

**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))
-

## 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.**

**Description**

99.1

Press Release dated December 22, 2014 entitled "BioCryst's RAPIVAB™ (peramivir injection)  
Receives FDA Approval for the Treatment of Acute Uncomplicated Influenza"

## **BioCryst's RAPIVAB(TM) (peramivir injection) Receives FDA Approval for the Treatment of Acute Uncomplicated Influenza**

RESEARCH TRIANGLE PARK, N.C., Dec. 22, 2014 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc., (Nasdaq:BCRX) a pharmaceutical company focused on the development and commercialization of treatments for rare and infectious diseases, today 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 is the first neuraminidase inhibitor that has shown to be safe and effective as a single-dose, i.v. therapy for patients with acute, uncomplicated influenza, and represents the first new antiviral treatment for influenza approved by the FDA in 15 years," said Richard Whitley, M.D, University of Alabama at Birmingham. "In a blinded, randomized placebo-controlled trial, a single dose of RAPIVAB alleviated flu symptoms, and reduced fever significantly faster than placebo."

"The approval of RAPIVAB provides a new choice to immediately deliver an effective treatment in one dose to adult patients with influenza," said Jon P. Stonehouse, President & Chief Executive Officer of BioCryst. "This is the first U.S. approval of a BioCryst discovered drug and represents an important milestone for our company. We thank our funding partner BARDA/HHS; the development and approval of RAPIVAB is an excellent example of a successful public/private partnership."

### **About RAPIVAB (peramivir injection)**

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<sup>®</sup> 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<sup>®</sup>. 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 (BARDA/HHS), a \$234.8 million contract.

### **INDICATION & IMPORTANT SAFETY INFORMATION**

#### **Indication**

RAPIVAB is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days.

#### **Contraindications**

None

#### **Warnings and Precautions**

Rare cases of serious skin reactions, including Stevens-Johnson syndrome and erythema multiforme have occurred with RAPIVAB.

Patients with influenza may be at an increased risk of hallucinations, delirium and abnormal behavior early in their illness. There have been post-marketing reports (from Japan) of delirium and abnormal behavior leading to injury in patients with influenza who were receiving neuraminidase inhibitors, including RAPIVAB. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made, but they appear to be uncommon.

Serious bacterial infections may begin with influenza-like symptoms or may coexist with or occur as complications during the course of influenza. RAPIVAB has not been shown to prevent such complications.

#### **Adverse Reactions**

The most common adverse reaction (incidence >2%) is diarrhea (8% RAPIVAB vs. 7% placebo).

Lab abnormalities (incidence >2%) occurring more commonly than placebo were elevated ALT 2.5 times the upper limit of normal (3% vs. 2%), elevated serum glucose greater than 160 mg/dL (5% vs. 3%), elevated CPK more than 6 times the upper limit of normal (4% vs. 2%) and neutrophils less than  $1.0 \times 10^9/L$  (8% vs. 6%).

#### **About BioCryst**

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst currently has several ongoing development programs: oral inhibitors of plasma kallikrein for hereditary angioedema, including BCX4161 and several second generation compounds; and BCX4430, a broad spectrum viral RNA polymerase inhibitor. For more information, please visit the Company's website at [www.BioCryst.com](http://www.BioCryst.com).

## Forward-Looking Statements

This press release 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.

BCRXW

CONTACT: Robert Bennett, BioCryst Pharmaceuticals,  
+1-919-859-7910 (investors)  
Catherine Kyroulis,  
+1-917-886-5586 (media)