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): September 24, 2019

UROGEN PHARMA LTD.
(Exact name of registrant as specified in its charter)

Israel	**001-38079**	**Not applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

499 Park Avenue **New York, New York** **(Address of principal executive offices)**	**10014** **(Zip Code)**

Registrant's telephone number, including area code: (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 8.01 Other Events.

On September 24, 2019, Urogen Pharma, Ltd. (the "Company") issued a press release titled "UroGen Reports Positive Data from Two Important Studies: UGN-101 OLYMPUS Pivotal Trial in LG UTUC and UGN-102 Phase 2b OPTIMA II Trial in LG Bladder Cancer" (the "Data Press Release"). A copy of the Data Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

On September 24, 2019, the Company delivered a presentation to investors via webcast relating to, among other things, the data that is the subject of the Data Press Release. A copy of the presentation is filed herewith as Exhibit 99.2 and incorporated herein by reference.

On September 24, 2019, the Company issued a press release titled "UroGen Investor Day Details Positive Clinical Updates, UGN-101 Launch Preparedness, and Pipeline Advances" (the "Recap Press Release"). A copy of the Recap Press Release is filed herewith as Exhibit 99.3 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release, dated September 24, 2019.
99.2	Investor Presentation, dated September 24, 2019.
99.3	Press Release, dated September 24, 2019.
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: September 24, 2019

UROGEN PHARMA LTD.

By: /s/ Peter Pfreundschuh
Peter Pfreundschuh
Chief Financial Officer

Exhibit 99.1

UroGen Reports Positive Data from Two Important Studies: UGN-101 OLYMPUS Pivotal Trial in LG UTUC and UGN-102 Phase 2b OPTIMA II Trial in LG Bladder Cancer

UGN-101:

Consistent Complete Response (CR) Rate of 59 Percent in Patients with Low-Grade Upper Tract Urothelial Cancer (LG UTUC)

Durability of Response Determined to be 89 Percent at Six Months and 84 Percent at 12 Months

Rolling NDA Submission on Track for Q4 2019 with Planned Launch in 1H 2020

UGN-102:

Data Demonstrates CR Rate of 63 Percent in Patients with Intermediate Risk Low-Grade Non-Muscle Invasive Bladder Cancer (LG NMIBC)

Company Completes Enrollment Ahead of Schedule in OPTIMA II Phase 2b Trial

NEW YORK, September 24, 2019 — UroGen Pharma Ltd. (Nasdaq: URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of uro-oncology, today announced updated findings from the UGN-101 Phase 3 OLYMPUS Trial in patients with low-grade upper tract urothelial cancer (LG UTUC), as well as initial CR data from the UGN-102 Phase 2b OPTIMA II Trial in patients with intermediate risk low-grade non-muscle invasive bladder cancer (LG NMIBC).

Results from a final analysis of the primary endpoint for pivotal Phase 3 OLYMPUS showed that investigational UGN-101 (mitomycin gel) for instillation demonstrated a 59 percent CR rate in patients with LG UTUC. Findings were consistent with previously presented results.

The final analysis of the primary endpoint showed that in the OLYMPUS intent-to-treat population, 42 of the 71 patients (59 percent) achieved a CR. Forty-one patients entered follow-up, which is still ongoing. Durability of response was determined by Kaplan-Meier to be 89 percent at 6 months and 84 percent at 12 months after primary disease evaluation (PDE). The estimated median time-to-recurrence was 13.0 months. Thirty four of the 71 patients treated in the study were initially characterized by the treating physician as having endoscopically unresectable tumor at baseline. Twenty of 34 patients (59 percent) achieved a CR at the PDE assessment and 12-month durability was identical for this subgroup.

In OLYMPUS, the most common treatment emergent adverse events (TEAE) included ureteral stenosis, urinary tract infection, hematuria, flank pain, dysuria, renal impairment, hydronephrosis and frequency. Most TEAEs were characterized as mild to moderate and transient. Sixty-seven percent (48/71) of patients in the trial experienced an adverse event involving the renal/urinary tract. Of these, 23 percent (11/48) did not require surgical intervention, 50 percent (24/48) required temporary ureteral stent placement, 23 percent (11/48) required a long-term ureteral stent and 4 percent (2/48) required nephroureterectomy. At the time of database lock, the most common Grade 3 TEAE's included ureteral stenosis (8.5 percent), hematuria, flank pain, and urinary tract infection (3 percent each). There was one Grade 4 TEAE of subdural hematoma (1.4 percent).

"We are pleased that the six-month durability from this analysis remains consistent with previously presented results and are very pleased with the durability observed at 12 months in evaluated

patients. These findings provide further support for the concept of chemoablation with UGN-101 as an initial kidney-sparing treatment option for patients with LG UTUC," said Liz Barrett, President and Chief Executive Officer of UroGen. "We are on track to complete our New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in Q4 2019 and will be prepared for anticipated approval and launch in 1H 2020 of the first drug for the non-surgical treatment of LG UTUC."

The Company also presented interim results from the Phase 2b OPTIMA II trial of investigational UGN-102 (mitomycin gel) for intravesical instillation for patients with intermediate risk LG NMIBC, defined as those with one or two of the following criteria: multifocal disease, large tumors and rapid rates of recurrence. The single-arm, open label study trial recently completed enrollment of 62 patients at clinical sites across the U.S. and Israel. Patients are treated with six weekly instillations of UGN-102 and undergo assessment of CR (the primary endpoint) four to six weeks following the last instillation. In an interim cohort of 32 patients, 63 percent (20/32) achieved a CR.

	Response Rate Overall (n=32)
CR at PDE	63% (20/32)

"Achieving our enrollment goal ahead of schedule is a testament to the enthusiasm and need for this type of innovative approach to treatment in LG NMIBC. 'Intermediate risk' patients experience what can be viewed as a form of surgical failure, and many undergo multiple surgical procedures, known as transurethral resection of bladder tumor (TURBT), to manage these recurrences. We are encouraged by the data observed in this tough-to-treat population for whom the standard of care is really not effective," said Mark Schoenberg, MD, Chief Medical Officer of UroGen. "While OPTIMA II remains ongoing and a Phase 3 study is anticipated, the results presented today further support our belief that UGN-102 has the potential to be an effective treatment option for this patient population of approximately 80,000, as there are no other options for these patients aside from repetitive surgical intervention. Based on literature, these patients have a high likelihood of recurrence at one year due to the chronicity of this disease, so we will continue to follow them and assess durability at 12 months."

In the interim data from OPTIMA II, the most common adverse events observed were dysuria, pollakiuria, fatigue, hematuria and urinary tract infection. The majority of these treatment-emergent adverse events were characterized as mild or moderate and transient.

The Company intends to initiate a pivotal Phase 3 trial in 2020 following discussion with the FDA.

About The Phase 3 OLYMPUS Trial

OLYMPUS (Optimized DeLivery of Mitomycin for Primary UTUC Study) is a pivotal, open-label, single-arm Phase 3 clinical trial of UGN-101 (mitomycin gel) for instillation to evaluate the safety, tolerability and tumor ablative effect of UGN-101 in patients with low-grade UTUC. The trial enrolled 71 patients at clinical sites across the United States and Israel. Study participants were treated with six weekly instillations of UGN-101 administered via a standard catheter. Four to six weeks following the last instillation, patients underwent a PDE to determine response, the primary endpoint of the study. PDE involved a ureteroscopy and wash cytology, a standard microscopic test of cells obtained from the urine to detect cancer. Patients who achieved a CR at the PDE timepoint were then followed for up to 12 months to determine the durability of disease control with UGN-101.

About UGN-101

UGN-101 (mitomycin gel) for instillation is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade upper tract urothelial cancer (LG UTUC). Utilizing the

RTGel™ technology platform, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-101 is designed to enable longer exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-101 is delivered to patients using standard ureteral catheters. The Company initiated its rolling submission of the UGN-101 New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in December 2018. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of UTUC. If approved, UGN-101 would be the first drug approved for the non-surgical treatment of LG UTUC.

