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): January 14, 2025

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 may be used by the Company in meetings with investors, analysts and others.

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 January 2025
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: January 14, 2025

UROGEN PHARMA LTD.

By: /s/ Chris Degnan
Chris Degnan
Chief Financial Officer

Exhibit 99.1

Developing Innovative Medicines to Treat Urothelial Cancers

January 2025

UroGen Pharma

Disclaimers

This investor presentation contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation: the potential of UroGen's proprietary technology to enhance proven and novel medicines and deliver them aligned with the way urologists practice; the estimated addressable patient population and market and revenue opportunity for JELMYTO in LG-UTUC, UGN-102 and UGN-103 in LG-IR-NMIBC, and UGN-301 in HG-NMIBC; the potential of UroGen's proprietary RTGel® technology platform to improve therapeutic effects of existing products; the expectations regarding the continued growth of JELMYTO revenue; the potential of JELMYTO® and UGN-104, UGN-102 and UGN-103, and UGN-301 to transform the treatment paradigm in LG-UTUC, LG-IR-NMIBC, and HG-NMIBC, respectively; the potential that JELMYTO and UGN-102, if approved, are adopted as a standard of care; UroGen's pipeline supporting long-term sustainable growth; the interpretation and summary of results of OLYMPUS Phase 3, OPTIMA Phase 2b, ATLAS, and ENVISION trials; the potential of UGN-102, including to be the first FDA approved medicine for LG-IR-NMIBC and to set the new standard of care for LG-IR-NMIBC; the potential advantages of UGN-102 over TURBT; the expected timing for ODAC and PDUFA target action date for UGN-102; the potential launch of UGN-102, increasing adoption of JELMYTO, if approved; the potential of UGN-301 to expand to Immuno-Oncology with potential monotherapy and combination therapy; the ongoing and planned clinical studies for UGN-301; the potential benefits of and expected patent protection for UGN-103 and UGN-104; the ongoing Phase 3 UTOPIA study of UGN-103 in LG-IR-NMIBC; UroGen's plans for the future including initiating Phase 3 studies to evaluate UGN-104 in LG-UTUC, and the timing thereof, the expansion of the JELMYTO uTRACT registry, publishing OLYMPUS LTFU data, supporting pilot investigator-initiated study of JELMYTO in HG-UTUC and UroGen's field organization size, positions and responsibilities; UroGen's priorities including advancing pre-commercial and launch activities for UGN-102; focusing on strategic and efficient capital deployment, extending UroGen's leadership in addressing unmet needs in Urothelial cancers and building a long-term sustainable growth business; and UroGen's ability to draw down the remaining $75M under its credit facility. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: there is no guarantee that the NDA will be sufficient to support approval of UGN-102 by the target PDUFA date of June 13, 2025, or at all; UroGen's pending patent applications, may not be successful and in such event the duration of its intellectual property protection would be more limited; the timing and success of clinical trials and potential safety or other complications encountered therein; results from prior or ongoing clinical trials and the real-world retrospective studies of JELMYTO 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; 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; UroGen's financial condition and need for additional capital; UroGen's inability to meet the closing conditions required to draw down additional funds under its credit facility; the impacts of macroeconomic and geopolitical conditions, high inflation, and uncertain credit and financial markets on UroGen's business, clinical trials and financial position; 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 September 30, 2024, filed with the Securities and Exchange Commission (SEC) on November 6, 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 Pharma

Investment Highlights

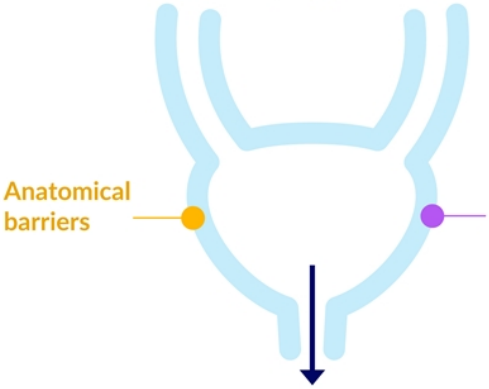
UroGen is pioneering new therapies to meet the unique needs of patients with urothelial cancers by utilizing proprietary technology with the potential to enhance proven and novel medicines and deliver them aligned with the way urologists practice

Commercial Product	Late-Stage Clinical Asset	Immuno-Oncology Pipeline	Strong Balance Sheet
JELMYTO is the first and only FDA-approved non-surgical treatment for patients with LG-UTUC.	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. Target PDUFA of June 13, 2025. 10x larger potential patient population than LG-UTUC[1].	UGN-301 is an anti-CTLA 4 monoclonal antibody for monotherapy and combination intravesical solution for use in high grade NMIBC.	$254.2 million in cash, cash equivalents and marketable securities at September 30, 2024.

