



May 8, 2014

BioCryst Reports First Quarter 2014 Financial Results

RESEARCH TRIANGLE PARK, N.C., May 8, 2014 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq:BCRX) today announced financial results for the first quarter ended March 31, 2014.

"We have completed enrollment in the OPuS-1 Phase 2 trial to evaluate orally-administered [BCX4161](#) in patients with hereditary angioedema and we look forward to reporting results from this proof of concept trial by the end of June," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "In addition, we continue to advance our 2nd generation oral kallikrein inhibitors with a goal of initiating clinical trials during the first half of 2015."

First Quarter Financial Results

For the three months ended March 31, 2014, revenues were \$3.5 million and consistent with \$3.6 million of revenues reported in the first quarter of 2013. Collaborative revenue in 2014 of \$1.6 million was predominantly associated with BCX4430 development under the contract with the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) as a treatment for Marburg virus disease, as well as activities supporting the filing of a New Drug Application (NDA) seeking regulatory approval for intravenous (i.v.) peramivir in the U.S.

Research and Development (R&D) expenses for the first quarter of 2014 increased to \$9.2 million from \$7.2 million in the first quarter of 2013. The increase in R&D expense in 2014 as compared to 2013 resulted from higher development costs associated with the hereditary angioedema (HAE) and BCX4430 programs, and was partially offset by lower R&D costs associated with conclusion of clinical development of peramivir and the termination of BCX5191 development during 2013.

General and administrative (G&A) expenses for the first quarter of both 2014 and 2013 were \$1.6 million and reflect stabilization of administrative expenses following the restructuring of the Company's operations and cost structure, as announced in December 2012.

Interest expense, which is related to non-recourse notes, was \$1.2 million in the first quarter of 2014 and 2013. Also, a \$1.5 million mark-to-market loss on the Company's foreign currency hedge was recognized in the first quarter of 2014, compared to a \$2.0 million mark-to-market gain in the first quarter of 2013. These losses and 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 first quarter of 2014 was \$10.1 million, or \$0.17 per share, compared to a net loss of \$4.5 million, or \$0.09 per share, for the first quarter 2013.

Cash, cash equivalents and investments totaled \$34.2 million at March 31, 2014 and represented a \$6.6 million decrease from the \$40.8 million at December 31, 2013. Net operating cash use for the first quarter of 2014 was \$5.0 million, as compared to \$8.9 million for the first quarter of 2013.

Clinical Development Update & Outlook

- BioCryst recently completed enrollment in [OPuS-1 \(Oral Prophylaxis-1\)](#), a Phase 2a trial of orally-administered BCX4161 in patients with hereditary angioedema. The Company expects to report results during the second quarter 2014. The OPuS-1 clinical trial is testing 400 mg of BCX4161 administered three times daily for 28 days in up to 25 HAE patients who have a high frequency of attacks (≥ 1 per week), in a randomized, placebo-controlled, two-period cross-over design.
- Nonclinical development of our two second-generation plasma kallikrein inhibitors continues to progress as planned. The most advanced compound has completed additional nonclinical dosing studies, with results that continue to support a profile of once-daily dosing for HAE in the clinic.
- Earlier this year, the NDA for i.v. peramivir was accepted with a PDUFA date of December 23, 2014. Following the issuance of a Warning Letter and a recent re-inspection by FDA, our contract manufacturer for peramivir drug product received a Form 483, which contained a number of observations that need to be addressed. It is unclear how these findings may impact the peramivir NDA or supply of peramivir drug product. BioCryst and its contract manufacturer are working with the FDA to meet the requirements for approval of the peramivir NDA.

- In March, BioCryst announced the publication in the journal [Nature](#) of compelling BCX4430 efficacy results in animal models of infection with [Marburg virus](#) and [Ebola virus](#), two highly virulent pathogens responsible for viral hemorrhagic fever diseases. The *Nature* online publication, "[Protection against filovirus diseases by a novel broad-spectrum nucleoside analog BCX4430](#)," represents the first report of protection of non-human primates from filovirus disease by a small molecule drug. This research was chosen for oral presentation at the [6th International Symposium on Filoviruses](#) in Galveston, TX, on April 2 and also at [The 27th International Conference on Antiviral Research](#) (ICAR) in Raleigh, NC on May 14.
- During the first quarter 2014, BioCryst's research team started small molecule drug discovery programs addressing two rare disease targets. These programs are intended to refill the clinical development pipeline in the timeframe our HAE assets come to market.

Financial Outlook for 2014

Based upon current trends, assumptions, and development plans, BioCryst expects its 2014 net operating cash use to be in the range of \$35 to \$43 million, and its operating expenses to be in the range of \$48 to \$59 million. Our operating expense range excludes equity-based compensation expense due to the difficulty in 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, May 8, 2014 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 infectious and rare diseases, with the goal of addressing unmet medical needs of patients and physicians. BioCryst's core development programs include [BCX4161](#) and two next generation oral inhibitors of plasma kallikrein for hereditary angioedema; [peramivir](#), a viral neuraminidase inhibitor for the treatment of influenza; and [BCX4430](#), a broad spectrum antiviral for hemorrhagic fevers. 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 Phase 2a clinical trial for BCX4161 may not have a favorable outcome; that ongoing and future preclinical and clinical development of HAE second generation candidates may not have positive results; that BioCryst or its licensees may not be able to enroll the required number of subjects in planned clinical trials of other product candidates; that the Company or its licensees 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 government funding to further support the development of BCX4430 or peramivir; that BARDA/HHS and NIAID may further condition, reduce or eliminate future funding; that peramivir may never be approved for any use by the FDA; that the Company's peramivir supply could be limited or delayed due to regulatory issues at our manufacturer; that the Company or its licensees may not be able to continue development of ongoing and future development programs; that such development programs may never result in future product, license or royalty payments being received; that the Company may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of product candidates, that its actual financial results may not be consistent with its expectations, including that 2014 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.

BIOCRIST PHARMACEUTICALS, INC.
FINANCIAL SUMMARY
(in thousands, except per share numbers)

Statements of Operations (Unaudited)

	Three Months Ended	
	March 31,	
	2014	2013
Revenues:		
Royalty	\$ 1,821	\$ 1,924
Collaborative and other research and development	1,637	1,630
Total revenues	3,458	3,554
Expenses:		
Research and development	9,183	7,215
General and administrative	1,588	1,578
Royalty	73	77
Total operating expenses	10,844	8,870
Loss from operations	(7,386)	(5,316)
Interest and other income	17	33
Interest expense	(1,242)	(1,180)
Gain (loss) on foreign currency derivative	(1,526)	1,957
Net loss	\$ (10,137)	\$ (4,506)
Basic and diluted net loss per common share	\$ (0.17)	\$ (0.09)
Weighted average shares outstanding	59,589	51,073

Note: For the three months ended March 31, 2013, \$196 of legal patent costs are now classified as General and Administrative expense, whereas they were previously classified as Research and Development expense.

Balance Sheet Data (in thousands)

	March 31, 2014	December 31, 2013
	(Unaudited)	(Note 1)
Cash, cash equivalents and investments	\$ 34,070	\$ 40,637
Restricted cash	150	151
Receivables from collaborations	3,280	2,115
Total assets	43,387	48,866
Non-recourse notes payable	30,000	30,000
Accumulated deficit	(432,846)	(422,709)
Stockholders' deficit	(5,723)	(1,126)

Note 1: Derived from audited financial statements.

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Source: BioCryst Pharmaceuticals

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