

BIOCRYST PHARMACEUTICALS INC

Form 425

November 09, 2012

Filed by BioCryst Pharmaceuticals, Inc.

Pursuant to Rule 425 under the Securities Act of 1933

and deemed filed pursuant to Rule 14a-12

of the Securities Exchange Act of 1934 as amended

Subject Company: BioCryst Pharmaceuticals, Inc.

Commission File No.: 000-23186

The following are prepared remarks relating to the proposed acquisition of Presidio Pharmaceuticals, Inc. by BioCryst Pharmaceuticals, Inc. presented during BioCryst's quarterly earnings conference call held on November 8, 2012. Excerpts from the transcript of the question-and-answer portion of the conference call are also included beneath the prepared remarks.

BioCryst's Prepared Remarks:

**Robert Bennett** *BioCryst Investor Relations*

Good morning and welcome to BioCryst's third quarter 2012 corporate update and financial results conference call. Today's press release and accompanying slides for this call are available on our website at [www.BioCryst.com](http://www.BioCryst.com). At this time, all participants are in a listen-only mode. Later, we will open up the call for your questions, and instructions for queuing up will be provided at that time. Joining me on the call today are Jon Stonehouse, Chief Executive Officer of BioCryst, Dr. William Sheridan, our Chief Medical Officer and Tom Staab, Chief Financial Officer.

Before we begin, I will read a formal statement as shown on slide 2, regarding risk factors associated with today's call. Today's conference call will contain forward-looking statements, including statements regarding future results, unaudited and forward-looking financial information and Company performance or achievements. These statements are subject to known and unknown risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from any future results or performance expressed or implied in this presentation. You should not place undue reliance on the forward-looking statements. For additional information, including important risk factors, please refer to BioCryst's documents filed with the SEC, which can be found on our Company website.

With that, I will turn the call over to Jon.

**Jon Stonehouse** *BioCryst CEO & President*

Good morning and thanks to everyone for joining us today.

I'll start out today's call with a review of the peramivir interim analysis, and then address both the opportunities and challenges that lie ahead for BioCryst.

Obviously, we are disappointed with the results of the interim analysis of our peramivir Phase 3 trial in patients hospitalized with serious influenza. The preplanned interim analysis indicated that the recalculated sample size for the primary efficacy analysis exceeded 320 subjects, the predefined futility boundary for the trial. There was only a small difference in time to clinical resolution between the standard of care plus peramivir treated arm compared to the standard of care plus placebo arm.

After we received notice from the DMC regarding the result, we promptly shared the outcome with HHS/BARDA. Consistent with the DMC recommendation, BioCryst suspended enrollment in the study. We are now proceeding with a full analysis of the trial. Although we will discuss the findings from the analysis with our partners, the most likely outcome is termination of the program.

This Phase 3 trial in hospitalized influenza patients was unprecedented and challenging, due to the general lack of research in this specific area and the novelty of this endpoint, time to clinical resolution. These factors increase clinical risk for the trial. However, we chose to pursue this program, based on the high unmet medical need for i.v. therapy for hospitalized influenza patients, and the interest and funding by HHS. While we failed to show a large enough difference in this trial with peramivir, it is important to remember that peramivir was successfully approved in Japan and Korea based on a different indication and primary endpoint in clinical trials that supported approval. In January 2010, Shionogi received approval of peramivir for the treatment of outpatient influenza in Japan and launched peramivir under the commercial name RAPIACTA.

Going forward, we need to focus on the rest of our portfolio; we are fortunate to have other promising assets. Our top priorities include advancing BioCryst's pipeline and the Presidio merger to create a company with a two prong focus on antivirals and orphan disease drugs, initially for HCV and hereditary angioedema. We also need to carefully manage our cash; to that end we will evaluate operational changes that would further decrease our cost structure; and we will focus our resources on advancing the pipeline to potential value creating milestones that can put us back on a path to long-term success and sustainability.

