BioCryst Reports Second Quarter 2010 Financial Results and Provides Corporate Update

BIRMINGHAM, Ala., Aug 05, 2010 (BUSINESS WIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ: BCRX) today announced financial results for the second quarter and six months ended June 30, 2010.

Recent Highlights

- BioCryst today announces positive top-line results from its Phase 2a monotherapy BCX4208 gout study after completion of dose cohorts at 160 mg and 240 mg per day
- In June 2010, BioCryst initiated enrollment in an additional blinded Phase 2 study to evaluate the efficacy and safety of BCX4208 alone and in combination with allopurinol, another urate-lowering treatment for gout

"We are excited by the recent gout data, which is a further demonstration of our ability to execute on our clinical plans. During the balance of this year, we look forward to reporting clinical data from our second BCX4208 gout study and from our two ongoing forodesine studies in patients with cancer," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst Pharmaceuticals. "The approval of peramivir in Japan and the significant steps forward in our clinical programs demonstrate the substantial progress that BioCryst has made to date in 2010. We also remain focused on enrolling our Phase 3 peramivir studies and driving towards regulatory filing for the U.S. market."

Results of BCX4208 Phase 2a Gout Study (Part Two)

This Phase 2a, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered BCX4208 in patients with gout is now completed, with positive top-line results in part two. Positive results from part one of this study were announced April 2010. The primary endpoint of the study was the change in serum uric acid (sUA) concentration at day 22, following 21 days of once-daily treatment, compared to baseline sUA concentration prior to treatment. Final data were evaluated using least square means (LSM) and an analysis of covariance (ANCOVA) model with factors for treatment and baseline sUA.

All doses of BCX4208 evaluated met the primary endpoint of the study, including both doses studied in part two. BCX4208 doses of 160 mg and 240 mg per day showed LSM reductions in sUA levels of 3.6 and 4.5 mg/dL at day 22 ($p<0.001$ for both doses), compared to placebo reduction of 0.02 mg/dL. The LSM reduction of sUA concentration percent change from baseline was 35.7 percent for the 160 mg dose and 46.0 percent for the 240 mg dose ($p<0.001$ for both doses). BCX4208 also demonstrated a statistically significant difference in the proportion of subjects with sUA levels less than 6 mg/dL, compared to subjects treated with placebo, on day 22. The proportion of subjects achieving sUA levels less than 6 mg/dL was 47 percent for the 160 mg dose and 77 percent for the 240 mg dose, compared to zero percent in the placebo group.

Part two of the study was designed to sequentially evaluate the safety and efficacy of up to three higher doses (160 mg, 240 mg and 320 mg once-daily) of BCX4208, and included various stopping criteria related to both safety and efficacy. Enrollment in the study was closed after the 240 mg treatment group achieved two efficacy stopping criteria: greater than 4 mg/dL reduction in sUA from baseline, and greater than 60 percent of patients achieving sUA concentration below 6 mg/dL.

BCX4208 was generally safe and well-tolerated at all doses evaluated in this study. Reductions in peripheral blood lymphocytes were observed in patients treated with BCX4208. The protocol included individual subject stopping criteria for CD4+ cell counts below certain thresholds; no subjects were discontinued for this reason. Overall, the frequency of adverse events in each of the BCX4208 treatment groups was comparable to that observed in the placebo group.

"This successful first evaluation of BCX4208 as monotherapy in gout patients provides valuable insights into dose-response, and demonstrates an appropriate efficacy-safety balance for short-term treatment," said Dr. William P. Sheridan, Chief Medical Officer at BioCryst. "These results support continued evaluation of BCX4208 alone and in combination with allopurinol, as well as studies of longer-term administration."

Second Quarter Financial Results

For the three months ended June 30, 2010, total revenues increased to $7.6 million compared to $4.8 million for the three months ended June 30, 2009. This $2.8 million increase was driven primarily by higher revenue from the contract with the Department of Health & Human Services (HHS) for the continued development of intravenous (i.v.) peramivir.

Research and development (R&D) expenses increased to $14.7 million for the quarter from $11.2 million in the same quarter of last year. The $3.5 million increase resulted primarily from higher development costs associated with the BCX4208 program for the treatment of gout and the peramivir program for influenza. These increases in R&D expenses were partially offset by a decrease in development costs associated with the forodesine program.

General and administrative (G&A) expenses increased to $3.2 million for the second quarter of 2010 from $2.3 million in the same quarter as last year. This increase was primarily due to higher consulting fees and personnel related costs.

The Company's net loss for the three months ended June 30, 2010 was $10.2 million, or $0.23 per share, compared to a net loss of $8.7 million, or $0.23 per share for the three months ended June 30, 2009.

Year to Date Financial Results

For the six months ended June 30, 2010, total revenues increased to $33.7 million compared to $9.1 million for the six months ended June 30, 2009. This $24.6 million increase was driven primarily by a $9.8 million increase in revenue from the contract with HHS, as well as the receipt of a $7.0 million milestone payment from the Company's partner, Shionogi & Co., Ltd. (Shionogi), and the sale of $6.4 million of peramivir active pharmaceutical ingredient (API) to collaborators Shionogi and Green Cross Corporation during the first quarter 2010.

