UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ADAM COCKRELL, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. UROGEN PHARMA LTD., ELIZABETH BARRETT, CHRIS DEGNAN, and DON KIM, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

Plaintiff Adam Cockrell ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by UroGen Pharma Ltd. ("UroGen" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by UroGen; and (c) review of other publicly available information concerning UroGen.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired UroGen securities between July 27, 2023 and May 15, 2025, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. UroGen engages in the development and commercialization of solutions for specialty cancers. The Company's lead pipeline product is UGN-102 (mitomycin), an intravesical solution intended to treat low-grade intermediate risk non-muscle invasive bladder cancer.

3. On August 14, 2024, the Company completed the submission of the rolling new drug application ("NDA") for UGN-102. UroGen sought U.S. Food and Drug Administration ("FDA") approval for UGN-102 based on data from several studies, including the pivotal ENVISION trial, the earlier OPTIMA II study, and the partially completed ATLAS randomized trial.

4. On May 16, 2025, before the market opened, the FDA published a briefing document in advance of its Oncologic Drugs Advisory Committee meeting regarding UroGen's NDA for UGN-102, which stated the agency doubted whether the submitted data was sufficient to conclude that UGN-102 was effective. In the briefing document, the FDA stated: "[g]iven that ***ENVISION lacked a concurrent control arm,*** the primary endpoints of complete response (CR) and duration of response (DOR) are difficult to interpret." The FDA also said it had "recommended a randomized trial design to the Applicant several times during their product's development due to concerns with interpreting efficacy results" but UroGen "chose not to conduct a randomized trial with a design and endpoints that the FDA considered appropriate." On this news, UroGen's stock price fell $2.54, or 25.8%, to close at $7.31 per share on May 16, 2025, on unusually heavy trading volume.

5. Then, on May 21, 2025, before the market opened, the Oncologic Drugs Advisory Committee voted against approving the UGN-102 NDA. The committee found that the overall benefit-risk of the investigational therapy UGN-102

(intravesical mitomycin) is ***not*** favorable in patients with recurrent low-grade, intermediate-risk non-muscle invasive bladder cancer. On this news, UroGen's stock price fell $3.37, or 44.7%, to close at $4.17 per share on May 21, 2025, on unusually heavy trading volume.

6. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the ENVISION clinical study was not designed to demonstrate substantial evidence of effectiveness of UGN-102 because it lacked a concurrent control arm; (2) as a result, the Company would have difficulty demonstrating that the duration of response endpoint was attributable to UGN-102; (3) UroGen failed to heed the FDA's warnings about the study design used to support a drug application for UGN-102; (4) as a result of the foregoing, there was a substantial risk that the NDA for UGN-102 would not be approved; and (5) as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

8. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

10. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

11. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

12. Plaintiff Adam Cockrell, as set forth in the accompanying certification, incorporated by reference herein, purchased UroGen securities during the Class

Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

13. Defendant UroGen is incorporated under the laws of Israel with its principal executive offices located in Princeton, New Jersey. UroGen's ordinary shares trade on the NASDAQ exchange under the symbol "URGN."

14. Defendant Elizabeth Barrett ("Barrett") was the Company's Chief Executive Officer ("CEO") at all relevant times.

15. Defendant Chris Degnan ("Degnan") has been the Company's Chief Financial Officer ("CFO") since October 9, 2024.

16. Defendant Don Kim ("Kim") was the Company's CFO from March 25, 2022 until October 8, 2024.

17. Defendants Barrett, Degnan, and Kim (together, the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the

Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

18. UroGen engages in the development and commercialization of solutions for specialty cancers. The Company's lead pipeline product is UGN-102 (mitomycin), an intravesical solution intended to treat low-grade intermediate risk non-muscle invasive bladder cancer. Since commencing operations, the Company has devoted substantially all of its efforts to develop UGN-102 and obtain regulatory approval.

Materially False and Misleading Statements Issued During the Class Period

19. The Class Period begins on July 27, 2023.[1] On that date, UroGen announced topline data from its Phase 3 trials, ATLAS and ENVISION. the

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added, and all footnotes are omitted.

Company filed a Form 8-K with the SEC that attached as exhibits a press release and presentation slides, stating in relevant part:

> **Item 8.01 Other Events.**
>
> *ATLAS and ENVISION Phase 3 Trial Results*
>
> On July 27, 2023, the Company announced topline data from its Phase 3 trials, ATLAS and ENVISION, studying UGN-102 (mitomycin) for intravesical solution in patients with low-grade, intermediate-risk non-muscle invasive bladder cancer.
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> In the ATLAS trial, UGN-102 met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55%. UGN-102 also showed a 64.8% complete response rate at three months for patients who only received UGN-102, compared to a 63.6% complete response rate at three months for patients who only received a trans-urethral resection of bladder tumor (TURBT).
>
> The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.2% rate of complete response at 3-months following the initial treatment. Additional data evaluating the secondary endpoint of duration of response from ENVISION and the submission of a New Drug Application (NDA) (assuming additional positive findings) to the U.S. Food and Drug Administration (FDA) are anticipated in 2024.
>
> In both trials, UGN-102 was generally well-tolerated, with a side effect profile similar to that of previous clinical trials of UGN-102.
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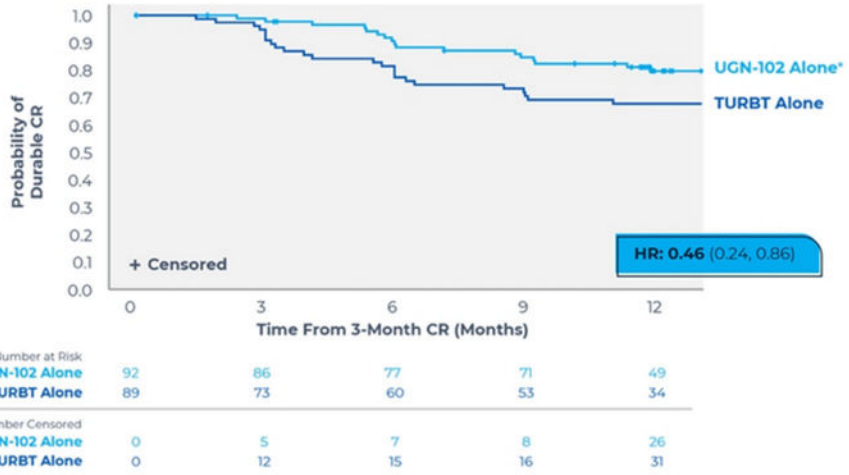
> * * *

Summary of Disease-Free Survival: Significantly More Total Recurrence and Progression in TURBT Alone Arm

