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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 19, 2007**

**BioCryst Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other Jurisdiction of Incorporation)	<b>000-23186</b> (Commission File Number)	<b>62-1413174</b> (IRS Employer Identification No.)
<b>2190 Parkway Lake Drive, Birmingham, Alabama</b> (Address of Principal Executive Offices)		<b>35244</b> (Zip Code)

Registrant's telephone number, including area code: **(205) 444-4600**

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(Former name or former address if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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### **Item 8.01 Other Events.**

On September 19, 2007, BioCryst Pharmaceuticals, Inc. ("Registrant") held a conference call, broadcast live by webcast, to present and discuss the preliminary results from its Phase II clinical trial of peramivir. A copy of the slide presentation from this call is being filed as Exhibit 99.1 to this Current Report on Form 8-K.

Certain statements in the slide presentation contain 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 our belief that many subjects in the Phase II clinical trials of peramivir did not receive adequate dosing by i.m. injection may not be correct, that final results and analysis of the peramivir Phase II trial may differ from the preliminary results and analysis, that DHHS and the FDA may not agree with our analysis, that DHHS may further condition, reduce or eliminate future funding of the peramivir program, that we may not commence in timely fashion or at all the planned Phase III trial for peramivir and if commenced, it may not be successful, that the Phase II trial of BCX-4208 for psoriasis may not be successfully completed, that development and commercialization of Fodosine™ in both T-ALL and CTCL may not be successful, that we may not resolve satisfactorily the particulate matter issue with the intravenous formulation of Fodosine™, that DHHS could reduce or eliminate funding for peramivir, 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 clinical trials may not have positive results, that we may not be able to complete successfully the Phase IIb trials for Fodosine™ that are currently planned to be pivotal, that we may not be able to announce preclinical developments for additional compounds by year-end 2007 as currently proposed, 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 reach favorable agreements with potential pharmaceutical and biotech partners for further development of its product candidates, 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 (File No. 333-145638), Quarterly Reports on Form 10-Q, current reports on Form 8-K which identify important factors that could cause the actual results to differ materially from those contained in the projections or forward-looking statements.

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**Item 9.01 Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	Slide presentation dated September 19, 2007 entitled "Intramuscular Peramivir Phase II Preliminary Results."

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 19, 2007

**BioCryst Pharmaceuticals, Inc.**

By: \_\_\_\_\_ /s/ Michael A. Darwin  
Michael A. Darwin  
Vice President Finance

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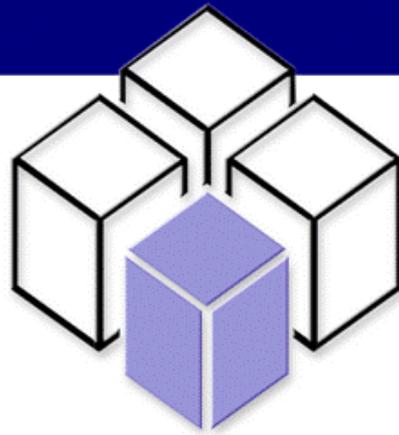
## EXHIBIT INDEX

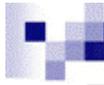
<b>Exhibit No.</b>	<b>Description</b>
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# Intramuscular Peramivir Phase II Preliminary Results

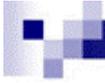
Conference call  
September 19, 2007





## Forward Looking Statements

This presentation contains projections or other forward looking statements regarding future events or the future financial performance of BioCryst Pharmaceuticals, Inc., including predictions of timing and potential success of clinical trials by us and our collaborators, and that HHS will continue funding our peramivir program. These statements are only predictions and the actual events or results may differ materially. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Some of the factors that could affect the forward-looking statements contained herein include, among others, 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 with positive results, that we or our 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, and that HHS could eliminate, reduce or delay funding from our contract. This information will likely change over time and we are not undertaking an obligation to provide updates in the future. Please refer to the documents the Company files from time to time with the Securities and Exchange Commission, specifically the Company's most recent Form 10-K, Form S-3, Form 10-Q and Form 8-K. These documents contain and identify important factors that could cause the actual results to differ materially from those contained in the projections or forward-looking statements.