About The Phase 2b OPTIMA II Trial

OPTIMA II (OPTimized Instillation of Mitomycin for BlAdder Cancer Treatment) is an open-label, single-arm, multi-center Phase 2b clinical trial of UGN-102 (mitomycin gel) for intravesical instillation to evaluate the safety and efficacy of UGN-102 in patients with intermediate risk low-grade non-muscle invasive bladder cancer (LG NMIBC) at intermediate risk of recurrence. Intermediate risk of progression is defined as one or two of the following: multiple tumors, solitary tumor >3 cm, or recurrence (³ 1 occurrence of LG NMIBC within 1 year of the current diagnosis). The trial enrolled 62 patients at clinical sites across the United States and Israel. Study participants were treated with six weekly instillations of UGN-102 administered via a standard intravesical catheter. Four to six weeks following the last instillation, patients undergo a PDE to determine response, the primary endpoint of the study. PDE involves a cystoscopy and wash cytology, a standard microscopic test of cells obtained from the urine to detect cancer. Patients who achieve a CR at the PDE timepoint are then followed for up to 9 months to determine the durability of disease control with UGN-102.

About UGN-102

UGN-102 (mitomycin gel) for instillation is an investigational drug formulation of mitomycin in Phase 2b development for the treatment of low-grade non-muscle invasive bladder cancer (LG NMIBC). Utilizing the RTGel™ Technology Platform, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using standard intravesical catheters. The Company completed enrollment in the Phase 2b OPTIMA II trial of UGN-102 for the treatment of LG NMIBC in September 2019 and intends to advance the program to a pivotal study to further investigate UGN-102 in the treatment of this condition.

About UroGen Pharma Ltd.

UroGen Pharma Ltd. (Nasdaq:URGN) is a clinical-stage biopharmaceutical company developing advanced non-surgical treatments to address unmet needs in the field of urology, with a focus on uro-oncology. UroGen has developed RTGel™ reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based platform technology that has the potential to improve therapeutic profiles of existing drugs. UroGen's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. UroGen's lead investigational candidates, UGN-101 (mitomycin gel) for instillation, and UGN-102 (mitomycin gel) for intravesical instillation, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and low-grade non-muscle invasive bladder cancer, respectively. UroGen is headquartered in New York, NY with operations in Los Angeles, CA and Israel.

Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation: the potential of UGN-101 for LG UTUC; the timing for completion of the rolling NDA for UGN-101; the potential approval of UGN-101 and the timing thereof; the expectation that UGN-101, if approved, will be the first drug approved for the non-surgical treatment of LG UTUC; the expected readiness of UroGen for a potential commercial launch of UGN-101 in 1H 2020; the potential of UroGen's proprietary RTGel™

technology platform to improve therapeutic profiles of existing drugs; the opportunity and potential of UGN-102 for LG NMIBC; and the planned initiation of a Phase 3 pivotal study of UGN-102 in LG NMIBC. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials, including the OLYMPUS Phase 3 trial and the OPTIMA II Phase 2b 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 achieving commercial readiness for the launch of a new product; the labeling 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; 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 SEC on August 9, 2019, 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 press release and are based on information available to UroGen as of the date of this release.

UROGEN CONTACT:

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Kate.Bechtold@urogen.com
914-552-0456

Exhibit 99.2

OPENING REMARKS

ARIE BELLDEGRUN, MD, FACS

Chairman, UroGen Pharma

UROGEN: BUILDING A GROWTH COMPANY

LIZ BARRETT

Chief Executive Officer, 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 of UGN-101 for LG UTUC; the timing for completion of the rolling NDA for UGN-101; the potential approval of UGN-101 and the timing thereof; the expectation that UGN-101, if approved, will be the first drug approved for the non-surgical treatment of LG UTUC; the timing for completion of pre-commercial activities and infrastructure build-out in anticipation of a potential commercial launch of UGN-101; the expected readiness of UroGen for a potential commercial launch of UGN-101 in 1H 2020 and the strength and timing of the potential commercial launch of UGN-101; plans for distribution and product packaging for UGN-101; plans for the retention of field-based personnel in support of the launch of UGN-101; the potential of UroGen's proprietary RTGel™ technology platform to improve therapeutic profiles of existing drugs; the opportunity and potential of UGN-102 for LG NMIBC; plans to commence a pivotal trial for UGN-102 in LG NMIBC in 2020; UGN-102's potential to replace current standard of care in LG NMIBC; plans to initiate a Phase 1 study with UGN-201; UroGen's anticipated status relating to Q3' 2019 financial guidance; plans to build a sustainable growth company; projections of revenue opportunities in markets of interest; plans to develop a global footprint; plans with Janssen to conduct an early stage feasibility evaluation in an area of mutual interest; and the anticipated completion of a Phase 2 trial of RTGel with Botox. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials, including the OLYMPUS Phase 3 trial and the OPTIMA II Phase 2b 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 achieving commercial readiness for the launch of a new product; 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; 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 SEC on August 9, 2019, 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.

AGENDA

- Opening Remarks
  Arie Belldegrun, MD, FACS, Chairman
- UroGen: Building a Growth Company
  Liz Barrett, CEO
- Clinical Update
  Mark Schoenberg, MD, CMO
- Innovation in Practice: KOL Panel and Q&A
  Mark Schoenberg (Moderator), MD, CMO
  Karim Chamie, MD, MSHS
  Jennifer Linehan, MD
  Phil Pierorazio, MD
  Sandip Prasad, MD
  Dan Saltzstein, MD
- Management Q & A
  Liz Barrett, Mark Schoenberg, Peter Pfreundschuh, Jeff Bova + Extended Team
- Closing Remarks
  Liz Barrett, CEO

UroGen Pharma

OUR TEAM

Leadership


Liz Barrett
Chief Executive Officer


Peter Pfreundschuh
Chief Financial Officer


Mark Schoenberg, MD
Chief Medical Officer


Stephen Mullennix
Chief Operating Officer


Jeff Bova
SVP, Commercial


Woody Bryan, PhD
SVP, Business Development


Marina Konorty, PhD
SVP, R&D & Head of Israel Operations


Jim Ottinger, RPh
SVP, Regulatory Affairs


Elyse Seltzer, MD
SVP, Clinical Development


John O'Reilly
VP, Associate General Counsel


Dalit Strauss-Ayali
VP, Non-clinical Research, Science, Discovery

Board of Directors


Arie Belldegrun, MD, FACS


Cynthia Butitta


Fred E. Cohen, MD


Kate Falberg


Stuart Holden, MD


Ran Nussbaum


Shawn C. Tomasello

UroGen Pharma

UROGEN: BUILDING A GROWTH COMPANY

- RTGel™ Technology
- Near-Term Catalysts
  - UGN-101
    - The Road to Anticipated Launch
  - UGN-102
  - UGN-201
  - Collaborations/Partnerships
- Long-Term Strategy
- Leading in Uro-Oncology & Beyond

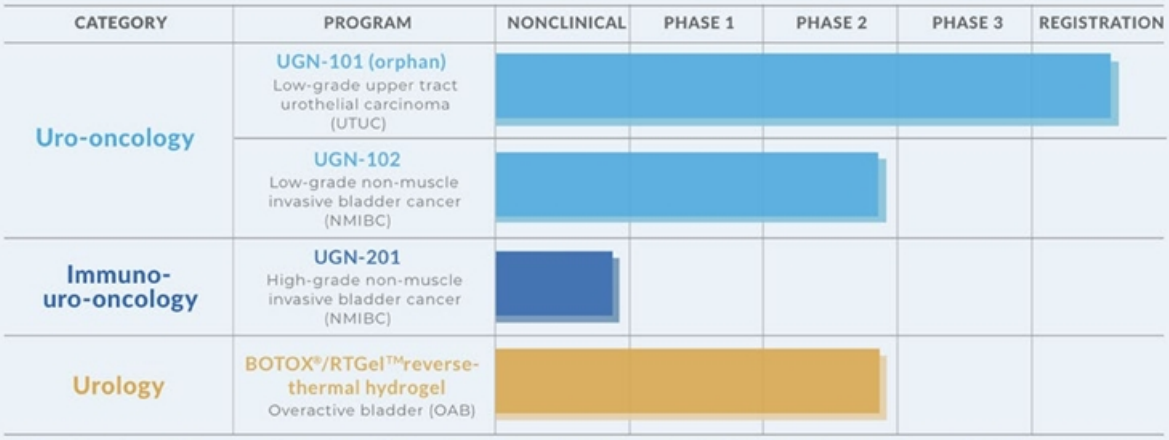
UroGen Pharma

UroGen Pharma

RTGel™ TECHNOLOGY

RTGel TECHNOLOGY IS NOT COMMERCIALLY AVAILABLE. THE SAFETY AND EFFECTIVENESS OF UROGEN'S INVESTIGATIONAL PRODUCT CANDIDATES THAT UTILIZE RTGel TECHNOLOGY HAVE NOT BEEN ESTABLISHED. FOR ILLUSTRATIVE PURPOSES ONLY.

