

BIOCRYST PHARMACEUTICALS INC

Form 8-K

December 22, 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 22, 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 22, 2014, BioCryst Pharmaceuticals, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has approved RAPIVAB™ (peramivir injection), an intravenous ("i.v.") neuraminidase inhibitor for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days.

RAPIVAB's approval was supported by data from over 2,700 subjects treated with peramivir in 27 clinical trials. In January 2010, Shionogi & Co., Ltd. launched intravenous peramivir in Japan under the name RAPIACTA® and in August 2010, Green Cross Corporation announced that it had received marketing and manufacturing authorization for i.v. peramivir in Korea under the name PeramiFlu®. It is estimated that more than one million patients have received peramivir treatment to date. The recommended dose of RAPIVAB in most adult patients 18 years of age or older with acute uncomplicated influenza is a single 600 mg dose, administered via intravenous infusion for 15 to 30 minutes. RAPIVAB was developed under contract number HHSO10020070032C from the Biomedical Advanced Research and Development Authority, a \$234.8 million contract.

On December 22, 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 our 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 approve peramivir for use in pediatric patients, or that FDA approval for pediatric use may be limited; demand for RAPIVAB in this flu season is unpredictable; the supply of RAPIVAB may be limited; the Company may not be able to successfully commercialize RAPIVAB; and that RAPIVAB may never be purchased by any government entity for stockpiling. 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 22, 2014 entitled "BioCryst's RAPIVAB™ (peramivir injection) Receives FDA Approval for the Treatment of Acute Uncomplicated Influenza"

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

December 22, 2014

(Date)

Alane Barnes

*Vice President, General Counsel,
and Corporate Secretary*

EXHIBIT INDEX

Exhibit No.

99.1

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