

ARBIOS SYSTEMS INC  
Form 8-K  
May 12, 2008

**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): May 12, 2008

**ARBIOS SYSTEMS, INC.**  
**(Exact Name of Registrant as Specified in its Charter)**

**Delaware**  
(State or other  
jurisdiction of  
incorporation)

**000-32603**  
(Commission  
File Number)

**91-1955323**  
(IRS Employer  
Identification No.)

**1050 Winter Street, Suite 1000, Waltham, Massachusetts, 02451**  
**(Address of Principal Executive Offices) (Zip Code)**

**(781) 839-7292**  
**(Registrant's Telephone Number, Including Area Code)**

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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 (*see* General Instruction A.2. below):

- ☐ 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 7.01 Regulation FD Disclosure.**

On May 12, 2008, Arbios Systems, Inc. (the “Company”) announced that the Company received approval from the U.S. Food and Drug Administration of an Investigational Device Exemption to begin the pivotal clinical trial for SEPET™, the Company’s extracorporeal (outside the body) liver assist device for blood purification of chronically ill patients suffering from acute liver failure. We anticipate that a significant capital raise is necessary in order to continue operations and development of planned products, including the development of SEPET™ and the commencement of the SEPET™ pivotal trial.

A copy of the press release announcing the approval is attached as Exhibit 99.1 to this report and is incorporated by reference.

**ITEM 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

**Exhibit No. Exhibit**

99.1 Press Release dated May 12, 2008.

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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.

ARBIOS SYSTEMS, INC.

Date: May 12, 2008

By: /s/ SHAWN P. CAIN

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Shawn P. Cain, Interim President and Chief Executive Officer

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EXHIBIT INDEX

**Exhibit No. Exhibit**

99.1 Press Release dated May 12, 2008.