



**UroGen<sup>®</sup>**  
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 *JELMYTO*; 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

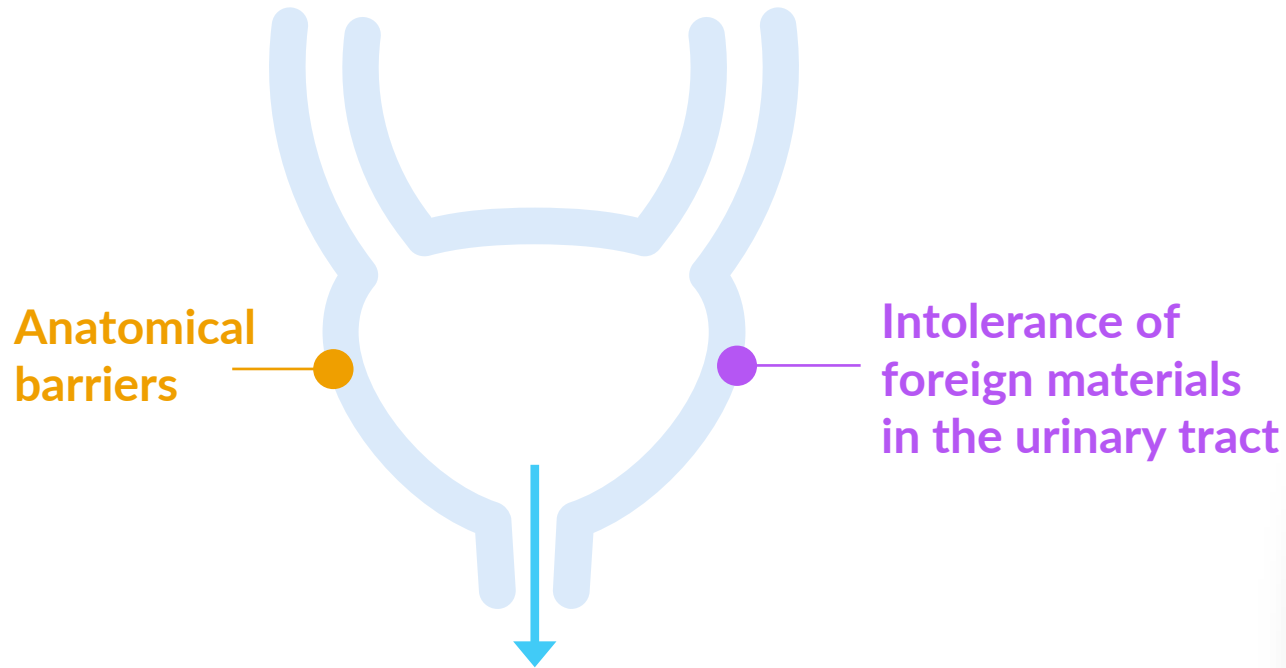


### **Strong Balance Sheet:**

\$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<sup>®</sup> 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**



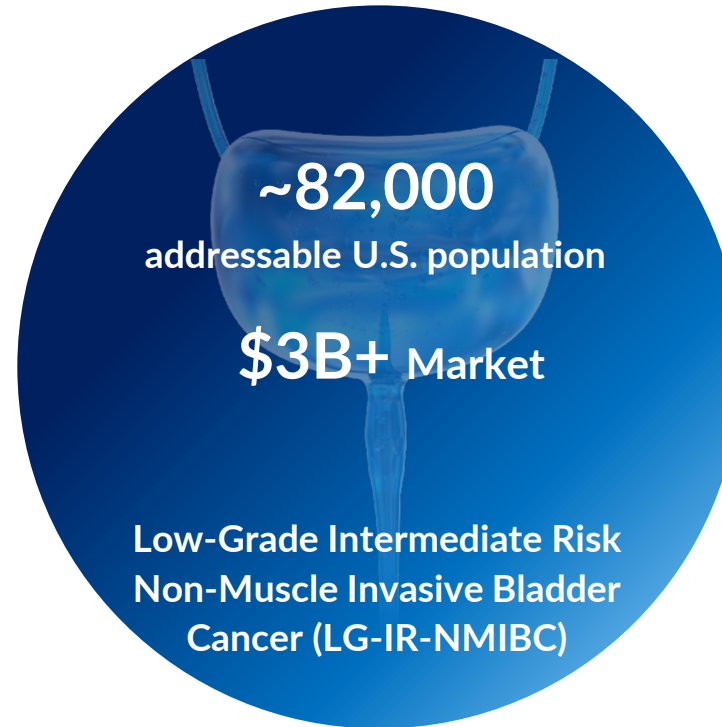
# Unlocking A Strong Foundational Pipeline Supporting Long-Term Sustainable Growth

