



February 18, 2015

## BioCryst Reports Fourth Quarter & Full Year 2014 Financial Results

RESEARCH TRIANGLE PARK, N.C., Feb. 18, 2015 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](http://www.biocryst.com) (Nasdaq:BCRX) today announced financial results for the fourth quarter and full year ended December 31, 2014.

"We are proud of our 2014 achievements; most notably our successful completion of the BCX4161 OPuS-1 trial and the initiation of OPuS-2 for the treatment of hereditary angioedema, as well as our first U.S. regulatory approval of a BioCryst discovered drug, [RAPIVAB](#)<sup>TM</sup> for the treatment of acute uncomplicated influenza in patients 18 years and older," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "We have also made substantial progress in our 2<sup>nd</sup> generation kallikrein inhibitor program and are now preparing BCX7353 to enter Phase 1 testing as a potential once-daily oral treatment to prevent HAE attacks."

### Fourth Quarter Financial Results

For the three months ended December 31, 2014, total revenues decreased to \$5.4 million from \$10.6 million in the fourth quarter of 2013. The decrease in revenues resulted primarily from the June 2014 expiration and related completion of development activities under the [Biomedical Advanced Research and Development Authority/Health and Human Services \(BARDA/HHS\)](#) peramivir development contract.

Research and Development (R&D) expenses for the fourth quarter of 2014 increased to \$18.5 million from \$15.5 million in the fourth quarter of 2013. The increase in 2014 R&D expense, as compared to the fourth quarter of 2013, resulted from higher development costs associated with the hereditary angioedema (HAE) and [BCX4430](#) programs, which were partially offset by a decrease in peramivir development expenses associated with the completion of the BARDA/HHS peramivir contract.

General and administrative (G&A) expenses for the fourth quarter of 2014 increased to \$2.0 million compared to \$1.4 million in the fourth quarter of 2013, largely due to the vesting of performance-based stock options and RAPIVAB (peramivir injection) distribution expenses incurred in advance of approval.

Interest expense, which is related to non-recourse notes, was \$1.3 million in the fourth quarter of 2014 and \$1.2 million in the fourth quarter of 2013. Also, a \$4.8 million mark-to-market gain on the Company's foreign currency hedge was recognized in the fourth quarter of 2014, compared to a \$2.1 million mark-to-market gain in the fourth quarter of 2013. 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 2014 was \$11.7 million, or \$0.16 per share, compared to a net loss of \$5.4 million, or \$0.09 per share, for the fourth quarter 2013.

### 2014 Financial Results

For the year ended December 31, 2014, total revenues decreased to \$13.6 million from \$17.3 million in 2013. The decrease was primarily the result of the June 2014 contract expiration and completion of activities under the BARDA/HHS peramivir development contract.

R&D expenses increased to \$51.8 million for 2014 from \$41.9 million in 2013. This increase was primarily the result of higher HAE program and BCX4430 development costs incurred in 2014, which were partially offset by the wind down of peramivir development expenses. In addition, 2014 equity compensation expense increased due to the vesting of performance-based stock options associated with the successful outcome of OPuS-1 and U.S. RAPIVAB approval. Most of this charge was reflected in R&D expense. In addition, expenses for 2013 included a one-time \$5.0 million non-cash write-off of a "deferred collaboration costs" asset.

G&A expenses increased to \$7.5 million in 2014 from \$6.0 million in 2013, due primarily to RAPIVAB distribution expenses and unrestricted grants awarded to the U.S. and international HAE patient advocacy groups.

Interest expense, which is related to non-recourse notes, was \$5.0 million in 2014 and \$4.8 million in 2013. In addition, a \$5.5 million mark-to-market gain on the Company's foreign currency hedge was recognized in 2014, compared to a \$5.3 million

mark-to-market gain in 2013. 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 2014 increased to \$45.2 million or \$0.68 per share, compared to a net loss of \$30.1 million, or \$0.55 per share for 2013.

Cash, cash equivalents and investments totaled \$114.0 million at December 31, 2014 and represented a \$73.2 million increase from \$40.8 million at December 31, 2013. The increase in cash and investments relates to our successful equity raise in June 2014, which raised \$106.6 in net proceeds. Net operating cash use for 2014 was \$33.3 million as compared to \$22.8 million utilized in 2013.

