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 11, 2021

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

N/A
(Former name or former address, if changed since last report.)

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.

Included as Exhibit 99.1 to this Current Report on Form 8-K is our corporate presentation, dated January 2021, which is incorporated herein by reference. We intend to utilize this presentation and its contents in various meetings with securities analysts, investors and others commencing January 11, 2021 in connection with the Annual J.P. Morgan Healthcare Conference.

The information in 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 (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Investor Presentation, dated January 11, 2021
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 11, 2021

UROGEN PHARMA LTD.

By: /s/ Molly Henderson
Molly Henderson
Chief Financial Officer

UROGEN PHARMA

J.P. MORGAN 2021 HEALTHCARE CONFERENCE
JANUARY 11, 2021

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 market opportunity of Jelmyto in LG-UTUC; commercial plans for favorable market access and both patient and physician uptake; expected interest in prescribing Jelmyto; the continued successful launch of Jelmyto; 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 opportunity and potential of UGN-102 for LG-NMIBC and potential advantages over TURBT; the market opportunity for UGN-102 in LG-NMIBC; plans to initiate a Phase 1 study with UGN-201 in HG-NMIBC; the anticipated enrollment and design of the ATLAS Phase 3 trial for UGN-102 in LG-IR-NMIBC the estimated U.S. population treated annually for LG-NMIBC, HG-NMIBC and UTUC; plans to investigate UGN-201 in combination with UGN-301 (AGEN1884) in HG-NMIBC; the market opportunity and potential of UGN-301 in HG-NMIBC; plans to build a sustainable growth company; projections of revenue opportunities in markets of interest; capitalization to advance Jelmyto launch and specific clinical development programs; anticipated collaborations and partnerships with leading academic institutions, biotech and pharma; plans to continue exploration of the RTGel hydrogel formulation in combination with AbbVie's portfolio of clostridial toxins in OAB and other patient populations; and financial strength and guidance, including expected cash runway. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the risks associated with Covid-19 and other pandemic risks,, the timing and success of clinical trials,, our ability to enroll patients in the ATLAS trial on a timely basis, or at all; the ATLAS Phase 3 trial and potential safety and other complications thereof; 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, including complications resulting from the ongoing COVID-19 pandemic; the labeling and packaging for any approved product; the scope, progress and expansion of developing and commercializing UroGen'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; UroGen's ability to attract or retain key management, members of the board of directors and personnel and any negative effects on UroGen's business, commercialization and product development plans caused by or associated with COVID-19. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Form 10-Q filed with the SEC on November 9, 2020, 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 at a Key Inflection Point to Deliver for Patients

EXECUTE	ACCELERATE	INNOVATE	PARTNER
Launched **JELMYTO®** for **LG-UTUC** in U.S. in June 2020 **Strong momentum and early uptake** with physicians and patients within first 6 months	**UGN-102** developed to potentially transform standard of care for **LG-IR-NMIBC** Drawing on experience and similarities from **Jelmyto**	Pipeline focused on unmet need in **URO-ONCOLOGY** Leading **novel immuno-oncology** product candidate combines agonist and antagonist	Advancing **RTGel** technology through strategic collaborations including leading academic centers Potential **ex-US** expansion

UroGen Pharma

RTGel™ Reverse-Thermal Hydrogel Technology Offers New Approach

Urothelial cancers have been challenging to treat due to physiologic barriers and intolerance of foreign materials in the urinary tract