## JELMYTO (UGN-101)



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

## UGN-102 Phase 3



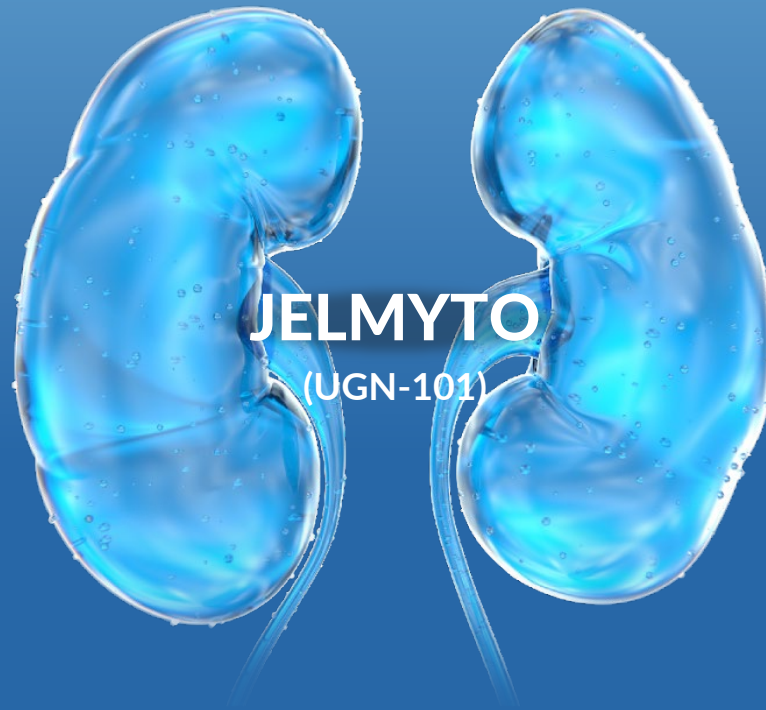
## UGN-301 Phase 1



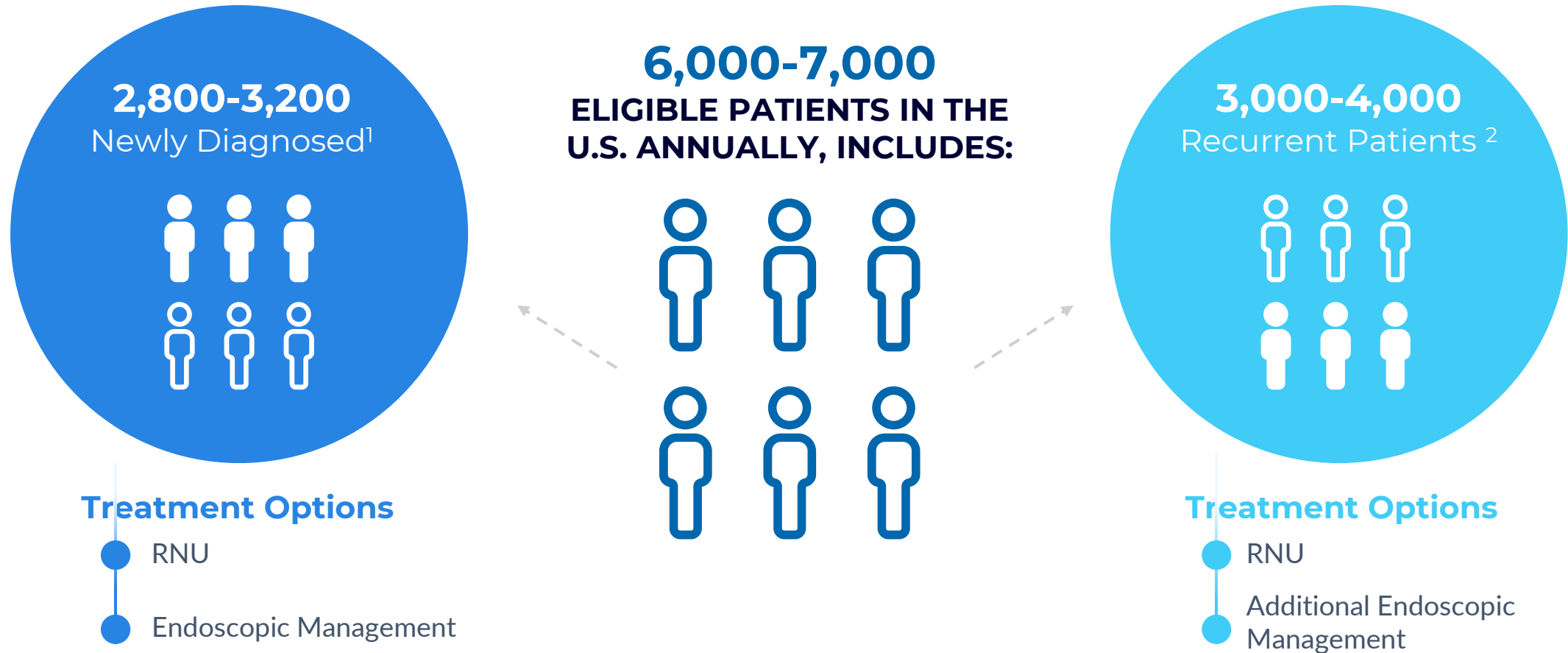
High-Grade Non-Muscle  
Invasive Bladder Cancer  
(HG-NMIBC)

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.

