

**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): March 18, 2021**

**UROGEN PHARMA LTD.**

(Exact name of registrant as specified in its charter)

**Israel**  
(State or other jurisdiction  
of incorporation)

**001-38079**  
(Commission  
File Number)

**98-1460746**  
(IRS Employer  
Identification No.)

**400 Alexander Park Drive, 4<sup>th</sup> Floor**  
**Princeton, New Jersey**  
(Address of principal executive offices)

**08540**  
(Zip Code)

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

**N/A**  
(Former name or former address, if changed since last report.)

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
<b>Ordinary Shares, par value NIS0.01 per share</b>	<b>URGN</b>	<b>The Nasdaq Stock Market LLC</b>

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 1.01. Entry into a Material Definitive Agreement.**

On March 18, 2021, UroGen Pharma Ltd. (the “Company”) and RTW Investments ICAV, for and on behalf of RTW Fund 2 (“RTW”), entered into a Pre-Paid Forward Contract (the “Agreement”) pursuant to which the Company granted to RTW the right to receive certain future cash payments from the Company in exchange for \$75 million in cash. The Agreement and the transactions contemplated thereby (the “RTW Funding Transaction”) were unanimously approved by the Board of Directors of the Company on March 17, 2021.

Under the Agreement, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of Jelmyto® (mitomycin) for pyelocalyceal solution in an amount equal to: (i) 9.5% of annual net sales up to \$200 million, (ii) 3.0% of annual net sales for annual net sales between \$200 million and \$300 million, and (iii) 1.0% of annual net sales for annual net sales above \$300 million. If certain revenue thresholds for Jelmyto aggregate worldwide annual net sales are not met, the future cash payments to RTW with respect to Jelmyto annual net sales up to \$200 million will increase by 3.5%, and may decrease back to 9.5% dependent on the Company meeting certain subsequent Jelmyto aggregate worldwide annual net sales thresholds.

In addition, subject to U.S. Food and Drug Administration (“FDA”) approval of UGN-102 (mitomycin) for intravesical solution, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of UGN-102 in an amount equal to: (i) 2.5% of annual net sales up to \$200 million, (ii) 1.0% of annual net sales for annual net sales between \$200 million and \$300 million, and (iii) 0.5% of annual net sales for annual net sales above \$300 million. If the Company does not receive FDA approval for UGN-102 by a specified date, the future cash payments to RTW with respect to aggregate worldwide annual net sales of Jelmyto across all Jelmyto annual net sales tiers will increase by 1.5%.

The Company will be required to make payments of amounts owed to RTW each calendar quarter, and the future cash payments based on both Jelmyto and UGN-102 (together, the “Products”) aggregate worldwide annual net sales will terminate following the quarter during which the aggregate cash payments received by RTW are equal to or greater than \$300 million.

The Agreement is subject to customary closing conditions and contains customary representations and warranties of the Company and RTW, including with respect to organization, authorization and tax matters, indemnification obligations, and certain covenants with respect to payment, reports, intellectual property, in-licenses, out-licenses, and certain other actions with respect to the Products. Until the earlier of such time that (i) the Company’s aggregate worldwide annual net product sales of the Products reach a certain threshold or (ii) the Company’s market capitalization reaches a certain threshold, (a) RTW will be granted a security interest in the Products and the regulatory approvals, intellectual property, material agreements, proceeds and accounts receivable related to the Products (the “Product Collateral”) and (b) the Company will be subject to a negative pledge in respect of the Product Collateral.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Agreement, which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ending March 31, 2021.