## Clinical Development Update & Outlook

- On December 18, 2014, the first patient was dosed in [OPuS-2](#) (Oral ProphylaxiS-2), a blinded, randomized, placebo-controlled clinical trial of orally-administered [BCX4161](#) in patients with HAE. OPuS-2 is a 12-week, three-arm, parallel cohort design trial to evaluate the efficacy and safety of two doses of BCX4161, 300 mg and 500mg, administered three-times daily compared with placebo. This trial is being conducted in the U.S. and several European countries. The trial is expected to enroll approximately 100 HAE patients. The primary efficacy endpoint is the mean angioedema attack rate.
- On December 19, 2014, the [U.S. Food and Drug Administration](#) (FDA) approved RAPIVAB™ (peramivir injection), an intravenous (I.V.) viral neuraminidase inhibitor for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days.
- Orphan drug designation for BCX4161 was granted by the FDA in December 2014 for the prevention of acute attacks of angioedema in patients with HAE, and the [Committee for Orphan Medicinal Products](#) (COMP) of the [European Medicines Agency](#) (EMA) issued a positive opinion on the application for orphan drug designation for BCX4161 for the treatment of patients with HAE in January 2015, which subsequently has been confirmed by the European Commission. In addition, BCX4161 was granted Fast Track designation by the FDA in January 2015.
- In December 2014, we announced the start of a randomized, placebo-controlled Phase 1 clinical trial to evaluate intramuscular (I.M.) administration of [BCX4430](#) in healthy volunteers. We also announced positive results showing a survival benefit from BCX4430 in a proof-of-concept study of Ebola virus infection in rhesus macaques. BCX4430 is being developed as a potential treatment for hemorrhagic fever viruses, including [Ebola](#) and [Marburg](#) virus disease.
- On February 12, the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) exercised an additional option under its [BCX4430](#) development contract, which provides \$2.7 million to BioCryst for I.V. BCX4430 investigational new drug ("IND") enablement and submission. \$25.0 million of option funding has been awarded to date under the NIAID contract, which totals \$29.1 million, if all options are exercised.
- In January, Ms. [Lynne Powell](#) joined BioCryst as Senior Vice President and Chief Commercial Officer. Lynne's primary responsibility will be to formulate our global commercial strategy and to build the global organization that launches our oral kallikrein inhibitors for the prophylactic treatment of hereditary angioedema.

## Financial Outlook for 2015

Based upon development plans and assumptions and our awarded government contracts, BioCryst expects its 2015 net operating cash use to be in the range of \$65 to \$80 million, and its 2015 operating expenses to be in the range of \$75 to \$95 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 18, 2015 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](http://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 [BCX4161](#), 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](http://www.BioCryst.com). In December 2014, [RAPIVAB™](#) (peramivir injection), a viral neuraminidase inhibitor, was approved by the FDA. For more information regarding RAPIVAB, please visit <http://rapivab.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 OPuS-2 clinical trial and other planned trials of BCX4161 may not have a favorable outcome; that developing a commercial formulation for BCX4161 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 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 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 2015 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.

BCRXW

**BIOCRIST PHARMACEUTICALS, INC.**  
**CONSOLIDATED FINANCIAL SUMMARY**

(in thousands, except per share)

### Statements of Operations (Unaudited)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2014	2013	2014	2013
Revenues:				
Product sales, net	\$ 33	\$ --	\$ 33	\$ --
Royalty revenue	1,074	520	3,025	2,562
Collaborative and other research and development	4,339	10,047	10,550	14,769
Total revenues	5,446	10,567	13,608	17,331
Expenses:				
Cost of goods sold	1	--	1	--
Research and development	18,510	15,466	51,796	41,943
General and administrative	2,048	1,418	7,461	6,007
Royalty	43	17	121	98
Total expenses	20,602	16,901	59,379	48,048
Loss from operations	(15,156)	(6,334)	(45,771)	(30,717)

Interest and other income	43	21	93	93
Interest expense	(1,314)	(1,242)	(4,998)	(4,778)
Gain on foreign currency derivative	4,755	2,126	5,487	5,294
	<u>43</u>	<u>21</u>	<u>93</u>	<u>93</u>
Net loss	<u>\$ (11,672)</u>	<u>\$ (5,429)</u>	<u>\$ (45,189)</u>	<u>\$ (30,108)</u>
Basic and diluted net loss per common share	<u>\$ (0.16)</u>	<u>\$ (0.09)</u>	<u>\$ (0.68)</u>	<u>\$ (0.55)</u>
Weighted average shares outstanding	71,867	59,091	66,773	55,216

Note: For the three months and twelve months ended December 31, 2013, \$0.1m and \$0.8m of patent costs, respectively, were reclassified to General and Administrative expense. Previously, these costs were classified as Research and Development expense.

**Balance Sheet Data** (in thousands)

	December 31, 2014 (Unaudited)	December 31, 2013 (Note 1)
Cash, cash equivalents and investments	\$ 113,888	\$ 40,637
Restricted cash	150	151
Receivables from product sales	5,641	--
Receivables from collaborations	3,849	2,115
Total assets	136,874	48,866
Non-recourse notes payable	30,000	30,000
Accumulated deficit	(467,898)	(422,709)
Stockholders' equity (deficit)	75,635	(1,126)

Note 1: Derived from audited financial statements.

CONTACT: Robert Bennett, BioCryst Pharmaceuticals, +1-919-859-7910



Source: BioCryst Pharmaceuticals

News Provided by Acquire Media