

**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): **November 5, 2015**

BioCryst 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
(IRS Employer Identification No.)

4505 Emperor Blvd., Suite 200
Durham, North Carolina
(Address of principal executive offices)

27703
(Zip Code)

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

(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 2.02. Results of Operations and Financial Condition.

On November 5, 2015, BioCryst Pharmaceuticals, Inc. issued a news release announcing recent corporate developments and its financial results for the quarter ended September 30, 2015, 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

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press release dated November 5, 2015 entitled "BioCryst Reports Third Quarter 2015 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.

(Registrant)

/s/ **ALANE BARNES**

November 5, 2015

(Date)

Alane Barnes
*Vice President, General Counsel,
and Corporate Secretary*

EXHIBIT INDEX

Exhibit No.

99.1

Description

Press release dated November 5, 2015 entitled "BioCryst Reports Third Quarter 2015 Financial Results"

BioCryst Reports Third Quarter 2015 Financial Results

RESEARCH TRIANGLE PARK, N.C., Nov. 5, 2015 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) today announced financial results for the third quarter ended September 30, 2015.

"The completion of enrollment of our OPuS-2 trial of avoralstat and the successful outcome of the Phase 1 healthy volunteer study of BCX7353 have positioned both programs to reach important value creating events in 2016. We expect to initiate the APeX-1 (Angioedema ProphylaXis) proof of concept trial of BCX7353 in HAE patients and to report OPuS-2 results by early 2016," said Jon P. Stonehouse, President & Chief Executive Officer of BioCryst. "These oral kallikrein inhibitors have the potential to revolutionize HAE treatment, providing patients the ability to lead normal lives."

Third Quarter Financial Results

For the three months ended September 30, 2015, revenues increased to \$11.0 million from \$3.2 million in the third quarter of 2014. The increase was the result of higher levels of product and collaboration revenue associated with the sale of RAPIVAB[®] (peramivir injection) and the Seqirus, formerly bioCSL, out-licensing transaction, as well as increased collaboration revenue associated with BCX4430 development as a medical counter measure for Ebola virus and other filovirus diseases.

Research and development (R&D) expenses for the quarter increased to \$20.1 million from \$13.0 million in the third quarter of 2014. The increase in 2015 R&D expenses was primarily due to the advancement of the Company's hereditary angioedema (HAE) programs, and to a lesser extent, higher expenses associated with two discovery-stage rare disease projects.

Selling, general and administrative (SG&A) expenses for the third quarter 2015 increased to \$2.7 million from \$1.8 million in 2014. This increase was due primarily to the initiation of activities in preparation for commercialization of the Company's HAE product candidates, and to a lesser extent, commercial expenses associated with RAPIVAB.

In the third quarter of both 2015 and 2014, interest expense was \$1.2 million and related to non-recourse notes payable. In addition, a mark-to-market loss on our foreign currency hedge of \$460,000 was recognized in the third quarter of 2015, compared to a gain of \$4.1 million in the third quarter of 2014. These gains and losses resulted from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement. During the third quarter of 2015, we also realized a currency hedge gain of \$108,000 from the exercise of a U.S. Dollar/Japanese yen currency option.

The net loss for the third quarter of 2015 was \$14.6 million, or \$0.20 per share, as compared to a net loss of \$8.7 million, or \$0.12 per share, for the third quarter of 2014.

Cash, cash equivalents and investments totaled \$119.7 million at September 30, 2015, compared to \$114.0 million at December 31, 2014. Net operating cash use for the third quarter of 2015 was \$12.3 million, as compared to \$8.0 million in the third quarter of 2014. Net operating cash use for the first nine months of 2015 was \$28.1 million, as compared to \$19.8 million for the 2014 period.

Year to Date Financial Results

For the nine months ended September 30, 2015, total revenues increased to \$43.7 million from \$8.2 million in the same period of 2014. The increase in 2015 was primarily due to revenue recognition of \$21.7 million associated with the upfront payment from the Seqirus out-licensing transaction, RAPIVAB product revenue, and increased collaboration revenue associated with BCX4430 development.

R&D expenses increased to \$53.7 million for the first nine months of 2015 from \$33.3 million in the same period of 2014. The increase in 2015 expenses was primarily due to increased spending associated with the Company's HAE development programs, and to a lesser extent, higher BCX4430 development costs and discovery activity on two rare disease projects.

SG&A expenses increased to \$10.3 million for the nine months ended September 30, 2015 from \$5.4 million for the nine months ended September 30, 2014. The increase was primarily associated with the initiation of a commercial organization in preparation for commercialization of the Company's HAE drug candidates, unrestricted grants awarded to the U.S. and international HAE patient advocacy groups, as well as deal-related expenses associated with the Seqirus out-licensing transaction.

In the first nine months of 2015 and 2014, interest expense was \$3.9 million and \$3.7 million, respectively, and related to the non-recourse notes payable. In addition, a mark-to-market loss on our foreign currency hedge of \$793,000 was recognized in the first nine months of 2015, compared to a gain of \$732,000 in the same period of 2014. These gains and losses result from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement. We also realized a currency hedge gain of \$1.7 million from the exercise of a U.S. Dollar/Japanese yen currency option.

The net loss for the nine months ended September 30, 2015 decreased to \$24.9 million, or \$0.34 per share, compared to a net loss of \$33.5 million, or \$0.52 per share, for the same period in 2014.

