

August 7, 2014



# KaloBios Provides Clinical Update and Reports Second Quarter Financial Results

SOUTH SAN FRANCISCO, Calif., Aug. 7, 2014 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today provided an update on its current clinical programs and announced financial results for the second quarter of 2014.



## Development Program Updates

### KB004

KaloBios completed enrollment in July in the open-label Phase 1 dose escalation study of KB004 in hematologic malignancies. This study has enrolled a total of 50 patients in the Phase 1 portion of the study, including patients with myelodysplastic syndrome (MDS), myelofibrosis (MF) and acute myeloid leukemia (AML), with 80% of patients enrolled being late-stage AML patients. The drug continues to be well tolerated with the most commonly reported side effects being first-dose infusion reactions. No maximum tolerated dose (MTD) was reached in this study. Based on the outcome of the Phase 1 portion of the study, KaloBios has declared 250mg as the high dose for purposes of the Phase 2 expansion portion of the study.

The Phase 2 expansion portion of the study will be enrolling patients with hematologic malignancies that are pre-screened to be EphA3 positive. Now that the high-dose has been declared, KaloBios will seek to enroll one high-dose cohort of 10 MDS patients, a second high-dose cohort of 10 AML patients, and a third high-dose cohort comprised of 10 MF patients.

### KB001-A

In July, KaloBios announced that target enrollment in the Phase 2 study in cystic fibrosis (CF) patients with chronic *Pseudomonas aeruginosa* (*Pa*) lung infections was achieved with the enrollment of the 180<sup>th</sup> patient. KaloBios expects to release top-line data on this study early in the first quarter of 2015.

KaloBios also at that time announced that it had regained full global rights to KB001-A in all indications as a result of the execution of a negotiated termination of the company's collaboration agreement with Sanofi Pasteur. KaloBios has stated that it intends to seek a

partner with a focus on infectious disease, hospital pharmaceuticals, or cystic fibrosis who can accelerate and financially support the future development of KB001-A.

"We are very excited about the recent progress we have made on our programs," said Nestor A. Molfino, MD, MSc, Chief Medical Officer of KaloBios. "Completing enrollment in our Phase 2 KB001-A study in CF patients in a timeframe that will potentially allow us to report out top-line data in early 2015 was a major achievement for the company. At the same time, completing enrollment in the KB004 Phase 1 dose escalation study sets the stage for us to initiate enrollment in the high-dose cohorts in the Phase 2 efficacy-seeking portion of our KB004 study in the second half of 2014."

### **Key Anticipated Milestones for 2014-2015**

**2H 2014:Full enrollment of the KB001-A CF Phase 2 study (completed in July 2014)**

**Q4 2014:** Completion of enrollment in at least one indication in the Phase 2 expansion portion of our KB004 study in hematologic malignancies

**Q1 2015:** Top line KB001-A CF Phase 2 study results

### **Second Quarter 2014 Financial Results**

Net loss for the three months ended June 30, 2014 was \$9.8 million or \$0.30 per common share, as compared to \$11.8 million or \$0.49 per common share for the same period in 2013.

No contract revenue was reported for the second quarter of 2014 as compared to \$15,000 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.

Research and development (R&D) expenses were \$6.7 million for the three months ended June 30, 2014 as compared to \$9.6 million for the same period in 2013. The decrease in R&D expense was primarily due to decreased clinical trial activity compared with the prior period largely as a result of the completion of the KB003 Phase 2 study in patients with severe asthma in the first quarter of 2014. General and administrative (G&A) expenses were \$2.8 million for the second quarter of 2014 compared to \$1.9 million for the same period in 2013. The increase in G&A expenses was due primarily to costs incurred in our move into a new facility in the second quarter of 2014 as well as higher legal, accounting and consulting costs associated with becoming a public reporting company.

