

**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): August 27, 2021**

**BIOCRYSST PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation)

**000-23186**  
(Commission File Number)

**62-1413174**  
(I.R.S. Employer Identification No.)

**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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	BCRX	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

### Item 1.01. Entry into a Material Definitive Agreement.

On August 27, 2021, BioCryst Pharmaceuticals, Inc. (the “Company”) entered into an amendment (the “Amendment”) to its contract dated September 1, 2018 with the Department of Health and Human Services (“HHS”) for the procurement of the Company’s approved antiviral influenza therapy, RAPIVAB® (peramivir injection). Pursuant to the Amendment, HHS exercised Option Period 3 under the contract to purchase an additional 10,000 doses of RAPIVAB during the period of September 1, 2021 through August 31, 2022 for a total price of approximately \$6.9 million. This description of the Amendment is qualified in its entirety by reference to the full text of the Amendment filed as Exhibit 10.1 to this Current Report on Form 8-K.

### Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding sales of RAPIVAB. These statements involve known and unknown risks, uncertainties, and other factors which may cause actual sales to be materially different from those 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: the U.S. government may purchase smaller quantities of RAPIVAB than currently anticipated, or none at all; the Company relies on third-party manufacturers to manufacture RAPIVAB in a timely manner and in accordance with applicable governmental regulations, and any failure of such third-party manufacturers to perform their obligations could impact the Company’s ability to supply RAPIVAB pursuant to the government contract; government contracts contain certain terms and conditions, including termination provisions, that subject the Company to additional risks; and the ongoing COVID-19 pandemic, which could create challenges in all aspects of the Company’s business, including without limitation delays, stoppages, difficulties, and increased expenses with respect to the Company’s and its partners’ supply chains, negatively impact the Company’s ability to access the capital or credit markets to finance its operations, or have the effect of heightening the other risks described herein or in the documents the Company files periodically with the Securities and Exchange Commission. Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically the Company’s most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, which identify important factors that could cause actual results to differ materially from those contained in the Company’s forward-looking statements.

### Item 7.01. Regulation FD Disclosure.

On September 1, 2021, the Company issued a news release announcing the events described in Item 1.01 of this Current Report on Form 8-K. A copy of the news release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

The information contained in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">10.1</a>	<a href="#">Amendment, dated August 27, 2021, to the Contract dated September 1, 2018 between BioCryst Pharmaceuticals, Inc. and the Department of Health and Human Services</a>
<a href="#">99.1</a>	<a href="#">Press release dated September 1, 2021 entitled “U.S. Government Exercises Option to Purchase Additional RAPIVAB® (peramivir injection) from BioCryst for Delivery to Strategic National Stockpile”</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: September 1, 2021

By: /s/ Alane Barnes

Alane Barnes

Senior Vice President and Chief Legal Officer

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE	PAGE OF PAGES 1 2
2. AMENDMENT/MODIFICATION NO. P00004	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS281551	5. PROJECT NO. (If applicable)
6. ISSUED BY ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	CODE ASPR/SNS	7. ADMINISTERED BY (If other than Item 6)	CODE
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) BIOCRYST PHARMACEUTICALS, INC. 4505 EMPEROR BLVD STE 200 DURHAM NC 277038457		(x) 9A. AMENDMENT OF SOLICITATION NO.	9B. DATED (SEE ITEM 11)
CODE 726613	FACILITY CODE	x 10A. MODIFICATION OF CONTRACT/ORDER NO. 75D30118C02984	10B. DATED (SEE ITEM 13) 08/30/2018

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended.  is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
2021.199SN21.26088 Net Increase: \$6,932,000.00

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)
X	52.217-7 Option for Increased Quantity (March 1989)

**E. IMPORTANT:** Contractor  is not  is required to sign this document and return 1 copies to the issuing office.



14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  
Tax ID Number: 62-1413174  
DUNS Number: 618194609  
This modification is issued to make the following changes:

A. In accordance with FAR 52.217-7 entitled Option for Increased Quantity (March 1989), the Government hereby exercises Option Year 3 for the period of September 1, 2021 - August 30, 2022.

