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): August 4, 2021

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

Israel	**001-38079**	**98-1460746**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

400 Alexander Park Drive, 4th Floor **Princeton, New Jersey**	**08540**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +1 (646) 768-9780

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value NIS0.01 per share	**URGN**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 4, 2021, UroGen Pharma Ltd. (the "Company") announced its financial results for the quarter ended June 30, 2021 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated August 4, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 4, 2021

UROGEN PHARMA LTD.

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

Exhibit 99.1

UroGen Pharma Reports Second Quarter 2021 Financial Results and Recent Corporate Developments

- *Strong Jelmyto® net product revenue of $13.0 million for the second quarter of 2021, representing more than 70% growth over the first quarter of 2021*
- *Nearly 100 global centers activated for Phase 3 landmark ATLAS trial with lead pipeline candidate, UGN-102*
- *Commenced Jelmyto geographic expansion efforts with Neopharm license in Israel*
- *Conference call and webcast to be held today at 8:30 AM ET*

PRINCETON, N.J., August 4, 2021—UroGen Pharma Ltd. (Nasdaq: URGN), a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases, today announced financial results for the second quarter ended June 30, 2021, and provided an overview of the Company's recent developments.

"At UroGen, every day we are working towards our goal of fundamentally changing the way urologic cancers are treated because we believe patients deserve better options than invasive or repetitive surgeries to treat chronic recurrences," said Liz Barrett, President and Chief Executive Officer of UroGen. "Jelmyto was the first of our product candidates to demonstrate this paradigm-shift towards more innovative therapies. Our strong revenue in the second quarter reinforces our belief in the value of this novel treatment for adult patients suffering from low-grade upper tract urothelial cancer. This provides a strong foundation and clear proof of concept of the power of our platform and reinforces our commitment to revolutionizing the treatment of urologic cancers globally while we advance our pipeline in critical areas of uro-oncology and specialty cancers."

Business Highlights:

Jelmyto (mitomycin) for pyelocalyceal solution:

- UroGen achieved net product revenue of $13.0 million for the second quarter of 2021, representing more than 70% growth over the first quarter of 2021. Net product revenue was $20.5 million for the first half of 2021.
- As of August 1, 2021, 407 sites have been activated, which means they have completed their internal processes and have treated or are ready to treat patients. This represents a 29% increase since May 1, 2021.
- Sites that have treated more than one patient as of August 1, 2021, increased to 63, compared to 40 as of May 1, 2021: an increase of approximately 58%.

UGN-102 (mitomycin) for intravesical solution:

- ATLAS, the pivotal Phase 3 trial of UGN-102, continues to enroll patients with low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC) with nearly 100 sites activated in the U.S., Europe and Israel. Today, patients are treated with repetitive surgical intervention, and this trial has the potential to demonstrate that a therapeutic treatment can be as effective, if not more effective, than a surgical intervention.
- The ATLAS trial is expected to enroll approximately 630 patients and is the first of its kind, evaluating UGN-102 as a primary non-surgical treatment compared to standard of care – transurethral resection of bladder tumor (TURBT) – in adult patients diagnosed with LG-IR-NMIBC.

Platform expansion:

- In the second quarter, UroGen commenced a non-human primate toxicity study for UGN-301, an immune checkpoint inhibitor, delivered using UroGen's proprietary RTGel platform to increase dwell time. The Company intends to study UGN-301 as monotherapy and in combination with UGN-201, referred to as UGN-302. Work is ongoing with MD Anderson with a primary focus on high grade non-muscle invasive bladder cancer.
- The Company continues to explore potential pre-clinical work looking at UroGen's pipeline candidates and gel technology platform in other solid tumors, including glioblastoma multiforme.

Geographic expansion:

- UroGen announced a license and supply agreement with Neopharm to pursue regulatory approval and commercialization for Jelmyto in Israel.
- Path forward in place to extend Jelmyto access in Japan and Europe; update expected in the second half of 2021.

Second Quarter 2021 Financial Results:

Jelmyto Revenue: UroGen reported net product sales of Jelmyto for the second quarter ended June 30, 2021 of $13.0 million.

R&D Expense: Research and development expenses for the second quarter ended June 30, 2021 were $12.1 million, including non-cash share-based compensation expense of $1.0 million. This compares to $8.1 million, including non-cash share-based compensation expense of $1.6 million, for the same period in 2020.

SG&A Expense: Selling, general and administrative expenses for the second quarter ended June 30, 2021 were $22.3 million, including non-cash share-based compensation expense of $5.0 million. This compares to $24.0 million, including non-cash share-based compensation expense of $5.5 million, for the same period in 2020.

Financing on Prepaid Forward Obligation: UroGen reported financing expense related to the prepaid forward obligation to RTW Investments of $3.1 million for the second quarter ended June 30, 2021.

