

**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 6, 2019

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))

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 2.02. Results of Operations and Financial Condition.

On August 6, 2019, BioCryst Pharmaceuticals, Inc. (the “Company”) issued a news release announcing recent corporate developments and its financial results for the quarter ended June 30, 2019, which also referenced a conference call and webcast to discuss these recent corporate developments and financial results. A copy of the news release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

The information furnished on Exhibit 99.1 is incorporated by reference under this Item 7.01 as if fully set forth herein.

The information furnished 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 [Press release dated August 6, 2019 entitled “BioCryst Reports Second Quarter 2019 Financial Results”](#)

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: August 6, 2019

By: /s/ Alane Barnes

Alane Barnes

Senior Vice President and Chief Legal Officer

BioCryst Reports Second Quarter 2019 Financial Results

—*New drug application for once-daily oral BCX7353 for prophylaxis of hereditary angioedema attacks on-track for submission in Q4 2019*—

—*Data from ongoing Phase 1 trial of oral Factor D inhibitor, BCX9930, expected in Q4 2019*—

RESEARCH TRIANGLE PARK, N.C., Aug. 06, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced financial results for the second quarter ended June 30, 2019 and provided a corporate update.

“We have just returned from the 2019 HAEA National Patient Summit with more than 1,000 attendees from the U.S. and around the world. Patients’ excitement about BCX7353 was resounding as they told us an oral option with our safety and efficacy profile could change their lives and the lives of their family members with HAE. Our customers want our product, and we cannot wait to deliver it to them next year,” said Jon Stonehouse, president and chief executive officer of BioCryst.

“We are on-track to submit an NDA to the FDA in the fourth quarter, followed by regulatory submissions in Europe and Japan in the first quarter of 2020. We are also preparing for the commercial launch of BCX7353 in the U.S. later in 2020, and we look forward to seeing informative clinical data with our oral Factor-D inhibitor, BCX9930, next quarter,” Stonehouse added.

Upcoming Key Milestones

HAE Program – BCX7353

- Submit a new drug application (NDA) for oral once-daily BCX7353 for the prevention of HAE attacks with the FDA (Q4 2019)
- Submit a marketing authorization application for oral once-daily BCX7353 for the prevention of HAE attacks with the European Medicines Agency (EMA) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) (Q1 2020)
- The company now plans to begin ZENITH-2, a Phase 3 clinical trial of oral BCX7353 (750 mg) for the acute treatment of HAE in 2020, pending the completion of its interactions with regulators on the Phase 3 program and additional CMC formulation work on the acute oral formulation. The company had previously planned to begin ZENITH-2 this summer.

Complement Oral Factor D Inhibitor Program – BCX9930

- Report results from ongoing Phase 1 trial of BCX9930 (Q4 2019). The Phase 1 data will inform plans for a proof of concept study in PNH patients in 2020.

ALK-2 Inhibitor Program – BCX9250

- Begin a Phase 1 clinical trial of BCX9250, an oral ALK-2 kinase inhibitor for treatment of FOP, in healthy subjects (2H 2019)

Recent Corporate Developments

- On July 1, 2019, the company announced it had appointed Megan Sniecinski as chief business officer.
- On June 27, 2019, the company announced it had begun enrollment of a Phase 1 trial of BCX9930, an oral Factor D inhibitor discovered and developed by BioCryst, for the treatment of complement-mediated diseases. The trial will evaluate the safety and tolerability and characterize the pharmacokinetic and pharmacodynamic profiles of BCX9930 in single and multiple ascending doses of BCX9930 in healthy subjects.
- On May 21, 2019, the company announced the successful outcome of APeX-2, a Phase 3 randomized, double-blind, placebo-controlled trial of once-daily, oral BCX7353 for the prevention of hereditary angioedema (HAE) attacks.
- On May 10, 2019, the company announced the successful outcome of a randomized, placebo-controlled Phase 1 clinical trial to evaluate intravenous (IV) galidesivir in healthy volunteers.

Second Quarter 2019 Financial Results

For the three months ended June 30, 2019, total revenues were \$1.4 million, compared to \$12.5 million in the second quarter of 2018. The decrease was primarily due to \$7.0 million of deferred revenue and a \$5.0 million milestone recognized in the second quarter of 2018, both associated with the EMA’s approval of peramivir (ALPIVABTM).

Research and development (R&D) expenses for the second quarter of 2019 increased to \$27.7 million from \$21.0 million in the second quarter of 2018, primarily due to increased spending as our HAE programs have progressed and our complement-mediated diseases program entered clinical testing. In addition, the company began recognizing stock option expense for two tranches of

performance-based options totaling approximately \$2.0 million of expense in the second quarter of 2019. While this expense is allocated to both R&D and G&A, it had a more meaningful impact on R&D expenses for the quarter.

