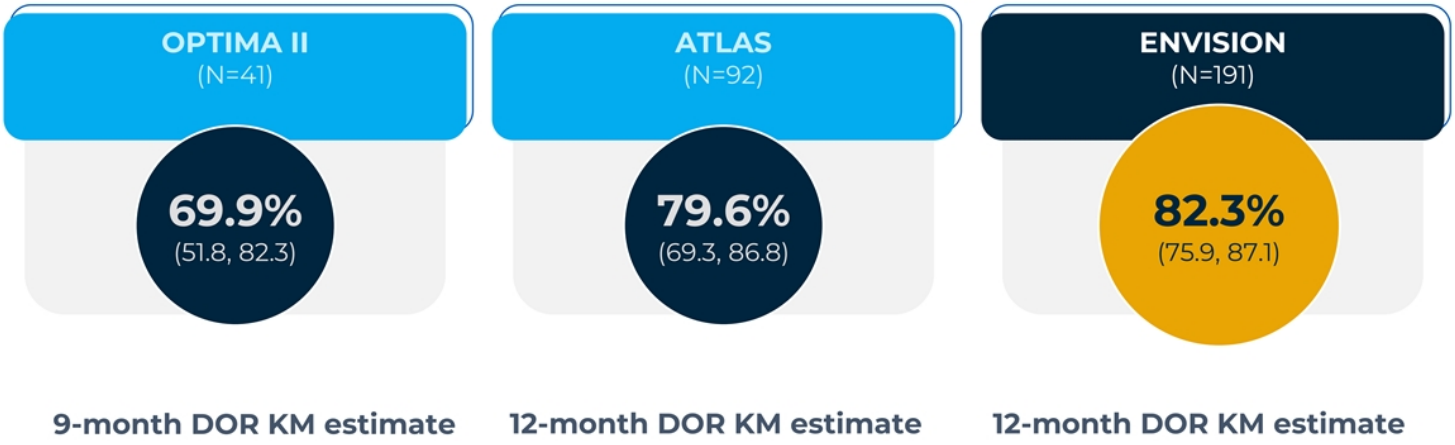
High CR Rates Maintained with Robust Duration of Response



UroGen Data on File
ATLAS DOR estimates based on treatment with UGN-102 alone
Based on Kaplan-Meier (KM) Estimates.

