BioCryst Reports Third Quarter 2010 Financial Results and Provides Corporate Update

RESEARCH TRIANGLE PARK, N.C., Oct 28, 2010 (BUSINESS WIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) today announced financial results for the third quarter and nine months ended September 30, 2010.

Recent Highlights

- BioCryst's partner Shionogi & Co., Ltd. received approval for an additional indication for use of intravenous (i.v.) peramivir to treat children and infants with influenza in Japan, where it is marketed under the commercial name RAPIACTA(R).
- In August, Green Cross Corporation received regulatory approval for i.v. peramivir under the commercial name PeramiFlu(R) in Korea to treat patients with influenza.
- In September, BioCryst announced positive results from its Phase 2 study of BCX4208 alone and in combination with allopurinol for the treatment of gout. Lower doses of BCX4208 combined with allopurinol demonstrated synergistic effects in serum uric acid (sUA) reduction.
- In September, BioCryst reported results from two oral forodesine studies which demonstrated its clinical activity against cutaneous T-cell lymphoma (CTCL) and chronic lymphocytic leukemia (CLL).

"We are making strong progress in building BioCryst towards sustainability, on a foundation of new product approvals, advances in key development programs and emerging opportunities from our discovery engine," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst Pharmaceuticals. "The market authorizations obtained by our partners, the advancement of the gout program and the decision to move forward with BCX4161 as a potential novel treatment for hereditary angioedema all enhance our ability to create value over the short- and long-term."

Third Quarter Financial Results

For the three months ended September 30, 2010, total revenues increased to $12.0 million compared to $10.5 million for the three months ended September 30, 2009. This $1.5 million increase was driven by higher revenue from the contract with the Department of Health & Human Services (HHS) for the continued development of i.v. peramivir, offset by lower revenue from the Company's collaboration with Shionogi & Co., Ltd.

Research and development (R&D) expenses increased to $19.2 million for the third quarter of 2010 from $18.2 million in the same quarter of last year. This increase was driven by higher development costs of $2.8 million associated with the BCX4208 program for the treatment of gout, partially offset by decreases in development costs of $1.9 million associated with the forodesine and peramivir clinical programs.

General and administrative (G&A) expenses increased to $3.8 million for the third quarter of 2010 from $3.1 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 September 30, 2010 was $10.9 million, or $0.24 per share, compared to a net loss of $10.6 million, or $0.28 per share for the three months ended September 30, 2009.

Year to Date Financial Results

For the nine months ended September 30, 2010, total revenues increased to $45.7 million compared to $19.7 million for the nine months ended September 30, 2009. This $26.0 million increase was driven primarily by a $12.4 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 and the sale of $6.4 million of peramivir active pharmaceutical ingredient (API) to collaborators Shionogi and Green Cross Corp. during the first quarter 2010.

R&D expenses increased to $58.9 million for the first nine months of 2010 from $40.7 million in the same period as last year. The $18.2 million increase was primarily due to an increase of $6.5 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 Corp., $6.3 million in higher development costs associated with the BCX4208 program and $1.0 million in higher pre-clinical program costs.

These increases in R&D expenses were partially offset by a decrease of $2.1 million in development costs associated with the forodesine program.

G&A expenses increased to $10.8 million for the nine months ended September 30, 2010 from $7.8 million for the nine months ended September 30, 2009, primarily due to increases in consulting fees and personnel related costs.

The net loss for the nine months ended September 30, 2010 was $23.7 million, or $0.53 per share, compared to a net loss of $28.6 million, or $0.75 per share for the nine months ended September 30, 2009.

As of September 30, 2010, the Company held cash, cash equivalents and securities of $72.0 million, a decrease of $22.2 million as compared to December 31, 2009.

During the August 2010 quarterly update, we projected 2010 cash use to be within, but at the high end of its previous guidance range of $25 to $30 million. Initiation of the modified Phase 3 program for peramivir will lead to a ramp up in development expenses during the fourth quarter of 2010. This creates a timing effect on our 2010 cash use, as these expenses will be reimbursed by HHS during the first quarter of 2011. As a result, we now expect our cash use for 2010 to be approximately $33 million.

