BIOCRYST PHARMACEUTICALS INC
Form 8-K
December 20, 2013

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): December 20, 2013

BioCryst Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-23186**	**62-1413174**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4505 Emperor Blvd., Suite 200

Durham, North Carolina 27703

(Address of Principal Executive Offices)

(919) 859-1302

(Registrant s telephone number, including area code)

(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 210.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On December 20, 2013, BioCryst Pharmaceuticals, Inc. (the Company) announced that it has submitted a New Drug Application (NDA) filing for intravenous (i.v.) peramivir to the U.S. Food & Drug Administration (FDA). BioCryst is seeking an indication as the first i.v. neuraminidase inhibitor approved in the U.S. for the treatment of acute uncomplicated influenza in adults. Peramivir is approved in Japan and Korea for the treatment of influenza.

In June 2013, BioCryst completed a pre-NDA meeting with the FDA regarding peramivir. BioCryst reached agreement with FDA regarding all requirements for a complete NDA submission. The peramivir NDA submission includes results in over 2700 subjects treated with peramivir in 27 clinical trials.

BioCryst requested and was granted a small business waiver of the application fee for the peramivir NDA filing. The waiver confirmation was submitted with the NDA filing.

On December 20, 2013, the Company issued a news release announcing the events described in this Item 8.01. A copy of the news release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst s actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may not provide regulatory approval for any use of peramivir or that the approval may be limited; that BARDA/HHS may further condition, reduce or eliminate future funding of the peramivir program; that the Company may not be able to access adequate capital to move peramivir forward; that the Company may not reach favorable agreements with potential pharmaceutical and biotechnology partners for the commercialization of peramivir. Please refer to the documents BioCryst files periodically with the Securities and Exchange Commission, specifically BioCryst s most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, all of which identify important factors that could cause the actual results to differ materially from those contained in BioCryst s projections and forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated December 20, 2013 entitled BioCryst Files Peramivir NDA for the Treatment of Influenza

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.

Dated: December 20, 2013

BioCryst Pharmaceuticals, Inc.

By: /s/ Alane Barnes
Alane Barnes
Vice President, General Counsel, and Corporate Secretary,

EXHIBIT INDEX

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