



August 5, 2014

BioCryst Reports Second Quarter 2014 Financial Results

RESEARCH TRIANGLE PARK, N.C., Aug. 5, 2014 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (Nasdaq:BCRX) today announced financial results for the second quarter ended June 30, 2014.

"The successful [OPuS-1](#) Phase 2 clinical trial of [BCX4161](#) in patients with hereditary angioedema (HAE) established proof of concept for prophylaxis with an oral kallikrein inhibitor. We were also able to raise a significant amount of capital to support the advancement of BCX4161 and our second generation HAE program," said [Jon P. Stonehouse, President & Chief Executive Officer](#) of BioCryst. "We intend to initiate our OPuS-2 clinical trial before year end. The two most advanced second generation HAE compounds are on track to enter clinical development in the first half of next year."

Second Quarter Financial Results

For the three months ended June 30, 2014, revenues increased to \$1.5 million from \$821,000 in the second quarter of 2013. Increased collaboration revenue was associated with the relatively new BCX4430 development contract with the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) to evaluate BCX4430 as a treatment for Marburg virus disease. This increase was partially offset by lower collaborative revenue under the BARDA/HHS advanced development contract due to a decline in reimbursable peramivir expenses, compared to the second quarter of 2013.

Research and development expenses for the quarter decreased to \$11.1 million from \$11.5 million in the second quarter of 2013, due primarily to a one-time \$5.0 million asset write-off in the second quarter of 2013. The relative decrease in 2014 R&D expenses, as compared to 2013, was mostly offset by increased R&D expenses associated with the Company's HAE programs and the vesting of performance-based stock options associated with positive OPuS-1 (**O**ral **P**rophylaxi**S**-1) results. The Company recorded a \$2.2 million non-cash compensation charge in the second quarter of 2014 as a result of the vesting of these stock options. Most of the charge was reflected as a R&D expense.

General and administrative expenses for the second quarter 2014 increased to \$2.0 million compared to \$1.4 million in 2013. The increase was due primarily to unrestricted grants awarded to the U.S. and international HAE patient advocacy groups.

In the second 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 loss on our foreign currency hedge of \$1.8 million was recognized in the second quarter of 2014, compared to a gain of \$1.1 million in the second quarter 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 second quarter of 2014 was \$14.7 million, or \$0.23 per share, compared to a net loss of \$12.2 million, or \$0.23 per share, for the second quarter of 2013.

Cash, cash equivalents and investments totaled \$132.9 million at June 30, 2014, compared to \$40.8 million at December 31, 2013. This significant increase in cash and investments resulted from the Company's successful public offering of common stock. Net operating cash use for the second quarter of 2014 was \$6.8 million, as compared to \$4.1 million for the second quarter of 2013. Net operating cash use for the first six months of 2014 was \$11.8 million as compared to \$13.0 million for the 2013 period.

Year to Date Financial Results

For the six months ended June 30, 2014, total revenues increased to \$4.9 million from \$4.4 million in the first half of 2013. The increase in 2014 was primarily due to increased collaboration revenue associated with the BCX4430 NIAID development contract.

R&D expenses increased to \$20.3 million for the first half of 2014 from \$18.7 million in the same period of 2013. The increase in 2014 expenses was primarily due to increased spending associated with the Company's HAE programs and the stock option compensation charge associated with our positive OPuS-1 results, partially offset by the 2013 one-time asset write-off mentioned above.

G&A expenses increased to \$3.6 million for the six months ended June 30, 2014 from \$3.0 million for the six months ended

June 30, 2013, due primarily to unrestricted grants awarded to the U.S. and international HAE patient advocacy groups.

In the first half 2014 and 2013, interest expense was \$2.5 million and \$2.4 million, respectively, and related to the non-recourse notes payable. In addition, a mark-to-market loss on our foreign currency hedge of \$3.4 million was recognized in the first half of 2014, compared to a gain of \$3.1 million in the first half 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 six months ended June 30, 2014 increased to \$24.8 million, or \$0.40 per share, compared to a net loss of \$16.7 million, or \$0.32 per share for the same period last year.

