BioCryst Reports Fourth Quarter and Full Year 2019 Financial Results and Upcoming Key Milestones

March 5, 2020

—Berotralstat NDA accepted by FDA; PDUFA date December 3, 2020—

—JNDA accepted by PMDA under Sakigake timeline; approval expected 2H 2020—

—PNH proof of concept data with oral Factor D inhibitor, BCX9930, expected 2Q 2020—

RESEARCH TRIANGLE PARK, N.C., March 05, 2020 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq:BCRX) today announced financial results for the fourth quarter and full year ended December 31, 2019, and provided a corporate update.

“2020 is off to a strong start, with NDAs accepted and approvals lined up later this year in the U.S. and Japan, and continued progress with our oral Factor D program as we approach proof of concept data in PNH patients in the second quarter of the year,” said Jon Stonehouse, president and chief executive officer of BioCryst.

“We are hearing increasing excitement from both HAE patients and physicians about the availability of an oral option to manage their disease, and we are attracting outstanding commercial talent to bring this new medicine to patients,” Stonehouse added.

Upcoming Key Milestones

HAE Program – Berotralstat (BCX7353)

- Submit Marketing Authorization Application (MAA) for oral, once-daily berotralstat for the prevention of hereditary angioedema (HAE) attacks with the European Medicines Administration (EMA) (Q1 2020)
- Approval and launch of oral, once-daily berotralstat in Japan (2H 2020)
- Approval and launch of oral, once-daily berotralstat in U.S. (December 3, 2020 PDUFA date)

Complement Oral Factor D Inhibitor Program – BCX9930

- Report data from a proof of concept study in paroxysmal nocturnal hemoglobinuria (PNH) patients receiving oral BCX9930 (2Q 2020)

ALK-2 Inhibitor Program – BCX9250

- Report data from Phase 1 clinical trial of BCX9250, an oral ALK-2 kinase inhibitor for treatment of fibrodysplasia ossificans progressiva (FOP), in healthy subjects (2H 2020)

Coronavirus Antiviral Update – Galidesivir (BCX4430)
Galidesivir is a broad-spectrum antiviral currently being developed in a Phase 2 clinical trial (Yellow Fever) under contracts with the National Institute of Allergy and Infectious Diseases (NIAID) and U.S. Department of Health and Human Services (HHS).

Galidesivir has been shown to be active against more than 20 RNA viruses in nine different families, including coronaviruses. In Phase 1 trials in healthy volunteers, galidesivir was generally safe and well tolerated.

The company is in active dialogue with relevant U.S. public health authorities as they assess potential approaches to treat and prevent COVID-19, and whether galidesivir could be useful.

Recent Corporate Developments

- On March 5, 2020, the company announced it had dosed its first PNH patients in a proof of concept study with its oral Factor D inhibitor, BCX9930.
- On March 3, 2020, the company announced it will present at the Barclays Global Healthcare Conference in Miami Beach, Florida on Tuesday, March 10, 2020. The company’s presentation time has been changed to 8:30 a.m. ET that day.
- On February 27, 2020, the company announced it will present abstracts with new data on oral, once-daily berotralstat (BCX7353) at the upcoming annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) March 13-16 in Philadelphia.

- On February 25, 2020 the company announced the appointment of former Pfizer CFO, Alan G. Levin, to its Board of Directors.

- On February 18, 2020, the company announced that the U.S. Food and Drug Administration (FDA) had accepted and filed its new drug application (NDA) for the approval of oral, once-daily berotralstat (BCX7353) for the prevention of hereditary angioedema (HAE) attacks. The Prescription Drug User Fee Act (PDUFA) date for the NDA is December 3, 2020. In the NDA filing acceptance letter, the FDA stated that they are not currently planning to hold an advisory committee meeting to discuss the NDA.

- On February 3, 2020, the company announced that it had submitted a new drug application (JNDA) to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for approval of oral, once-daily berotralstat for the prophylactic treatment of HAE.

- On January 15, 2020 the company announced the appointments of Charles Gayer as chief commercial officer and Allen Hodge as vice president and general manager for the United States.

- On January 12, 2020, the company announced that the APeX-J trial in Japan met its primary endpoint (p=0.003) for prevention of HAE attacks, and berotralstat was safe and generally well-tolerated.

- On December 11, 2019, the company announced it had submitted a new drug application to the FDA for approval of oral, once-daily berotralstat (BCX7353) for the prevention of HAE attacks.

- On November 18, 2019, the company announced it had completed a public offering of common stock and received gross proceeds of approximately $63.3 million. In addition, the company completed a pre-funded warrants transaction on November 21, 2019 that provided gross proceeds of $19.9 million.

Fourth Quarter 2019 Financial Results

For the three months ended December 31, 2019, total revenues were $39.7 million, compared to $2.7 million in the fourth quarter of 2018. The increase was primarily due to the recognition of $20.1 million of the $22.0 million upfront payment from Torii for commercialization rights in Japan for berotralstat for the prevention of HAE attacks, and $13.9 million of RAPIVAB® (peramivir injection) product sales under our procurement contract with the Centers for Disease Control.

