

BIOCRYST PHARMACEUTICALS INC

Form 8-K

April 01, 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): March 26, 2013

BioCryst Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-23186
(Commission

File Number)

62-1413174
(IRS Employer

Identification No.)

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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 March 26, 2013, BioCryst Pharmaceuticals, Inc. (the Company) received written notification from the U.S. Department of Health and Human Services in the form of a stop-work order directing the Company to stop work on the clinical development of peramivir under its Agreement dated January 3, 2007 with the U.S. Department of Health and Human Services, as amended (the Agreement), and to only continue performing certain activities under the Agreement related to an upcoming U.S. Food & Drug Administration (FDA) type C meeting, which is scheduled. The notification confirmed that the Biomedical Advanced Research and Development Authority (BARDA/HHS) will continue to support and fund certain activities under the Agreement that are necessary to achieve immediate milestones, as well as activities deemed essential to maintain compliance with FDA regulations or to fulfill pending FDA requests. Following an In-Process Review meeting, which the Company anticipates in the second quarter, BARDA/HHS is expected to determine the path forward for the Agreement.

In addition to the stop-work order with respect to the Agreement, on March 28, 2013, the Company also received a preliminary comment letter from the FDA outlining a pathway by which the Company could file a New Drug Application (NDA) seeking regulatory approval of intravenous (i.v.) peramivir. The letter was sent in response to questions the Company submitted to the FDA in advance of an upcoming Type C regulatory meeting regarding i.v. peramivir. The FDA also suggested the Company request a pre-NDA meeting to reach agreements on a complete NDA submission and to address review issues identified in its comment letter.

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 Company or its licensees may not be able to enroll the required number of subjects in planned clinical trials of its product candidates and that such clinical trials may not be successfully completed; that the Company or its licensees may not commence as expected additional human clinical trials with product candidates; that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances that may result in delay of planned clinical trials, may impose a clinical hold with respect to such product candidate, or may withhold market approval for product candidates; 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 approval and peramivir may never be approved for any use by the FDA; that ongoing and future preclinical and clinical development may not have positive results; that the Company or its licensees may not be able to continue future development of current and future development programs; that such development programs may never result in future product, license or royalty payments being received; 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 8.01. Other Events.

On April 1, 2013, the Company issued a news release announcing the events described in Item 1.01. A copy of the news release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

**Exhibit
No.**

Description

99.1	Press Release dated April 1, 2013 entitled BioCryst Pharmaceuticals Provides Update Regarding Peramivir
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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 1, 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 1, 2013 entitled BioCryst Pharmaceuticals Provides Update Regarding Peramivir