

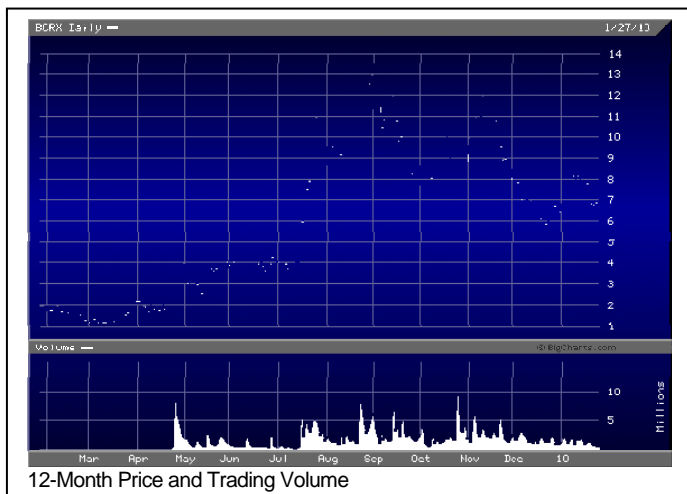


# WBB Securities, LLC

Stephen G. Brozak • [sbrozak@wbbsec.com](mailto:sbrozak@wbbsec.com) • (908) 518-7610

Daniel T. Mallin, PhD • [dmallin@wbbsec.com](mailto:dmallin@wbbsec.com) • (908) 518-7610

## BioCryst Pharmaceuticals, Inc. (BCRX) (01/29/2010) Initiating Coverage with a Buy Rating and \$8.50 Price Target



### Rating Legend:

**Strong Buy** – Should be aggressively purchased.

**Buy** - Should be purchased on market weakness.

**Hold** - Fairly valued.

**Sell** - Stock should be sold on market strength.

**Sell Short** - Should be aggressively sold.

**Speculative Buy** – For aggressive accounts only.

<b>Current Price</b>	\$6.45
<b>12-Month Trading Range</b>	\$1.13 – 13.47
<b>Market Capitalization (Mil)</b>	283.16
<b>Shares Outstanding (Mil)</b>	43.9*
<b>Avg. Daily Volume</b>	2,091,240
<b>L. T. Debt (Mil)</b>	-
<b>Dividend/Yield</b>	N/A
<b>Book Value P/S</b>	0.536
*Diluted weighted average 12/31/09	
<b>NASDAQ Composite</b>	2,179.00
<b>S&amp;P 500</b>	1,084.53
<b>12 Month Target Price</b>	\$8.50
Source: QUODD	

### A Treatment for Severe Flu Cases

BioCryst Pharmaceuticals, Inc. (BCRX) announced on January 26, 2010 that partner, Shionogi & Co., Ltd., will launch intravenous peramivir in Japan for treatment of influenza under the name Rapiacta.

Shionogi received the world's first marketing and manufacturing approval for both single dose administration of 300 mg i.v. peramivir for adult uncomplicated seasonal influenza infection, and single and multiple dose administration of 600 mg i.v. peramivir for high-risk influenza patients. Shionogi intends to prepare an adequate supply for approximately 700,000 people by March 31, 2010.

In September, 2009, BCRX received contract modification for an additional \$77.2 million from the Biomedical Advanced Research and Development Agency (BARDA) to fund Phase III trials of peramivir. BCRX has now initiated two Phase III trials of peramivir, received Emergency Use Authorization, filled a government order for 10,000 treatments and announced several international partnerships.

EPS	2008	2009	2010
Q1	(0.34)A	(0.24)A	
Q2	(0.33)A	(0.23)A	
Q3	(0.24)A	(0.28)A	
Q4	0.26A	.15E	
Year	(0.65)A	(0.60)E	(0.60)E
P/E	NM	NM	NM
EPS Growth	NM	NM	NM
FY Rev. (Mil)	56.6A	50.0E	50.0E
<b>FY:DEC</b>			

Peramivir is earning an increasingly important place in worldwide treatment of influenza. We are therefore initiating coverage on BCRX with a Buy rating and a 12-month price target of \$8.50 per share.