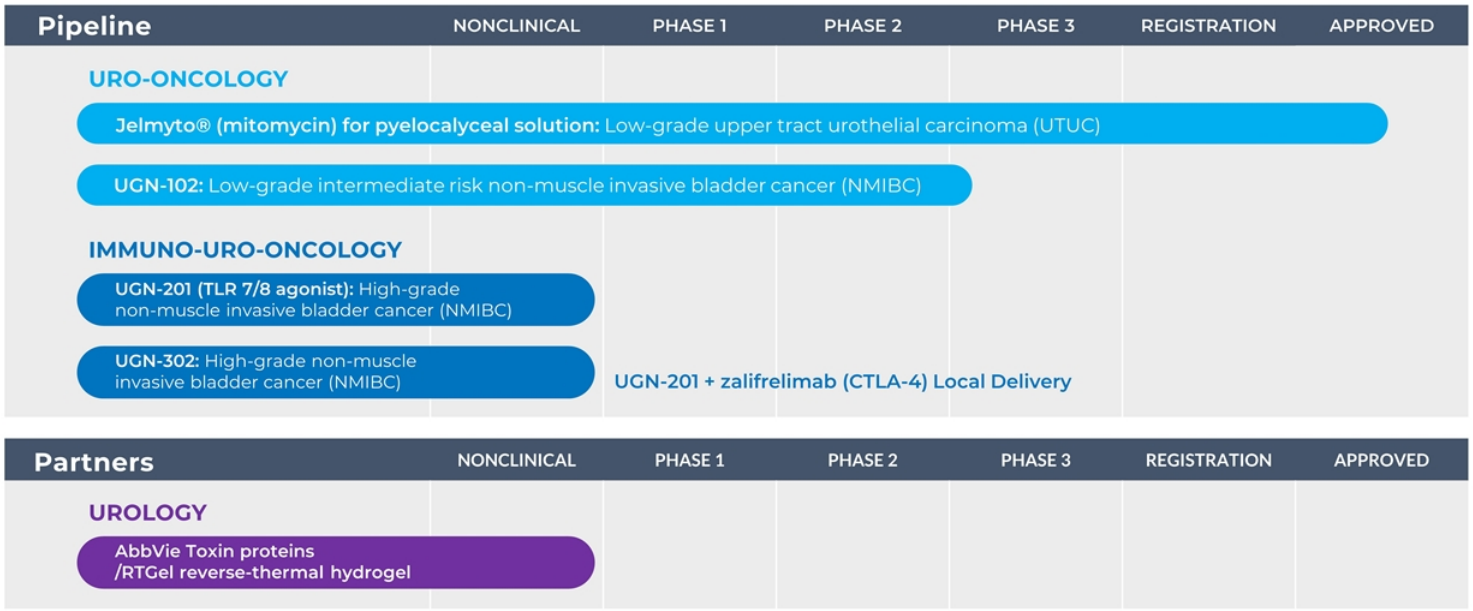
RTGel exists as a liquid at lower temperatures and converts to gel form at body temperature

RTGel has the potential to advance the treatment of specialty cancers and urologic diseases by:

- Increasing dwell time and exposure of active drugs, potentially improving the therapeutic effects of existing products
- Potentially increasing the viability of organ-sparing techniques and providing alternatives to radical surgery
- Leveraging physiologic flow of urine to provide natural exit from the body

UroGen Pharma

Advancing Novel Uro-Oncology Programs



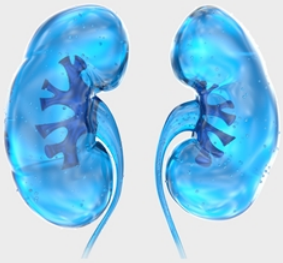
The safety and efficacy of UGN-102, UGN-201, UGN-302 for the specific conditions have not been established.

[1] Worldwide license agreement with Agenus; does not include Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions.

UroGen Pharma

Unlocking the Uro-Oncology Market-Building a Company

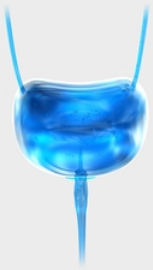
Low-grade Upper Tract Urothelial Carcinoma (UTUC)



~6,000 – 7,000 addressable population

Jelmyto – only FDA-approved medicine

Low-grade Non-muscular Invasive Bladder Cancer (NMIBC)



