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, 2019

BioCryst Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-23186**	**62-1413174**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 November 6, 2019, BioCryst Pharmaceuticals, Inc. (the "Company") issued a news release announcing recent corporate developments and its financial results for the quarter ended September 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.

Also on November 6, 2019, the Company issued a news release announcing 48-week results from its APeX-S and APeX-2 trials and comprehensive market research which support the significant commercial opportunity for oral, once daily BCX7353 in HAE. A copy of the news release is furnished as Exhibit 99.2 hereto and is incorporated herein by reference.

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, 2019 entitled "BioCryst Reports Third Quarter 2019 Financial Results and Upcoming Key Milestones"
99.2	Press release dated November 6, 2019 entitled "New Clinical Trial Results and Market Research Support Significant Commercial Opportunity for Oral, Once Daily BCX7353 in HAE"

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, 2019

By: /s/ Alane Barnes
Alane Barnes
Senior Vice President and Chief Legal Officer

EXHIBIT 99.1

BioCryst Reports Third Quarter 2019 Financial Results and Upcoming Key Milestones

—New drug application for oral, once-daily BCX7353 for prevention of hereditary angioedema attacks on-track for submission to FDA in Q4 2019—

—Data from proof of concept study in PNH patients with oral Factor D inhibitor, BCX9930, expected in 1H 2020—

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

“BioCryst is positioned for a transformational 2020, with the potential approval and launch of BCX7353 in the U.S., regulatory filings for BCX7353 in Japan and Europe, and data from our PNH proof of concept study with BCX9930 reading out in the first half of the year,” said Jon Stonehouse, president and chief executive officer of BioCryst.

“We are also actively evaluating multiple approaches to add capital to the balance sheet by the end of 2019, as we did with the Japanese licensing agreement for BCX7353, which we announced earlier this week,” Stonehouse added.

Upcoming Key Milestones

HAE Program – BCX7353

- Submit a new drug application (NDA) for oral, once-daily BCX7353 for the prevention of hereditary angioedema (HAE) attacks with the U.S. Food and Drug Administration (FDA) (Q4 2019)
- Submit a marketing authorization application for oral, once-daily BCX7353 for the prevention of HAE attacks with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and the European Medicines Agency (EMA) (Q1 2020)
- Commence ZENITH-2, a Phase 3 clinical trial of oral BCX7353 (750 mg) for the treatment of acute HAE attacks, in 2020, pending the completion of interactions with regulators on the Phase 3 program and additional work on the acute oral formulation (2020)

Complement Oral Factor D Inhibitor Program – BCX9930

- Report data from a proof of concept study in paroxysmal nocturnal hemoglobinuria (PNH) patients receiving oral BCX9930 (1H 2020)

ALK-2 Inhibitor Program – BCX9250

- Continue ongoing Phase 1 clinical trial of BCX9250, an oral ALK-2 kinase inhibitor for treatment of fibrodysplasia ossificans progressiva (FOP), in healthy subjects

Recent Corporate Developments

- On November 6, 2019, the company provided a commercial update based on new 48-week clinical data from the APeX-2 and APeX-S trials, and detailed market research conducted with HAE patients, physicians who treat HAE and payors.
- On November 5, 2019, the company announced it had licensed commercialization rights in Japan to Torii Pharmaceutical, Co. for BCX7353 for up to $42 million of upfront and potential milestone payments, including a $22 million upfront payment.
- On November 1, 2019, the company announced it had begun enrollment of a Phase 1 trial of BCX9250, an oral ALK-2 inhibitor discovered and developed by BioCryst, for the treatment of FOP. The trial will evaluate the safety and tolerability and characterize the pharmacokinetic and pharmacodynamic profiles of BCX9250 in single and multiple ascending doses in healthy volunteers.
- On November 1, 2019, the company announced results from a Phase 1 trial of BCX9930, an oral Factor D inhibitor discovered and developed by BioCryst, showing that BCX9930 was safe and generally well tolerated, and demonstrated rapid, sustained and >95% suppression of the alternative pathway of the complement system at 100 mg every 12 hours. Based on these results, the company is advancing the program into a proof of concept (PoC) study in PNH patients and plans to report data from the PoC study in the first half of 2020.
- On September 26, 2019, the company announced the U.S. Department of Health and Human Services (HHS) had exercised its option to purchase an additional 10,000 doses of BioCryst’s approved antiviral influenza therapy, RAPIVAB® (peramivir injection).
- On September 23, 2019, the company announced it had appointed clinical rare disease expert, Helen Thackray, M.D., FAAP, to its board of directors.