## Management

**Jon P. Stonehouse – President and Chief Executive Officer**, most recently served as Senior Vice President of Corporate Development at Merck KGaA with responsibility for global licensing and business development, corporate mergers and acquisitions, corporate strategic planning and alliance management.

**Stuart Grant – Senior Vice President and Chief Financial Officer**, joined the Senior Management Team at BCRX in August of 2007. Prior to joining BCRX, Mr. Grant was Chief Financial Officer at The Serono Group, based in Geneva, Switzerland. He has held a variety of Senior Operating and Financial positions at Serono in Europe and in the United States.

**William Sheridan, MB BS – Chief Medical Officer**, joined BCRX in July 2008. Prior to joining BCRX, Dr. Sheridan organized and led the Amgen's U.S. Medical Affairs function, leading several product development teams. At Amgen, Dr. Sheridan held titles at the Vice President level in North American Medical Affairs, International Medical Affairs, Global Health Economics and Outcomes Research, U.S. Medical Affairs, and Product Development. Dr. Sheridan earned his MB BS degree (M.D. equivalent) at the University of Melbourne in Victoria, Australia. Dr. Sheridan is a board-certified fellow of the Royal Australasian College of Physicians (FRACP), with a sub-specialty in medical oncology, and a Fellow of the American College of Physicians.

**Yarlagadda S. Babu, PhD – Vice President, Drug Discovery**, was BCRX's first full-time employee having joined the Company in 1988. Prior to joining BCRX, he served five years on the biochemistry faculty at the University of Alabama at Birmingham (UAB). He obtained his Ph.D. from the Indian Institute of Science, Bangalore and spent three years in the Laboratory of Molecular Biophysics at the University of Oxford, UK before joining UAB.

**Elliott Berger, PhD – Senior Vice President, Regulatory Affairs**, joined BCRX in August 2007. Prior to joining BCRX, he was Vice President, Regulatory Affairs and Quality Assurance, Head of Global Regulatory Strategy at EMD Pharmaceuticals, the North American subsidiary of Merck KGaA. Prior to EMD, Dr. Berger was a member of the Senior Executive Team at Astra Pharmaceuticals, most recently serving as Vice President, Regulatory Affairs. Dr. Berger received both his Ph.D. and M.S. degrees in Biometrics as well as his B.A. degree in Mathematics from Temple University.

**Walter G. Gowan, PhD – Vice President, Pharmaceutical Development**, joined BCRX in September 2006. Prior to joining BCRX, Dr. Gowan held the position of Senior Director Pharmaceutical Sciences at Cubist Pharmaceuticals. Prior to joining Cubist, he held the position of Director Product Development at Solvay Pharmaceuticals. Dr. Gowan received his Ph.D. in Pharmaceutics, B.S. in Pharmacy and B.S. in Biology from the University of Texas.

**David S. McCullough – Vice President, Strategic Planning, Commercialization and Corporate Development**, joined BCRX in April, 2007. Prior to joining BCRX, Mr. McCullough served as Director, Global Corporate Development in the Ethical Pharmaceuticals Division at Merck KGaA in Darmstadt, Germany. Prior to that position, Mr. McCullough was part of the Business Operations and Market Research Team in the Oncology Business Unit of Eli Lilly and

Company. Mr. McCullough received his Bachelor of Science degree from Western Illinois University.

## Company Background

BCRX was founded in 1986. It has operations in Birmingham, Alabama and Durham, North Carolina. The company has over 80 employees.

The company has three lead products:

- Peramivir is an intravenously administered anti-viral agent that operates as a neuraminidase inhibitor.
- Forodesine is a highly target specific, drug for inducing apoptosis in both T-cells and B-cells. It is currently being tested for treatment of cutaneous T-cell lymphoma (CTCL) and chronic lymphocytic leukemia (CLL).
- BCX4208 is currently being tested to treat gout in a Phase II study. A prior Phase II study in psoriasis patients showed that BCX4208 is generally safe and well tolerated.