~80,000 intermediate-risk LG NMIBC

Last drug approved >15 years ago

~$1 Billion Potential Peak Revenue Opportunity

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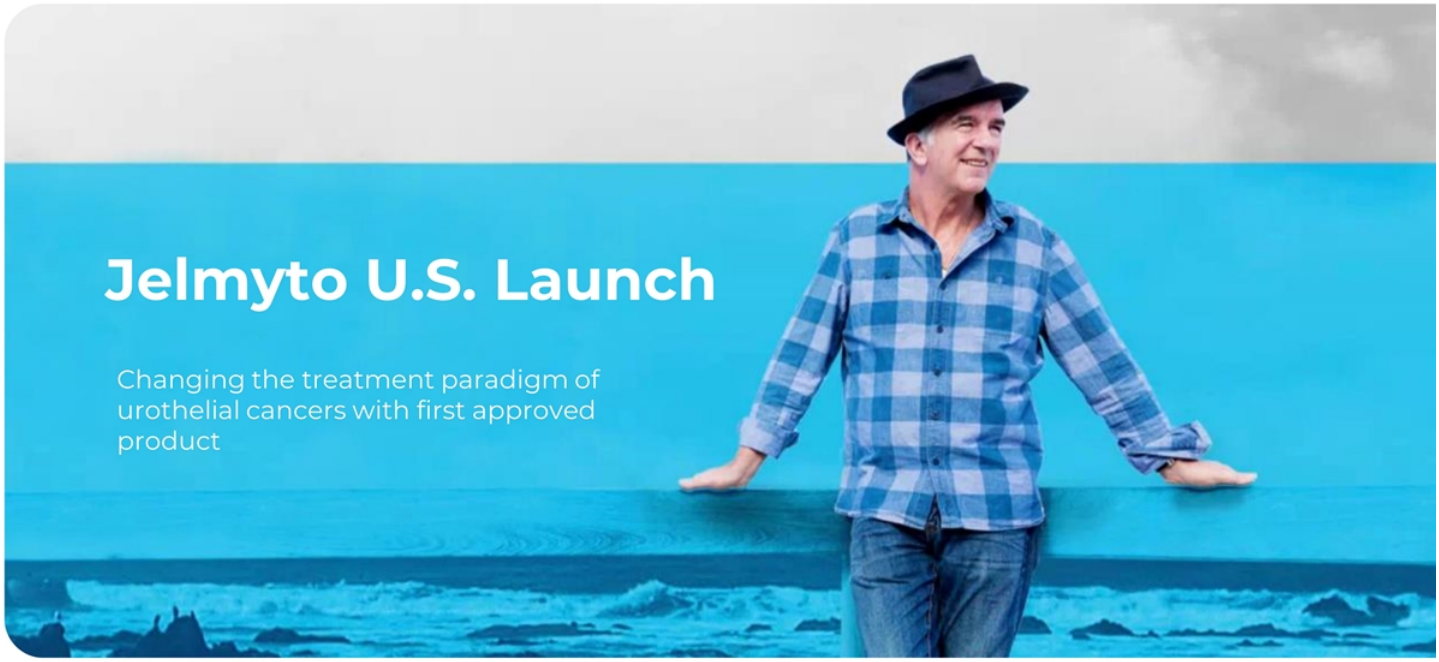
2020 Achievements and Upcoming Milestones

2020	1H 2021	2H 2021
✓ Jelmyto FDA approval	✓ Implementation of Jelmyto permanent J-code in January	❑ Jelmyto life-cycle management
✓ Jelmyto U.S. launch	❑ Potential UGN-102 Phase 2b publication	❑ Expected update on ex-US opportunity with Jelmyto
✓ J-code received	❑ Advancement of UGN-302 program	❑ UGN-102 Phase 3 ATLAS trial enrollment updates
✓ UGN-102 OPTIMA II final topline results	❑ Potential collaborations and partnerships with leading academic institutions, biotech and pharma	❑ Potential collaborations and partnerships with leading academic institutions, biotech and pharma
✓ UGN-102 ATLAS Phase 3 initiation		
✓ Expansion of leadership team		

UroGen Pharma



JELMYTO (mitomycin) for pyelocalyceal solution; formerly known as UGN-101

UroGen Pharma

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

- **Approved in U.S. on April 15, 2020**
- **Strong initial launch execution**
  - Launched on June 1, 2020
  - NCCN guidelines updated within two weeks of approval
- **Rapid adoption**
  - **3Q20** revenue of **$3.5 million** in first quarter of commercial launch
- **Clinically meaningful data**
  - 58% Complete Response in OLYMPUS trial[1]
  - Kaplan-Meier estimated duration of CR at 12-months of 81.8%; median time to recurrence not reached[2]

1. Important Safety Information and the full Prescribing Information available at https://www.urogen.com/download/pdf/jelmyto_prescribing.pdf
2. Matin, Surena F. SUO 2020, #1003

UroGen Pharma

JELMYTO Potential to Avoid Kidney Removal in Low-Grade Upper Tract Urothelial Carcinoma (LG-UTUC)