Third Quarter 2019 Financial Results

For the three months ended September 30, 2019, total revenues were $1.8 million, compared to $1.5 million in the third quarter of 2018. The increase was primarily due to the recognition of $0.3 million of peramivir product sales to Shionogi & Co., Ltd., the company's commercial partner in Japan.

Research and development (R&D) expenses for the third quarter of 2019 increased to $25.1 million from $22.0 million in the third quarter of 2018, primarily due to increased spending on our complement-mediated diseases programs, which entered Phase 1 clinical testing in June 2019.

Selling, general and administrative (SG&A) expenses for the third quarter of 2019 increased to $11.7 million, compared to $7.9 million in the third quarter of 2018. The increase was primarily due to increased spending on commercial activities and medical affairs to support the U.S. commercial launch of BCX7353 in 2020.

Interest expense was $3.0 million in the third quarter of 2019, compared to $2.3 million in the third quarter of 2018, and was primarily due to an increase in the outstanding balance of the company's secured credit facility in February 2019.

Net loss for the third quarter of 2019 was $37.6 million, or $0.34 per share, compared to a net loss of $29.6 million, or $0.28 per share, for the third quarter of 2018.

Cash, cash equivalents and investments totaled $70.0 million at September 30, 2019, and reflect a decrease from $128.4 million at December 31, 2018. Operating cash use for the third quarter of 2019 was $24.5 million. Net operating cash use for the first nine months of 2019 was $77.9 million, as compared to $70.7 million for the first nine months of 2018.

Financial Outlook

BioCryst continues to expect full year 2019 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.

Conference Call and Webcast

BioCryst management will host a conference call and webcast at 8:00 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 # 4891026. A live webcast of the call and any slides 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 # 4891026.

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 BCX9250, an oral ALK-2 inhibitor 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 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.

BCRXW

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

Statements of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales	$ 335	$ -	$ 2,014	$ -
Royalty revenue	508	523	3,526	4,326
Collaborative and other research and development	932	931	3,570	13,598
Total revenues	1,775	1,454	9,110	17,924
Expenses:				
Cost of product sales	-	-	1,399	-
Research and development	25,120	22,006	80,294	61,457
Selling, general and administrative	11,735	7,923	26,632	25,024
Royalty	18	18	131	401
Total operating expenses	36,873	29,947	108,456	86,882
Loss from operations	(35,098)	(28,493)	(99,346)	(68,958)
Interest and other income	402	611	1,545	1,566
Interest expense	(3,044)	(2,346)	(8,805)	(6,762)
Gain on foreign currency derivative	148	631	331	334
Net loss	$ (37,592)	$ (29,597)	$ (106,275)	$ (73,820)
Basic and diluted net loss per common share	$ (0.34)	$ (0.28)	$ (0.96)	$ (0.73)
Weighted average shares outstanding	110,416	105,410	110,308	100,955

Balance Sheet Data (in thousands)

	September 30, 2019 (Unaudited)	December 31, 2018 (Note 1)
Cash, cash equivalents and investments	$ 68,435	$ 126,843
Restricted cash	1,547	1,544
Receivables from collaborations	3,598	4,293
Total assets	90,500	146,841
Non-recourse notes payable	29,451	29,121
Senior credit facility	50,077	29,952
Accumulated deficit	(838,006)	(731,969)
Stockholders' (deficit) equity	(41,253)	49,235
Shares of common stock outstanding	110,438	110,063

Note 1: Derived from audited financial statements.