	UGN-102 +/- TURBT (N = 142) / n (%)	TURBT Alone (N = 140) / n (%)
Patients with Events, n (%)	**37 (26.1)**	**55 (39.3)**
Recurrence of LG Disease	20 (14.1)	39 (27.9)
Progression to HG Disease	17 (12.0)	15 (10.7)
Death	0	1 (0.7)
Patients Censored, n (%)	**105 (73.9)**	**85 (60.7)**
Hazard Ratio (95% CI)	**0.45 (0.29, 0.68)**	

* * *

DOR - 54% Reduction of Risk for Recurrence, Progression, or Death in Patients Who had a 3-Month CR



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*UGN Alone Subgroup of the UGN 102 +/- TURBT arm in ATLAS
UroGen Data on File
Source: Table 14.2.1.1a
Kaplan-Meier Plot of Duration of Response in Complete Responders

UroGen Pharma

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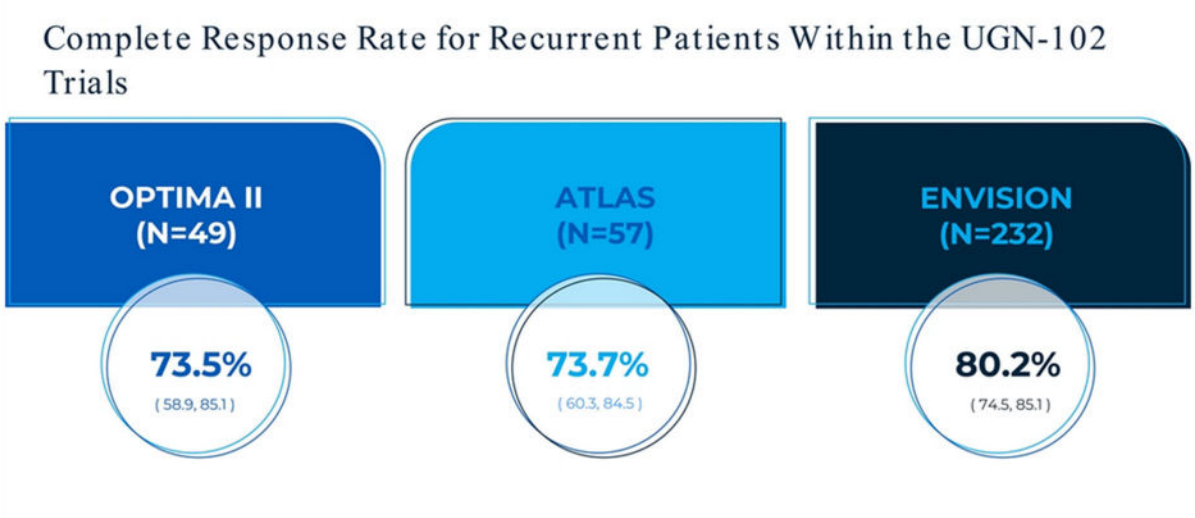

20. On November 14, 2023, UroGen announced its financial results for the quarter ended September 30, 2023 in the press release, claiming that the Company had reached "agreement with the FDA" that the ENVISION trial would support an NDA submission. Specifically, the press release stated as follows in relevant part:

> **UroGen Pharma Reports Third Quarter 2023 Financial Results**
>
> • Continued strong growth with JELMYTO® net product revenues of $20.9 million in Q3 2023; an increase of ~30% from the same period last year
>
> ***•Agreement with United States Food & Drug Administration (FDA) to proceed with rolling New Drug Application (NDA) for UGN-102 beginning in January 2024***
>
> * * *
>
> "During the third quarter, UroGen achieved several notable milestones, including announcement of unprecedented positive results from our ENVISION and ATLAS Phase 3 trials of UGN-102 in LG-IR-NMIBC," said Liz Barrett, President, and Chief Executive Officer of UroGen. ***"Those seminal events paved the way for our recent pre-NDA meeting with the FDA where we aligned with the Agency on an efficient, rolling NDA review for UGN-102 starting in 2024***. If approved, UGN-102 will be the first medicine approved for this patient

population. The NDA will leverage the full strength of our clinical data with ENVISION as the pivotal trial and underscores our unwavering commitment to transforming the LG-IR-NMIBC treatment landscape, as we strive to reduce recurrence rates and minimize the need for multiple surgeries in this highly underserved patient population."

Business Highlights:

UGN-102 (mitomycin) for intravesical solution:

• ***Announced agreement with the FDA that the current development plan evaluating duration of response at 12 months from the pivotal ENVISION trial will support submission of an NDA for the treatment of LG-IR-NMIBC***. The FDA also agreed to a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls (CMC) sections of the NDA, presently slated for January 2024.

• Both ENVISION and ATLAS Phase 3 clinical trials met their primary endpoints in treating LG-IR-NMIBC.

• ENVISION demonstrated an unprecedented 79.2% complete response rate (CRR) among 242 patients at three months after first instillation of UGN-102. Additional data evaluating the key secondary endpoint of duration of response is expected in Q2 2024.

• The ATLAS trial met its primary endpoint of disease-free survival, with topline results demonstrating a reduced risk of recurrence, progression, or death by 55% for UGN-102 ± TURBT. ATLAS also demonstrated a 64.8% CRR at three months for patients who only received UGN-102, compared to 63.6% for those patients who only received TURBT. The estimated probability of remaining disease free 15-months after randomization was 72% for UGN-102 ± TURBT and 50% for TURBT monotherapy (hazard ratio 0.45).

21. On March 14, 2024, the Company submitted its annual report for the fiscal year ended December 31, 2023 on a Form 10-K filed with the SEC, which claimed that the ENVISION trial was designed based on the Company's "dialogue"

with the FDA and that the agency had accepted the "single-arm approach," stating as follows in relevant part:

> We initiated our Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial comparing UGN-102 with or without TURBT to standard of care, TURBT. ***In parallel, we continued to engage in discussions with the FDA and, based on this dialogue, we designed a trial in order to demonstrate the efficacy and safety of UGN-102. This Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with low-grade intermediate risk NMIBC.*** The design of the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population has similar clinical characteristics, receives the same investigational treatment regimen and undergoes similar efficacy and safety assessments and qualitative follow-up. Study participants receive six once-weekly intravesical instillations of UGN-102. The primary endpoint is CR rate at three months after the first instillation, and the key secondary endpoint is durability of response in patients who achieve CR at the three-month assessment.
>
> In February 2022, we announced the initiation of the Phase 3 ENVISION trial, targeting enrollment of 220 patients across 90 sites. ***In December 2022 we completed our target enrollment of the Phase 3 ENVISION trial. As a result of the FDA's acceptance of a single arm approach, we stopped enrollment of the Phase 3 ATLAS trial.*** However, at the time enrollment was stopped, patients who had signed an informed consent were able to complete screening, and if eligible were randomized into the trial.
>
> ***On July 27, 2023, we announced topline data from our Phase 3 trials, ATLAS and ENVISION. In the ATLAS trial, UGN-102 met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55%. Results of the ATLAS trial also showed a 64.8% CR rate at three months for patients who only received UGN-102, compared to a 63.6% CR rate at three months for patients who only received a TURBT.*** The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.2% rate of CR at three months following the initial

treatment. Additional data evaluating the secondary endpoint of duration of response from ENVISION is anticipated in 2024. In both trials, the safety profile of UGN-102 was acceptable, with a safety profile comparable to that observed in previous clinical trials of UGN-102.