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

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 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**

UroGen Pharma

Unlocking a Strong Foundational Pipeline Supporting Long-Term Sustainable Growth

JELMYTO/UGN-104

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

UGN-102/UGN-103

Phase 3

UGN-301

Phase 1

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

1. Upfill-Brown 2018,
2. Cutress 2012
3. ACS Cancer Facts & Figures 2023
4. SEER, AUA/SUO joint guideline
5. Babjuk et al. European Urology (2019), Simon et al (2019) PLoS ONE 14(2): e0211721
6. UroGen commissioned third party assessment (Lion Healthcare Strategies, Ambaw)

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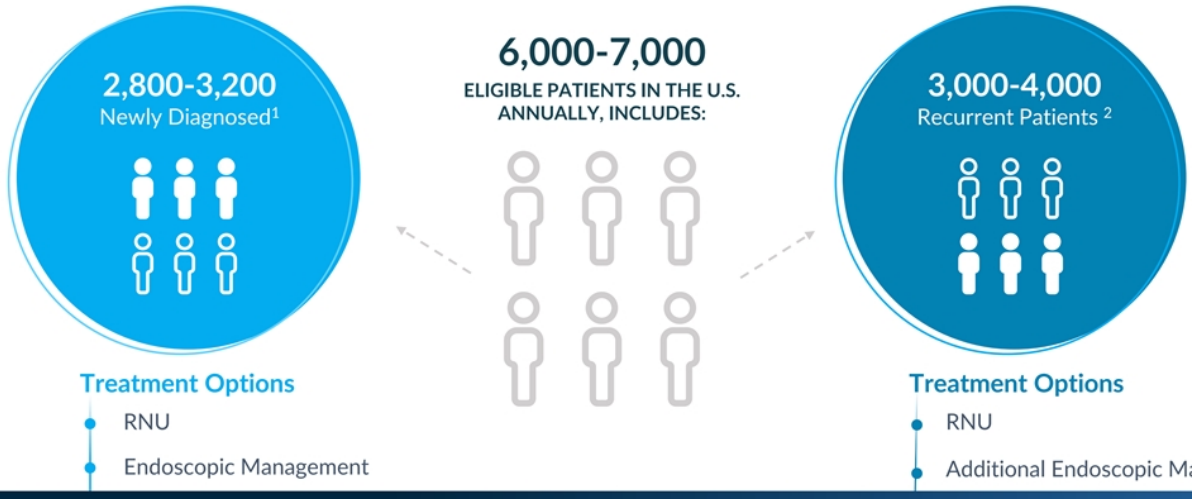
Changing the Treatment Paradigm for Urothelial Cancers
(UGN-101)
JELMYTO
UroGen Pharma

LG-UTUC Is a Rare Disease that Recurs Often



Treatment Options

- RNU
- Endoscopic Management

Treatment Options

- RNU
- Additional Endoscopic Management

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

50%-80% of LG-UTUC patients ultimately receive nephroureterectomies[1,3]

1. Upfill-Brown 2018 2. Cutress et al. (2012 BJU International 2012) 3. Kohut R, Zhu H. JUrol May 2012, Hui Zhu 4. Yeung et al. (2014) Pharmacoeconomics 5. RNU = radical nephroureterectomy

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JELMYTO First and 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]

47.8 months Median Duration of Response (95%CI: 13.1, 57.5; n=41) data from long-term OLYMPUS 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. UroGen Data on File: Post-hoc analysis from the OLYMPUS trial that evaluated the long-term efficacy of JELMYTO in patients who experienced a CR
4. Limitations of long-term follow-up study include patient population N=41. Amongst the 41 patients followed after initial complete response at 3-months median duration of response was 47.8 months (95% CI 13.0, not estimable) (median follow-up 28.1 months (95% CI: 13.1, 57.5)). Please refer to the referenced citations disclosures of such limitations.

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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 58% 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*.

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

UroGen Pharma

JELMYTO Retrospective Analysis Results Presented at AUA 2024*

JELMYTO treatment demonstrates favorable Recurrence Free Survival (RFS) rates for patients with LG-UTUC who respond to initial induction[1]

86%

RFS at 24-months for LG-UTUC patients who were complete responders to induction therapy[1]

100%

RFS at 24-months in patients who received maintenance therapy of JELMYTO, compared to 61% in those who did not[2]

Additional Insights

No differences in RFS were observed regarding[1,2]:

- Usage of chemoablation vs. post-endoscopic resection
- Tumor size
- Multifocality
- Tumor location

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

1.Woldu et al. Exploring Recurrence After Initial Response to UGN-101 Induction in Expanded Settings. AUA 2024 Presentation
2.Woldu et al. Longitudinal Follow Up of Multicenter Study of UGN-101 for Upper Tract Urothelial Cancer. AUA 2024 Presentation

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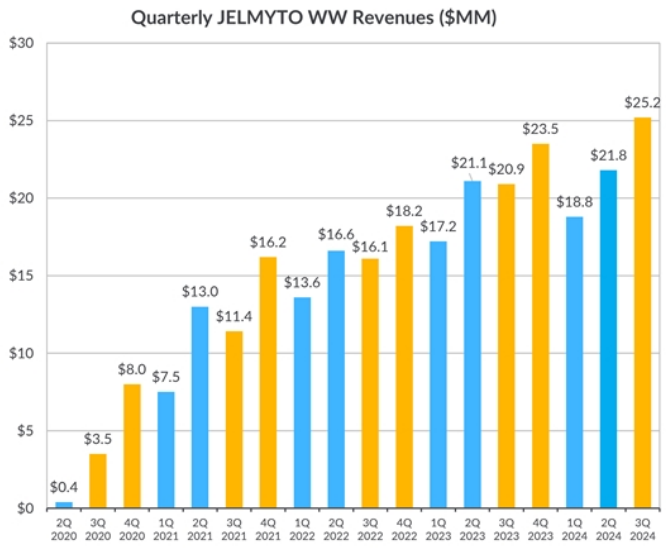
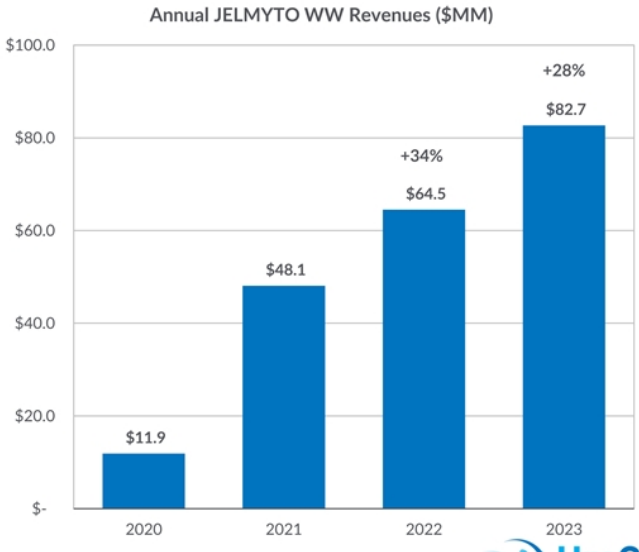
JELMYTO Revenue Trend Reflects Continued Growth






