BIOCRYST PHARMACEUTICALS INC
Form 8-K
July 11, 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): July 11, 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 July 11, 2013, BioCryst Pharmaceuticals, Inc. (the Company) announced that the Biomedical Advanced Research and Development Authority (BARDA/HHS) has released funding under the current $234.8 million contract to enable completion of a New Drug Application (NDA) filing for intravenous peramivir. The decision by BARDA/HHS was a result of an In-Process Review (IPR) meeting that occurred in the second quarter of 2013. Based on the results of the IPR, and considering first and foremost what it viewed as in the best interest of the U.S. Government and the nation s preparedness for pandemic influenza, BARDA/HHS decided to modify the existing stop-work order relating to the contract to support only those activities directly associated with the NDA and to allow no more than $12.8M of funding already obligated on the contract to be used for that purpose. In light of this funding decision, the Company currently believes that it will incur some modest costs associated with the NDA filing.

The Company is seeking an indication for the treatment of acute uncomplicated influenza and expects to submit the peramivir NDA by the end of 2013. The Company has completed a pre-NDA meeting with the Food and Drug Administration (FDA) regarding peramivir at which the Company reached agreement with FDA regarding all requirements for a complete NDA submission.

On July 11, 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 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 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 peramivir forward; 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 July 11, 2013 entitled BioCryst to File Peramivir NDA Supported by BARDA/HHS Funding

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: July 11, 2013

BioCryst Pharmaceuticals, Inc.

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

EXHIBIT INDEX

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