



BioCryst Reports Third Quarter 2009 Financial Results and Provides Corporate Update

BIRMINGHAM, Ala., Oct 29, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced financial results for the quarter and nine months ended September 30, 2009 and provided a corporate update regarding clinical programs and potential emergency use of intravenous (i.v.) peramivir.

"BioCryst has made significant progress in its efforts to enable the U.S. and other governments to acquire i.v. peramivir for use as a potential treatment option during this influenza emergency. The recent Emergency Use Authorization, or EUA, issued by the FDA, was an important milestone. BioCryst is prepared to provide peramivir if requested by the U.S. and other governments," said Jon P. Stonehouse, President and Chief Executive Officer of BioCryst Pharmaceuticals. "BioCryst remains committed to completing the U.S. development of peramivir through the traditional regulatory pathway."

"In recent months we have advanced BioCryst's clinical pipeline by starting Phase 3 studies to support U.S. registration of i.v. peramivir and by initiating a Phase 2 study of BCX4208 in patients with gout," said Dr. William P. Sheridan, Chief Medical Officer at BioCryst. "Additionally, we are in the process of completing a portfolio review of our clinical and pre-clinical programs and molecules so that we can optimize our development plan for the mid-term."

Third Quarter Financial Results

For the three months ended September 30, 2009, collaborative and other research and development (R&D) revenues were \$10.5 million compared to \$8.9 million for the three months ended September 30, 2008. This increase was the result of higher revenues from our contract with the Department of Health and Human Services (HHS) for the development of peramivir and from our collaboration with Shionogi & Co., Ltd. These increases in revenues were offset by a reduction in revenue from our collaboration with Mundipharma International Holdings Limited, as well as lower amortization of deferred revenue from our collaboration arrangements.

R&D expenses increased to \$18.2 million for the third quarter of 2009 from \$16.0 million for the third quarter of 2008. The higher R&D expenses resulted from an increase in manufacturing costs associated with our peramivir program, offset by reductions in clinical development costs for our peramivir and forodesine programs. In addition, general operating costs as well as personnel related costs were lower in the current quarter of 2009 compared to the same quarter of the prior year.

General and administrative (G&A) expenses increased to \$3.1 million for the third quarter of 2009 from \$2.5 million for last year's third quarter, primarily due to increases in legal and consulting fees.

Interest income for the third quarter 2009 was \$0.1 million as compared to \$0.6 million for the same period last year. The decrease was driven by a lower average cash and securities balance as well as a significantly lower yield earned on interest-bearing assets.

The net loss for the third quarter of 2009 was \$10.6 million, or \$0.28 per share, compared to a net loss of \$9.0 million, or \$0.24 per share for the third quarter of 2008.

As of September 30, 2009, the Company held cash, cash equivalents and investments of \$38.5 million, a decrease of \$3.8 million during the third quarter of 2009. This reduction is net of \$5.0 million that was returned by HHS relative to the purchase of excess active pharmaceutical ingredient (API). In July 2009, BioCryst indicated that it was in the process of purchasing excess peramivir API from HHS as permitted under the development contract. HHS is completing its review of this excess in light of the peramivir clinical development plan, as well as the calculation for the acquisition cost for the purchase. Pending completion of that review, HHS has returned the payment to BioCryst. HHS acknowledges that at least half of the API is excess. When HHS has completed its review, we will determine the final acquisition process for the API.

Year to Date Financial Results

BioCryst's cash, cash equivalents and investments balance has decreased \$24.8 million during the first nine months of 2009. Given certain manufacturing activities initiated in anticipation of government needs, and pending certain clinical activities, BioCryst now expects cash use for 2009 to be near the top end of the previous guidance range of \$30 to \$38 million. Cash use during the remainder 2009 will depend on potential events such as the level of i.v. peramivir manufacturing, stockpiling activities and the timing of Shionogi's filing for Japanese approval of peramivir. During the upcoming planning cycle, the Company will align its cash needs and clinical development activities to carry its clinical programs through 2010.

Collaborative and other R&D revenues decreased to \$19.7 million for the nine months ended September 30, 2009 as compared to \$22.3 million for the nine months ended September 30, 2008. This change was driven by a reduction in revenue from our collaboration with Mundipharma and lower amortization of deferred revenue from our collaboration arrangements. Revenues related to our contract with HHS for the development of peramivir were higher during the first nine months of the current year compared to the same period of last year due to a \$4.9 million reserve recorded against revenue in 2008 for amounts we had previously expected to receive from HHS. Revenue from our collaboration with Shionogi was higher during the nine months ended September 30, 2009.

R&D expenses decreased to \$40.7 million for the first nine months of 2009 from \$51.3 million for the same period of the prior year. This was due to lower clinical development and toxicology study costs associated with peramivir and forodesine programs, a reduction in manufacturing costs associated with our forodesine program, and lower costs incurred on the pre-clinical compounds. In addition, general operating costs as well as personnel related costs were lower in the first nine months of 2009 compared to the first nine months of 2008. These reductions in R&D expenses were partially offset by higher manufacturing costs and consulting fees associated with our peramivir program.

G&A expenses decreased to \$7.8 million for the nine months ended September 30, 2009 from \$8.0 million for the same period last year. The lower expenses were primarily due to decreases in personnel related costs and consulting fees, offset by an increase in legal fees.

Interest income for the nine months ended September 30, 2009 was \$0.2 million as compared to \$2.2 million for the nine months ended September 30, 2008, due to a lower average cash and securities balance as well as significantly lower yield earned on interest-bearing assets.

The net loss for the nine months ended September 30, 2009 was \$28.6 million, or \$0.75 per share, compared to a net loss of \$34.8 million, or \$0.91 per share for the nine months ended September 30, 2008.