Changing the Treatment Paradigm for Urothelial Cancers
UGN-102
UroGen Pharma

UGN-102: The First Potential Breakthrough Localized Therapy For Patients with LG-IR-NMIBC in Over 30 Years[1,2]

UGN-102 represents a new approach specifically for LG-IR-NMIBC, with strong efficacy and safety data in the ENVISION phase 3 trial[1]

Innovative reverse-thermal hydrogel containing mitomycin offers potent tumor ablation:[1]

- **79.6%** complete response at 3 months*† (95% CI: 73.9, 84.5; n=191/240)[1]
- **82.3%** of patients who achieved CR estimated to remain tumor free at 12 months (95% CI: 75.9, 87.1; n=108/191)[1]
- Can be administered intravesically in an outpatient setting[1]

†:Complete response was defined as negative white light cystoscopy, negative urine cytology, and when indicated, a negative for-cause biopsy at 3 months.1
CI=confidence interval.

1. Prasad et al. JUrol, 25Feb2024; 2. Steinberg RL, Thomas LJ, O'Donnell MA. Bacillus Calmette-Guérin (BCG) treatment failures in non-muscle invasive bladder cancer: What truly constitutes unresponsive disease. Bladder Cancer. 2015;1(2):105-116. doi:10.3233/blc-150015

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LG-IR-NMIBC Market has Key Differences to HG-NMIBC Market

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 Focuses on Improving Patient Outcomes with Non-Invasive, Durable Option for LG-IR-NMIBC

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

59,000
Recurrent Patients[1,2,3]

23,000
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. Chang et al. JUii 2016 Diagnosis and Treatment of NMIBC AUA SUO Guideline

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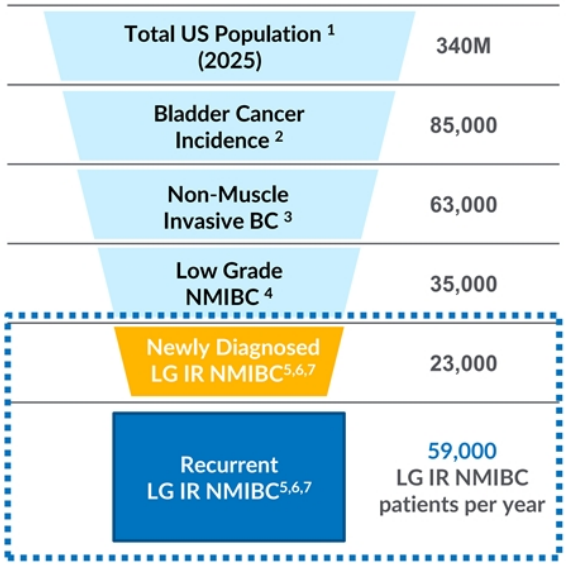
There Are Approximately 82K Annual Cases of Eligible LG IR NMIBC Patients



1. US Census; 2.NIH; 3. SEER; 4. SEER; 5. ACS Cancer Facts & Figures 2023; 6. SEER, AUA/SUO joint guideline; 7. Babjuk et al. European Urology (2019), Simon (2019)

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LG-IR 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 et al.. 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),
5. Simon M et al. ed. PLOS ONE. 2019;14(2):e0211721. doi:https://doi.org/10.1371/journal.pone.0211721

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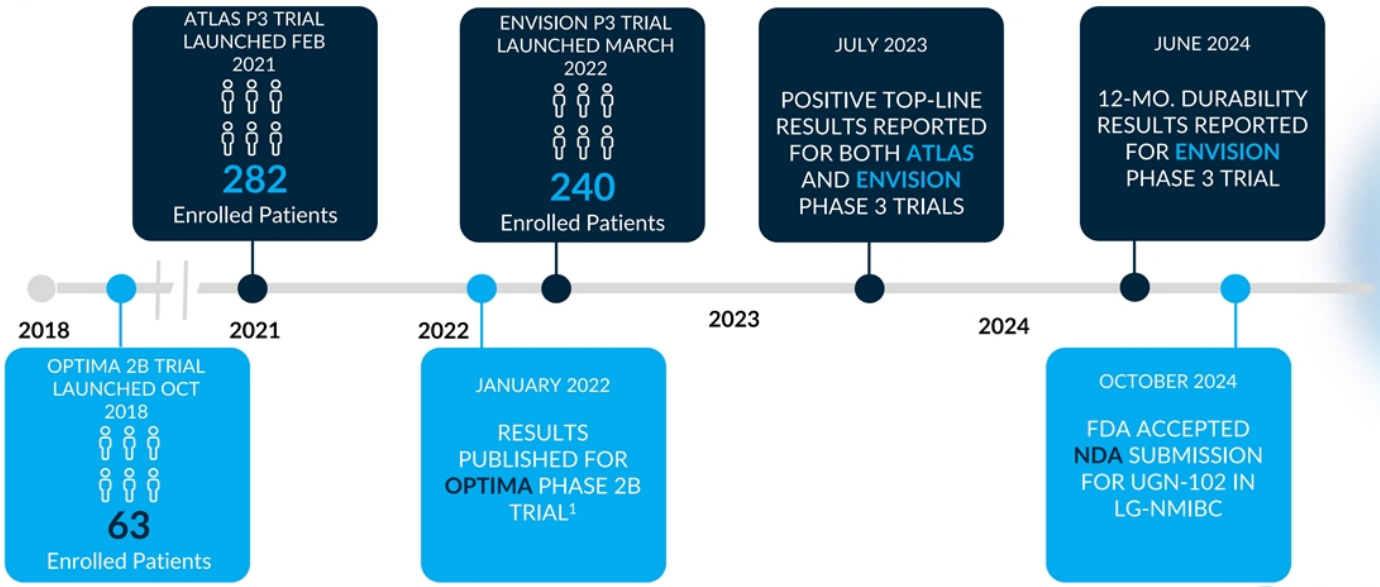
Overview of UGN-102 Clinical Program