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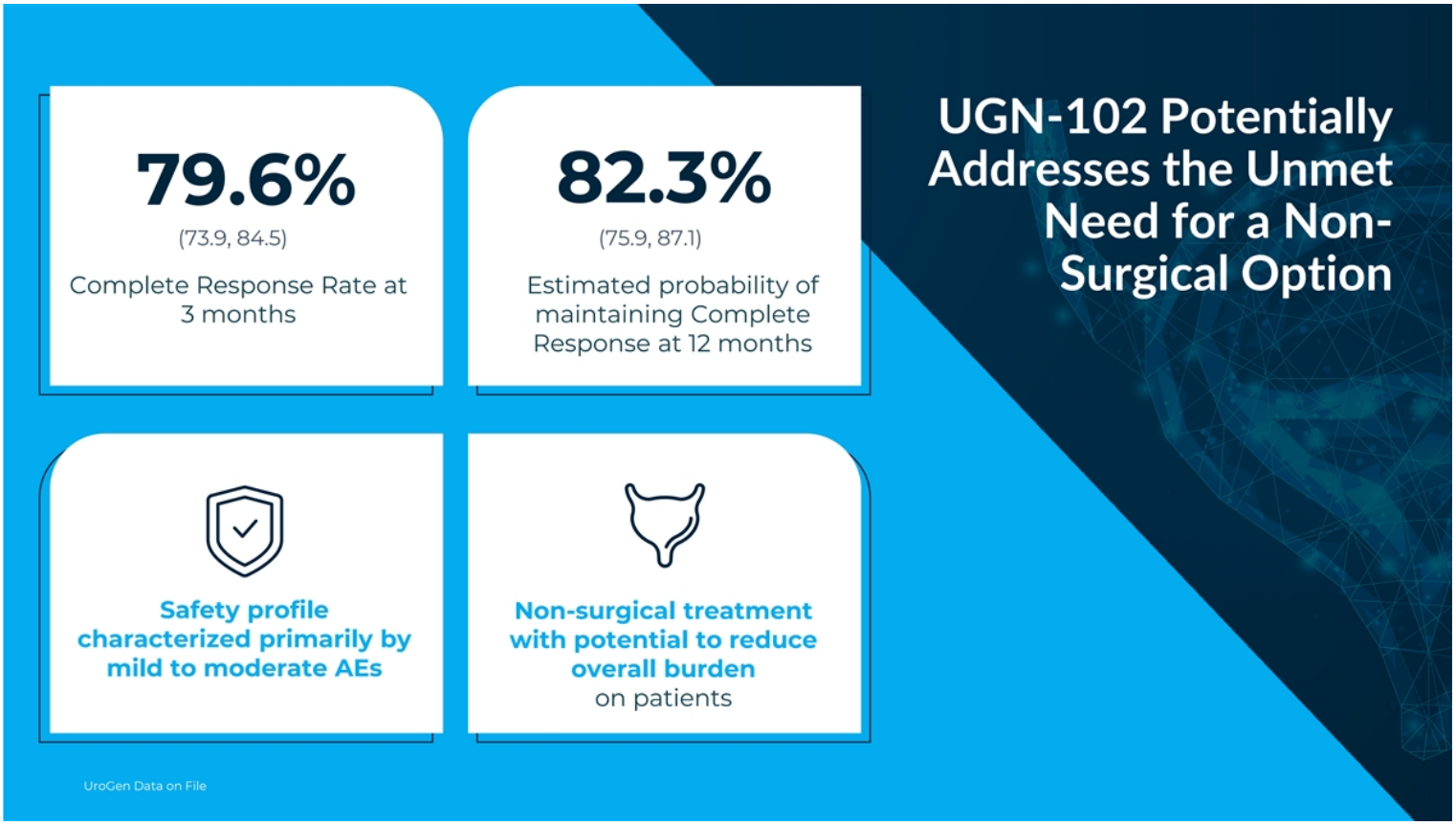
79.6%
(73.9, 84.5)
Complete Response Rate at 3 months
82.3%
(75.9, 87.1)
Estimated probability of maintaining Complete Response at 12 months
UGN-102 Potentially Addresses the Unmet Need for a Non-Surgical Option
Safety profile characterized primarily by mild to moderate AEs
Non-surgical treatment with potential to reduce overall burden on patients
UroGen Data on File

PATIENT PERSPECTIVES FROM ENVISION

ANGELA STOVER, PH.D.
ASSOCIATE PROFESSOR
DEPARTMENT OF HEALTH POLICY AND MANAGEMENT AT
UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH

ABOUT DR. ANGELA STOVER

Angela Stover, PhD

- Associate Professor, Department of Health Policy and Management at UNC Gillings School of Global Public Health
- A health services researcher with expertise in patient-reported outcomes (PRO) methods and implementation science
- Co-directs the NC TraCS' Implementation Science Methods Unit
- Associate member of Lineberger Comprehensive Cancer Center
- Research program quantifies the impact of treatment for chronic health conditions on symptom burden, identifies important gaps in implementing evidence-based practices in clinics, and determines how those gaps are related to poor patient and clinic outcomes
- Dr. Stover's research program is funded by NIH, PCORI, AHRQ, Pfizer Global, and foundations