We also initiated a Phase 3b study with the objective of demonstrating whether UGN-102 can be administered at home by a qualified home health professional, avoiding the need for repeated visits to a healthcare setting for instillation. As per the study design, patients in this study received six once-weekly intravesical instillations of UGN-102 with the initial treatment visit occurring at the investigative site and instillation performed by a qualified physician. Treatment visits two to six took place at the patient's home and instillations were performed by a properly trained and qualified home health professional. The primary endpoints of the study include safety and tolerability, discontinuations from at home study treatment and feedback from patients, home health professionals and investigators via standardized questionnaires. The study completed enrollment with a total of eight patients across four centers and all study visits for these enrolled patients have been completed. Preliminary results were reported through a press release in February 2023, finding that UGN-102 was suitable to administer at home by a visiting nurse under the supervision of a treating physician and resulted in 75% of patients achieving a CR, defined as no detectable disease three months after starting treatment. Patients, nurses and investigators also completed home instillation feasibility questionnaires. These standardized feasibility questionnaires highlighted that all eight patients preferred at-home to in-office treatment, and five of six patients recommended UGN-102 home instillation instead of TURBT. Home instillation was reported as feasible for visiting nurses, and three of four investigators considered at-home treatment “not different” than in-office treatment.

In October 2023 we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of CR at 12 months from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate risk NMIBC. The FDA indicated that it may seek the advice of the Oncology Drug

Advisory Committee as part of the NDA review process. The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls ("CMC") sections of the NDA, which we submitted in January 2024. Based on our agreement with the FDA, we expect to complete the submission of the rolling NDA for UGN-102 in September 2024.

22. On August 13, 2024, UroGen issued a press release announcing its financial results for the quarter ended June 30, 2024. The press release touted the Company's results from the ENVISION study, stating as follows in relevant part:

UroGen Pharma Ahead of Schedule to Complete UGN-102 NDA Submission and Reports 2024 Second Quarter Financial Results and Business Highlights

• Potential for an FDA decision as early as the first quarter of 2025, assuming priority review

• UGN-102 Phase 3 ENVISION trial demonstrated an unprecedented 82.3% Duration of Response at 12 Months by Kaplan-Meier analysis in LG-IR-NMIBC patients who achieved a complete response at three months

* * *

"Our immediate priority is completing the submission of a New Drug Application in the very near term for UGN-102, which we believe has the potential to be a practice-changing therapy for the treatment of low-grade intermediate-risk non-muscle invasive bladder cancer," said Liz Barrett, President and Chief Executive Officer of UroGen. ***"The compelling body of clinical data, including the ENVISION trial, which demonstrated an unprecedented 82.3% 12-month duration of response by Kaplan-Meier analysis in patients who had previously achieved a complete response at three months, reinforces the opportunity for UGN-102 to be the first FDA-approved medicine for the treatment of low-grade intermediate-risk non-muscle invasive bladder cancer."***

Ms. Barrett continued, "We estimate that approximately 82,000 patients suffering from this highly recurrent disease each year may benefit from an innovative treatment, creating an estimated five-billion-dollar market opportunity. Our immediate commercial focus is preparing for UGN-102's potential approval and launch with the goal to establish our leadership in urothelial cancers."

Q2 2024 and Recent Business Highlights:

UGN-102 (mitomycin) for intravesical solution:

• ***In June 2024, UroGen reported positive 12-month duration of response (DOR) data from the Phase 3 ENVISION pivotal trial evaluating UGN-102 (mitomycin) for intravesical solution in patients with low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).*** The 12-month DOR was 82.3% (95% CI, 75.9%, 87.1%) by Kaplan-Meier estimate in patients who had achieved complete response (CR) at three months from the first instillation of investigational drug UGN-102. The ENVISION trial previously met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.6% (95% CI, 73.9%, 84.5%) CR rate at three months following the first instillation of UGN-102. UGN-102 was well tolerated, with a safety profile that was consistent with previous clinical trials.

• The ENVISION 12-month DOR data were presented in a virtual event "New Horizons in Bladder Cancer" hosted by UroGen on June 13. This event included presentations by company management and several key opinion leaders with expertise in urology. There was also a panel discussion on the treatment of LG-IR-NMIBC and insights from a patient from the ENVISION trial. A replay of the event can be accessed here.

• ***The latest DOR data is expected to support a New Drug Application (NDA) for UGN-102 as a treatment for LG-IR-NMIBC, which the Company plans to complete in the very near term.*** There is potential for an FDA decision as early as the first quarter of 2025, assuming the FDA grants priority review. UroGen initiated submission of the rolling NDA for UGN-102 in January 2024.

23. On August 13, 2024, the Company submitted its quarterly report for the period ended June 30, 2024 on a Form 10-Q filed with the SEC. The quarterly report touted the design of the ENVISION trial, as follows in relevant part:

> We initiated our Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial comparing UGN-102 with or without TURBT to standard of care, TURBT alone. ***In parallel, we continued to engage in discussions with the FDA and based on this dialogue, we designed a pivotal trial in order to demonstrate the efficacy and safety of UGN-102. This Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with low-grade intermediate risk NMIBC.*** The design of the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population has similar clinical characteristics, receives the same investigational treatment regimen and undergoes similar efficacy and safety assessments and qualitative follow-up. Study participants receive six once-weekly intravesical instillations of UGN-102. The primary endpoint is CR rate at three months after the first instillation, and the key secondary endpoint is durability of response in patients who achieve CR at the three-month assessment.
>
> In February 2022, we announced the initiation of the Phase 3 ENVISION trial, targeting enrollment of 220 patients across 90 sites. In December 2022, we completed our target enrollment of the Phase 3 ENVISION trial. ***As a result of the FDA's acceptance of a single arm approach, we stopped enrollment of the Phase 3 ATLAS trial without knowledge of the data.*** However, at the time enrollment was stopped, patients who had signed an informed consent were able to complete screening, and if eligible were randomized into the trial. ATLAS continued until the last ongoing patient completed the month 15 visit.
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> * * *
>
> ***In October 2023 we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of response***

> ***12 months after 3-month CR from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate risk NMIBC. The FDA indicated that it may seek the advice of the Oncologic Drugs Advisory Committee as part of the NDA review process.*** The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls ("CMC") sections of the NDA, which we submitted in January 2024. Based on our agreement with the FDA, we expect to complete the submission of the rolling NDA for UGN-102 in the third quarter of 2024, with a potential FDA acceptance in the fourth quarter of 2024 and potential FDA approval in the first quarter of 2025 (assuming priority review) or the second quarter of 2025 (assuming standard review).

