BioCryst Provides Peramivir Update and Reports First Quarter 2009 Financial Results

BIRMINGHAM, Ala., May 8, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that, based on discussions with the U.S. Department of Health and Human Services/Biomedical Advanced Research and Development Authority (HHS-BARDA), it is preparing a portion of its inventory of finished peramivir for addition to the U.S. Centers for Disease Control and Prevention (CDC) Strategic National Stockpile. This inventory is sufficient for the treatment of approximately one thousand patients and will be delivered in the event that the government so instructs. Intravenous (i.v.) peramivir is currently undergoing a pre-emergency use authorization (EUA) review. Government agencies are considering the future option of providing peramivir through an EUA in the event of a severe influenza outbreak with significant hospitalizations. BioCryst is advancing the clinical development of peramivir under terms of a $102.6 million, four-year contract from the HHS.

"BioCryst is working diligently with government agencies to provide i.v. peramivir as a treatment option for an influenza emergency," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst. "With its parenteral route of administration, peramivir has the potential to help patients who may have difficulty with an oral or inhaled anti-viral medication. In addition, BioCryst is in negotiations with the Division of Microbiology and Infectious Diseases (DMID) and the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) to conduct a study of peramivir in a pediatric patient population."

The clinical activity of peramivir has previously been demonstrated in various clinical studies. The sensitivity of the swine flu virus to peramivir has recently been reported by the CDC (1). Ten of the thirteen isolates of the H1N1 virus were tested for sensitivity to peramivir and all ten isolates were susceptible to peramivir.

Intramuscular Peramivir Phase 2 Study Results for Seasonal Influenza

BioCryst also announced preliminary results from its Phase 2 study of intramuscular (i.m.) peramivir for the treatment of seasonal influenza. While the study demonstrated a numerical trend in its primary endpoint of improvement in the median time to alleviation of symptoms (TTAS) in subjects with confirmed, acute, uncomplicated influenza infection versus placebo, the difference between the two study groups was not statistically significant.

The median TTAS was 91.1 hours for those receiving a single 600 mg injection of i.m. peramivir, compared to 106.1 hours observed in those patients receiving placebo (p=0.22). The trial indicated that peramivir was generally safe and well tolerated with a similar adverse event profile noted in the peramivir and placebo treatment groups.

"The efficacy of intravenous peramivir demonstrated in a prior study conducted by Shionogi & Company Ltd. indicates its potential as a treatment for acute uncomplicated influenza," commented Dr. William P. Sheridan, Chief Medical Officer of BioCryst. "Based on the clinical evidence of activity, safety and tolerability of peramivir, we are currently in discussions with HHS-BARDA and the U.S. Food and Drug Administration (FDA) regarding further development of i.v. peramivir as a treatment for influenza."

This Phase 2 study (BCX1812-212) was a randomized, double-blind, placebo-controlled trial conducted in influenza seasons in the Southern Hemisphere (Australia, New Zealand and South Africa) in 2008 and the Northern Hemisphere (United States) in 2008 - 2009. It enrolled 405 subjects 18 years of age or older with acute uncomplicated influenza confirmed by positive rapid antigen test, whose symptom duration was 36 hours or less. The primary analysis population consisted of patients with confirmed influenza A. Approximately 79 percent of subjects with influenza A (H1N1) demonstrated the H274Y mutation. This mutation has been associated with resistance to the anti-viral treatment oseltamivir.(2)

Financial Results for the First Quarter Ended March 31, 2009

For the three months ended March 31, 2009, the Company reported collaborative and other research and development revenues of $4.4 million, compared to $10.8 million for the three months ended March 31, 2008. This decrease was driven by a reduction in revenue from the contract with the HHS for the development of peramivir. In addition, the Company recognized less revenue during the quarter related to its deferred collaboration arrangements.

Research and development (R&D) expenses were $11.3 million for the three months ended March 31, 2009, compared to $21.9 million for the three months ended March 31, 2008. The decrease in R&D expenses was primarily attributable to a reduction in clinical development costs associated with the peramivir program, a reduction in manufacturing costs associated

with both the peramivir and forodesine programs and a reduction in costs incurred related to the Company's preclinical programs.

General and administrative (G&A) expenses were $2.5 million for the three months ended March 31, 2009, compared to $2.9 million for the three months ended March 31, 2008. The lower expenses were primarily due to decreases in professional fees and operating costs.

Net loss for the quarter ended March 31, 2009, was $9.3 million, or $0.24 per share, compared to a net loss for the quarter ended March 31, 2008, of $13.1 million, or $0.34 per share.

As of March 31, 2009, the Company held cash, cash equivalents and investments of $54.2 million. BioCryst continues to expect the Company's net cash use in 2009 will be between $30.0 and $38.0 million, dependent on the achievement of certain clinical milestones.