STRONG MOMENTUM ACROSS PIPELINE



*Licensed to Allergan. The safety and efficacy of the above product candidates for the specified conditions have not been established.
BOTOX is a registered trademark of Allergan plc.

UroGen Pharma

UNLOCKING THE URO-ONCOLOGY MARKET

LOW-GRADE UPPER TRACT
UROTHELIAL CARCINOMA (UTUC)

~6,000 – 7,000 addressable population

No available FDA-approved medicines

LOW-GRADE NON-MUSCULAR
INVASIVE BLADDER CANCER (NMIBC)

~80,000 intermediate-risk LG NMIBC

Last drug approved >15 years ago

UroGen Pharma

KEY ACCOMPLISHMENTS IN 2019

- Completed phase III OLYMPUS trial for UGN-101 in LG UTUC; obtained breakthrough therapy designation and advanced rolling submission with FDA
- Fully enrolled phase **2b study of UGN-102** in intermediate-risk low-grade NMIBC and conducted interim analysis
- Enhanced the pipeline with UGN-201 preclinical work and announcement of the **early-stage feasibility agreement** with Janssen
- Organizational and commercial readiness for anticipated launch of UGN-101
- Developed long-term vision and strategy for sustainable growth
- **Strong cash position** and delivery of guidance

Established RTGel™ as the first innovation UroGen expects to bring to market

UroGen Pharma

OUR PIPELINE: **UGN-101**

Low-grade upper tract urothelial carcinoma (LG UTUC)

UGN-101 is an investigational agent. The safety and effectiveness of UGN-101 have not been established.

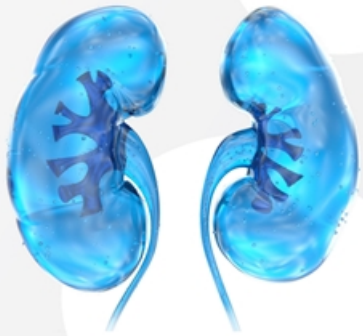
UROTHELIAL CARCINOMA
COMMON, COSTLY CANCER WITH SIGNIFICANT QOL IMPACT

Urothelial carcinoma (UC) is the **9th most common** cancer globally[1]

UC is the **most costly cancer** in the US health care system on a per-patient basis[1]

LOW-GRADE UPPER TRACT UROTHELIAL CARCINOMA (UTUC)

Cancer that happens in the lining of the kidneys or the ureters



LOW-GRADE UTUC

- Kidney-sparing treatments are achievable and may decrease overtreatment and loss of renal units
- 70%-80% of LG UTUC patients receive nephroureterectomies

Yeung et al. (2014) Pharmacoeconomics

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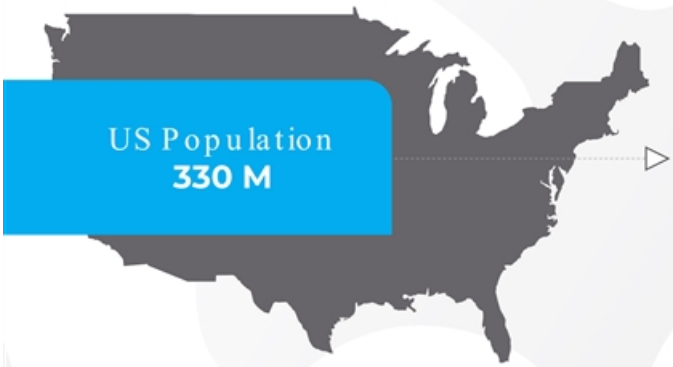
POTENTIAL OPPORTUNITY IS ~6,000 US PATIENTS



US Population
330 M

LG UTUC
Prevalence:
15,000-18,000

Newly Incident:
2,500-2,700

Recurrent:
3,000-4,000

Remission:
10,000-11,800

~6,000 potential patients annually.

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UPDATED **UGN-101** TOPLINE

	RESPONSE RATE	
	Overall (n=71)	**Endoscopically Unresectable Tumors 48% (34/71)**
CR Rate	59%	59%
6-month CR Durability*	89%	85%
12-month*	84%	84%

- Majority of adverse events were reported as mild or moderate
- Serious adverse events occurred in 36.6% of patients, most notably ureteric stenosis, hydronephrosis, flank pain, and urosepsis

❖ More complete discussion of UGN-101's efficacy and safety profile is reserved for clinical presentation.

*Kaplan-Meier Analysis

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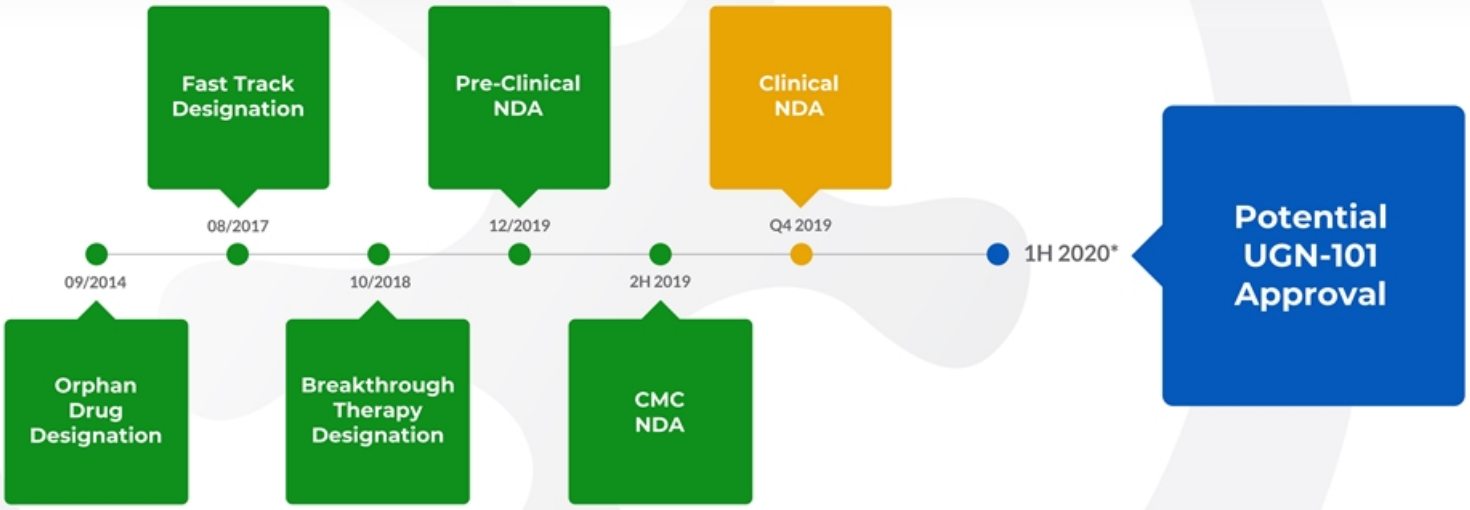
ON TRACK FOR NDA SUBMISSION: ROADMAP TO ANTICIPATED FDA APPROVAL OF UGN-101



*Assumes 6-month PDUFA based on Fast Track & Breakthrough Therapy Designations

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UROGEN: BUILDING A GROWTH COMPANY

THE ROAD TO ANTICIPATED LAUNCH: **UGN-101**

Focusing on and planning for the anticipated approval

ORGANIZATIONAL READINESS: UROGEN IS ON TRACK TO BE LAUNCH READY FOR UGN-101 BY JANUARY 2020

UroGen Pharma

UGN-101 OPPORTUNITY: UROLOGISTS RECOGNIZE THE NEED TO DELAY RADICAL SURGERY, AND IDENTIFY MULTIPLE OPPORTUNITIES TO INCORPORATE UGN-101 INTO THEIR TREATMENT OF LG UTUC, FOLLOWING ANTICIPATED FDA APPROVAL

Treatment Continuum: Low-Grade UTUC

★ = Percent of urologists who are "likely/very likely to use" UGN-101 in each specific setting.