**Item 7.01. Regulation FD Disclosure.**

On March 18, 2021, the Company issued a press release announcing the RTW Funding Transaction. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for 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 into any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the closing of the RTW Funding Transaction; the investment of the proceeds from the RTW Funding Transaction; and the potential of the Company’s proprietary RTGel technology platform to improve therapeutic profiles of existing drugs. 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 the Company'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; the Company's ability to attract or retain key management, members of the board of directors and personnel; and any negative effects on the Company'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 the Company's Form 10-K filed with the SEC on March 18, 2021, and other filings that UroGen makes with the SEC from time to time, the events and circumstances discussed in such forward-looking statements may not occur, and the Company'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 Current Report on Form 8-K and are based on information available to the Company as of such date.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated March 18, 2021</a>
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: March 18, 2021

**UROGEN PHARMA LTD.**

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

**UroGen Pharma Announces \$75 Million of Non-Dilutive Funding from RTW Investments**

- *RTW Investments, LP will provide UroGen with an upfront cash payment of \$75 million and will receive tiered future payments based on worldwide annual net product sales of Jelmyto® and UGN-102, if approved*
- *Strategic funding partnership with RTW Investments, LP enables UroGen to further support the ongoing commercial launch of Jelmyto and advance clinical development of UGN-102*

**PRINCETON, N.J.**, March 18, 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 that the Company has entered into a strategic funding agreement with RTW Investments, LP and its affiliated entities ("RTW").

Under the terms of the agreement, subject to customary closing conditions, UroGen will receive \$75 million in upfront cash from RTW in return for tiered, future cash payments based on aggregate worldwide annual net product sales of Jelmyto® (mitomycin) for pyelocalyceal solution as well as UGN-102, if approved. In exchange for the \$75 million upfront payment, RTW will receive tiered, future cash payments on worldwide annual net product sales of Jelmyto ranging from high to low single digits based on certain annual sales thresholds, subject to upward adjustment if certain annual sales and regulatory milestones are not met. RTW will also receive tiered, future cash payments on worldwide annual net product sales of UGN-102, if approved, in the low single digits based on certain annual sales thresholds.

The future payments on both Jelmyto and UGN-102 will terminate following the date that RTW has received an aggregate amount pursuant to such payments of \$300 million.

"UroGen's RTGel™ platform has demonstrated the ability to overcome historical treatment barriers, work with anatomical complexity and thus unlock new therapeutic potential, including those conditions targeted by Jelmyto and UGN-102," said Brad Sitko, Managing Director of Strategic Finance, RTW Investments, LP. "We are proud to partner with the UroGen management team and look forward to supporting the Company's goal of building a leading uro-oncology company."

"This important non-dilutive transaction provides a clear path to fund the ongoing launch of Jelmyto and to advance our UGN-102 program, including the ongoing Phase 3 ATLAS study," said Molly Henderson, Chief Financial Officer of UroGen Pharma. "We are proud to partner with RTW, a leading, research-driven healthcare investor, allowing us to access capital that is aligned with our vision and invest further in our mission of developing treatments for patients with urologic and specialty cancers."

Cowen acted as financial advisor to UroGen on the transaction. Cooley acted as legal advisor to UroGen. Gibson Dunn acted as legal advisor to RTW.

## **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 first commercial product, and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with low-grade non-muscle invasive bladder cancer, are designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. Visit [www.urogen.com](http://www.urogen.com) to learn more or follow us on Twitter, @UroGenPharma.

## **About RTW Investments, LP**

RTW Investments, LP (RTW) is a New York-based, global, full life-cycle investment firm that focuses on identifying transformational and disruptive innovations in biopharmaceutical and medical technologies. As a leading partner of industry and academia, RTW combines deep scientific expertise with a solution-oriented investment approach to support emerging medical therapies and the companies and/or academics developing them.

For further information about RTW, please visit [www.RTWfunds.com](http://www.RTWfunds.com).

## **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: the closing of the RTW transaction; the investment of the proceeds from the RTW transaction; and the potential of UroGen's proprietary RTGel technology platform to improve therapeutic profiles of existing drugs. 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 November 9, 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.

## **INVESTOR CONTACT:**

Sara Blum Sherman  
Head of Investor Relations  
[investors@urogen.com](mailto:investors@urogen.com)  
609-467-4975

## **MEDIA CONTACT:**

Eric Van Zanten  
Senior Director, Communications  
[Eric.VanZanten@urogen.com](mailto:Eric.VanZanten@urogen.com)  
610-529-6219

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