



August 4, 2016

BioCryst Reports Second Quarter 2016 Financial Results

RESEARCH TRIANGLE PARK, N.C., Aug. 04, 2016 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) today announced financial results for the second quarter ended June 30, 2016.

"We continue to make progress, and have initiated subject screening to start the APeX-1 trial evaluating our once daily oral kallikrein inhibitor BCX7353 to prevent HAE attacks," said [Jon P. Stonehouse, President & Chief Executive Officer](#). "Our goal remains to report out initial data by year end for this trial."

Second Quarter Financial Results

For the three months ended June 30, 2016, revenues decreased to \$4.8 million from \$25.8 million in the second quarter of 2015. The decrease was primarily due to the one time, partial recognition of a large upfront payment from [Seqirus UK Limited](#) (Seqirus) associated with the licensing of [RAPIVAB®](#) (peramivir injection) in the second quarter of 2015, as well as lower collaborative revenue associated with BCX4430 development in the second quarter of 2016.

Research and Development (R&D) expenses for the second quarter of 2016 decreased to \$14.2 million from \$16.5 million in the second quarter of 2015. This decrease was primarily due to lower development costs associated with the Company's BCX4430 program.

General and administrative (G&A) expenses for the second quarter of 2016 decreased to \$2.7 million compared to \$3.5 million for the second quarter of 2015, due to a general reduction of administrative expenses throughout the Company during the second quarter of 2016, as compared to the second quarter of 2015.

Interest expense, which is primarily related to Company's non-recourse notes payable, was \$1.4 million in the second quarter of 2016 and \$1.3 million in the second quarter of 2015. In addition, a \$3.7 million mark-to-market loss on the Company's foreign currency hedge was recognized in the second quarter of 2016, as compared to a \$796,000 mark-to-market loss in the second quarter of 2015. These gains and 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. During the second quarters of 2016 and 2015, we also realized currency gains of \$811,000 and \$1.5 million, respectively, from the exercise of a U.S. Dollar/Japanese yen currency option within our foreign currency hedge.

The net loss for the second quarter of 2016 was \$16.3 million, or a \$0.22 net loss per share, compared to net income of \$4.9 million, or \$0.06 net income per fully diluted share, for the second quarter 2015.

Cash, cash equivalents and investments decreased to \$64.3 million at June 30, 2016, as compared to \$100.9 million at December 31, 2015. Net operating cash use for the second quarter of 2016 was \$15.4 million, as compared to \$12.0 million for the second quarter of 2015.

Year to Date Financial Results

For the six months ended June 30, 2016, total revenues decreased to \$9.6 million from \$32.7 million in the first half of 2015. The decrease in revenue resulted from the recognition of approximately \$21.7 million of collaborative revenue in the second quarter of 2015 associated with the RAPIVAB out-licensing transaction with Seqirus in June 2015.

R&D expenses increased to \$34.7 million in the first half of 2016 from \$33.6 million in the first half of 2015. The increase in 2016 R&D expense, as compared to 2015, reflects increased spending in our RAPIVAB program, somewhat offset by decreased development activity in our BCX4430 program. The majority of R&D spending was associated with the Company's HAE development program.

G&A expenses decreased to \$5.9 million for the six months ended June 30, 2016 from \$7.6 million for the six months ended June 30, 2015, due primarily to lower unrestricted grants awarded to HAE patient advocacy groups, as well as a general reduction of administrative expenses in the first half of 2016.

In the first half of 2016 and 2015, interest expense was \$2.9 million and \$2.6 million, respectively, and was primarily related to the Company's non-recourse notes payable. A mark-to-market loss on our foreign currency hedge of \$6.4 million was recognized in the first half of 2016, compared to a mark-to-market loss of \$332,000 in the first half of 2015. These gains and 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. As noted above, we also realized currency gains of \$811,000 and \$1.5 million from the exercise of U.S. dollar/Japanese yen currency options during the first half of 2016 and 2015, respectively.

The net loss for the six months ended June 30, 2016 increased to \$39.1 million, or \$0.53 per share, from \$10.3 million, or \$0.14 per share for the same period last year.

Corporate Update & Outlook

- | The APeX-1 clinical trial of BCX7353 for prophylaxis of angioedema attacks in patients with HAE has received regulatory approval in Canada and several European countries, and patient screening has commenced. We expect initial data from APeX-1 to be available by year end 2016.
- | A clinical pharmacology study of several dosage formulations of avoralstat is nearing completion. Cohorts of healthy volunteers have received single doses ranging from 200 mg to 2000 mg of avoralstat in tablet or suspension formulations, with no clinically significant adverse events reported. While these dosing formulations have improved total avoralstat exposure (AUC) up to approximately five-fold compared to a 500 mg dose given as soft gel capsules, the plasma concentration-time profile has not met our objectives of twice-daily dosing with drug levels at or above the target range. For that reason, we have decided to stop further development of avoralstat.
- | A phase 1 first-in-human study of the broad-spectrum antiviral drug BCX4430 has been completed. Study drug was administered by i.m. injection to healthy volunteers. Single doses of BCX4430 ranging from 0.3 to 10 mg/kg were administered, and daily doses of 2.5 mg/kg to 10 mg/kg were administered for 7 days. Exposure to BCX4430 was dose-proportional. BCX4430 dosing was generally safe and well-tolerated, and there were no grade 3 or 4 adverse events.
- | On July 5, 2016, BioCryst announced that the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) has provided additional funding for efficacy studies of [BCX4430](#) in non-human primates to further assess effective dose regimens. This funding represents an increase of \$5.5 million for the development of BCX4430 as a treatment for hemorrhagic fever viruses. The NIAID contract value now totals \$39.5 million, if all contract options are exercised. To date, approximately \$35.4 million of funding has been awarded under the contract.