1 J Urol. 2022 Jan; 207(1): 61–69.

Envision Phase 3 Summary of Response Rate At 3-Month Disease Assessment: CRR of 79.6%

	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)	

Prasad et al. 25Feb2024, JUROL

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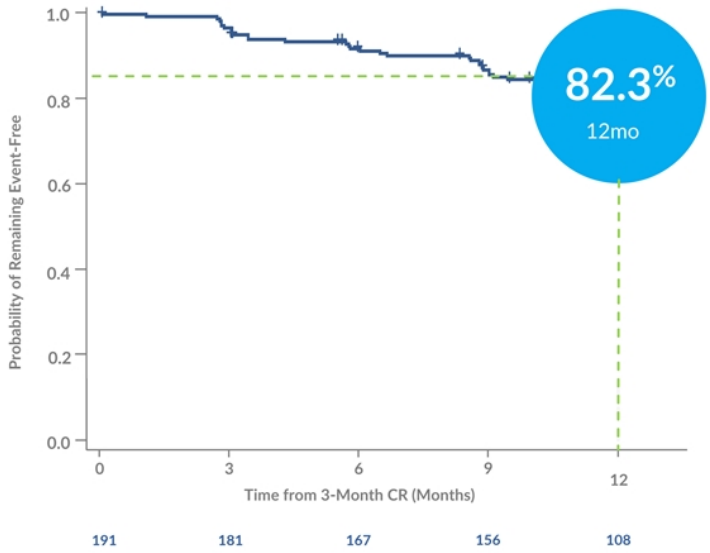
Envision Phase 3 Duration of Response (DOR): 82.3% at 12 months



	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 (n=43)	**80.9%** (73.9, 86.2)
18 months (n=9)	**80.9%** (73.9, 86.2)

*Time from 3-month CR

Prasad et al. JUrol, 25Feb2024

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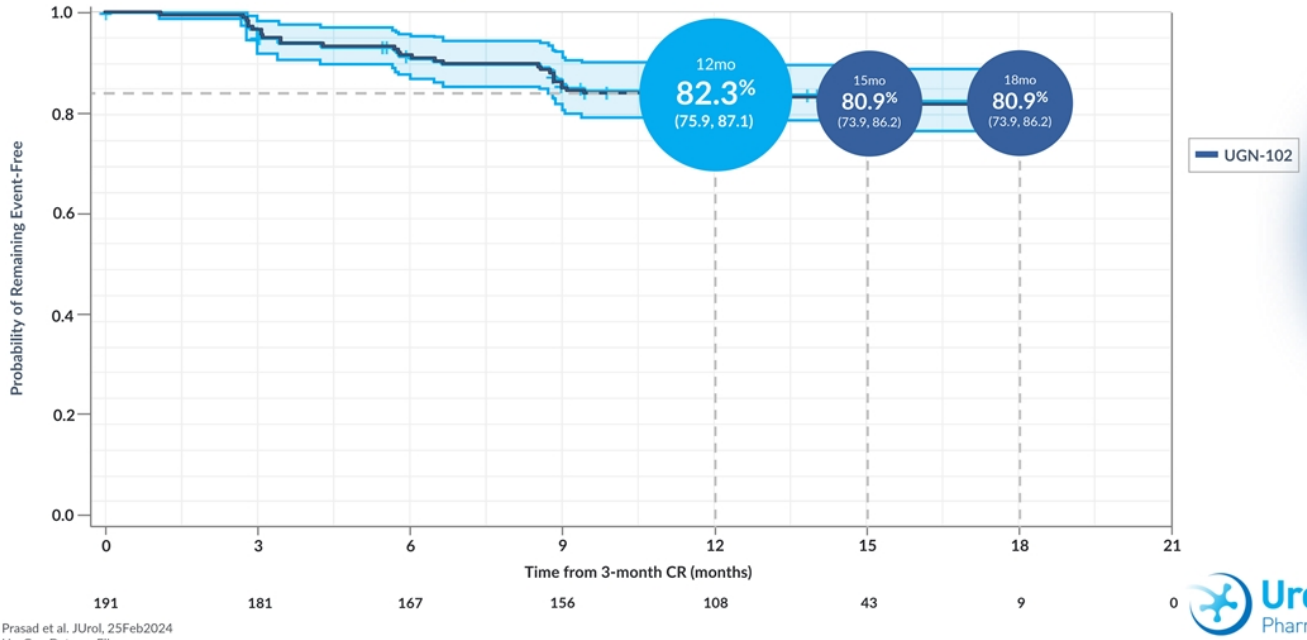
Large Sample Size Resulted In Tight Confidence Intervals