Addressable Patients: 6,000-7,000 eligible patients in the U.S. annually, includes:

Newly Diagnosed: **2,800-3,200**[1]	Recurrent Patients: **3,000-4,000**[2]
Newly Diagnosed Treatment Options	**Recurring Patients Treatment Options**
• **RNU**	• **RNU**
• **Endoscopic Management**	• **Additional Endoscopic Management**

- **70%-80% of LG UTUC patients ultimately receive nephroureterectomies[3]**
- **Jelmyto may decrease the need for RNU, potentially sparing the kidney**
- **UC is the most costly cancer in the U.S. health care system on a per-patient basis[4]**

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

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JELMYTO Changing the LG-UTUC Landscape - U.S. Launch Update*

Patient Adoption

Over 210
practices/hospitals activated

- High volume of completed patient enrollment forms suggest **future uptake** in patients for **Jelmyto**
- **Aided awareness of over 90%** due to commercial efforts[1]

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

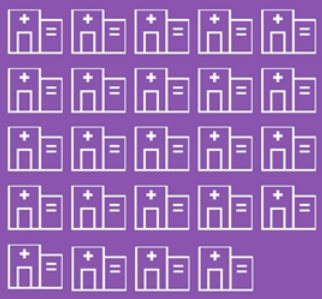
Reimbursement

- **Permanent J code** effective January 1, 2021 to standardize and facilitate reimbursement in surgery centers and hospitals; **ASP +6% implemented**
- Majority of large commercial plans have policies in place, covering over

150 million lives

Seamless Integration Into Physician Practice

24 accounts
have treated more than one patient



*Numbers as of December 31, 2020
[1]Urogen market research (Mar 18 n=106, Feb 19 n=108, Dec 19 n=108, Aug 20 n=101)
[2]UroGen market research, 87 urologists surveyed who are not currently prescribing Jelmyto (September 2020)

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UGN-102 (mitomycin) for intravesical solution is an investigational agent. The safety and effectiveness of UGN-102 have not been established.
LG-IR-NMIBC = Low Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer

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

Defining Non-Muscle Invasive Bladder Cancer

Low Grade IR

- **Issue:** chronic relapse
- Current treatment:
  - Repetitive **TURBT**
- Incidence: ~**20 K**
- Recurrent: ~**60 K**
- Limited competition
  - **UGN-102** is furthest along in clinical development as primary chemoablative therapy

BCG is not used in low-grade disease

VS

High Grade

- **Issue**: progression, metastasis & death
- Current treatment:
  - **TURBT**
  - BCG
  - Clinical trials
  - Radical Cystectomy
- Incidence: **~25 K**
- BCG-refractory: **~15 K**
- Clinical trials ongoing in BCG-refractory populations
  - Significant unmet need given low response rates and durability
  - Goal is to avoid radical cystectomy (bladder removal)

SEER, AUA/SUO Joint Guidelines,
Babjuk et al. European Urology (2019) , Simon 2019

UroGen Pharma

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

Addressable Patients: ~80,000 patients in the U.S. annually, includes:

Newly Diagnosed: **20,000**[1]	Recurrent Patients: **60,000**[2]
Treatment Options	**Treatment Options**
• **TURBT**	• **TURBT** • **TURBT + adjuvant chemotherapy**[3*]

- **IR patients are characterized by 1-2 of the following:**
  – Multiple tumors, tumor size >3cm, early recurrence (<1 year), frequent recurrences (>1 per year)
- **More than 1 recurrence increases the likelihood of additional recurrences**
  – Ranges from 13% for recurrence one to 100% for recurrence seven onwards[4]
- **Median age of patients is in early 70's adding to risk of complications**
  – Morbidity substantial (highest rate of readmission for outpatient urologic surgery)

1. SEER, AUA/SUO joint guideline 2. Babjuk et al. European Urology (2019), Simon (2019), 3. 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; BCG = Bacillus Calmette-Guérin

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UGN-102 Patients and Physicians Seek a Better Therapeutic Experience

~68% of recurrent patients **have 2 or more recurrences**[1]

Repeat TURBT associated with **increased mortality** of **14%** independent of surgical risk [2]

Preliminary market research shows that physicians identify **25%** of these patients as **ineligible or averse to surgery**[3]

