



November 6, 2014

## BioCryst Reports Third Quarter 2014 Financial Results

RESEARCH TRIANGLE PARK, N.C., Nov. 6, 2014 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](http://www.biocryst.com) (Nasdaq:BCRX) today announced financial results for the third quarter ended September 30, 2014.

"The primary focus of our Company continues to be our oral kallikrein inhibitor program for hereditary angioedema (HAE). Preparations are underway for our OPuS-2 clinical trial of [BCX4161](#) and we expect to begin enrolling HAE patients before year end. We continue to make progress with our second generation HAE program and remain on track to enter Phase 1 clinical development in the second quarter of 2015," said [Jon P. Stonehouse, President & Chief Executive Officer](#) of BioCryst.

### Third Quarter Financial Results

For the three months ended September 30, 2014, revenues increased to \$3.2 million from \$2.4 million in the third quarter of 2013. Increased collaboration revenue was associated with the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) contract to develop our broad spectrum antiviral, [BCX4430](#), through Phase 1 clinical studies. This increase was partially offset by the lack of RAPIVAB<sup>TM</sup> ([peramivir injection](#)) collaborative revenue in the third quarter. This was due to the June 30, 2014 [Biomedical Advanced Research and Development Authority/Health and Human Services](#) (BARDA/HHS) development contract expiration and completion of contract activities, as compared to the third quarter of 2013, when activities under the contract were ongoing.

Research and development expenses for the quarter increased to \$13.0 million from \$7.7 million in the third quarter of 2013. The increase in 2014 R&D expenses was primarily associated with the advancement of the Company's HAE and BCX4430 programs, and partially offset by decreased expenditures for peramivir development.

General and administrative expenses for the third quarter 2014 increased to \$1.8 million compared to \$1.6 million in 2013. The increase was due primarily to costs associated with RAPIVAB commercialization.

In the third quarter of both 2014 and 2013, interest expense was \$1.2 million and related to non-recourse notes payable. In addition, a mark-to-market gain on our foreign currency hedge of \$4.1 million was recognized in the third quarter of 2014, compared to a gain of \$97,000 in the third quarter of 2013. These gains resulted 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 third quarter of 2014 was \$8.7 million, or \$0.12 per share, as compared to a net loss of \$8.0 million, or \$0.14 per share, for the third quarter of 2013.

Cash, cash equivalents and investments totaled \$127.6 million at September 30, 2014, compared to \$40.8 million at December 31, 2013. This significant increase in cash and investments resulted from the Company's successful June public offering of common stock. Net operating cash use for the third quarter of 2014 was \$8.0 million. Net operating cash use for the first nine months of 2014 was \$19.8 million, as compared to \$18.4 million for the 2013 period.

### Year to Date Financial Results

For the nine months ended September 30, 2014, total revenues increased to \$8.2 million from \$6.8 million in the same period of 2013. The increase in 2014 was primarily due to increased collaboration revenue associated with the BCX4430 NIAID development contract, and partially offset by lower collaborative revenue associated with a reduction in reimbursable RAPIVAB development expenses.

R&D expenses increased to \$33.3 million for the first nine months of 2014 from \$26.5 million in the same period of 2013. The increase in 2014 expenses was primarily due to increased spending associated with the Company's HAE and BCX4430 programs, as well as a stock option compensation charge associated with our positive OPuS-1 results and the related performance-based option grants, which vested in the second quarter of 2014. This increase was partially offset by a \$5.0 million non-cash write-off that occurred in the second quarter of 2013.

G&A expenses increased to \$5.4 million for the nine months ended September 30, 2014 from \$4.6 million for the nine months ended September 30, 2013. The increase was due primarily to unrestricted grants awarded to the U.S. and international HAE

patient advocacy groups and for costs associated with RAPIVAB commercialization.

In the first nine months of 2014 and 2013, interest expense was \$3.7 million and \$3.5 million, respectively, and related to the non-recourse notes payable. In addition, a mark-to-market gain on our foreign currency hedge of \$732,000 was recognized in the first nine months of 2014, compared to a gain of \$3.2 million in the same period of 2013. 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 the nine months ended September 30, 2014 increased to \$33.5 million, or \$0.52 per share, compared to a net loss of \$24.7 million, or \$0.46 per share for the same period last year.