Corporate Update & Outlook

- In May, BioCryst announced that the [OPuS-1](#) clinical trial of BCX4161 for HAE met its primary efficacy endpoint, several secondary endpoints and all other objectives established for the trial. The primary efficacy endpoint for the trial was the by-subject difference in mean angioedema attack rate on BCX4161 compared to placebo. Treatment with BCX4161 demonstrated a statistically significant mean attack rate reduction of 0.45 attacks per week versus placebo, $p < 0.001$.
- On June 3, BioCryst closed a successful public offering of 11,500,000 shares of common stock at a price of \$10.00 per share, which included the full exercise of the underwriters' over-allotment option. Net proceeds to BioCryst were approximately \$106.6 million.
- On June 30, the advanced development contract for peramivir with BARDA/HHS expired according to its terms. Earlier this year, the i.v. peramivir New Drug Application (NDA) was accepted by the FDA, which also set a PDUFA date of December 23, 2014. The Company continues to advance its plans to make peramivir available in the U.S. during the upcoming influenza season, pending FDA approval. BioCryst and its contract manufacturer continue to work with the FDA to meet the requirements for approval of the peramivir NDA. BioCryst previously announced a Warning Letter and subsequent Form 483 received by its contract manufacturer that may have an impact on the NDA. While discussions with both the FDA and our contract manufacturer have taken place, further interactions are expected and necessary to provide further clarity regarding the peramivir NDA and the availability of peramivir for the upcoming influenza season.
- Also in June, NIAID exercised an additional option under the BCX4430 development agreement to conduct drug product activities relating to the development of an i.v. formulation of BCX4430, including pre-formulation, stability studies and the manufacture of additional drug substance. Approximately \$9.4 million of option funding has been awarded under this \$22.0 million contract.
- BioCryst is advancing plans for its OPuS-2 trial to evaluate the efficacy and safety of BCX4161 treatment in patients with HAE. OPuS-2 is expected to start by the end of 2014.
- Toxicology programs are progressing for the two most advanced second generation compounds for the treatment of HAE, and first-in-human clinical trials are anticipated to begin in the first half of 2015.
- As of June 30, 2014, we expect the RAPIACTA[®] royalty stream from Shionogi & Co., our partner in Japan, to be insufficient to pay the accrued interest in arrears on the non-recourse Pharma Notes (Notes) by the September 1, 2014 payment date. If the royalty stream is insufficient to pay the interest in arrears, an event of default will occur with respect to the Notes. Accordingly, the Company has classified the Notes and related accrued interest as current liabilities on its balance sheet. An event of default would enable the holders of the Notes to pursue acceleration of the Notes and foreclosure on the collateral securing the Notes. Due to the non-recourse nature of the Notes, in the event of any potential foreclosure, the primary impact to the Company would be the loss of future royalty payments from Shionogi and legal costs associated with retiring the Notes. In addition, the Company may incur costs associated with liquidating a related currency hedge agreement, which would no longer be required. The Notes are obligations of JPR Royalty Sub and, as a result, we do not currently expect an event of default on the Notes to have a significant impact on the Company's future results of operations or cash flows.

Financial Outlook for 2014

Based upon current trends, assumptions, and development plans, BioCryst continues to expect 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 on Tuesday, August 5, 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 rare diseases. BioCryst currently has several ongoing development programs: oral inhibitors of plasma kallikrein for hereditary angioedema, including BCX4161 and several second generation compounds; peramivir, 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.

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 other 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 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 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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BIOCRYS T PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL SUMMARY
(in thousands, except per share)

Statements of Operations (Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Revenues:				
Royalty revenue	\$ 125	\$ 110	\$ 1,946	\$ 2,034
Collaborative and other research and development	1,341	711	2,978	2,341
Total revenues	1,466	821	4,924	4,375
Expenses:				
Research and development	11,067	11,527	20,250	18,742

General and administrative	2,013	1,432	3,601	3,010
Royalty	5	4	78	81
Total expenses	<u>13,085</u>	<u>12,963</u>	<u>23,929</u>	<u>21,833</u>
Loss from operations	(11,619)	(12,142)	(19,005)	(17,458)
Interest and other income	19	21	36	54
Interest expense	(1,225)	(1,165)	(2,467)	(2,345)
Gain (loss) on foreign currency derivative	<u>(1,824)</u>	<u>1,114</u>	<u>(3,350)</u>	<u>3,071</u>
Net loss	<u>\$ (14,649)</u>	<u>\$ (12,172)</u>	<u>\$ (24,786)</u>	<u>\$ (16,678)</u>
Basic and diluted net loss per common share	<u>\$ (0.23)</u>	<u>\$ (0.23)</u>	<u>\$ (0.40)</u>	<u>\$ (0.32)</u>
Weighted average shares outstanding	63,647	53,468	61,629	52,277

Note: For the three months & six months ended June 30, 2013, \$0.2 million & \$0.4 million, respectively, have been reclassified to reflect that patent costs are now classified as General and Administrative expense. Previously, these costs were classified as Research and Development expense.

Balance Sheet Data (in thousands)

	June 30, 2014 (Unaudited)	December 31, 2013 (Note 1)
Cash, cash equivalents and investments	\$ 132,710	\$ 40,637
Restricted cash	150	151
Receivables from collaborations	897	2,115
Total assets	141,975	48,866
Non-recourse notes payable	30,000	30,000
Accumulated deficit	(447,495)	(422,709)
Stockholders' equity (deficit)	90,089	(1,126)

Note 1: Derived from audited financial statements.

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Source: BioCryst Pharmaceuticals

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