

BIOCRYST PHARMACEUTICALS INC

Form 8-K

January 14, 2015

**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) **January 14, 2015**

---

**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))
-

## Item 8.01. Other Events.

On January 14, 2015, BioCryst Pharmaceuticals, Inc. (the "Company") announced that the Committee for Orphan Medicinal Products ("COMP") of the European Medicines Agency ("EMA") issued a positive opinion on the application for orphan drug designation for BCX4161 for the treatment of patients with hereditary angioedema ("HAE"). The European Commission will make a final decision on European Orphan Drug Designation based upon the COMP positive opinion. On December 23, 2014, the U.S. Food and Drug Administration ("FDA") granted orphan drug designation for BCX4161.

On January 14, 2015, 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 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, EMA or similar regulatory agency may refuse to approve subsequent HAE studies, or delay approval of clinical studies which may result in a delay of other planned clinical studies and increased development costs of BCX4161; that regulatory agencies may withhold market approval for BCX4161; that ongoing and future preclinical and clinical development of HAE second generation candidates 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. 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

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press Release dated January 14, 2015 entitled "BioCryst Receives Positive Opinion on European Orphan Drug Designation for BCX4161 for the Treatment of Hereditary Angioedema."

---

**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**

---

**January 14, 2015**

---

(Date)

Alane Barnes

*Vice President, General Counsel,  
and Corporate Secretary*

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press Release dated January 14, 2015 entitled "BioCryst Receives Positive Opinion on European Orphan Drug Designation for BCX4161 for the Treatment of Hereditary Angioedema."