



BioCryst Provides Corporate Update and Reports Fourth Quarter and Full Year 2010 Financial Results

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) today announced financial results for the fourth quarter and full year ended December 31, 2010.

Recent Highlights

- In November, BioCryst presented new findings related to the efficacy and safety of BCX4208 monotherapy for the treatment of gout at the 74th Annual ACR Scientific Meeting, and in December initiated a 250-patient Phase 2b study of BCX4208 as add-on therapy in gout patients who have not responded adequately to allopurinol monotherapy
- In January, BioCryst announced results from its 234-patient intravenous (i.v.) Phase 3 peramivir safety and virology study (303); the largest, prospective study of an i.v. influenza anti-viral in the hospital setting completed to date
- In November, BioCryst was awarded \$1.1 million in grants under the U.S. Government's Qualifying Therapeutic Discovery Project (QTDP) program to advance the development of its clinical and pre-clinical programs

"Over the last year, we have rapidly advanced our BCX4208 gout program by completing two successful Phase 2 studies and starting a large add-on study in patients not reaching goal on allopurinol alone. We expect to complete our BCX4208 Phase 2 program by the end of this year and plan to seek regulatory advice regarding our Phase 3 program in the first half of 2012," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst Pharmaceuticals. "BioCryst and its partners have also made important progress with peramivir, including approval in two countries and completion of a large Phase 3 safety study."

Fourth Quarter Financial Results

For the three months ended December 31, 2010, research and development (R&D) expenses decreased to \$23.6 million from \$31.6 million in the same quarter of last year. This decrease was driven by lower development costs associated with the peramivir and forodesine clinical programs, partially offset by higher development costs associated with the BCX4208 gout program, as well as higher pre-clinical program expenses.

Fourth quarter 2010 total revenues of \$17.8 million consisted primarily of reimbursement of collaboration expenses, including \$14.9 million from the contract with the Department of Health and Human Services (HHS) for the continued development of i.v. peramivir and the recognition of \$1.1 million in grant income from the U.S. Government's QTDP program. Fourth quarter 2009 total revenues of \$54.9 million were boosted by exceptional items related to the H1N1 pandemic and peramivir development, including \$22.9 million in emergency use product sales of peramivir, primarily to HHS, and a \$7.0 million milestone payment from Shionogi & Co., Ltd. (Shionogi) related to the filing of a New Drug Application (NDA) for i.v. peramivir in Japan. Fourth quarter 2009 revenue also included reimbursement of \$21.5 million in i.v. peramivir development expenses from HHS.

In the fourth quarter 2010, \$0.7 million of royalty revenue related to Shionogi's sales of RAPIACTA[®] in Japan, which was originally recorded during the first quarter 2010, was reversed. RAPIACTA[®] received an accelerated Japanese approval in January 2010 so it could be made available as a treatment option during the H1N1 pandemic. At the time of approval, RAPIACTA[®] stability testing was ongoing and as a result, the product sold during early 2010 had a short shelf life. During the fourth quarter 2010, Shionogi chose to accept returns of the product shipped early in 2010. All RAPIACTA[®] currently shipping during this flu season has a longer shelf life.

General and administrative (G&A) expenses decreased to \$3.4 million from \$3.6 million in the same quarter as last year. This decrease was primarily due to lower consulting and legal fees.

The Company's net loss for the fourth quarter 2010 was \$9.1 million, or \$0.20 per share, compared to net income of \$15.2 million, or \$0.37 per basic share and \$0.35 per diluted share, for the fourth quarter 2009.

Full Year 2010 Financial Results

For the year ended December 31, 2010, R&D expenses increased to \$82.5 million for 2010 compared to \$72.3 million last year. The \$10.2 million increase was primarily due to higher development costs associated with the peramivir and BCX4208 programs as well as the Company's pre-clinical programs. These increases in R&D expenses were partially offset by a decrease in development costs associated with the forodesine program.

Full year 2010 total revenues of \$63.5 million consisted primarily of reimbursement of collaboration expenses, including \$43.7 million from HHS for the continued development of i.v. peramivir and the sale of \$8.3 million of peramivir active pharmaceutical ingredient (API) and other starting materials to Shionogi and Green Cross Corporation, as well as a \$7.0 million milestone payment from Shionogi related to the marketing and manufacturing approval of RAPIACTA[®] in Japan during the first quarter 2010. Full year 2009 total revenue of \$74.6 million was significantly impacted by the fourth quarter 2009 exceptional items mentioned above, and includes \$37.9 million of peramivir development expense reimbursement from HHS. In addition, the Company recognized less revenue from its collaboration with Mundipharma during 2010 compared to 2009.

G&A expenses increased to \$14.2 million for the year ended December 31, 2010 from \$11.5 million for the year ended December 31, 2009 primarily due to increases in consulting fees related to supply chain and other commercial activities, as well as legal fees, operating and personnel related costs.