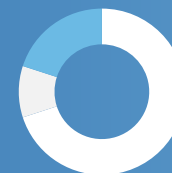
# Changing the Treatment Paradigm for Urothelial Cancers



# 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<sup>4</sup>



**70%-80%**  
of LG-UTUC patients ultimately  
receive nephroureterectomies<sup>3</sup>



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



## Clinically Meaningful OLYMPUS Phase 3 Data<sup>1</sup>

● **58%** Complete Response Rate at 3-months<sup>2</sup>

● **82%** Durability of Response at 12-months by KM estimate<sup>2</sup>

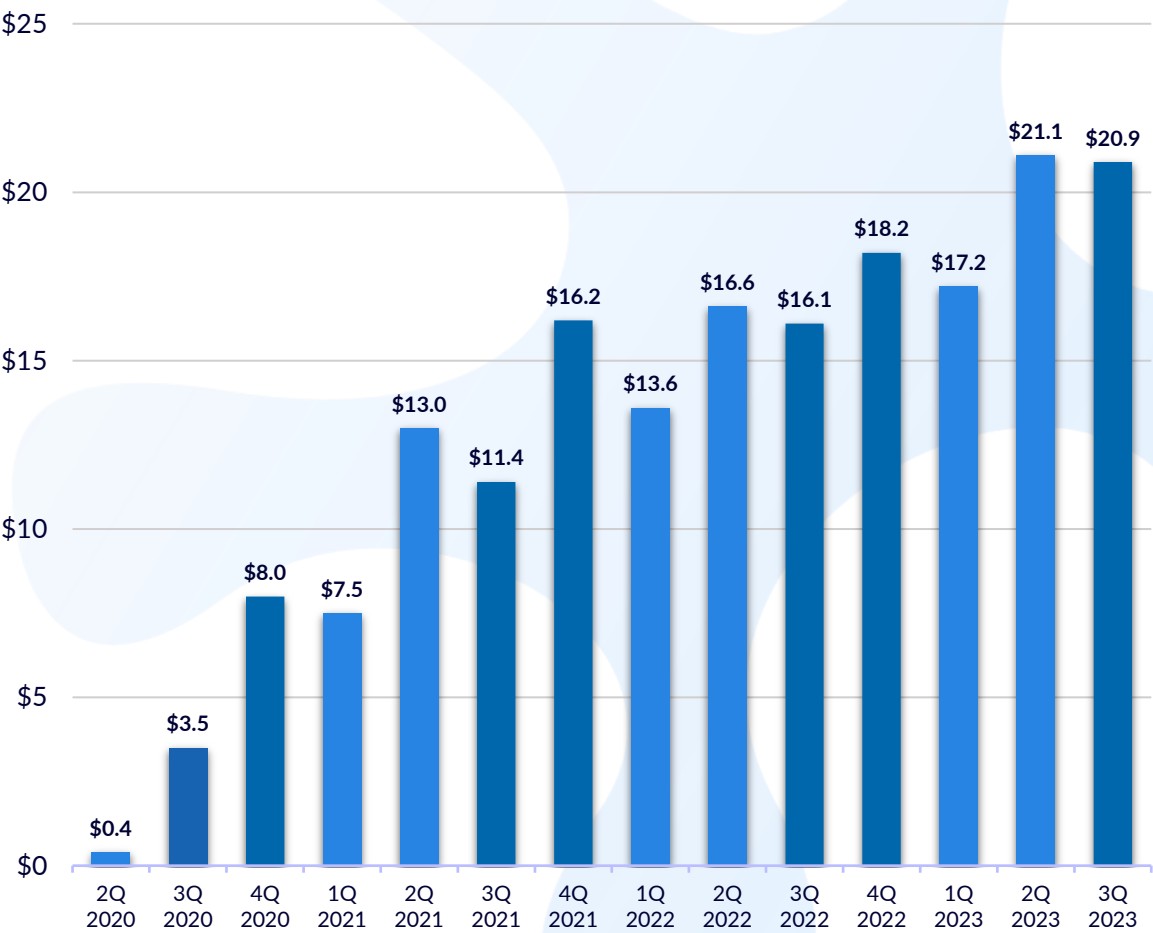
● **29 months** Median Durability of Response (14.6 to 47.6 months) data from long-term follow-up study<sup>3,4</sup>

1. Important Safety Information and the full Prescribing Information available at [https://www.urogen.com/download/pdf/jelmyto\\_prescribing.pdf](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.

