

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

**KALOBIOS PHARMACEUTICALS INC**

CIK: **1293310** | IRS No.: **770557236** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **000-54735** | Film No.: **13523338**  
SIC: **2834** Pharmaceutical preparations

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

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 10, 2013**

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**KaloBios Pharmaceuticals, Inc.**

**(Exact name of registrant as specified in its charter)**

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**Delaware**  
**(State or other Jurisdiction  
of Incorporation)**

**000-54735**  
**(Commission  
File No.)**

**77-0557236**  
**(IRS Employer  
Identification No.)**

**260 East Grand Avenue**  
**South San Francisco, CA 94080**  
**(Address of principal executive offices, including zip code)**

**(650) 243-3100**  
**(Registrant's telephone number, including area code)**

**(Former Name or Former Address, if Changed Since Last Report)**

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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):

- 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 January 10, 2013, KaloBios Pharmaceuticals, Inc. issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

**Exhibit****Number****Description**

99.1	Press release issued by KaloBios Pharmaceuticals, Inc. on January 10, 2013.
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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.

KaloBios Pharmaceuticals, Inc.

By: /s/ David Pritchard

\_\_\_\_\_  
David Pritchard  
Chief Executive Officer

Dated: January 10, 2013

260 East Grand Avenue  
South San Francisco, CA 94080



**KaloBios Initiates Phase 2 Study with KB001-A  
Humaneered® Monoclonal Antibody in Cystic Fibrosis Patients**

**SOUTH SAN FRANCISCO, CA (January 10, 2013):** KaloBios Pharmaceuticals, Inc. today announced that dosing has begun in a randomized, double-blind, placebo-controlled Phase 2 clinical trial of KB001-A, the company's anti-PcrV Humaneered®, PEGylated monoclonal antibody fragment. The study will investigate the safety and efficacy of intravenously administered KB001-A as a treatment for chronic *Pseudomonas aeruginosa* (*Pa*) infection in cystic fibrosis patients.

The Phase 2 study is being conducted in the United States at multiple centers and is designed to enroll 180 patients who will receive repeated doses of KB001-A over a 16-week period. The primary endpoint of the study will be time to need for antibiotics to treat worsening of respiratory tract signs and symptoms. Secondary endpoints will include changes in inflammatory markers, respiratory symptoms, subject-reported outcomes, measurements of lung function, pharmacokinetics, safety, and tolerability. This study is designed to expand upon the positive Phase 1/2 results in cystic fibrosis patients with the precursor compound KB001. KaloBios expects to complete the study of KB001-A and announce results by mid-2014.

"Cystic fibrosis patients are subject to chronic lung infections with *Pa*, a gram negative bacteria which is a leading contributor to the deterioration of pulmonary function leading to respiratory failure," said Néstor A. Molino, M.D., KaloBios' Chief Medical Officer. "The only currently approved treatments for *Pa* infections are antibiotics, but despite their therapeutic benefit, mortality and morbidity remain high due to *Pa* antibiotic resistance. KB001-A is designed to neutralize *Pa* pathogenicity which reduces inflammation and allows the body's natural immune system to kill and clear the bacteria. As a result, we believe KB001-A may offer a novel approach to preventing and treating *Pa* infections when added to antibiotics, and may not be subject to the typical drug resistance mechanisms."

"KB001-A is our second drug in a Phase 2 clinical trial," said David Pritchard, KaloBios' Chief Executive Officer. "We plan to use data from this Phase 2 study of intravenous KB001-A, if positive, to support pivotal trials of a subcutaneous formulation of KB001-A."

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## About KaloBios

KaloBios Pharmaceuticals, Inc. is developing a portfolio of proprietary, patient-targeted, first-in-class monoclonal antibodies (mAbs) designed to significantly improve the lives of seriously ill patients with difficult-to-treat diseases.

Currently, KaloBios has three drug development programs:

KB001-A, an anti-PcrV mAb fragment, is partnered exclusively with Sanofi Pasteur and is being developed for the prevention and treatment of *Pseudomonas aeruginosa* (*Pa*) infection. KaloBios has retained rights for the cystic fibrosis (CF) indication and has initiated a 180 patient Phase 2 study in CF subjects with chronic *Pa* infection in the United States. Sanofi is pursuing a ventilator associated pneumonia prevention indication in the intensive care setting.

KB003, an anti-GM-CSF mAb with potential to treat inflammatory diseases, is being developed for the treatment of severe asthma and is currently enrolling patients in a 150 patient Phase 2 study in the United States, Europe and Australia.

KB004, an anti-EphA3 mAb, has potential in treating hematologic malignancies and solid tumors. KaloBios is currently testing this drug in a Phase 1 study in subjects with hematologic malignancies.

All of the company's antibodies were generated using its proprietary Humaneered® technology, a method that converts nonhuman antibodies (typically mouse) into recombinant antibodies that have a high binding affinity to their target and are designed for chronic therapeutic use. The company believes that antibodies produced using its Humaneered® technology offer important clinical and economic advantages over antibodies generated by other methods in terms of high binding affinity, high manufacturing yields, and minimal to no immunogenicity (inappropriate immune response) upon repeat administration in humans.

For more information, visit <http://www.kalobios.com>.

This release contains “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including those related to the company's clinical development of KB001-A (including clinical activities being conducted by Sanofi Pasteur), KB003 and KB004. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, the company's limited cash reserves and its ability to obtain additional capital on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that the company has initiated or plans to initiate; the company's dependence on Sanofi Pasteur for the development and

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commercialization of KB001-A; the company's ability to successfully complete further development of its programs; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; the company's ability to protect the company's intellectual property; competition; changes in the regulatory landscape or the imposition of regulations that affect the company's products; and other factors listed under "Risk Factors" in the company's Form 10-Q for the quarter ended September 30, 2012 filed with the Securities and Exchange Commission on November 9, 2012 and the company's other filings with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The company has no obligation, and expressly disclaims any obligation to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

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