## Structure-Based Drug Design

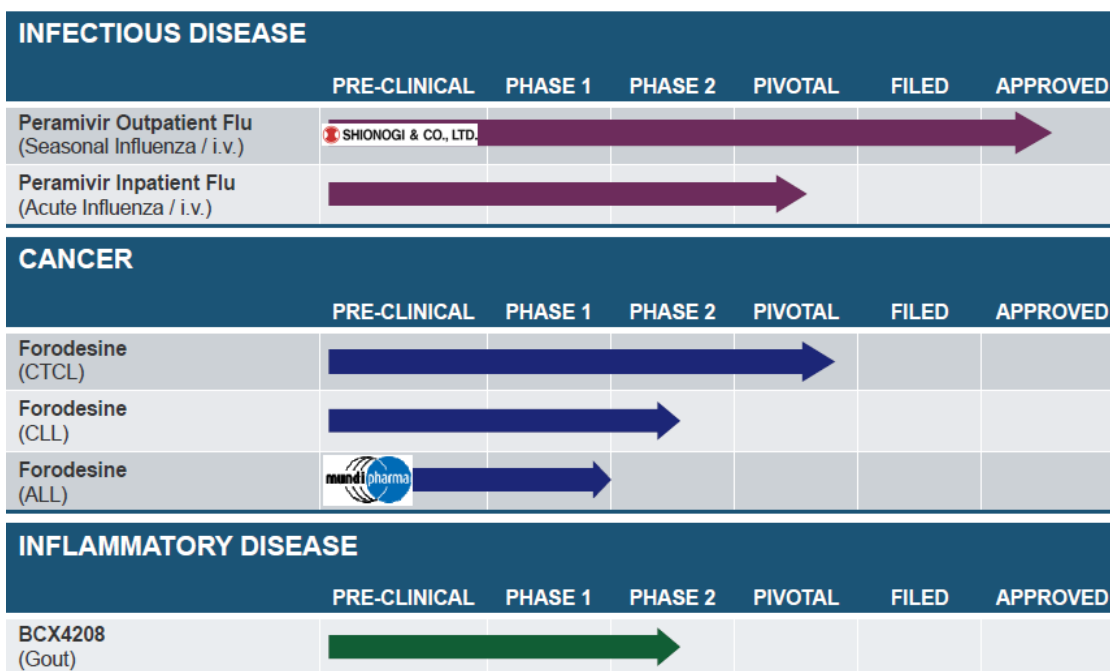
BCRX's drug discovery process, known as structure-based drug design, is used to synthesize proprietary small molecule pharmaceuticals that block key enzymes associated with infectious diseases, inflammatory diseases and cancer. The first step in the process is to select the target enzyme that normally drives the chemical reaction that fuels an infection or disease.

Next, BCRX researchers use x-ray crystallography to compose a 3-dimensional representation of the molecular structure of the enzyme, which will in turn direct the researchers toward how to design their candidate. A potential compound is designed to fit the active site of the enzyme, then constructed atom by atom. Tests are performed and data collected on how the candidate interacts with the enzyme, and the structure is refined in an iterative process that further uses x-ray crystallography to analyze and modify the compound.

If designed correctly, the BCRX product will bind to the active site of the enzyme, thereby preventing the enzyme from carrying out its intended chemical reaction and thus altering the mechanism of the disease. The structure-based drug design serves as a highly efficient method to develop a specific solution against a particular enzyme target.

## Product Pipeline

BCRX currently has three products in clinical trials: peramivir for influenza, forodesine for cancer and BCX-4208 for gout.



Source: BioCryst Pharmaceuticals, Inc.

## Peramivir

BCRX's lead candidate, derived from structure-based drug design, is Peramivir. Peramivir is an anti-viral that inhibits neuraminidase, an enzyme that assists in the spread of influenza virus by aiding its ability to replicate. Under its five-year contract with BARDA, BCRX is currently testing peramivir in two Phase III trials for treating in-patient influenza infections. Peramivir is being developed for intravenous administration, a route that is preferred for hospitalized patients. Several important events in the development of Peramivir took place during the second half of 2009. Below is an outline of the major events:

### September 21, 2009 – BARDA Funding and Request For Proposal

BCRX announced an additional BARDA award of \$77.2 million for Phase III testing of peramivir. Under the agreement, the term of the contract was also extended to five years from four. The company expects that this award will fully fund all costs associated with the remaining US trials. This award was an extension of a January 2007 contract for \$102.6 million for development of peramivir.