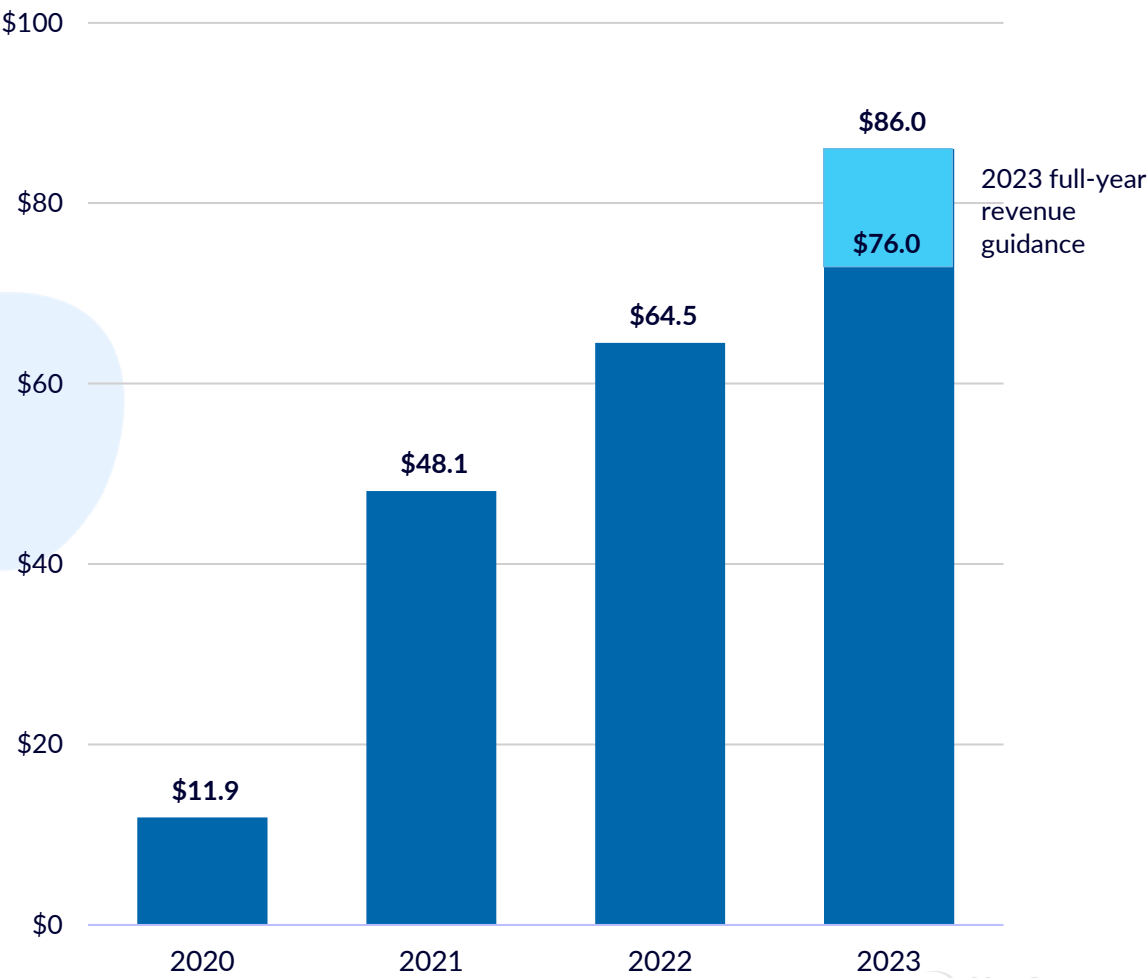
# JELMYTO Revenue Trend Reflects Long-term Growth

Observed QoQ Variability Is Expected with Summer/Holiday Seasonality

Quarterly JELMYTO WW Revenues (\$MM)



Annual JELMYTO WW Revenues (\$MM)