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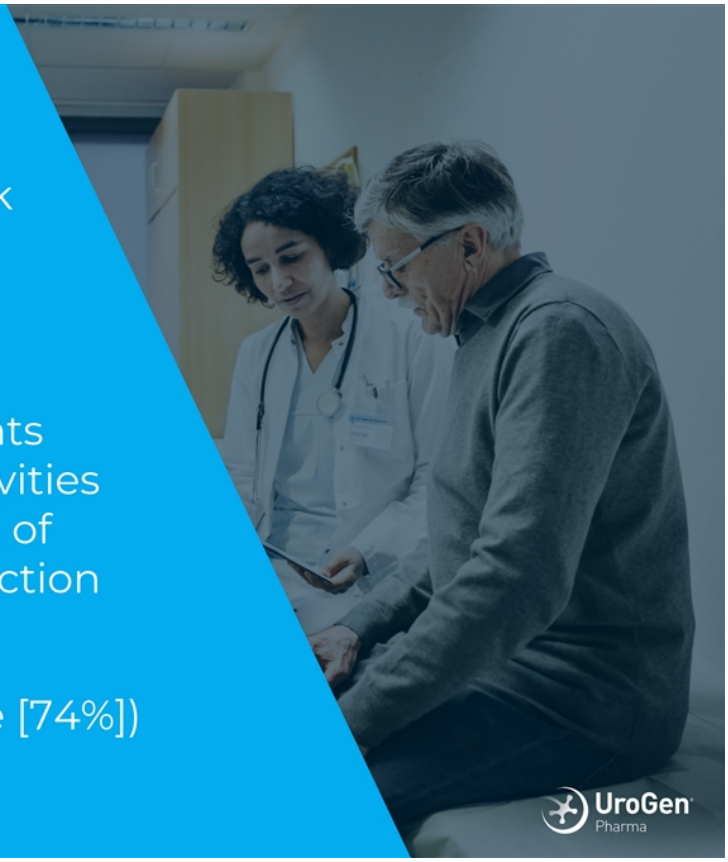
ENVISION PATIENT PERCEPTIONS OF UGN-102 AND TURBT: IMPACT ON DAILY ACTIVITIES

UNC

ENVISION Interviews

- Patients with NMIBC commonly ask urologists how their daily activities/responsibilities will be affected by treatment(s)
- In ENVISION, we interviewed patients about the impact on their daily activities with UGN-102 and their recollection of standard of care (transurethral resection of bladder tumor [TURBT])
- N=29 U.S. patients (out of 39 eligible [74%])



Stover and Smith, under review

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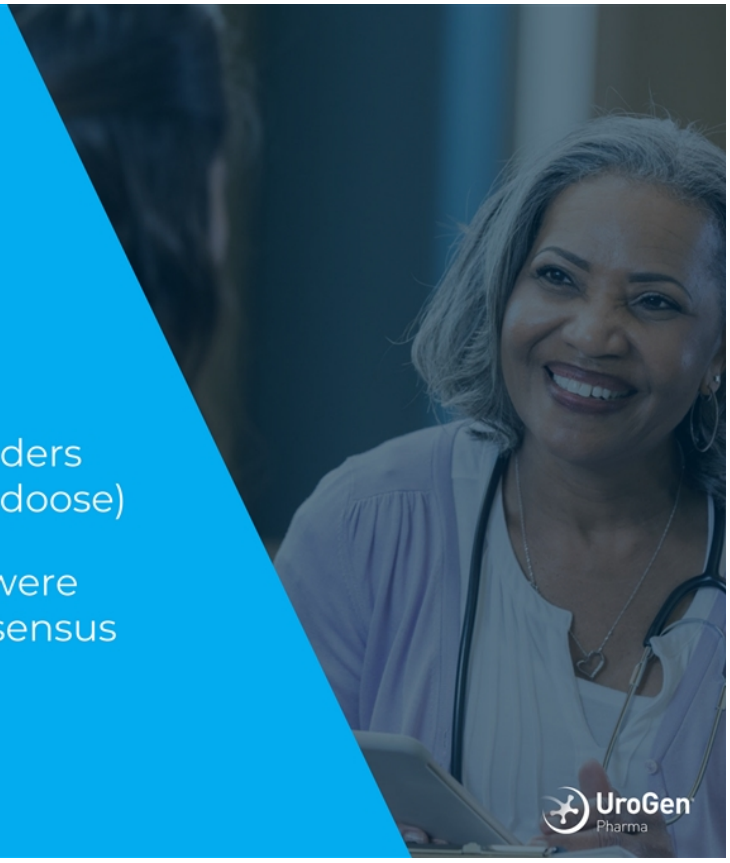
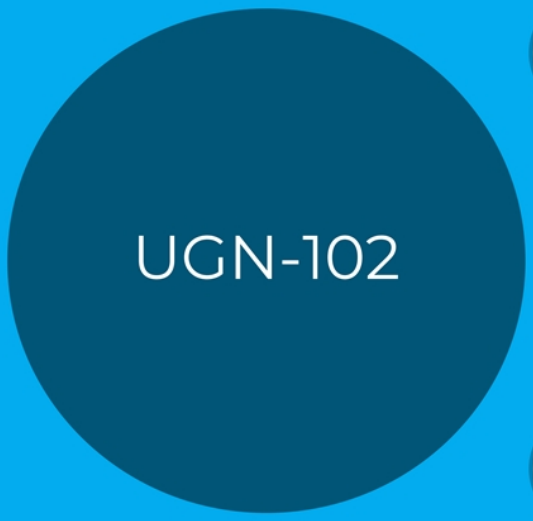
Methods