Also on the same day, the company announced that it received a Request For Proposal (RFP) from the Department of Health and Human Services (HHS), outlining the minimum and maximum order quantities of intravenous peramivir. Under this RFP, and with the issuance of an emergency use

authorization (EUA) (which was granted on October 23), the government could place an order for between 1,000 and 40,000 treatment courses.

### **September 30, 2009 – Initiation Two Phase III Trials**

The company announced the initiation of its two Phase III trials of peramivir. The first is a randomized, double-blind and controlled study and will evaluate the safety and efficacy of a single daily dose of peramivir with the standard of care over a five day period, compared to standard of care alone. The study will include patients who are hospitalized with serious influenza. The second study is an open-label, randomized study measuring the anti-viral activity, safety and tolerability of a single daily dose of 600mg of peramivir compared with split doses twice-daily also over a five day period. Enrollees will include hospitalized individuals with confirmed or suspected influenza infection. BCRX expects the combined enrollment for these studies to total approximately 700 patients.

### **October 23, 2009 – Emergency Use Authorization**

BCRX announced that, in response to a request from the CDC, the FDA issued an EUA for peramivir in patients with suspected or confirmed 2009 H1N1 influenza infection. Under the EUA, intravenous peramivir may be used only for hospitalized adult and pediatric patients and based on one or more of the following conditions: when the patient is not responding to either oral or inhaled anti-viral therapy, when drug delivery by a non-intravenous route is not feasible and when the clinician believes the intravenous treatment is appropriate due to other circumstances. The final condition applies to adults only.

### **November 5, 2009 – First Government Order Placed**

The company announced that it received an initial order for 10,000 treatment courses of intravenous peramivir. The value of the order totaled \$22.5 million, and BCRX shipped the entire order on November 4<sup>th</sup>. Under the RFP, HHS may request an additional 30,000 courses, but the company is prepared to produce much more if orders from other agencies or governments are placed.

### **Peramivir Partnerships**

BCRX has established seven partnerships in ten countries plus Europe and the Mid-East for stockpiling of peramivir. The company retains all rights within the US.

On January 11, 2010, the company announced the addition of two partners for peramivir: Merck Serono, a division of Merck KGaA and UK-based Hikma Pharmaceuticals PLC. Merck Serono will represent BCRX for stockpiling efforts in the territories of Europe, Russia, Canada and Singapore. Hikma Pharmaceuticals will be responsible for distribution in the Middle East, excluding Israel, and North Africa.

In September 2009, BCRX announced three partners for commercializing peramivir, including moksha8 Pharmaceuticals, Inc. for Mexico and Brazil, NT Pharma Group Co., Ltd for China and Neopharm Group for Israel. Each partner will be responsible for seeking stockpiling contracts in its respective region. On January 12, 2010, BCRX released that moksha8 was granted approval for the importation and use of peramivir in patients with 2009 H1N1 influenza.

In March 2007, the company announced that it had entered into an agreement with Shionogi & Co., Ltd. to develop and commercialize peramivir in Japan and Taiwan. BCRX received an upfront payment of \$14 million and is eligible to receive milestone payments and double digit royalties on sales under the agreement.

In November 2009, BCRX announced that Shionogi filed an NDA in Japan to seek regulatory approval for intravenous peramivir. This resulted in a \$7 million milestone payment. Then on January 13, 2010, BCRX announced that Shionogi received marketing and manufacturing approval for intravenous peramivir in Japan. This resulted in another \$7 million milestone payment. BCRX will be eligible to receive an additional \$95 million in commercial event milestones.

Shionogi received the world's first marketing and manufacturing approval for both single dose administration of 300 mg i.v. peramivir for adult uncomplicated seasonal influenza infection, as well as single and multiple dose administration of 600 mg i.v. peramivir for the patients at high-risk for complications associated with influenza.