# 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<sup>1</sup>

**~70%**

Expected interest in prescribing  
JELMYTO over next 12 months<sup>2</sup>

## 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<sup>1</sup>

## Demonstration of Strong Support from Urologists

**296 accounts**  
have treated more than one patient<sup>1</sup>

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

## 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**



**UGN-102**

**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

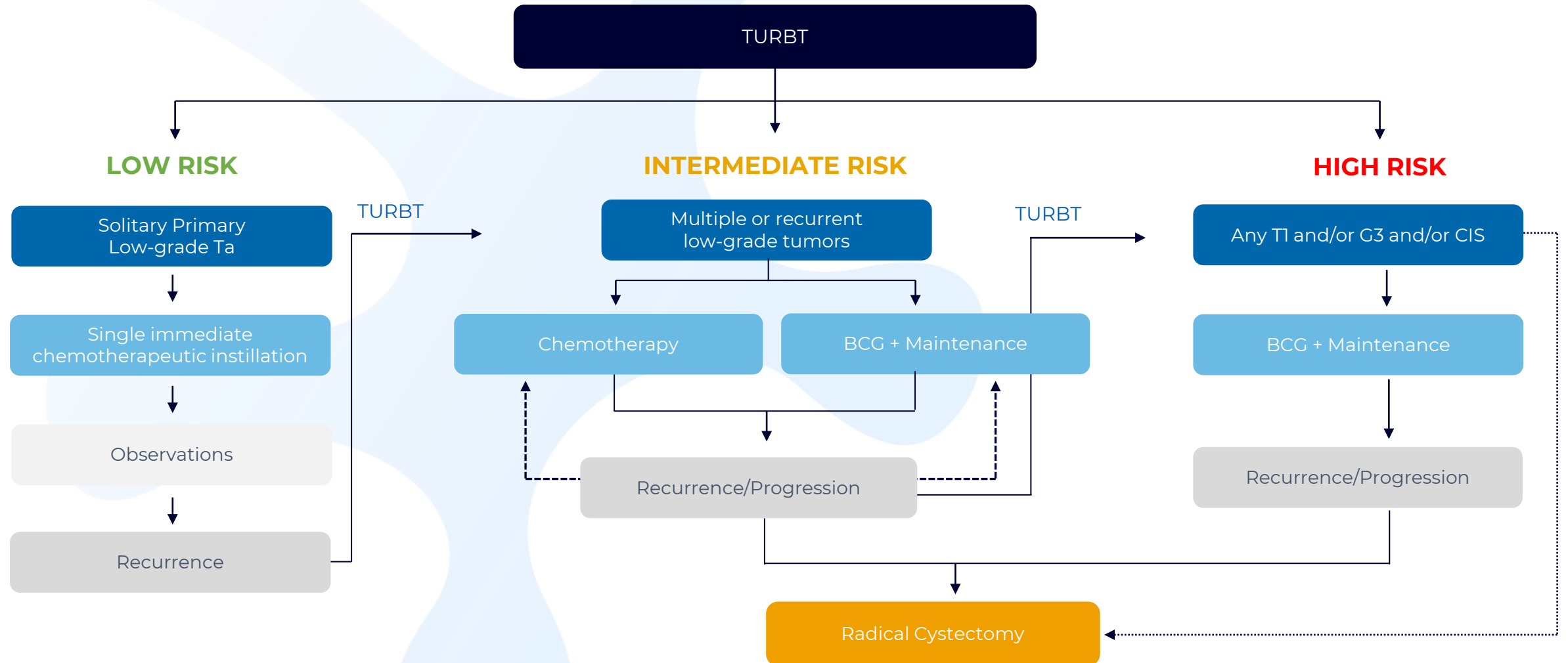
**BCG-refractory:** 18.7K

**Clinical trials ongoing** in BCG-refractory populations.

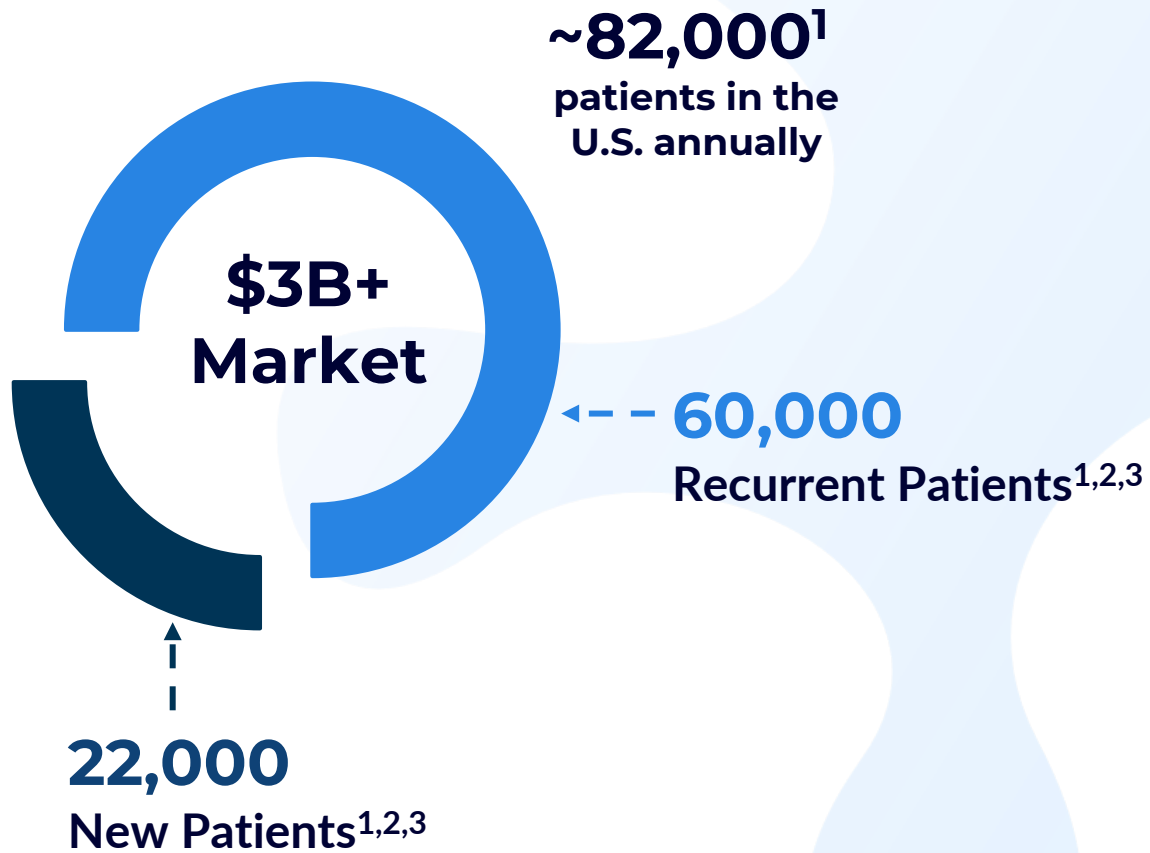
Significant unmet need given low response rates and durability

