

UROGEN PHARMA

SEPTEMBER 2021



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 May 13, 2021, 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.

We Build Novel Solutions to Treat Specialty Cancers and Urologic Diseases Because Patients Deserve Better Options



Address challenging disease with transformative therapies in urologic and specialty cancers



Maximize benefit of local therapy with novel RTGel delivery platform



Offer patients better treatments than outdated surgical procedures



Innovative, early-stage pipeline could generate additional therapeutic alternatives to surgery

VALUES : Act Boldly | Be Inventive | Stay Connected

RTGel™ Proprietary Reverse-Thermal Hydrogel Technology is Unique and Innovative Allowing for Locally Delivered Medicines

Urothelial cancers have been challenging to treat due to anatomical 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 urologic and specialty cancers 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

Advancing Novel Urological and Specialty Oncology Programs

Pipeline	NONCLINICAL	PHASE 1	PHASE 2	PHASE 3	REGISTRATION	APPROVED
URO-ONCOLOGY: Low-Grade Disease						
Jelmyto® (mitomycin) for pyelocalyceal solution: Low-grade upper tract urothelial carcinoma (UTUC)						
UGN-102: Low-grade intermediate risk non-muscle invasive bladder cancer (NMIBC)						
IMMUNO-URO-ONCOLOGY: UGN-301 Pipeline						
UGN-301: anti-CTLA-41 as monotherapy or combination therapy in uro-oncology						
UGN-301 + UGN-201 (TLR 7/8 agonist): High-grade non-muscle invasive bladder cancer (NMIBC)						

Academic Collaborations



AbbVie partnership with potential for combination with RTGel reverse-thermal hydrogel

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

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



Unlocking the Uro-Oncology Market: Strong Foundation with Jelmyto

Low-grade Upper Tract Urothelial Carcinoma (UTUC)



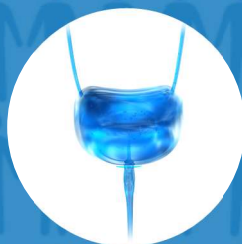
~6,000 – 7,000
addressable
population

Jelmyto – only
FDA-approved
medicine

~\$1+ Billion

Potential Peak Revenue
Opportunity by 2027

Low-grade intermediate risk Non-Muscle Invasive Bladder Cancer (NMIBC)



~80,000

Addressable population

No FDA- approved
primary therapies

UroGen Continues to Advance Care and Deliver for Patients

RECENT ACCOMPLISHMENTS

- ✓ Jelmyto FDA approval and U.S. launch
- ✓ UGN-102 ATLAS Phase 3 initiation
- ✓ Sponsored research agreement with the Johns Hopkins University
- ✓ Strategic research collaboration with MD Anderson
- ✓ Neopharm license in Israel for Jelmyto commences global expansion efforts

2021 PRIORITIES

- Continued Jelmyto U.S. launch momentum
- UGN-102 ATLAS Phase 3 enrollment
- Advancement of immuno-oncology pipeline, focusing on UGN-301 as monotherapy and combination therapy
- Understand geographic expansion Opportunities
- Drive further growth with Business Development



JELMYTO U.S. LAUNCH

Changing the treatment paradigm of
urothelial cancers with first approved
product

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

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**
 - Total revenues of **\$32.3 million** in first four quarters of launch, **\$20.0** through Q2 2021
- **Clinically meaningful data**
 - 58% Complete Response in OLYMPUS trial¹
 - Kaplan-Meier estimated duration of CR at 12-months of 81.8%; median time to recurrence not reached²

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

Addressable Patients: 6,000-7,000 eligible patients (\$700mm market) in the U.S. annually, includes:

Newly Diagnosed: 2,800-3,200¹

Newly Diagnosed Treatment Options

- RNU
- Endoscopic Management

Recurrent Patients: 3,000-4,000²

Recurring Patients Treatment Options

- RNU
- Additional Endoscopic Management

- 70%-80% of LG UTUC patients ultimately receive nephroureterectomies³
- 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 basis⁴

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

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

Patient Adoption

407

practices/hospitals activated

- **Aided awareness of over 90%** due to commercial efforts¹



Expected interest in prescribing JELMYTO over next 12 months²

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

63 accounts

have treated more than one patient

- High volume of completed patient enrollment forms suggest future uptake in patients for Jelmyto

*Numbers as of August 1, 2021

¹UroGen market research (Mar 18 n=106, Feb 19 n=108, Dec 19 n=108, Aug 20 n=101)

²UroGen market research, 87 urologists surveyed who are not currently prescribing Jelmyto (September 2020)

UGN-102

Potential to transform the treatment paradigm in Low Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)



UGN-102 (mitomycin) for intravesical solution is an investigational agent. The safety and effectiveness of UGN-102 have not been established.

