
**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): February 27, 2017

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))
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Item 8.01. Other Events.

On February 27, 2017, BioCryst Pharmaceuticals, Inc. (the “Company”) announced positive results from an interim analysis of its Phase 2 APeX-1 trial in hereditary angioedema (“HAE”). APeX-1 is a dose ranging trial designed to evaluate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of orally administered once daily BCX7353 for 28 days, as a preventative treatment to reduce the frequency of attacks in HAE patients.

On February 27, 2017, 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 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: developing any HAE drug candidate may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of HAE second generation drug candidates (including APeX-1) 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 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; that BioCryst may not receive additional government funding to further support the development of galidesivir; that galidesivir development may not be successful; that BARDA and/or NIAID may further condition, reduce or eliminate future funding; that revenue from peramivir is unpredictable and commercialization of peramivir may never result in significant revenue for the Company; that the Company may not be able to continue development of ongoing and future development programs; that such development programs may never result in future products; that actual financial results may not be consistent with expectations, including that 2017 operating expenses and cash usage may not be within management’s expected ranges. 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 February 27, 2017 entitled “BioCryst Reports Positive Interim Results from its APeX-1 Trial”

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: February 27, 2017

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 27, 2017 entitled "BioCryst Reports Positive Interim Results from its APeX-1 Trial"

BioCryst Reports Positive Interim Results from its APeX-1 Trial

Reduction of 63% in overall attack rate in HAE patients with severe disease (p=0.006)

RESEARCH TRIANGLE PARK, N.C., Feb. 27, 2017 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) today announced results from an interim analysis of its Phase 2 APeX-1 trial in hereditary angioedema (HAE). APeX-1 is a dose ranging trial designed to evaluate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of orally administered once daily (QD) BCX7353 for 28 days, as a preventative treatment to reduce the frequency of attacks in HAE patients.

“The results of this interim analysis are extraordinarily encouraging,” said Dr. Emel Aygören-Pürsün, MD, principal investigator for the APeX-1 trial and Head of Interdisciplinary Competence Center for Hereditary Angioedema, and Specialist in Internal Medicine and Hemostaseology Department of Child and Adolescent Medicine, Goethe University Hospital Frankfurt. “Confirmation of the results would lead to a huge step forward in the treatment of hereditary angioedema, towards an effective, safe and easy to administer prophylaxis for the debilitating attacks connected with this condition.”

“We are extremely excited to have such a strong treatment effect in reducing HAE attacks with our once daily oral therapy,” said Jon Stonehouse, Chief Executive Officer & President of BioCryst. “What is even more encouraging is the dramatic benefit seen in the reduction of peripheral attacks and mixed peripheral and abdominal attacks. A once daily oral therapy with an 88% reduction in these attacks has the potential to make a huge difference in HAE patients’ lives.”

Twenty-eight subjects, randomized equally to receive BCX7353 350 mg QD or placebo for 28 days, were included in the interim analysis. The baseline attack rate was approximately 1/week, and average C1 inhibitor levels were less than 20% of the normal mean, indicating a severely affected patient population. Baseline characteristics were generally well balanced between the two groups with the exception of prior androgen use, which was more common in the BCX7353 group (11 of 14 compared with 6 of 14 on placebo). Compliance with study drug dosing was excellent (> 98%).

The pre-specified per-protocol (PP) interim analysis included data on 24 subjects with confirmed Type 1 or Type 2 HAE completing 28 days of treatment (11 treated with BCX7353 and 13 with placebo). The mean rate of independently-adjudicated angioedema attacks for the pre-defined effective dosing period (weeks 2 through 4) in BCX7353-treated subjects was 0.34/week compared to 0.92/week for placebo, a reduction of 0.57/week (63%), $p = 0.006$. In the intent-to-treat (ITT) population of 28 subjects, the rates of attacks for the effective dosing period for BCX7353 and placebo groups were 0.44/week and 0.91/week, a reduction of 0.47/week (52%), $p = 0.035$.

