

**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): November 8, 2019

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.)

499 Park Avenue
New York, New York
(Address of principal executive offices)

10022
(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 1.01 Entry into a Material Definitive Agreement.

On November 8, 2019, UroGen Pharma Ltd. (the “Company”) entered into a license agreement (the “License Agreement”) with Agenus Inc. (“Agenus”), pursuant to which Agenus granted to the Company an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicenseable license under Agenus’s intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus’ anti-PD-1 antibody in solid tumors. Initially, the Company plans to develop AGEN1884 in combination with UGN-201 for the treatment of high-grade non-muscle invasive bladder cancer.

Pursuant to the License Agreement, the Company paid Agenus an upfront fee of \$10.0 million and has agreed to pay Agenus up to \$115.0 million upon achieving certain clinical development and regulatory milestones, up to \$85.0 million upon achieving certain commercial milestones, and royalties on net sales of licensed products in the 14%-20% range. The Company will be responsible for all development and commercialization activities. Under the terms of the License Agreement, Agenus has agreed to use commercially reasonable efforts to supply AGEN1884 to the Company for use in preclinical studies or clinical trials.

Unless earlier terminated in accordance with the terms of the License Agreement, the License Agreement will expire on a product-by-product and country-by-country basis at the later of (a) the expiration of the last to expire valid claim of a licensed patent right that covers the licensed product in such country or (b) 15 years after the first commercial sale of the licensed product in such country. The Company may terminate the License Agreement for convenience upon 180 days’ written notice to Agenus. Either party may terminate the License Agreement upon 60 days’ notice to the other party if, prior to the first commercial sale of a licensed product, the Company substantially ceases to conduct development activities of the licensed products for 12 consecutive months (and during such period, Agenus has complied with its obligations under the License Agreement) other than in response to a requirement of an applicable regulatory authority or an event outside of the Company’s control. In addition, either party may terminate the License Agreement in the event of an uncured material breach of the other party.

Forward-Looking Statements

Statements in this report that are not strictly historical in nature, including statements regarding the Company’s plans and expectations with respect to its planned development of AGEN1844, are forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including risks relating to those inherent in the development of products for the treatment of urological cancer. For a discussion of these and other factors, please refer to the Company’s quarterly report on Form 10-Q for the quarter ended June 30, 2019 as well as the Company’s subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and the Company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d)

<u>Exhibit Number</u>	<u>Description</u>
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: November 12, 2019

UROGEN PHARMA LTD.

By: /s/ Peter Pfreundschuh

Peter Pfreundschuh

Chief Financial Officer