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 similar diseases at a genetic mutational driver level

Approach is consistent: chemoablate the tumor, avoid surgery

- ✓ Same urologists treating both patient populations
- ✓ Well understood safety profile
- ✓ Consistent manufacturing and supply chain

UGN-102 may offer additional ease of administration

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

Jelmyto Phase 3 OLYMPUS study (LG-UTUC)

58% CR

81.8%* Duration of Response

UGN-102 Phase 2B OPTIMA study (LG-IR-NMIBC)

65% CR

72.5%* Duration of Response

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

¹³ CR = complete response evaluated at 3 months
*Duration of response estimated at 12 months from initiation of therapy by Kaplan-Meier method

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: clinical trials
 - **TURBT** – Radical Cystectomy
 - BCG
- 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-102 Focus on Improving Patient Outcomes with Non-Invasive, Durable Option for LG-IR-NMIBC

Addressable Patients: ~80,000 patients (\$3B+ Market) in the U.S. annually, includes:

Newly Diagnosed: **20,000¹**

Recurrent Patients: **60,000²**

Current Treatment Option

- TURBT

Current Treatment Options

- TURBT
- TURBT + adjuvant chemotherapy^{3*}

- **Intermediate Risk (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 onwards⁴
- **Median age of patients is in early 70s, 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

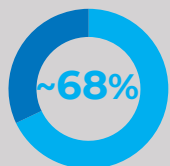
R Coll Surg Engl (2010)

*Adjuvant chemotherapy only used in 0-30% of U.S. eligible population

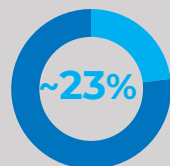
TURBT = trans urethral resection of bladder tumor

UGN-102 Provides Potential Locally-Delivered, Non-Surgical Alternative for LG-IR-NMIBC Patients

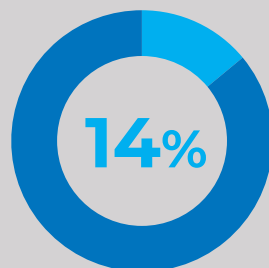
~**68%** of recurrent patients **have 2 or more recurrences**¹



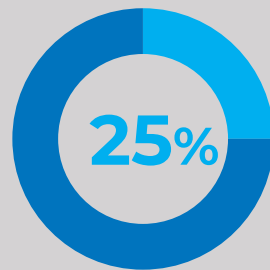
~**23%** of recurrent patients **have 5 or more recurrences**¹



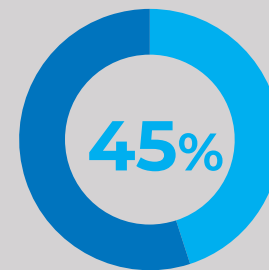
Repeat TURBT associated with **increased mortality** of **14%** independent of surgical risk ²



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 TURBT⁴



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

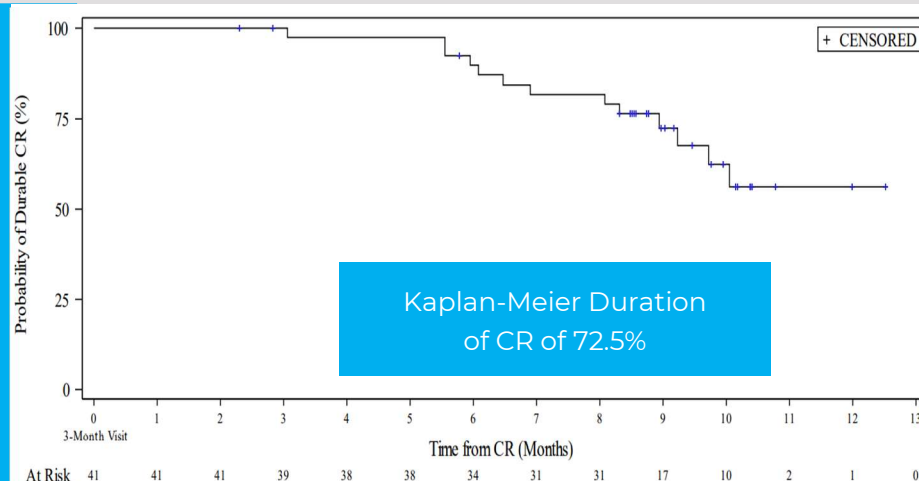
1. Babjuk et al. European Urology (2019), Simon (2019), UroGen projections based on SEER (2016) 2. Erikson et al. Scan J Urol & Nephrol (2020) 3. UroGen market research (n=20 urologists, October 2019) 4. Parisse et al. SUO 2020

