



BioCryst Reports Second Quarter 2009 Financial Results And Provides Corporate Update

BIRMINGHAM, Ala., July 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced financial results for the quarter and six months ended June 30, 2009 and provided a corporate update regarding clinical programs and potential emergency use of intravenous (i.v.) peramivir in the U.S.

"Our efforts at BioCryst remain focused on moving our leading peramivir and forodesine clinical development programs forward," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst Pharmaceuticals. "BioCryst continues to work diligently with government agencies to provide i.v. peramivir as a potential treatment option for an influenza emergency, as well as working to complete the U.S. development of peramivir through the traditional regulatory pathway. The successful Phase 3 studies conducted by our partner Shionogi add to the growing body of data characterizing the efficacy and safety of peramivir as a potential treatment for influenza."

Second Quarter Financial Results

For the three months ended June 30, 2009, collaborative and other research and development revenues were \$4.8 million compared to \$2.7 million for the three months ended June 30, 2008. Revenues related to the Company's contract with the U.S. Department of Health and Human Services (HHS) for the development of peramivir were higher in this year's quarter compared to the prior year period due to a \$4.9 million reserve recorded against revenue in 2008 for amounts BioCryst had previously expected to receive from HHS. The increase in peramivir related revenues was offset by a reduction in revenue from the Company's collaborations with Mundipharma, as well as lower amortization of deferred revenue from our collaboration arrangements.

Research and development (R&D) expenses decreased to \$11.2 million for the second quarter of 2009 from \$13.4 million for the second quarter of 2008. The lower R&D expenses resulted from a reduction in clinical development costs associated with the peramivir program, a reduction in manufacturing costs associated with the forodesine program, and lower pre-clinical program costs. In addition, general operating costs as well as personnel related costs were lower in the current quarter of 2009 compared to the same quarter of the prior year.

General and administrative (G&A) expenses decreased to \$2.3 million for the second quarter of 2009 from \$2.7 million for the second quarter of 2008, primarily due to a decrease in consulting fees.

Interest income for the three months ended June 30, 2009 was \$0.1 million as compared to \$0.7 million in last year's second quarter, as a result of a lower average cash and securities balance as well as a significantly lower yield earned on interest-bearing assets.

The net loss for the second quarter of 2009 was \$8.7 million, or \$0.23 per share, compared to a net loss of \$12.7 million, or \$0.33 per share for the second quarter of 2008.

As of June 30, 2009, the Company held cash, cash equivalents and investments of \$42.3 million. The \$12.0 million decrease in cash, cash equivalents and investments during the second quarter 2009 included a \$5.0 million payment to HHS to purchase peramivir active pharmaceutical ingredient (API) as permitted under the contract. BioCryst has determined that this API is in excess of the amount necessary to support U.S. regulatory approval. HHS is reviewing the purchase in light of the clinical development plan to complete U.S. registration and as a result, the \$5 million has been recorded as a prepayment on the Company's June 30, 2009 balance sheet. Excluding this one-time use of cash, BioCryst continues to expect that 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.

Year to Date Financial Results

Collaborative and other R&D revenues decreased to \$9.1 million for the six months ended June 30, 2009 as compared to \$13.4 million for the six months ended June 30, 2008. This change was driven by a reduction in revenue from the contract with HHS for the development of peramivir as well as reductions in revenue from the Company's collaborations with Mundipharma. In addition, lower amortization of deferred revenue from our collaboration arrangements was recognized during the six months ended June 30, 2009.

R&D expenses decreased to \$22.5 million for the first half of 2009 from \$35.3 million for the same period of the prior year. The decrease in R&D expenses was due to a decrease in clinical development costs and toxicology costs associated with the

peramivir program, a reduction in manufacturing costs associated with the forodesine program, and lower costs incurred on the pre-clinical compounds. In addition, general operating costs as well as personnel related costs were lower in the first six months of 2009 compared to the first six months of 2008. These reductions in R&D expenses were partially offset by an increase in clinical development costs associated with the forodesine program.

G&A expenses decreased to \$4.8 million for the six months ended June 30, 2009 from \$5.6 million for the six months ended June 30, 2008, primarily due to decreases in consulting fees and personnel related costs.

Interest income for the six months ended June 30, 2009 was \$0.2 million as compared to \$1.6 million for the six months ended June 30, 2008, due to a lower average cash and securities balance as well as significantly lower yield earned on interest-bearing assets.