A pre-planned analysis of peripheral and abdominal attacks showed reductions of 88% and 24%, respectively, for BCX7353 compared with placebo (PP analysis, weeks 2 through 4). To understand this difference, patient diaries were reviewed and abdominal attacks ($n = 9$, BCX7353 and $n = 14$, placebo) were subdivided into two groups: attacks with abdominal symptoms only and attacks with a combination of abdominal and peripheral symptoms (mixed attacks). This post-hoc analysis showed that there were 2, 2 and 7 peripheral, mixed and abdominal-only attacks on BCX7353 compared with 22, 12 and 2 attacks, respectively, for placebo. Based on this distribution, it is likely that subjects recorded transient abdominal adverse events as HAE attack symptoms in their diary.

Steady state BCX7353 plasma levels in HAE subjects were similar to those in healthy subjects administered the same dose in a previously completed Phase 1 trial. Steady state trough drug levels (24 hours after dosing) were 11 – 32 times the 50% effective concentration (EC_{50}) for plasma kallikrein inhibition.

Daily oral dosing with BCX7353 strongly inhibited plasma kallikrein throughout the 24 hour dosing interval; the degree of inhibition was similar to that seen with this dose in the healthy subject Phase 1 trial.

Oral BCX7353 350 mg once-daily for 28 days was generally safe and well tolerated in subjects with HAE. There were no serious adverse events (AEs) and no related severe AEs. Two subjects in the BCX7353 treatment group discontinued study drug before day 28, one due to an unrelated pre-existing condition, and one due to an adverse event of gastroenteritis associated with elevated liver enzymes. Treatment-emergent adverse events occurring in at least 2 subjects overall, enumerated by treatment group (BCX7353 [$n=14$] and placebo [$n=14$]), were: common cold (3, 4); diarrhea (4, 2); flatulence (2, 0); and fatigue (2, 0).

No clinically significant changes in hematology parameters, renal function tests, electrolytes, or urinalysis were observed. One subject treated with BCX7353, with pre-existing colitis, hepatic steatosis (fatty liver) and more than 20 years of prior androgen use, had an elevation of alanine aminotransferase (ALT) > 3 times the upper limit of normal at the end of treatment, which resolved.

The efficacy, safety and tolerability profile of BCX7353 observed in this interim analysis strongly supports its continued investigation as a prophylactic treatment for HAE. The steady state drug levels observed far exceeded the proposed therapeutic target range of 4 – 8 times the EC_{50} , supporting evaluation of lower doses. Therefore, the APeX-1 trial has been amended to add a 62.5 mg QD dose level and to increase the number of subjects at the 125 mg QD and 250 mg QD dose levels, in order to more fully characterize dose response.

Conference Call and Webcast

BioCryst's leadership team will host a conference call and webcast with Dr. Emel Ayyören-Pürsün, MD and Prof. Bruce Zuraw, MD, Division Chief, Professor of Medicine UC San Diego School of Medicine and Director of the U.S. HAEA Angioedema Center today, February 27, 2017 at 9:00 a.m. Eastern Time, to discuss its APeX-1 interim analysis and to respond to questions on the APeX-1 interim results and the Company's full year 2016 financial results. To participate in the conference call, please dial 1-877-303-8027 (United States) or 1-760-536-5165 (International). No passcode is needed for the call. The webcast can be accessed by logging onto www.BioCryst.com. Please connect to the website at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary.

About BioCryst Pharmaceuticals

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: BCX7353 and second generation oral inhibitors of plasma kallikrein for hereditary angioedema, and galidesivir, a broad spectrum viral RNA polymerase inhibitor that is a potential treatment for filoviruses. Peramivir, a viral neuraminidase inhibitor, is approved for the treatment of influenza, in the U.S., Canada, Japan, Taiwan and Korea. Post-marketing commitment development activities are ongoing, as well as other activities to support additional peramivir regulatory approvals. For more information, please visit the Company's website at www.BioCryst.com.

Forward-Looking Statements

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