As previously reported, and in accordance with U.S. generally accepted accounting principles, the Company anticipates accruing approximately $12 to $15 million in non-operating financing expense relating to the RTW transaction, of which cash payments for 2021 will equal 9.5% of net Jelmyto sales recognized subsequent to the May 2021 closing.

Net Loss: UroGen reported a net loss of $26.2 million, or basic and diluted net loss per ordinary share of $1.17, for the second quarter ended June 30, 2021. This compares to $31.3 million, or basic and diluted net loss per ordinary share of $1.44, for the same period in 2020.

Cash & Cash Equivalents: As of June 30, 2021, cash, cash equivalents and marketable securities totaled $129.3 million.

2021 Operating Expense Guidance: The Company continues to anticipate operating expenses in the range of $155 to $165 million, including non-cash share-based compensation expense of $24 to $28 million, subject to market conditions.

Conference Call & Webcast Information:

Members of UroGen's management team will host a live conference call and webcast today at 8:30 AM Eastern Time to review the Company's financial results and provide a general business update.

The live webcast can be accessed by visiting the Investors section of the Company's website at http://investors.urogen.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (855) 765-5685 (U.S.) or (615) 247-5916 (International) to listen to the live conference call. The conference ID number for the live call will be 1539383. An archive of the webcast will be available for two weeks on the Company's website.

UROGEN PHARMA LTD.
SELECTED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	June 30, 2021	December 31, 2020
Cash and cash equivalents and marketable securities	$ 129,322	$ 103,911
Total assets	$ 153,768	$ 122,005
Total liabilities	$ 97,497	$ 25,650
Total shareholders’ equity	$ 56,271	$ 96,355

UROGEN PHARMA LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenue	$ 13,032	$ 372	$ 20,517	$ 372
Cost of revenue	1,427	48	2,324	48
Gross profit	11,605	324	18,193	324
Operating expense:				
Research and development expense	12,124	8,106	22,637	24,694
Selling, general and administrative expense	22,304	24,018	44,493	45,991
Total operating expense	34,428	32,124	67,130	70,685
Operating loss	(22,823)	(31,800)	(48,937)	(70,361)
Financing on prepaid forward obligation	(3,120)	—	(3,120)	—
Interest and other income, net	33	451	212	1,219
Loss before income taxes	$ (25,910)	$ (31,349)	$ (51,845)	$ (69,142)
Income tax expense	312	—	312	—
Net loss	$ (26,222)	$ (31,349)	$ (52,157)	$ (69,142)
Net loss per ordinary share basic and diluted	$ (1.17)	$ (1.44)	$ (2.34)	$ (3.22)
Weighted average shares outstanding, basic and diluted	22,331,119	21,753,001	22,287,037	21,454,341

About *Jelmyto*®

Jelmyto (mitomycin) for pyelocalyceal solution, is a drug formulation of mitomycin indicated for the treatment of adult patients with low-grade upper tract urothelial cancer (LG-UTUC). Utilizing the RTGel™ technology platform, UroGen's proprietary sustained release, hydrogel-based formulation, Jelmyto is designed to enable longer exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. Jelmyto is delivered to patients using standard ureteral catheters or nephrostomy tube. The U.S. FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to Jelmyto for the treatment of LG-UTUC. On April 15, 2020, the FDA approved Jelmyto, making it the first drug approved for the treatment of LG-UTUC in adult patients.

APPROVED USE FOR JELMYTO

JELMYTO® is a prescription medicine used to treat adults with a type of cancer of the lining of the upper urinary tract including the kidney called low-grade Upper Tract Urothelial Cancer (LG-UTUC).

IMPORTANT SAFETY INFORMATION

You should not receive JELMYTO if you have a hole or tear (perforation) of your bladder or upper urinary tract.

Before receiving JELMYTO, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. JELMYTO can harm your unborn baby. You should not become pregnant during treatment with JELMYTO. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with JELMYTO.

  Females who are able to become pregnant: You should use effective birth control (contraception) during treatment with JELMYTO and for 6 months after the last dose.

  Males being treated with JELMYTO: If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with JELMYTO and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if JELMYTO passes into your breast milk. Do not breastfeed during treatment with JELMYTO and for 1 week after the last dose.
- **Tell your healthcare provider if you take water pills (diuretic).**

How will I receive JELMYTO?

- Your healthcare provider will tell you to take a medicine called sodium bicarbonate before each JELMYTO treatment.
- You will receive your JELMYTO dose from your healthcare provider 1 time a week for 6 weeks. It is important that you receive all 6 doses of JELMYTO according to your healthcare provider's instructions. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. Your healthcare provider may recommend up to an additional 11 monthly doses.
- JELMYTO is given to your kidney through a tube called a catheter.
- During treatment with JELMYTO, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

After receiving JELMYTO:

- JELMYTO may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at least 6 hours.

- To urinate, **males and females should sit** on a toilet and flush the toilet several times after you use it. After going to the bathroom, wash your hands, your inner thighs, and genital area well with soap and water.
- Clothing that comes in contact with urine should be washed right away and washed separately from other clothing.