Here are things we plan to do in the coming months:

First, stay on course to bring the BCX4161 hereditary angioedema program into phase 1 before year end. Upon successful completion of Phase 1, we can then move quickly to HAE patient trials with a modest investment. The key at this stage of the program is to demonstrate we have adequate and consistent oral bioavailability to inhibit kallikrein and ultimately prevent HAE attacks. If we are successful, 4161 could revolutionize the treatment of HAE.

Second, initiate additional preclinical studies of BCX5191 before the end of 2012. If we are successful in demonstrating meaningful preclinical antiviral activity of 5191 in chimpanzees infected with HCV, we will seek to re-engage the FDA regarding potential pathways to move the program forward to clinical development.

Third, secure a partner for ulodesine. We are in discussions with potential partners. While it is difficult to predict when the process will conclude, partnering remains a top priority and we will work to get this done as soon as possible so ulodesine can enter Phase 3.

While these last two weeks have been challenging, we remain committed to honoring our signed merger agreement with Presidio and advancing our assets to their next important milestones between now and the end of next year.

With that, I will now turn it over to our CFO, Tom Staab, who will discuss our third quarter financial results.

**Tom Staab** *BioCryst Chief Financial Officer*

Thank you Jon and good morning everyone.

I am pleased to share with you some details regarding our third quarter 2012 financial results. Throughout 2012, we have consistently achieved the financial goals established for the company, and the third quarter is further evidence of our accomplishments. We continue to deliver substantially reduced general & administrative expenses in 2012, which are roughly half of 2011 levels. These cost reductions continue to illustrate our commitment to a key operating principle focusing our cash resources on advancing our development programs, while minimizing non-critical and non-project spending. In addition, we are narrowing our development focus and related expenditures to antivirals and hereditary angioedema.

Now, I would like to discuss our third quarter financial results for 2012, which are summarized on slide 3. Revenues for the third quarter of 2012 were \$5.8 million compared to \$5.2 million in third quarter of 2011. This revenue increase resulted primarily from the recognition of \$2.8 million of deferred RAPIACTA royalty revenue from Shionogi, which was largely offset by a decrease in collaboration revenue from HHS/BARDA. Our revenue situation in the third quarter of 2012 is unique as we recognized seven quarters of deferred RAPIACTA royalty revenue. This recognition occurred in the third quarter of 2012 as we needed two complete and representative flu seasons in Japan to give us reasonable historical experience to record an appropriate amount of RAPIACTA royalty revenue in accordance with generally accepted accounting principles. As mentioned in the press release, there is no underling impact to our cash balance as all royalty payments were directed to pay obligations on our non-recourse notes payable.

Continuing the revenue discussion, the increase in royalty revenue was substantially offset by a decrease in the amount of revenue associated with reimbursement for peramivir development. Peramivir development activity, and related reimbursement under the

HHS/BARDA contract, is below levels in 2011, as 2012 peramivir development activity was predominantly focused on the 301 clinical trial, for which there was slower enrollment due to mild flu seasons, whereas in 2011, there was more substantial and broader peramivir development activity.

Third quarter 2012 R&D expenses were \$12.1 million, down from \$15.1 million in last year's quarter. Our R&D program expense mix has changed, as lower development costs associated with the ulodesine and peramivir programs were partially offset by higher development costs associated with the 5191 and 4161 preclinical programs. We expect our R&D concentration to continue toward our preclinical programs, especially on our BCX4161 drug candidate for HAE, as we expect it to begin phase 1 testing this quarter. In addition, the R&D mix will be further impacted by the recent suspension of patient enrollment in our peramivir 301 study and completion of the ulodesine Phase 2 development program.

Third quarter 2012 General and Administrative costs were \$1.6 million and reflect a 46% reduction from the \$3.0 million of expense incurred in the third quarter of 2011. This decrease in administrative expenses is even more impressive as 2012 expenses included a portion of Presidio due diligence and merger costs, which when excluded provide for an over 53% decrease in 2012 administrative expenses. As mentioned earlier, we are extremely pleased with our ability to curtail administrative costs and more fully dedicate resources toward advancing our drug candidate portfolio.

