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BioCryst Reports Fourth Quarter and Full Year 2012 Financial Results

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- [BioCryst Pharmaceuticals, Inc.](http://www.biocryst.com) (NASDAQ:BCRX) today announced financial results for the fourth quarter and full year ended December 31, 2012.

"Our team is focused on achieving near-term milestones to rebuild shareholder value. Our primary goal is to advance our potentially ground-breaking oral kallikrein inhibitors for hereditary angioedema. Phase 1 clinical trials for the lead compound, [BCX4161](#), are scheduled to begin in the next few months and we are finalizing lead optimization for our second generation compound," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "Furthermore, we are advancing BCX4430, a broad spectrum antiviral that could fill an important gap in the U.S. Government's medical countermeasure stockpile. Based on [BCX4430](#)'s efficacy in treating various hemorrhagic fever viruses in animals, this compound could satisfy this important unmet need."

Fourth Quarter Financial Results

For the three months ended December 31, 2012, revenues decreased to \$4.1 million, from \$5.2 million in the fourth quarter of 2011. This decrease resulted primarily from a reduction in collaboration revenue from a contract with the Biomedical Advanced Research and Development Authority, within the U.S. Department of Health and Human Services (BARDA/HHS), for the development of [peramivir](#).

Research and development (R&D) expenses for the fourth quarter of 2012 decreased to \$11.1 million from \$14.2 million in the fourth quarter of 2011. In 2012, lower development costs associated with the peramivir and [ulodesine](#) programs were partially offset by higher development costs associated with the preclinical [BCX5191](#) and BCX4161 programs.

General and administrative (G&A) expenses for the fourth quarter of 2012 decreased to \$1.9 million compared to \$2.1 million in the fourth quarter of 2011, largely due to reductions in administrative expenses during 2012 associated with the continued realization of cost containment measures and the Company's restructuring of its operations. Fourth quarter 2012 expenses included a \$1.8 million charge related to the corporate restructuring announced in December 2012.

Interest expense related to non-recourse notes was \$1.2 million in the fourth quarter of 2012 and 2011. In addition, a \$0.8 million mark-to-market gain on the Company's foreign currency hedge was recognized in the fourth quarter of 2012, compared to a \$1.1 million mark-to-market loss in the fourth quarter of 2011. These hedge gains and losses resulted from changes in the U.S. dollar/Japanese yen exchange rate related to a foreign currency hedge arrangement entered into in conjunction with the RAPIACTA[®] royalty monetization transaction.

The net loss for the fourth quarter 2012 was \$11.1 million, or \$0.22 per share, compared to a net loss of \$13.2 million, or \$0.29 per share, for the fourth quarter 2011.

2012 Financial Results

For the year ended December 31, 2012, total revenues increased to \$26.3 million from \$19.6 million in 2011. The increase was due to the recognition of \$7.8 million of previously deferred forodesine-related revenue in the first quarter 2012, as well as the recognition of \$3.3 million royalty revenue from Shionogi & Co., Ltd. related to RAPIACTA[®] sales in the second half of 2012. The aggregate revenue increase was partially offset by a decrease in peramivir collaboration revenue from BARDA/HHS due to a reduction of peramivir development activity in 2012, as compared to 2011.

R&D expenses decreased to \$51.5 million for 2012 from \$57.2 million in 2011. A decrease in 2012 development costs related to the ulodesine and peramivir programs were partially offset by higher BCX5191 and BCX4161 development costs, as compared to 2011. Expenses for 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 the first quarter of 2012.

G&A expenses decreased significantly to \$6.8 million in 2012 from \$12.0 million in 2011, due to realization of cost containment measures, and the relocation of BioCryst's corporate headquarters in 2011. Total operating expenses decreased to \$60.2 million in 2012 from \$69.2 million in 2011.

The net loss for 2012 decreased to \$39.1 million, or \$0.79 per share, compared to a net loss of \$56.9 million, or \$1.26 per share for 2011.

Cash and investments totaled \$37.1 million at December 31, 2012, a \$20.6 million decrease from the \$57.7 million balance at December 31, 2011. Net operating cash use for the fourth quarter of 2012 was \$7.1 million and excludes \$0.3 million of collateral received under the Company's foreign currency hedge arrangement. Net operating cash use for 2012 was \$36.8 million, which was at the low end of BioCryst's net operating cash use guidance of \$37 to \$43 million, and total cash use was \$38.5 million.