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** ($\geq 10\%$) were: dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection

57% of patients had **3 or more prior TURBTs** at baseline

*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

Approximately 630 patients

First patient enrolled in Jan 2021

Approximately 150 sites

United States, Eastern Europe, Israel

Treatment arms

- UGN-102 ± TURBT
- TURBT ± TURBT

Primary endpoint DFS

- Quarterly evaluations with cystoscopy, for cause biopsy and cytology to assess for recurrence
- 2 event driven interim analyses for superiority

Event driven trial

~1 year enrollment

~2 year follow up

NDA preparation and review

Anticipated late 2024 launch

(assuming Priority Review & approval)

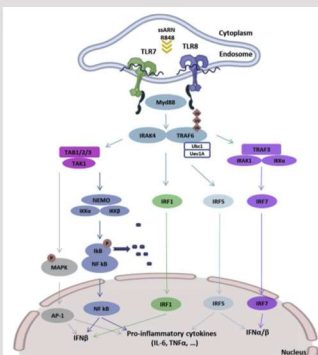


UGN-301

Expanding to Immuno-Oncology with potential monotherapy and combination therapy

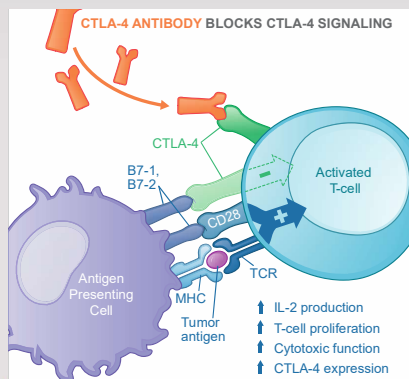
UGN-301 is an investigational agent being studied as monotherapy and combination therapy (UGN-302). The safety and effectiveness of UGN-301, UGN-201 and UGN-302 have not been established.

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



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

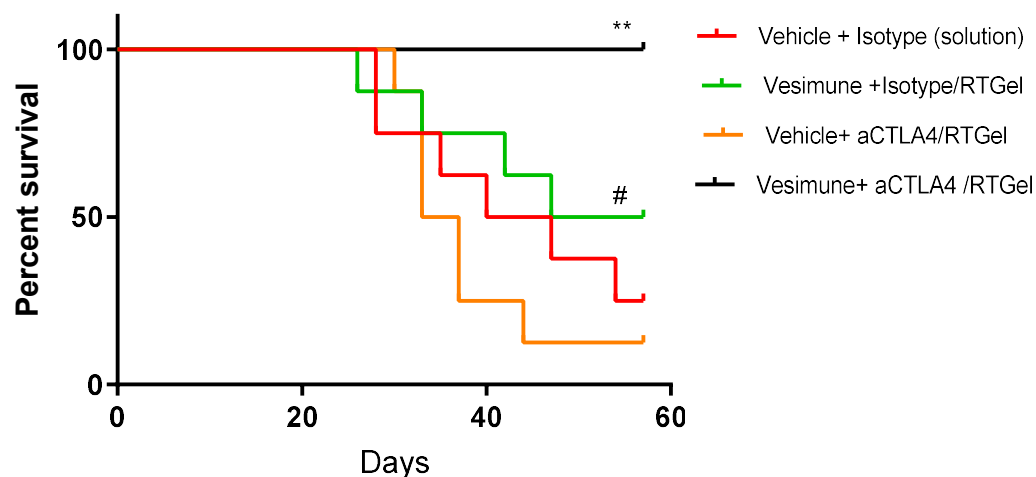
Phase 1&2 human
data suggest
UGN-201 activity
in human bladder
cancer