Goal is to avoid radical cystectomy

# Bladder Cancer Treatment Algorithm



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



INTERMEDIATE RISK (IR) PATIENTS ARE CHARACTERIZED BY 1-2 OF THE FOLLOWING<sup>4</sup>:

- 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<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>

# Patient Populations with Expected **Rapid Adoption** of UGN-102



**Multiple recurrences<sup>1</sup>**



**Surgically ineligible<sup>1</sup>**



**Early recurrences<sup>2</sup>**

In a recent survey, **92%** of Urologists stated they would use UGN-102<sup>3</sup>

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:

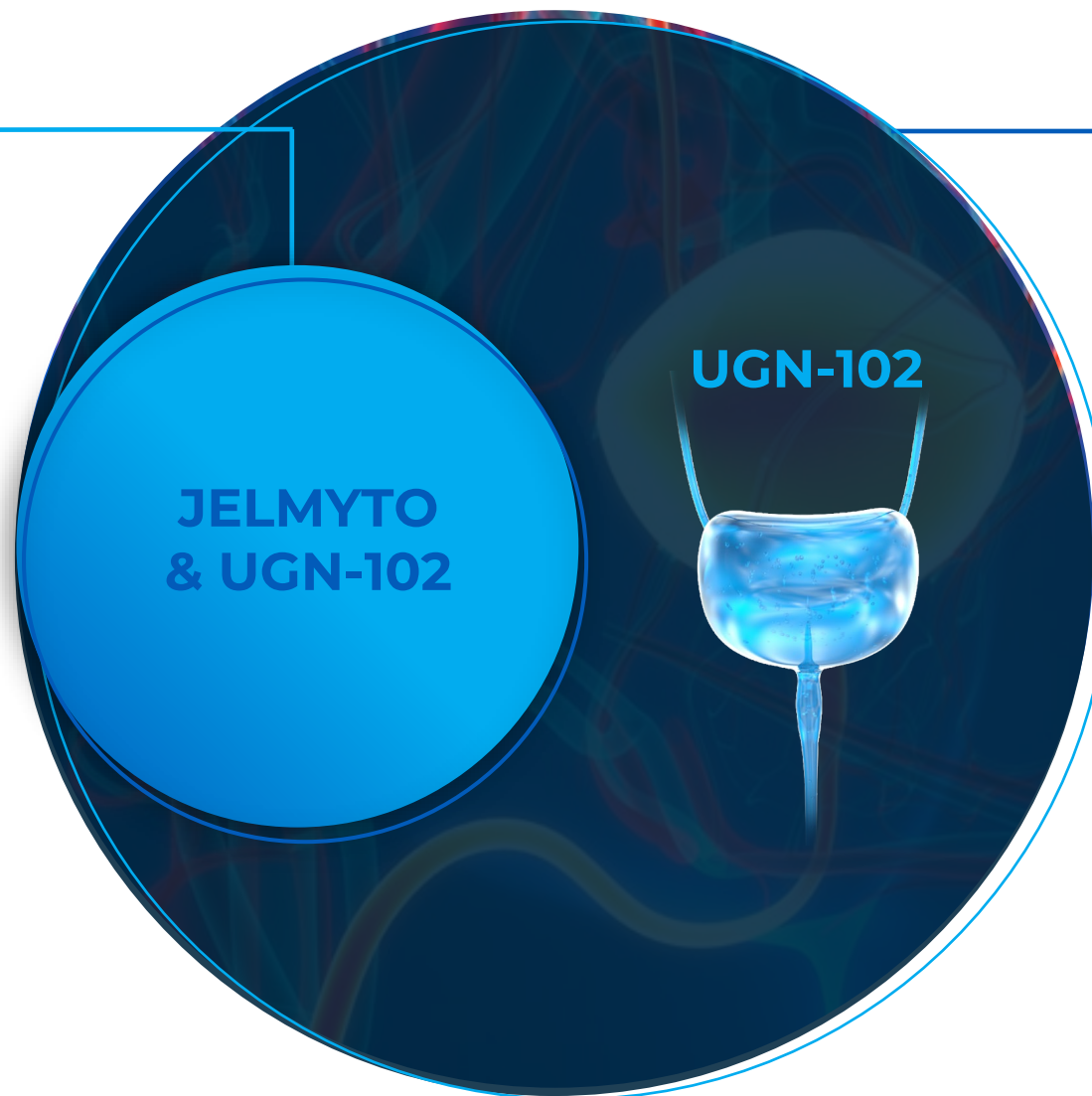
- Lack of disruption to daily life
- Less invasive
- Less painful
- Less time-consuming
- No post-op catheter