24. On August 14, 2024, UroGen announced that it completed its submission of its NDA to the FDA for UGN-102 for the treatment of low-grade intermediate-risk non-muscle invasive bladder cancer, stating as follows in relevant part:

> **UroGen Submits Completed UGN-102 NDA Seeking Approval as the First FDA-Approved Treatment for Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer**
>
> UroGen Pharma Ltd. (Nasdaq: URGN), a leading biotech company specializing in novel therapies for urothelial and specialty cancers, today announced the successful completion of its New Drug Application (NDA) submission for investigational drug UGN-102, (mitomycin) for intravesical solution, a significant step forward in potentially addressing the urgent need for innovative treatments for low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). UroGen anticipates potential FDA approval in early 2025, if the NDA is accepted for filing by the FDA and priority review is granted.
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> * * *
>
> ***The NDA is supported by the clinical program for UGN-102, including the long-term durability results from the Phase 3***

ENVISION study. The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.6% complete response (CR) rate at three months following the first instillation. UGN-102 demonstrated an 82.3% 12-month duration of response (DOR) by Kaplan-Meier estimate (n=108) in patients who achieved a CR at three months. The DOR estimates at 15 (n=43) and 18 (n=9) months after 3-month CR were both 80.9%.

25. On October 15, 2024, UroGen issued a press release announcing the FDA's acceptance of its NDA, which, in part, touted UGN-102's clinical results, as follows in relevant part:

UroGen Announces FDA Acceptance of its New Drug Application for UGN-102

• PDUFA goal date set for June 13, 2025

• UGN-102 would be the first FDA-approved medicine for LG-IR-NMIBC, if approved

* * *

Dr. Mark Schoenberg, Chief Medical Officer of UroGen, stated, "The NDA for UGN-102 is backed by a robust data set demonstrating impressive durability of response across three clinical trials and a favorable safety profile. Notably, the ENVISION trial successfully met its primary endpoint, showing a 79.6% complete response rate at three months after the first instillation of UGN-102. Additionally, the latest results from that trial revealed an 82.3% 12-month duration of response by Kaplan-Meier estimate in patients who achieved a complete response at 3 months. The most common treatment-emergent adverse events in the ENVISION trial were dysuria, hematuria, urinary tract infection, pollakiuria, fatigue, and urinary retention. Additionally, the safety profile observed in the ENVISION trial was consistent with that seen in other studies of UGN-102. We believe that, if approved, UGN-102's ability to achieve durable complete responses and potentially reduce recurrence rates while extending treatment-free intervals will represent a significant advance in managing LG-IR-NMIBC."

26. On October 28, 2024, UroGen issued a press release that announced additional results from the ENVISION trial, stating as follows in relevant part:

> **ENVISION Trial Results Published in the Journal of Urology Report 82.3% Duration of Response 12 Months after Achieving Complete Response for UGN-102, Potentially First FDA-Approved Non-Surgical Treatment for LG-IR-NMIBC**
>
> • The Kaplan-Meier Estimate of Duration of Response at 12 Months in Patients Who Achieved a Complete Response at Three Months was 82.3%
>
> • Patients Receiving UGN-102 had a 79.6% Complete Response Rate at Three Months
>
> • Side Effect Profile Consistent with Previous Clinical Trials of UGN-102
>
> UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that ***new long-term durability of response results from the Phase 3 ENVISION study of investigational drug UGN-102*** in patients with low-grade intermediate-risk non-muscle-invasive bladder cancer (LG-IR-NMIBC) were published online in the Journal of Urology.
>
> In ENVISION, UGN-102 treatment was associated with an unprecedented 82.3% (95% CI, 75.9%, 87.1%) 12-month duration of response (DOR) by Kaplan-Meier estimate (n=108) in patients who achieved complete response (CR) at three months after the first instillation of investigational drug UGN-102 (mitomycin) for intravesical solution. The DOR Kaplan-Meier estimates at 15 months (n=43) and 18 months (n=9) after 3-month CR were both 80.9% (95% CI, 73.9%, 86.2%). The ENVISION trial previously met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.6% (95% CI, 73.9%, 84.5%) CR rate at three months following the first instillation of UGN-102.
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> "These data demonstrate that treatment with UGN-102 results in a clinically meaningful CR rate and that the durability of the response in

patients with LG-IR-NMIBC is robust," said Sandip Prasad, MD, M.Phil., Director of Genitourinary Surgical Oncology, Morristown Medical Center/Atlantic Health System, NJ and Principal Investigator of the ENVISION trial. "This study adds to the mounting evidence supporting UGN-102 as a potentially valuable treatment option for patients with recurrent LG-IR-NMIBC."

UroGen initiated the submission of a rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for UGN-102 as a treatment for LG-IR-NMIBC in January 2024 and completed the NDA submission in August, ahead of schedule. The FDA accepted the NDA for UGN-102 with a PDUFA goal date of June 13, 2025.

Liz Barrett, President and CEO of UroGen, emphasized the significance of the DOR findings from the ENVISION study, stating, "LG-IR-NMIBC patients are typically elderly and currently treated with repeated surgeries under general anesthesia that are associated with physical and quality of life detriments. These new results continue to strengthen UGN-102's potential as a treatment option for these patients that extends their recurrence-free interval. The highly recurrent nature of LG-IR-NMIBC underscores the urgent need for innovative options for patients facing this challenging disease."

27. On November 6, 2024, UroGen issued a press release announcing its financial results for the quarter ended September 30, 2024, which stated that the UGN-102 NDA was supported by "clinically meaningful" trial results. The press release stated as follows in relevant part:

• ***The NDA for UGN-102 is supported by a comprehensive development program which demonstrated a clinically meaningful complete response rate and a strong duration of response across three late phase clinical trials and an acceptable safety profile.*** The Phase 3 ENVISION trial successfully met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.6% (95% CI, 73.9%, 84.5%) complete response (CR) rate at three months following the first instillation of UGN-102. More recently, durability data from ENVISION showed that UGN-102 demonstrated an 82.3% (95% CI, 75.9%, 87.1%) 12-month duration of response (DOR) by

Kaplan-Meier estimate in patients who had achieved a complete response at three months after the first instillation of UGN-102. This is the highest DOR ever reported in this patient population. The ENVISION trial demonstrated that UGN-102 has an acceptable safety profile that is consistent with the side effect profile observed in previous clinical trials.

