

BIOCRYST PHARMACEUTICALS INC

Form 8-K

December 18, 2013

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 18, 2013

BioCryst Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-23186
(Commission

File Number)
4505 Emperor Blvd., Suite 200

62-1413174
(IRS Employer

Identification No.)

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Durham, North Carolina 27703

(Address of Principal Executive Offices)

(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 (see General Instruction A.2 below):

- .. 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 210.14d-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 18, 2013, BioCryst Pharmaceuticals, Inc. (the Company) announced that it has selected two optimized plasma kallikrein inhibitors to advance into preclinical development as potential once-daily, oral treatments for the prevention of hereditary angioedema (HAE) attacks.

The second generation discovery program's goals of improving selectivity and bioavailability compared to BCX4161 were both met, with no effect on prothrombin time at high concentrations (>50 micromolar), and oral fraction absorbed exceeding 25%. Similar to BCX4161, these BioCryst discovered compounds demonstrate sub-nanomolar potency on the isolated enzyme and single digit nanomolar potency in suppressing kallikrein activity in an ex vivo activated human plasma kallikrein inhibition (aPKI) assay. Plasma concentrations of each of the optimized compounds exceeded the aPKI assay EC₈₀ concentration at 24 hours after a single oral dose of 10 mg/kg in rats, indicating suitability for once-daily dosing.

On December 18, 2013, 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 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 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 ongoing and future preclinical and clinical development of BCX4161 and HAE second generation candidates may not have positive results; that either or both second generation candidates may not advance beyond preclinical development; that BioCryst may not be able to enroll the required number of subjects in the Phase 2a clinical trial of BCX4161; that the Phase 2a trial of BCX4161 may not have a favorable outcome or may not be successfully completed; that the Phase 2a trial may cost more or take longer to complete than expected; that the FDA or similar regulatory agency may refuse to approve subsequent studies, or delay approval of clinical studies, which may result in a delay of planned clinical studies and increase development costs of a product candidate; that the FDA may withhold market approval for product candidates; 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; that the Company may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Description

**Exhibit
No.**

99.1 Press Release dated December 18, 2013 entitled BioCryst Advances Second Generation Oral Plasma Kallikrein Inhibitors for Hereditary Angioedema into Preclinical Development

SIGNATURES

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.

Dated: December 18, 2013

BioCryst Pharmaceuticals, Inc.

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

EXHIBIT INDEX

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