BIOCRYST PHARMACEUTICALS INC
Form 8-K
February 26, 2014

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): February 21, 2014

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 1.01. Entry into a Material Definitive Agreement.

On February 21, 2014, BioCryst Pharmaceuticals, Inc. (the Company) and the U.S. Department of Health and Human Services (HHS) mutually agreed to amend the Agreement dated January 3, 2007 between the Company and HHS (the Agreement) to extend the Agreement s current expiration date of February 28, 2014 for 31 days. The new expiration date is changed to March 31, 2014. The extension of the Agreement will allow ongoing stability testing of peramivir to continue beyond the current contract expiration date. All other terms and conditions of the Agreement remain unchanged.

Item 2.02. Results of Operations and Financial Condition.

On February 26, 2014, BioCryst Pharmaceuticals, Inc. issued a news release announcing recent corporate developments and its financial results for the year ended December 31, 2013, which also referenced a conference call and webcast to discuss these recent corporate developments and financial results. A copy of the news release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure

The information furnished on Exhibit 99.1 is incorporated by reference under this Item 7.01 as if fully set forth herein.

The information furnished is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 8.01. Other Events.

On February 25, 2014, BioCryst Pharmaceuticals, Inc. (the Company) announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for intravenous (i.v.) peramivir that was submitted to the FDA in December 2013. The FDA assigned the NDA a standard review time, resulting in a PDUFA (Prescription Drug User Fee Act) action date of December 23, 2014. The FDA has informed BioCryst that at this time it does not plan to hold an Advisory Committee review of the NDA.

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 included results in over 2,700 subjects treated with peramivir in 27 clinical trials. Peramivir has been approved in Japan and Korea. It is estimated that more than one million patients have received peramivir treatment to date.

On February 25, 2014, 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 99.2 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; the Company may not be able to successfully commercialize peramivir on its own; that the Company may not reach favorable agreements with potential pharmaceutical and biotechnology partners for the commercialization of peramivir; and that peramivir may never be purchased by any government entity for stockpiling. 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
10.1	Amendment #17 to the Agreement between BioCryst Pharmaceuticals, Inc. and the U.S. Department of Health and Human Services, dated February 21, 2014
99.1	Press release dated February 26, 2014 entitled BioCryst Provides Fourth Quarter and Full Year 2013 Financial Results
99.2	Press Release dated February 25, 2014 entitled BioCryst Announces Peramivir NDA Acceptance by the FDA

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: February 26, 2014

BioCryst Pharmaceuticals, Inc.

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

EXHIBIT INDEX

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