



May 4, 2017

BioCryst Reports First Quarter 2017 Financial Results

RESEARCH TRIANGLE PARK, N.C., May 04, 2017 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](http://www.biocryst.com) (NASDAQ:BCRX) announced today financial results for the first quarter ended March 31, 2017.

"We have completed enrollment in Part 1 and 2 of the APeX-1 Phase 2 clinical trial of BCX7353 for prevention of angioedema attacks and will report top-line data in the second quarter of 2017 as planned," said Jon P. Stonehouse, President & Chief Executive Officer. "Enrollment in Part 3 has begun, and at the current enrollment pace, we expect to report complete APeX-1 results in the third quarter of 2017."

First Quarter Financial Results

For the three months ended March 31, 2017, revenues increased to \$9.4 million from \$4.8 million in the first quarter of 2016. The increase in revenue was primarily due to a \$4.4 million increase in royalty revenue from Shionogi & Co. Ltd., Green Cross Corporation and Seqirus, and a \$2.0 million milestone payment associated with the Canadian regulatory approval of RAPIVAB[®]. The increase in royalty revenue was largely the result of continued Japanese Government stockpiling of RAPIACTA[®]. Future government stockpiling orders are difficult to predict, as they are subject to the relevant appropriation and stockpiling processes. These revenue increases were somewhat offset by a decrease in galidesivir collaboration revenue under U.S. Government development contracts.

Research and Development expenses for the first quarter of 2017 decreased to \$16.8 million from \$20.6 million in the first quarter of 2016, following the termination of avoralstat development for the treatment of hereditary angioedema (HAE) and, to a lesser extent, a decrease in galidesivir expenses under U.S. Government development contracts.

General and administrative (G&A) expenses for the first quarter of 2017 of \$3.1 million were in line with \$3.2 million of G&A expense in the first quarter of 2016.

Interest expense was \$2.1 million in the first quarter of 2017 as compared to \$1.5 million in the first quarter of 2016, an increase related primarily to the September 2016 closing of a \$23 million senior credit facility. Also, a \$1.5 million mark-to-market loss on the Company's foreign currency hedge was recognized in the first quarter of 2017, as compared to a \$2.8 million mark-to-market loss in the first quarter of 2016. These 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 first quarter of 2017 was \$14.2 million, or \$0.19 per share, compared to a net loss of \$22.8 million, or \$0.31 per share, for the first quarter 2016.

Cash, cash equivalents and investments totaled \$105.3 million at March 31, 2017, and reflect an increase from \$65.1 million at December 31, 2016. Net operating cash use for the first quarter of 2017 was \$11.4 million, and excludes the impact of \$47.8 million of net proceeds from our March 2017 public offering.

Clinical Development Update & Outlook

- On February 27, BioCryst announced positive results from an interim analysis of Part 1 of the APeX-1 trial for the prevention of attacks in HAE patients. Following 28 days of dosing with 350 mg once daily BCX7353 or placebo, an overall reduction of 0.57 attacks/week (63%, $p = 0.006$) was observed in BCX7353-treated subjects, with reductions of 88% and 24% respectively in peripheral and abdominal attacks. Based upon additional post-hoc analyses, it appeared that subjects may have recorded transient abdominal adverse events as HAE attack symptoms. Oral BCX7353 350 mg once-daily for 28 days was generally safe and well tolerated in subjects with HAE. Evaluation of lower dose cohorts is ongoing in Part 2 and 3 of the APeX-1 trial.
- On April 12, BioCryst announced plans to explore a new oral liquid formulation of BCX7353 for the treatment of acute attacks in patients with HAE. The Company has received initial regulatory approvals in Europe to initiate the ZENITH-1 exploratory clinical trial, anticipated to start this summer. The goal of the trial is to explore whether single oral doses of a liquid formulation of BCX7353 could have utility in the treatment of acute angioedema attacks in patients with

HAE. ZENITH-1 is designed as a randomized, double-blind, placebo controlled, dose-ranging clinical trial with BCX7353 self-administered at home to treat attacks.