Prasad et al. JUrol, 25Feb2024
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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Adverse Events (AEs) Mainly Related To Lower Urinary Tract Symptoms

	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)

Treatment-emergent AEs (TEAEs) were generally **mild to moderate** in severity

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)

Prasad et al. JUrol, 25Feb2024

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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) 3-month disease assessment	79.6%	74% vs. 53%	65% vs. 64% Similar CRR; offers a less invasive option to patients
Duration of Response (DOR) 12-months following CR	82.3%	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) 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)	Not Reached	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; Prasad et al. JUrol, 25Feb2024
UroGen Data on File, Source: Table 14.2.2.2.1a

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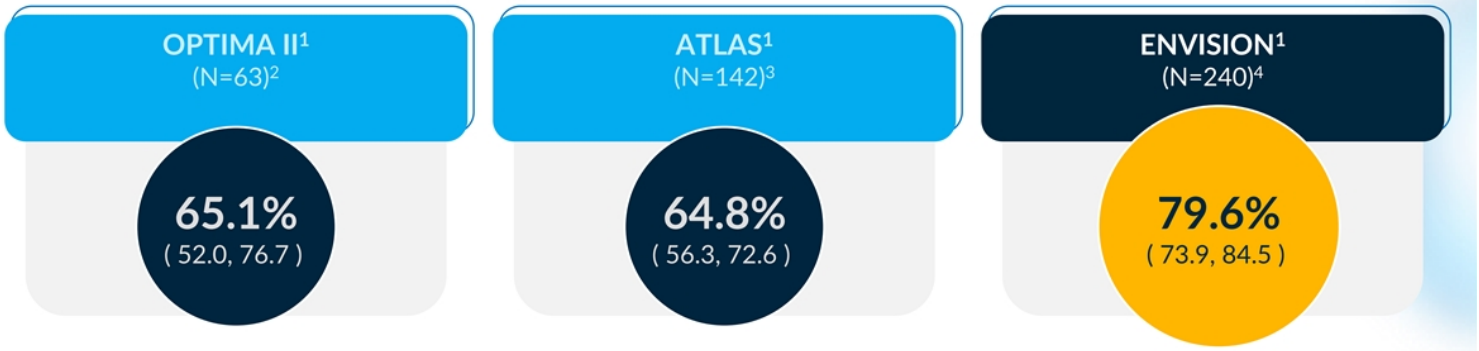
Consistently High Complete Response Rate At 3 Months



1. UroGen Data on File
2. OPTIMA II was a Phase 2B, single-arm, open-label study in patients with newly diagnosed and recurrent LG-IR-NMIBC.
3. 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.
4. ENVISION is a Phase 3, single-arm, open-label study in patients with LG-IR-NMIBC.

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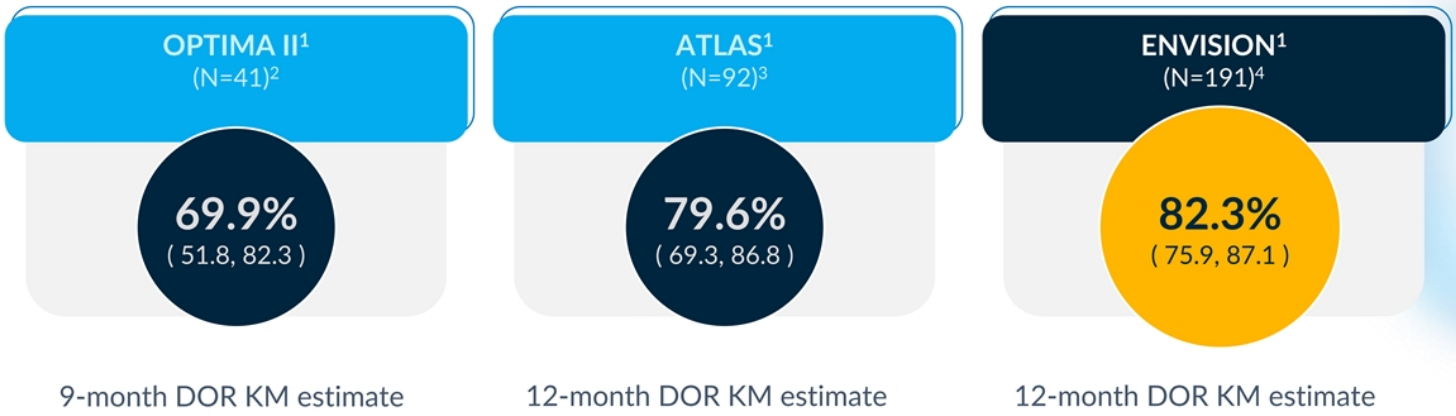
Robust Duration of Response



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2. OPTIMA II was a Phase 2B, single-arm, open-label study in patients with newly diagnosed and recurrent LG-IR-NMIBC.
3. 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.
4. ENVISION is a Phase 3, single-arm, open-label study in patients with LG-IR-NMIBC.