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

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

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



UGN-301 Potential Combinations 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** – Clinical trials
 - BCG – 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-301 Potential Combinations: 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: **25,000¹**

Treatment Options

- TURBT + intravesical chemotherapy (BCG)
- BCG alone

BCG-Refractory: **15,000²**

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

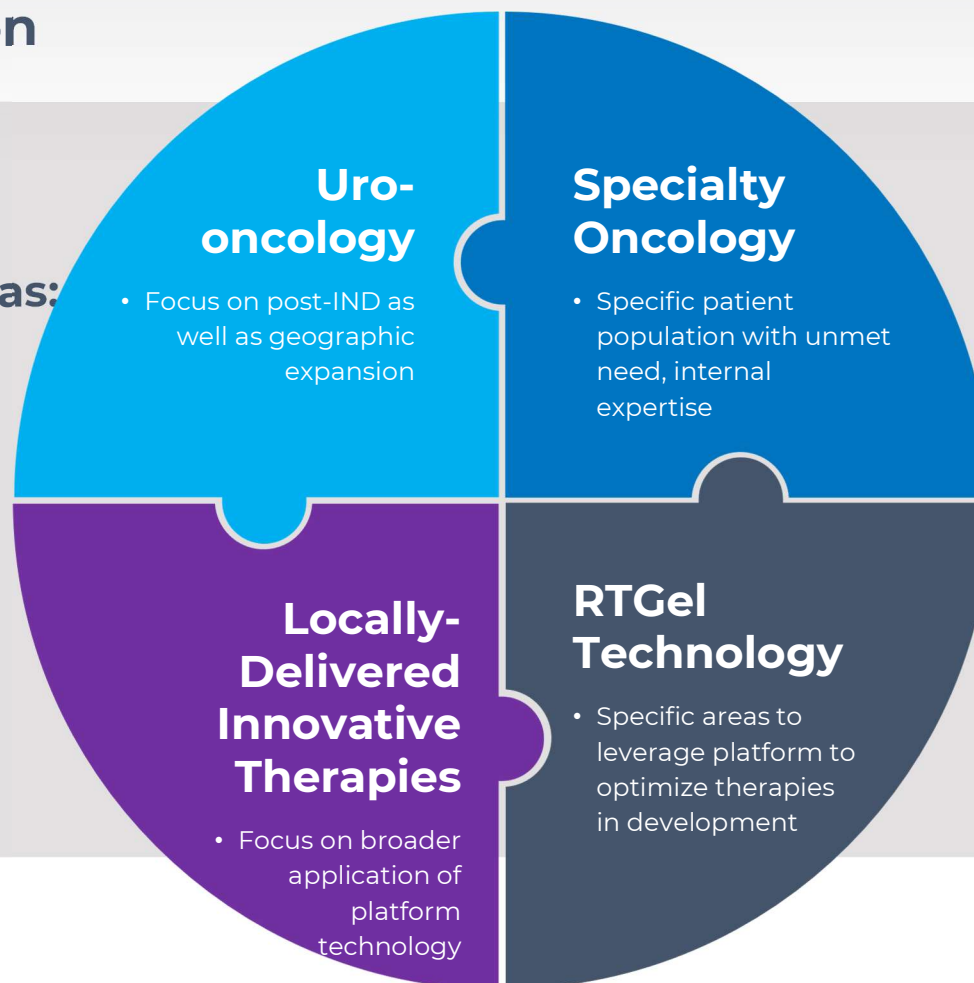


Looking Ahead

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

Financial Highlights for Second Quarter Ended June 30, 2021

\$13.0 Million

Jelmyto revenue in fourth full quarter of commercialization

\$129.0 Million

Cash and cash equivalents*

\$75 Million

RTW strategic funding received in second quarter 2021

No debt

22 millions shares outstanding (26.0 million fully diluted) as of 6/30/21

2Q 2021 Jelmyto revenue represents >70% increase over 1Q 2021

Preliminary second quarter financial reported via press release on 7/14/21

*Cash, cash equivalents, and marketable securities as of June 30, 2021 excludes restricted cash on Balance Sheet

THANK YOU



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



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

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

38

granted patents in
US, EU*, Israel,
Japan

Over
40

pending patent
applications

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

27 *EU patents validated in 7 countries (UK, Germany, France, Spain, Italy, Netherlands, Denmark)

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

Treatment arms:

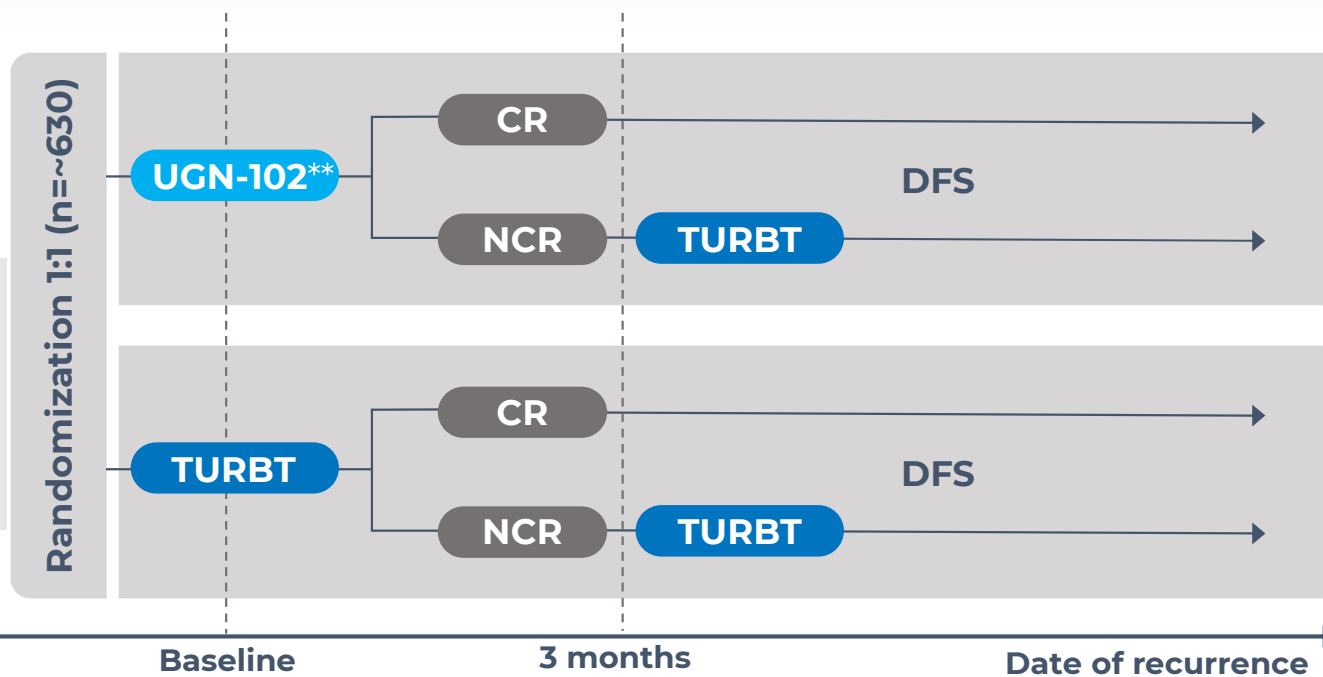
- UGN-102 +/- TURBT
- TURBT +/- TURBT

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

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

RTW Investments Strategic Financing

☐ Upfront cash payment of \$75M in exchange for tiered future cash payments:

☐ Jelmyto tiered payments based on net product sales*:

- (i) 9.5% of annual sales up to \$200M,
- (ii) 3.0% of annual sales between \$200M and \$300M,
- (iii) 1.0% of annual sales above \$300M.

☐ UGN-102 (Subject to FDA approval**) tiered payments based on net product sales:

- (i) 2.5% of annual net sales up to \$200M,
- (ii) 1.0% of annual net sales for annual net sales between \$200M and \$300M,
- (iii) 0.5% of annual net sales for annual net sales above \$300M.

☐ Total amount payable under the financing will not exceed \$300M over its life.

*(If certain revenue thresholds for Jelmyto worldwide annual net sales are not met, the future cash payments to RTW, with respect to Jelmyto annual net sales up to \$200M, will increase by 3.5% and may decrease back to 9.5% dependent on the Company meeting certain subsequent sales thresholds.)

** (If the Company does not receive FDA approval for UGN-102 by a specified date, the future cash payments to RTW with respect to aggregate worldwide annual net sales of Jelmyto across all Jelmyto annual net sales tiers will increase by 1.5%.)

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

Current Standard of Care