- Gold standard: content analysis
  - Data are patient quotes
- Semi-structured interview guides at enrollment and 3 months
- Transcripts coded by 3 experienced coders with detailed codebooks (software: Dedoose)
- Emerging themes and discrepancies were captured and reconciled through consensus



[35] Stover and Smith, under review

Three Interview Themes



N=29

- Less impact on activities/ responsibilities (work, recreation & exercise, sexual activity)
- Less bleeding, catheter issues shorter lasting
- Patients would recommend because UGN-102 was perceived to be less invasive, painful, and time-consuming

Stover and Smith, under review

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Recovery Time

TURBT

"Well, first off, they're [TURBTs] gettin' **more and more painful, and it's taken longer and longer to recover from them.** It's just a little bit of—every time they do it [TURBT], it's just little bit more incontinence. It's gotten much worse with each procedure." (17)

UGN-102

"**Yes. I think it took me a longer time to recover from the bladder resection than the gel.** [For TURBT], maybe at two weeks I felt better and things like that, and I start to exercise, but I do believe that I was not at my 100 percent until many weeks later." (27)

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[37] Stover and Smith, under review

No Impact on Daily Activities

TURBT

[TURBT not discussed]

UGN-102

"With the gel, the daily activity was a big difference, and I didn't worry at all. **Basically, I lived my normal life except the one day [instillation], which was well worth it."** (34)

"They [UGN-102] didn't have any impact on me. **I went in, and I went back to my normal activity…**I had no problems at all." (37)

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[38] Stover and Smith, under review

Impact on Work

TURBT

"It's [incontinence] mostly a big embarrassment and an absolute pain in the ass at work...some days are much worse than others and depending on what I'm doin'—but sometimes my pants get wet, and I have to go out to the car, get my clothes, change, and they're lookin' for me....**Runnin' to the bathroom all the time, everybody'll, 'Well, you're always in the bathroom'**." (17)

UGN-102

"The TURBT, I was basically missing for seven, eight days, I could do no work. **Here [with UGN-102], really, work has continued, I have not had an impact.** Again, postponing travel, meetings, things like that, but I was present, mostly, I was present. I do think the outcome is better with the gel than with the TURBT." (27)

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[39] Stover and Smith, under review

Treatment-Related Side Effects

TURBT

"I honestly have as much side effects **from the anesthesia**." (06)

"I'll tell you one thing. I do not look forward to spending the **rest of my life attached to a catheter**. That's a no-no for me." (08)

UGN-102

"For six weeks, I was in stages **of extreme to moderate to low level of pain/itching**—extreme internal itching."(20)

"It was **very itchy, all my bladder and everything**. The second time, I knew what it was. Knowing what it was, the scary part went away. I wasn't worried anymore. It was just toughing it out that one or two days." (29)

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40 Stover and Smith, under review

Bleeding

TURBT

"That [TURBT] was a lot of bleeding." (45)

"They removed five polyps at that time...**Then I bled for two weeks.** Finally shut off. [My urologist] told me that there would be some bleeding. **I don't think he realized that it was gonna be that long of a bleeding...**He told me that I would be bleeding for 'a while' after the surgery." (43)

[41] Stover and Smith, under review

UGN-102

"At least two occasions [for TURBT], one of which there was fair amounts of bleeding." (03)

