

BIOCRYST PHARMACEUTICALS INC

Form 8-K

December 23, 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) **December 23, 2014**

BioCryst Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-23186
(Commission File Number)

62-1413174
(IRS Employer Identification No.)

4505 Emperor Blvd., Suite 200
Durham, North Carolina
(Address of principal executive offices)

27703
(Zip Code)

Registrant's telephone number, including area code: **(919) 859-1302**

(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:

- 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 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events.

On December 23, 2014, BioCryst Pharmaceuticals, Inc. (the "Company") announced results from a proof-of-concept study of its broad spectrum antiviral BCX4430 for the treatment of experimental Ebola virus infection in rhesus macaques, conducted at the United States Army Medical Research Institute of Infectious Diseases ("USAMRIID").

The primary goal of the study was to assess the effect of BCX4430 treatment on survival through Day 41 in animals infected with Ebola virus. Dosing of placebo or BCX4430 by intramuscular ("i.m.") injection was initiated 30-120 minutes after virus challenge and continued twice a day ("BID") for 14 days.

Animals were dosed with either placebo, 16 mg/kg of BCX4430 BID or 25 mg/kg of BCX4430 BID. Survival at day 41 in the 16 mg/kg group of BCX4430 treated animals was 4 of 6 (66.7%, $p < 0.001$ compared to 0% survival in controls) and 6 of 6 in the 25 mg/kg treated group (100%, $p < 0.001$ compared to controls). The overall survival rate for BCX4430 treated animals at day 41 was 10 of 12 (83%, $p < 0.001$ compared to controls). Preliminary evaluation of the quantity of virus in the blood showed an approximate 3-log reduction in Ebola virus RNA copies/mL of plasma, compared with control animals.

On December 23, 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 99.1 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 are 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 commence as expected additional pre-clinical studies or human clinical trials; that the planned studies may not be successful or may not be successfully completed; that the FDA may require additional studies beyond those planned for BCX4430, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold on BCX4430, or withhold market approval for BCX4430; that the Company may not be able to obtain additional funding for BCX4430 development; that government funding or other contracts for BCX4430 may have certain terms and conditions, including termination provisions, that subject the Company to additional risks; that the Company may lose current funding for the program. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated December 23, 2014 entitled "BioCryst Announces Study Results for BCX4430 in a Non-Human Primate Model of Ebola Virus Infection."

SIGNATURE

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.

BioCryst Pharmaceuticals, Inc.

(Registrant)

/s/ **ALANE BARNES**

Alane Barnes
*Vice President, General Counsel,
and Corporate Secretary*

December 23, 2014

(Date)

EXHIBIT INDEX

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