BioCryst Reports Fourth Quarter and Full Year 2018 Financial Results

March 4, 2019

—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—

—Full ZENITH-1 results confirm safety and efficacy profile of oral 750 mg BCX7353 for upcoming Phase 3 trial in acute treatment of HAE—

—Oral Factor D inhibitor, BCX9930, advancing to Phase 1 development for complement-mediated diseases—

—Recent $100 million debt financing increases financial flexibility—

RESEARCH TRIANGLE PARK, N.C., March 04, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced financial results for the fourth quarter and full year ended December 31, 2018, and provided a corporate update.

“In a year with many transformative milestones for BioCryst, it has been exciting to see so much progress already in the first two months of the year. The strong Phase 2 clinical data from our now-completed ZENITH-1 trial propels our BCX7353 acute program for HAE into Phase 3 development. With the very favorable preclinical profile of BCX9930, another novel BioCryst-invented oral drug for rare diseases, we are advancing that program into the clinic in the second quarter for the treatment of complement-mediated diseases. We also added further rare disease expertise to our board and increased our financial flexibility with a $100 million debt agreement,” said Jon Stonehouse, president and chief executive officer of BioCryst.

“We remain on-track for the readout of our APeX-2 trial next quarter, and an NDA filing of BCX7353 for HAE prophylaxis by the end of the year. We are thoughtfully building our commercial leadership and infrastructure to execute a successful launch that meets the urgent demand for a once-daily oral therapy that will allow HAE patients to live a more normal life,” Stonehouse added.

Recent Milestones

- The company has 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 quarter 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.

Fourth Quarter 2018 Corporate Developments

- On November 20, 2018, BioCryst announced that it had appointed Theresa Heggie to its board of directors.
- On November 16, 2018, BioCryst presented data that showed an oral formulation of BCX7353 was rapidly absorbed and exhibited a long half-life, two important characteristics of desired new acute treatments for HAE attacks, at the annual scientific meeting of the American College of Allergy, Asthma & Immunology.

Upcoming Key Milestones

HAE Program – BCX7353

- Report 24-week safety and efficacy results from the APeX-2 clinical trial (Q2 2019)
- Begin a Phase 3 clinical trial of oral BCX7353 for the acute treatment of HAE (Summer 2019)

- File a new drug application (NDA) for oral BCX7353 for the prevention of HAE attacks with the U.S. Food and Drug Administration (FDA) (Q4 2019)

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 subjects (Q2 2019)

- 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 fibrodysplasia ossificans progressiva, in healthy subjects (2H 2019)

Fourth Quarter 2018 Financial Results

For the three months ended December 31, 2018, total revenues were $2.7 million, compared to $3.9 million in the fourth quarter of 2017. The decrease was primarily due to a reduction of royalty revenue associated with differences in the onset and severity of the influenza seasons between the two periods. This decrease was partially offset by increased revenue from government contracts for galidesivir development, which was higher in the fourth quarter of 2018.

Research and development (R&D) expenses for the fourth quarter of 2018 increased to $23.4 million from $16.9 million in the fourth quarter of 2017, primarily due to increased spending on the company's HAE and preclinical programs.

General and administrative (G&A) expenses for the fourth quarter of 2018 decreased slightly to $4.5 million, compared to $4.7 million in the fourth quarter of 2017. The decrease was primarily due to the lack of merger-related costs in the fourth quarter of 2018 associated with the company's terminated merger with Idera Pharmaceuticals, Inc. (Idera). The decrease in G&A expense due to the lack of merger expenses was largely offset by higher commercial and medical affairs expenses in the fourth quarter of 2018.

Interest expense was $2.4 million in the fourth quarter of 2018, compared to $2.2 million in the fourth quarter of 2017 and was associated with enhancing our secured credit facility in July 2018.

Net loss for the fourth quarter of 2018 was $27.4 million, or $0.25 per share, compared to a net loss of $19.5 million, or $0.20 per share, for the fourth quarter of 2017.

Cash, cash equivalents and investments totaled $128.4 million at December 31, 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 secured credit facility and an August 2018 public equity offering, offset by normal operating expenses and merger-related costs incurred in the 12-month period. Operating cash use for the fourth quarter of 2018 was $22.6 million, and for the full year of 2018 was $93.4 million.

On February 6, 2019, the company announced it had 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 provided additional financial flexibility by providing the ability to draw another $50 million of milestone-based non-dilutive capital.

Full Year 2018 Financial Results

For the full year ended December 31, 2018, total revenues were $20.7 million, compared to $25.2 million in the full year ended December 31, 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 $2.1 million decrease in revenue associated with development activities under U.S. government contracts in 2018. The non-recurring 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 from the company's commercial partner, Green Cross Corporation. These decreases were partially offset by a $5.0 million milestone associated with the European Medicines Agency's (EMA) approval of peramivir (ALPIVAB ™) recognized in the second quarter of 2018.

R&D expenses in 2018 increased to $84.9 million from $67.0 million in 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 in 2018 increased to $29.5 million, compared to $13.9 million in 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 $9.2 million in 2018, compared to $8.6 million in 2017.

Net loss for 2018 was $101.3 million, or $0.98 per share, compared to a net loss of $65.8 million, or $0.78 per share, for 2017.

Financial Outlook for 2019

BioCryst expects 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 # 1271286. 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# 1271286.

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

Statements of Operations (Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Product sales	$ -	$ -	$ -	$ 1,501
Royalty revenue	1,775	3,291	6,101	10,543
Collaborative and other research and development	954	599	14,552	13,142
Total revenues	2,729	3,890	20,653	25,186
Expenses:				
Cost of product sales	-	-	-	1,142
Research and development	23,431	16,924	84,888	66,962
General and administrative	4,490	4,698	29,514	13,933
Royalty	70	129	471	560
Total operating expenses	27,991	21,751	114,873	82,597

Loss from operations	(25,262)	(17,861)	(94,220)	(57,411)
Interest and other income	686	478	2,252	1,015
Interest expense	(2,414)	(2,231)	(9,176)	(8,565)
(Loss) gain on foreign currency derivative	(442)	71	(108)	(821)
Net loss	$ (27,432)	$ (19,543)	$ (101,252)	$ (65,782)
Basic and diluted net loss per common share	$ (0.25)	$ (0.20)	$ (0.98)	$ (0.78)
Weighted average shares outstanding	109,802	98,402	103,185	84,451

Balance Sheet Data (in thousands)

	December 31, 2018 (Unaudited)	December 31, 2017 (Note 1)
Cash, cash equivalents and investments	$ 126,843	$ 155,692
Restricted cash	1,544	3,286
Receivables from collaborations	4,293	6,117
Total assets	146,841	178,259
Non-recourse notes payable	29,121	28,682
Senior credit facility	29,952	23,214
Accumulated deficit	(731,969)	(631,843)
Stockholders' equity	49,235	83,767
Shares of common stock outstanding	110,063	98,411

Note 1: Derived from audited financial statements.