

May 14, 2013



# KaloBios Reports First Quarter 2013 Financial Results

SOUTH SAN FRANCISCO, Calif., May 14, 2013 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq:KBIO) a biopharmaceutical company with a portfolio of patient-targeted, first-in-class, antibodies to treat serious medical conditions with a primary clinical focus on respiratory diseases and cancer, announced today its financial results for the first quarter ended March 31, 2013.

(Logo: <https://photos.prnewswire.com/prnh/20130225/MM66380LOGO>)

"KaloBios marked the first quarter of 2013 with an important milestone in our company's evolution: the successful completion of our initial public offering, with net proceeds to KaloBios of approximately \$62 million," said David Pritchard, KaloBios President and Chief Executive Officer. "We also achieved an important clinical milestone this quarter with the start of a Phase 2 trial of KB001-A, our targeted agent against *Pseudomonas aeruginosa* (*Pa*), in patients with cystic fibrosis. We were pleased to announce shortly after the quarter's end our partner Sanofi Pasteur's receipt from the U.S. Food and Drug Administration of Fast Track Designation for KB001-A intended for protection against bacterial pneumonia caused by *Pa* in mechanically ventilated patients. Finally, in April, we achieved 50% clinical enrollment for our KB003 Phase 2 asthma study putting us on track for top line results in the first quarter of 2014.

The net loss for the first quarter of 2013 was \$8.6 million, or \$0.55 per basic and diluted share. This compared to a net loss of \$1.1 million, or \$.56 per basic and diluted share, for the same period in 2012. Increased spending for our clinical trial programs and general and administrative expenses associated with being a public company resulted in the reported loss during the first quarter of 2013. As of March 31, 2013, cash, cash equivalents and investments, excluding restricted cash, totaled \$76.9 million.

## Company Highlights to Date for 2013

January	Initiation of Phase 2 study with KB001-A Humaneered® antibody fragment in cystic fibrosis patients
February	Completion of initial public offering
February	Presentation of positive Phase 1/2 clinical results with anti-GM-CSF mAb KB002 in persistent asthma at American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting
April	Phase 2 study of KB003 in severe asthma achieved 50% enrollment
April	Sanofi awarded Fast Track Designation for KB001-A for protection against bacterial pneumonia caused by <i>Pa</i> in mechanically-ventilated patients

### **Anticipated Upcoming Milestones for 2013-2014**

2Q 2013:	File for Orphan Drug Status in the U.S.A. and European Union for KB001-A in CF
3Q 2013:	Full recruitment of the KB003 asthma study
3Q 2013:	Initiation of the Phase 1 expansion phase of the KB004 study in AML with EphA3 diagnostic test
4Q 2013:	Full recruitment of the KB001-A CF study
1Q 2014:	Initiation of Phase 2 KB004 study in at least one new indication
1Q 2014:	Top line KB003 Phase 2 asthma study results
2Q 2014:	Top line KB001-A Phase 2 CF study results
3Q/4Q 2014:	Initiation of Sanofi Phase 2b study for prevention of ventilator-associated pneumonia (VAP)
4Q 2014:	Completion of enrollment in at least one hematologic malignancy indication in the Phase 1 expansion phase of KB004

## **About KaloBios**

KaloBios Pharmaceuticals, Inc. is developing a portfolio of proprietary, patient-targeted, first-in-class monoclonal antibodies (mAbs) designed to treat serious life-threatening or debilitating disease for which there is an unmet medical need with a clinical focus on serious respiratory diseases and cancer.

Currently, KaloBios has three drug development programs:

- 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.
- KB001-A, an anti-PcrV mAb fragment, is partnered exclusively with Sanofi 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, an indication which has received U.S. FDA Fast Track Designation.
- 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<sup>®</sup> 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<sup>®</sup> 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 on KaloBios Pharmaceuticals, please visit our web site at

<http://www.kalobios.com>.

## **Safe Harbor Statement**

### **Forward Looking Statements**

*This release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including: the statements under the heading "Anticipated Upcoming Milestones for 2013-2014"; and statements regarding the company's clinical development of KB001-A, 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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2013 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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---- Tables to Follow --

**Consolidated Balance Sheets**  
**March 31, 2013 and December 31, 2012**  
(in thousands, except share and per share information)

	<b>March 31, 2013</b>	<b>December 31, 2012</b>
	<b>(unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 69,949	\$ 10,947
Marketable securities	6,901	9,351
Contract receivables	34	87
Prepaid expenses and other current assets	1,896	871
Total current assets	78,780	21,256
Restricted cash	205	205
Property and equipment, net	193	230
Deferred offering costs	-	2,803
Intangible and other assets	41	45
Total assets	<u>\$ 79,219</u>	<u>\$ 24,539</u>
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 6,199	\$ 2,448
Accrued compensation	828	628
Deferred rent, short-term	113	101
Accrued research and clinical liabilities	1,384	3,538
Notes Payable	811	-
Other accrued liabilities	275	502
Total current liabilities	9,610	7,217
Deferred rent, long-term	31	62
Notes payable, less current portion	9,050	9,826
Other liabilities, long-term	198	355
Total liabilities	18,889	17,460
Convertible preferred stock, \$0.001 par value: no shares and 60,152,555 shares authorized at March 31, 2013, and December 31, 2012, respectively; no shares and 12,329,330 shares issued and outstanding at March 31, 2013, and December 31, 2012, respectively; aggregate liquidation preference of \$105,512 at December 31, 2012	-	102,023
Stockholders' equity (deficit):		
Common stock, \$0.001 par value: 80,000,000 shares authorized at March 31,		

2013, and December 31, 2012, respectively; 24,147,815 and 2,186,695 shares issued and outstanding at March 31, 2013, and December 31, 2012, respectively	24	2
Additional paid-in capital	167,143	3,317
Accumulated other comprehensive income	4	4
Accumulated deficit	(106,841)	(98,267)
Total stockholders' equity (deficit)	60,330	(94,944)
Total liabilities and stockholders' equity (deficit)	\$ 79,219	\$ 24,539

**Consolidated Statements of Operations**  
**Three Months Ended March 31, 2013 and 2012**  
(in thousands, except share and per share information)  
(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
Contract revenue	\$ 16	\$ 3,018
Operating expenses:		
Research and development	6,320	3,220
General and administrative	2,019	945
Total operating expenses	8,339	4,165
Loss from operations	(8,323)	(1,147)
Other income (expense):		
Interest income (expense), net	(252)	6
Other income (expense), net	1	10
Net loss	\$ (8,574)	\$ (1,131)
Basic and diluted net loss per common share	\$ (0.55)	\$ (0.56)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	15,607,379	2,023,285

**Stock based Compensation Expense**  
**Three Months Ended March 31, 2013 and 2012**  
(in thousands)  
(Unaudited)

Total stock-based compensation expense included in the consolidated statements of operations is as follows:

**Three Months Ended March 31,**

	<u>2013</u>	<u>2012</u>
Research and development	\$ 96	\$ 12
General and administrative	<u>85</u>	<u>9</u>
Total stock-based compensation expense	<u>\$ 181</u>	<u>\$ 21</u>

SOURCE KaloBios Pharmaceuticals, Inc.