



May 8, 2014

## KaloBios Provides First Quarter 2014 Financial Results

### -- Provides Update on Clinical Programs and Timelines --

SOUTH SAN FRANCISCO, Calif., May 8, 2014 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today announced financial results for the first quarter of 2014 and provided an update on its current clinical programs and timelines.



### Development Program Updates

#### KB001-A

Enrollment in the Phase 2 study in cystic fibrosis (CF) patients with chronic *Pseudomonas aeruginosa* (*Pa*) lung infections is ongoing, and as of April 30<sup>th</sup> the study had enrolled a total of 145 patients, just over 80% of the total targeted enrollment of 180 patients. Despite initiating additional clinical sites in Australia, New Zealand and Israel, the competition from later stage clinical studies for patients continues to make it challenging to enroll patients as quickly as the company had intended. Based on updated enrollment projections, KaloBios now expects to complete enrollment in the second half of 2014, which we expect will enable the release of top-line data by early in the second quarter of 2015. Previously the company had targeted completion of enrollment by mid-year 2014 and expected to release top-line data by the end of 2014.

#### KB004

The open-label Phase 1 dose escalation study of KB004 in hematologic malignancies is ongoing and is currently enrolling patients in the 330mg cohort. Through May 1, 2014 this study has enrolled a total of 46 patients in the Phase 1 portion of the study, with 80% being patients with acute myeloid leukemia (AML). The drug appears to be well tolerated with the most commonly reported side effects being first dose infusion reactions. Despite the fact that the Phase 1 study is an "all-comers" study where patients are not being screened for positive EphA3 expression, we have seen three responders to date; one complete response with incomplete platelet recovery (CRp) in an AML patient, one clinical improvement, as defined by international guidelines, in a patient with myelodysplastic syndrome (MDS), and one clinical improvement, as defined by international guidelines, in a myelofibrosis (MF) patient. In all three cases the tumors were EphA3 positive and the responses were declared after at least 90 days of treatment with KB004.

KaloBios expects to complete the Phase I dose escalation portion of the study by mid-year 2014, which will enable commencement of enrollment and dosing in the high-dose cohorts of the Phase 2 expansion portion of the study by the third quarter. The Phase 2 expansion will enroll patients with hematologic malignancies that are pre-screened to be EphA3 positive. As previously planned, one high-dose cohort will enroll 10 MDS patients and a second high-dose cohort will enroll 10 AML patients. Additionally, KaloBios is now also planning on enrolling a third high-dose cohort comprised of 10 MF patients.

"We feel that there is a strong rationale for adding myelofibrosis patients to the Phase 2 expansion portion of the study given the reduction in bone marrow fibrosis we have seen in some early responders, as well as the clinical improvement we have observed in one of the few myelofibrosis patients treated," said Nestor A. Molfino, MD, MSc, Chief Medical Officer of KaloBios.

### Key Anticipated Milestones for 2014-2015

2H 2014:	Full enrollment of the KB001-A CF Phase 2 study
4Q 2014:	Completion of enrollment in at least one indication in the Phase 2 expansion portion of our KB004 study in hematologic malignancies
Q2 2015:	Top line KB001-A CF Phase 2 study results
Mid-year 2015:	Initiation of Sanofi Phase 2b study for prevention of ventilator-associated pneumonia (VAP)

### First Quarter 2014 Financial Results

Net loss for the three months ended March 31, 2014 was \$10.4 million or \$0.32 per common share, as compared to \$8.6 million or \$0.55 per common share for the same period in 2013.

No contract revenue was reported for the first quarter of 2014 as compared to \$16,000 reported in the same period in 2013. The decrease in contract revenues was due to the completion of all substantive performance obligations related to research

support activities under our agreement with Sanofi Pasteur (Sanofi), the vaccines division of Sanofi Group.

Research and development (R&D) expenses were \$7.7 million for the three months ended March 31, 2014 as compared to \$6.3 million for the same period in 2013. The increase in R&D expense was primarily due to increased clinical trial activity compared with the prior period. General and administrative (G&A) expenses were \$2.5 million for the first quarter of 2014 compared to \$2.0 million for the same period in 2013. The increase in G&A expenses was due primarily to higher legal, accounting and consulting costs associated with becoming a public reporting company.

