

BIOCRYST PHARMACEUTICALS INC
Form 8-K
September 07, 2016

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): September 7, 2016

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
(I.R.S. Employer Identification
Number)

**4505 Emperor Blvd., Suite 200, Durham, North
Carolina 27703**

(Address of Principal Executive Offices) (Zip Code)

(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:

- 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))

Item 8.01. Other Events.

On September 7, 2016, BioCryst Pharmaceuticals, Inc. (the “Company”) announced positive results from a proof-of-concept study of its broad spectrum antiviral, BCX4430, for the delayed treatment of Ebola virus infection in rhesus macaques.

The goals of this 28-day study were to assess the effect of different dosing regimens of BCX4430 administered by i.m. injection on survival in rhesus macaques with established Ebola virus disease. The study consisted of three treatment groups of six animals each treated with different BCX4430 dosing schedules and one control group of six animals.

Following inoculation of virus on Day 0, 6 of 6 (100%) animals survived after receiving 100 mg/kg BCX4430 twice on day 2, followed by 25 mg/kg twice daily for an additional nine days, compared to none of 6 controls ($p < 0.001$). Animals treated with the same loading and maintenance dose regimen of BCX4430, but starting on day 3, also showed improved survival (4 of 6, 67%, $p = 0.005$), as did animals treated with 25 mg/kg of BCX4430 twice daily for 14 days starting on day 2 (4 of 6, 67%, $p = 0.005$).

On September 7, 2016, 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 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; and/or that the Company may lose current funding for the program. 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 September 7, 2016 entitled “BioCryst Announces Positive Study Results for BCX4430 Delayed Treatment of Ebola Virus Infection in a Non-Human Primate Model”

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.

Date: September 7, 2016

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

EXHIBIT INDEX

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