



May 5, 2016

BioCryst Reports First Quarter 2016 Financial Results

RESEARCH TRIANGLE PARK, N.C., May 05, 2016 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) today announced financial results for the first quarter ended March 31, 2016.

"We are currently working through the start-up activities for the APeX-1 trial of BCX7353 for prevention of angioedema attacks in HAE patients and are targeting the end of the year to report results," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "In addition, we are conducting a Phase 1 clinical pharmacology study in healthy volunteers to determine if we are able to meaningfully increase exposure and get to a twice-daily oral dosage form of avoralstat. We expect to report results from this study this summer."

First Quarter Financial Results

For the three months ended March 31, 2016, revenues decreased to \$4.8 million from \$6.8 million in the first quarter of 2015. The decrease was primarily due to lower collaborative revenue associated with BCX4430 development under the advanced development contract with the [Biomedical Advanced Research and Development Authority](#) (BARDA/HHS) awarded in March 2015. In the first quarter of 2015, the Company recorded \$537,000 in RAPIVAB[®] revenue, representing drug sold under the sell-through revenue recognition methodology. No RAPIVAB revenue was received in the first quarter 2016 as RAPIVAB commercialization is now being handled by Seqirus UK Limited (Seqirus).

Research and Development (R&D) expenses for the first quarter of 2016 increased to \$20.6 million from \$17.1 million in the first quarter of 2015. The R&D expense increase in 2016 resulted primarily from higher development costs associated with the Company's hereditary angioedema (HAE) programs, as well as ongoing post approval clinical trials of RAPIVAB in both pediatric and elderly/high risk influenza patient populations.

General and administrative (G&A) expenses for the first quarter of 2016 decreased to \$3.2 million compared to \$4.1 million for the first quarter of 2015. G&A expenses decreased in 2016 due to a significant reduction in unrestricted grants, as well as the elimination of marketing and commercial consulting expense in 2016, as RAPIVAB is now being commercialized by Seqirus.

Interest expense, which is primarily related to non-recourse notes, was \$1.5 million in the first quarter of 2016 and \$1.3 million in the first quarter of 2015. Also, a \$2.8 million mark-to-market loss on the Company's foreign currency hedge was recognized in the first quarter of 2016, as compared to a \$464,000 mark-to-market gain in the first quarter of 2015. The change in the dollar/yen exchange rate between the quarters resulted in a \$3.2 million increase to the Company's net loss for the first quarter of 2016 as compared to 2015. These gains and losses 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 first quarter of 2016 was \$22.8 million, or \$0.31 per share, compared to a net loss of \$15.2 million, or \$0.21 per share, for the first quarter 2015.

Cash, cash equivalents and investments totaled \$78.9 million at March 31, 2016. Net operating cash use for the first quarter of 2016 was \$22.4 million, as compared to \$3.8 million for the first quarter of 2015. The first quarter of 2016 is expected to be the largest cash consumption quarter of the four quarters in 2016, and BioCryst expects to remain within previously issued cash use guidance.

Clinical Development Update & Outlook

- | BioCryst expects to report results of the APeX-1 clinical trial of the once-daily, second generation HAE compound, BCX7353, for prevention of angioedema attacks in HAE patients by year end.
- | A Phase 1 clinical pharmacology trial testing multiple avoralstat formulations is ongoing in healthy subjects with the aim to develop a twice-daily dosage for HAE patients. Pharmacokinetic results are expected this summer.
- | BioCryst has completed the Phase 1 clinical trial of single and multiple ascending doses of its broad spectrum antiviral BCX4430 administered by intramuscular (i.m.) injection in healthy volunteers. BCX4430 by i.m. injection was generally safe and well tolerated through doses up to 10mg/kg daily for seven days, the maximum dose planned in the trial.

- 1 Nonclinical experiments are continuing with BCX4430 in a model of Zika virus infection in interferon-receptor-deficient mice. Studies conducted to date have shown improved survival with dosing delayed up to 7 days after virus challenge, reduction in viral titer in the blood, and development of protective immunity in surviving animals. This research has been conducted in collaboration with Utah State University and NIAID.
- 1 In January, BioCryst submitted a New Drug Submission (NDS) for RAPIVAB in Canada, seeking approval for the treatment of acute uncomplicated influenza in adult patients.

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 Thursday, May 5, 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 currently has several ongoing development programs: oral inhibitors of plasma kallikrein for hereditary angioedema, including 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 future trials of avoralstat or BCX7353 may not have a favorable outcome; that developing a commercial formulation for avoralstat, BCX7353 or any other HAE compound may be unsuccessful, take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of HAE second generation candidates 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 BCX4430 may not successfully treat patients infected with Zika virus; that NIAID or BARDA 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 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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Statements of Operations (Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Product sales, net	\$ -	\$ 537
Royalty revenue	1,890	1,518
Collaborative and other research and development	2,930	4,771
Total revenues	4,820	6,826
Expenses:		
Cost of products sold	-	15
Research and development	20,579	17,120
General and administrative	3,212	4,061
Royalty	77	60
Total expenses	23,868	21,256
Loss from operations	(19,048)	(14,430)
Interest and other income	439	117
Interest expense	(1,470)	(1,315)
(Loss) gain on foreign currency derivative	(2,753)	464
Net loss	\$ (22,832)	\$ (15,164)
Basic and diluted net loss per common share	\$ (0.31)	\$ (0.21)
Weighted average shares outstanding	73,601	72,341

Balance Sheet Data (in thousands)

	March 31, 2016 (Unaudited)	December 31, 2015 (Note 1)
Cash, cash equivalents and investments	\$ 76,950	\$ 99,246
Restricted cash	1,965	1,612
Receivables from collaborations	7,384	6,243
Total assets	102,881	122,359
Non-recourse notes payable (Note 2)	27,914	27,804
Accumulated deficit	(533,749)	(510,917)
Stockholders' equity	27,798	47,724

Note 1: Derived from audited financial statements

Note 2: Reflects retrospective application of ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*

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 [Primary Logo](#)

Source: Biocryst Pharmaceuticals

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