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

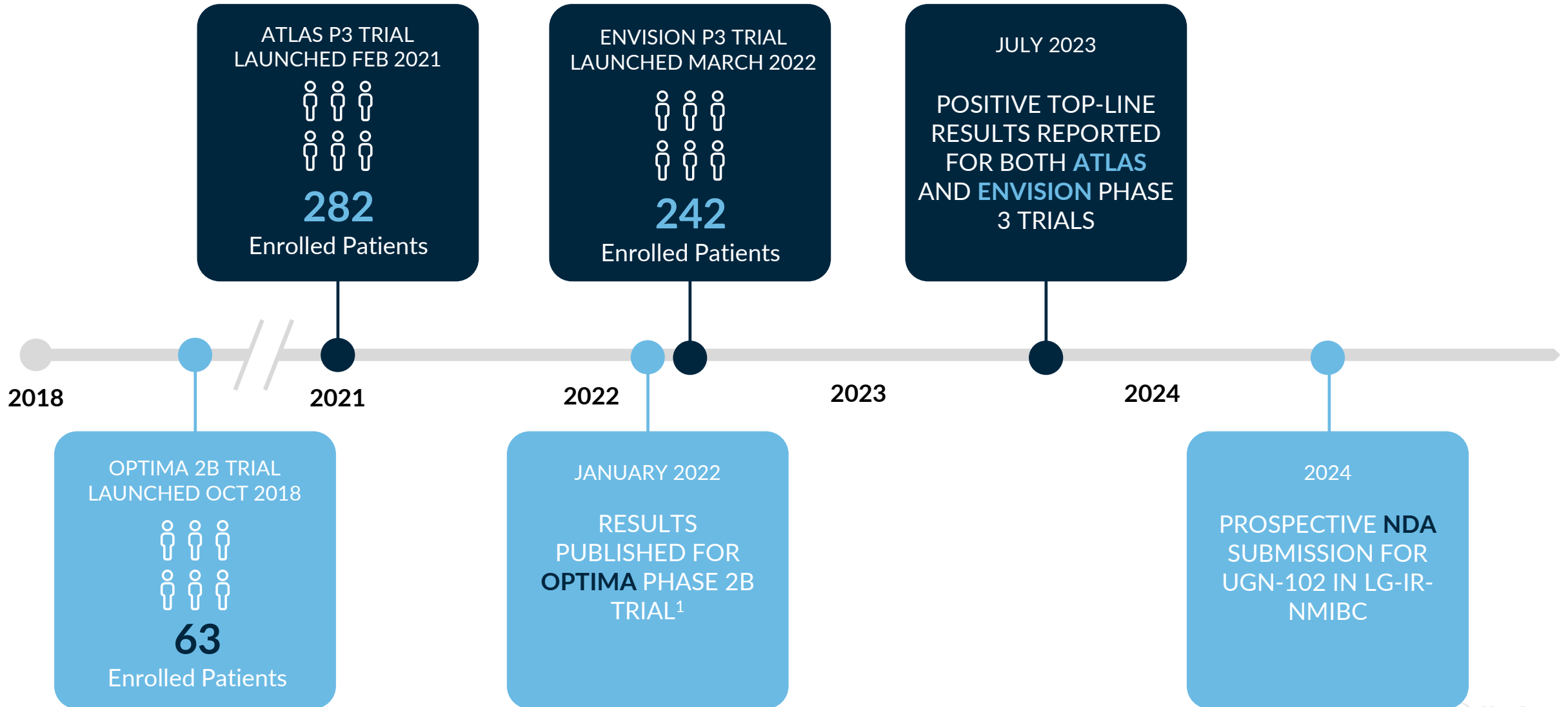
- **RTGel® & mitomycin formulations**
- **Mitomycin RTGel® combinations**
- Similar diseases at a **genetic & mutational** driver level
- **Share a 95% prescriber base**



## 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

# Overview of UGN-102 Program



# 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)	



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

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

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

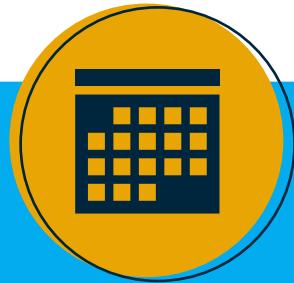
Prasad et al. JUrOl, 7Aug2023,  
UroGen Data on File, Source: Table 14.2.2.1a