B. Contract Line Item 0004 is hereby exercised in the amount of \$6,932,000.00 and made part of this contract.

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) Jon P. Stonehouse, CEO	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) KIMBERLY L. GOLDEN
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)	15C. DATE SIGNED 8/27/21
16B. UNITED STATES OF AMERICA  (Signature of Contracting Officer)	16C. DATE SIGNED 8/27/21

Previous edition unusable

NAME OF OFFEROR OR CONTRACTOR  
 BIOCRYST PHARMACEUTICALS, INC. 726613

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
4	<p>C. The original contract value for Base &amp; Options is \$34,660,000.00. The contract funded amount is increased by \$6,932,000.00 (Option Year 3). FROM: \$6,932,000.00 (Base Year) to \$6,932,000.00 (Option Year 1), \$6,932,000.00, (Option Year 2) \$6,932,000.00, (Option Year 3) \$6,932,000.00, totaling \$27,728,000.00 (Base + options Yrs. 1-3); (Unfunded amount) \$6,932,000.00</p> <p>D. CLIN 0004 is fully funded.</p> <p>Contracting Specialist: Demetrius Kittrell;            Demetrius.Kittrell@hhs.gov; 202-379-8256            Contracting Officer: Kimberly Golden;ixm8@cdc.gov, 770-488-2672            COR: Cornelious Martin; ioq8@cdc.gov; 404.639.0840            Vendor Representative: Ray Taylor;            rtaylor@biocryst.com; 919.641.4550            Appr. Yr.: 2021 CAN: 199SN21 Object Class: 26088            Period of Performance: 09/01/2021 to 08/31/2022</p> <p>Add Item 4 as follows:</p> <p>Peramivir            RAPIVAB 200mg 20ml vial - 3 doses per package)            Quantity- 10,000 Packages            Unit Price- \$693.20            Obligated Amount: \$6,932,000.00</p>				6,932,000.00

## U.S. Government Exercises Option to Purchase Additional RAPIVAB® (peramivir injection) from BioCryst for Delivery to Strategic National Stockpile

RESEARCH TRIANGLE PARK, N.C., Sept. 01, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the U.S. Department of Health and Human Services (HHS) has exercised its option to purchase an additional 10,000 doses of BioCryst's antiviral influenza therapy, RAPIVAB® (peramivir injection), for approximately \$7 million.

The RAPIVAB purchase by the HHS Office of the Assistant Secretary for Preparedness and Response will supply the Strategic National Stockpile (SNS), the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency.

"The Strategic National Stockpile is an important line of defense in our efforts to ensure availability of critical medical assets to protect the health of Americans in the event of a public health emergency. We are pleased to provide additional doses of RAPIVAB to the SNS as we enter another influenza season of unpredictable severity," said Dr. William Sheridan, chief medical officer of BioCryst.

The order is part of a \$34.7 million contract (Contract No. 75D301-18-C-02984) the Centers for Disease Control and Prevention awarded in 2018 for the procurement of up to 50,000 doses of RAPIVAB over a five-year period for the SNS. With the fulfillment of this new order, BioCryst will have delivered 40,000 doses under the contract.

### About RAPIVAB® (peramivir injection)

RAPIVAB® (peramivir injection) is approved in the United States for the treatment of acute uncomplicated influenza in patients six months and older who have been symptomatic for no more than two days. It is administered via an intravenous infusion for a minimum of 15 minutes at recommended doses of 600 mg/kg for adults and adolescents and 12 mg/kg for pediatric patients ages six months to 12 years. Efficacy of RAPIVAB is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus and a limited number of patients infected with influenza B virus. Visit <http://www.rapivab.com> to learn more.

### U.S. Indication and Important Safety Information

#### Indication

RAPIVAB is indicated for the treatment of acute uncomplicated influenza in patients 6 months and older who have been symptomatic for no more than 2 days.

#### Limitations of Use

- Efficacy of RAPIVAB is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus; a limited number of subjects infected with influenza B virus were enrolled.
- Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use RAPIVAB.
- The efficacy of RAPIVAB could not be established in patients with serious influenza requiring hospitalization.

#### Contraindications

RAPIVAB is contraindicated in patients with known serious hypersensitivity or anaphylaxis to peramivir or any component of the product. Severe allergic reactions have included anaphylaxis, erythema multiforme and Stevens-Johnson Syndrome.