The net loss for the year ended December 31, 2010 was \$32.7 million, or \$0.73 per share, compared to a net loss of \$13.5 million, or \$0.35 per share for the year ended December 31, 2009.

As of December 31, 2010, the Company held cash, cash equivalents and securities of \$66.3 million, a decrease of \$28.0 million as compared to December 31, 2009, and a decrease of \$5.7 million compared to September 30, 2010. BioCryst expects net cash use in 2011 to be approximately \$30 million.

Clinical Development Update & Outlook

- In December, BioCryst initiated enrollment in a Phase 2b randomized, double-blind, dose-response 250-patient study to evaluate the safety and efficacy of BCX4208 as add-on therapy to allopurinol in gout patients who have failed to reach the serum uric acid (sUA) objective of <6 mg/dL following treatment with allopurinol 300 mg alone. The primary endpoint of the study is the proportion of subjects with sUA <6 mg/dL at day 85. The study utilizes a parallel-group design, evaluating BCX4208 at doses of 5 mg, 10 mg, 20 mg, 40 mg and placebo administered once-daily for 12-weeks in combination with allopurinol's standard dose of 300 mg. BioCryst expects to complete this study in late 2011.
- BioCryst is revising the primary efficacy analysis of its ongoing i.v. peramivir efficacy study (301) to focus on the subset of patients not treated with neuraminidase inhibitors as standard of care in order to provide the greatest opportunity to demonstrate a statistically significant peramivir treatment effect. The Company has also submitted a contract modification request to HHS/Biomedical Advanced Research and Development Authority (BARDA) to seek additional Government funding to complete the development of i.v. peramivir. The additional funding would be used to increase the study sample size and the number of clinical site locations in other countries. BioCryst and HHS/BARDA expect to conclude contract modification discussions within the coming weeks.
- In January, BioCryst completed its Phase 3 study (303) of the safety, tolerability and anti-viral activity of i.v. peramivir administered either as a once-daily infusion of 600 mg or a twice-daily infusion of 300 mg to adult and adolescent subjects hospitalized with confirmed or suspected influenza infection. Both dose regimens of i.v. peramivir were generally safe and well-tolerated. The frequency and severity of adverse events was similar in the two groups and was consistent with the profile of influenza patients hospitalized during the 2009-2010 pandemic.

Conference Call and Web Cast

BioCryst's management team will host a conference call and webcast on Thursday, February 10, 2011 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 webcast can be accessed by logging onto <http://www.biocryst.com>. Please connect to the website 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 there can be no assurance that our compounds will prove effective in clinical studies; that development and commercialization of our compounds may not be successful; that HHS may further condition, reduce or eliminate future funding of the peramivir program; 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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The financial summary below is out of date. Please refer to the [Revised Fourth Quarter and Full Year 2010 Financial Results Issued on February 24, 2011.](#)

BIOCRYST PHARMACEUTICALS, INC. FINANCIAL SUMMARY

Statements of Operations (Unaudited)

(in thousands, except per share)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Revenues:				
Product sales	\$ -	\$ 22,922	\$ 325	\$ 22,922
Royalties	(711)	-	-	-
Collaborative and other research and development	18,525	31,973	63,176	51,667
Total revenues	<u>17,814</u>	<u>54,895</u>	<u>63,501</u>	<u>74,589</u>
Expenses:				
Cost of products sold	-	4,544	86	4,544
Research and development	23,622	31,619	82,473	72,302
General and administrative	3,380	3,647	14,179	11,481
Total expenses	<u>27,002</u>	<u>39,810</u>	<u>96,738</u>	<u>88,327</u>
(Loss) income from operations	(9,188)	15,085	(33,237)	(13,738)
Interest and other income, net	<u>107</u>	<u>66</u>	<u>504</u>	<u>286</u>
Net (loss) income	<u>\$ (9,081)</u>	<u>\$ 15,151</u>	<u>\$ (32,733)</u>	<u>\$ (13,452)</u>
Net (loss) income per share:				
Basic	\$ (0.20)	\$ 0.37	\$ (0.73)	\$ (0.35)
Diluted	\$ (0.20)	\$ 0.35	\$ (0.73)	\$ (0.35)

Weighted average shares outstanding:

Basic	44,918	40,778	44,564	38,926
Diluted	44,918	43,041	44,564	38,926

Balance Sheet Data (in thousands)

	December 31, 2010 (Unaudited)	December 31, 2009 (Note 1)
Cash, cash equivalents and securities	\$ 66,342	\$ 94,259
Receivables from collaborations	31,347	33,722
Total assets	110,567	142,190
Accumulated deficit	(295,453)	(262,720)
Stockholders' equity	66,623	86,266

Note 1: Derived from audited financial statements.

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Source: BioCryst Pharmaceuticals, Inc.

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