UroGen Pharma

ENVISION Patients Preferred UGN-102 to TURBT

- 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 (n=29)

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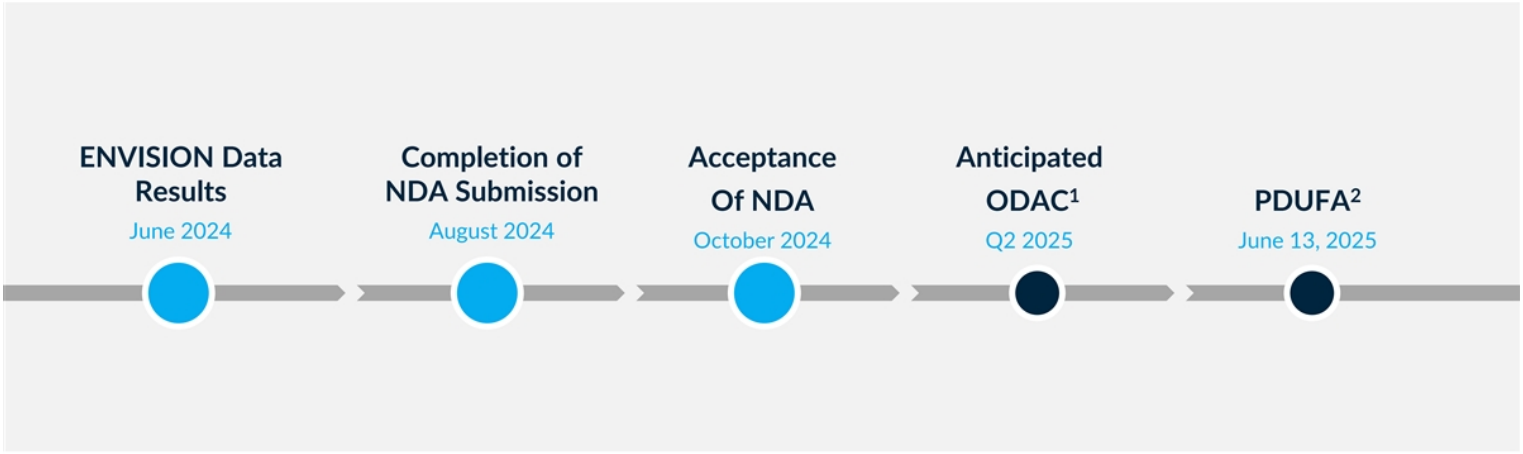
Projected NDA Review Timeline for UGN-102



1. ODAC (Oncologic Drugs Advisory Committee) anticipated in Q2 2025 based on most recent interactions with the U.S. Food and Drug Administration (FDA)
2. PDUFA Target Action Date

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Field Organization Will Deliver Industry-Leading Clinical Education and Operational Support, Covering 85% of Market Opportunity

Target HCPs (includes physicians and extenders) ~9,000

Territory Business Managers (TBM) at launch ~85

Sales Force	Regional Business Director (RBD)
	Territory Business Manager (TBM)
	National Business Executive (NBE)
Field Support	Clinical Nurse Educator (CNE)
	Regional Operation Manager (ROM)
Market Access	Key Account Director (KAD)
	Field Reimbursement Manager (FRM)
Medical	Medical Science Liaisons (MSL)

Note: Based on management expectations and latest forecast

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 use 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

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Urologists' feedback reflects growing interest for a new, innovative treatment option in LG-IR-NMIBC

- Urologists acknowledge the **rapid and frequent recurrences and numerous procedures** patients face, in addition to potential increased morbidity[1]
- Excitement around **promising and impressive** ENVISION data as the first potential product indicated for LG-IR-NMIBC[2]
- Urologists consider UGN-102 a **paradigm shifting novel therapeutic** with almost 80% of patients achieving CR at 3 months with an estimated DOR at 12 months around 82%[2]
- **Durability is "meaningful and differentiating"** when compared to TURBT in this LG-IR-NMIBC patient population[2]
- UGN-102 has a **favorable safety profile**[3]
- Urologists find the **prolonged dwell time a benefit** over other intravesical therapies; great option for "difficult to reach" tumors; for small, multifocal, LG, IR disease or for LG recurrence[2]
- **Challenges** urologists highlight include cost, delayed reimbursement, pharmacy logistics, and slow clinical and operational adoption, satisfaction and habit of TURBT[2]

1. Babjuk, 2019; Simon, 2019
2. UroGen Market Research and based on feedback from Ad Board comprised of Urology KOLs (n=21) held August and October 2024
3. Prasad et al, JUroL 25Feb2024

LG-IR-NMIBC = low-grade intermediate-risk non-muscle invasive bladder cancer, TURBT = transurethral resection of bladder tumor, CR = complete response, DOR = durability of response, LG = low-grade, IR = intermediate-risk