JELMYTO may cause serious side effects, including:

- **Swelling and narrowing of the tube that carries urine from the kidney to the bladder (ureteric obstruction).** If you develop swelling and narrowing, and to protect your kidney from damage, your healthcare provider may recommend the placement of a small plastic tube (stent) in the ureter to help the kidney drain. Tell your healthcare provider right away if you develop side pain or fever during treatment with JELMYTO.
- **Bone marrow problems.** JELMYTO can affect your bone marrow and can cause a decrease in your white blood cell, red blood cell, and platelet counts. Your healthcare provider will do blood tests prior to each treatment to check your blood cell counts during treatment with JELMYTO. Your healthcare provider may need to temporarily or permanently stop JELMYTO if you develop bone marrow problems during treatment with JELMYTO.

The most common side effects of JELMYTO include: urinary tract infection, blood in your urine, side pain, nausea, trouble with urination, kidney problems, vomiting, tiredness, stomach (abdomen) pain.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda/gov/medwatch or call 1-800-FDA-1088. You may also report side effects to UroGen Pharma at 1-855-987-6436.

Please see JELMYTO Full Prescribing Information, including the Patient Information, for additional information.

About Upper Tract Urothelial Cancer (UTUC)

Urothelial cancer is the ninth most common cancer globally and the eighth most lethal neoplasm in men in the U.S. Between five percent and ten percent of primary urothelial cancers originate in the ureter or renal pelvis and are collectively referred to as upper tract urothelial cancers (UTUC). In the U.S., there are approximately 6,000 - 7,000 new or recurrent low-grade UTUC patients annually. Most cases are diagnosed in patients over 70 years old, and these older patients often face comorbidities. There are limited treatment options for UTUC, with the most common being endoscopic surgery or nephroureterectomy (removal of the entire kidney and ureter). These treatments can lead to a high rate of recurrence and relapse.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin in Phase 3 development for the treatment of low-grade intermediate risk non-muscle invasive bladder cancer. 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 a standard urinary catheter. The Company reported topline interim results from the Phase 2b OPTIMA II trial in May 2020 and initiated a Phase 3 study to further investigate UGN-102 in the treatment of this condition in December 2020.

About the Phase 3 ATLAS Trial

ATLAS is a global, open-label, randomized controlled Phase 3 trial designed to assess the efficacy and safety of UGN-102, with or without transurethral resection of bladder tumor (TURBT), versus TURBT alone in patients diagnosed with low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC), defined as 1 or 2 of the following: new or recurrent multifocal bladder tumors, a solitary new or recurrent tumor >3 cm, or LG-IR-NMIBC recurrence in less than 12 months following a prior tumor diagnosis requiring endoscopic surgical resection or ablation. The trial is anticipated to enroll approximately 630 patients in over 100 clinical sites in the U.S., Europe and Israel.

Patients will be randomized 1:1 to either UGN-102 or TURBT. Patients in the UGN-102 arm will be treated with six weekly intravesical instillations of UGN-102. At the 3-month time point, patients will be assessed for response. Patients who have demonstrated a complete response to either UGN-102 or TURBT, will continue for long-term follow-up for evidence of recurrence. Patients who demonstrate presence of persistent disease at 3-months, in either arm, will undergo a TURBT and then will also continue for long-term follow up for evidence of recurrence. The primary endpoint of the study is disease free survival.

Learn more about the ATLAS trial at www.clinicaltrials.gov (NCT04688931)

About UroGen Pharma Ltd.

UroGen is a biopharmaceutical company dedicated to building novel solutions that treat specialty cancers and urologic diseases because patients deserve better options. 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. *Jelmyto*® (mitomycin) for pyelocalyceal solution and investigational treatment UGN-102 (mitomycin) for intravesical solution are designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. Visit www.urogen.com to learn more or follow us on Twitter, @UroGenPharma.

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, statements regarding: our goal of fundamentally changing the way urologic cancers are treated; our belief that our sales of Jelmyto during the second quarter of 2021 provides a strong foundation and clear proof of concept of the power of our platform; expected enrollment with respect to the Phase 3 ATLAS trial for UGN-102; the intended advancement of the UGN-302 program; UroGen's plan to extend Jelmyto access in Japan and Europe and the expected timing for updates on this plan; the potential of UroGen's proprietary RTGel technology platform to improve therapeutic profiles of existing drugs; and financial guidance for 2021. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials 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 commercialization activities, including complications resulting from the ongoing COVID-19 pandemic; 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; UroGen's ability to attract or retain key management, members of the board of directors and personnel; and any negative effects on UroGen's business, commercialization and product development plans caused by or associated with COVID-19. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Form 10-Q filed with the SEC on August 4, 2021, and other

filings that UroGen makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to UroGen as of the date of this release.

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