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 27, 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**	**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 8.01 Other Events.

On August 27, 2020, Urogen Pharma, Ltd. issued a press release titled "UroGen Pharma announces update on the Phase 2 Trial of an RTGel™ Hydrogel Formulation in Combination with BOTOX® (onabotulinumtoxinA) Intravesical Instillation for Overactive Bladder and Urinary Incontinence" (the "Press Release"). A copy of the Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release, dated August 27, 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 27, 2020

UROGEN PHARMA LTD.

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

Exhibit 99.1

UroGen Pharma Announces Update on the Phase 2 Trial of an RTGel™ Hydrogel Formulation in Combination with BOTOX® (onabotulinumtoxinA) Intravesical Instillation for Overactive Bladder and Urinary Incontinence

- *Trial Did Not Meet Primary Endpoint Believed to be the Result of BOTOX Not Effectively Permeating the Urothelium*
- *RTGel Delivered Treatment to the Bladder as Expected with Dwell Time of Up to 10 Hours*
- *UroGen and AbbVie will Continue to Explore Use of the RTGel Hydrogel Formulation with AbbVie's Portfolio of Toxin Proteins*
- *No Impact to UroGen's Current Financial Position*

PRINCETON, N.J., August 27, 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 that the Phase 2 APOLLO clinical trial of a RTGel hydrogel formulation in combination with BOTOX® (onabotulinumtoxinA) intravesical instillation in patients with overactive bladder (OAB) and urinary incontinence did not meet the primary endpoint of improvement of overactive bladder symptoms, as measured by the reduction in urinary incontinence episodes per day. Data suggests that this result may have been due to BOTOX not effectively permeating the urothelium.

Safety and tolerability were evaluated compared to placebo, as well as the dwell time manifested by hydrogel excretion. The combination was reported to be safe and well tolerated compared to placebo, with extended dwell time for up to 10 hours following initial instillation. Patients also reported satisfaction with the ease of hydrogel administration which is performed through a standard urinary catheter. A full evaluation of the data is underway, and the companies are working collaboratively on next steps in the partnership.

"In our own research experience, we have clearly demonstrated the ability of RTGel to successfully deliver active molecules to the urothelium resulting in a therapeutic effect. While we were disappointed with the results of the APOLLO trial, the data are very informative and provide important learnings for future experiments," said Dr. Mark Schoenberg, Chief Medical Officer at UroGen. "The topline data from this trial reinforces that our RTGel technology could be combined with a substantial library of molecules to deliver therapy where dwell time may improve outcomes and we look forward to our continued collaboration with AbbVie as they develop their portfolio of toxin proteins."

The Phase 2 trial was conducted by AbbVie under the license agreement entered into with UroGen in October 2016. This agreement granted an exclusive worldwide license to Allergan plc, now an AbbVie company, to research, develop, manufacture, and commercialize pharmaceutical products formulated with an RTGel hydrogel formulation and clostridial toxins, including BOTOX. The license agreement allows the companies to continue exploration of the RTGel hydrogel formulation in combination with AbbVie's portfolio of clostridial toxins in OAB and other patient populations. UroGen is eligible to receive payments from AbbVie related to the achievement of certain development, regulatory, and commercial milestones, in addition to royalties on potential net sales.

“Our RTGel sustained release technology has repeatedly established its unique ability to reach and remain in body cavities that have long presented treatment challenges to the medical community,” said Liz Barrett, President and Chief Executive Officer of UroGen. “With one drug on the market and a second soon to enter a pivotal study, we remain confident that our innovative technology is a true advance and are committed more than ever to find ways in which our novel approach could expand therapy options for patients.”

BOTOX® injection into the bladder is approved as a pharmacologic therapy for the treatment of overactive bladder in adults when another type of medication (anticholinergic) does not work well enough or cannot be taken. UroGen’s innovative, hydrogel-based technology platform is designed to enable longer exposure to active pharmaceutical ingredients. Jelmyto® (mitomycin) for pyelocalyceal solution, which utilizes the RTGel technology, was recently approved in the U.S. for the treatment of adults with low-grade upper tract urothelial cancer.

About the Phase 2 APOLLO Trial

The trial is a multi-center, randomized, double-blind, placebo-controlled, single-treatment, two-stage, dose-finding clinical trial on patients with overactive bladder with urgency urinary incontinence who have an inadequate response to or are intolerant to pharmacologic therapy. The first stage of the trial is a placebo-controlled, dose escalation design, followed by the second stage, a randomized, placebo-controlled design. Patients received a single bladder instillation of an RTGel hydrogel formulation in combination with BOTOX®. The primary efficacy endpoint is the improvement of overactive bladder symptoms as measured by the reduction in urinary incontinence episodes per day.

BOTOX® Indication and Important Safety Information

Indication

BOTOX® is a prescription medicine that is injected into the bladder muscle and used to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents, going too often, and the strong, sudden need to go in adults 18 years and older when another type of medication (anticholinergic) does not work well enough or cannot be taken.

IMPORTANT SAFETY INFORMATION

BOTOX® may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX®. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

Do not receive BOTOX® if you: are allergic to any of the ingredients in BOTOX® (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have a skin infection at the planned injection site.

Do not receive BOTOX® for the treatment of urinary incontinence if you: have a urinary tract infection (UTI) or cannot empty your bladder on your own (and are not routinely catheterizing). Due to the risk of urinary retention (difficulty fully emptying the bladder), only patients who are willing and able to initiate self-catheterization post treatment, if required, should be considered for treatment.

In clinical trials, 36 of the 552 patients had to self-catheterize for urinary retention following treatment with BOTOX® compared to 2 of the 542 treated with placebo. Patients with diabetes mellitus treated with BOTOX® were more likely to develop urinary retention than nondiabetics.

The dose of BOTOX® is not the same as, or comparable to, another botulinum toxin product.

Serious and/or immediate allergic reactions have been reported including itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.

Tell your doctor about all your muscle or nerve conditions such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX®.

Tell your doctor about all your medical conditions, including if you: have or have had bleeding problems; have plans to have surgery; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence (symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever); have problems emptying your bladder on your own and are being treated for urinary incontinence; are pregnant or plan to become pregnant (it is not known if BOTOX® can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX® passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX® in the past.**

Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*®, *Dysport*®, or *Xeomin*® in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.

Other side effects of BOTOX® include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, dry eyes; drooping eyebrows; and upper respiratory tract infection. In people being treated for urinary incontinence, other side effects include: urinary tract infection, painful urination, and/or inability to empty your bladder on your own. If you have difficulty fully emptying your bladder after receiving BOTOX®, you may need to use disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.

For more information, refer to the Medication Guide or talk with your doctor.

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.

Please see BOTOX® full Product Information, including Boxed Warning and Medication Guide.

Learn more about the APOLLO trial at http://www.clinicaltrials.gov.

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.

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 deliver large protein molecules to the interior of the urinary bladder with extended dwell time for up to 10 hours and improve therapeutic profiles of existing drugs; UroGen's intent to continue exploration of the RTGel hydrogel formulation in combination with AbbVie's portfolio of clostridial toxins in OAB and other patient populations; and the potential of UGN-102 for LG NMIBC. 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 product development and 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.

RTGel™ is a trademark of UroGen Pharma Ltd.
BOTOX® is a registered trademark of Allergan, an AbbVie company

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