
**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): May 4, 2018

Proteon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-36694
(Commission File Number)

20-4580525
(I.R.S. Employer Identification Number)

200 West Street, Waltham, MA 02451
(Address of Principal Executive Offices) (Zip Code)

(781) 890-0102
(Registrant's telephone number, including area code)

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 obligation 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
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 May 4, 2018, Proteon Therapeutics, Inc. (the “Company”) and Lonza Ltd. (“Lonza”) entered into an amendment (the “Amendment”) to the Manufacturing Services Agreement dated as of June 30, 2015 and signed on July 9, 2015 (as previously amended, the “Lonza Agreement”) for the commercial supply of the active pharmaceutical ingredient in the Company’s lead product candidate, vonapanitase. The Amendment extends the term of the Lonza Agreement for a period of seven (7) years from June 30, 2022 until June 30, 2029. The Amendment also allows for termination of the Lonza Agreement by either party upon 36 months’ prior written notice to the other party, provided that the Company shall not exercise this termination right before January 1, 2020 and Lonza shall not exercise this termination right before January 1, 2023. In addition, the Amendment implements a change in the price per batch to be supplied by Lonza pursuant to the Agreement and provides that, contingent upon the approval of the product by the U.S. Food and Drug Administration (the “FDA”), the Company is required to place orders for a minimum quantity of batches commencing in calendar year 2022. The parties further agreed to adjust the limitations of liability to cover the proposed manufacturing schedule and to replace the Company’s outstanding purchase obligation for one batch scheduled to commence before the end of 2019 with the right to make one batch, if requested by the Company, coincident with a pre-approval inspection of Lonza by the FDA.

The foregoing is only a brief description of the material terms of the Amendment and, therefore, does not purport to be complete and is qualified in its entirety by reference to the Amendment which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the fiscal quarter ending June 30, 2018.

Item 8.01. Other Events.

On May 8, 2018, the Company issued a joint press release announcing the Lonza Amendment and the completion of its drug substance process validation runs. The press release is attached to this Current Report as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

[99.1](#) Press Release, dated May 8, 2018, issued by Proteon Therapeutics, Inc.

SIGNATURE

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.

Proteon Therapeutics, Inc.

Date: May 8, 2018

By: /s/ Matthew P. Kowalsky
Matthew P. Kowalsky
Vice President of Legal & Secretary

EXHIBIT INDEX

<u>Exhibit No</u>	<u>Description</u>
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<u>99.1</u>	Press Release dated May 8, 2018, issued by Proteon Therapeutics, Inc.
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Proteon Therapeutics and Lonza Extend Manufacturing Agreement for Commercial Supply

- Partners extend existing contract for manufacture of vonapanitase to 2029 as ongoing Phase 3 trial nears completion
- Lonza Pharma & Biotech successfully scaled up a lab process at their Microbial facility in Visp, Switzerland, providing flexible solutions as Proteon moves toward possible commercialization
- Lonza's experience in products with Breakthrough Therapy Designation provides expert support for these fast paced, challenging projects

BASEL, Switzerland and WALTHAM, Mass., May 08, 2018 (GLOBE NEWSWIRE) – Proteon Therapeutics, Inc. (Nasdaq:PRTO), a company developing novel, first-in-class therapeutics to address the medical needs of patients with kidney and vascular diseases, today announced a long-term contract extension with Lonza Pharma & Biotech for the commercial supply of investigational vonapanitase's active pharmaceutical ingredient (API).

"Proteon and Lonza have had a strong relationship for nearly a decade, and this amendment extends that relationship," said Timothy Noyes, President and Chief Executive Officer of Proteon. "The amendment provides Proteon with access to a top-tier manufacturing site for the long-term commercial supply of investigational vonapanitase after potential FDA approval."

"Lonza's microbial expertise and versatile assets will enable us to anticipate and deliver API for Proteon at this critical phase in the lifecycle of their therapy," said Marc Funk, COO Lonza Pharma & Biotech.

Karen Fallen, VP, Head of Clinical Development and Manufacturing for Lonza, added: "It's always motivating for our teams to support biotechs like Proteon from Phase I studies through to commercialization and to see the impact for patients."

