



February 23, 2016

BioCryst Reports Fourth Quarter & Full Year 2015 Financial Results

RESEARCH TRIANGLE PARK, N.C., Feb. 23, 2016 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) today announced financial results for the fourth quarter and full year ended December 31, 2015.

"In 2015, we gained clarity on both of our HAE drug candidates and brought in additional capital by out-licensing [RAPIVAB](#). Our efforts are now focused on completing the bioavailability study of a solid dosage form of avoralstat and completing the APeX-1 clinical trial of BCX7353," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "We ended 2015 with a balance sheet that enables us to achieve these two near-term data events without the need to raise capital. These two programs give us two shots at achieving our goal of developing a highly effective, conveniently dosed, oral drug candidate for the prophylactic treatment of HAE patients."

Fourth Quarter Financial Results

For the three months ended December 31, 2015, total revenues decreased to \$4.6 million from \$5.4 million in the fourth quarter of 2014. The decrease resulted primarily from lower 2015 RAPIVAB royalty revenue, as well as lower collaborative revenue associated with BCX4430 development under contracts with the [National Institute of Allergy and Infectious Diseases](#) (NIAID) and the [Biomedical Advanced Research and Development Authority](#) (BARDA).

Research and Development (R&D) expenses for the fourth quarter 2015 of \$19.0 million were consistent with the \$18.5 million incurred in the fourth quarter 2014. R&D expense in the fourth quarter 2015 was more heavily concentrated in the Company's hereditary angioedema (HAE) programs, and to a lesser extent, [BCX4430](#) development costs under the NIAID and BARDA contracts, as compared to R&D expenses in the fourth quarter 2014.

Selling, general and administrative (SG&A) expenses for the fourth quarter 2015 increased to \$2.7 million compared to \$2.0 million in the fourth quarter 2014, largely due to the initiation of activities in preparation for the future commercialization of the Company's HAE product candidates.

Interest expense, which is related to non-recourse notes, was \$1.3 million for the fourth quarter of both 2015 and 2014. Also, a \$229,000 mark-to-market gain on the Company's foreign currency hedge was recognized in the fourth quarter 2015, compared to a \$4.8 million mark-to-market gain in the fourth quarter 2014. These gains result from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement.

The net loss for the fourth quarter of 2015 was \$18.1 million, or \$0.25 per share, compared to a net loss of \$11.7 million, or \$0.16 per share, for the fourth quarter 2014.

2015 Financial Results

For the year ended December 31, 2015, total revenues increased to \$48.3 million from \$13.6 million in 2014. The increase in 2015 revenues was primarily due to the recognition of \$21.8 million of revenue associated with a \$33.7 million upfront payment from the RAPIVAB out-licensing transaction, \$6.3 million of RAPIVAB product revenue, and increased collaboration revenue associated with BCX4430 development.

R&D expenses increased to \$72.8 million for 2015 from \$51.8 million for 2014. This increase was primarily the result of significantly higher HAE development costs and slightly higher RAPIVAB and BCX4430 development costs incurred in 2015, as compared to 2014.

SG&A expenses increased to \$13.0 million in 2015 from \$7.5 million in 2014, due primarily to increased marketing, medical affairs activities associated with HAE programs, as well as unrestricted grants awarded to the U.S. and international HAE patient advocacy groups.

Interest expense, which is related to non-recourse notes, was \$5.2 million in 2015 and \$5.0 million in 2014. In addition, a \$564,000 mark-to-market loss on the Company's foreign currency hedge was recognized in 2015, compared to a \$5.5 million mark-to-market gain in 2014. These gains result from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement. We also realized a currency hedge

gain of \$1.7 million from the exercise of a U.S. Dollar/Japanese yen currency option.

The 2015 net loss decreased to \$43.0 million, or \$0.59 per share, compared to a net loss of \$45.2 million, or \$0.68 per share for 2014.

Cash, cash equivalents and investments totaled \$100.9 million at December 31, 2015 and represented a \$13.1 million decrease from \$114.0 million at December 31, 2014. Net operating cash use for 2015 was \$42.2 million, as compared to \$33.3 million utilized in 2014.

Clinical Development Update & Outlook

- On February 8, 2016, we announced results from [OPuS-2 \(Oral P rophylaxiS-2\)](#), a clinical trial of [avoralstat](#) administered three times daily in a liquid-filled soft gel formulation for the prophylactic treatment of HAE attacks. The primary efficacy endpoint was angioedema attack frequency. Treatment with 500 mg and 300 mg of avoralstat three times daily failed to demonstrate a statistically significantly lower mean attack rate versus placebo. Statistically significant improvements in duration of attacks and in the Angioedema Quality of Life total score were observed comparing the 500 mg three times a day avoralstat arm to placebo. Following the analysis of OPuS-2 results, the decision was made to discontinue further development of softgel avoralstat formulation in order to focus development efforts on a novel solid dosage form of avoralstat.
- BioCryst expects to report results from a relative bioavailability study testing the novel solid dosage form of avoralstat by mid-year 2016. The primary goal of this study is to achieve meaningfully better drug exposure in a twice daily dosing regimen.
- BioCryst expects to report results from the BCX7353 APeX-1 dose ranging study in HAE patients by year end. The design of APeX-1 trial will be described once it is initiated.

Financial Outlook for 2016

Based upon development plans and our awarded government contracts, BioCryst expects its 2016 net operating cash use to be in the range of \$55 to \$75 million, and its 2016 operating expenses to be in the range of \$78 to \$98 million. Our 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's leadership team will host a conference call and webcast today, February 23, 2016 at 11:00 a.m. Eastern Time, to discuss these financial results and recent corporate developments. To participate in the conference call, please dial 1-877-303-8027 (United States) or 1-760-536-5165 (International). No passcode is needed for the call. The webcast can be accessed by logging onto www.BioCryst.com. Please connect to the website at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst's ongoing development programs include oral plasma kallikrein inhibitors for hereditary angioedema, [avoralstat](#), BCX7353 and other second generation compounds, and [BCX4430](#), a broad spectrum viral RNA polymerase inhibitor. 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 the planned PK trials of the solid dose form of avoralstat in healthy volunteers may not have a favorable outcome; that developing a commercial formulation for avoralstat or any other HAE compound may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of HAE second generation candidates (including APeX-1) 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 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 BioCryst may not receive additional government funding to further support the development of BCX4430; that BCX4430 development may not be successful; that BARDA and/or NIAID may further condition, reduce or eliminate future funding; that revenue from RAPIVAB is unpredictable and commercialization of RAPIVAB may never result in significant commercial revenue for the Company; that the Company may not be able to continue development of ongoing and future development programs; that such development programs may never result in future products; that actual financial results may not be consistent with expectations, including that 2016 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,	
	2015	2014	2015	2014
Revenues:				
Product sales, net	\$ 55	\$ 33	\$ 6,291	\$ 33
Royalty revenue	610	1,074	2,386	3,025
Collaborative and other research and development	3,937	4,339	39,580	10,550
Total revenues	<u>4,602</u>	<u>5,446</u>	<u>48,257</u>	<u>13,608</u>
Expenses:				
Cost of goods sold	7	1	1,368	1
Research and development	19,047	18,510	72,758	51,796
Selling, general and administrative	2,721	2,048	13,047	7,461
Royalty	21	43	528	121
Total expenses	<u>21,796</u>	<u>20,602</u>	<u>87,701</u>	<u>59,379</u>
Loss from operations	(17,194)	(15,156)	(39,444)	(45,771)
Interest and other income	168	43	535	93
Interest expense	(1,338)	(1,314)	(5,200)	(4,998)
Gain on foreign currency derivative	229	4,755	1,090	5,487
Net loss	<u>\$ (18,135)</u>	<u>\$ (11,672)</u>	<u>\$ (43,019)</u>	<u>\$ (45,189)</u>
Basic and diluted net loss per common share	<u>\$ (0.25)</u>	<u>\$ (0.16)</u>	<u>\$ (0.59)</u>	<u>\$ (0.68)</u>
Weighted average shares outstanding	73,345	71,867	72,901	66,773

Balance Sheet Data (in thousands)

	December 31, 2015 (Unaudited)	December 31, 2014 (Note 1)
Cash, cash equivalents and investments	\$ 99,246	\$ 113,888
Restricted cash	1,612	150
Receivables from product sales	-	5,641
Receivables from collaborations	6,243	3,849

Total assets	124,555	136,874
Non-recourse notes payable	30,000	30,000
Accumulated deficit	(510,917)	(467,898)
Stockholders' equity	47,724	75,635

Note 1: Derived from audited financial statements.

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 [Primary Logo](#)

Source: Biocryst Pharmaceuticals

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