Moving below the operating line, we incurred \$1.2 million of non-cash interest expense and mark-to-market losses of approximately \$600,000 in the third quarter of both 2012 and 2011. The interest expense and hedge loss for both periods relate to our non-recourse debt and our hedge arrangement enacted in conjunction with the RAPIACTA royalty monetization completed in the first quarter of 2011.

Our nine month financial results for 2012 and 2011 are summarized on slide 4. Revenue for the nine months ending September 30, 2012 increased to \$22.2 million compared to \$14.4 million for the nine months ending September 30, 2011. The increase was primarily due to the recognition of approximately \$8 million of previously deferred forodesine-related revenue during the first quarter 2012, and the \$2.8 million RAPIACTA royalty revenue from Shionogi during the third quarter. Revenue from reimbursement on peramivir development for the nine months of 2012 decreased \$1.7 million or 14 percent compared to the same period of 2011.

Nine month 2012 R&D expenses were \$40.4 million, down slightly from \$43 million in the first nine months of 2011. Lower ulodesine and peramivir development costs were partially offset by higher development costs in 2012 associated with the BCX5191 and 4161 preclinical programs, and recognition of \$1.9 million of previously deferred forodesine expenses associated with amendment of the Mundipharma agreement.

General and Administrative costs through September 30, 2012 decreased sharply to \$4.9 million from \$9.9 million in the nine month period of 2011. The 51% decrease resulted from a significant reduction of non-critical consulting and other administrative expenses, as well as one-time expenses incurred in the 2011 relocation of our corporate headquarters

In the first nine months of 2012, we incurred \$3.5 million of interest expense compared to \$2.6 million in 2011. The difference resulted from 9 months of interest in 2012 versus approximately 7.5 months in 2011. The 2012 period also included a mark-to-market loss of \$1.5 million, compared to \$2.9 million for the same period of 2011, reflecting changes in the U.S. dollar/Japanese yen exchange rate.

Now moving to slide 6, I would like to discuss our cash usage and our 2012 financial outlook. At September 30, 2012, we had cash and investments of \$43.8 million, compared to \$57.7 million at the end of 2011. Our operating cash usage for the third quarter and nine months ending September 30, 2012 was \$9.7 million and \$29.7 million, respectively. As a reminder, operating cash use excludes any impact of our royalty monetization, hedge collateral posted or returned, sale of stock in the marketplace, and any other non-routine cash inflows. Considering recent events in our peramivir and BCX5191 programs, we are evaluating operation changes to decrease our cost structure to better position our company to achieve value creating milestones with our drug candidate portfolio, and to conserve our cash resources to extend further into the future.

In regards to our outlook for the remainder of 2012, we are reiterating our prior operating cash utilization guidance range of \$37 to \$43 million and operating expense guidance of \$57 to \$69 million as we announced in August. As a reminder, our outlook depends on peramivir-related operating expenses and excludes any consideration of cash in-flows derived from out-licensing ulodesine.

That concludes my financial review, and I would like to turn the call over to, Dr. Bill Sheridan, Bill.

**Bill Sheridan** *BioCryst Chief Medical Officer*

Thanks, Tom.

The medical need for an oral, safe prophylactic treatment for hereditary angioedema is high, making HAE a compelling opportunity. Kallikrein inhibition is a well validated approach, and the development pathway is well understood in this orphan disease. Our HAE program consists of two kallikrein inhibitor projects: the lead compound BCX4161, poised to enter phase 1 clinical studies by year end, and a next generation research project. The key goal for the 4161 study is to demonstrate oral bioavailability in humans we need to see consistent PK with adequate exposure levels that suppress KK. Fortunately the levels of 4161 needed to fully inhibit kallikrein are quite low, less than 100 nM. We will learn about PK and PD quickly, and anticipate having results in early 2013. If 4161 passes this test, we should be able to move this project through trials in HAE patients expeditiously.

At the same time, our discovery team has been working on new compounds for HAE with a totally different chemical scaffold, with the main goal of improving bioavailability. This discovery project is now at the stage of advanced lead optimization, and could be ready to move into preclinical development during 2013.

