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 10, 2020

UROGEN PHARMA LTD.

(Exact name of registrant as specified in its charter)

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

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

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

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 10, 2020, UroGen Pharma Ltd. (the "Company") announced its financial results for the quarter ended June 30, 2020 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 10, 2020.
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 10, 2020

UROGEN PHARMA LTD.

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

UroGen Pharma Reports Second Quarter 2020 Financial Results and Recent Corporate Developments

Received U.S. FDA Approval of Jelmyto®*, the First and Only Non-Surgical Treatment for Patients with Low-Grade Upper Tract Urothelial Cancer (LG-UTUC)*

Successfully Commenced Launch of Jelmyto *on June 1st as Planned; Initial Commercial Performance Demonstrates Strong Execution*

Announced Positive Complete Response and Durability Data of UGN-102 in Patients with Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC); On Track to Commence Pivotal Phase 3 Trial by Year End

Conference Call and Webcast to be Held Today at 8:30 AM ET

PRINCETON, N.J., August 10, 2020 - 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, 2020 and provided an overview of the Company's recent developments.

"The second quarter of 2020 has proved to be the most transformational time for UroGen, marked by the U.S. Food and Drug Administration approval of *Jelmyto* for patients with low-grade upper tract urothelial cancer and our successful transition to a commercial-stage company. Despite global challenges and uncertainty as a result of the ongoing COVID-19 pandemic, the innovative solutions developed by our team have led to strong launch execution; a testament to our commitment to advancing this important medicine for patients in need of better options," said Liz Barrett, President and Chief Executive Officer of UroGen. "In addition to continuing our commercialization efforts of *Jelmyto*, we are on track to start our planned Phase 3 pivotal study of UGN-102 in patients with low-grade intermediate risk non-muscle invasive bladder cancer by the end of this year."

Recent Highlights and Upcoming Milestones

Jelmyto *(mitomycin) for pyelocalyceal solution, formerly known as UGN-101, for adult patients with low-grade upper tract urothelial cancer (LG-UTUC)*

- On April 15, 2020, the U.S. FDA granted approval of *Jelmyto* for the treatment of adult patients with LG-UTUC. *Jelmyto* is the first and only FDA approved non-surgical treatment option for patients with LG-UTUC.
- UroGen successfully commenced the commercial launch of *Jelmyto* on June 1, 2020.
- The commercial team continues to utilize innovative solutions, such as its virtual platform, to effectively engage health care professionals and patients in this unprecedented environment.
- To date, approximately 100 sites have been activated, which means they have completed their internal processes and have treated or are ready to treat patients.
- Multiple treatments have been successfully reimbursed – both in the hospital and community setting – and the Company has submitted both our C-Code and J-Code applications and continues to expect receipt of a C-Code by October 2020 and a J-Code in January 2021.

UGN-102 (mitomycin) for intravesical solution for patients with low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC)

- UroGen announced the presentation of positive interim data from the investigational agent UGN-102 Phase 2b OPTIMA II trial in patients with LG-IR-NMIBC, which was accepted for the 2020 AUA Annual Meeting, published as a supplement to the April 2020 issue of The Journal of Urology®, and presented as part of the AUA Virtual Experience.
    - The trial results demonstrated that 65% (41/63) of patients treated with UGN-102 achieved a complete response (CR) three months after the start of therapy.
    - In this subset of patients, 97% (35/36) of patients (95% Confidence Interval), 86% (24/28) of patients and 85% (11/13) of patients who were present for evaluation at each timepoint, remained disease free at six, nine and 12 months following treatment initiation, respectively. Follow-up will continue until all patients have reached the 12-month time point.
    - The most common adverse events (≥ 10%) were reported as mild to moderate and include dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection.
- The Company remains on track to initiate a pivotal UGN-102 Phase 3 trial by year end.
- UGN-102 has the potential to provide a non-surgical treatment alternative for approximately 80,000 patients diagnosed with LG-IR-NMIBC in the United States. There are no drugs currently approved by the FDA as first-line treatment for LG-IR-NMIBC.

UGN-302 (combination of UGN-201 and zalifrelimab) for patients with high-grade non muscle invasive bladder cancer (HG NMIBC)

- UGN-302 is the combination of UGN-201, a TLR7/8 agonist, and zalifrelimab, an anti-CTLA-4 antibody, and is initially targeting HG NMIBC.
- Delivering the investigational combination intravesically has the potential to sidestep certain systemic side effects and adverse events associated with systemic CTLA-4 antibody administration.
- In murine models, UGN-201, given sequentially with local anti-CTLA-4, increased survival.

Second Quarter 2020 Financial Results; 2020 Guidance

- UroGen recorded net product sales of *Jelmyto* for the second quarter ended June 30, 2020 of approximately $371,500.
- As of June 30, 2020, cash, cash equivalents and marketable securities totaled $151.6 million, excluding restricted cash.
- Research and development expenses for the second quarter ended June 30, 2020 were $8.1 million, including non-cash share-based compensation expense of $1.6 million. This compares to $10.0 million, including non-cash share-based compensation expense of $2.0 million, for the same period in 2019. Research and development expenses for the six months ended June 30, 2020 were $24.7 million, including non-cash share-based compensation expense of $3.5 million. This compares to $19.7 million, including non-cash share-based compensation expense of $4.3 million, for the same period in 2019.
- Selling, general and administrative expenses for the second quarter ended June 30, 2020 were $24.0 million, including non-cash share-based compensation expense of $5.5 million. This compares to $13.8 million, including non-cash share-based compensation expense of $5.2 million, for the same period in 2019. Selling, general and administrative expenses for the six months ended June 30, 2020 were $46.0 million, including non-cash share-based compensation expense of $11.2 million. This compares to $26.5 million, including non-cash share-based compensation expense of $10.3 million, for the same period in 2019.
- UroGen reported a net loss of $31.3 million, or basic and diluted net loss per ordinary share of $1.44, for the second quarter ended June 30, 2020. This compares to $22.5 million, or basic and diluted net loss per ordinary share of $1.08, for the same period in 2019. UroGen reported a net loss of $69.1 million, or basic and diluted net loss per ordinary share of $3.22,

for the six months ended June 30, 2020. This compares to $43.9 million, or basic and diluted net loss per ordinary share of $2.19, for the same period in 2019.

