
**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 6, 2018

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))

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 November 6, 2018, BioCryst Pharmaceuticals, Inc. issued a news release announcing recent corporate developments and its financial results for the quarter ended September 30, 2018, 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 November 6, 2018 entitled “BioCryst Reports Third Quarter 2018 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: November 6, 2018

By: /s/ Alane Barnes

Alane Barnes

Senior Vice President and Chief Legal Officer

BioCryst Reports Third Quarter 2018 Financial Results

APeX-2 study enrollment completed, results on-track for Q2 2019

RESEARCH TRIANGLE PARK, N.C., Nov. 06, 2018 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced financial results for the third quarter ended September 30, 2018.

“With enrollment in APeX-2 complete, and the successful results from ZENITH-1, we are excited with the momentum that is building towards meeting the urgent demand of HAE patients for an oral therapy option to prevent and treat their attacks,” said Jon Stonehouse, president and chief executive officer of BioCryst.

“We have many significant milestones lined up over the next several months and we are focused on delivering high quality APeX-2 data in the second quarter of 2019, filing our New Drug Application (NDA) for BCX7353 in the fourth quarter of 2019 and advancing at least one additional pipeline program into the clinic in the first half of the year,” Stonehouse added.

Upcoming Key Milestones:

- Complete the 250 mg and 500 mg dose cohorts of the ZENITH-1 clinical trial for acute treatment of hereditary angioedema (HAE) attacks with BCX7353 (Q1 2019)
- Meet with U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for input on the design of a Phase 3 clinical trial of BCX7353 for acute treatment of HAE attacks, and commence the Phase 3 trial (Summer 2019)
- Report results from the APeX-2 clinical trial (Q2 2019)
- Advance at least one preclinical program into the clinic and begin the Phase 1 clinical trial (1H 2019)
- File NDA for BCX7353 for prevention of HAE attacks with FDA (Q4 2019)

Third Quarter 2018 Financial Results

For the three months ended September 30, 2018, total revenues were \$1.5 million, compared to \$8.8 million in the third quarter of 2017. The decrease was primarily associated with two infrequent 2017 events that did not recur in 2018. A \$5.0 million milestone payment associated with the FDA approval of a supplemental New Drug Application (sNDA) for RAPIVAB® (peramivir injection), extending its availability for the treatment of acute uncomplicated influenza to pediatric patients two years and older, and the recognition of \$1.5 million of peramivir product sales to the company's commercial partner, Green Cross Corporation.

Research and development (R&D) expenses for the third quarter of 2018 increased to \$22.0 million from \$17.5 million in the third quarter of 2017, primarily due to increased spending on the company's HAE and preclinical programs.

General and administrative (G&A) expenses for the third quarter of 2018 increased to \$7.9 million, compared to \$3.3 million in the third quarter of 2017. The increase was primarily due to merger-related costs associated with the company's terminated merger with Idera Pharmaceuticals, Inc. (Idera).

Interest expense was \$2.3 million in the third quarter of 2018, compared to \$2.1 million in the third quarter of 2017.

Net loss for the third quarter of 2018 was \$29.6 million, or \$0.28 per share, compared to a net loss of \$15.1 million, or \$0.18 per share, for the third quarter 2017.

Cash, cash equivalents and investments totaled \$151.0 million at September 30, 2018, and reflect a decrease from \$159.0 million at December 31, 2017. Cash and investments reflect the proceeds from a July 2018 enhancement to our credit facility and an August 2018 public equity offering, offset by normal operating expenses and merger related costs incurred in the nine-month period. Net operating cash use for the third quarter 2018 was \$29.4 million, and for the first nine months of 2018 was \$70.7 million.

Year to Date 2018 Financial Results

For the nine months ended September 30, 2018, total revenues were \$17.9 million, compared to \$21.3 million in the first nine months of 2017. The decrease in revenue was primarily associated with infrequent revenue events that occurred in 2017 that did not recur in 2018, as well as a decrease of revenue from galidesivir development under U.S. Government contracts. Those 2017 events were the recognition of \$4.1 million of royalty revenue from Japanese government stockpiling of RAPIACTA® and the recognition of \$1.5 million of peramivir product sales to the company's commercial partner, Green Cross Corporation. In the nine-month periods, there was a \$5.0 million milestone and \$7.0 million of deferred revenue both associated with the EMA's approval of peramivir (ALPIVAB™) recognized in the second quarter of 2018, and two infrequent events that occurred in the third quarter of 2017, as discussed in the third quarter commentary above.

R&D expenses in the first nine months of 2018 increased to \$61.5 million from \$50.0 million in the first nine months of 2017, primarily due to increased spending on our HAE and preclinical programs. These increases were partially offset by a decrease in

the company's peramivir and galidesivir development spending in 2018.

G&A expenses for the first nine months of 2018 increased to \$25.0 million, compared to \$9.2 million in the first nine months of 2017. The increase was primarily due to approximately \$11 million of merger-related costs associated with the company's terminated merger with Idera and a \$4.9 million reserve for collectability of the EMA approval milestone of peramivir.

Interest expense was \$6.8 million in the first nine months of 2018, compared to \$6.3 million in the first nine months of 2017.

Net loss for the first nine months of 2018 was \$73.8 million, or \$0.73 per share, compared to a net loss of \$46.2 million, or \$0.58 per share, for the first nine months of 2017.