In June 2006, BCRX announced an agreement with Green Cross Corp. to develop and commercialize peramivir in South Korea. Under the agreement, Green Cross will fund the development, regulatory and commercialization costs of peramivir in South Korea. BCRX received an initial payment of \$250,000 and is eligible to receive milestone and royalty payments. On January 8, 2010, BCRX announced that Green Cross filed an NDA in South Korea for intravenous peramivir.

## **Forodesine**

Forodesine, also derived from the structure-based drug design platform, is an orally-administered drug that inhibits the enzyme purine nucleoside phosphorylase (PNP). PNP is associated with proliferation of T- and B-cells, which are the cancerous cells in some forms of lymphoma and leukemia. By inhibiting PNP, in these cells, apoptosis, also known as programmed cell death, is induced.

BCRX is testing forodesine in two cancers that can be selectively targeted through PNP: refractory cutaneous T-cell lymphoma (CTCL), chronic lymphocyte leukemia (CLL), and a partner is developing forodesine for acute lymphoblastic leukemia (ALL). Forodesine has been granted Orphan Drug status by the FDA on all three indications, and has also been granted "fast track" status for the treatment of relapsed or refractory T-cell leukemia.

Forodesine for CTCL is currently being tested under a Special Protocol Assessment (SPA) with the FDA in a Phase III trial. On January 15, 2010, BCRX announced that the company reached its enrollment target of 100 late-stage CTCL patients under the SPA. In total, 143 patients are enrolled. The study will measure complete or partial response rates that are sustained at least 28 days. Top-line results are expected in the second half of 2010. CTCL affects approximately 18,000 people in the US with 1,500 diagnosed each year. It accounts for nearly 50 percent of all T-Cell malignancies.

Forodesine is undergoing a Phase II test for CLL and Phase I/II for ALL. As of January 15, 2009, the CLL trial had enrolled 15 of the targeted 26 patients. About 15 percent of all non-Hodgkin's

lymphoma patients are considered to have CLL. CLL affects 90,000 people in the US with 15,000 patients diagnosed annually. ALL is the most common form of leukemia in children.

In February 2006, BCRX entered into an exclusive agreement with Mundipharma International Holdings Limited for the development and commercialization of forodesine throughout Europe, Asia and Australia. BCRX received an initial upfront payment of \$10 million and is eligible to receive milestone and royalty payments.

### **BCX-4208**

BCX-4208, also a PNP inhibitor, is being developed for the treatment of gout. Gout is an inflammatory arthritis caused by elevated levels of uric acid in the blood.

On September 28, 2009, BCRX announced the initiation of a Phase II trial of BCX-4208. The study is randomized, double blind and placebo-controlled with an expected enrollment of up to 120 patients. Researchers will test the safety and efficacy in gout patients in two parts. The first part is measuring multiple doses of BCX-4208 against a placebo and the second is studying escalating doses. Data from the first part of the trial is expected in mid-2010.

### **Valuation**

Our valuation of BCRX is based on a discounted price to earnings model. We estimate 2012E earnings per share to be approximately \$0.94E per share. We then discount 30 percent and implement an industry P/E of 20. Assuming a fully diluted average weighted share count of 43.9 million, we arrive at our 12-month price target of \$8.50 per share.

Distribution of Ratings and Disclosure of Banking Relationships: The following table shows WBB's ratings distribution expressed as a percentage of all securities rated as of the end of the most recent calendar quarter, as well as the percentage of subject companies within each rating category for whom WBB has provided investment banking services within the previous 12 months. *WBB has acted as a Selling Member in the past 12 months for BCRX.*

	<b>Percentage of Covered Securities</b>	<b>Percentage of Banking Clients</b>
Buy	77%	10%
Hold	4%	0%
Sell	19%	0%

*The research analysts who are primarily responsible for the research contained in this research report and whose names are listed on this report: (1) attest that all of the views expressed in this research report accurately reflect that of the research analysts' personal views about any and all of the securities and issuers that are the subject of this research report; and (2) attest that no part of the research analysts' compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by the research analysts in this research report.*

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