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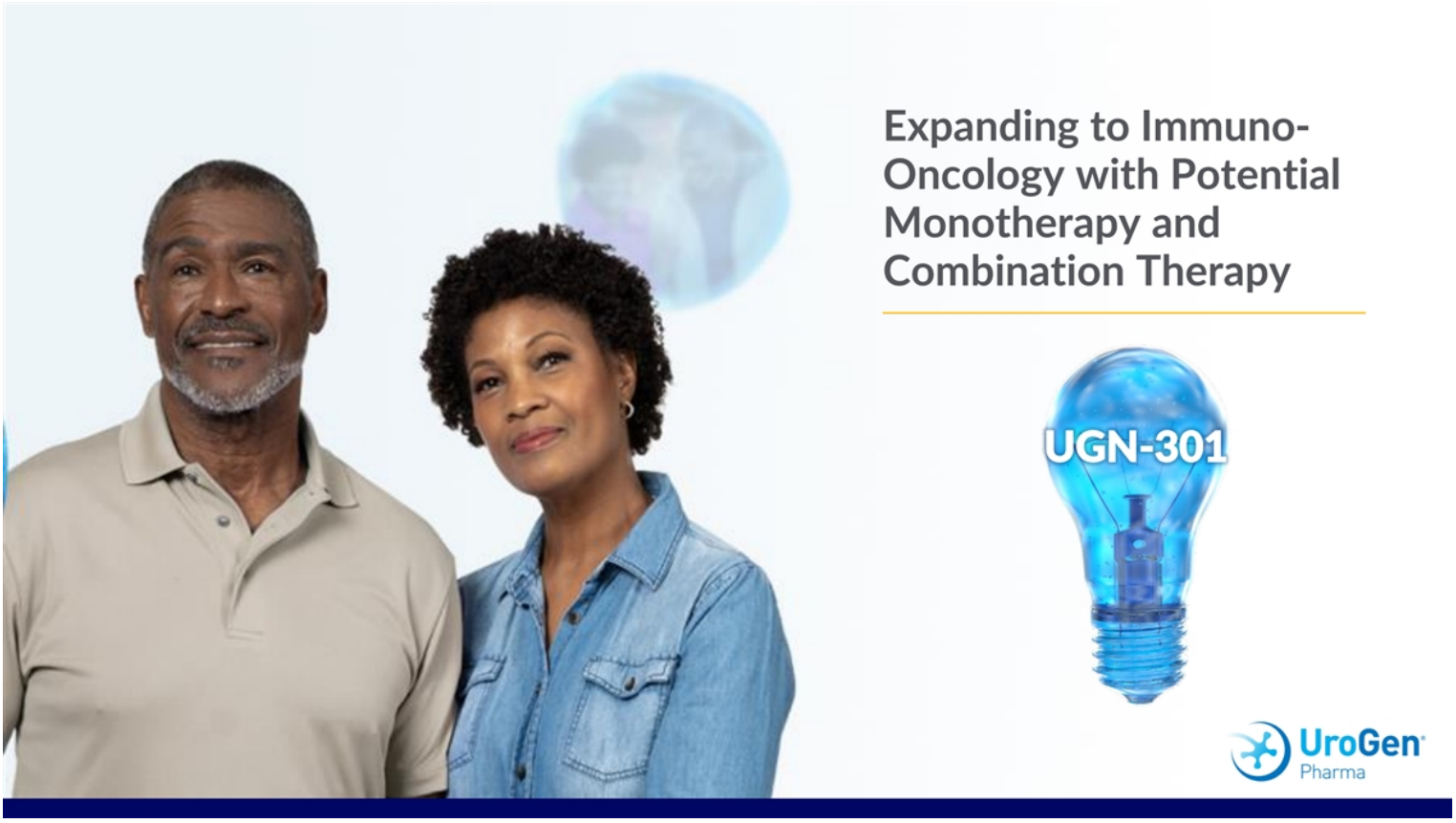
Expanding to Immuno-Oncology with Potential Monotherapy and Combination Therapy
UGN-301
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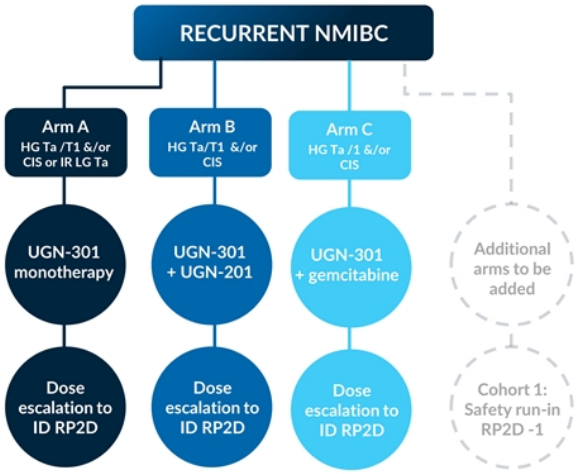
Ongoing Multi-arm Phase 1 Trial of UGN-301 (zalifrelimab) Anti-CTLA4 Antibody for Use in High-Grade Bladder Cancer



- 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 presented late 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

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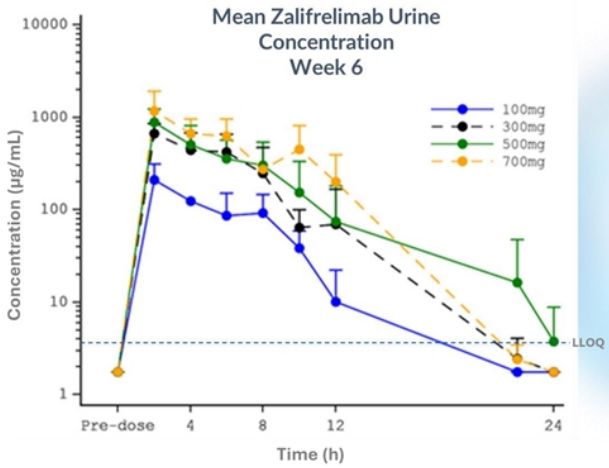
UGN-301 Phase 1 Dose Escalation Study

- UGN-301 is well tolerated and has a favorable safety profile at all dose levels
  - No DLTs & no TEAEs leading to treatment discontinuation
  - Mild or moderate TRAEs
- Local delivery of UGN-301, formulated in an RTgel, allows sustained exposure of zalifrelimab in the bladder while limiting systemic exposure
- Among the evaluable patients, 46% (6 of 13) and 33% (2 of 6), respectively, were recurrence-free or had a complete response at Week 12