28. On November 6, 2024, the Company submitted its quarterly report for the period ended September 30, 2024 on a Form 10-Q filed with the SEC, stating as follows in relevant part:

> We initiated our Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial comparing UGN-102 with or without TURBT to standard of care, TURBT alone. ***In parallel, we continued to engage in discussions with the FDA and based on this dialogue, we designed a pivotal trial in order to demonstrate the efficacy and safety of UGN-102. This Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with low-grade intermediate risk NMIBC.*** The design of the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population has similar clinical characteristics, receives the same investigational treatment regimen and undergoes similar efficacy and safety assessments and qualitative follow-up. Study participants receive six once-weekly intravesical instillations of UGN-102. The primary endpoint is CR rate at three months after the first instillation, and the key secondary endpoint is durability of response in patients who achieve CR at the three-month assessment.
>
> * * *
>
> ***In October 2023 we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of response 12 months after 3-month CR from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate risk NMIBC***. The FDA indicated that it may seek the

advice of the Oncologic Drugs Advisory Committee as part of the NDA review process. The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls ("CMC") sections of the NDA, which we submitted in January 2024.

On June 13, 2024, we announced positive secondary endpoint DOR data from the Phase 3 ENVISION trial investigating UGN-102 for intravesical solution in patients with low-grade intermediate risk NMIBC. In the ENVISION trial, the 12-month DOR data by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 was 82.3% (95% CI, 75.9%, 87.1%). The ENVISION trial met its primary endpoint with patients having a 79.6% (73.9%, 84.5%) CR rate at three months after the first instillation of UGN-102. Among the patients in the ENVISION trial who achieved a CR at three months, 76.4% (69.8%, 82.3%) maintained a CR at 12 months. Among all 240 patients enrolled in the ENVISION trial, 60.8% (54.3%, 67.0%) were in CR at 12 months. In the ENVISION trial, DOR Kaplan-Meier estimates at 15 (n=43) and 18 (n=9) months were both 80.9% (95% CI, 73.9%, 86.2%). The ENVISION trial demonstrated a similar safety profile to that observed in the OPTIMA II and ATLAS trials, with treatment-emergent adverse events typically mild-to-moderate in severity.

In August 2024, we completed the submission of the rolling NDA for UGN-102. In October 2024, the FDA accepted our NDA for UGN-102 (mitomycin) for intravesical solution and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 13, 2025. We anticipate, and are preparing for, an FDA advisory committee meeting. We expect to receive notification from the FDA in early 2025 regarding such meeting. If approved, UGN-102 would become the first FDA-approved medicine for the treatment of low-grade intermediate-risk NMIBC.

29. On December 5, 2024, UroGen issued a press release which claimed that the UGN-102 demonstrated "clinically meaningful" results, stating as follows in relevant part:

UGN-102 Showed Promising Long-Term Results in the Phase 3 ENVISION Trial, Potentially Paving the Way for First FDA-Approved Treatment for LG-IR-NMIBC

• UGN-102 demonstrated 82.3% duration of response (DOR) at 12 months in patients who achieved complete response at 3 months

• 79.6% complete response rate at 3 months in patients treated with UGN-102

• Safety profile consistent with prior clinical trials of UGN-102

UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced the presentation of the Phase 3 ENVISION trial's efficacy and safety results at the Society of Urologic Oncology (SUO) annual meeting in Dallas, TX. These results, published online in the Journal of Urology in October, ***demonstrate that treatment with investigational therapy UGN-102, a mitomycin-based intravesical solution, resulted in a high and clinically meaningful complete response rate that was durable in patients with recurrent low-grade intermediate-risk non-muscle-invasive bladder cancer (LG-IR-NMIBC).***

* * *

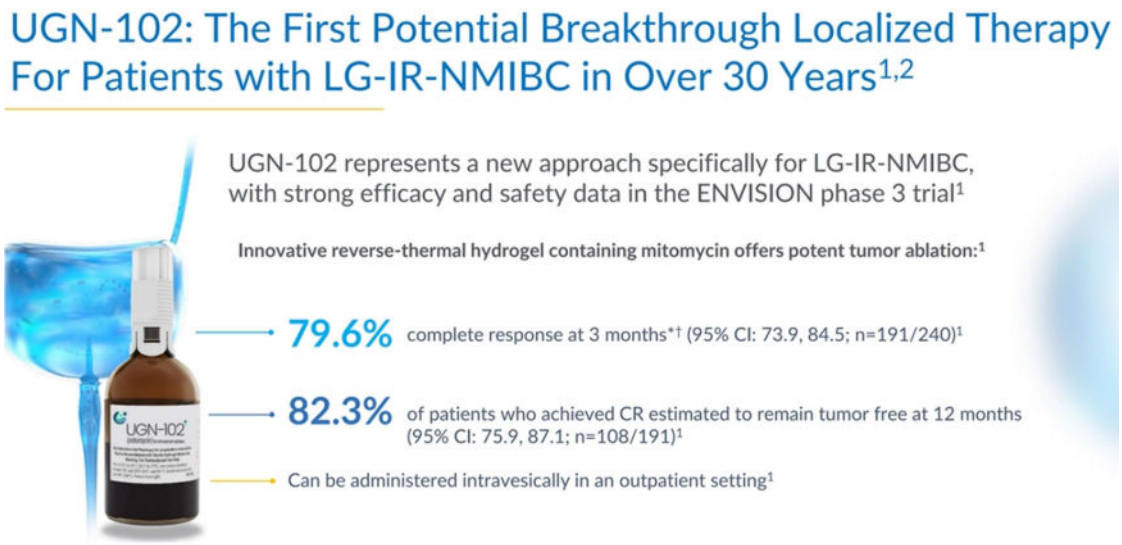
In the ENVISION study, UGN-102 treatment showed an impressive 82.3% (95% CI: 75.9%, 87.1%) duration of response (DOR) at 12 months, according to the Kaplan-Meier estimate, in patients who achieved a complete response (CR) at 3 months following the initial treatment with UGN-102. The DOR at 15 months (n=43) and 18 months (n=9) remained robust, both at 80.9% (95% CI: 73.9%, 86.2%) according to the Kaplan-Meier estimates. These results build upon the trial's positive primary endpoint, a 79.6% (95% CI: 73.9%, 84.5%) CR rate 3 months after the first instillation of UGN-102.

The side effect profile of UGN-102 was consistent with previous clinical trials, further supporting its potential as a new treatment option for patients with LG-IR-NMIBC.

"We are excited by the progress made in advancing UGN-102 as a potential treatment for LG-IR-NMIBC and securing a PDUFA goal date

of June 13, 2025, from the FDA," said Mark Schoenberg, M.D., Chief Medical Officer, UroGen. "The strong durability of response observed in the ENVISION study highlights UGN-102's promising potential for patients. Given that many LG-IR-NMIBC patients are elderly and endure multiple surgeries under general anesthesia for their condition that impact their health and quality of life, there is an urgent need for alternative treatment options that can prolong recurrence-free periods and enhance patient outcomes."