Clinical Development Update & Outlook

- BioCryst recently announced that the OPuS-2 (Oral Prophylaxis-2) clinical trial of avoralstat completed enrollment of approximately 100 HAE patients, and the Company expects to report results in early Q1 2016.
- BioCryst also announced that the randomized, placebo-controlled, Phase 1 clinical trial of orally-administered BCX7353 in healthy volunteers successfully met all of its objectives. Oral BCX7353 was generally safe and well tolerated at all doses up to 500 mg once-daily for 7 days and 350 mg once-daily for 14 days in healthy volunteers, and no dose-limiting toxicity was identified. There were no serious adverse events (AEs) and most AEs were mild. The safety, tolerability, drug exposure and on-target plasma kallikrein inhibition results strongly support advancing the development program into the (APeX-1) Phase 2 proof of concept clinical trial of BCX7353 in HAE patients.
- The APeX-1 (Angioedema Prophylaxis) Phase 2, four week dose ranging trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of BCX7353 as a preventative treatment to reduce or eliminate attacks in HAE patients is expected to begin by early 2016, with results expected mid-2016.
- On October 27, The Japanese Ministry of Health Labor & Welfare (MHLW) announced that BioCryst's BCX7353 was one of six products designated under MHLW's new "Sakigake" fast track review system. The Sakigake Designation System promotes R&D in Japan, aiming at early market availability for innovative pharmaceutical products. This designation provides for additional interactions with the regulatory agency in Japan (PMDA) from early development through filing, prioritized development and review, and introduction of the product as soon as possible to address a serious unmet medical need.

Financial Outlook for 2015

Based upon current trends, assumptions, and development plans, BioCryst expects its 2015 net operating cash use to be in the range of \$8 to \$18 million, upon adjusting the Company's previously predicted range for the first nine months of operations and including the favorable impact of the Seqirus transaction. In addition, BioCryst continues to expect its operating expenses to be within the range of \$75 to \$95 million. Our operating expense range excludes equity-based compensation expense due to the difficulty in accurately projecting this expense, as it is significantly impacted by the volatility and price of the Company's stock, as well as vesting of the Company's outstanding performance-based stock options.

Conference Call and Webcast

BioCryst's leadership team will host a conference call and webcast on Thursday, November 5, 2015 at 11:00 a.m. Eastern Time to discuss these financial results and recent corporate developments. 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's ongoing development programs include oral plasma kallikrein inhibitors for hereditary angioedema, avoralstat, BCX7353 and other second generation compounds, and BCX4430, a broad spectrum viral RNA polymerase inhibitor. 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 the OPuS-2 clinical trial and other planned trials and development for avoralstat, BCX7353 or other HAE compounds may not start on time and may not have a favorable outcome; that developing a commercial formulation for avoralstat or any other HAE compound may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of HAE candidates 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 or other regulatory agencies may require changes to our development plan or 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 BCX4430; that BCX4430 development may not be successful; that NIAID may further condition, reduce or eliminate future funding; that revenue from RAPIVAB is unpredictable and may never be significant; that the Company may not be able to continue development of ongoing and future development or post approval programs; that such programs may never result in future products; that actual financial results may not be consistent with expectations, including that 2015 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.

BCRXW

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

Statements of Operations (Unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|---------------------------|--------------------------|---------------------------|---------------------------|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Revenues: | | | | |
| Product sales, net | \$ 5,699 | \$ -- | \$ 6,236 | \$ -- |
| Royalty revenue | 126 | 5 | 1,776 | 1,951 |
| Collaborative and other research and development | 5,162 | 3,233 | 35,643 | 6,211 |
| Total revenues | 10,987 | 3,238 | 43,655 | 8,162 |
| Expenses: | | | | |
| Cost of products sold | 1,346 | -- | 1,361 | -- |
| Research and development | 20,067 | 13,036 | 53,711 | 33,286 |
| Selling, general and administrative | 2,731 | 1,812 | 10,326 | 5,413 |
| Royalty | 5 | -- | 507 | 78 |
| Total expenses | 24,149 | 14,848 | 65,905 | 38,777 |
| Loss from operations | (13,162) | (11,610) | (22,250) | (30,615) |
| Interest and other income | 134 | 14 | 367 | 50 |
| Interest expense | (1,241) | (1,217) | (3,862) | (3,684) |
| (Loss) gain on foreign currency derivative | (352) | 4,082 | 861 | 732 |
| Net loss | <u>\$ (14,621)</u> | <u>\$ (8,731)</u> | <u>\$ (24,884)</u> | <u>\$ (33,517)</u> |
| Basic and diluted net loss per common share | <u>\$ (0.20)</u> | <u>\$ (0.12)</u> | <u>\$ (0.34)</u> | <u>\$ (0.52)</u> |
| Weighted average shares outstanding | 73,262 | 71,801 | 72,752 | 65,057 |

Balance Sheet Data (in thousands)

| | September 30, 2015 | December 31, 2014 |
|--|--------------------|-------------------|
| | (Unaudited) | (Note 1) |
| Cash, cash equivalents and investments | \$ 118,114 | \$ 113,888 |
| Restricted cash | 1,622 | 150 |
| Receivables from product sales | -- | 5,641 |
| Receivables from collaborations | 7,495 | 3,849 |
| Total assets | 138,956 | 136,874 |
| Non-recourse notes payable | 30,000 | 30,000 |
| Accumulated deficit | (492,782) | (467,898) |
| Stockholders' equity (deficit) | 64,045 | 75,635 |

Note 1: Derived from audited financial statements.

CONTACT: Robert Bennett, BioCryst Pharmaceuticals, +1-919-859-7910