It [TURBT] was more painful, there was a lot of blood came out — not a little, a lot." (27)

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Impact on Sexual Activity

TURBT

"Basically, I would like to get away from having them [tumors] extracted from me 'cause my doctor told me the more surgeries they keep doin', my bladder—especially since I've been doing it so young—**that it would mess up good things like erectile function, things like peeing**..." (41)

UGN-102

"I would say that I didn't have any difference in performance, but **I took longer to have relationships with my wife with TURBT [than UGN-102]."** (27)

"You have this medicine in you and you don't wanna be having sex with your partner...but once that was done, everything was back to normal." (15)

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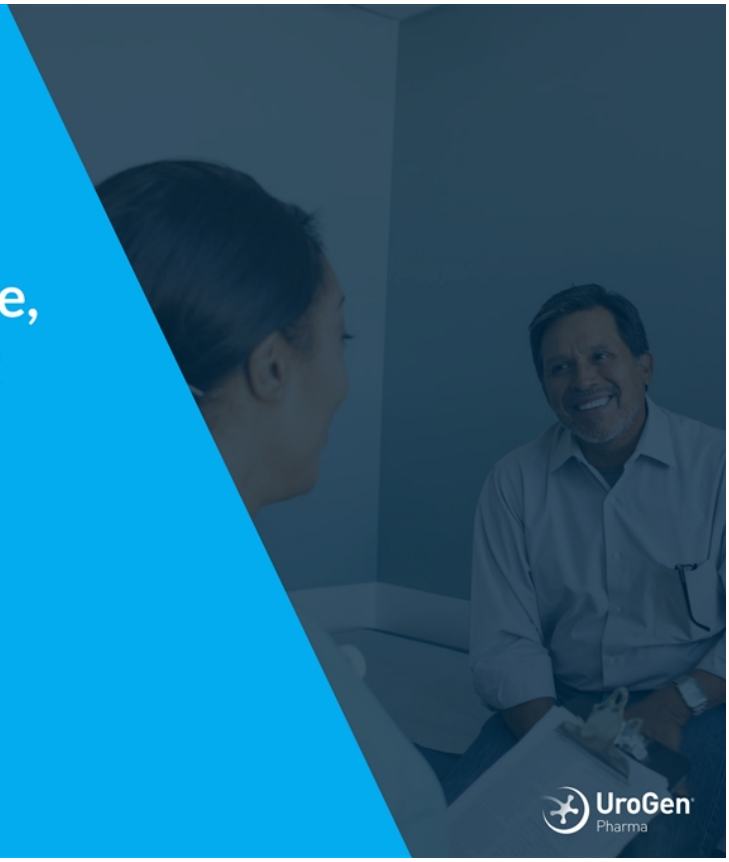
[42] Stover and Smith, under review

From the patient perspective, UGN-102 meets an unmet need in care delivery for a non-surgical treatment alternative for NMIBC



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PATIENT INTERVIEW: JULIO LAGO

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THOUGHT LEADER PANEL

Max Kates, MD, is an Associate Professor of Urology and Oncology in the Brady Urological Institute and directs the Division of Urologic Oncology for the Brady Urological Institute at Johns Hopkins School Of Medicine, where he works with the team at the Johns Hopkins Greenberg Bladder Cancer Institute to deliver a personalized approach to bladder cancer utilizing cutting edge precision medicine approaches.

Jennifer Linehan, MD is a board-certified urologist, and is an Associate Professor of Urology and Urologic Oncology at the Saint John's Cancer Institute. She also practices general urology, including both male and female voiding dysfunction and treatment for kidney stones.

James McKiernan, MD, the John K. Lattimer Professor of Urology, is the chair of the Department of Urology of the College of Physicians and Surgeons at Columbia University Irving Medical Center and urologist-in-chief at New York Presbyterian/Columbia. Dr. McKiernan is only the sixth physician to hold this title since the founding of the department in 1917.