As of June 30, 2014, KaloBios had cash, cash equivalents and investments totaling \$59.2 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 being developed for the prevention and treatment of *Pseudomonas aeruginosa* (*Pa*) infection. KaloBios is conducting a 180 patient Phase 2 study in cystic fibrosis (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. KB001-A has also received Fast Track Status from the U.S. FDA for the prevention of ventilator associated pneumonia. KaloBios is planning to seek a partner to help accelerate the development of this program.
- 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 fully enrolled with dosing ongoing. KaloBios initiated the Phase 2 expansion portion of the study focused on patients with certain EphA3 positive hematologic malignancies in 2014.
- KB003 is an anti-GM-CSF mAb with potential to treat inflammatory diseases that was being developed for the treatment of severe asthma. In early 2014, KaloBios completed a Phase 2 clinical study in 160 patients with severe asthma which did not meet its primary endpoint of improvement in FEV<sub>1</sub> from baseline as compared to placebo. As a result, KaloBios discontinued development of this compound in severe asthma, and is continuing to analyze the Phase 2 data to review with thought leaders. KaloBios is currently evaluating 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® 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 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 ability of the company to timely source adequate supply of its development products from third party manufacturers on whom the company depends; 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 ability to successfully progress, partner 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 most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission on May 8, 2014, the Annual Report on Form 10-K filed on March 13, 2014, 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>.

**Contact:**

Herb Cross  
Chief Financial Officer  
KaloBios Pharmaceuticals, Inc.  
(650) 243-3114  
[ir@kalobios.com](mailto:ir@kalobios.com)

**Media Contact:**

Joan E. Kureczka  
Kureczka/Martin Associates  
Tel: (415) 821-2413  
Mobile: (415) 690-0210  
[Joan@Kureczka-Martin.com](mailto:Joan@Kureczka-Martin.com)

**Consolidated Balance Sheets**

**June 30, 2014 and December 31, 2013**

**(in thousands, except share and per share information)**

	<b>June 30,</b>	<b>December 31,</b>
	<b>2014</b>	<b>2013</b>
(unaudited)		
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,053	\$ 54,220
Marketable securities	48,981	22,511
Prepaid expenses and other current assets	1,698	786
Restricted cash	205	205
Total current assets	59,937	77,722
Restricted cash	193	-
Property and equipment, net	334	276
Marketable securities, non-current	752	-
Other assets	121	706
Total assets	\$ 61,337	\$ 78,704

## **Liabilities and stockholders' equity**

### **Current liabilities:**

Accounts payable	\$ 2,658	\$ 3,197
Accrued compensation	1,009	1,091
Accrued research and clinical liabilities	2,208	3,309
Notes payable, short-term	5,131	3,182
Other accrued liabilities	492	603
Total current liabilities	11,498	11,382
Deferred rent, long-term	157	-
Notes payable, long-term	8,292	6,786
Total liabilities	19,947	18,168

### **Stockholders' equity:**

Common stock, \$0.001 par value: 85,000,000 shares and 47,500,000 shares authorized at June 30, 2014 and December 31, 2013, respectively; 32,981,396 and 32,931,092 shares issued and outstanding at June 30, 2014, and December 31, 2013, respectively	33	33
Additional paid-in capital	201,793	200,715
Accumulated other comprehensive income	1	3
Accumulated deficit	(160,437)	(140,215)

Total stockholders' equity	41,390	60,536
Total liabilities and stockholders' equity	\$ 61,337	\$ 78,704

### **Consolidated Statements of Operations**

**Three and Six Months Ended June 30, 2014 and 2013**

**(in thousands, except share and per share information)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
	<b>(unaudited)</b>			
Contract revenue	\$ -	\$ 15	\$ -	\$ 31
Operating expenses:				
Research and development	6,721	9,646	14,411	15,966
General and administrative	2,813	1,940	5,283	3,959
Total operating expenses	9,534	11,586	19,694	19,925
Loss from operations	(9,534)	(11,571)	(19,694)	(19,894)

**Other income (expense):**

Interest expense	(290)	(236)	(550)	(488)
Interest and other income (expense), net	10	(2)	22	(1)
Net loss	(9,814)	(11,809)	(20,222)	(20,383)

**Other comprehensive  
income (loss):**

Net unrealized gains (losses) on marketable securities	2	17	(2)	17
Comprehensive loss	\$ (9,812)	\$ (11,792)	\$ (20,224)	\$ (20,366)

Basic and diluted net loss per common share	\$ (0.30)	\$ (0.49)	\$ (0.61)	\$ (1.02)
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Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	32,981,396	24,189,819	32,973,892	19,922,307
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**Stock Based Compensation Expense**

**Three and Six Months Ended June 30, 2014 and 2013**

**(in thousands)**

Total stock-based compensation expense included in the consolidated statements of

operations is as follows:

	Three Months Ended June 30		Six Months Ended June 30,	
	2014	2013	2014	2013
Research and development	\$ 280	\$ 199	\$ 545	\$ 295
General and administrative	247	174	473	259
Total stock-based compensation expense	\$ 527	\$ 373	\$ 1,018	\$ 554

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