- | On January 30, BioCryst announced that the [European Medicines Agency](#) (EMA) accepted the filing of its peramivir Marketing Authorization Application (MAA) for treatment of symptoms typical of influenza in adults 18 years and older. The acceptance of the MAA begins the review process by the EMA under the centralized licensing procedure for all 28 member states of the European Union, Norway and Iceland.
- | On March 24, BioCryst filed a supplemental New Drug Application (sNDA) for [RAPIVAB](#) (peramivir injection). The sNDA seeks to expand the current indication to include pediatric patients aged 2 to 17 years with acute uncomplicated influenza.
- | On January 8, BioCryst announced that Health Canada approved [RAPIVAB](#) (peramivir injection), an intravenous (I.V.) treatment for acute, uncomplicated influenza. RAPIVAB was approved by the U.S. Food & Drug Administration (FDA) in 2014 and is being commercialized by Seqirus.
- | On March 15, BioCryst closed an underwritten public offering of 6,061,115 shares of common stock at \$8.50 per share. Net proceeds, after deducting all offering expenses, were \$47.8 million.
- | On April 3, BioCryst announced that Mundipharma obtained regulatory approval of Mundesine[®] (forodesine hydrochloride) for the treatment of relapsed/refractory PTCL (Peripheral T-Cell Lymphoma) by the Ministry of Health, Labor and Welfare in Japan. Mundesine is a purine-nucleoside phosphorylase (PNP) inhibitor developed by BioCryst under an exclusive license with Albert Einstein College of Medicine and Victoria Link Limited.

Financial Outlook for 2017

Based upon development plans and our awarded government contracts, BioCryst expects its 2017 net operating cash use to be in the range of \$30 to \$50 million, and its 2017 operating expenses to be in the range of \$53 to \$73 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 Thursday, May 4, 2017 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 APeX-1

APeX-1 is a Phase 2, randomized, double-blind, placebo-controlled, 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. APeX-1 has three component parts evaluating 28 days of dosing with BCX7353 versus placebo. Part 1 evaluated a dose of 350 mg once daily. Part 2 will evaluate 250 mg and 125 mg doses once daily and Part 3 will further evaluate 250 mg and 125 mg versus 62.5 mg once daily. The clinical trial is being conducted in several European countries, Australia and Canada.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst has several ongoing development programs: BCX7353 and other second generation oral inhibitors of plasma kallikrein for hereditary angioedema, and galidesivir, a broad spectrum viral RNA polymerase inhibitor that is a potential treatment for filoviruses. RAPIVAB[®] (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Japan, Taiwan and Korea. Post-marketing commitment development activities for RAPIVAB are ongoing, as well as activities to support regulatory approvals in other territories. 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: developing any HAE drug candidate may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of HAE second generation drug candidates (including APeX-1 and ZENITH-1) 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 galidesivir; that galidesivir development may not be successful; that BARDA and/or NIAID may further condition, reduce or eliminate future funding; that revenue from peramivir injection is unpredictable and may never result in significant 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 2017 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.
FINANCIAL SUMMARY
(in thousands, except per share numbers)

Statements of Operations (Unaudited)

	Three Months Ended	
	March 31,	
	2017	2016
Revenues:		
Royalty revenue	\$ 6,321	\$ 1,890
Collaborative and other research and development	3,116	2,930
Total revenues	<u>9,437</u>	<u>4,820</u>
Expenses:		
Research and development	16,770	20,579
General and administrative	3,058	3,212
Royalty	294	77
Total operating expenses	<u>20,122</u>	<u>23,868</u>
Loss from operations	(10,685)	(19,048)
Interest and other income	109	439
Interest expense	(2,100)	(1,470)
Loss on foreign currency derivative	<u>(1,543)</u>	<u>(2,753)</u>
Net loss	<u>\$ (14,219)</u>	<u>\$ (22,832)</u>
Basic and diluted net loss per common share	<u>\$ (0.19)</u>	<u>\$ (0.31)</u>
Weighted average shares outstanding	75,167	73,601

Balance Sheet Data (in thousands)

	March 31, 2017 <u>(Unaudited)</u>	December 31, 2016 <u>(Note 1)</u>
Cash, cash equivalents and investments	\$ 102,485	63,576
Restricted cash	2,798	1,546
Receivables from collaborations	9,564	8,768
Total assets	129,513	89,847
Non-recourse notes payable	28,353	28,243
Senior credit facility	22,887	22,777
Accumulated deficit	(580,280)	(566,061)
Stockholders' equity	38,530	1,578
Shares of common stock outstanding	80,381	73,782

Note 1: Derived from audited financial statements

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 [Primary Logo](#)

Source: BioCryst Pharmaceuticals

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