BioCryst Reports Third Quarter 2019 Financial Results and Upcoming Key Milestones

November 6, 2019

—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.

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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.