UroGen Pharma

CREATIVE SOLUTIONS TO REMOVE BARRIERS

UGN-101 Awareness	• Hire experienced field teams with **expertise in uro-oncology, rare disease** • Strong **marketing awareness** efforts • **Real-time patient alerts** where possible
Ensure Reimbursement Confidence	• **Early Payer engagement** -- National Account Directors in field 2019 • **Dedicated team of Field Reimbursement Managers + independent HUB services** to support appropriate coding, benefits verifications, issue resolution
Product Distribution	• **National Pharmacy partner** will provide pre-mixed formulation to urology clinics • **All-in-one convenience kit** will be provided to hospital pharmacies who prefer to self-mix

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ROLES TO SUPPORT ACCOUNT-BASED APPROACH

33% OF ACCOUNTS HAVE 90% OF THE PATIENT POTENTIAL

7 RBM: Regional Business Manager
Responsible for all commercial activity

48 TBM: Territory Business Manager
Customer lead and demand generation

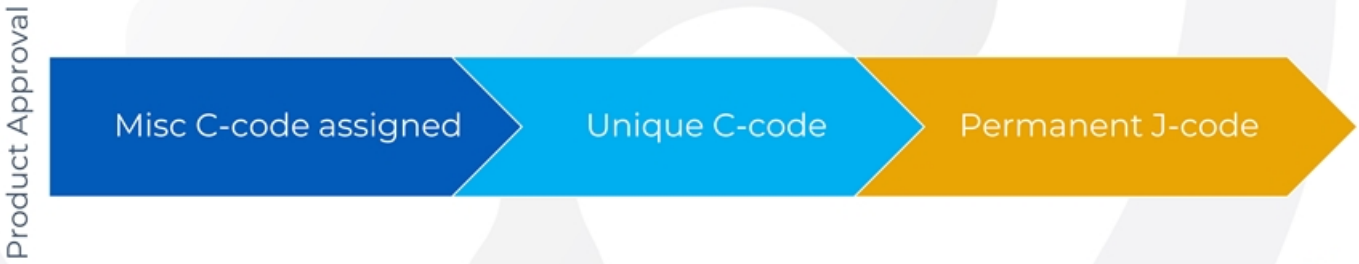
7 FRM: Field Reimbursement Manager
Account experts on billing and coding

7 CNE: Certified Nurse Educator
Provide technical training and support for mixing and product instillation

UroGen Pharma

UGN-101 TREATMENT IS EXPECTED TO **FIT WELL** INTO EXISTING PHYSICIAN REIMBURSEMENT MODELS

- **Professional fee:** Physicians expected to utilize existing CPT codes for UGN-101 instillation
- **Technical fee:** Hospitals and surgery centers expected to use existing codes for facility reimbursement
- **Product reimbursement:** UGN-101 will ultimately be reimbursed via a product-specific **J-Code**. In the interim, a **C-Code** will be utilized to facilitate smooth reimbursement in the hospital/ASC setting



UroGen Pharma

PLANNED UGN-101 ALL-IN-ONE KIT: MAKING UGN-101 PREPARATION AND ADMINISTRATION CONVENIENT FOR PRACTITIONERS

Network of pharmacies will be established to ensure delivery of pre-mixed product to all practitioners needing mixing services

All-in-one kit will be available to any practice in the US

Packaging Prototype

UroGen will coordinate all logistics through a reimbursement support center for a seamless customer experience

*The UGN-101 All-In-One Kit remains subject to ongoing internal development and future FDA evaluation. FDA approved packaging for UGN-101 may differ from current planned packaging.

UroGen Pharma

EXPERIENCED TEAM IS PRIMED FOR LAUNCH UPON APPROVAL

- ✓ Hired an internal team with a **track record of success** in oncology
- ✓ Hired a veteran sales force leadership team with **deep uro-oncology relationships**
- ✓ Consulted with our customers, and we are **ready to deliver** on their needs
  - HCPs
  - Pharmacists
  - Payers
- ✓ Launched a **successful** disease education campaign
- ✓ **Tested and validated** a launch campaign with urologists
- ✓ Developed **partnerships** with seasoned vendors

✓ Aligned and prepared for **launch readiness January 2020**

UroGen Pharma

OUR PIPELINE: **UGN-102**

Low-grade non-muscle invasive bladder cancer (LG NMIBC)

UGN-102 is an investigational agent. The safety and effectiveness of UGN-102 have not been established.

UGN-102 TOPLINE

UGN-102 enrollment complete ahead of schedule

- CR 63%*

**Interim CR based on half of patients*

Safety: Most AEs mild to moderate in severity, related to local tolerability, no related SAEs

- More complete discussion of UGN-102's efficacy and safety profile is reserved for clinical presentation.

UroGen Pharma

BLADDER CANCER MARKET OPPORTUNITY

POTENTIAL TO BE THE FIRST PRIMARY NON-SURGICAL CHEMOABLATIVE THERAPY FOR BLADDER CANCER

LG NMIBC: Large Patient Population
343 K prevalence
40 K incidence
~80 K intermediate risk

Surgical SOC with high relapse rate for intermediate risk

High rate of relapse after TURBT (SOC)

Drug therapy outdated, unused

Drugs currently used **only as adjuvant** after surgery

UGN-102: POTENTIAL TO REPLACE SOC:
Moves care from **OR to office/ASC** with a potential to **decrease cost** and morbidity of contemporary therapy

SEER Data – US
UGN-102 is an investigational product candidate not approved by the FDA

UroGen Pharma

OUR PIPELINE: **UGN-201**

UGN-201 is an investigational agent. The safety and effectiveness of UGN-201 have not been established.

UGN-201 PROVIDES US WITH **MULTIPLE SHOTS** ON GOAL

- UGN-201 is a TLR 7/8 agonist that is believed to stimulate innate and adaptive antitumor immunity. It likely works in conjunction with other potent immunoregulatory molecules
- Preclinical experiments as monotherapy and in combination with checkpoint inhibitors provide signals of efficacy
- Plan is to optimize combinations and move into human studies as soon as is feasible

UroGen Pharma

COLLABORATIONS & PARTNERSHIPS

ADVANCING LOCAL DELIVERY THROUGH STRATEGIC COLLABORATIONS

Strategic collaborations in urology and oncology

ALLERGAN™
Overactive bladder (phase 2)

JANSSEN™
Early-stage feasibility evaluation

RTGel has the potential to provide meaningful improvement over the current standard of care across urologic cancers and beyond

*The above trademarks are the property of their respective owners.

UroGen Pharma

BUILDING UROGEN'S **GLOBAL FOOTPRINT**

* Gathering data for EU and Japan

* Develop plan and decide on next steps-License/partner

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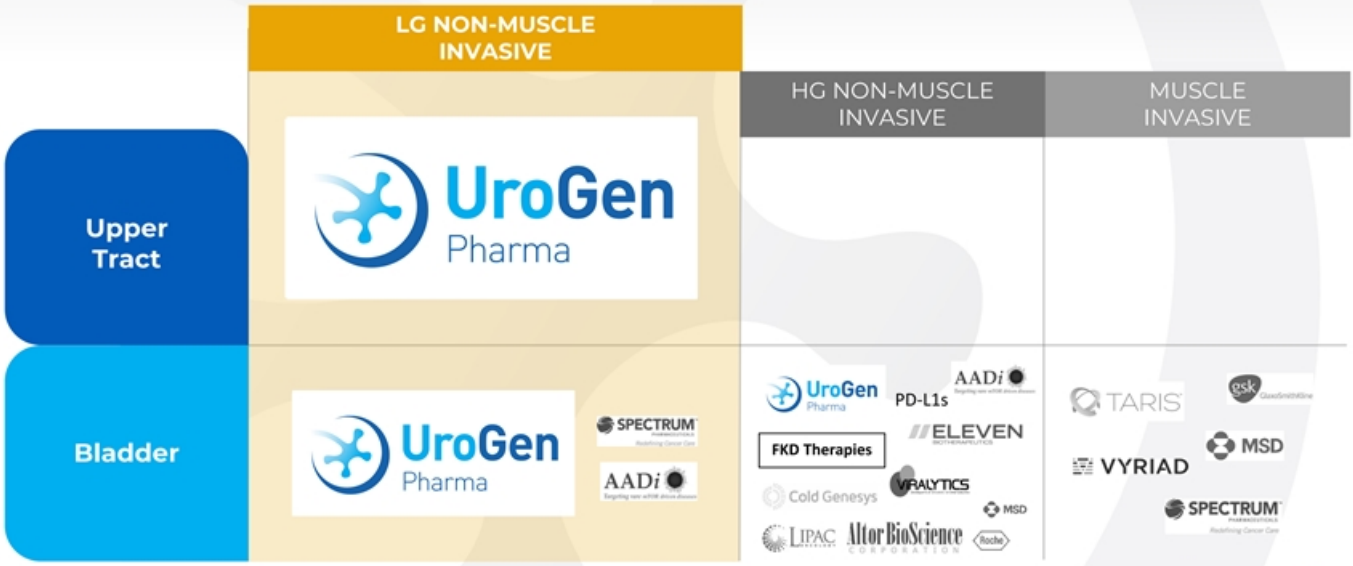
LEADING IN **URO-ONCOLOGY & BEYOND**

