

BIOCRYST PHARMACEUTICALS INC

Form 8-K

March 20, 2012

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): March 19, 2012

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
(IRS Employer

Identification No.)

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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

On March 19, 2012, BioCryst Pharmaceuticals, Inc. (BioCryst or the Company) reports that it has filed a suggestion with the United States Patent & Trademark Office (USPTO) to declare an interference to remedy the apparent error made by the USPTO when it issued US Patent 8,119,607 to Biota Holdings Limited containing a claim that covers the structure of BCX5191, a BioCryst discovered nucleoside analog hepatitis C viral RNA polymerase (NS5B) inhibitor. BioCryst's patent application covering BCX5191 is PCT/US2008/050929, having an international filing date of January 11, 2008 and claiming priority to U.S. Provisional Application Number 60/880,278, dated January 12, 2007, was filed approximately 18 months prior to Biota's application. At least with respect to the hepatitis C inhibitor BCX5191 discovered and being developed by BioCryst, the Company believes the Biota patent was improvidently granted by the USPTO.

An interference action is a proceeding within the USPTO which arises when two or more pending applications, or at least one pending application and an unexpired patent, contain claims covering the same or substantially the same subject matter. The Board of Patent Appeals and Interferences (Board) will formally consider the issue only after the USPTO declares the interference as BioCryst suggested in its filing today. Statistics available on the USPTO website indicate that during fiscal year 2011 interferences were concluded on average at about nine months. Because BioCryst filed its patent application prior to Biota's filing, BioCryst expects to be the senior party in the process at the USPTO and expects to prevail. BioCryst intends to pursue its interests vigorously to seek a resolution. BioCryst has hired the Finnegan Henderson law firm as its legal counsel to represent it in any interference before the USPTO.

BioCryst plans to initiate its IND-enabling GLP toxicology studies of BCX5191 soon, and remains committed to the development plan announced on February 16, 2012. This plan also includes comparative pharmacology studies and in vitro evaluations of BCX5191 in combination with other hepatitis C drugs, such as Ribavirin. The Company expects to begin first-in-human studies before the end of 2012.

This 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 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 there can be no assurance that our compounds will prove effective in clinical studies; that BioCryst or its licensees may not commence as expected human clinical trials with BCX5191; that the patent proceedings will take longer or will not turn out as expected; that ongoing and future preclinical and clinical development may not have positive results; that we or our licensees may not be able to continue future development of our current and future development programs; that our development programs may never result in future product, license or royalty payments being received by BioCryst; that BioCryst may not have sufficient cash to continue funding the development, manufacturing, marketing or distribution of its products and that additional funding, if necessary, may not be available at all or on terms acceptable to BioCryst. 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 our projections and forward-looking statements.

The information in this report is furnished and 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: March 19, 2012

BioCryst Pharmaceuticals, Inc.

By: /s/ Alane Barnes

Alane Barnes

Vice President, General Counsel and Corporate Secretary