Recent Program Highlights

Peramivir Program

- The U.S. Food and Drug Administration (FDA) recently issued an Emergency Use Authorization (EUA) that allows BioCryst's i.v. peramivir to be used to treat certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital. BioCryst donated and transferred 1,200 courses of i.v. peramivir 600 mg once-daily for five days to HHS to enable the Government to move rapidly to deploy an initial supply of peramivir. To prepare for peramivir orders that BioCryst may receive from the U.S. or other governments during this pandemic emergency, BioCryst is completing additional production of approximately 130,000 courses of i.v. peramivir and is prepared to make more, if required.
- As of October 23, 2009, BioCryst received 42 requests within the U.S. from treating physicians to supply peramivir through an emergency use investigational new drug process (EIND) for eligible patients with influenza requiring hospitalization. Supply of peramivir has been managed under the EUA since its issuance on October 23.
- Negotiations are continuing between BioCryst and HHS regarding the HHS request for proposal (RFP) for the supply of i.v. peramivir for the treatment of critically ill influenza patients under an EUA. BioCryst management intends to provide an update once the RFP process has reached a conclusion.
- In September, BioCryst was awarded a \$77.2 million contract modification by the HHS to complete development of i.v. peramivir and it subsequently initiated two Phase 3 studies of i.v. peramivir for the treatment of hospitalized patients with serious influenza.

- Shionogi & Co., Ltd. recently stated that they intend to file its New Drug Application (NDA) soon to seek marketing approval for peramivir in Japan. This filing would trigger another milestone payment to BioCryst under the current license agreement between the companies.

- In September, BioCryst announced that it signed binding letters of intent with three partners - moksha8 Pharmaceuticals for Brazil and Mexico, NT Pharma Co., Ltd. for China and Neopharm Group for Israel - who will exclusively represent BioCryst and its anti-viral peramivir for influenza stockpiling opportunities, as well as for marketing and distribution of peramivir for seasonal influenza upon local regulatory approval. Each partner has initiated and advanced discussions with key government officials in their respective territories to discuss peramivir's availability during this global health emergency.

Forodesine Program

- BioCryst has advanced enrollment of its pivotal Phase 2 study of forodesine for the treatment of cutaneous T-cell lymphoma (CTCL) towards the study's target enrollment of 130 to 140 patients. The Company continues to expect preliminary data in the first half of 2010.

- A Phase 2 single-arm, open-label study evaluating 200 mg of forodesine twice-daily in patients with chronic lymphocytic leukemia (CLL) is ongoing, and the Company expects to provide an update on this study by the end of 2009.

BCX4208 Program

- BioCryst announced the initiation of a randomized, double-blind, placebo-controlled Phase 2 study to evaluate the efficacy and safety of BCX4208 in subjects with gout. The study's primary objective is to determine the effect of different doses of orally administered BCX4208 on serum uric acid levels in patients with gout. The trial is expected to enroll up to 120 subjects.

Conference Call and Web Cast

BioCryst's management team will host a conference call and Web cast on Thursday, October 29, 2009, at 11:00 a.m. Eastern Time to discuss the financial results and recent corporate developments. To participate in the conference call, please dial 1-888-297-0353 (United States) or 1-719-325-2266 (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 into late-stage pivotal clinical trials; peramivir, an anti-viral for influenza, and forodesine, a purine nucleoside phosphorylase (PNP) inhibitor for cutaneous T-cell lymphoma (CTCL). 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. 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 Limited validate its scientific foundation and the utility of its product candidates. For more information, please visit the Company's Web site at

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 cutaneous T-cell lymphoma (CTCL) may not meet its endpoint; that development and commercialization of forodesine 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 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, most recent Registration Statement on Form S-3 (filed November 28, 2008), 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 | | Nine Months Ended | |
|--|--------------------|-----------|-------------------|------------|
| | September 30, | | September 30, | |
| | 2009 | 2008 | 2009 | 2008 |
| | ---- | ---- | ---- | ---- |
| Revenues: | | | | |
| Collaborative and other research and development | \$10,548 | \$8,894 | \$19,694 | \$22,321 |
| Expenses: | | | | |
| Research and development | 18,181 | 15,996 | 40,683 | 51,267 |
| General and administrative | 3,064 | 2,471 | 7,834 | 8,023 |
| | ----- | ----- | ----- | ----- |
| Total expenses | 21,245 | 18,467 | 48,517 | 59,290 |
| | ----- | ----- | ----- | ----- |
| Loss from operations | (10,697) | (9,573) | (28,823) | (36,969) |
| Interest and other income | 70 | 578 | 220 | 2,167 |
| | -- | --- | --- | ----- |
| Net loss | \$(10,627) | \$(8,995) | \$(28,603) | \$(34,802) |
| | ===== | ===== | ===== | ===== |

| | | | | |
|--|--------------------|--------------------|--------------------|--------------------|
| Basic and diluted net loss per common share | \$ (0.28) ===== | \$ (0.24) ===== | \$ (0.75) ===== | \$ (0.91) ===== |
| Weighted average shares outstanding | 38,460 | 38,095 | 38,300 | 38,040 |

Balance Sheet Data (in thousands)

| | September 30, 2009 (Unaudited) ----- | December 31, 2008 (Note 1) ----- |
|--|--|--|
| Cash, cash equivalents and securities | \$38,492 | \$63,314 |
| Receivables from collaborations | 11,626 | 11,982 |
| Total assets | 60,588 | 84,692 |
| Accumulated deficit | (277,871) | (249,268) |
| Stockholders' equity | 23,545 | 46,426 |

Note 1: Derived from audited financial statements.

SOURCE BioCryst Pharmaceuticals, Inc.

<http://www.biocryst.com>

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