BIOCRYST PHARMACEUTICALS INC
Form 8-K
January 08, 2016

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 8, 2016

BioCryst Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-23186**	**62-1413174**
(State or Other Jurisdiction of Incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

4505 Emperor Blvd., Suite 200
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 7.01. Regulation FD Disclosure.

BioCryst has previously reported results from a Phase 1 study of healthy volunteers (NCT02448264). At that time, a total of 34 subjects had received single doses and 40 subjects had received multiple doses of BCX7353. Subsequently, cohorts of healthy Japanese volunteers were added to the study to support development of BCX7353 in Japan under the Sakigake accelerated R&D designation. Following assessment of single oral doses of BCX7353 of 100 mg (6 subjects) and 500 mg (6 subjects), 250 mg of BCX7353 was administered orally and daily for seven days to ten subjects. Compared to Western subjects administered the same dose level, plasma drug levels in Japanese subjects were moderately higher. Kallikrein inhibition on day seven of daily dosing with 250 mg in Japanese subjects was similar to that seen at the 350 mg daily and 500 mg daily dose levels in Western subjects.

Oral BCX7353 has been generally safe and well tolerated in a total of 96 Western and Japanese healthy volunteers treated, 46 with single doses and 50 with multiple doses. Dose levels have included single doses of up to 1000 mg, once-daily doses of up to 500 mg for seven days, and once-daily doses of 350 mg for 14 days. No serious adverse events have been seen and no dose-limiting toxicity has been identified. There have been no clinically significant laboratory abnormalities, ECG changes, or vital sign changes observed.

In single dose subjects, 89% (31 of 35) of adverse events (AEs) have been grade 1. The four grade 2 AEs observed were: nausea (1) and vomiting (1) occurring in one subject; hay fever (1); and diarrhea (1, from Japanese cohort).

In multiple dose subjects, 90% (63 of 70) of adverse events (AEs) have been grade 1. The six grade 2 AEs observed were: upper abdominal pain (1, discontinued from study); syncope (1); headache (1); diarrhea (1) and upper abdominal pain (1) occurring in one subject (discontinued from study), and maculopapular rash (1, from Japanese cohort, described below). One grade 3 AE was observed, cutaneous delayed-type hypersensitivity reaction, described below.

The incidence of drug-related skin rash across all multiple-dose cohorts was 4% (2 of 50 subjects). One Japanese subject dosed at 250 mg daily for seven days developed a grade 2 maculopapular skin rash following cessation of dosing, and one previously reported Western subject dosed at 500 mg daily for seven days developed a grade 3 hypersensitivity reaction, described as a maculopapular skin rash, following cessation of dosing. Both AEs were assessed by the investigator as drug-related. The Japanese subject received antihistamines and the Western subject received corticosteroids, and in both cases the rash resolved within a few days.

In early 2016, BioCryst intends to begin a proof-of-concept randomized placebo-controlled trial of BCX7353 in hereditary angioedema (HAE) patients, APeX-1, and report results in mid-2016.

BioCryst recently initiated dosing of subjects in OPuS-4, a long-term safety study of avoralstat (BCX4161). OPuS-4 is a single arm, open-label study to evaluate the long-term safety of avoralstat prophylaxis in HAE subjects who have completed previous studies of avoralstat, and in new subjects for whom oral prophylaxis is considered appropriate. Eligible subjects will receive the top dose of 500 mg three times a day that is being evaluated in the OPuS-2 study. Subjects will be eligible to receive study drug for as long as they are deemed to derive clinical benefit with an acceptable safety profile, or until the product receives regulatory approval. The study will evaluate the long-term safety and tolerability of avoralstat administered as oral prophylaxis in subjects with HAE, assess HAE attack frequency, severity and disease activity, and evaluate changes in quality of life during long-term treatment. Further details of the study will be posted on www.clinicaltrials.gov.

The information furnished in this Item 7.01 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.

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: January 8, 2016 **BioCryst Pharmaceuticals, Inc.**

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