Sandip Prasad, MD, is s a member of Garden State Urology and serves currently as the director of Genitourinary Surgical Oncology and Vice-Chair of Urology at Morristown Medical Center/Atlantic Health System in New Jersey. He is also a Clinical Associate Professor at Rutgers NJMS and a Clinical Assistant Professor at Thomas Jefferson University. He has published over 60 peer-reviewed journal articles and book chapters and serves as an associate editor or editorial reviewer for nine specialty journals in Urology.

Angela Stover, PhD, Associate Professor, Department of Health Policy and Management at UNC Gillings School of Global Public Health, is a health services researcher with expertise in patient-reported outcomes (PRO) methods and implementation science. She co-directs the NC TraCS' Implementation Science Methods Unit and is an associate member of Lineberger Comprehensive Cancer Center.

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WHAT IS NEXT?

Unprecedented Clinical Results Further Support Completion of NDA Submission

Strong Complete Response Rate At 3 Months

ENVISION
(N=240)

79.6%
(73.9, 84.5)

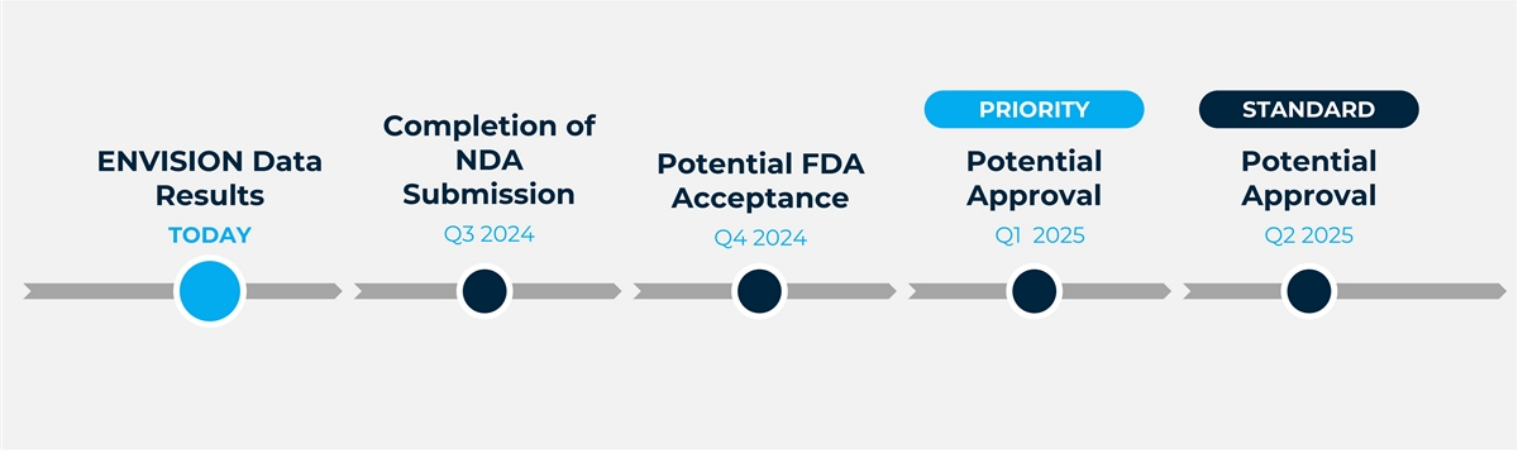
Robust Duration of Response KM Estimate At 12 Months

ENVISION
(N=191)

82.3%
(75.9, 87.1)

UroGen Data on File

Potential to Launch UGN-102 in One Year If Approved



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UroGen is Uniquely Positioned to Transform the Way Bladder Cancer is Treated

#1

UGN-102 may become the **first FDA approved medicine** for LG-IR-NMIBC

~82,000[1]

Annual addressable U.S. population, indicating potential to reduce burden for large population of LG-IR-NMIBC patients

$5B+TAM[2]

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

Prolonged **disease-free intervals**

Generally well tolerated

RTGel uniquely treats what you can see and what you can't

>86% of patients interviewed would recommend UGN-102

1. ACS Cancer Facts & Figures 2023; SEER, AUA/SUO joint guideline; Babjuk et al. European Urology (2019), Simon et al (2019) PLoS ONE 14(2): e0211721
2. UroGen estimates based on market research