## Corporate Update & Outlook

- Activities are underway to initiate the (**Oral Prophylaxis-2**) OPuS-2 clinical trial of BCX4161 before the end of 2014. OPuS-2 is a 12-week, three-arm, parallel cohort design trial to evaluate the efficacy and safety of two different dose regimens of BCX4161 administered three-times daily, 300 mg and 500 mg, compared with placebo. The trial, to be conducted in the U.S. and selected European countries, is expected to enroll approximately 100 HAE patients whose average historical attack rate is lower than that observed for patients enrolled in OPuS-1. The primary efficacy endpoint for the trial will be the mean angioedema attack rate for each BCX4161 dose group compared to placebo. The OPuS-2 trial will use 100 mg soft-gel capsules that have demonstrated relative bioavailability of approximately 80% compared with the hard gel capsule formulation used in OPuS-1, which tested 400mg three-times daily.
- Non-clinical safety studies for two second generation compounds for the treatment of HAE are progressing as planned, and first-in-human clinical trials are expected to begin during the second quarter of 2015.
- Non-human primate (NHP) studies with BCX4430 have commenced to evaluate whether BCX4430 shows a meaningful benefit for survival in Ebola virus NHP disease models. A dose-ranging study of BCX4430 for the treatment of cynomolgus macaques infected with Ebola virus demonstrated a statistically significant prolongation of survival at the highest dose regimen tested; however, no animals survived past 21 days. An additional NIAID-funded study to evaluate BCX4430 in Rhesus macaques infected with Ebola virus will include a higher dose regimen of BCX4430, and is expected to start in November. In addition, BioCryst anticipates filing a BCX4430 Investigational New Drug (IND) application with the Food and Drug Administration (FDA) in November.
- NIAID has increased the BCX4430 development contract value to \$28.7 million, if all options are exercised. The contract includes an additional \$2.4 million awarded on October 29 to conduct the second NHP study. Approximately \$22.3 million of option funding has been awarded to date under the NIAID contract.
- The Company is completing activities to make RAPIVAB available in the U.S. during the upcoming influenza season, pending FDA approval. BioCryst previously announced a Warning Letter and subsequent Form 483 received by its contract manufacturer that may have an impact on the RAPIVAB New Drug Application (NDA). A satisfactory FDA general Good Manufacturing Practice (GMP) inspection of the contract manufacturer's plant is required for removal of the Warning Letter status.

## Financial Outlook for 2014

Based upon current trends, assumptions, and development plans, BioCryst expects its 2014 net operating cash use to be in the lower end of our previously disclosed range of \$35 to \$43 million, and its operating expenses to be within our previously disclosed 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 on Thursday, November 6, 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](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 and several second generation compounds; RAPIVAB™, a viral neuraminidase inhibitor for the treatment of influenza, 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).

## 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 and development for BCX4161 may not start on time and 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 RAPIVAB may never be approved for any use by the FDA or that such approval may be delayed; that the Company's RAPIVAB supply could be limited or delayed due to regulatory issues at our manufacturer; 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 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.

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

### Statements of Operations (Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Revenues:				
Royalty revenue	\$ 5	\$ 8	\$ 1,951	\$ 2,042
Collaborative and other research and development	3,233	2,381	6,211	4,722
Total revenues	3,238	2,389	8,162	6,764
Expenses:				
Research and development	13,036	7,735	33,286	26,477
General and administrative	1,812	1,579	5,413	4,589
Royalty	--	--	78	81
Total expenses	14,848	9,314	38,777	31,147
Loss from operations	(11,610)	(6,925)	(30,615)	(24,383)
Interest and other income	14	18	50	72
Interest expense	(1,217)	(1,191)	(3,684)	(3,536)

Gain (loss) on foreign currency derivative	<u>4,082</u>	<u>97</u>	<u>732</u>	<u>3,168</u>
Net loss	<u><u>\$ (8,731)</u></u>	<u><u>\$ (8,001)</u></u>	<u><u>\$ (33,517)</u></u>	<u><u>\$ (24,679)</u></u>
Basic and diluted net loss per common share	<u><u>\$ (0.12)</u></u>	<u><u>\$ (0.14)</u></u>	<u><u>\$ (0.52)</u></u>	<u><u>\$ (0.46)</u></u>
Weighted average shares outstanding	71,801	57,124	65,057	53,910

Note: For the three months and nine months ended September 30, 2013, \$0.2m and \$0.6m, respectively, have been reclassified to reflect that patent casts are now classified as General and Administrative expense. Previously, they were classified as Research and Development expense.

**Balance Sheet Data** (in thousands)

	September 30, 2014 (Unaudited)	December 31, 2013 (Note 1)
Cash, cash equivalents and investments	\$ 127,436	\$ 40,637
Restricted cash	150	151
Receivables from collaborations	3,238	2,115
Total assets	137,125	48,866
Non-recourse notes payable	30,000	30,000
Accumulated deficit	(456,226)	(422,709)
Stockholders' equity (deficit)	83,454	(1,126)

Note 1: Derived from audited financial statements.

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Source: BioCryst Pharmaceuticals

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