R&D expenses increased to $39.7 million for the first half of 2010 from $22.5 million in the same period as last year. The $17.2 million increase was primarily due to an increase of $7.4 million in development costs associated with the peramivir program, $6.3 million of manufacturing costs related to production of peramivir API for Shionogi and Green Cross, as well as higher development costs associated with the BCX4208 program. In addition, personnel related costs and general operating expenses were modestly higher during the first six months of 2010 as compared to the same period in 2009. These increases in R&D expenses were partially offset by lower development costs associated with the forodesine program.

G&A expenses increased to $7.0 million for the six months ended June 30, 2010 from $4.8 million for the six months ended June 30, 2009, primarily due to increases in consulting fees and personnel related costs.

The net loss for the six months ended June 30, 2010 was $12.8 million, or $0.29 per share, compared to a net loss of $18.0 million, or $0.47 per share for the six months ended June 30, 2009.

As of June 30, 2010, the Company held cash, cash equivalents and securities of $81.2 million, a decrease of $13.1 million as compared to December 31, 2009.

BioCryst expects its 2010 cash use to be within, but at the high end of, its previous guidance range of between $25 and $30 million. This is due in part to lower than expected royalty income as a result of the mild flu activity following approval in Japan. In response, the Company has taken action to reduce costs, while maintaining momentum within its clinical programs. This outlook may change depending on the timing of payments from HHS related to the peramivir program.

Clinical Development Update & Outlook

- The pivotal Phase 2 study for forodesine in the treatment of cutaneous T-cell lymphoma (CTCL) achieved its protocol-specified objective of enrolling 100 late-stage patients (Stage IIB to IVA) in January, and BioCryst expects to report data from the study in the second half of 2010.
- The Phase 2 single-arm, open-label study evaluating 200 mg of forodesine twice-daily in patients with chronic lymphocytic leukemia (CLL) has reached its enrollment target of 26 patients and is ongoing. The Company expects to report data from this study in the second half of 2010.
- Enrollment in the Phase 2 study to evaluate the efficacy and safety of BCX4208 alone and in combination with allopurinol in gout patients is proceeding, and the Company expects to announce top-line results from this study by the end of 2010.
- The Phase 3 development program of i.v. peramivir is ongoing, with investigator sites enrolling patients in the southern hemisphere. Additional studies to provide further evidence of the efficacy of i.v. peramivir in patients with influenza are under discussion with the U.S. Food & Drug Administration and HHS**.**

Conference Call and Web Cast

BioCryst's management team will host a conference call and Web cast on Thursday, August 5, 2010 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 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 infectious diseases, cancer and inflammatory diseases. BioCryst has progressed two novel compounds that are in late-stage pivotal trials; peramivir, a neuraminidase inhibitor for the treatment of influenza, and forodesine, an orally-available purine nucleoside phosphorylase (PNP) inhibitor for cutaneous T-cell lymphoma (CTCL). Additionally, BioCryst has a third product candidate, BCX4208--a next generation PNP inhibitor--in mid-stage trials for the treatment of gout. Utilizing crystallography and structure-based drug design, BioCryst continues to discover additional compounds and to progress others through pre-clinical and early development to address the unmet medical needs of patients and physicians. 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 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 CTCL may not meet its endpoint; that development and commercialization of forodesine in CTCL may not be successful; that ongoing and future pre-clinical and clinical development of BCX4208 may not have positive results; 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, 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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Revenues:				
Product sales	$ -	$ -	$ 325	$ -
Royalties	-	-	711	-
Collaborative and other research and development	7,616	4,787	32,651	9,146
Total revenues	7,616	4,787	33,687	9,146
Expenses:				
Cost of products sold	-	-	86	-
Research and development	14,737	11,213	39,654	22,502
General and administrative	3,209	2,313	7,006	4,770

Total expenses	17,946	13,526	46,746	27,272
Loss from operations	(10,330)	(8,739)	(13,059)	(18,126)
Interest and other income	137	55	271	150
Net loss	$ (10,193)	$ (8,684)	$ (12,788)	$ (17,976)
Basic and diluted net loss per common share	$ (0.23)	$ (0.23)	$ (0.29)	$ (0.47)
Weighted average shares outstanding	44,517	38,232	44,222	38,218

Balance Sheet Data (in thousands)

	June 30, 2010 (Unaudited)	December 31, 2009 (Note 1)
Cash, cash equivalents and securities	$ 81,158	$ 94,259
Receivables from collaborations	20,531	33,722
Total assets	116,103	142,190
Accumulated deficit	(275,508)	(262,720)
Stockholders' equity	83,608	86,266

Note 1: Derived from audited financial statements.

SOURCE: BioCryst Pharmaceuticals, Inc.

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