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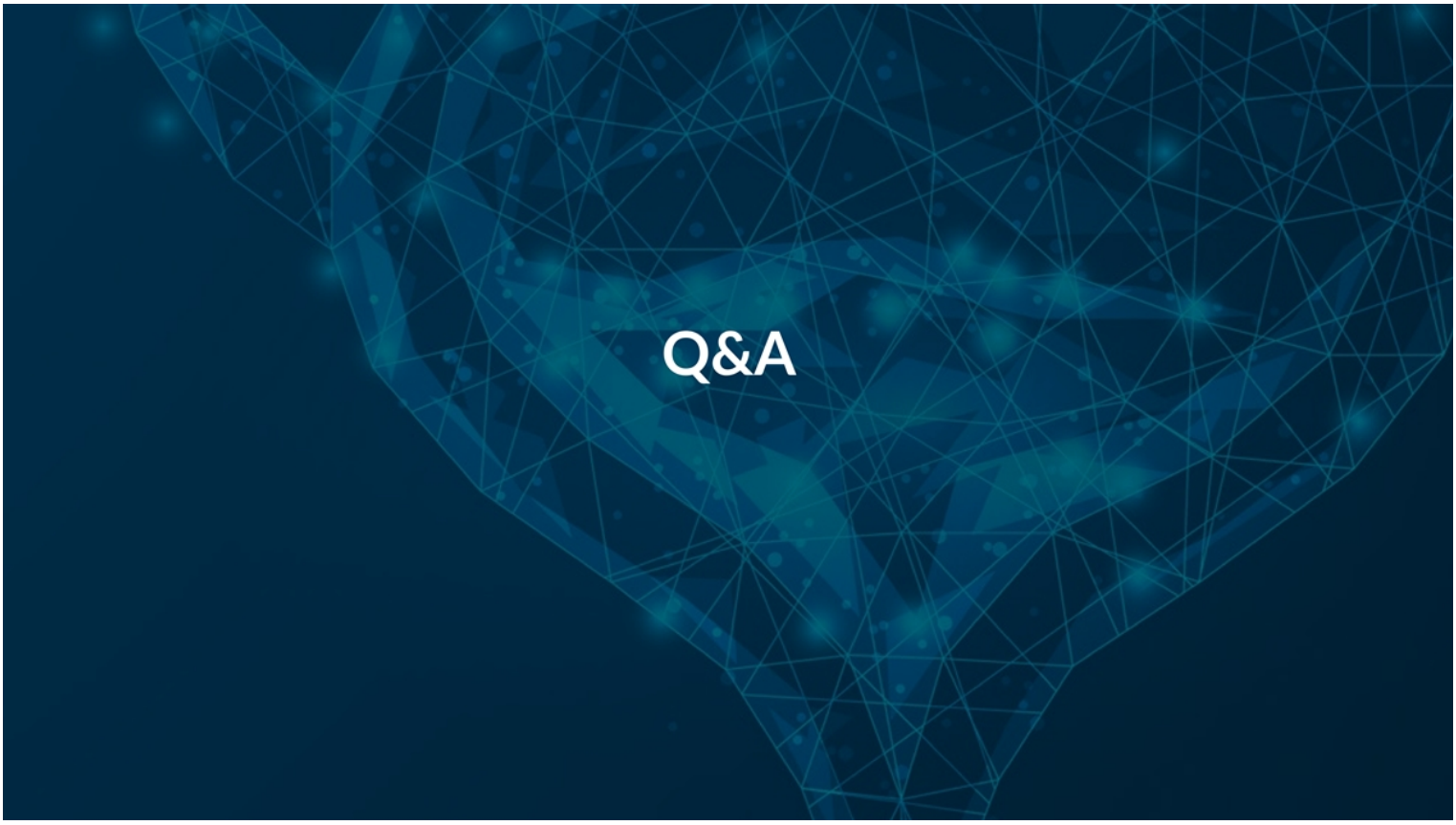
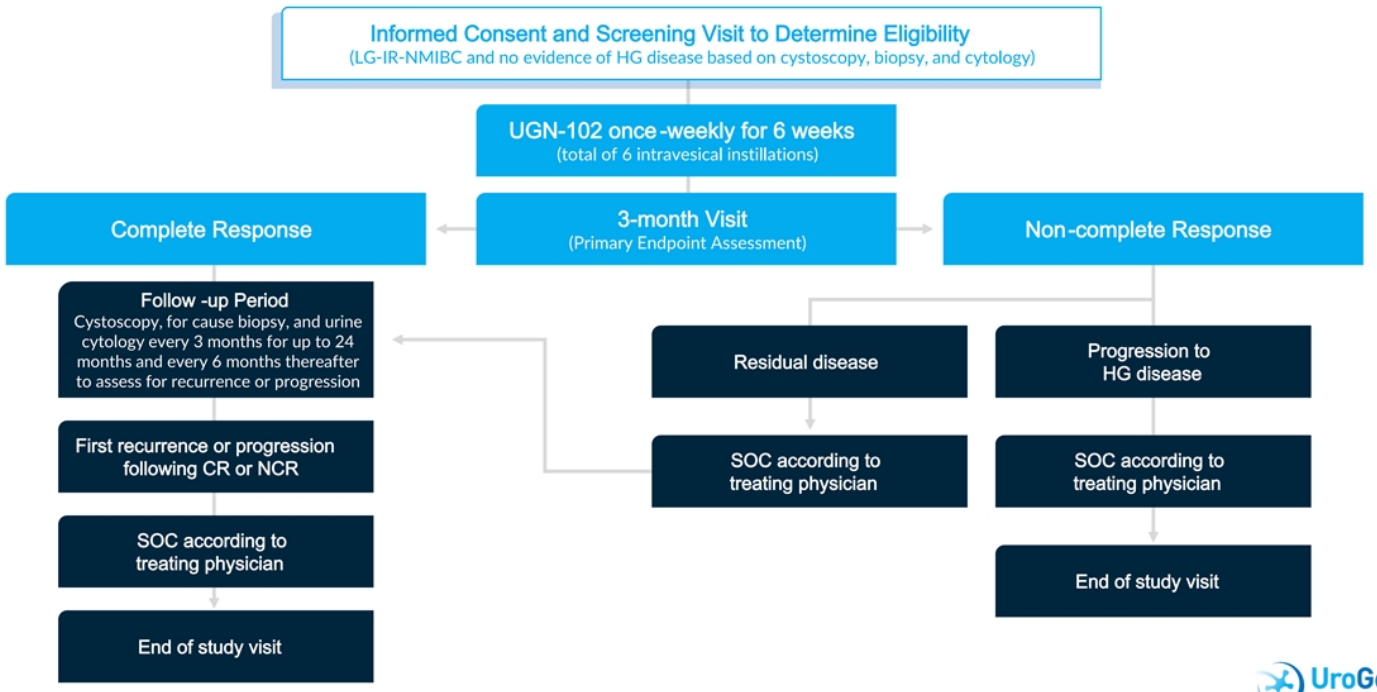

Q&A


THANK YOU!

APPENDIX

ENVISION Trial Design



SOC: Standard of Care

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Summary of Demographics and Baseline Characteristics

Characteristic Statistic	**UGN-102** (N = 240) / **n** (%)
Age	
Median Age (Min, Max)	70.0 (30, 92)
Age Group 2 (Years), n (%)	
>= 65	162 (67.5)
Sex, n (%)	
Male	147 (61.3)
Female	93 (38.8)
Prior TURBT, n (%)	
Yes	232 (96.7)
No	8 (3.3)
Previous LG NMIBC Episodes, n (%)	
Yes	229 (95.4)
No	11 (4.6)
Treatment Course, n (%)	
6 instillations	228 (95.0)
< 6 instillations	12 (5.0)

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Summary of Adverse Events Occurring in ≥5.0% of Participants

	UGN-102 (N=240)
Patients with Any TEAE	**137 (57.1)**
Dysuria	54 (22.5)
Haematuria	20 (8.3)
Urinary tract infection	17 (7.1)
Pollakiuria	16 (6.7)
Fatigue	13 (5.4)
Urinary retention	12 (5.0)

UroGen Data on File

UroGen Pharma