BioCryst's HCV portfolio consists of two NS5B nuc projects: BCX5191, and a next generation research program. Last week we outlined the next steps for 5191 - the key here is to find out whether 5191 achieves substantial antiviral effects in chimpanzees with HCV infection at exposure levels equivalent to or below the NOAEL level identified in rats. We are focused on initiating these studies by year end. If we are successful in demonstrating meaningful antiviral activity of 5191 in this animal model, we will seek to re-engage the FDA regarding potential pathways to move the program forward to clinical development.

While this work is progressing, we will continue to develop a set of compounds that may have a superior therapeutic index compared to 5191. This research is at the stage of selecting several compounds to take into screening animal safety experiments, and if successful, could provide an optimized lead to advance into full preclinical development during H1 2013.

Today, we would like to introduce an additional BioCryst antiviral project, BCX4430, the lead compound in our broad spectrum antiviral program, or BSAV. It is targeted at viruses that cause serious, life-threatening viral hemorrhagic fevers, or VHFs, diseases characterized by both high morbidity and mortality and lack of any approved therapies. The VHF pathogens include filoviruses such as Marburg virus and Ebola virus, and flaviviruses such as yellow fever virus. These viruses are categorized by Government agencies as high priority pathogens for development of medical countermeasures to protect civilian and military populations.

Our lead compound 4430 has shown a very broad spectrum of antiviral activity in cell culture experiments with inhibitory activity against at least 15 viruses from 9 different families, and activity in several different animal models. In the next weeks and months, we will be presenting results of testing for 4430 in models of infection for filoviruses and flaviviruses. Next week, studies of BCX4430 in yellow fever virus infection will be presented at the 2nd Antiviral Congress in Cambridge, MA and we look forward to highlighting those results in more detail then.

We plan to apply for federal funding to bring this project forward into full preclinical development, and could submit an IND within a year of securing development funding. The path forward for this project is development under the animal rule for one or more high priority biothreats, to enable USG stockpiling as a medical countermeasure

With that we will now open up the call for your questions.

Excerpts from Q&A

[Text Omitted]

**Heather Behanna** *JMP Securities Biotechnology Equity Research Associate*

Hi guys, good morning. Most of my questions were answered, I just, so when we, when we think about the backups, your next generation, are these also from the nucleoside class, and are you looking for more targeted liver exposure or, or is your goal still to have something that is readily available in the plasma, sort of in the similar profile as 5191?

**Dr. William Sheridan** *BioCryst Chief Medical Officer*

In general, I, you know, to answer your question, yes they're in the nucleoside class in BioCryst's research program. Obviously with the pending merger, you know, there are other things that we can work on as well and we talked about that in a previous call. But, specifically with, what might be the goal, I think that the, the likely type of drug there is something that we would be able to measure in the plasma but, you know, we have specific targets that I don't want to get into today about liver exposure and the like.

[Text Omitted]

[Text Omitted]

**Ed Arce** *MLV & Co. Analyst, Healthcare*

Hi, good morning, thanks for taking my questions. I just wanted to start off with a question about the Presidio acquisition. I realize that, that you've got a portfolio of next generation research projects following up behind 5191, but in the event that, you know, the, the, the 5191 development is terminated, the, the, the remaining projects are clearly very early stage. I'm just wondering, I realize that you've signed a definitive Merger Agreement, but are there clauses or avenues for Presidio to decide to exit from the deal?

**John P. Stonehouse** *BioCryst President and CEO*

So thanks for the question Ed. You know, we believe that the rationale for the deal still makes sense, you know, for the reasons that I listed before when we talked about 5191. So the first one is HCV's very attractive area. Second, Presidio has high quality assets that, and capability. We've, we always said when we announced the Merger, that we weren't going to be limited to any one combination, that we'd pursue, you know, all types of combinations, both internal molecules and external, and that we still think that that makes sense. So, so, whether it's 5191 or other combinations, we think that that's still good strategic rationale. Then, if you look at the balance of the portfolio, right, the HCV compounds and HAE, I think, you know, both companies need more assets and so, that, that I think, you know, makes sense from a strategic perspective. And then lastly, as you said, we have a signed Merger Agreement in place and we intend to honor it. So, you know, we still, like I said before, we still believe that the strategic rationale for this deal makes sense.