As of March 31, 2014, KaloBios had cash, cash equivalents and investments totaling \$64.8 million, compared to \$76.7 million at December 31, 2013.

### **About KaloBios**

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

Currently, KaloBios has advanced three programs to clinical development:

- KB001-A is an anti-PcrV mAb fragment, 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 is conducting a 180 patient Phase 2 study in CF subjects with chronic *Pa* lung infection. KaloBios has received Orphan Drug designation from both the U.S. FDA and the European Medicines Agency for KB001-A for the treatment of *Pa* lung infection in CF patients. 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 is an anti-EphA3 mAb with potential in treating hematologic malignancies and solid tumors. KaloBios is running an ongoing Phase 1/2 study evaluating KB004 in hematologic malignancies. The Phase 1 dose escalation portion of that study in subjects with hematologic malignancies is ongoing. KaloBios initiated the Phase 2 expansion portion of the study focused on patients with certain EphA3 positive hematologic malignancies in early 2014.
- KB003 is an anti-GM-CSF mAb with potential to treat inflammatory diseases that was being developed for the treatment of severe asthma. A Phase 2 clinical study in 160 patients with severe asthma has been completed in the United States, Europe and Australia, which did not meet its primary endpoint of improvement in FEV<sub>1</sub> from baseline as compared to placebo. KaloBios has discontinued development of this compound in severe asthma, and is continuing to analyze the Phase 2 data to review with thought leaders and evaluate other possible indications in order to determine next steps, if any, in the development of KB003.

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>.

### **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, and statements regarding the company's clinical development of KB001-A, KB004 and KB003. 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 potential timing and outcomes of clinical studies of KB001-A and KB004 undertaken now or in the future; the potential, if any, for future development of KB003; 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 manufacture, development and commercialization of KB001-A; the company's ability to successfully progress or 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 March 13, 2014, the quarterly reports on Form 10-Q filed on May 14, August 19, and November 12, 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.

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

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**Consolidated Balance Sheets**  
**March 31, 2014 and December 31, 2013**  
**(in thousands, except share and per share information)**

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,397	\$ 54,220
Marketable securities	29,303	22,511
Prepaid expenses and other current assets	765	786
Restricted cash	205	205
Total current assets	63,670	77,722
Restricted cash	193	-
Property and equipment, net	210	276
Marketable securities, non-current	1,692	-
Other assets	814	706
Total assets	\$ 66,579	\$ 78,704
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,634	\$ 3,197
Accrued compensation	637	1,091
Accrued research and clinical liabilities	3,691	3,309
Notes payable, short-term	3,187	3,182
Other accrued liabilities	750	603
Total current liabilities	9,899	11,382
Notes payable, long-term	6,006	6,786
Total liabilities	15,905	18,168

Stockholders' equity:

Common stock, \$0.001 par value: 47,500,000 shares authorized at March 31, 2014, and December 31, 2013; 32,981,396 and 32,931,092 shares issued and outstanding at March 31, 2014, and December 31, 2013, respectively

Additional paid-in capital	201,265	200,715
Accumulated other comprehensive income (loss)	(1)	3
Accumulated deficit	(150,623)	(140,215)
Total stockholders' equity	50,674	60,536
Total liabilities and stockholders' equity	\$ 66,579	\$ 78,704

**Consolidated Statements of Operations**  
**Three Months Ended March 31, 2014 and 2013**  
(in thousands, except share and per share information)

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(unaudited)</b>	
Contract revenue	\$ -	\$ 16
Operating expenses:		
Research and development	7,690	6,320
General and administrative	2,470	2,019
Total operating expenses	10,160	8,339
Loss from operations	(10,160)	(8,323)
Other income (expense):		
Interest expense	(260)	(263)
Interest and other income, net	12	12
Net loss	(10,408)	(8,574)
Other comprehensive income (loss):		
Net unrealized gains (losses) on marketable securities	(4)	-
Comprehensive loss	\$ (10,412)	\$ (8,574)
Basic and diluted net loss per common share	\$ (0.32)	\$ (0.55)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	32,966,471	15,607,379

**Stock Based Compensation Expense**  
**Three Months Ended March 31, 2014 and 2013**  
(in thousands)

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

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Research and development	\$ 265	\$ 96
General and administrative	226	85
Total stock-based compensation expense	\$ 491	\$ 181

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