



BioCryst Pharmaceuticals Provides Corporate Update and Reports Third Quarter 2011 Financial Results

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) today announced financial results for the third quarter and nine months ended September 30, 2011.

"We are pleased with the recent results of our 12-week Phase 2b gout study, which showed that adding low doses of [BCX4208](#) to allopurinol doubled the proportion of patients reaching therapeutic goal compared to the standard of care of allopurinol alone," said [Jon P. Stonehouse](#), President and Chief Executive Officer of BioCryst Pharmaceuticals. "BCX4208 has been shown to work synergistically with allopurinol and represents an innovative new class of compound that is differentiated from other approved and experimental gout treatments. BCX4208 has been safely studied in a wide range of patients with gout, including patients with co-morbid diseases and kidney stones. Our ongoing development program is intended to confirm BCX4208 is not metabolized and should not impact patient's other medications. BCX4208 represents a unique late-stage opportunity with the potential to address the high unmet medical needs of the large and expanding gout population."

Third Quarter Financial Results

For the three months ended September 30, 2011, revenues decreased to \$5.2 million from \$12.0 million in last year's quarter due to lower collaboration revenue from the Department of Health and Human Services/Biomedical Advanced Research and Development Authority (HHS/BARDA) under the contract for the continued development of [peramivir](#), resulting from the completion of peramivir clinical studies. All revenue in both periods related to reimbursement of peramivir development costs by HHS/BARDA.

Third quarter 2011 research and development (R&D) expenses decreased to \$14.8 million from \$19.2 million in the third quarter of 2010. This decrease was driven by lower development costs associated with the peramivir and forodesine clinical programs following the completion of various clinical studies during 2010, partially offset by higher BCX4208 gout program development costs associated with increased clinical activity in that program.

General and administrative (G&A) expenses for the third quarter of 2011 decreased to \$3.3 million compared to \$3.8 million in last year's quarter, due to lower third-party professional expenses.

During the third quarter 2011, the Company realized financing costs associated with its non-dilutive peramivir royalty monetization transaction completed in the first quarter of 2011. These costs relate to a \$0.6 million mark-to-market loss on its foreign currency hedge, resulting from changes in the U.S. dollar/yen exchange rate and a \$1.2 million interest expense related to the non-recourse notes issued in conjunction with the financing transaction.

The net loss for the third quarter 2011 was \$14.5 million, or \$0.32 per share, compared to a net loss of \$10.9 million, or \$0.24 per share, for the three months ended September 30, 2010.

As of September 30, 2011, the Company held cash, cash equivalents and investments of \$61.0 million, compared to \$66.3 million as of December 31, 2010. Net operating cash use for the recent quarter was \$10.4 million and \$25.3 million through nine months of 2011. Operating cash use for the three and nine months ending September 30, 2011 excludes \$0.6 million and \$3.0 million, respectively, in cash used as hedge collateral. BioCryst continues to expect net operating cash use in 2011 to be approximately \$35 million.

Year to Date Financial Results

For the nine months ended September 30, 2011, total revenues were \$14.4 million, reflecting a \$16.4 million decrease in HHS/BARDA collaboration revenue compared to the same period last year. Nine month 2010 revenue of \$45.7 million also included a \$7.0 million milestone payment from the Company's partner, Shionogi & Co., Ltd., and the sale of \$6.4 million of peramivir active pharmaceutical ingredient (API) to Shionogi and Green Cross Corporation.

R&D expenses decreased to \$41.7 million for the first nine months of 2011 from \$58.9 million in the same period of 2010, primarily due to lower development costs associated with the peramivir and forodesine clinical programs following the completion of various clinical studies during 2010. Additionally, R&D expenses in the same period last year included \$6.3 million of manufacturing costs related to production of peramivir API for collaborators Shionogi and Green Cross Corp. This API

expense did not recur in 2011.

G&A expenses of \$11.3 million for the nine months ended September 30, 2011 were approximately equivalent to the \$10.8 million for the same period in 2010.

The net loss for the nine months ended September 30, 2011 was \$43.8 million, or \$0.97 per share, compared to a net loss of \$23.7 million, or \$0.53 per share, for the same period last year.