Clinical Development Update & Outlook

- In December, BioCryst restructured its operations and implemented a focused R&D strategy to advance its hereditary angioedema (HAE) and antiviral programs. The restructuring and R&D focus significantly reduced BioCryst's future cost structure. The Company expects to reduce its operating cash burn by 30% to 40% and its operating expenses by 40% to 60% in 2013, as compared to 2012. These reductions enable the Company to extend its cash runway to achieve important near-term milestones in its oral HAE and broad spectrum antiviral programs.
- In January, the Company announced the termination of its antiviral development program for treatment of the hepatitis C virus (HCV). Following seven days of treating HCV-infected animals with BCX5191, the viral load reduction observed was insufficient to justify continued development.
- BioCryst plans to initiate its BCX4161 Phase 1 program for HAE around the end of the first quarter 2013. The main success factors for the BCX4161 Phase 1 clinical trial are to demonstrate safety, adequate and consistent drug exposure, and pharmacodynamic effects after oral administration. In addition, BioCryst has identified several second generation oral HAE compounds, and plans to select a lead candidate later in 2013.
- Proof-of-principle data demonstrating that BCX4430 was efficacious and well tolerated in a preclinical yellow fever virus infection disease model was presented at the 2nd Antivirals Congress in Cambridge in November. BioCryst is continuing its collaboration with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) regarding filoviruses, while seeking additional U.S. Government funding for the further development of BCX4430. BioCryst expects to provide additional BCX4430 updates throughout 2013.
- In November, the independent data monitoring committee (DMC) overseeing the peramivir [Phase 3](#) clinical trial in hospitalized influenza patients informed the Company that the recalculated sample size for the clinical trial had crossed the pre-specified futility boundary of 320 subjects. Following this notification, BioCryst terminated the clinical trial, completed its analysis of the Phase 3 results and shared the data and findings with BARDA/HHS. In the coming months, the Company plans to have additional discussions with BARDA/HHS and the Food and Drug Administration to determine the future of the U.S. peramivir program.

Financial Outlook for 2013

Based upon current trends and assumptions, as well as the Company's restructured operations, BioCryst expects 2013 net operating cash use to be in the range of \$22 to \$26 million, and its 2013 operating expenses to be in the range of \$25 to \$35 million.

Conference Call and Webcast

BioCryst's leadership team will now host a conference call and webcast today, February 19, 2013 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 inflammatory diseases, with the goal of addressing unmet medical needs of patients and physicians. BioCryst currently has two late-stage development programs: peramivir, a viral neuraminidase inhibitor for the treatment of influenza, and ulodesine, a purine nucleoside phosphorylase (PNP) inhibitor for the treatment of gout. In addition, BioCryst has several early-stage programs: BCX4161 and a next generation oral inhibitor of plasma kallikrein for hereditary angioedema 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 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 or its licensees may not be able to enroll the required number of subjects in planned clinical trials of its product candidates and that such clinical trials, including the planned Phase 1 clinical trial for BCX4161, may not be successfully completed; that the Company or its licensees may not commence as expected additional human clinical trials with product candidates; 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, 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 support the further development of BCX4430; that BARDA/HHS may further condition, reduce or eliminate future funding of the peramivir program; that peramivir may never be approved for any use by the FDA; that ongoing and future preclinical and clinical development may not have positive results; that the Company or its licensees may not be able to continue future development of current 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, including ulodesine; 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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BIOCRIST PHARMACEUTICALS, INC.
FINANCIAL SUMMARY
(in thousands, except per share amounts)
Statements of Operations

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Revenues:				
Royalty revenue	\$ 469	\$-	\$ 3,317	\$ -
Collaborative and other research and development	3,632	5,224	22,976	19,643
Total revenues	<u>4,101</u>	<u>5,224</u>	<u>26,293</u>	<u>19,643</u>
Expenses:				
Research and development	11,090	14,198	51,464	57,249
General and administrative	1,929	2,068	6,826	11,981
Royalty expense	18	-	132	-
Restructuring costs	1,759	-	1,759	-
Total expenses	<u>14,796</u>	<u>16,266</u>	<u>60,181</u>	<u>69,230</u>
Loss from operations	(10,695)	(11,042)	(33,888)	(49,587)
Interest and other income	40	84	222	413
Interest expense	(1,180)	(1,160)	(4,666)	(3,774)
Loss on foreign currency derivative	<u>782</u>	<u>(1,074)</u>	<u>(749)</u>	<u>(4,000)</u>
Net loss	<u>\$ (11,053)</u>	<u>\$ (13,192)</u>	<u>\$ (39,081)</u>	<u>\$ (56,948)</u>
Basic and diluted net loss per common share	<u>\$ (0.22)</u>	<u>\$ (0.29)</u>	<u>\$ (0.79)</u>	<u>\$ (1.26)</u>
Weighted average shares outstanding	50,883	45,266	49,474	45,144

Balance Sheet Data

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Cash, cash equivalents and securities	\$ 36,750	\$ 57,100
Restricted cash	308	625
Receivables from collaborations	4,562	5,831
Total assets	57,439	82,208
Non-recourse notes payable	30,000	30,000
Accumulated deficit	(392,601)	(353,520)
Stockholders' (deficit) equity	(454)	14,806

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Source: BioCryst Pharmaceuticals

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