Building a growth company starts with the unmet need

UROGEN LEADERSHIP POSITION IN LOW-GRADE UROLOGIC DISEASE



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UGN-101 & **UGN-102** ADVANCE SOC AND PROVIDE A **STRONG FOUNDATION TO BUILD A SUSTAINABLE COMPANY**

DRIVING INNOVATION IN URO-ONCOLOGY WITH **RTGEL**

LG UPPER TRACT UROTHELIAL CANCER	LG NON-MUSCLE INVASIVE BLADDER CANCER
UGN-101 (LG) Phase 3 *Annual US addressable market: ~**6 K***	***Intermediate-Risk LG-NMIBC Phase 2B*** *Annual US addressable market: **~80 K***

~$1 BILLION POTENTIAL PEAK REVENUE OPPORTUNITY

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WE **BUILD NOVEL SOLUTIONS** TO TREAT SPECIALTY CANCERS AND UROLOGIC DISEASES BECAUSE **PATIENTS DESERVE BETTER**

ADDRESS CHALLENGING DISEASE WITH TRANSFORMATIVE THERAPIES

Addressing ***high unmet need diseases*** *in* ***Urology & gyn/GI cancers***

Must advance SOC

MAXIMIZE BENEFIT OF LOCAL DELIVERY

Leverage ***RTGel capabilities and expertise*** where unique solutions are needed to overcome anatomical and biological barriers

Opportunistically gain access to additional delivery platforms

PATIENT CENTRICITY

Ensure patients who can benefit from our ***medicines*** have ***access*** to them.

Provide a **holistic approach** with tools that help patients manage their disease and live their ***best lives*** possible

NIMBLE, SOLUTION-ORIENTED ORGANIZATION

Through our ***nimble approach***, UroGen is designed to develop and commercialize medicines faster and more efficiently while creating a dynamic environment for employees

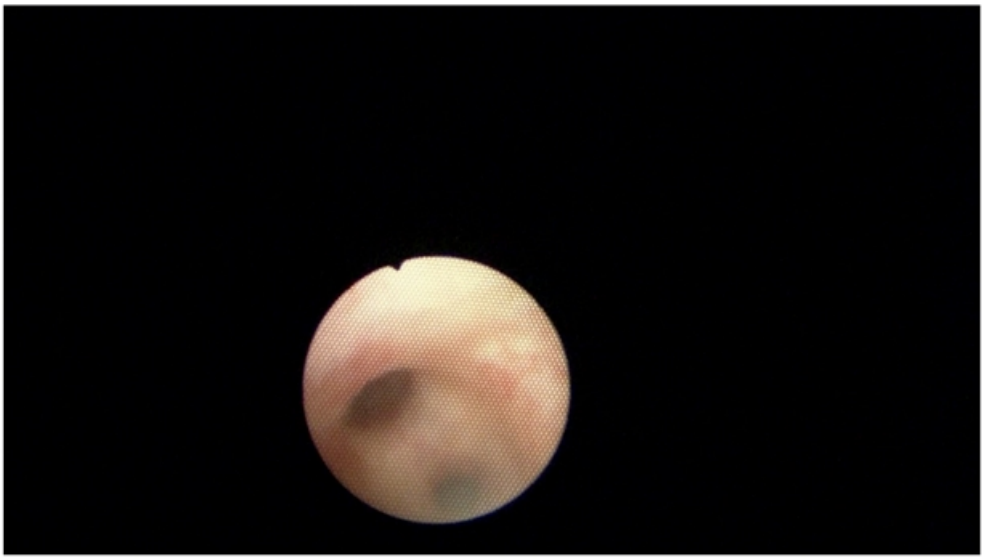
UroGen Pharma

CLINICAL UPDATE: UGN-101, UGN-102, UGN-201

MARK SCHOENBERG, MD

Chief Medical Officer, UroGen Pharma

LASER RESECTION OF LG UTUC



Courtesy of Dr. Scott Hubosky, Dept. of Urology, Jefferson University, Philadelphia, PA

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DEFINING LOW-GRADE VERSUS HIGH-GRADE DISEASE

LOW GRADE

- Chronic relapse
- Current treatment
  - Repetitive surgery
  - Risks
  - Incidence: 42 K
  - Prevalence: ~500 K

HIGH GRADE

- Progression
  - Metastasis & death
- Current treatment:
  - TURBT
  - BCG
  - Clinical trials
  - RCP/TMT
- Incidence: ~18 K
- Prevalence: ~200 K

BCG is not used in low-grade disease

THE UNMET MEDICAL NEED IN LG UTUC

70%-80%
will lose their kidney

RNU is a major surgery with complications

Repetitive endoscopic ablation
- Average time to recurrence: 6 months
- Treats visible disease but not occult disease

Elderly patient population

Complications associated with loss of kidney
- Chronic renal insufficiency
- Risk of dialysis
- Exacerbation of comorbidities (eg, cardiac disease)

45% of patients have unresectable tumors at presentation

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THE MUTATIONAL LANDSCAPE OF UCB DEMONSTRATES MAJOR DIFFERENCES IN INVASIVE AND NON-INVASIVE DISEASE

Hurst & Knowles (2017) Urol Oncol

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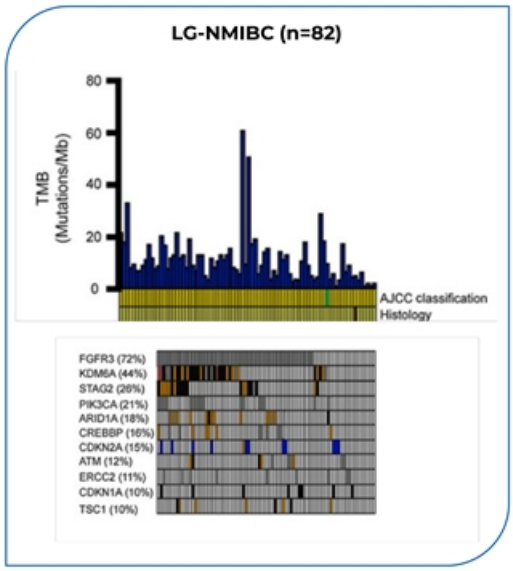
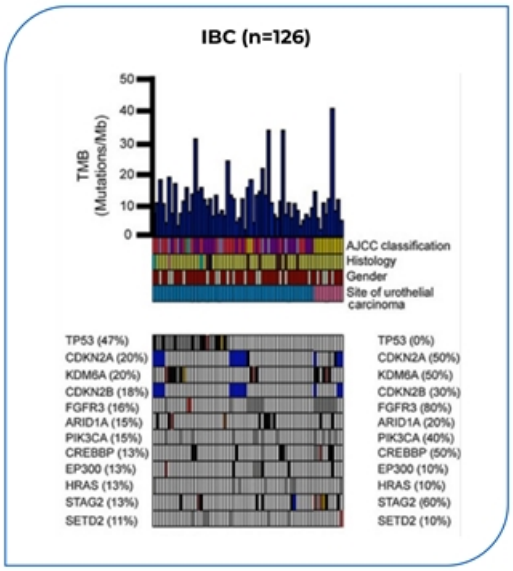
MOLECULAR PROFILING REVEALS: LG BC=LG UTUC





Nassar et al. (2019) Clin Ca Res.