About APeX-1

APeX-1 is a two part, Phase 2, randomized, double-blind, placebo-controlled proof of concept and dose ranging trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of BCX7353 as a preventative treatment to eliminate or reduce the frequency of angioedema attacks in HAE patients. Up to a total of approximately 50 eligible subjects with HAE will be enrolled in the trial.

In part 1 of APeX-1, up to 36 subjects with HAE will be randomized in a 1:1 ratio to receive an oral dose of either 350 mg of BCX7353 once daily or placebo once daily for four weeks. An interim analysis will be conducted after the first 24 subjects have completed treatment through study day 28. If a robust treatment effect is observed at the interim analysis, Part 2 of the study will be initiated. In the event the treatment effect is not well characterized with 24 subjects, a total of up to approximately 36 subjects will be enrolled in part 1. The sample size in Part 1 was kept flexible to cover a range of response options that would achieve 90% power with an alpha of 0.05, based on reduction of attack rate of at least 70% on BCX7353, placebo response rate of approximately 30%, and standard deviation of approximately 0.45 attacks per week.

To characterize dose-response in part 2 of APeX-1, 14 additional subjects with HAE will be randomized to 250mg of BCX7353 once daily (n=6), 125mg of BCX7353 once daily (n=6) or placebo (n=2).

The primary efficacy endpoint of APeX-1 is the number of angioedema attacks; attack rate per week, counts of attacks, proportion of subjects with no attacks, and number of attack-free days will be analyzed. Efficacy analyses will be conducted for HAE attacks reported over the entire dosing interval (Days 1 through 28) and during the dosing period in which plasma concentrations of BCX7353 should be at steady-state conditions (Days 8 through 28). Secondary efficacy endpoints include severity and duration of angioedema attacks, and measures of health-related quality of life. Safety will be characterized through evaluation of adverse events and laboratory testing. Pharmacokinetics and pharmacodynamic effects will be assessed through measurement of plasma drug levels and kallikrein inhibition.

About BCX7353

Discovered by BioCryst, BCX7353 is a novel, once-daily, selective inhibitor of plasma kallikrein in development for the prevention of angioedema attacks in patients diagnosed with HAE. By inhibiting plasma kallikrein, BCX7353 suppresses bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients. BCX7353 has been generally safe and well tolerated in clinical pharmacology studies that have enrolled 117 healthy volunteers, 46 receiving single doses of up to 1000 mg, and 71 receiving once-daily doses of up to 500 mg for 7 days and 350 mg for 14 days. In the second week of study, approximately 4-5% of healthy volunteers administered daily doses of '7353 for at least 7 days developed a drug-related skin rash that resolved within a few days.

Financial Outlook for 2016

Based upon development plans and our awarded government contracts, BioCryst expects its 2016 net operating cash use to be in the range of \$55 to \$75 million, and its 2016 operating expenses to be in the range of \$78 to \$98 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 on Thursday, August 4, 2016 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's ongoing development programs include oral plasma kallikrein inhibitors 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 planned trials of BCX7353 may not have a favorable outcome, including the APeX-1 trial; that developing a commercial formulation of BCX7353 or any other HAE compound may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of other plasma kallikrein inhibitor 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 or BARDA may further condition, reduce or eliminate future funding; that revenue from RAPIVAB is unpredictable and commercialization of RAPIVAB by Seqirus may never result in significant commercial revenue for the Company; that RAPIVAB may not be approved in other countries; that a stockpiling order of RAPIVAB may be delayed or may never occur; that actual financial results may not be consistent with expectations, including that 2016 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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(in thousands, except per share)

Statements of Operations (Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Revenues:				
Product sales, net	\$ -	\$ -	\$ -	\$ 537
Royalty revenue	629	132	2,519	1,650
Collaborative and other research and development	4,158	25,710	7,088	30,481
Total revenues	4,787	25,842	9,607	32,668
Expenses:				
Cost of products sold	-	-	-	15
Research and development	14,166	16,524	34,745	33,644
General and administrative	2,724	3,534	5,936	7,595
Royalty	27	442	104	502
Total expenses	16,917	20,500	40,785	41,756
(Loss) income from operations	(12,130)	5,342	(31,178)	(9,088)
Interest and other income	147	116	586	233
Interest expense	(1,421)	(1,306)	(2,891)	(2,621)
(Loss) gain on foreign currency derivative	(2,877)	749	(5,630)	1,213
Net (loss) income	<u>\$ (16,281)</u>	<u>\$ 4,901</u>	<u>\$ (39,113)</u>	<u>\$ (10,263)</u>
Net (loss) income per common share, basic	<u>\$ (0.22)</u>	<u>\$ 0.07</u>	<u>\$ (0.53)</u>	<u>\$ (0.14)</u>
Net (loss) income per common share, diluted	<u>\$ (0.22)</u>	<u>\$ 0.06</u>	<u>\$ (0.53)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding, basic	73,695	72,642	73,648	72,492
Weighted average shares outstanding, diluted	73,695	76,760	73,648	72,492

Balance Sheet Data (in thousands)

	June 30, 2016	December 31, 2015
	(Unaudited)	(Note 1)
Cash, cash equivalents and investments	\$ 59,894	\$ 99,246
Restricted cash	4,426	1,612
Receivables from collaborations	2,234	6,243
Total assets	82,217	122,359
Non-recourse notes payable (Note 2)	28,023	27,804
Accumulated deficit	(550,030)	(510,917)
Stockholders' equity	13,387	47,724

Note 1: Derived from audited financial statements.

Note 2: Reflects retrospective application of ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*

 Primary Logo

Source: BioCryst Pharmaceuticals

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