Lonza has manufactured API for Proteon at its microbial manufacturing facility in Visp (CH) since 2009. Initially, a small-scale process was transferred into Lonza's development labs for process optimization and consistency studies. The process was then scaled up to 1,000L scale cGMP manufacture to support Proteon's early clinical studies and potential commercial requirements.

As Proteon worked to complete enrollment in its ongoing Phase 3 clinical trial, PATENCY-2, Lonza supported Proteon with three process validation batches at 1,000L commercial scale, each of which met the intended release criteria. If PATENCY-2 is successful, Proteon expects to include results from these validation runs in a potential Biologics License Application (BLA) filing in the second half of 2019, which Lonza will support.

About Vonapanitase

Vonapanitase is an investigational drug intended to improve hemodialysis vascular access outcomes. Vonapanitase is currently being studied in a Phase 3 clinical trial in patients with chronic kidney disease (CKD). It has received Breakthrough Therapy, Fast Track and Orphan Drug designations from the FDA, and Orphan Medicinal Product designation from the European Commission, for hemodialysis vascular access indications. Proteon is also currently conducting a Phase 1 clinical trial of vonapanitase in patients with peripheral artery disease (PAD).

About Proteon Therapeutics

Proteon Therapeutics is committed to improving the health of patients with kidney and vascular diseases through the development of novel, first-in-class therapeutics. Proteon's lead product candidate, vonapanitase, is an investigational drug intended to improve hemodialysis vascular access outcomes. Proteon is evaluating vonapanitase in patients with CKD undergoing surgical creation of a radiocephalic arteriovenous fistula. Proteon is also evaluating vonapanitase in a Phase 1 clinical trial in patients with PAD. For more information, please visit www.proteontx.com.

About Microbial Manufacturing at Lonza Pharma & Biotech

Recent developments in next generation biotherapeutics including antibody mimetics and novel scaffolds have spurred a renewed interest in microbial protein expression and manufacture technologies. Lonza's proven XS[®] Microbial Expression Platform combined with more than 30 years of process development and cGMP manufacture expertise make us an ideal partner to successfully support clinical and commercial programs. More information can be found at: pharma.lonza.com/microbial.

About Lonza

Lonza is one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. As an integrated solutions provider, Lonza is boosting its value creation along and beyond the healthcare continuum with a strong focus on patient healthcare, consumer preventive healthcare and consumer's healthy environment.

Lonza harnesses science and technology to create products that support safer and healthier living and that enhance the overall quality of life. With the recent Capsugel acquisition, Lonza now offers products and services from the custom development and manufacturing of active pharmaceutical ingredients to innovative dosage forms for the pharma and consumer health and nutrition industries.

Benefiting from its regulatory expertise, Lonza is able to transfer its know-how from pharma to hygiene and fast-moving consumer goods all the way to coatings and composites and the preservation and protection of agricultural goods and other natural resources.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 14,500 full-time employees worldwide. The company generated sales of CHF 5.1 billion in 2017 with a CORE EBITDA of CHF 1.3 billion. Further information can be found at www.lonza.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are, or may be deemed to be, "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding Proteon's product candidate, vonapanitase, and plans for its commercial manufacture. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks relating to: whether data from early nonclinical or clinical studies will be indicative of the data that will be obtained from future clinical trials; whether vonapanitase will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; and whether Proteon can successfully manufacture,

commercialize and market its product candidates. These risks and uncertainties are described more fully in Proteon's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission ("SEC") on March 14, 2018, and Proteon's subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as filed with the SEC, particularly in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In light of the significant uncertainties in these forward-looking statements, no person should place undue reliance on these statements or regard these statements as a representation or warranty by the Proteon or any other person that Proteon will achieve its objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this press release represent Proteon's estimates and assumptions only as of the date of this press release and, except as required by law, Proteon undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this press release.

Additional Information and Disclaimer

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited ("SGX-ST"). Lonza Group Ltd is not subject to the SGX-ST's continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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