# Looking Ahead

ENVISION DOR data expected in

**2Q 2024**



Planned NDA Submission by

**4Q 2024**



# 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

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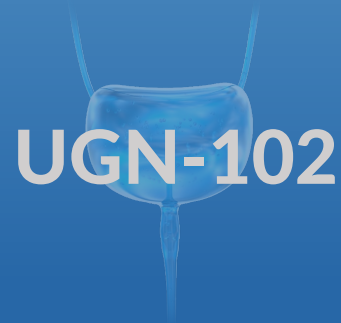
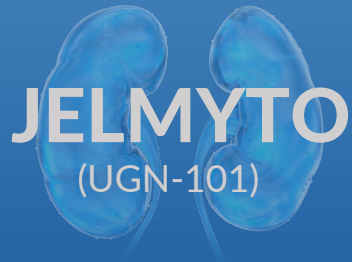
UroGen plans to initiate a Phase 3 study in 2024 to evaluate UGN-103 in LG-IR-NMIBC

Potential IP protection until 2041

## POTENTIAL ADVANTAGES

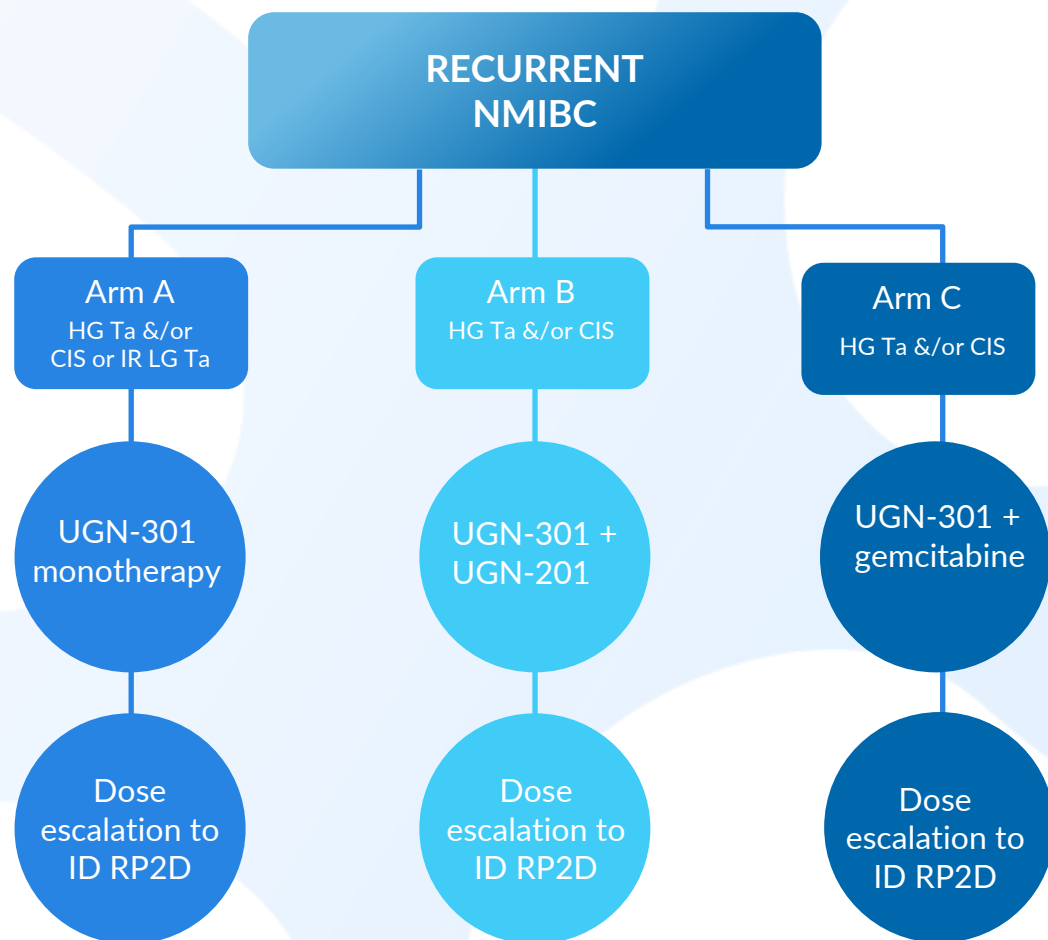
- ✓ Production
- ✓ Supply
- ✓ Cost
- ✓ Product convenience

# Expanding to Immuno-Oncology with Potential Monotherapy and Combination Therapy



# 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<sup>1</sup> 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

**\$154M**

Cash, cash equivalents and marketable securities<sup>1</sup>

**\$20.9M**

JELMYTO revenue in Q3 2023

**\$76-  
\$86M**

Full-year 2023 Jelmyto revenue guidance

**\$120M**

Private placement of ordinary shares & pre-funded warrants<sup>2</sup>

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<sup>®</sup>**  
Pharma

**Thank You**

March 2024

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