45% of surveyed patients **chose intravesical chemotherapy** over TURBT[4]

UGN-102 is designed to be primary therapy, not adjuvant therapy, providing a potential alternative to invasive surgery

1. Babjuk et al. European Urology (2019), Simon (2019), UroGen projections based on SEER (2016) 2. Erikson et al. Scan J Urol & Nephrol (2020) 3. UroGen market research (n=20 urologists, October 2019) 4. Parisse et al. SUO 2020

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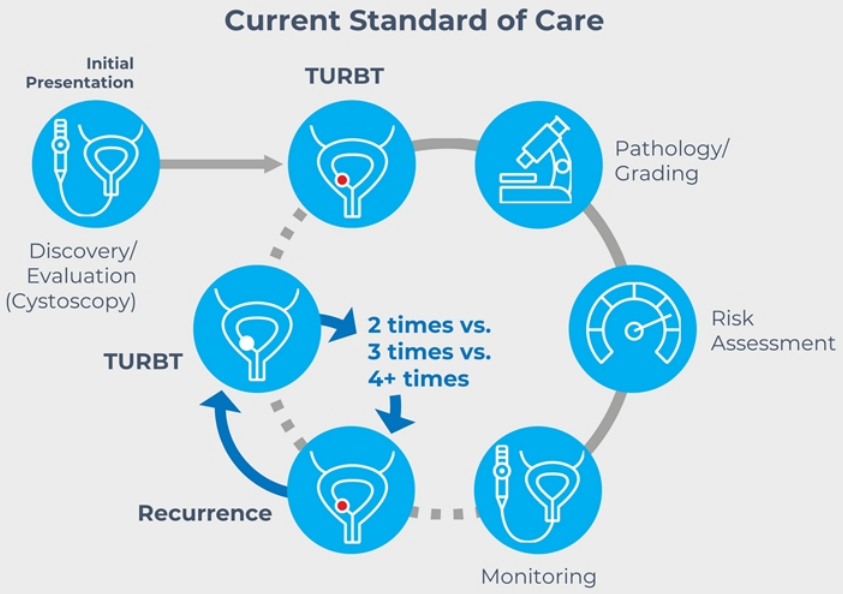
UGN-102 Clear Opportunity to Treat Recurring Patients with Efficacious Alternative to TURBT

Patients fall Into a cycle of frequent recurrences after repeated TURBT failures

- High unmet need exists with "surgical failures": recurrence high, risk of progression low
- In UGN-102 Phase 2b study, 57% of patients had 3 or more prior TURBT at baseline
- UGN-102, if approved, moves care from OR to office/ASC with a potential to decrease cost and morbidity of contemporary therapy



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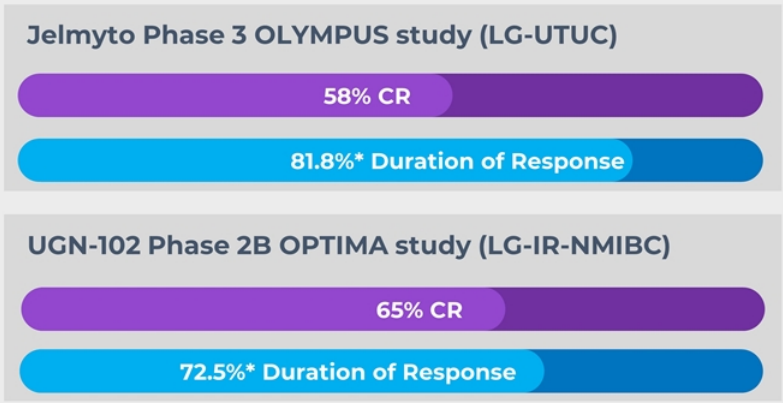
UGN-102 Clinical and Regulatory Success in LG-UTUC Encouraging for LG-IR-NMIBC Opportunity

Molecular profiling shows that LG-NMIBC and LG-UTUC are likely the same disease at a genetic mutational driver level

Approach is consistent: chemoablate the tumor, avoid surgery

- ✓ Same urologists treating both patient populations
- ✓ Similar proposed in-office dosing
- ✓ Well understood safety profile
- ✓ Consistent manufacturing and supply chain

Similar complete and durable response rates from **Jelmyto** and **UGN-102**:



Clinically meaningful data and approval of **Jelmyto** in **LG-UTUC** bodes well for **'102** program in **LG-IR-NMIBC**

CR = complete response evaluated at 3 months

 *Duration of response estimated at 12 months from initiation of therapy by Kaplan-Meier method

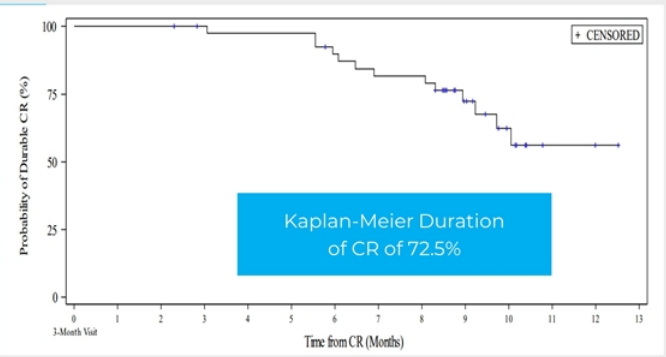
UroGen Pharma

UGN-102 Complete and Durable Responses Observed with UGN-102 in Phase 2b OPTIMA II trial

65% (41/63) **Complete Response** at 3-months*

Duration of response estimated to be **72.5%** at 12 months from initiation of therapy by Kaplan-Meier method

Median duration of response was not reached



The majority of adverse events were reported as mild or moderate; the most commonly reported **AEs** (≥ 10%) were: dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection

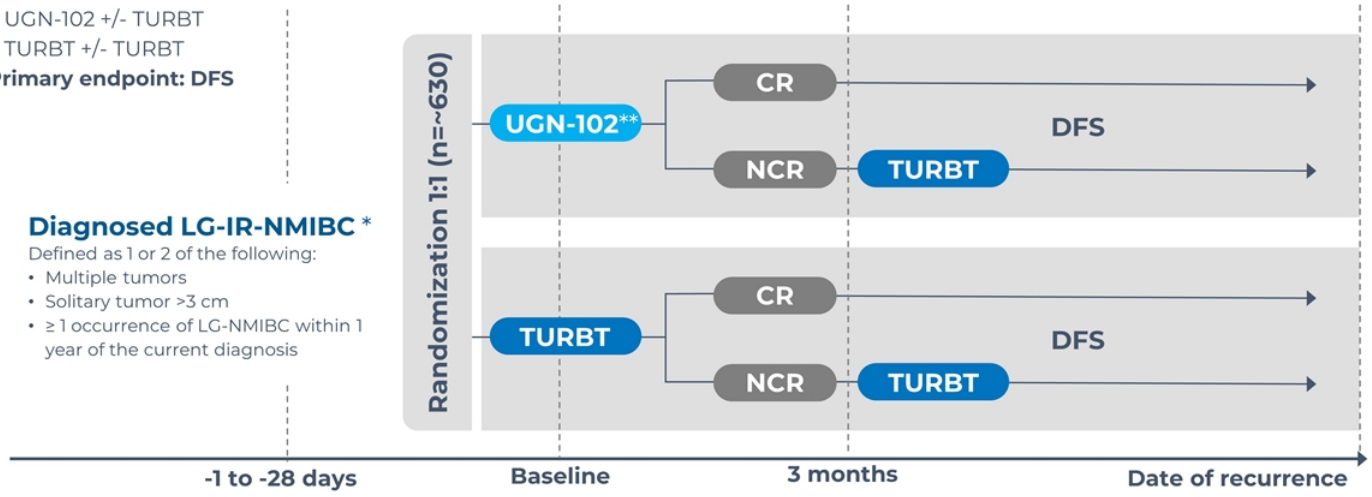
*Primary endpoint of complete response based on evaluation at 3-month timepoint

UGN-102 ATLAS Trial: Studying Differentiated Therapeutic Option vs. Standard of Care Surgery

Treatment arms:
- UGN-102 +/- TURBT
- TURBT +/- TURBT

Primary endpoint: DFS

Diagnosed LG-IR-NMIBC *
Defined as 1 or 2 of the following:
- Multiple tumors
- Solitary tumor >3 cm
- ≥ 1 occurrence of LG-NMIBC within 1 year of the current diagnosis



*Screening procedures to provide evidence of low grade NMIBC; no evidence of high-grade disease; **6 weekly doses

CR = complete response, NCR= non-complete response, DFS= disease-free survival, TURBT= transurethral resection of bladder tumor

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UGN-302 is a combination therapy evaluating the investigational agents UGN-201 and UGN-301. The safety and effectiveness of UGN-302 have not been established.