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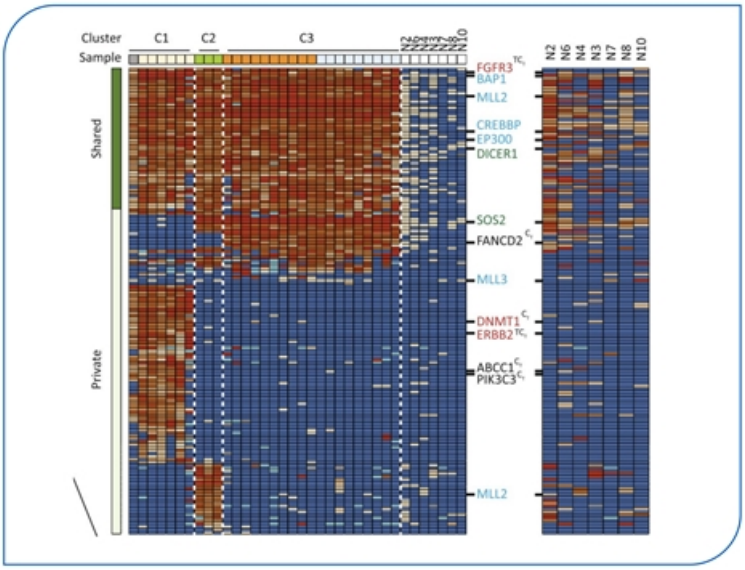
MOLECULAR ANALYSIS REVEALS "NORMAL TISSUE" HARBORS CANCER MUTATIONS



Thomsen et al. (2017) Nature/Scientific Reports

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OLYMPUS TRIAL

Enrollment Criteria

- New & recurrent LG UTUC
  - Solitary or multifocal
- Renal pelvis
- 5 mm-15 mm
- No HG, CIS
  - Cytology negative for HG
- Partial resection permitted

Rationale

- LG UTUC like LG NMIBC
- Anatomic complexity
- Limitation of current tools
- RNU ~70%-80%

Goal: Decrease renal loss and avoid repetitive surgery

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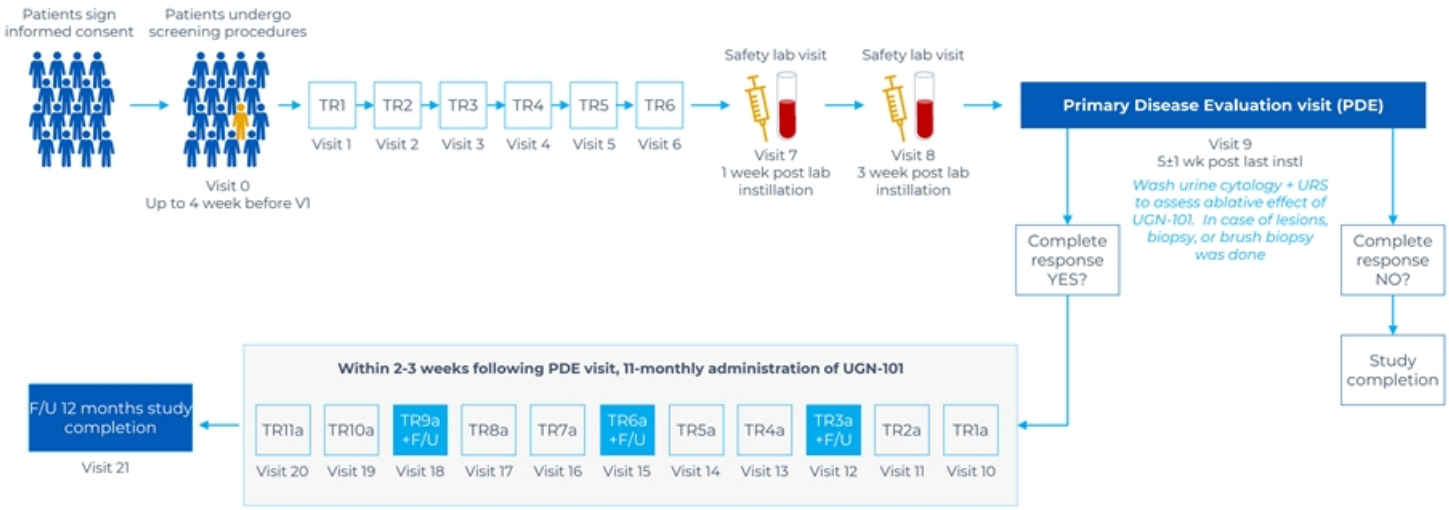
STUDY FLOW CHART FOR PROTOCOL TC-UT-03



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OLYMPUS STUDY DATA SUMMARY (DATABASE LOCK: 5/22/19)

74 enrolled
71 treated
87% Caucasian
68% male
75% >65 yo

	RESPONSE RATE*	
	Overall (n=71)	Endoscopically unresectable tumors 48% (34/71)
CR rate at PDE	**59% (42/71)**	**59% (20/34)**

*76% of CR cohort through 6-month follow-up.

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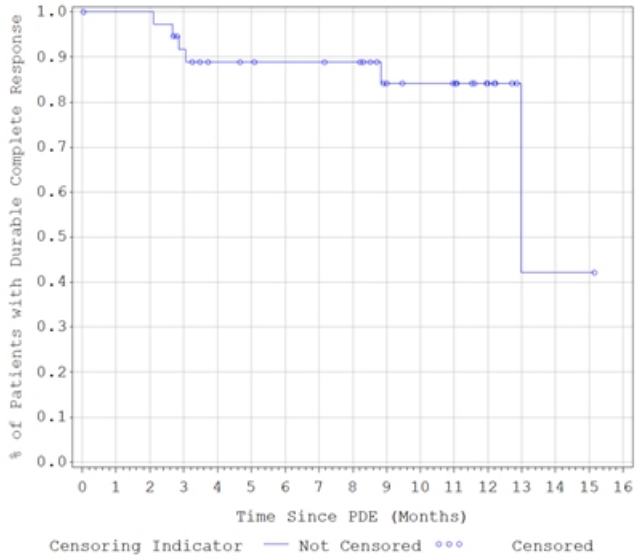
KAPLAN-MEIER CURVE OF DURABILITY OF RESPONSE DURING THE MAINTENANCE PERIOD (PDE_{CR} ANALYSIS SET)



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MOST COMMON GRADE 3 OR HIGHER TREATMENT-EMERGENT ADVERSE EVENTS

Adverse Event	Graded as Severe N (%)
Ureteric stenosis	6 (8.5)
UTI	2 (2.8)
Hematuria	2 (2.8)
Flank pain	2 (2.8)
Nausea	1 (1.4)
Renal impairment	1 (1.4)
Vomiting	3 (4.2)
Abdominal pain	1 (1.4)
Hydronephrosis	4 (5.6)

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RENAL URINARY TOXICITY

48 patients

11 (23%) no surgical intervention

24 (50%) transient stent

11 (23%) long-term stent

2 (4%) RNU

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PEER REVIEWED LITERATURE: URETERAL STRICTURES FOLLOWING ENDOSCOPIC SURGERY

Study	N (%)	Follow-Up months	Complication/Stricture Rate N/%
Schmeller et al 1989	16 (50)	Median 14	4 (25) strictures
Engelmeyer et al 1996	10 (70)	Mean 43	2 (20) strictures
Martinez-Pinero et al 1996	59 (24)	Mean 31	9/39 (23) strictures/ureteric perforations
Daneshmand et al 2003	30	Mean 31	5 (17) strictures
Reisiger et al 2007	10	Mean 73	1 (10) stricture
Krambeck et al 2007	37 (100)	Mean 32	19 (51) overall; 5 (14) strictures
Cutress et al 2012	73 (11)	Median 54	12 (16) strictures; 1x bowel perforation with Nd:YAG laser

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OLYMPUS SUMMARY

- 71 patients treated
- 59% CR
  –Efficacy consistent in endoscopically unresectable pts
- Durability stable at 6 and 12 months (84% per KM analysis)
- AE profile
  –Consistent with upper tract manipulation for cancer
  –Stricture consistent with published literature
- Follow-up ongoing

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UGN-102 PROGRAM FOR INTERMEDIATE-RISK LG UBC

- Similarities between LG NMIBC and LG UTUC
  - –Histology
  - –Recurrence pattern
  - –Clinical behavior
  - –**High risk of recurrence**
  - –**Low risk of progression**
- New molecular data
- Sensitivity to locally administered drugs

