

PROTEON THERAPEUTICS INC

Form 8-K

July 13, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): July 9, 2015

Proteon Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware 001-36694 20-4580525
(State or other jurisdiction (Commission (IRS Employer
of incorporation) File Number) Identification No.)

200 West Street 02451
Waltham, MA
(Address of principal executive offices) (Zip Code)

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

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 (see General Instruction A.2. below):

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))

Introductory Comment

Throughout this Current Report on Form 8-K, the terms "we," "us," "our", "Company" and "Proteon" refer to Proteon Therapeutics, Inc.

Item 1.01 Entry Into a Material Definitive Agreement.

On July 9, 2015, Proteon entered into a Manufacturing Services Agreement with Lonza Ltd. ("Lonza") by which Proteon has engaged Lonza to process, develop and manufacture the active pharmaceutical ingredient ("API") in its lead product candidate, vonapanitase (the "Lonza Agreement").

The Lonza Agreement is effective as of June 30, 2015 and has a term of seven years, and may be extended or terminated earlier as provided in the Lonza Agreement. Pursuant to the Lonza Agreement, Lonza will perform various development and manufacturing services (the "Services") that will be further set forth in future mutually agreed upon project plan or plans (each, a "Project Plan"). Specifically under the Lonza Agreement, Lonza will first manufacture Process Validation Batches and Engineering Batches (each, as defined in the Lonza Agreement) to ensure that the manufacturing process developed under Proteon's Process Development and Manufacturing Services Agreement effective as of September 1, 2009, as amended, with Lonza (attached as Exhibit 10.9 to Proteon's S-1 Registration Statement), is replicated and used during Lonza's performance of services under the Lonza Agreement. Lonza will then manufacture batches in accordance with current Good Manufacturing Practices ("cGMP") and deliver them to Proteon along with certain documentation that is necessary for regulatory compliance. Proteon will execute purchase orders authorizing Lonza to manufacture the batches and will pay for the Services and batches in accordance with terms and assumptions to be set forth in a Project Plan.

Lonza is also responsible for procuring all required raw materials to prepare the batches, while Proteon will be responsible for the cost. Each of Proteon and Lonza will appoint a project manager to oversee the project plan and work in conjunction with the project manager appointed by the other party. The Lonza Agreement provides for Proteon to maintain one representative of the Company at the Lonza facility during the manufacturing process. Pursuant to the Lonza Agreement, quality assurance and control is the responsibility of both Lonza and Proteon during the process and manufacture.

Proteon has the right to inspect and approve all batches to ensure compliance with the manufacturing specifications within 30 days after release of a batch. In the event of a dispute regarding compliance with the manufacturing specifications, the dispute will be resolved ultimately by independent analysis and testing.

The Lonza Agreement contains customary warranties and disclaimers, confidentiality provisions as well as mutual indemnifications common in agreements of this type.

The foregoing is only a brief description of the material terms of the Lonza Agreement and therefore, does not purport to be complete and is qualified in its entirety by the Lonza Agreement that will be filed as an exhibit to Proteon's quarterly report on Form 10-Q for the quarter ending September 30, 2015.

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.

Date: July 13, 2015 PROTEON
THERAPEUTICS, INC.
(Registrant)

By: /s/ Timothy P. Noyes
Name: Timothy P. Noyes
Title: President & Chief
Executive Officer