BIOCRYST PHARMACEUTICALS INC
Form 8-K
June 17, 2015

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): **June 16, 2015**

BioCryst Pharmaceuticals, Inc.

(Exact name of registrant as specified in its 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)	(Zip Code)

Registrant's telephone number, including area code: **(919) 859-1302**

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(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))

Item 1.01. Entry into a Material Definitive Agreement.

On June 16, 2015, BioCryst Pharmaceuticals, Inc. ("we" or the "Company") and Seqirus UK Limited, a limited company organized under the laws of the UK ("SUL") and a subsidiary of CSL Limited, a company organized under the laws of Australia ("CSL"), entered into a License Agreement (the "Agreement") granting SUL and its affiliates worldwide rights to develop, manufacture and commercialize RAPIVAB® (peramivir injection) for the treatment of influenza except for the rights to conduct such activities in Israel, Japan, Korea and Taiwan (the permitted geographies together constituting, the "Territory"). RAPIVAB® is an intravenous treatment for acute uncomplicated influenza and is currently licensed for use in the United States, Japan and Korea. RAPIVAB® is the first and only intravenous influenza treatment in the world and was approved by the U.S. Food and Drug Administration (the "FDA") in December 2014 for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days. Under the terms of the Agreement, SUL obtains worldwide rights to commercialize RAPIVAB®, with the exception of Japan, Korea, Taiwan and Israel. The Company retains all rights and associated economics to procure pandemic stockpiling orders for RAPIVAB® from the U.S. government, while SUL has the right to pursue government stockpiling outside the U.S.

Pursuant to the Agreement, RAPIVAB® will be commercialized by CSL's subsidiary, bioCSL, which specializes in influenza prevention through the supply of seasonal and pandemic vaccine to global markets. bioCSL will manufacture, commercialize and exercise decision-making authority with respect to the development and commercialization of RAPIVAB® within the Territory and be responsible for all related costs, including sales and promotion. We will exercise sole decision-making authority with regard to the development and commercialization of RAPIVAB® outside of the Territory and are responsible for all associated costs.

In December 2013, we submitted a New Drug Application ("NDA") to the FDA. Under the terms of the Agreement, we are responsible for fulfilling all post-marketing approval commitments in connection with the FDA's approval of the NDA, and upon fulfillment we will transfer ownership of and financial responsibility for the NDA to SUL. Pursuant to potential rights to sell RAPIVAB® in Canada and the European Union, we are also responsible for regulatory filings and interactions with the Health Products and Food Branch of Health Canada ("Health Canada") and the European Medicines Agency ("EMA") until marketing approval for RAPIVAB® is obtained and assigned to SUL. In accordance with the Agreement, we and SUL will also form a joint steering committee, composed of an equal number of representatives from each party, to oversee, review and coordinate the conduct and progress of the commercialization of RAPIVAB® in the Territory and any additional development.

Under the terms of the Agreement, we will receive an upfront payment of $33.7 million, and we may receive up to $12.0 million in additional payments related to the successful achievement of regulatory milestones, including marketing approval (i) by the FDA for a pediatric indication, (ii) by the EMA for an adult indication in the European Union and (iii) by Health Canada for an adult indication in Canada. We are also entitled under the Agreement to receive tiered royalties at a percentage rate beginning in the mid-teens contingent upon meeting minimum thresholds of net sales, as well as a low-thirties percentage of the gross profit from stockpiling purchases made outside the United States. Specifically, we receive tiered royalties at a percentage rate in the mid-teens to low-forties on net sales in the United States during a calendar year and tiered royalties at a percentage rate in the mid-teens to mid-twenties on net sales in the Territory, other than in the United States, during a calendar year, each subject to certain downward adjustments for circumstance or events impacting the overall market opportunity. SUL's royalty payment obligations commence on the date of the Agreement and expire, on a country-by-country basis, upon the later of (i) the expiration of legal exclusivity in such country and (ii) ten years from the date of the Agreement (the "Royalty Term").

The term of the Agreement shall continue on a country-by-country basis until the expiration of the last-to-expire Royalty Term in any such country in the Territory. Either party may terminate the Agreement in its entirety if the other party breaches a payment obligation, otherwise materially breaches the Agreement, subject to applicable cure periods, or if the other party suffers an insolvency event. We may also terminate the Agreement if SUL or any of its affiliates seek to challenge the validity of the Company's patents. Termination does not affect a party's rights which

have accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations exercised by the Company, the Agreement provides for the termination of any sublicenses granted by SUL to third parties, and in the case of termination by the Company for cause, the ceasing of SUL's activities with respect to RAPIVAB®, the discontinued use of all Company intellectual property and the termination of licenses and rights previously granted to SUL. If requested by the Company, SUL shall also promptly sell to the Company all licensed product it then holds in stock, otherwise, SUL may continue to sell such licensed product for designated periods.

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 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: our commercialization efforts and the commercialization efforts of our licensees may not achieve ultimate success; the costs and effort associated with meeting regulatory requirements, including post-marketing requirements in the United States and obtaining regulatory approval in the various geographies in which we wish to sell our product; the costs of our ongoing and future preclinical and clinical development and the inherent uncertainty of such development; that such development programs may never result in future product, license or royalty payments being received; and that we and SUL may not achieve, with respect to RAPIVAB®, the royalties and sales that we each anticipate under the Agreement. Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically our 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.

Item 8.01. Other Events.

On June 17, 2015, the Company issued a news release announcing the events described in Item 1.01. A copy of the news release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated June 17, 2015 entitled "BioCryst Licenses Worldwide Rights to Commercialize RAPIVAB® Influenza Treatment to CSL Limited."

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.

(Registrant)

June 17, 2015

(Date)

/s/ ALANE BARNES

Alane Barnes
Vice President, General Counsel, and Corporate Secretary

EXHIBIT INDEX

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