Third Quarter 2018 Corporate Developments

- On September 17, 2018, BioCryst announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, had awarded BioCryst an additional \$3.5 million to support clinical trials of galidesivir in patients with yellow fever.
- On September 6, 2018, BioCryst announced that the Centers for Disease Control and Prevention (CDC) had awarded BioCryst a \$34.7 million contract for the procurement of up to 50,000 doses of BioCryst's approved antiviral influenza therapy, RAPIVAB[®] (peramivir injection) over a five-year period.
- On September 4, 2018, BioCryst announced initial results from the ZENITH-1 trial showing that a single 750 mg oral dose of BCX7353 was well tolerated and superior to placebo ($p < 0.05$) against the majority of efficacy endpoints evaluated in HAE patients suffering an acute attack.
- On August 6, 2018, BioCryst announced it has received Fast Track Designation by the FDA for BCX7353 for the prevention of angioedema attacks in patients with hereditary angioedema.
- On August 6, 2018, BioCryst announced the full exercise of the underwriters' option to purchase additional shares and the completion of its public offering resulting in the sale of 10,454,546 shares of its common stock at a price of \$5.50 per share. The net proceeds from this offering were approximately \$53.4 million, after deducting underwriting discounts and commissions and other estimated offering expenses.
- On July 25, 2018, BioCryst announced that results from the Phase 2, APeX-1 trial of BCX7353 for the prevention of attacks in patients with HAE were published in the July 26th issue of *The New England Journal of Medicine*.
- On July 20, 2018, BioCryst entered into a \$30 million secured loan facility with MidCap Financial Trust as administrative agent and lender (MidCap), pursuant to the terms and conditions of that certain Amended and Restated Credit and Security Agreement. The Credit Agreement replaces the Credit and Security Agreement dated as of September 23, 2016.
- On July 10, 2018, BioCryst announced that it had terminated the previously announced merger agreement with Idera following the company's stockholders' failure to approve the adoption of the merger agreement. Pursuant to the merger agreement, the company reimbursed Idera \$6 million in July 2018.

Financial Outlook for 2018

Based upon development plans, merger-related incurred costs from the terminated merger agreement with Idera and awarded government contracts, BioCryst continues to expect its previously issued 2018 financial outlook to be appropriate, with net operating cash use to be in the range of \$85 to \$105 million, and its 2018 operating expenses to be in the range of \$90 to \$110 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.

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 #9090479. A live webcast of the call and slides will be available online at the investors section of the company website at 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. 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 # 9090479.

About BCX7353

Discovered by BioCryst, BCX7353 is a novel, oral, once-daily, selective inhibitor of plasma kallikrein currently in development for the prevention and treatment of angioedema attacks in patients diagnosed with HAE. BCX7353 was generally safe and well tolerated in the Phase 2 APeX-1 clinical trial. BioCryst is currently conducting the Phase 3 APeX-2 clinical trial and the long-term safety APeX-S clinical trial, both evaluating two dosage strengths of BCX7353 administered orally once-daily as a preventive treatment to reduce the frequency of attacks in patients with HAE. BioCryst is also conducting the ZENITH-1 clinical trial.

ZENITH-1 is a proof-of-concept Phase 2 clinical trial testing an oral liquid formulation of BCX7353 for the treatment of acute angioedema attacks.

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, galidesivir, a potential treatment for filoviruses, 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 HAE second generation drug candidates (including ZENITH-1, APeX-2, APeX-S and APeX-J) 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 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. 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

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

Statements of Operations (Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales	\$ -	\$ 1,501	\$ -	\$ 1,501
Royalty revenue	523	442	4,326	7,252
Collaborative and other research and development	931	6,817	13,598	12,543
Total revenues	1,454	8,760	17,924	21,296
Expenses:				
Cost of product sales	-	1,142	-	1,142
Research and development	22,006	17,509	61,457	50,038
General and administrative	7,923	3,343	25,024	9,235
Royalty	18	115	401	431
Total operating expenses	29,947	22,109	86,882	60,846
Loss from operations	(28,493)	(13,349)	(68,958)	(39,550)

Interest and other income	611	225	1,566	537
Interest expense	(2,346)	(2,140)	(6,762)	(6,334)
Gain (loss) on foreign currency derivative	631	130	334	(892)
	<u>611</u>	<u>225</u>	<u>1,566</u>	<u>537</u>
Net loss	\$ <u>(29,597)</u>	\$ <u>(15,134)</u>	\$ <u>(73,820)</u>	\$ <u>(46,239)</u>
Basic and diluted net loss per common share	\$ <u>(0.28)</u>	\$ <u>(0.18)</u>	\$ <u>(0.73)</u>	\$ <u>(0.58)</u>
Weighted average shares outstanding	105,410	83,570	100,955	79,749

Balance Sheet Data (in thousands)

	September 30, 2018 (Unaudited)	December 31, 2017 (Note 1)
	<u>\$</u>	<u>\$</u>
Cash, cash equivalents and investments	149,478	155,692
Restricted cash	1,506	3,286
Receivables from collaborations	3,394	6,117
Total assets	168,308	178,259
Non-recourse notes payable	29,012	28,682
Senior credit facility	29,914	23,214
Accumulated deficit	(704,537)	(631,843)
Stockholders' equity	72,873	83,767
Shares of common stock outstanding	109,625	98,411

Note 1: Derived from audited financial statements.