[Text Omitted]

### **Important Additional Information and Where to Find It**

BioCryst intends to file with the Securities and Exchange Commission ( SEC ) a registration statement on Form S-4, which will also include a proxy statement and prospectus with respect to its previously announced proposed acquisition of Presidio Pharmaceuticals, Inc. ( Presidio ). The final proxy statement/prospectus will be mailed to the stockholders of BioCryst and Presidio. Investors and security holders are urged to read the proxy statement/prospectus regarding the proposed transaction carefully and in its entirety when it becomes available because it will contain important information regarding BioCryst, Presidio and the proposed merger. Investors will be able to obtain a free copy of the proxy statement/prospectus, as well as other filings containing information about BioCryst, without charge, at the SEC 's website (<http://www.sec.gov/>). Investors may also obtain these documents, without charge, from BioCryst 's website at <http://investor.shareholder.com/biocryst/sec.cfm>.

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities in the equity financing connected to the acquisition of Presidio.

### **Participants in the Merger Solicitation**

BioCryst and its directors, executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies from shareholders with respect to the transactions contemplated by the definitive merger agreement signed with Presidio. Information regarding BioCryst 's directors and executive officers is contained in BioCryst 's 2011 Annual Report on Form 10-K filed with the SEC on March 6, 2012 and its definitive proxy statement filed with the SEC on April 9, 2012 in connection with its 2012 meeting of stockholders. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement/prospectus and other relevant materials to be filed with the SEC when they become available.

### **BioCryst Forward-Looking Statements**

This Current Report 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 BioCryst 's 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 the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances (e.g. BCX5191) which may result in delay of planned clinical trials, clinical hold with respect to such product candidate



or inability to move forward with development or the lack of market approval for such product candidate; that ongoing and future preclinical and clinical development may not have positive results; that the company or licensees may not be able to continue future development of current and future development programs; that such development programs may never result in future product, license or royalty payments being received; that the company may not be able to retain its current pharmaceutical and biotechnology partners for further development of its product candidates or may not reach favorable agreements with potential pharmaceutical and biotechnology partners for further development of product candidates; that actual cash burn rate may not be consistent with expectations; that the peramivir interim analysis may not be favorable or that BARDA/HHS may further condition, reduce or eliminate future funding of the peramivir program; that the planned merger with Presidio might not be completed for any number of reasons, most of which are outside of the control of BioCryst; that BioCryst may not be able to obtain the requisite financing to complete the planned merger with Presidio on commercially reasonable terms or that or that the financing may be raised at prices below the currently prevailing price for BioCryst common stock; that integration of BioCryst and Presidio may prove more challenging than anticipated or that anticipated benefits of the merger may not be achieved, or may be achieved less rapidly than anticipated; the outcome of any legal proceedings that may be instituted against BioCryst or Presidio; risks relating to any unforeseen liabilities, future capital expenditures, revenues, expenses, earnings, economic performance, indebtedness, financial condition, losses and future prospects, business and management strategies or the expansion and growth of Presidio's operations; BioCryst's ability to integrate Presidio's business successfully after the closing of the merger agreement; and the risk that disruptions from the merger agreement will harm BioCryst's or Presidio's businesses. There can be no assurance that the proposed merger and financing will in fact be consummated. Other important factors include: that there can be no assurance that BioCryst's or Presidio's compounds will prove effective in clinical trials; that development and commercialization of BioCryst's or Presidio's compounds may not be successful; that BioCryst, Presidio or licensees may not be able to enroll the required number of subjects in planned clinical trials of its product candidates and that such clinical trials may not be successfully completed; that the companies or licensees may not commence as expected additional human clinical trials with product candidates; that 2012 operating expenses and cash usage will be within management's expected ranges; that BioCryst or Presidio may not have sufficient cash to continue funding the development, manufacturing, marketing or distribution of products and that additional funding, if necessary, may not be available at all or on terms acceptable to BioCryst or Presidio. 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 BioCryst's projections and forward-looking statements.