BioCryst Reports Third Quarter 2008 Financial Results and Provides Corporate Update

BIRMINGHAM, Ala., Oct 31, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced financial results for the quarter ended September 30, 2008.

Third Quarter 2008 Financial Results

For the three months ended September 30, 2008, the Company reported collaborative and other research and development revenues of $8.9 million compared to $20.5 million for the three months ended September 30, 2007. This decrease is driven by a reduction in peramivir clinical development costs and associated revenue from the contract with the U.S. Department of Health and Human Services (HHS) for the development of peramivir. Currently, the majority of the Company's revenues are derived from the reimbursement of costs under the contract with HHS.

Research and development (R&D) expenses were $16.0 million for the three months ended September 30, 2008, compared to $29.7 million for the three months ended September 30, 2007. The decrease in R&D expenses is 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 HCl program and a reduction in costs incurred related to the Company's preclinical programs. These reductions were partially offset by an increase in BioCryst's clinical development costs in the forodesine HCl program.

General and administrative (G&A) expenses were $2.5 million for the three months ended September 30, 2008, compared to $2.6 million for the three months ended September 30, 2007.

The net loss for the quarter ended September 30, 2008 was $9.0 million, or $0.24 per share, compared to a net loss for the quarter ended September 30, 2007 of $11.0 million or $0.32 per share.

As of September 30, 2008, the Company held cash, cash equivalents and investments of $67.9 million.

Year-to-Date 2008 Financial Results

Collaborative and other research and development revenues were $22.3 million for the nine months ended September 30, 2008, compared to $43.1 million for the nine months ended September 30, 2007. This decrease is driven by a reduction in peramivir related clinical development costs leading to a reduction in costs and associated revenue from HHS, plus the $4.9 million reserve taken in the second quarter of 2008 for amounts BioCryst previously expected to receive from HHS related to costs incurred in the Phase 3 program in intramuscular peramivir for outpatient influenza. These costs were associated with the Phase 3 program for peramivir that was voluntarily discontinued earlier this year and reimbursement of these costs is under discussion with HHS.

R&D expenses were $51.3 million for the nine months ended September 30, 2008, compared to $64.9 million for the nine months ended September 30, 2007. The decrease in R&D expenses is due to a reduction in the clinical development costs and toxicology costs associated with the peramivir program and a reduction in manufacturing costs associated with both the peramivir and forodesine HCl programs. These reductions were partially offset by an increase in the Company's clinical development costs for forodesine HCl and increases in personnel related costs and professional services.

G&A expenses were $8.0 million for the nine months ended September 30, 2008, compared to $7.0 million for the nine months ended September 30, 2007. The higher expenses were primarily due to an increase in professional fees and personnel related costs.

The net loss for the nine months ended September 30, 2008 was $34.8 million, or $0.91 per share, compared to a net loss for the nine months ended September 30, 2007 of $26.8 million or $0.86 per share.

"As a result of prudent cash control, we reconfirm that the cash burn for the year ended December 31, 2008 will remain at the lower end of $25 to $30 million guidance provided earlier this year," said Stuart Grant, BioCryst's Chief Financial Officer. "We have implemented strategic initiatives, including a recent 20 percent reduction in our workforce, to focus the Company's resources on the execution of our late-stage clinical trials and the development of our most promising pre-clinical compounds. We have full funding of our peramivir program through Phase 2 clinical trials from HHS and a strong cash position that will allow

us to execute on our plan without depending on the capital markets."

"We have recently made significant advancements in our clinical programs and are encouraged by the positive peramivir efficacy data reported in the Phase 2 study we conducted in subjects with influenza requiring hospitalization, and the Phase 2 study in subjects with acute uncomplicated influenza conducted by our partner, Shionogi & Co., Ltd.," said Jon Stonehouse, President and Chief Executive Officer of BioCryst. "Over the next year, we have several key value-driving milestones for both our peramivir and PNP programs and remain committed to advancing our products towards market."