EXHIBIT 99.2

New Clinical Trial Results and Market Research Support Significant Commercial Opportunity for Oral, Once Daily BCX7353 in HAE

—Results of the APeX-S and APeX-2 trials show patients taking 150 mg of oral, once daily BCX7353 achieved a stable average attack rate of ≤ 1 attack per month at 48 weeks—

—75 percent of patients taking 150 mg BCX7353 completed 48 weeks of dosing in the Phase 3 APeX-2 trial—

—Comprehensive market research from 100 HAE patients and 175 treating physicians shows strong demand for oral, once daily BCX7353—

RESEARCH TRIANGLE PARK, N.C., Nov. 06, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced 48-week results from its APeX-S and APeX-2 trials and comprehensive market research which support the significant commercial opportunity for oral, once daily BCX7353 in HAE.

“The 48-week clinical trial data we now have from APeX-S and APeX-2 highlight the control patients are having over their attacks with oral, once daily BCX7353, and consequently why 75 percent of patients stayed on-study through 48 weeks when they had other choices,” said Jon Stonehouse, chief executive officer of BioCryst.

“Since receiving the 24-week data from APeX-2 in May, we have conducted detailed and comprehensive market research to update our understanding of the commercial potential and value of BCX7353 with patients, treating physicians and payors. It is clear from this work that, regardless of their current treatment, HAE patients are eager to use, physicians are expecting to prescribe and payors are willing to reimburse oral once a day BCX7353,” Stonehouse added.

Key Findings from 48-week APeX-S and APeX-2 Data:

- In APeX-2, patients experienced a rapid and sustained decrease in their attack frequency over 48 weeks. Thirty patients who were randomized to 150 mg of BCX7353 at the beginning of the study and completed 48 weeks of therapy had a baseline attack rate of 2.9 attacks per month, which declined to 1.4 attacks per month after one month and to 1.0 attacks per month at month 12.

- APeX-2 patients who switched from placebo to 150 mg of BCX7353 at the week 24 visit saw dramatic and sustained reductions in their HAE attack rate. Their mean attack rate dropped to 0.5 attacks per month at month seven and to 0.4 attacks per month at month 12.

- APeX-S patients taking 150 mg of BCX7353 had similar attack control as those in APeX-2. Patients completing 48 weeks of treatment on 150 mg of BCX7353 (n=73) had a median attack rate of zero attacks per month in six of the 12 months, including month 12 (week 48).

- 75 percent of HAE patients who were on 150 mg of oral BCX7353 in the APeX-2 trial completed 48 weeks of treatment.

- The integrated 48-week analysis across both APeX-2 and APeX-S showed no new safety findings. BCX7353 was safe and generally well tolerated in a total of 342 patients with a total of 232 patient-years of daily oral dosing. The most common adverse event was the common cold, which occurred with similar frequency in BCX7353 and placebo patients. Gastrointestinal events led to discontinuation of BCX7353 in three percent of patients. Drug-related serious adverse events occurred in three of 342 subjects (0.9%) and resolved after stopping or interrupting BCX7353 dosing.

- In APeX-S, alanine aminotransferase levels >3xULN were seen in 14 of 49 patients who discontinued androgens within 28 days prior to study entry, compared to one of 104 patients who discontinued androgens more than 28 days prior to study entry and zero of 74 patients who had never used androgens. These observations support a proposed four-week washout period for current androgen patients before beginning therapy with BCX7353.

Key Findings from Market Research

- The prevalence of HAE in the U.S. is higher than previously estimated. A comprehensive study of U.S. administrative claims data from 274 million covered lives establishes a prevalence of approximately 10,000 total HAE patients and 7,500 diagnosed and treated HAE patients in U.S.

- More than 80 percent of the 100 HAE patients in the market research self-reported being on prophylactic therapy.

- The 175 physicians in the market research, who in total treat more than 1,300 HAE patients, report they currently treat 58 percent of HAE patients with prophylactic therapy and anticipate they will treat 80 percent of HAE patients with prophylactic therapy in the future.

- Patient demand for BCX7353 is strong, regardless of their current therapy. When 100 patients were shown the APeX-2 24-week product profile, 60 percent of HAE patients said they would be very willing to use BCX7353.

- HAE-treating physicians expect to prescribe BCX7353 to 41 percent of their HAE patients.

- Payors expressed a broad willingness to reimburse oral BCX7353 in pricing research with insurance plans and pharmacy benefit managers representing more than 100 million covered lives.

Conference Call and Webcast

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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 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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