## Agenda

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- Phase II Study Design
- Preliminary Results
- Next Steps

## Summary of Peramivir Phase II Study

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- **Designed to test if peramivir could reduce duration of symptoms when administered acutely in high doses intramuscularly**
  - Randomized, double-blind, placebo-controlled trial of 344 subjects (outpatient) with uncomplicated acute influenza
  - Subjects identified through positive rapid antigen test (intent to treat)
  - Confirmed influenza by laboratory PCR (intent to treat infected) 313 subjects
  - Time since onset of symptoms  $\leq$  48 hours
  - Randomized equally into 3 arms: 300mg, 150mg, placebo
  - Northern and Southern Hemispheres
- **Endpoints**
  - Primary:
    - Time to alleviation of symptoms
  - Secondary:
    - Time to resolution of fever
    - Time to resumption of ability to perform usual activities
    - Change in influenza virus titer by TCID<sub>50</sub>

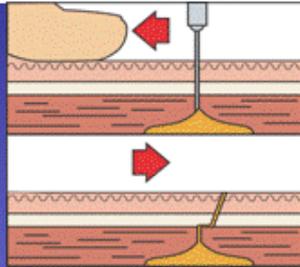
## Summary of Findings

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- In the intent to treat infected study population the primary endpoint of time to alleviation of symptoms was missed. Both doses demonstrated an improvement over placebo, but this improvement was not statistically significant:
  - 22.9 hour reduction – 150 mg dose vs. placebo (p=0.284)
  - 21.1 hour reduction – 300 mg dose vs. placebo (p=0.152)
  
- When a single dose of peramivir is delivered by an adequate intramuscular injection:
  - Peramivir showed improvement of up to 2.6 days over placebo as measured by time to alleviation of symptoms, in approximately 30% of the population:
    - 44.6 hour reduction – 150 mg dose vs. placebo
    - 64.8 hour reduction – 300 mg dose vs. placebo
  - A clear dose response was observed
  
- Peramivir demonstrated a similar safety and tolerability profile to placebo at both doses and independent of the adequacy of intramuscular injection

## For i.m. Injection, Technique and Needle Length Matter

*Technique for i.m. injection is critical to ensure successful penetration of drug into muscle*

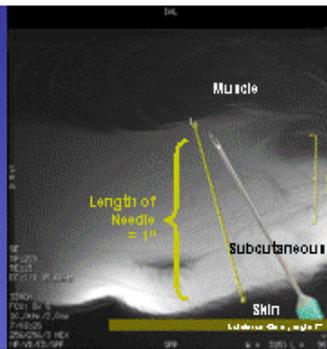


Source: Workman et al 1999, *Nursing Standard* 13: 47-53  
Wynaden et al 2005, *Contemporary Nurs* 20: 267-77

### Guidelines

- Massachusetts Department of Public Health for Tetanus, Diphtheria and Acellular Pertussis Vaccine (April 2007)
- Cambridge University Healthcare Governance Committee (April 2006)
- Nursing Procedures (3<sup>rd</sup> Edition 2000)  
Guidelines for needle length: 200 lb (90 kg) person 2" needle; 100 lb (45 kg) person 1.25 – 1.5" needle

*In subjects with excess adipose tissue needle length is critical*

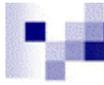


Source: Becton Dickinson and Company Presentation

**"Intramuscular injections into the buttocks: Are they truly intramuscular?"**

- Radiologic study of i.m. injections into the buttocks with a 30mm (1 1/4") needle
- 32% of injections reached muscle tissue and the majority of injections were subcutaneous
- By gender 56% of males and 8% of females had i.m. injections
- Authors concluded that needle selection is critical for successful i.m. injection

Source: Chan et al 2006, *Br J Radiology* 58: 480-484

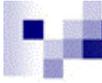


## **For i.m. Injection, Technique and Needle Length Matter**

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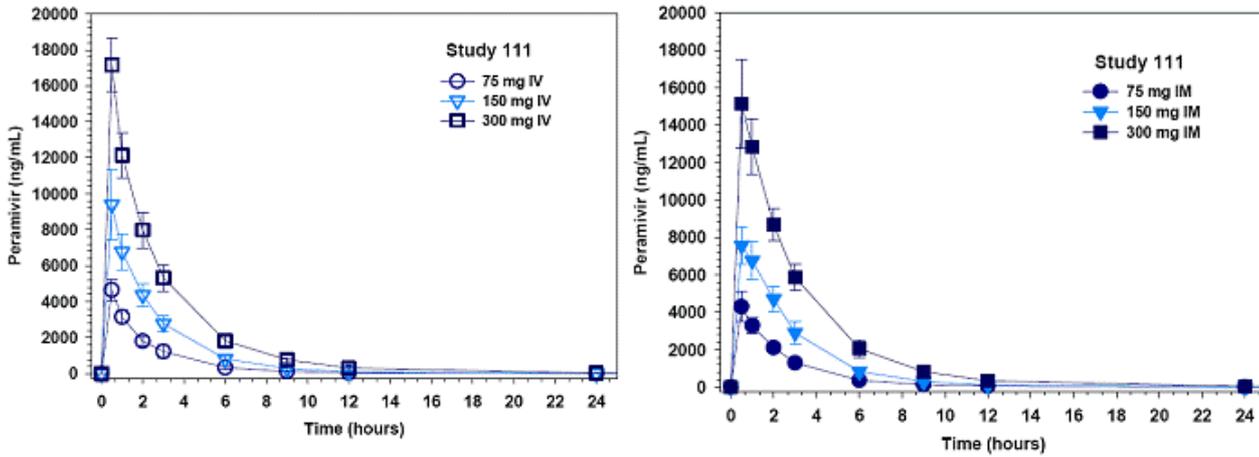
- **Needle length matters for drugs injected by the i.m. route of administration**
- **Body habitus and weight influence choice of needle length**
- **Extensive literature supports importance of this issue for adequate i.m. drug delivery**