30. On January 14, 2025, the Company filed an investor presentation as Exhibit 99.1 to a Form 8-K. The presentation touted the Company's clinical results for UGN-102, as follows in relevant part:



* * *

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

Endpoint	ENVISION Previously diagnosed with prior TURBT	ATLAS[4] Recurrent sub-group with prior TURBT	ATLAS ITT[4] Newly diagnosed and recurrent patients
Complete Response Rate[1] (CR) 3-month disease assessment	79.6%	74% vs. 53%	65% vs. 64% Similar CRR; offers a less invasive option to patients
Duration of Response (DOR) 12-months following CR	82.3%	66% vs. 40%[2] HR = 0.34 (66% Risk Reduction)	80% vs. 68%[2] HR = 0.46 (54% Risk Reduction)
Disease-Free Survival[3] (DFS) 12-months following randomization	N/A	72% vs. 37% HR=0.295 (70% Risk Reduction)	72% vs. 50%[3] HR= 0.45 (55% Risk Reduction)
Median Disease-Free Survival (DFS)	Not Reached	Not reached vs. 7.2 months	Not reached vs. 14.8 months

31. On January 15, 2025, UroGen issued a press release which claimed there was "compelling evidence" that UGN-102 was effective, stating as follows in relevant part:

> **ENVISION Trial Results Published in the February Issue of The Journal of Urology Highlight UGN-102 Achievement of 82.3% Duration of Response at 12 Months Paving the Way for the Potential First FDA-Approved Treatment for LG-IR-NMIBC in June 2025**
>
> ENVISION Reports 79.6% Complete Response Rate at 3 Months, 82.3% Duration of Response at 12 Months, and Consistent Safety Profile
>
> UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that the 3-month complete response (CR) rate and 12-month durability of response from the Phase 3 ENVISION study of investigational drug UGN-102 in patients with low-grade intermediate-risk non-muscle-invasive bladder cancer (LG-IR-NMIBC) were published in the February issue of The Journal of Urology.
>
> In the ENVISION trial, UGN-102 treatment demonstrated an impressive 82.3% (95% CI, 75.9%, 87.1%) 12-month duration of response (DOR) by Kaplan-Meier estimate (n=108) in patients who

achieved a CR at three months after the first instillation of UGN-102 (mitomycin) for intravesical solution. The Kaplan-Meier estimates for DOR at 15 months (n=43) and 18 months (n=9) following the 3-month CR were both 80.9% (95% CI, 73.9%, 86.2%). The ENVISION trial also met its primary endpoint, showing a 79.6% (95% CI, 73.9%, 84.5%) CR rate at three months in patients treated with UGN-102.

"These data from the ENVISION trial provide compelling evidence that treatment with UGN-102 achieves a clinically meaningful complete response rate and also demonstrates remarkable durability in patients with LG-IR-NMIBC," said Sandip Prasad, MD, M.Phil., Director of Genitourinary Surgical Oncology at Morristown Medical Center/Atlantic Health System, NJ, and Principal Investigator of the ENVISION trial. "The long-term results, with 82.3% duration of response at 12 months, further strengthen UGN-102's potential as a non-surgical, effective treatment for patients facing the recurrent and challenging nature of LG-IR-NMIBC."

According to Mark Schoenberg, M.D., Chief Medical Officer, UroGen, "The impressive duration of response data from the ENVISION trial further highlights UGN-102's potential to transform the treatment landscape for patients with LG-IR-NMIBC. Many of these patients are elderly and face the burden of repeated surgeries under general anesthesia, so there is a critical need for innovative treatment options for this patient population. We believe that, if approved, UGN-102's ability to achieve durable complete responses and potentially reduce recurrence rates while extending treatment-free intervals will represent a significant advance in managing LG-IR-NMIBC."

UroGen initiated the submission of a rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for UGN-102 as a treatment for LG-IR-NMIBC in January 2024 and completed the NDA submission in August, ahead of schedule. The FDA accepted the NDA for UGN-102 with a PDUFA goal date of June 13, 2025.

32. On March 10, 2025, the Company submitted its annual report for the fiscal year ended December 31, 2024 on a Form 10-K filed with the SEC, which stated as follows in relevant part:

We initiated our Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial comparing UGN-102 with or without TURBT to standard of care, TURBT. ***In parallel, we continued to engage in discussions with the FDA and, based on this dialogue, we designed a trial in order to demonstrate the efficacy and safety of UGN-102. This Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with low-grade intermediate risk NMIBC***. The design of the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population has similar clinical characteristics, receives the same investigational treatment regimen and undergoes similar efficacy and safety assessments and qualitative follow-up. Study participants receive six once-weekly intravesical instillations of UGN-102. The primary endpoint is CR rate at three months after the first instillation, and the key secondary endpoint is durability of response in patients who achieve CR at the three-month assessment.

In June 2024, we announced positive secondary endpoint duration of response ("DOR") data from the Phase 3 ENVISION trial investigating UGN-102 for intravesical solution in patients with low-grade intermediate risk NMIBC. In the ENVISION trial, the 12-month DOR data by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 was 82.3% (95% CI, 75.9%, 87.1%). The ENVISION trial met its primary endpoint with patients having a 79.6% (73.9%, 84.5%) CR rate at three months after the first instillation of UGN-102. Among the patients in the ENVISION trial who achieved a CR at three months, 76.4% (69.8%, 82.3%) maintained a CR at 12 months. Among all 240 patients enrolled in the ENVISION trial, 60.8% (54.3%, 67.0%) were in CR at 12 months. In the ENVISION trial, DOR Kaplan-Meier estimates at 15 (n=43) and 18 (n=9) months were both 80.9% (95% CI, 73.9%, 86.2%) with a median follow-up time of 13.8 months after the 3-month CR. The ENVISION trial demonstrated a similar safety profile to that observed in the OPTIMA II and ATLAS trials, with treatment-emergent adverse events typically mild-to-moderate in severity. The ENVISION trial data was published online in The Journal of Urology in October 2024 and was included in the February 2025 print edition.

In March 2025, we announced updated 18-month DOR data from the Phase 3 ENVISION trial. The 18-month DOR by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 remained consistent with the 12-month DOR data: 80.6% (95% CI, 74.0%, 85.7%) at 18-months (n=101) compared to 82.5% (76.1%, 87.3%) at 12-months (n=146). Median follow-up time was 18.7 months after the 3-month CR.

* * *

In October 2023, we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of CR at 12 months from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate risk NMIBC. The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls ("CMC") sections of the NDA, which we submitted in January 2024. In August 2024, we completed the submission of the rolling NDA for UGN-102. In October 2024, the FDA accepted our NDA for UGN-102 (mitomycin) for intravesical solution and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 13, 2025. We anticipate, and are preparing for, an FDA advisory committee meeting. If approved, UGN-102 would become the first FDA-approved medicine for the treatment of low-grade intermediate-risk NMIBC.