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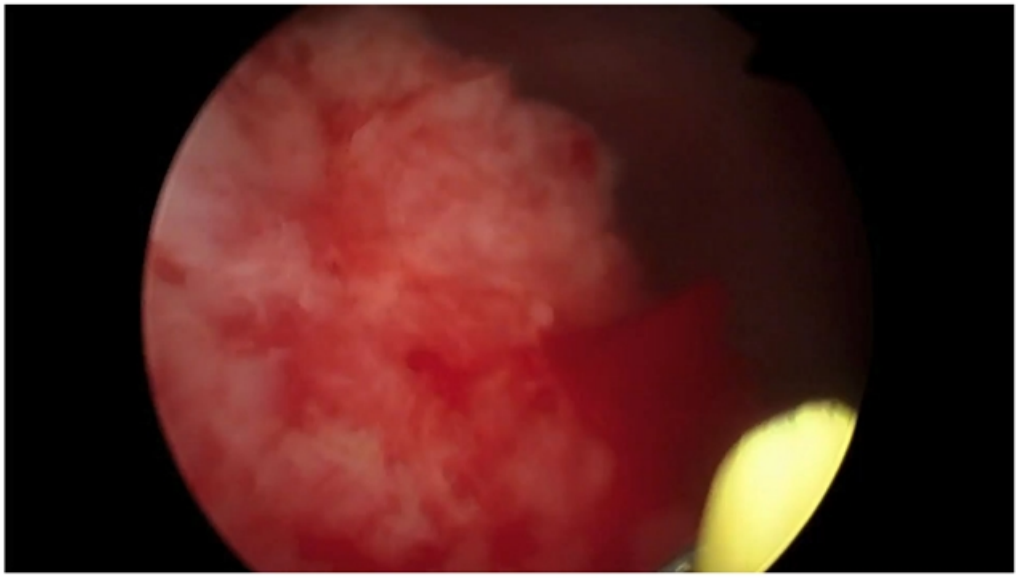
CYSTOSCOPIC APPEARANCE OF TURBT



Courtesy of Alex Sankin, MD, Montefiore Medical Center & The Albert Einstein College of Medicine, Bronx, NY

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WHY INTERMEDIATE-RISK NMIBC?

- **"Surgical failure"** cohort: risk of progression low, recurrence high
- Cost & morbidity of repetitive surgery

How many of the following 4 factors does the patient have?

- Multiple tumors
- Tumor size >3cm
- Early recurrence (<1 year)
- Frequent recurrences (>1 per year)

0

Treatment similar to low risk

- TURBT + single immediate post-op chemotherapeutic dose, or
- Office fulguration
- Intravesical chemotherapy

1-2

Treatment as intermediate risk

- TURBT plus adjuvant intravesical therapy

≥3

Treatment as high risk

- TURBT + BCG induction + maintenance

Kamat et al. (2014) J. Urology

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OPTIMA II DESIGN

- Patients with IR NMIBC (1-2/3: multifocal, lesion >3 cm, recurrence within 12 months)
- UGN-102 q wk X 6
- Primary endpoint: CR at 3-month visit
  –CR pts followed quarterly x 9 months
- Secondary endpoint: 12-month durability & safety

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UGN-102 INTERIM ANALYSIS

- The majority of adverse events were reported as mild or moderate; the most commonly reported AEs were:
  - –Dysuria (38%),
  - –Hematuria (16%),
  - –Frequency (13%),
  - –Urinary tract infection (13%)

	RESPONSE RATE*
	Total enrolled (n=32)
CR rate	**63% (20/32)**

*PDE based on evaluation at 3 months. Patients will continue to be followed for durability at 12 months.

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NEXT STEPS FOR UGN-102

- Continued follow-up of patients in the trial
- Discuss with FDA
- Scenario planning for phase 3 pivotal study
  - –Streamline & expedite registrational path
  - –Randomized H2H vs TURBT likely
    - We are prepared to execute
- Pivotal study planned for 2020

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UGN-201

UC is an "immune" responsive tumor

- "Early" experience with BCG (local)
- CPI trials for MIBC (systemic)

201: TLR 7/8 agonist

- Activates "innate" immune response
- May potentiate "adaptive" antitumor response
- Phase 1b: "signal" when applied locally to CIS

Hypothesis:

Combinatorial immunotherapy is feasible and clinically meaningful

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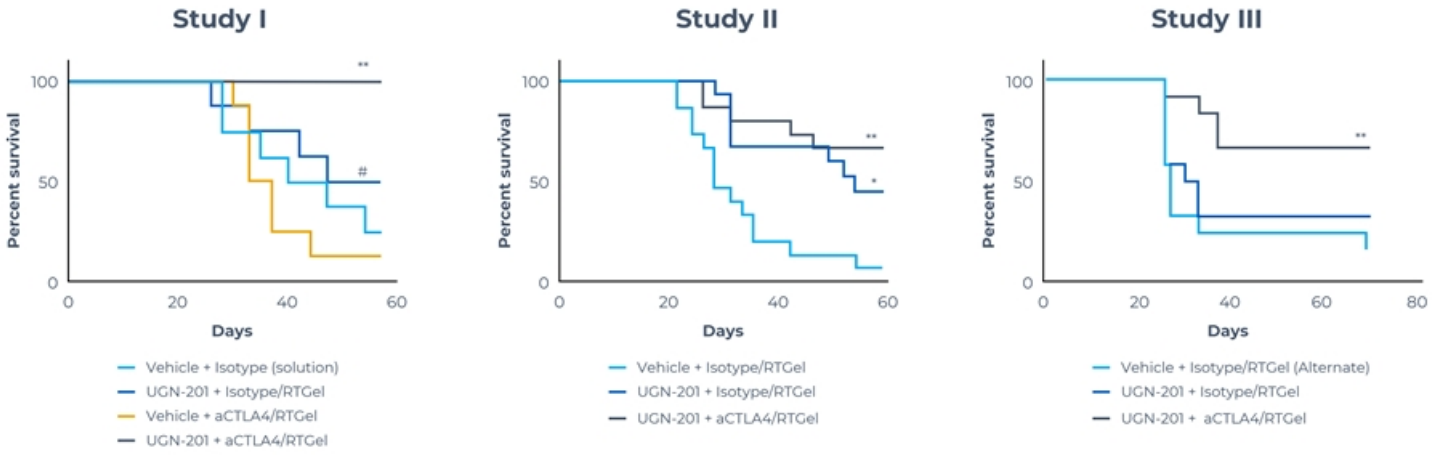
IN MICE: UGN-201 + aCTLA4/RTGEL RESULT IN BETTER SURVIVAL



*$P \leq 0.05$ vs control
**$P \leq 0.005$ vs control
#$P \leq 0.05$ vs combo

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SUMMARY OF MAJOR FINDINGS FROM MURINE STUDIES

- Intravesical UGN-201+aCTLA4/RTGel:
  - –Smaller tumors and better survival rate
  - –Decreases T regulatory cells
  - –Increases the ratio of CD8+/T regulatory cells
- Data support continued progression toward human trials
- May represent a novel approach to HG NMIBC

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SUMMARY

UGN-101: First primary chemoablative therapy for urothelial cancer

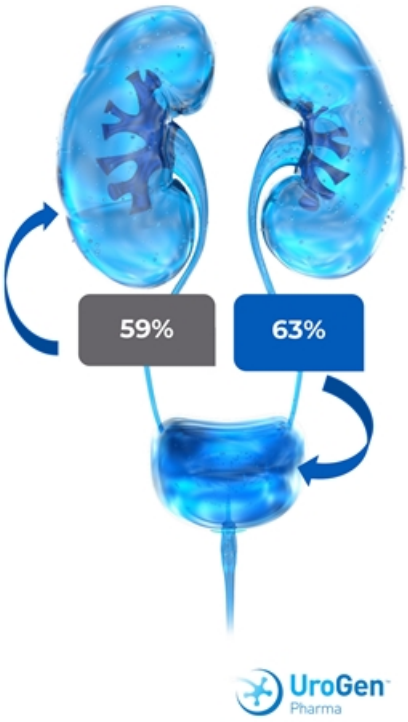
- Robust efficacy & durability in LG UTUC
  - CR: 59%
  - 12-month durability 84% (KM) including “unresectable” pts

UGN-102 in IR NMIBC:

- Interim data encouraging
  - CR: 63%
  - AE profile: mostly mild to moderate, local & transient

UGN-201 Immunotherapy:

- Local aCTLA4+UGN-201 increased survival UBC (Murine)



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CREDIT WHERE CREDIT IS DUE

- Elyse Seltzer, MD
- Jim Ottinger, RPh
- Marina Konorty, PhD
- Dalit Strauss-Ayali, PhD DVM
- Ifat Klein, PhD
- Yael Agmon
- Nimrod Gabai
- Elinor Schreiber
- Dima Zolotaryov
- Baruch Narotzki
- Pallavi Rajput
- Roman Bromblin
- Diana Licis
- Eric Smith
- Madlen Malinowski
- Tami Gerassi
- Swati Chiktara
- Ruby Salmo
- Sunil Raju, MD
- Robert Kirshoff