*References:*      *Journal of Advanced Nursing* 2007, 58(6), 552–556  
                         *Can Assoc Radiol J.* 2007 Apr;58(2):72-5  
                         *European Journal of Radiology* 58 (2006) 480–484  
                         *Arch Fam. Med.* 1994;3:146–8  
                         *Cockshott, et al. N Engl J Med.* 1982; 307:356–358  
                         *Gamble, et al. Anaesthesia* 1975, 30:164-9



## Unique Pharmacokinetic Profile of Peramivir

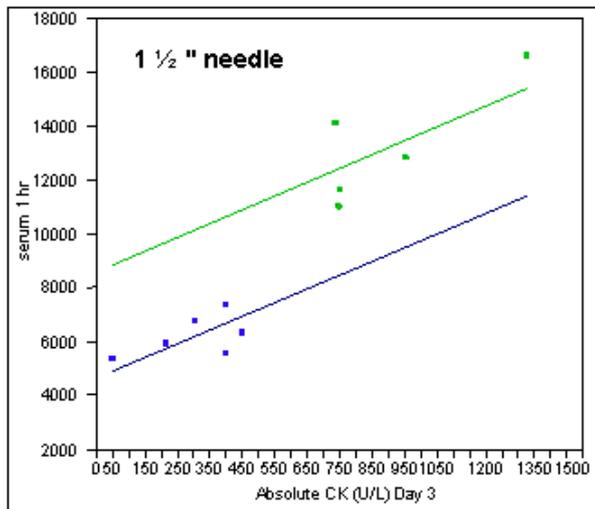
### Intramuscular Administration Produces PK Profile That Parallels Intravenous Dosing



J. Kilpatrick, Pharmacokinetics and Safety of Peramivir by Intramuscular Administration, Options for the Control of Influenza VI Toronto, 2007

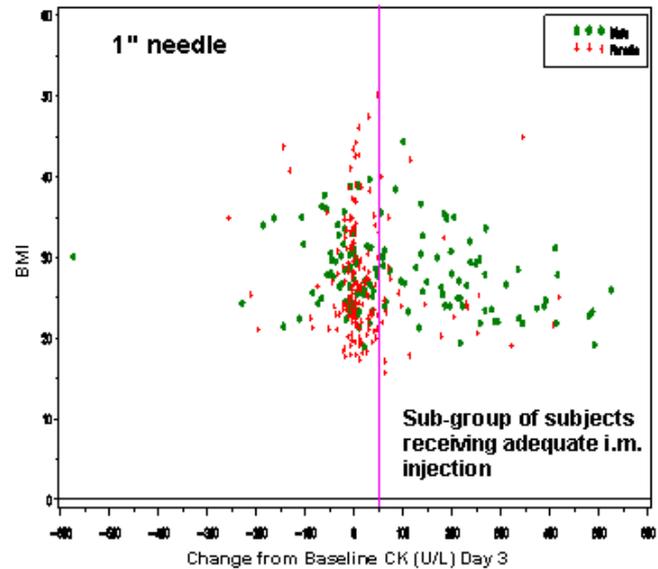
# Day 3 Creatine Kinase Increase from Baseline Correlates with Adequate i.m. Injection

## Phase I:



- 300mg Peramivir (2 injections- 4mL)
- 150mg Peramivir (1 injection- 2mL)

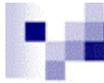
## Phase II:



- All subjects received 2 injections- 4mL
- Overall lower CK rises suggest 1 inch needle produced inadequate i.m. injection in majority of subjects in Phase II

## The Degree of Symptom Alleviation in Subjects Treated with Peramivir Increases with Increasing Rise in Creatine Kinase at Day 3