33. On April 26, 2025, UroGen issued a press release announcing updated results from its Envision Trial, stating as follows in relevant part:

UroGen Announces Updated 18-Month Duration of Response (DOR) of 80.6% from the Phase 3 ENVISION Trial of UGN-102, an Investigational Treatment for Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

• 18-month DOR of 80.6% by Kaplan-Meier estimate was attained in patients who achieved a complete response (CR) at three months (79.6%)

• Data unveiled during a Podium Presentation at the American Urological Association (AUA) 2025 Annual Meeting in Las Vegas, Nevada

UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced an updated 18-month DOR of 80.6% (95% CI: 74.0, 85.7), by Kaplan-Meier estimate, from the Phase 3 ENVISION trial of UGN-102 (mitomycin) for intravesical solution, an investigational treatment for recurrent LG-IR-NMIBC. These data were featured today in an Oral Presentation Session (Abstract ID: PD12) at the AUA 2025 Annual Meeting in Las Vegas, Nevada.

"This new update from the pivotal ENVISION trial of UGN-102 demonstrated a compelling probability of remaining in complete response of 80.6% at 18 months in patients who achieved a complete response (CR) at three months (79.6%)," said Sandip Prasad M.D., M.Phil., Director of Genitourinary Surgical Oncology, Vice Chair of Urology at Morristown Medical Center/Atlantic Health System, NJ, and Principal Investigator of the ENVISION trial.

34. On May 12, 2025, the Company submitted its quarterly report for the period ended March 31, 2025 on a Form 10-Q filed with the SEC, stating as follows in relevant part:

In August 2024, the Company completed the submission of the rolling new drug application ("NDA") for UGN-102. In October 2024, the FDA accepted the Company's NDA for UGN-102 (mitomycin) for intravesical solution and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 13, 2025.

* * *

We initiated our Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial comparing UGN-102 with or without TURBT to standard of care, TURBT, alone. ***In parallel, we continued to engage in discussions with the FDA and based on this dialogue, we designed a pivotal trial in order to***

demonstrate the efficacy and safety of UGN-102. This Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with recurrent low-grade intermediate risk NMIBC. The design of the Phase 3 ENVISION trial was similar to our Phase 2 OPTIMA II trial in that the patient population had similar clinical characteristics, received the same investigational treatment regimen and underwent similar efficacy and safety assessments and qualitative follow-up. Study participants received six once-weekly intravesical instillations of UGN-102. The primary endpoint was CR rate at three months after the first instillation, and the key secondary endpoint was DOR in patients who achieved CR at the three-month assessment.

* * *

In October 2023, we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of CR at 12 months from the pivotal ENVISION trial, will support submission of an NDA for the treatment of recurrent low-grade intermediate risk NMIBC. The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the CMC sections of the NDA, which we submitted in January 2024. In August 2024, we completed the submission of the rolling NDA for UGN-102. In October 2024, the FDA accepted our NDA for UGN-102 (mitomycin) for intravesical solution and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 13, 2025. The FDA has scheduled an Oncologic Drugs Advisory Committee meeting for May 21, 2025 to review the NDA for UGN-102. If approved, UGN-102 would become the first FDA-approved medicine for the treatment of recurrent low-grade intermediate-risk NMIBC.

35. The above statements identified in ¶¶19-34 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (1) the ENVISION clinical study was not designed to demonstrate

substantial evidence of effectiveness of UGN-102 because it lacked a concurrent control arm; (2) as a result, the Company would have difficulty demonstrating that the duration of response endpoint was attributable to UGN-102; (3) UroGen failed to heed the FDA's warnings about the study design used to support a drug application for UGN-102; (4) as a result of the foregoing, there was a substantial risk that the NDA for UGN-102 would not be approved; and (5) as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

36. On May 16, 2025, before the market opened, the FDA published a briefing document in advance of its Oncologic Drugs Advisory Committee meeting regarding the NDA for UGN-102, which stated the agency doubted whether the submitted data was sufficient to conclude that UGN-102 was effective. In the briefing document, the FDA stated: "[g]iven that ***ENVISION lacked a concurrent control arm,*** the primary endpoints of complete response (CR) and duration of response (DOR) are difficult to interpret." The FDA also said it had "recommended a randomized trial design to the Applicant several times during their product's development due to concerns with interpreting efficacy results" but UroGen "chose not to conduct a randomized trial with a design and endpoints that the FDA considered appropriate." When UroGen opted to conduct a large single-arm trial, the

FDA had warned that "such a trial would require a large sample size and sufficient duration of follow-up," that "demonstrating treatment effect that is distinct from the natural history of the disease would be critical," that "safety results would be considered," and that "the proposed follow up of 18 months after response may not adequately capture durability." Specifically, on that date, the FDA published the Combined FDA and Applicant ODAC Briefing Document for NDA 215793 in anticipation of the Oncologic Drugs Advisory Committee Meeting on May 21, 2025, which stated as follows, in relevant part:

> **FDA's Summary of the Purpose of the Meeting:**
>
> The Applicant has submitted a New Drug Application (NDA) for their investigational product UGN- 102, which is an intravesically administered mitomycin formulation intended for use in patients with low-grade, intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). No drugs are currently FDA-approved for the treatment of patients with LG-IR-NMIBC; this is a novel disease setting for drug development. The U.S. Food and Drug Administration (FDA) is convening the Oncologic Drugs Advisory Committee (ODAC) to discuss whether:
>
> > a. Durable complete response assessed in a single-arm trial can establish efficacy in the LG-IR-NMIBC population.
> >
> > b. The overall benefit-risk of the investigational treatment is favorable.
>
> The FDA considers the Applicant's ENVISION trial to be the primary source of evidence to support this NDA. ENVISION was a single-arm trial conducted in patients with recurrent LG-IR- NMIBC. In this disease setting, there is a wide range of recurrence probabilities that depend on several factors. ***Given that ENVISION lacked a concurrent control arm, the primary endpoints of complete response (CR) and duration of response (DOR) are difficult to interpret.***

While CR indicates drug activity of UGN-102, it is unclear whether the observed DOR can be attributed to the investigational product or instead reflects the natural history of the disease.

The lack of a concurrent control also does not allow for generation of comparative safety data to standard of care therapies in this setting, which typically includes transurethral resection of bladder tumor (TURBT) with or without a single post-operative instillation of intravesical chemotherapy. ***The FDA recommended a randomized trial design to the Applicant several times during their product's development due to these concerns.***

As the Applicant chose not to conduct a randomized trial with a design and endpoints that the FDA considered appropriate to demonstrate substantial evidence of effectiveness for UGN-102, the FDA informed the Applicant that a large single-arm trial could potentially serve as a major trial to support approval of UGN-102. The FDA stated that such a trial would require a large sample size and sufficient duration of follow-up to evaluate whether the therapy demonstrated a clinically meaningful DOR and did not impact the safety of subsequent TURBT. The FDA further stated that demonstrating treatment effect that is distinct from the natural history of the disease would be critical, safety results would be considered, and the proposed follow up of 18 months after response may not adequately capture durability. Lastly, the FDA noted to the Applicant that an NDA supported by data generated in a single-arm trial would likely require discussion at ODAC.