General and administrative (G&A) expenses for the second quarter of 2019 decreased to \$8.7 million, compared to \$9.5 million in the second quarter of 2018. The decrease was primarily due to a \$4.9 million reserve recorded in the second quarter of 2018 for concern regarding the collectability of the EMA approval milestone for peramivir, as well as merger-related costs. These decreases were partially offset by an overall increase in G&A expenses as we prepare for the commercial launch of BCX7353 and an increase in legal costs associated with our ongoing Seqirus UK Limited (Seqirus) dispute.

Interest expense was \$3.0 million in the second quarter of 2019, compared to \$2.2 million in the second quarter of 2018. The increase was primarily associated with enhancements to the company's secured credit facility in July 2018 and February 2019.

Net loss for the second quarter of 2019 was \$37.6 million, or \$0.34 per share, compared to a net loss of \$18.5 million, or \$0.19 per share, for the second quarter of 2018.

Cash, cash equivalents and investments totaled \$97.5 million at June 30, 2019, and reflect a decrease from \$128.4 million at December 31, 2018. Operating cash use for the second quarter of 2019 was \$26.3 million. Net operating cash use for the first six months of 2019 was \$53.4 million as compared to \$41.3 million for the first six months of 2018.

Financial Outlook for 2019

BioCryst continues to expect net operating cash use to be in the range of \$105 to \$130 million, and its operating expenses to be in the range of \$120 to \$145 million. The company's operating expense range excludes equity-based compensation expense due to the difficulty in reliably projecting this expense, as it is impacted by the volatility and price of the company's stock, as well as by the vesting of the company's outstanding performance-based stock options. Although not in our operating expense guidance above, approximately \$3.5 million of stock option expense will be recognized in the remaining two quarters of 2019 associated with the two tranches of performance-based options mentioned above.

Conference Call and Webcast

BioCryst management will host a conference call and webcast at 8:30 a.m. ET today to discuss the financial results and provide a corporate update. The live call may be accessed by dialing 877-303-8027 for domestic callers and 760-536-5165 for international callers and using conference ID # 8954869. A live webcast of the call will be available online at the investors section of the company website at www.biocryst.com. A telephone replay of the call will be available by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference ID # 8954869.

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. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, galidesivir, a potential treatment for Marburg virus disease and Yellow Fever, and a preclinical program to develop oral ALK-2 inhibitors for the treatment of fibrodysplasia ossificans progressiva. RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. For more information, please visit the Company's website at www.BioCryst.com.

Forward-Looking Statements

This press release 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: that developing any HAE product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of BCX9930, BCX9250 and our HAE drug candidates (including APeX-S, APeX-J, and the BCX9930 Phase 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, EMA, PMDA or other applicable regulatory agency 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 actual financial results may not be consistent with expectations, including that 2019 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.

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BIOCRIST PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL SUMMARY
(in thousands, except per share)

Statements of Operations (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Product sales	\$ -	\$ -	\$ 1,679	\$ -
Royalty revenue	696	142	3,018	3,803
Collaborative and other research and development	752	12,352	2,638	12,667
Total revenues	<u>1,448</u>	<u>12,494</u>	<u>7,335</u>	<u>16,470</u>
Expenses:				
Cost of product sales	-	-	1,399	-
Research and development	27,681	21,010	55,174	39,451
General and administrative	8,659	9,492	14,897	17,101
Royalty	26	243	113	383
Total operating expenses	<u>36,366</u>	<u>30,745</u>	<u>71,583</u>	<u>56,935</u>
Loss from operations	(34,918)	(18,251)	(64,248)	(40,465)
Interest and other income	547	493	1,143	955
Interest expense	(3,035)	(2,195)	(5,761)	(4,416)
(Loss) gain on foreign currency derivative	(223)	1,507	183	(297)
Net loss	<u>\$ (37,629)</u>	<u>\$ (18,446)</u>	<u>\$ (68,683)</u>	<u>\$ (44,223)</u>
Basic and diluted net loss per common share	<u>\$ (0.34)</u>	<u>\$ (0.19)</u>	<u>\$ (0.62)</u>	<u>\$ (0.45)</u>
Weighted average shares outstanding	110,338	98,787	110,253	98,690

Balance Sheet Data (in thousands)

	June 30, 2019 (Unaudited)	December 31, 2018 (Note 1)
Cash, cash equivalents and investments	\$ 92,888	\$ 126,843
Restricted cash	4,629	1,544
Receivables from collaborations	3,602	4,293
Total assets	<u>116,344</u>	<u>146,841</u>
Non-recourse notes payable	29,341	29,121
Senior credit facility	49,847	29,952
Accumulated deficit	(800,414)	(731,969)
Stockholders' (deficit) equity	(9,193)	49,235
Shares of common stock outstanding	<u>110,370</u>	<u>110,063</u>

Note 1: Derived from audited financial statements.