Corporate Update

- A poster entitled "A Double-Blind, Placebo-Controlled Study of Intravenous Peramivir in Acute Influenza Patients" was presented at the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), detailing the results of a Shionogi & Co., Ltd.-sponsored, placebo-controlled, Phase 2 study of intravenous (i.v.) peramivir, a neuraminidase inhibitor, in outpatients with acute, uncomplicated influenza. The study 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) (hazard ratios were 0.681 for 300 mg dose and 0.666 for the 600 mg dose). The median time to alleviation of symptoms was 59.1 hours for those receiving the 300 mg dose, 59.9 hours for those receiving the 600 mg dose and 81.8 hours for those receiving placebo. The study also met all secondary endpoints. Peramivir was generally well-tolerated in the study, with a similar adverse event profile to that of placebo. Shionogi is currently preparing to initiate a Phase 3 program with i.v. peramivir in the outpatient setting.
- BioCryst reported results of an exploratory Phase 2 trial of i.v. peramivir in subjects hospitalized for acute serious or potentially life-threatening influenza. The Phase 2 trial compared the efficacy and safety of five days of therapy with either 200 mg i.v. peramivir per day, 400 mg i.v. peramivir per day or 75 mg oral oseltamivir twice a day, in subjects who required hospitalization related to influenza. The primary objective of the study was to evaluate a novel composite endpoint, time to clinical stability, which is comprised of normalization of temperature, oxygen saturation, respiratory rate, systolic blood pressure and heart rate. Secondary objectives of the study included evaluation of viral shedding, mortality, clinical relapse and time to resumption of usual activities. In the primary efficacy population, for all groups combined, the study demonstrated a median of 25.3 hours to clinical stability, a median of 2.0 log reduction in time weighted change from baseline in viral titer, zero mortality, no clinical relapse and a median of 10.8 days of time to resumption of usual activities. There were no statistically significant differences in any of the efficacy endpoints between the three treatment arms. Peramivir was generally safe and well-tolerated at these dose levels. Detailed results will be submitted to an upcoming medical meeting.
- BioCryst reported top-line results from the completed Phase 2a trial of BCX-4208 in subjects with moderate to severe plaque psoriasis were consistent with interim findings. BCX-4208, a potent, rationally designed, orally available purine nucleoside phosphorylase inhibitor, met its primary endpoint of safety and tolerability and displayed dose-dependant reductions in peripheral blood lymphocyte counts. The pharmacokinetic and pharmacodynamic results suggest that BCX-4208 may have utility in diseases dependant on T-cells, B-cells or uric acid. The Phase 2a results have been accepted for presentation at the 50th American Society of Hematology Annual Meeting and Exposition (ASH), which will be held in San Francisco, December 6-9, 2008.
- The forodesine HCl pivotal trial in cutaneous T-cell lymphoma (CTCL) continues to enroll subjects with CTCL stages IIB through IVA who have failed three systemic therapies. The multinational study is evaluating once daily oral forodesine HCL treatment and is being conducted in accordance with a Special Protocol Assessment agreement between the U.S.

Food and Drug Administration and BioCryst. A laboratory study of forodesine HCl in leukemia cells has been accepted for presentation at ASH.

Conference Call and Web cast

BioCryst's management team will host a conference call and Web cast on Friday, October 31, 2008, at 8:30 a.m. Eastern Time to discuss the financial results and recent developments within the Company's programs. 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.

About BioCryst

BioCryst is an integrated biopharmaceutical company utilizing crystallography and structure-based drug design to develop a deep pipeline of novel therapeutics targeting major illnesses. 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 our belief that many subjects in the Phase 2 clinical trials of peramivir did not receive adequate dosing by intramuscular injection may not be correct, that HHS and the Food & Drug Administration (FDA) may not agree with our analysis, that HHS may further condition, reduce or eliminate future funding of the peramivir program, that ongoing peramivir clinical trials may not be successful, that the peramivir program may not be successful, that the pivotal trial with forodesine HCl in cutaneous T-cell lymphoma (CTCL) may not meet its endpoint, that development and commercialization of forodesine HCl 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 projected 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 (File No. 333-145638), Quarterly Reports on Form 10-Q, current reports on Form 8-K which identify important factors that could cause the actual results to differ materially from those contained in the projections or forward-looking statements.

BCRXW

BIOCRYST PHARMACEUTICALS, INC.
FINANCIAL SUMMARY

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

	Three Months Ended	Nine Months Ended

	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Revenues:				
Collaborative and other research and development	$8,894	$20,463	$22,321	$43,066
Expenses:				
Research and development	15,996	29,730	51,267	64,938
General and administrative	2,471	2,595	8,023	6,980
Total expenses	18,467	32,325	59,290	71,918
Loss from operations	(9,573)	(11,862)	(36,969)	(28,852)
Interest and other income	578	878	2,167	2,080
Net loss	$(8,995)	$(10,984)	$(34,802)	$(26,772)
Basic and diluted net loss per common share	$(0.24)	$(0.32)	$(0.91)	$(0.86)
Weighted average shares outstanding	38,095	34,277	38,040	31,024

Balance Sheet Data (in thousands)

	September 30, 2008 (Unaudited)	December 31, 2007 (Audited)
Cash, cash equivalents and securities	$67,928	$85,008
Receivables from collaborations	13,102	39,128
Total assets	99,351	142,717
Accumulated deficit	(259,338)	(224,536)
Stockholders' equity	35,008	64,905

SOURCE BioCryst Pharmaceuticals, Inc.

http://www.biocryst.com

Copyright (C) 2008 PR Newswire. All rights reserved

News Provided by COMTEX