Clinical Development Update & Outlook

- The Phase 2 study to evaluate the efficacy and safety of BCX4208 alone and in combination with allopurinol in gout patients met its primary endpoint related to sUA reduction. A dose-response was demonstrated for both BCX4208 and allopurinol, and the combination of BCX4208 and allopurinol was shown to be superior to either drug alone in sUA reduction. In five of these nine combination groups, 80 percent or more of the patients achieved a sUA concentration of less than 6 mg/dL. Combinations of lower doses of BCX4208 with allopurinol showed synergistic effects in sUA reduction. The doses of BCX4208 alone and in combination with allopurinol evaluated in the study were generally safe and well-tolerated.
- In the pivotal Phase 2 study of 200 mg once-daily forodesine in the treatment of CTCL, eleven percent of late-stage patients (Stage IIB to IVA) achieved a partial cutaneous response. An interim analysis of the ongoing exploratory Phase 2 study evaluating 200 mg of forodesine twice-daily in 25 patients with CLL showed that three patients demonstrated a confirmed partial response to forodesine. Final results from this study are expected later in 2010, and the Company plans to present these results at an upcoming medical meeting. BioCryst is exploring the interest level of potential partners as a possible path forward for the future development of forodesine in the U.S.
- BioCryst has submitted a contract modification to HHS/Biomedical Advanced Research and Development Authority (BARDA), to include an additional efficacy study and Government funding to complete the Phase 3 development of i.v. peramivir. Start-up activities for the upcoming flu season have been approved by HHS/BARDA under the existing contract and are underway.
- BioCryst has recently presented new clinical safety and influenza B virologic data for i.v. peramivir at two medical meetings, ICAAC and IDSA.
- BioCryst is finalizing plans for a 12 week, randomized, controlled study of BCX4208 as add-on therapy in gout patients who have failed to adequately respond to allopurinol. The 200+ subject study is expected to begin enrollment in early 2011. The Company also plans to initiate a long-term safety study in 2011.
- During BioCryst's Investor Day event in September, the Company announced plans to conduct additional pre-clinical development activities to support the advancement of BCX4161 as a potential novel plasma kallikrein inhibitor for the treatment of hereditary angioedema.

Conference Call and Web Cast

BioCryst's management team will host a conference call and Web cast on Thursday, October 28, 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, inflammatory diseases and cancer. BioCryst currently has three novel late-stage compounds in development: peramivir, a neuraminidase inhibitor for the treatment of influenza, BCX4208, a purine nucleoside phosphorylase (PNP) inhibitor for the treatment of gout, and forodesine, an orally-available PNP inhibitor for hematological malignancies.

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 development and commercialization of forodesine 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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Product sales	$ -	$ -	$ 325	$ -
Royalties	-	-	711	-
Collaborative and other research and development	12,000	10,548	44,651	19,694
Total revenues	12,000	10,548	45,687	19,694
Expenses:				
Cost of products sold	-	-	86	-
Research and development	19,197	18,181	58,851	40,683
General and administrative	3,793	3,064	10,799	7,834
Total expenses	22,990	21,245	69,736	48,517
Loss from operations	(10,990)	(10,697)	(24,049)	(28,823)
Interest and other income	126	70	397	220
Net loss	$ (10,864)	$ (10,627)	$ (23,652)	$ (28,603)
Basic and diluted net loss per common share	$ (0.24)	$ (0.28)	$ (0.53)	$ (0.75)
Weighted average shares outstanding	44,884	38,460	44,445	38,300

Balance Sheet Data (in thousands)

	September 30, 2010 (Unaudited)	December 31, 2009 (Note 1)
Cash, cash equivalents and securities	$ 72,042	$ 94,259

Receivables from collaborations	25,564	33,722
Total assets	111,354	142,190
Accumulated deficit	(286,372)	(262,720)
Stockholders' equity	74,349	86,266

Note 1: Derived from audited financial statements.

SOURCE: BioCryst Pharmaceuticals, Inc.

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