

# **BioCryst Reports First Quarter 2019 Financial Results**

May 8, 2019

---Phase 3 APeX-2 24-week safety and efficacy data of once-daily oral BCX7353 for prophylaxis of hereditary angioedema (HAE) attacks on-track for Q2 2019---

-Phase 3 ZENITH-2 trial of oral BCX7353 for acute treatment of HAE attacks to commence this summer-

-Phase 1 trial of oral Factor D inhibitor, BCX9930, to begin in Q2 2019-

-Phase 1 trial of oral BCX9250 for fibrodysplasia ossificans progressiva (FOP) to begin in 2H 2019-

RESEARCH TRIANGLE PARK, N.C., May 08, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced financial results for the first quarter ended March 31, 2019 and provided a corporate update.

"In a year with many milestones across our multiple advancing programs of oral medicines for rare diseases, BioCryst has achieved significant progress in the first quarter and we look forward to reporting data from our APeX-2 trial in the second quarter and filing a new drug application by the end of the year," said Jon Stonehouse, president and chief executive officer of BioCryst.

"We believe that oral BCX7353 could be transformative for many HAE patients and provide them with the opportunity for a normal life without the burden and discomfort of frequent injections and infusions," Stonehouse added.

# First Quarter 2019 Corporate Developments

- The company dosed the first patients in its APeX-J trial in Japan, designed to support potential Japanese approval of BCX7353 for the prevention of HAE attacks.
- On March 4, 2019, the company announced that it is advancing BCX9930, an oral Factor D inhibitor, into Phase 1 clinical development in the second guarter of 2019 for the treatment of complement-mediated diseases.
- On February 23, 2019, the company announced data from the completed ZENITH-1 trial (including the 250 mg and 500 mg dose cohorts) of BCX7353 for the acute treatment of HAE attacks at the annual meeting of the American Academy of Allergy, Asthma & Immunology. The company plans to commence a Phase 3 trial, ZENITH-2, in the summer of 2019.
- On February 6, 2019, the company announced it had entered into a \$100 million secured credit facility with MidCap Financial Trust pursuant to the terms and conditions of an amended and restated credit and security agreement.
- On January 4, 2019, the company announced it had appointed Steve Aselage to its board of directors.
- On January 2, 2019, the company announced the dosing of the first subject in a randomized, placebo-controlled Phase 1 clinical trial to evaluate intravenous galidesivir, its investigational broad-spectrum antiviral drug, in healthy volunteers.

# **Upcoming Key Milestones**

# HAE Program – BCX7353

- Report 24-week safety and efficacy results from the Phase 3 APeX-2 clinical trial (Q2 2019)
- Begin ZENITH-2, a Phase 3 clinical trial of oral BCX7353 (750 mg) for the acute treatment of HAE (Summer 2019)
- File a new drug application for oral BCX7353 for the prevention of HAE attacks with the U.S. Food and Drug Administration (FDA) (Q4 2019)
- File a marketing authorization application for oral BCX7353 for the prevention of HAE attacks with the European Medicines Agency (EMA) (Q1 2020)

# Complement Factor D Inhibitor Program – BCX9930

• Begin a Phase 1 trial of BCX9930, an oral Factor D inhibitor for treatment of complement-mediated diseases, in healthy

• Report Phase 1 results (Q4 2019)

# 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)

# First Quarter 2019 Financial Results

For the three months ended March 31, 2019, total revenues were \$5.9 million, compared to \$4.0 million in the first quarter of 2018. The increase was primarily due to the recognition of \$1.7 million of peramivir product sales to Green Cross, the company's commercial partner in Korea, and an increase in revenue from galidesivir development under U.S. government contracts, and partially offset by lower royalty revenue.

Research and development (R&D) expenses for the first quarter of 2019 increased to \$27.5 million from \$18.4 million in the first quarter of 2018, primarily due to increased spending on the HAE, preclinical and galidesivir programs.

General and administrative (G&A) expenses for the first quarter of 2019 decreased to \$6.2 million, compared to \$7.6 million in the first quarter of 2018. The decrease was primarily due to approximately \$4.7 million of merger-related costs that were incurred in the first quarter of 2018 but did not recur in 2019, offset by an overall increase in G&A expenses as the company prepares for the commercial launch of BCX7353.

Interest expense was \$2.7 million in the first quarter of 2019, compared to \$2.2 million in the first quarter of 2018 and was primarily associated with enhancements to the company's secured credit facility in July 2018 and February 2019.

Net loss for the first quarter of 2019 was \$31.1 million, or \$0.28 per share, compared to a net loss of \$25.8 million, or \$0.26 per share, for the first quarter of 2018.

Cash, cash equivalents and investments totaled \$121.6 million at March 31, 2019, and reflect a decrease from \$128.4 million at December 31, 2018. Cash and investments reflect the proceeds from an enhancement to our secured credit facility in February 2019 and were partially offset by normal operating expenses. Operating cash use for the first quarter of 2019 was \$27.1 million.

In February 2019, the company entered into a \$100 million secured credit facility with MidCap Financial Trust which further enhanced the company's cash position with \$20 million of immediate additional non-dilutive capital and also provided additional financial flexibility through the ability to draw another \$50 million of milestone-based non-dilutive capital.

### **Financial Outlook for 2019**

BioCryst continues to expect net operating cash use to be in the range of \$105 to \$130 million, and its 2019 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 8:30 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 # 1777029. 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 # 1777029.

#### **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-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; 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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### Contact:

John Bluth +1 919 859 7910 jbluth@biocryst.com

# BIOCRYST PHARMACEUTICALS, INC. CONSOLIDATED FINANCIAL SUMMARY

(in thousands, except per share)

# Statements of Operations (Unaudited)

		Three Months Ended March 31,		
		2019		2018
Revenues:				
Product sales	\$	1,679	\$	-
Royalty revenue		2,322		3,661
Collaborative and other research and developmen	t	1,886		315
Total revenues		5,887		3,976
Expenses:				
Cost of product sales		1,399		-
Research and development		27,493		18,441
General and administrative		6,238		7,609
Royalty		87		140
Total operating expenses		35,217	_	26,190
Loss from operations		(29,330)		(22,214)
Interest and other income		596		462
Interest expense		(2,726)		(2,221)
Gain (loss) on foreign currency derivative		406		(1,804)
Net loss	\$	(31,054)	\$	(25,777)
Basic and diluted net loss per common share	\$	(0.28)	\$	(0.26)
Weighted average shares outstanding		110,167		98,592

### Balance Sheet Data (in thousands)

	March 31, 2019 (Unaudited)	December 31, 2018 (Note 1)
Cash, cash equivalents and investments	\$ 119,212	\$ 126,843
Restricted cash	2,394	1,544
Receivables from collaborations	5,002	4,293
Total assets	142,338	146,841
Non-recourse notes payable	29,231	29,121
Senior credit facility	49,616	29,952
Accumulated deficit	(762,785)	(731,969)
Stockholders' equity	22,507	49,235
Shares of common stock outstanding	110,270	110,063

Note 1: Derived from audited financial statements.