BIOCRYST PHARMACEUTICALS INC
Form 8-K
April 16, 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): April 16, 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 April 16, 2013, BioCryst Pharmaceuticals, Inc. (the Company) announced that it has completed its Type C meeting regarding intravenous peramivir with the U.S. Food & Drug Administration (FDA) and has received final meeting minutes. The minutes of the meeting were consistent with the FDA s preliminary comment letter, which was previously referenced in the Company s Current Report on Form 8-K filed April 1, 2013. In addition, the meeting minutes confirmed that the Company s proposed peramivir New Drug Application (NDA) content supports a reviewable NDA submission for the indication of acute uncomplicated influenza. In accordance with FDA s recommendation, the Company is in the process of requesting a pre-NDA meeting to reach agreement on a complete NDA submission and to address review issues identified in the minutes.

The Company anticipates that The Biomedical Advanced Research and Development Authority (BARDA/HHS) will schedule and hold its In-Process Review meeting in the second quarter of this year with the objective of determining the future for the underlying peramivir development contract.

On April 16, 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 that may cause the Company 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 require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for peramivir; 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 never file an NDA for peramivir regulatory approval in any country; that the Company may not be able to access adequate capital to move its programs forward; and that the Company may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of product candidates. Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically the Company 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 the Company s projections and forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 16, 2013 entitled BioCryst Pharmaceuticals Completes Peramivir Type C Meeting

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: April 16, 2013

BioCryst Pharmaceuticals, Inc.

By: /s/ Alane Barnes
Alane Barnes
General Counsel, Corporate Secretary

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated April 16, 2013 entitled BioCryst Pharmaceuticals Completes Peramivir Type C Meeting