- UroGen adjusted expense guidance down for 2020, driven by change in estimated non-cash share-based compensation expense for 2020. UroGen now expects 2020 total operating expenses in the range of $143 to $153 million, including non-cash share-based compensation expense of $30 to $34 million, subject to market conditions. No other changes have occurred regarding our previously provided guidance for 2020.

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 9168696. An archive of the webcast will be available for two weeks on the Company's website.

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	June 30, 2020	December 31, 2019
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 36,350	$ 49,688
Marketable securities	88,773	97,389
Restricted cash	1,224	523
Accounts receivable	402	-
Inventory	1,125	-
Prepaid expenses and other current assets	2,069	1,034
TOTAL CURRENT ASSETS	129,943	148,634
NON-CURRENT ASSETS:		
Property and equipment, net	1,401	977
Restricted deposit	223	223
Right of use asset	3,011	3,735
Marketable securities	26,499	48,555
Other non-current assets	-	264
TOTAL ASSETS	$ 161,077	$ 202,388
Liabilities and Shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 9,203	$ 11,186
Employee related accrued expenses	5,744	6,711
Other current liabilities	1,476	1,585
TOTAL CURRENT LIABILITIES	16,423	19,482
NON-CURRENT LIABILITIES:		
Long-term lease liability	1,994	2,604
TOTAL LIABILITIES	18,417	22,086
TOTAL SHAREHOLDERS' EQUITY	142,660	180,302
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 161,077	$ 202,388

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,	
	2020	2019	2020	2019
REVENUES	$ 372	$ 18	$ 372	$ 18
COST OF REVENUES	48	—	48	—
GROSS PROFIT	324	18	324	18
OPERATING EXPENSES:				
Research and development expenses	8,106	9,996	24,694	19,722
Selling, general and administrative expenses	24,018	13,775	45,991	26,482
OPERATING LOSS	(31,800)	(23,753)	(70,361)	(46,186)
INTEREST AND OTHER INCOME, NET	451	1,276	1,219	2,265
NET LOSS	$ (31,349)	$ (22,477)	$ (69,142)	$ (43,921)
STATEMENT OF COMPREHENSIVE LOSS				
NET LOSS	$ (31,349)	$ (22,477)	$ (69,142)	$ (43,921)
OTHER COMPREHENSIVE INCOME:				
UNREALIZED GAIN ON MARKETABLE SECURITIES	449	281	484	281
COMPREHENSIVE LOSS	$ (30,900)	$ (22,196)	$ (68,658)	$ (43,640)
NET LOSS PER ORDINARY SHARE, BASIC AND DILUTED	$ (1.44)	$ (1.08)	$ (3.22)	$ (2.19)
WEIGHTED AVERAGE SHARES OUTSTANDING, BASIC AND DILUTED	21,753,001	20,833,671	21,454,341	20,095,174

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.

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 2b 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 completed enrollment in the Phase 2b OPTIMA II trial in September 2019 and intends to advance the program to a pivotal study to further investigate UGN-102 in the treatment of this condition.

About the Phase 2b OPTIMA II Trial
OPTIMA II (OPTimized Instillation of Mitomycin for Bladder Cancer Treatment) is an open-label, single-arm, multi-center Phase 2b clinical trial of investigational agent UGN-102 (mitomycin) for intravesical solution to evaluate its safety and efficacy in patients with low-grade non-muscle invasive bladder (LG NMIBC) cancer at intermediate risk of recurrence. Intermediate risk is defined as one or two of the following: multiple tumors, solitary tumor >3 cm, or recurrence (≥ 1 occurrence of LG NMIBC within one year of the current diagnosis).

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. UroGen's approved product, Jelmyto (mitomycin) for pyelocalyceal solution, and investigational treatment UGN-102 (mitomycin) for intravesical solution, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and low-grade non-muscle invasive bladder cancer, respectively. UroGen is headquartered in Princeton, NJ with operations in Israel. Visit www.urogen.com to learn more or follow us on Twitter, @UroGenPharma.

COVID-19 Pandemic Potential Impact
UroGen continues to gather information in this very fluid and rapidly-evolving environment regarding the potential impact of the COVID-19 pandemic on our Company, however, we are not currently able to quantify or predict with any certainty the overall scope of impact on UroGen, its research and product development plans, or its commercialization plans for *Jelmyto*. Our primary focus is on the health and well-being of patients, caregivers, and UroGen employees at this critical juncture.

Forward Looking Statements
This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation: the potential of UroGen's proprietary RTGel technology platform to improve therapeutic profiles of existing drugs; UroGen's plans to secure coding and reimbursement for *Jelmyto*; the potential of UGN-102 for LG NMIBC; the potential initiation of a pivotal Phase 3 study of UGN-102 in LG-NMIBC by the end of 2020; the potential of UGN-102 to provide a non-surgical treatment alternative for approximately 80,000 patients diagnosed with LG-IR-NMIBC in the United States; and financial guidance for 2020. 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 10, 2020, and other filings that UroGen makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and UroGen's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to UroGen as of the date of this release.

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