Clinical Development Update & Outlook

- In October, BioCryst announced positive top-line results from its 279-patient Phase 2b randomized, double-blind, dose-response study of [BCX4208](#) added to allopurinol 300 mg in gout patients who had failed to reach the clinically important serum uric acid (sUA) goal of <6 mg/dL on allopurinol alone. BCX4208 doses evaluated in the study showed response rates ranging from 33% to 49%, approximately doubling the proportion of patients reaching goal on placebo (18%). BCX4208 added to allopurinol was generally safe and well-tolerated at all doses studied. Over half of the patients originally randomized into this study continued treatment into a 3-month extension phase, totaling 6-months of uninterrupted BCX4208 add-on treatment. The Company is also conducting a Phase 1 study to evaluate the metabolic profile of BCX4208. Results from both of these studies are expected in January 2012
- Additional results from the [BCX4208](#) Phase 2b study have been accepted as a late-breaker oral presentation at the 2011 American College of Rheumatology and the Association of Rheumatology Health Professionals (ACR/ARHP) Annual Scientific Meeting. The oral presentation of the study results is titled "BCX4208 Combined With Allopurinol Increases Response Rates in Patients With Gout Who Fail to Reach Goal Range Serum Urate on Allopurinol Alone: A Randomized, Double-Blind, Placebo-Controlled Trial" and is scheduled for November 8, 2011 at 2:30-4:30 p.m. Central Time (Presentation Number L10)
- BioCryst has opened enrollment of patients into its 12-week Phase 2 study of BCX4208 in patients with gout and moderately impaired renal function
- BioCryst has activated approximately 50 additional clinical sites to support enrollment in the ongoing Phase 3 efficacy study of the influenza anti-viral i.v. peramivir. Sites in Europe, North America and India are prepared to enroll patients during the upcoming Northern Hemisphere flu season. A planned interim analysis to confirm or revise the study's current enrollment target of 160 patients for the primary efficacy analysis population is expected to be conducted no later than mid-2012
- The Company continues to advance both of its leading pre-clinical assets towards IND filings during the second half of 2012. These novel compounds include BCX4161, a potent inhibitor of kallikrein for potential development as an oral, prophylactic treatment for hereditary angioedema, and BCX5191, a potent and selective nucleoside analog targeting RNA polymerase for the potential treatment of hepatitis C

Conference Call and Webcast

BioCryst's leadership team will host a conference call and webcast on Wednesday, November 2, 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 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 Pharmaceuticals

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: 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 website 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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BIOCRIST PHARMACEUTICALS, INC.
FINANCIAL SUMMARY

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Product sales	\$ -	\$ -	\$ -	\$ 325
Royalties	-	-	-	711
Collaborative and other research and development	5,249	12,000	14,419	44,651
Total revenues	<u>5,249</u>	<u>12,000</u>	<u>14,419</u>	<u>45,687</u>
Expenses:				
Cost of products sold	-	-	-	86
Research and development	14,772	19,197	41,687	58,851
General and administrative	3,282	3,793	11,277	10,799
Total expenses	<u>18,054</u>	<u>22,990</u>	<u>52,964</u>	<u>69,736</u>
Loss from operations	(12,805)	(10,990)	(38,545)	(24,049)
Interest and other income	92	126	329	397
Interest expense	(1,160)	-	(2,614)	-
Loss on foreign currency derivative	(586)	-	(2,926)	-
Net loss	<u>\$ (14,459)</u>	<u>\$ (10,864)</u>	<u>\$ (43,756)</u>	<u>\$ (23,652)</u>
Basic and diluted net loss per common share	<u>\$ (0.32)</u>	<u>\$ (0.24)</u>	<u>\$ (0.97)</u>	<u>\$ (0.53)</u>
Weighted average shares outstanding	45,178	44,884	45,103	44,445

Balance Sheet Data (in thousands)

September 30, 2011
(Unaudited)

December 31, 2010
(Note 1)

Cash, cash equivalents and securities	\$	61,040	\$	66,341
Receivables from collaborations		11,634		30,227
Total assets		92,511		109,447
Non-recourse notes payable		30,000		-
Accumulated deficit		(340,328)		(296,572)
Stockholders' equity		26,042		65,503

Note 1: Derived from audited financial statements.

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Source: BioCryst Pharmaceuticals

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