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UGN-302 Designed to Address Life-Threatening Disease with Risk of Disease Progression

Defining Non-Muscle Invasive Bladder Cancer

Low Grade IR

- **Issue:** chronic relapse
- Current treatment:
  - Repetitive **TURBT**
- Incidence: ~20 K
- Recurrent: ~60 K
- Limited competition
  - **UGN-102** is furthest along in clinical development as primary chemoablative therapy

BCG is not used in low-grade disease

VS

High Grade

- **Issue**: progression, metastasis & death
- Current treatment:
  - **TURBT**
  - BCG
  - Clinical trials
  - Radical Cystectomy
- Incidence: ~25 K
- BCG-refractory: ~15 K
- Clinical trials ongoing in BCG-refractory populations
  - Significant unmet need given low response rates and durability
  - Goal is to avoid radical cystectomy (bladder removal)

UGN-302 Significant Need for Durable Treatments to Avoid Bladder Removal in HG-NMIBC

Initial focus on BCG-refractory patients: ~15,000 addressable patients in the U.S. annually

Newly Diagnosed HG NMIBC: **25,000**[1]	BCG-Refractory: **15,000**[2]
Treatment Options • **TURBT + intravesical chemotherapy (BCG)** • **BCG alone**	**Treatment Options** • **Intravesical chemotherapy:** – Gemcitabine / Docetaxel • **Keytruda** • **Clinical trials** • **Cystectomy**

Radical cystectomy (bladder removal) is characterized by high complication rates (sepsis, bowel obstruction, urinary incontinence)

BCG is in short supply, with limited options post BCG failure

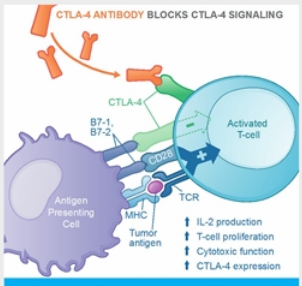
– Estimated 1-2 years to cystectomy for patients who are BCG-refractory

– Risk of progression to muscle invasive cancer

1. Nielsen, 2014 analysis of SEER data, 2. UroGen market research, at 1L, 35% will not respond.

UGN-302 Encouraging Activity with Novel Agonist / Antagonist Immunotherapy Combination

TLR 7/8 (UGN-201): stimulate cytokines and T & B cells

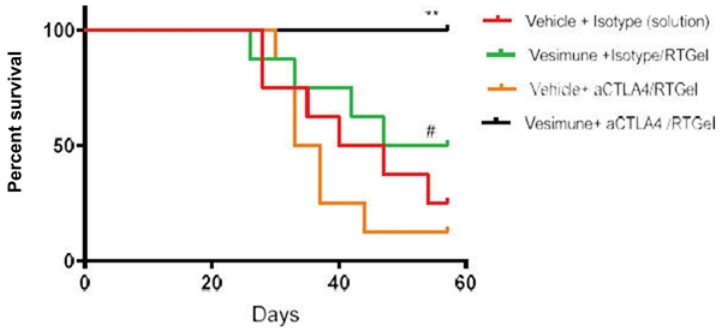


Anti-CTLA4 (UGN-301): blocks "cancer masking" action of CTLA4

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

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

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



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

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Broad IP Estate and Significant Know-How To Protect Our Innovations

16 granted U.S. patents protecting **Jelmyto, UGN-102,** proprietary **RTGel** technology, as well as local compositions comprising **different active ingredients or combinations thereof**

Jelmyto:

- **Composition of matter to 2031**
- **Orphan drug exclusivity to 2027**

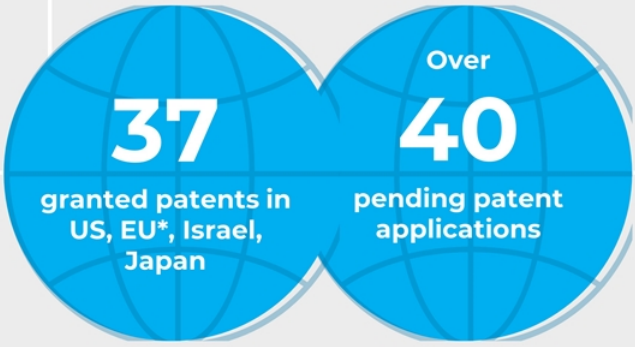
UGN-102:

- **Composition of matter to 2031**

UGN-302:

- **Method of treatment (with the combination of UGN-201 & UGN-301) to 2037**

IP focused on cancer in internal cavities, in particular urinary tract cancer



Pending patents covering methods, systems and compositions for treating cancer locally, intravesically and using various active ingredients and combinations

If issued, will expire **between 2031 and 2037**

Key patents for future product candidates in development expected to expire between 2031-2037

Agenus patent covering zalifremab composition of matter expires in 2035
*EU patents validated in 7 countries (UK, Germany, France, Spain, Italy, Netherlands, Denmark)

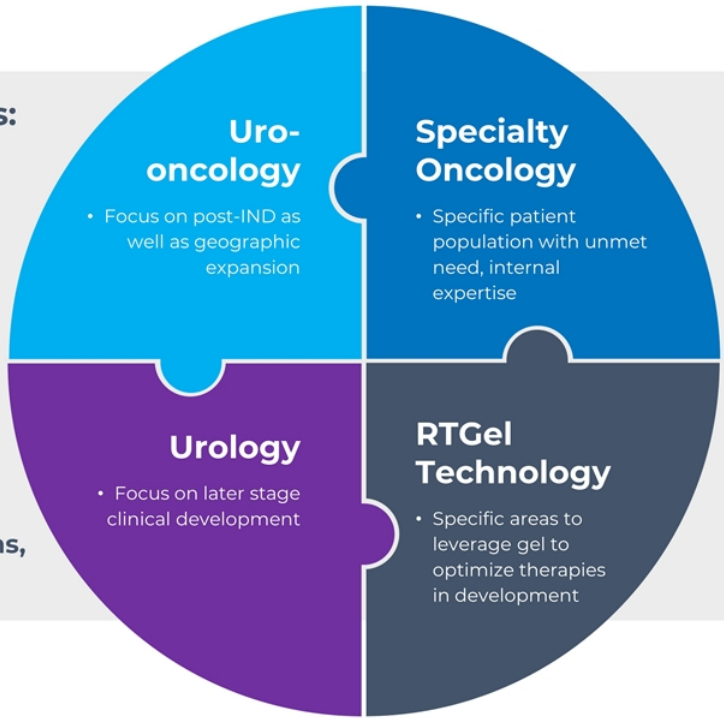
UroGen Pharma

Driving Further Growth with Business Development and Geographic Footprint Expansion

Focused on 4 key areas:

- **Sustained, nearer-term revenue growth**
- **Innovation**
- **High unmet need**
- **Cost-effective, value-creating**

Potential partnerships with leading academic institutions, biotech, pharma



Learnings from **RTGel** with **Botox** help inform future opportunities and selection of size of molecule

UroGen Pharma

Financial Highlights as of September 30, 2020

$3.5 Million

Jelmyto revenue in first full quarter of commercialization

$125.5 Million

Cash and cash equivalents*

Into 2022

Expected cash runway with cash on hand

22.1 million

Shares outstanding (25.5 million fully diluted)

3Q 2020 10-Q Filed with the SEC on November 9, 2020

*Cash, cash equivalents, and marketable securities as of September 30, 2020 excludes restricted cash on Balance Sheet

UroGen Pharma

Transforming Uro-Oncology and Achieving Value Recognition in 2021

- ❑ **Continue Jelmyto launch momentum and efforts to establish as standard of care in LG-UTUC**
- ❑ **Execute ongoing Phase 3 ATLAS trial in LG-IR-NMIBC offering the potential to transform the treatment paradigm**
- ❑ **Develop UGN-302 as novel immuno-oncology combination to treat aggressive disease**
- ❑ **Drive portfolio expansion through potential business development and academic partnerships**
- ❑ **Expand reach of innovative pipeline and platform with ex-US expansion**

ACT BOLDLY | BE INVENTIVE | STAY CONNECTED

UroGen Pharma


THANK YOU
UroGen
Pharma