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INNOVATION IN PRACTICE

KOL Panel and Q&A

MANAGEMENT Q&A

CLOSING REMARKS

Liz Barrett

IN SUMMARY

UroGen is committed to leading in challenging areas of **high unmet need**

UroGen is poised for near-term catalysts behind positive data in **UGN-101** and **UGN-102**

UroGen will focus on **urology** and **Gyn/GI oncology**

UroGen plans to leverage our **proprietary expertise in RTGel** but grow beyond local delivery

UroGen is in a **strong financial position** that will take us through launch and advance the pipeline

UroGen is designed to build a **sustainable** growth company while maintaining the culture of **creativity** and **problem solving** that got us here

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Exhibit 99.3

UroGen Investor Day Details Positive Clinical Updates, UGN-101 Launch Preparedness, and Pipeline Advances

UGN-101 and UGN-102 Demonstrate Positive Clinical Data in Low-Grade Upper Tract Urothelial Cancer (LG UTUC) and Low-Grade Non-Muscle Invasive Bladder Cancer (LG NMIBC)

UGN-101 Final Data Modules for NDA Submission On-Track for Q4 2019

UGN-101 Plans for Launch Readiness by January 2020

UGN-201 Plans for Advancement into Phase 1 for High-Grade NMIBC in 2020

NEW YORK, September 24, 2019 — UroGen Pharma Ltd. (Nasdaq: URGN), a clinical-stage biopharmaceutical company developing treatments to address unmet needs in the field of urology, today presented updates on its advancing pipeline for urologic cancers and UGN-101 launch readiness at its Investor Day in New York on September 24, 2019.

“At UroGen, we are 100 percent committed to overcoming obstacles that have stunted much needed innovation in uro-oncology,” said Liz Barrett, President and Chief Executive Officer of UroGen. “While we prepare for a potential launch of UGN-101, we believe this is just the beginning of what is possible with our pipeline. The data from an interim analysis for UGN-102 unveiled at our Investor Day further highlight the potential of our RTGel™ platform to transform treatments in this space for an even larger patient population with bladder cancer. We look forward to pushing innovation beyond our foundational platform and moving UGN-201, our TLR 7/8 agonist for high-grade bladder cancer, into clinical studies in 2020.”

UroGen detailed data updates for its lead investigational product candidates UGN-101 and UGN-102:

- **UGN-101** (mitomycin gel) for instillation for patients with low-grade upper tract urothelial cancer (LG UTUC):
  - Complete response (CR) rate of 59 percent observed in 71 patients with LG UTUC from Phase 3 OLYMPUS trial. Data remain consistent with previously presented data.
  - Durability of response determined to be 89 percent at six months and 84 percent at twelve months.
  - In the OLYMPUS trial, the most common treatment emergent adverse events (TEAE) included ureteral stenosis, urinary tract infection, hematuria, flank pain, dysuria, renal impairment, hydronephrosis and frequency. Most TEAEs were characterized as mild to moderate and transient.
  - At the time of database lock, the most common Grade 3 TEAE’s included ureteral stenosis (8.5%), hematuria, flank pain, and urinary tract infection (3% each). There was one Grade 4 TEAE of subdural hematoma (1.4%).
  - Rolling NDA submission is on track for Q4 2019 with potential approval and launch in 1H 2020.
  - If approved, UGN-101 will be the first drug for the primary chemoablative treatment of LG UTUC.
- **UGN-102** (mitomycin gel) for intravesical instillation for patients with intermediate risk low-grade non-muscle invasive bladder cancer (LG NMIBC):

- In an interim analysis, 63% (20/32) of patients from the Phase 2b OPTIMA II trial achieved a CR.
- In an interim analysis, the most common treatment emergent adverse events (TEAEs) observed were dysuria, pollakiuria, fatigue, hematuria and urinary tract infection. The majority were characterized as mild or moderate and transient.
- Patients will continue to be followed with 12-month durability to be reported at a later date.
- Trial enrolled patients with intermediate risk LG NMIBC, defined as those with one or two of the following criteria: multifocal disease, large tumors and rapid rates of recurrence.
- Trial completed enrollment of 62 patients ahead of schedule.
- The Company intends to initiate a pivotal Phase 3 trial in 2020 following discussion with the FDA.

UroGen discussed its ongoing activities to build awareness of unmet needs in UTUC, educate the market and commercialize UGN-101 following anticipated regulatory approval:

- Increased scientific awareness of UGN-101 clinical data developments in urologic community.
- Engagement with payers and proactive market access strategy to ensure patient access and reimbursement.
- UGN-101 treatment expected to fit well into existing physician reimbursement models.
- Planned convenience kit for UGN-101 will facilitate preparation and administration for practitioners.
- Experienced commercial team with track record of success in uro-oncology.
- Nimble salesforce with seven Regional Business Managers (RBMs) hired, and 50 sales reps to be hired by end of 2019.

The Company also provided an update on **UGN-201**, it's investigational TLR 7/8 agonist for the treatment of high-grade NMIBC. UGN-201 is believed to stimulate innate and adaptive antitumor immunity. It likely works in conjunction with other potent immunoregulatory molecules. Nonclinical data shows an efficacy signal when UGN-201 is administered locally with anti-CTLA4 antibody in a murine model of high-grade bladder cancer. The Company plans to optimize combinations and advance into human studies.

About UGN-101

UGN-101 (mitomycin gel) for instillation is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade upper tract urothelial cancer (LG UTUC). Utilizing the RTGel™ technology platform, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-101 is designed to enable longer exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-101 is delivered to patients using standard ureteral catheters. The Company initiated its rolling submission of the UGN-101 New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in December 2018. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of UTUC. If approved, UGN-101 would be the first drug approved for the non-surgical treatment of LG UTUC.

About UGN-102

UGN-102 (mitomycin gel) for instillation is an investigational drug formulation of mitomycin in Phase 2b development for the treatment of low-grade non-muscle invasive bladder cancer (LG NMIBC). Utilizing the RTGel™ Technology Platform, UroGen's proprietary sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using standard intravesical catheters. The Company completed enrollment in the Phase 2b OPTIMA II trial of UGN-102 for the

treatment of LG NMIBC in September 2019 and intends to advance the program to a pivotal study to further investigate UGN-102 in the treatment of this condition.

About UroGen Pharma Ltd.

UroGen Pharma Ltd. (Nasdaq:URGN) is a clinical-stage biopharmaceutical company developing advanced non-surgical treatments to address unmet needs in the field of urology, with a focus on uro-oncology. UroGen has developed RTGel™ reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based platform technology that has the potential to improve therapeutic profiles of existing drugs. UroGen's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. UroGen's lead investigational candidates, UGN-101 (mitomycin gel) for instillation, and UGN-102 (mitomycin gel) for intravesical instillation, are designed to potentially ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and low-grade non-muscle invasive bladder cancer, respectively. UroGen is headquartered in New York, NY with operations in Los Angeles, CA and Israel.

Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation: the potential of UGN-101 for LG UTUC; the timing for completion of the rolling NDA for UGN-101; the potential approval of UGN-101 and the timing thereof; the expectation that UGN-101, if approved, will be the first drug approved for the non-surgical treatment of LG UTUC; the timing for completion of pre-commercial activities and infrastructure build-out in anticipation of a potential commercial launch of UGN-101; the expected readiness of UroGen for a potential commercial launch of UGN-101 in 1H 2020 and the strength and timing of the potential commercial launch of UGN-101; plans for the retention of field-based personnel in support of the launch of UGN-101; the potential of UroGen's proprietary RTGel™ technology platform to improve therapeutic profiles of existing drugs; the opportunity and potential of UGN-102 for LG NMIBC; plans to commence a pivotal trial for UGN-102 in LG NMIBC in 2020; UGN-102's potential to replace current standard of care in LG NMIBC; and plans to initiate a Phase 1 study with UGN-201. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials, including the OLYMPUS Phase 3 trial and the OPTIMA II Phase 2b 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 achieving commercial readiness for the launch of a new product; 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; 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 SEC on August 9, 2019, 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 press release and are based on information available to UroGen as of the date of this presentation.

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