Recent Clinical Highlights

Peramivir Program

-- BioCryst's partner, Shionogi & Company, Ltd. (Shionogi), initiated a Phase 3 program with i.v. peramivir in the outpatient setting. The Phase 3 study is a 1,050 subject study. BioCryst anticipates that Shionogi will complete its study within this influenza season and expects to file for new drug approval in Japan by fiscal year end. Shionogi initiated its Phase 3 study based on positive clinical results from a Phase 2 study that investigated the efficacy and safety of a single administration of 300 mg and 600 mg. i.v. peramivir for the treatment of seasonal influenza in the outpatient setting. The Phase 2 study, which was also sponsored by Shionogi, met its primary endpoint of time to alleviation of symptoms for both the 300 mg dose (p=0.0046) and 600 mg dose (p=0.0046).

Forodesine Program

-- BioCryst has enrolled more than half of the target number of patients in the pivotal Phase 2 study of forodesine for the treatment of cutaneous T-cell lymphoma. The target enrollment for this study is approximately 130 patients. The Company expects to report preliminary data in the first half of 2010.

-- BioCryst's forodesine Phase 2 single-arm, open-label study evaluating 200 mg of forodesine twice-daily in patients with chronic lymphocytic leukemia is ongoing, and the Company expects to provide an update on this study by the end of 2009.

Conference Call and Web Cast

BioCryst's management team will host a conference call and Web cast on Friday, May 8, 2009, at 8:30 a.m. Eastern Time to discuss the financial results and recent corporate developments. To participate in the conference call, please dial 1-800-860-2442 (United States) or 1-412-858-4600 (International). No passcode is needed for the call. The Web cast can be accessed by logging onto http://www.biocryst.com. Please connect to the Web site at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary.

References

(1) CDC Morbidity and Mortality Weekly Report dated April 28, 2009: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5816a6.htm

(2) CDCFluView Weekly Influenza Report: http://www.cdc.gov/flu/weekly/

About BioCryst

BioCryst is a biopharmaceutical company that has developed a deep pipeline of novel therapeutics targeting major illnesses by employing crystallography and structure-based drug design. BioCryst is currently advancing investigational new drugs discovered in-house in late-stage clinical trials for influenza and lymphoma. In addition, the Company has a pre-clinical portfolio of novel compounds, directed against infectious, cardiovascular and autoimmune disease targets, to create long-term sustainable value. The Company's strategic alliances with the U.S. Department of Health and Human Services, Shionogi & Co., Ltd., Green Cross Corporation and Mundipharma International Holdings Ltd. validate its scientific foundation and the utility of its product candidates. For more information, please visit the Company's Web site 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 our 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 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 peramivir may not receive emergency use authorization; that the U.S. government may choose not to ship peramivir to the CDC Strategic National Stockpile; that to the extent peramivir is used as a treatment for H1N1 flu (or other strains of flu), there can be no assurance that it will prove effective; that HHS may further condition, reduce or eliminate future funding of the peramivir program; that ongoing peramivir clinical trials or our peramivir program in general may not be successful; that the pivotal trial with forodesine in cutaneous T-cell lymphoma (CTCL) may not meet its endpoint; that development and commercialization of forodesine in CTCL may not be successful; that we or our licensees may not be able to enroll the required number of subjects in planned clinical trials of our product candidates and that such clinical trials may not be successfully completed; that BioCryst or its licensees may not commence as expected additional human clinical trials with our product candidates; that our product candidates may not receive required regulatory clearances from the FDA, that ongoing and future preclinical and clinical development may not have positive results; that we or our licensees may not be able to continue future development of our current and future development programs, that our development programs may never result in future product, license or royalty payments being received by BioCryst; that BioCryst may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or it may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of its product candidates, that our actual burn rate may not be consistent with our expectations; that BioCryst may not have sufficient cash to continue funding the development, manufacturing, marketing or distribution of its products and that additional funding, if necessary, may not be available at all or on terms acceptable to BioCryst. 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, most recent Registration Statement on Form S-3 (filed November 28, 2008), 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 our projections and forward-looking statements.

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BIOCRYST PHARMACEUTICALS, INC.
FINANCIAL SUMMARY

Statements of Operations (Unaudited)
(in thousands, except per share)

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Collaborative and other research and development	$4,359	$10,768
Expenses:		
Research and development	11,289	21,898
General and administrative	2,457	2,886
Total expenses	13,746	24,784
Loss from operations	(9,387)	(14,016)

Interest and other income	95	918
Net loss	$(9,292)	$(13,098)
Basic and diluted net loss per common share	$(0.24)	$(0.34)
Weighted average shares outstanding	38,204	38,059

Balance Sheet Data
(in thousands)

	March 31, 2009 (Unaudited)	December 31, 2008 (Note 1)
Cash, cash equivalents and securities	$54,214	$63,314
Receivables from collaborations	9,847	11,982
Total assets	72,602	84,692
Accumulated deficit	(258,560)	(249,268)
Stockholders' equity	38,517	46,426

Note 1: Derived from audited financial statements.

SOURCE BioCryst Pharmaceuticals, Inc.

http://www.biocryst.com