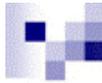
Increase in Day 3 Creatine Kinase from Baseline	n	Median Time to Alleviation of Symptoms (Hrs) Δ indicates improvement over placebo		
		Placebo	Peramivir 150mg Improvement (hrs)	Peramivir 300mg Improvement (hrs)
≥ 40 U/L	112	162.3	Δ48.2	Δ58.3
≥ 50 U/L	<b>101</b>	<b>152.2</b>	<b>Δ44.6</b>	<b>Δ64.8</b>
≥ 60 U/L	95	152.2	Δ54.8	Δ64.8
≥ 70 U/L	85	163.2	Δ62.0	Δ100.1
≥ 80 U/L	83	163.2	Δ65.8	Δ100.1
≥ 90 U/L	82	163.2	Δ65.8	Δ100.4



## Subjects Who Received An Adequate i.m. Injection Showed Up to 2.6 Days of Improvement over Placebo

	Placebo	Peramivir 150mg	Peramivir 300mg
<b>Total Intent-to-Treat-Infected* Population (n = 313)</b>	n = 107	n = 104	n = 102
Median time to alleviation of symptoms (hrs)	137.0	114.1	115.9
(95% Confidence Interval)	(115.9-165.8)	(95.2-145.5)	(77.8-136.6)
Improvement over placebo (hrs)	–	22.9	21.1
		p=0.284	p=0.152
<b>Adequate Injection Population (n = 101)</b>	n = 40	n = 32	n = 29
Median time to alleviation of symptoms (hrs)	152.2	107.6	87.4
(95% Confidence Interval)	(103.8-183.9)	(76.8-175.1)	(40.8-163.8)
Improvement over placebo (hrs)	–	44.6	64.8

\*Intent-to-treat/infected (ITT): PCR + for either influenza A and/or influenza B at baseline / screening visit



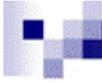
## Peramivir Was Well Tolerated at Both Doses

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	Placebo	Peramivir 150mg	Peramivir 300mg
<b>Total Safety Population* (n = 342)</b>			
No. of subjects	114	113	115
Diarrhea	3 (3%)	3 (3%)	3 (3%)
Nausea	3 (3%)	4 (4%)	5 (4%)
Vasovagal reaction	4 (4%)	1 (1%)	0 (0%)
Vomiting	1 (1%)	2 (2%)	0 (0%)
<b>Adequate Injection Population** (n = 105)</b>			
No. of subjects	41	33	31
Diarrhea	1 (2%)	1 (3%)	0 (0%)
Nausea	1 (2%)	0 (0%)	1 (2%)
Vasovagal reaction	0 (0%)	1 (3%)	0 (0%)
Vomiting	0 (0%)	0 (0%)	0 (0%)

\* Total Safety Population: all randomized subject who received study drug

\*\* Adequate injection population: ITTI subjects (PCR +) in whom study drug was introduced into target muscle tissue, as evidenced by increase in serum CK levels of  $\geq 50$  U/L over baseline at day 3 of study



## Achievement of Goals – Phase II

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- |   |  |  |
|---|--|--|
| <p>✓ Provide preliminary efficacy data to establish the proof of concept for a single i.m. injection of peramivir in uncomplicated influenza and confirm dose selection for the pivotal phase III program</p> |   | <p>Peramivir showed improvement of up to 2.6 days over placebo as measured by time to alleviation of symptoms, in the population (n=101) that received an adequate intramuscular injection</p> <p>Based on preliminary findings, and assuring appropriate needle length and training at the site, we believe larger Phase III studies would produce a statistically significant treatment effect</p> |
| <hr/>   |  |  |
| <p>✓ Establish the safety and tolerability profile of single doses of i.m. peramivir to support exposure of a larger population of subjects in phase III</p>  |   | <p>Safety and tolerability of both doses of peramivir studied were similar to placebo</p>  |
| <hr/>   |  |  |
| <p>✓ Gain further understanding of use of the i.m. formulation of peramivir to assure success of the pivotal phase III program</p>  |  | <p>Will ensure proper needle length based on gender and BMI</p> <p>Will develop further training and control over correct administration of injections in phase III</p>  |

## Next Steps

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- **Complete analysis of Phase II data**
  - Full package of safety and efficacy
  - Quantitative change in viral shedding
- **Meet with FDA to review data**
- **Start the Phase III studies – be ready to enroll first subject by year-end**
- **Detailed PK study focused on:**
  - Needle length
  - Subject BMI
  - Pharmacokinetics

# Intramuscular Peramivir Phase II Preliminary Results

Conference call  
September 19, 2007