* * *

2.3.5 Efficacy Conclusions

* * *

The FDA's Position: The FDA considers the reported CR rate in ENVISION (77.6%, 95% CI: 71.5, 82.9) to be interpretable and consistent with the CR rate in the subgroup analyses of patients with recurrent LG-IR-NMIBC from ATLAS (72.5%, 95% CI: 58.3, 84.1). Duration of response in ENVISION demonstrates that 79.2% of patients (95 % CI: 72.3, 85.0) maintain a CR at 12 months post-CR (i.e. 15 months from initial treatment)***. Due to limited follow up, ascertaining the number of patients who remain in response for***

longer time periods is confounded or unavailable. Additionally, subgroup analyses of the CR rate and duration of response based on whether patients had 1 or 2 protocol-specified risk factors for intermediate risk NMIBC were consistent with the overall population results in ENVISION.

Given the heterogeneity of the IR-NMIBC population, it must be considered that some patients may recur infrequently or never recur, while others may have frequent recurrences. The recurrence risk in this population has wide probabilities, with the natural history of the disease varying based on several known and unknown factors. ***The FDA thus considers a randomized trial the preferred design to demonstrate efficacy in this disease setting and the lack of a concurrent control in the single-arm ENVISION trial makes interpretation of efficacy challenging. The FDA does not agree with the Applicant's statement regarding direct comparison of UGN-102 vs TURBT; the FDA does not consider ATLAS appropriately designed to compare efficacy in the recurrent-only population given the loss of randomization when considering this exploratory subgroup as well as the issues regarding the non-inferiority design and primary endpoint definition. Further, treatment effects may be misleading as the control arm, which excluded post-operative chemotherapy instillation, did not reflect the most active standard of care.***

Attaining a complete response to treatment of recurrent LG-IR-NMIBC would result in surveillance monitoring in clinical practice. If patients recurred in the future, they would be candidates for further treatment depending on the type/stage of disease identified. Per guidelines, those with recurrent LG-IR-NMIBC would most likely undergo further TURBT with one post-operative instillation of intravesical chemotherapy.

A CR may be clinically meaningful if the duration of response is long, which may delay or obviate the need for further treatment, including repeat TURBTs. Thus, duration of response is a critical component of the efficacy evaluation. The single arm trial design of ENVISION does not allow for a robust evaluation of duration of response. Because there is no concurrent control, selection bias is possible, meaning that the population enrolled can have characteristics that may not represent the broader LG-IR-NMIBC population. The single arm trial design does not allow for distinguishing whether the observed duration of response

> in ENVISION is due to the investigational therapy, UGN-102, or the natural history of the disease. Assessing duration of response for this application requires comparison to historical (external) control, and as described above, recurrence probabilities are wide in this population and there is no well- established historical control.
>
> ***Therefore, the Applicant's proposed utility of UGN-102 as a therapy that may "reduce the burden of repeated TURBTs under general anesthesia in the elderly, comorbid, LG-IR-NMIBC population" is unclear because of challenges in determining recurrence risk in this population.***

37. On this news, UroGen's stock price fell $2.54, or 25.8%, to close at $7.31 per share on May 16, 2025, on unusually heavy trading volume.

38. Then, on May 21, 2025, before the market opened, the Oncologic Drugs Advisory Committee voted against approving the UGN-102 NDA. UroGen's press release announcing the outcome of the meeting stated as follows, in relevant part:

> UroGen Announces Outcome of Oncologic Drugs Advisory Committee for UGN-102 for the Treatment of Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)
>
> UroGen Pharma Ltd. (Nasdaq: URGN), a leading biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, announced the outcome of today's meeting of the Oncologic Drugs Advisory Committee (ODAC) of the U.S. Food and Drug Administration (FDA), which discussed the new drug application (NDA) for investigational drug UGN-102 (mitomycin) for intravesical solution. By a narrow margin, the ODAC voted 4 to 5 that the benefit/risk of UGN-102 (mitomycin) for intravesical solution was favorable for the treatment of recurrent LG-IR-NMIBC.

39. On this news, UroGen's stock price fell $3.37, or 44.7%, to close at $4.17 per share on May 21, 2025, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

40. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired UroGen securities between July 27, 2023 and May 15, 2025, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

41. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, UroGen's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of UroGen shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by UroGen or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

42. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

43. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

44. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of UroGen; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

45. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it

impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

46. The market for UroGen's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, UroGen's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired UroGen's securities relying upon the integrity of the market price of the Company's securities and market information relating to UroGen, and have been damaged thereby.

47. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of UroGen's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about UroGen's business, operations, and prospects as alleged herein.

48. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the

Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about UroGen's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

49. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

50. During the Class Period, Plaintiff and the Class purchased UroGen's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

51. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding UroGen, their control over, and/or receipt and/or modification of UroGen's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning UroGen, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

52. The market for UroGen's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, UroGen's securities traded at artificially inflated prices during the Class Period. On August 14, 2023, the Company's share price closed at a Class Period high of $22.64 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying on

the integrity of the market price of UroGen's securities and market information relating to UroGen, and have been damaged thereby.

53. During the Class Period, the artificial inflation of UroGen's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about UroGen's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of UroGen and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

54. At all relevant times, the market for UroGen's securities was an efficient market for the following reasons, among others:

(a) UroGen shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, UroGen filed periodic public reports with the SEC and/or the NASDAQ;

(c) UroGen regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) UroGen was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

55. As a result of the foregoing, the market for UroGen's securities promptly digested current information regarding UroGen from all publicly available sources and reflected such information in UroGen's share price. Under these circumstances, all purchasers of UroGen's securities during the Class Period suffered similar injury through their purchase of UroGen's securities at artificially inflated prices and a presumption of reliance applies.

56. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*,

406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

57. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants

are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of UroGen who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

58. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

59. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase UroGen's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

60. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices,

and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for UroGen's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

61. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about UroGen's financial well-being and prospects, as specified herein.

62. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of UroGen's value and performance and continued substantial growth, which included the making of, or the participation in making, untrue statements of material facts and/or omitting to state material facts necessary to make the statements made about UroGen and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

63. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

64. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing UroGen's financial well-being and prospects from the investing public

and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

65. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of UroGen's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired UroGen's securities during the Class Period at artificially high prices and were damaged thereby.

66. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be

true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that UroGen was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their UroGen securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

67. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

68. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

69. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

70. Individual Defendants acted as controlling persons of UroGen within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the

false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

71. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

72. As set forth above, UroGen and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: