



February 26, 2014

BioCryst Reports Fourth Quarter and Full Year 2013 Financial Results

RESEARCH TRIANGLE PARK, N.C., Feb. 26, 2014 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq:BCRX) today announced financial results for the fourth quarter and full year ended December 31, 2013.

"Since our last quarterly results update, we have initiated the OPuS-1 Phase 2 trial to evaluate orally-administered [BCX4161](#) in patients with hereditary angioedema, advanced two optimized plasma kallikrein inhibitors into preclinical development for HAE and filed BioCryst's first NDA seeking FDA approval of [peramivir](#)," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "Our team is committed to sustaining the momentum and tight expense management we established last year. In 2014, you can expect us to advance all three of our HAE assets as well as both of our infectious disease programs. This includes making peramivir available in the U.S. for the 2014-15 influenza season, provided our NDA is approved."

Fourth Quarter Financial Results

For the three months ended December 31, 2013, revenues increased to \$10.6 million from \$4.1 million in the fourth quarter of 2012, primarily as a result of an increase in collaborative revenue under our contract with the [Biomedical Advanced Research and Development Authority/Health and Human Services](#) (BARDA/HHS) for the development of peramivir. The collaborative revenue from BARDA/HHS was predominantly associated with activities supporting the December 20, 2013 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 fourth quarter of 2013 increased to \$15.6 million from \$11.1 million in the fourth quarter of 2012. The increase in R&D expense in 2013, as compared to the fourth quarter of 2012, resulted from higher development costs associated with the peramivir and hereditary angioedema (HAE) programs, which were partially offset by lower development costs associated with the ulodesine and BCX5191 programs.

General and administrative (G&A) expenses for the fourth quarter of 2013 decreased to \$1.3 million compared to \$1.9 million in the fourth quarter of 2012, largely due to lower administrative expenses during 2013 as a consequence of restructuring 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 fourth quarter of 2013 and 2012. Also, a \$2.1 million mark-to-market gain on the Company's foreign currency hedge was recognized in the fourth quarter of 2013, compared to a \$782,000 mark-to-market gain in the fourth quarter of 2012. 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 2013 was \$5.4 million, or \$0.09 per share, compared to a net loss of \$11.1 million, or \$0.22 per share, for the fourth quarter 2012.

2013 Financial Results

For the year ended December 31, 2013, total revenues decreased to \$17.3 million from \$26.3 million in 2012. The decrease was primarily due to the recognition of \$7.8 million of previously deferred forodesine-related revenue in the first quarter of 2012.

R&D expenses decreased to \$42.7 million for 2013 from \$51.5 million in 2012. The decrease from 2012 resulted primarily from lower BCX5191 and ulodesine development costs, as well as reduced R&D infrastructure costs. This decrease was partially offset by higher BCX4161 and BCX4430 development costs incurred in 2013. Expenses for 2013 also included a one-time \$5.0 million non-cash write-off of a "deferred collaboration costs" asset associated with ulodesine and our Purine Nucleoside Phosphorylase Inhibitor (PNP) licensing agreement. R&D expenses in 2012 included the recognition of \$1.9 million of non-cash, previously deferred expenses associated with the transfer of forodesine development activity to Mundipharma International Holdings Ltd. in 2012 and an amendment of the underlying forodesine license agreement.

G&A expenses decreased to \$5.2 million in 2013 from \$6.8 million in 2012, due to realization of cost containment measures resulting from our 2012 restructuring. Total operating expenses decreased to \$48.0 million in 2013 from \$60.2 million in 2012. In addition to the decreases in R&D and G&A expenses discussed above, 2012 operating expenses included \$1.8 million of restructuring expense, which contributed to the decrease in 2013 operating expenses as compared to 2012.

Interest expense, which is related to non-recourse notes, was \$4.8 million in 2013 and \$4.7 million in 2012. In addition, a \$5.3 million mark-to-market gain on the Company's foreign currency hedge was recognized in 2013, compared to a \$749,000 mark-to-market loss in 2012. These gains/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 2013 decreased to \$30.1 million or \$0.55 per share, compared to a net loss of \$39.1 million, or \$0.79 per share for 2012.

Cash, cash equivalents and investments totaled \$40.8 million at December 31, 2013 and represented a \$3.7 million increase from the \$37.1 million at December 31, 2012. Net operating cash use for the fourth quarter of 2013 was \$4.4 million. Net operating cash use for 2013 was \$22.8 million and decreased 38 percent from \$36.8 million utilized in 2012.

Clinical Development Update & Outlook

- In November, BioCryst dosed the first subject in OPuS-1 (**Oral Prophylaxis-1**), a Phase 2a proof of concept clinical trial of orally-administered BCX4161 in patients with hereditary angioedema. 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. The ongoing trial has advanced to a point where we now expect to report results by the end of the second quarter 2014.
- BioCryst announced in December that it has selected two optimized plasma kallikrein inhibitors to advance into preclinical development as potential once-daily, oral treatments for the prevention of HAE attacks.
- In December, the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) exercised an additional option to conduct the investigational new drug (IND) enabling program and to submit an IND. This option represented an additional \$2.5 million to BioCryst in order to advance the development of [BCX4430](#) as a treatment for Marburg virus disease, and represents a total of \$7.5 million of funding granted under a \$22 million contract awarded in September 2013.
- In December, BioCryst submitted an NDA filing for i.v. [peramivir](#) to the U.S. Food & Drug Administration (FDA) seeking an indication as the first i.v. neuraminidase inhibitor approved in the U.S. for the treatment of acute uncomplicated influenza in adults. On February 24, 2014, the FDA notified BioCryst that its NDA filing was accepted for standard review with a PDUFA (Prescription Drug User Fee Act) action date of December 23, 2014. The FDA has informed BioCryst that it does not currently plan to hold an Advisory Committee review of the NDA.
- Peramivir has been developed by BioCryst under a \$234.8 million contract from BARDA/HHS since 2007. With the completion of the NDA filing, this development contract is expected to expire on March 31, 2014.
- Two scientific posters describing BioCryst's research related to the treatment of HAE are scheduled for presentation at the 2014 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting February 28 - March 4, 2014 in San Diego.
- BioCryst plans to initiate a new drug discovery program against at least one rare disease target during the first quarter of 2014.

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. In addition, based upon forecasted development activity and the related revenue under the Company's U.S. Government contracts, the Company expects its 2014 revenue to decrease from 2013 levels.

Conference Call and Webcast

BioCryst's leadership team will host a conference call and webcast today, February 26, 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 BioCryst may not be able to enroll the required number of subjects in its ongoing Phase 2a clinical trial for BCX4161; that the Phase 2a clinical trial for BCX4161 may not have a favorable outcome or be successfully completed; that the Phase 2a clinical trial for BCX4161 may take longer or cost more than expected; 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 ongoing and future preclinical and clinical development of HAE second generation candidates may not have positive results; 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 2013 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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BIOCRYSST PHARMACEUTICALS, INC.

FINANCIAL SUMMARY

(in thousands, except per share amounts)

Statements of Operations (Unaudited)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2013	2012	2013	2012
Revenues:				
Royalty revenue	\$ 520	\$ 469	\$ 2,562	\$ 3,317
Collaborative and other research and development	10,047	3,632	14,769	22,976
Total revenues	10,567	4,101	17,331	26,293
Expenses:				
Research and development	15,614	11,090	42,730	51,464
General and administrative	1,270	1,929	5,220	6,826
Royalty	17	18	98	132
Restructuring costs	--	1,759	--	1,759
Total expenses	16,901	14,796	48,048	60,181

Loss from operations	(6,334)	(10,695)	(30,717)	(33,888)
Interest and other income	21	40	93	222
Interest expense	(1,242)	(1,180)	(4,778)	(4,666)
Gain (loss) on foreign currency derivative	<u>2,126</u>	<u>782</u>	<u>5,294</u>	<u>(749)</u>
Net loss	<u>\$ (5,429)</u>	<u>\$ (11,053)</u>	<u>\$ (30,108)</u>	<u>\$ (39,081)</u>
Basic and diluted net loss per common share	<u>\$ (0.09)</u>	<u>\$ (0.22)</u>	<u>\$ (0.55)</u>	<u>\$ (0.79)</u>
Weighted average shares outstanding	59,091	50,883	55,216	49,474

Balance Sheet Data (in thousands)	December 31, 2013	December 31, 2012
	(Unaudited)	(Note 1)
Cash, cash equivalents and investments	\$ 40,637	\$ 36,750
Restricted cash	151	308
Receivables from collaborations	2,115	4,562
Total assets	48,866	57,439
Non-recourse notes payable	30,000	30,000
Accumulated deficit	(422,709)	(392,601)
Stockholders' deficit	(1,126)	(454)

Note 1: Derived from audited financial statements.

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Source: BioCryst Pharmaceuticals

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