		Cohort 1	Cohort 2	Cohort 3	Cohort 4	Total
	Dose level	**100 mg**	**300 mg**	**500 mg**	**700 mg**	
Ta/T1 patients	**Evaluable @ wk 12**	N=3	N=5	N=3	N=2	N=13
	Recurrence Free	1	3	2	0	6
	Recurrence	2	2	1	2	7
CIS +/- Ta/T1 patients	**Evaluable @ wk 12**	N=0	N=1	N=4	N=1	N=6
	Complete Response	N/A	0	2	0	2
	Non-Complete Response	N/A	1	2	0	3
	Indeterminate	0	0	0	1	1



Currently evaluating safety of UGN-301 as a combination therapy with intravesical UGN-201 or gemcitabine in HG recurrent NMIBC to establish RP2D

Dose limiting toxicity (DLT); Treatment emergent adverse event (TEAE); Treatment related adverse event (TRAE); Recommended Phase 2 dose (RP2D)


Looking Ahead
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UGN-103 & UGN-104: Next-Generation Novel Mitomycin-Based Formulation

Received New U.S. Patent Allowance for Next-Generation Mitomycin-Based Products Expected to Provide Protection Until December 2041

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

Initiated Phase 3 UTOPIA trial of UGN-103 in recurrent LG-IR-NMIBC patients, with UGN-104 Phase 3 trial expected to start in 1H 2025

Potential Advantages

☑	Production
☑	Supply
☑	Cost
☑	Product convenience

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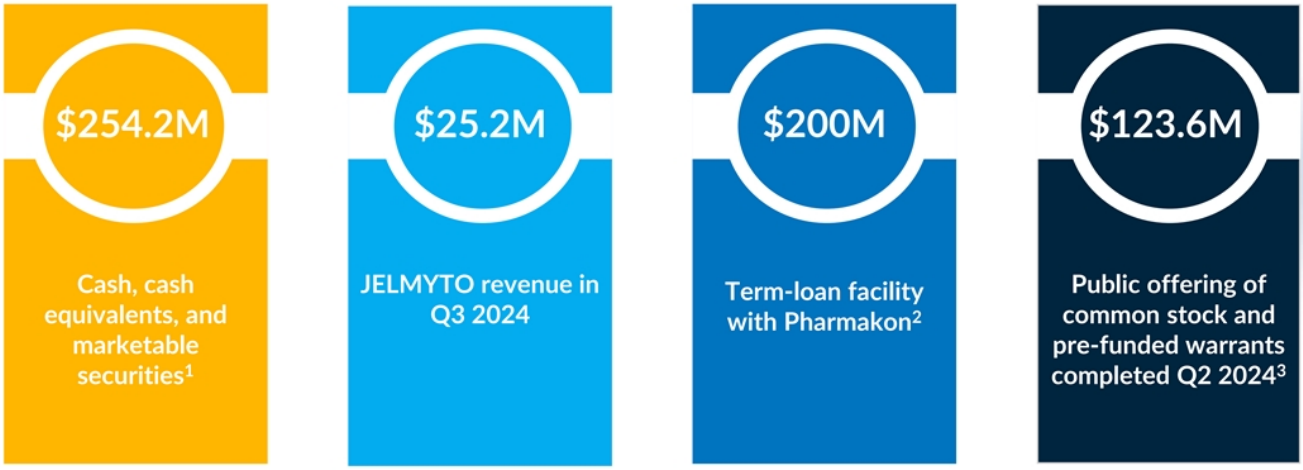
Financial Position



1. Cash, cash equivalents, and marketable securities as of 09/30/2024. Excludes restricted cash on Balance Sheet
2. In Q1 2024, UroGen entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25 million was drawn on September 23, 2024. The fourth tranche of $75 million may be drawn down at UroGen's discretion if UGN-102 is approved in the U.S. on or before June 30, 2025
3. The closing of the sale of $16.1 million of common stock pursuant to the underwriters' option to purchase additional shares was completed in July 2024

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In Summary....

With unprecedented data in LG-IR-NMIBC, we are focused on pre-commercial and launch activities for UGN-102 with a target PDUFA date of June 13, 2025

We continue to increase adoption of JELMYTO with recent Durability Data supporting continued use

We have a strong balance sheet with focus on UGN-102 commercial execution, and strategic and efficient capital deployment

Our next generation novel mitomycin formulations will provide an opportunity to extend our leadership in addressing unmet needs in Urothelial cancers

Through Organic and In-Organic opportunities, we plan to build a long-term sustainable growth business


Thank You
January 2025
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APPENDIX

UGN-102 Potentially Addresses the Unmet Need for a Better Treatment Option

79.6%
(73.9, 84.5)
Complete Response Rate at 3 months

82.3%
(75.9, 87.1)
Estimated probability of maintaining durable response at 12 months

Safety profile characterized primarily by mild to moderate AEs

Non-surgical treatment with potential to reduce overall burden on patients

UroGen Data on File

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UroGen is Striving 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+
Potential TAM[2]

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

Prolonged **disease-free intervals**

Generally well tolerated

RTGel is designed to uniquely address 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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Redefine SOC for LG-UTUC as Kidney-Sparing Management with JELMYTO

Amplify real-world experience with JELMYTO and generate additional data to inform clinical practice

Expand JELMYTO uTRACT Registry and support data collection around:

- Real-world durability and safety
- Effectiveness in broad patient and tumor types
- Adjunctive use after endoscopic ablation
- Outcomes following retreatment and maintenance therapy

Publish OLYMPUS long-term follow up data: In those achieving a CR, median DOR was ~4 years

Support pilot investigator-initiated study of JELMYTO in high-grade UTUC

Expected to Initiate Phase 3 Trial of UGN-104 in 1H 2025

- OLYMPUS-like trial to determine efficacy and safety of UGN-104
- UGN-104 to simplify reconstitution procedure and shorten the manufacturing process

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