The net loss for the six months ended June 30, 2009 was \$18.0 million, or \$0.47 per share, compared to a net loss of \$25.8 million, or \$0.68 per share for the six months ended June 30, 2008.

Recent Program Highlights

Peramivir Program

- The pre-emergency use authorization (EUA) review of i.v. peramivir announced in May has continued to progress. 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's partner, Shionogi & Co., Ltd. recently announced positive results from two Phase 3 studies of i.v. peramivir in patients with seasonal influenza. In the study of 1,099 patients with uncomplicated seasonal influenza comparing the efficacy and safety of a single dose of peramivir (either 300 mg or 600 mg) and treatment with oral oseltamivir phosphate 75 mg (Tamiflu((R))) twice a day for five days, both peramivir groups demonstrated non-inferiority for the primary endpoint, time to alleviation of symptoms (TTAS), compared to the oseltamivir group. Further, Shionogi stated it is making its best effort to file its New Drug Application (NDA) and to receive a manufacturing approval as soon as possible in Japan.
- BioCryst is currently finalizing its plans for peramivir Phase 3 studies intended to support U.S. regulatory approval for uncomplicated influenza and influenza requiring hospitalization. BioCryst has determined that there is an excess of approximately \$5 million of peramivir API beyond that necessary to support U.S. regulatory approval. As permitted under the contract, BioCryst has purchased the excess API from HHS. HHS has indicated that it is in the process of reviewing the purchase in light of the clinical development plan to complete U.S. registration.

Forodesine Program

- BioCryst has enrolled more than 100 patients in the pivotal Phase 2 study of forodesine for the treatment of cutaneous T-cell lymphoma (CTCL). The target enrollment for this study is 130 to 140 patients. The Company continues to expect preliminary data in the first half of 2010.
- Long-term data from a prior Phase 2 study of forodesine in patients with CTCL was presented at 45th Annual Meeting of the American Society of Clinical Oncology (ASCO). This poster reviewed the safety and efficacy

of forodesine for CTCL patients of stage Ib to stage IV who have failed standard therapies and received forodesine treatment for greater than 12 months.

- A 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 Thursday, July 30, 2009, at 11:00 a.m. Eastern Time to discuss the financial results and recent corporate developments. To participate in the conference call, please dial 1-877-627-6566 (United States) or 1-719-325-4922 (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.

About BioCryst

BioCryst Pharmaceuticals designs, optimizes and develops novel small-molecule pharmaceuticals that block key enzymes involved in oncology, infectious and autoimmune diseases. BioCryst has two product candidates in pivotal clinical trials; peramivir, an anti-viral for influenza, and forodesine, a purine nucleoside phosphorylase (PNP) inhibitor for cutaneous T-cell lymphoma (CTCL). Utilizing crystallography and structure-based drug design, BioCryst continues to expand its portfolio of next-generation therapeutic candidates with the potential to address the unmet medical needs of patients and physicians. 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 Limited 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 pre-clinical 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 cash 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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FINANCIAL SUMMARY
 Statements of Operations (Unaudited)
 (in thousands, except per share)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2009	2008	2009	2008
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Revenues:				
Collaborative and other research and development	\$4,787	\$2,659	\$9,146	\$13,427
Expenses:				
Research and development	11,213	13,373	22,502	35,271
General and administrative	2,313	2,666	4,770	5,552
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Total expenses	13,526	16,039	27,272	40,823
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Loss from operations	(8,739)	(13,380)	(18,126)	(27,396)
Interest and other income	55	671	150	1,589
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Net loss	\$(8,684)	\$(12,709)	\$(17,976)	\$(25,807)
	=====	=====	=====	=====
Basic and diluted net loss per common share	\$(0.23)	\$(0.33)	\$(0.47)	\$(0.68)
	=====	=====	=====	=====
Weighted average shares outstanding	38,232	38,117	38,218	38,088

Balance Sheet Data (in thousands)

	June 30, 2009	December 31, 2008
	(Unaudited)	(Note 1)
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Cash, cash equivalents and securities	\$42,256	\$63,314
Receivables from collaborations	8,075	11,982
Total assets	64,694	84,692
Accumulated deficit	(267,244)	(249,268)
Stockholders' equity	31,285	46,426

Note 1: Derived from audited financial statements.

SOURCE BioCryst Pharmaceuticals, Inc.

<http://www.biocryst.com>

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