Research and development (R&D) expenses for the fourth quarter of 2019 increased to $26.8 million from $23.4 million in the fourth quarter of 2018, primarily due to increased spending on the company's complement-mediated diseases program and other preclinical development initiatives.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2019 increased to $10.5 million, compared to $4.5 million in the fourth 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 berotralstat in 2020 and, to a lesser extent, legal expenses associated with our ongoing arbitration.

Interest expense was $3.1 million in the fourth quarter of 2019, compared to $2.4 million in the fourth quarter of 2018 and was associated with an increase in the outstanding balance of the company's secured credit facility in February 2019 and increased interest expense associated with the company's non-recourse notes payable.

Net loss for the fourth quarter of 2019 was $2.6 million, or $0.02 per share, compared to a net loss of $27.4 million, or $0.25 per share, for the fourth quarter of 2018.

Cash, cash equivalents and investments totaled $137.8 million at December 31, 2019, and reflect an increase from $128.4 million at December 31, 2018. Cash and investments reflect the proceeds from a November 2019 equity offering and a prefunded warrants transaction, as well as a $22.0 million upfront payment from Torii, offset by normal operating expenses. Net proceeds from these transactions yielded just over $100 million in capital in the fourth quarter and provide the company sufficient capital to fund the launch of berotralstat in the United States as well as its other planned operations through 2020. Operating cash use for the fourth quarter of 2019 was $33.5 million, and for the full year of 2019 was $111.4 million.

Full Year 2019 Financial Results

For the full year ended December 31, 2019, total revenues were $48.8 million, compared to $20.7 million in the full year ended December 31, 2018. The increase was primarily due to the recognition of $20.1 million of the $22.0 million upfront payment from Torii, $13.9 of RAPIVAB product sales under our procurement contract and $3.7 million of peramivir product sales to our licensing partners. The increase in revenues was partially offset by the recognition of $12.0 million of peramivir milestones recognized in 2018 that did not recur in 2019.

R&D expenses in 2019 increased to $107.1 million from $84.9 million in 2018, primarily due to increased spending on the company's complement-mediated diseases program and other preclinical development initiatives.

SG&A expenses in 2019 increased to $37.1 million, compared to $29.5 million in 2018. The increase was primarily due to increased spending on commercial activities and medical affairs to support the U.S. commercial launch of berotralstat in 2020. The increased commercial and medical affairs costs were partially offset by the non-recurring 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 $11.9 million in 2019, compared to $9.2 million in 2018. The increase was associated with an increase in the outstanding

balance of the company's secured credit facility in February 2019 and increased interest expense associated with the company's non-recourse notes payable.

Net loss for 2019 was $108.9 million, or $0.94 per share, compared to a net loss of $101.3 million, or $0.98 per share, for 2018.

Financial Outlook for 2020

BioCryst expects full year 2020 net operating cash use to be in the range of $125 to $150 million, and its operating expenses to be in the range of $135 to $160 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 # 7351587. 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 # 7351587.

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 berotralstat (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 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 galidesivir 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 2020 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,	
	2019	2018	2019	2018
Revenues:				
Product sales	$ 15,519	$ -	$ 17,533	$ -
Royalty revenue	2,777	1,775	6,303	6,101
Collaborative and other research and development	21,429	954	24,999	14,552
Total revenues	39,725	2,729	48,835	20,653

Expenses:				
Cost of product sales	2,327	-	3,726	-
Research and development	26,774	23,431	107,068	84,888
Selling, general and administrative	10,489	4,490	37,121	29,514
Royalty	244	70	375	471
Total operating expenses	39,834	27,991	148,290	114,873
Loss from operations	(109)	(25,262)	(99,455)	(94,220)
Interest and other income	388	686	1,933	2,252
Interest expense	(3,087)	(2,414)	(11,892)	(9,176)
Gain (loss) on foreign currency derivative	186	(442)	517	(108)
Net loss	$ (2,622)	$ (27,432)	$ (108,897)	$ (101,252)
Basic and diluted net loss per common share	$ (0.02)	$ (0.25)	$ (0.94)	$ (0.98)
Weighted average shares outstanding	131,303	109,802	115,600	103,185

Balance Sheet Data (in thousands)

	December 31, 2019 (Unaudited)	December 31, 2018 (Note 1)
Cash, cash equivalents and investments	$ 136,226	$ 126,843
Restricted cash	1,551	1,544
Receivables from collaborations	22,146	4,293
Total assets	175,282	146,841
Non-recourse notes payable	29,561	29,121
Senior credit facility	50,309	29,952
Accumulated deficit	(840,628)	(731,969)
Stockholders' equity	38,252	49,235
Shares of common stock outstanding	154,082	110,063

Note 1: Derived from audited financial statements.