#### Warnings and Precautions

- Cases of anaphylaxis and serious skin/hypersensitivity reactions such as Stevens-Johnson syndrome and erythema multiforme have occurred with RAPIVAB. Discontinue RAPIVAB and initiate appropriate treatment if anaphylaxis or serious skin reaction occurs or is suspected.
- Neuropsychiatric events: Patients with influenza may be at an increased risk of hallucinations, delirium and abnormal behavior early in their illness. Monitor for signs of abnormal behavior.
- Serious bacterial infections may begin with influenza-like symptoms or may coexist with or occur as complications during the course of influenza. RAPIVAB has not been shown to prevent such complications.

#### Adverse Reactions

The most common adverse reaction in adults (18 years of age and older) was diarrhea (8% RAPIVAB vs 7% placebo). Lab abnormalities (incidence  $\geq 2\%$ ) occurring more commonly with RAPIVAB than placebo were elevated ALT  $> 2.5$  times the upper limit of normal (3% vs 2%), elevated serum glucose  $> 160$  mg/dL (5% vs 3%), elevated CPK at least 6 times the upper limit of normal (4% vs 2%), and neutrophils  $< 1.0 \times 10^9/L$  (8% vs 6%). In a subset of subjects with serious influenza requiring hospitalization treated with RAPIVAB 600 mg as monotherapy (N=101), the following adverse reactions were also reported more

frequently with RAPIVAB as compared to placebo: constipation (4% versus 2%), insomnia (3% versus 0%), AST increased (3% versus 2%), and hypertension (2% versus 0%).

The safety profile of RAPIVAB in subjects 6 months to 17 years of age was generally similar to that observed in adults. The only adverse reaction reported in pediatric subjects treated with RAPIVAB (occurring in  $\geq 2\%$  of subjects) and not reported in adults was vomiting (3% versus 9% for oseltamivir). The only clinically significant laboratory abnormality (DAIDS Grade 2) occurring in  $\geq 2\%$  of pediatric subjects treated with RAPIVAB (and not previously reported in adults) was proteinuria by dipstick analysis (3% versus 0% for oseltamivir).

#### **Concurrent Use With Live Attenuated Influenza Vaccine**

Antiviral drugs may inhibit viral replication of a live attenuated influenza vaccine (LAIV) and thus may reduce vaccine efficacy. The concurrent use of RAPIVAB with LAIV intranasal has not been evaluated. Avoid use of LAIV within 2 weeks before or 48 hours after administration of RAPIVAB, unless medically indicated.

#### **Please see full prescribing information for RAPIVAB.**

You are encouraged to report negative side effects of prescription drugs to the FDA. To report suspected adverse reactions, contact BioCryst Pharmaceuticals at 1-833-633-2279 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

#### **About BioCryst Pharmaceuticals**

BioCryst Pharmaceuticals discovers novel, oral, small-molecule medicines that treat rare diseases in which significant unmet medical needs exist and an enzyme plays a key role in the biological pathway of the disease. Oral, once-daily ORLADEYO<sup>®</sup> (berotralstat) is approved in the United States, the European Union, Japan and the United Kingdom. BioCryst has several ongoing development programs including BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, BCX9250, an ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva, and galidesivir, a potential treatment for Marburg virus disease and Yellow Fever. RAPIVAB<sup>®</sup> (peramivir injection) has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan and Korea. Post-marketing commitments for RAPIVAB are ongoing. For more information, please visit the company's website at [www.biocryst.com](http://www.biocryst.com).

#### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding sales of RAPIVAB. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual sales to be materially different from those 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: the U.S. government may purchase smaller quantities of RAPIVAB than currently anticipated, or none at all; BioCryst relies on third-party manufacturers to manufacture RAPIVAB in a timely manner and in accordance with applicable governmental regulations, and any failure of such third-party manufacturers to perform their obligations could impact BioCryst's ability to supply RAPIVAB pursuant to the government contract; government contracts contain certain terms and conditions, including termination provisions, that subject BioCryst to additional risks; and the ongoing COVID-19 pandemic, which could create challenges in all aspects of BioCryst's business, including without limitation delays, stoppages, difficulties, and increased expenses with respect to BioCryst's and its partners' supply chains, negatively impact BioCryst's ability to access the capital or credit markets to finance its operations, or have the effect of heightening the other risks described herein or in the documents BioCryst files periodically with the Securities and Exchange Commission. 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 forward-looking statements.

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