
**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): May 24, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On May 24, 2018, BioCryst Pharmaceuticals, Inc. (the “Company”) announced that the European Medicines Agency’s (“EMA”) Committee for Orphan Medicinal Products issued a positive opinion on the Company’s application for orphan designation of BCX7353 for the treatment of hereditary angioedema (“HAE”). In addition, the United Kingdom’s Medicines and Healthcare products Regulatory Agency has granted a Promising Innovative Medicine designation to BCX7353.

On May 24, 2018, the Company issued a news release announcing the events described in this Item 7.01. A copy of the news release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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 developing any HAE product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of HAE drug candidates (including ZENITH-1, APeX-2 and APeX-S) may not have positive results; that the Company may not be able to enroll the required number of subjects in planned clinical trials of product candidates; that the Company may not advance human clinical trials with product candidates as expected; that the U.S. Food and Drug Administration, EMA or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold with respect to such product candidate, or withhold market approval for product candidates. 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

<u>No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release dated May 24, 2018 entitled “BioCryst’s BCX7353 Receives European Regulatory Designations for the Treatment of Hereditary Angioedema”</u>

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: May 24, 2018

By: /s/ Alane Barnes

Alane Barnes
Vice President, General Counsel,
and Corporate Secretary

BioCryst's BCX7353 Receives European Regulatory Designations for the Treatment of Hereditary Angioedema

*EMA Grants Orphan Designation
UK MHRA Grants Promising Innovative Medicine Designation*

RESEARCH TRIANGLE PARK, N.C., May 24, 2018 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX), a pharmaceutical company focused on the development and commercialization of treatments for rare diseases, today announced that the European Medicines Agency's ("EMA") Committee for Orphan Medicinal Products ("COMP") issued a positive opinion on BioCryst's application for orphan designation of BCX7353 for the treatment of hereditary angioedema ("HAE"). In addition, the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") has granted a Promising Innovative Medicine ("PIM") designation to BCX7353.

The positive opinion issued by COMP is expected to be adopted by the European Commission within 30 days. Orphan Drug Designation in Europe is available to companies developing products intended to treat a life-threatening or chronically debilitating condition that affects fewer than five in 10,000 persons in the European Union ("EU"). This designation allows for financial and regulatory incentives that include a 10-year period of marketing exclusivity in the EU after product approval. BCX7353 has previously received Orphan Drug Designation in the United States from the Food and Drug Administration.

A PIM designation is an early indication that a medicinal product is a promising candidate for the Early Access to Medicines Scheme ("EAMS") in the United Kingdom, which supports products intended for the treatment, diagnosis or prevention of a life-threatening or seriously debilitating condition, with the potential to address an unmet medical need.

"We are pleased to receive these important regulatory designations granted to BCX7353. These provide further support for the potential for BCX7353 to address a clear unmet medical need with an oral treatment for patients with HAE," said Jon P. Stonehouse, President & Chief Executive Officer.

About BCX7353

Discovered by BioCryst, BCX7353 is a novel, oral, once-daily, selective inhibitor of plasma kallikrein currently in development for the prevention and treatment of angioedema attacks in patients diagnosed with HAE. BCX7353 has been generally safe and well tolerated in the Phase 2 APeX-1 clinical trial. BioCryst is currently conducting the Phase 3 APeX-2 clinical trial and the long-term safety APeX-S clinical trial, both evaluating two dosage strengths of BCX7353 administered orally once-daily as a preventive treatment to reduce the frequency of attacks in patients with HAE. BioCryst is also conducting the ZENITH-1 clinical trial. ZENITH-1 is a proof-of-concept Phase 2 clinical trial testing an oral liquid formulation of BCX7353 for the treatment of acute angioedema attacks.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small-molecule medicines that address both common and rare conditions. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, galidesivir, a potential treatment for filoviruses, and a preclinical program to develop oral Alk-2 inhibitors for the treatment of fibrodysplasia ossificans progressive ("FOP"). RAPIVAB[®] (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. For more information, please visit the Company's website at 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 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 developing any HAE product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of HAE drug candidates (including ZENITH-1, APeX-2 and APeX-S) may not have positive results; that BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates; that the Company may not advance human clinical trials with product candidates as expected; that the FDA, EMA or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold with respect to such product candidate, or withhold market approval for product candidates. 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.

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