



March 13, 2014

KaloBios Announces Fiscal Year 2013 Financial Results

SOUTH SAN FRANCISCO, Calif., March 13, 2014 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today provided an update on corporate accomplishments in fiscal 2013 and key milestones for 2014 as well as announcing financial results for fiscal year 2013.

Fiscal 2013 Accomplishments

Key corporate accomplishments during fiscal 2013 included:

- KB001-A - Received orphan drug status for KB001-A from the U.S. Food and Drug Administration and the European Medicines Agency for treatment of *Pseudomonas aeruginosa* (*Pa*) lung infections in cystic fibrosis (CF) patients. KaloBios additionally laid the foundation to expand the Phase 2 study in CF patients to sites in New Zealand, Australia and Israel in early 2014 in order to drive additional enrollment. KaloBios' partner, Sanofi Pasteur, also received Fast Track approval from the FDA for their ventilator-associated pneumonia prevention indication.
- KB004 - Continued the Phase 1 dose escalation study in hematologic malignancies seeking a maximum tolerable dose for the Phase 2 expansion portion of the study, which was commenced in early 2014.
- KB003 - Completed enrollment of the Phase 2 study in severe asthma ahead of schedule, which enabled announcement of top-line data in early 2014.
- Funding - Completed the company's initial public offering and a secondary equity offering to strengthen the balance sheet and provide capital to fund the company's development programs.

"In 2013, we continued to advance development of our strong, differentiated clinical pipeline of first-in-class, patient-targeted therapies," said David Pritchard, KaloBios' President and Chief Executive Officer. "While our KB003 development program in severe asthma was discontinued in early 2014 based on the Phase 2 top-line data, we are continuing to focus on our KB004 and KB001-A antibodies targeting hematologic malignancies and *Pa* infections associated with CF and ventilator-associated pneumonia, respectively."

Mr. Pritchard continued, "In 2014, we will continue to focus on enrollment in our ongoing Phase 2 KB001-A study of *Pa* infection in CF patients, and in the recently initiated Phase 2 expansion portion of our ongoing study of KB004 in hematologic malignancies. We look forward to seeing data on both programs later this year."

Key Anticipated Milestones for 2014-2015

- 1Q 2014: Initiation of Phase 2 expansion portion of KB004 study in AML and MDS (**Achieved February 2014**)
- 2Q 2014: Full enrollment of the KB001-A CF Phase 2 study
- 4Q 2014: Top line KB001-A CF Phase 2 study results
- 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: Initiation of Sanofi Phase 2b study for prevention of ventilator-associated pneumonia (VAP)

Fiscal 2013 Financial Results

Net loss for the year ended December 31, 2013 was \$41.9 million or \$1.73 per common share, as compared to \$23.5 million or \$11.22 per common share for the same period in 2012.

Contract revenue was \$44,000 for the fiscal year 2013 as compared to \$6.1 million for 2012. The decrease in contract revenue 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 \$32.6 million for fiscal year 2013 compared to \$24.5 million in 2012. R&D expense increased during 2013 primarily due to increased clinical trial activity compared with the prior period. General and administrative (G&A) expenses were \$8.3 million for fiscal year 2013 compared to \$5.1 million in 2012. G&A expense increased in 2013 due primarily to higher legal, accounting and consulting costs. We expect operating expenses to continue to increase during 2014 as we further develop our clinical programs and incur expenses associated with being a public company.

As of December 31, 2013, KaloBios had cash, cash equivalents and marketable securities totaling \$76.7 million, compared to \$20.3 million at December 31, 2012.

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 *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 *Pseudomonas aeruginosa* (*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 EphA3 positive patients with acute myeloid leukemia and myelodysplastic syndrome 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 FEV₁ 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[®] 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 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 April 1, 2013, 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>.

Contact:

Herb Cross
Chief Financial Officer
KaloBios Pharmaceuticals, Inc.

(650) 243-3114
ir@kalobios.com

Media Contact:

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

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

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 54,220	\$ 10,947
Marketable securities	22,511	9,351
Contract receivables	44	87
Prepaid expenses and other current assets	742	871
Restricted cash	205	-
Total current assets	77,722	21,256
Restricted cash	-	205
Property and equipment, net	276	230
Deferred offering costs	-	2,803
Other assets	706	45
Total assets	\$ 78,704	\$ 24,539
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 3,197	\$ 2,448
Accrued compensation	1,091	628
Deferred rent, short-term	160	101
Accrued research and clinical liabilities	3,309	3,538
Notes payable, short-term	3,182	-
Other accrued liabilities	443	502
Total current liabilities	11,382	7,217
Deferred rent, long-term	-	62
Notes payable, long-term	6,786	9,826
Other liabilities, long-term	-	355
Total liabilities	18,168	17,460
Convertible preferred stock, \$0.001 par value: no shares and 60,152,555 shares authorized at December 31, 2013, and December 31, 2012, respectively; no shares and 12,329,330 shares issued and outstanding at December 31, 2013, and December 31, 2012, respectively	-	102,023
Stockholders' equity (deficit):		
Common stock, \$0.001 par value: 47,500,000 shares and 80,000,000 shares authorized at December 31, 2013, and December 31, 2012, respectively; 32,931,092 and 2,186,695 shares issued and outstanding at December 31, 2013, and December 31, 2012, respectively	33	2
Additional paid-in capital	200,715	3,317
Accumulated other comprehensive income	3	4
Accumulated deficit	(140,215)	(98,267)
Total stockholders' equity (deficit)	60,536	(94,944)
Total liabilities and stockholders' equity (deficit)	\$ 78,704	\$ 24,539

Consolidated Statements of Operations
Year Ended December 31, 2013 and 2012
(in thousands, except share and per share information)

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2012</u>
Contract revenue	\$ 44	\$ 6,098
Operating expenses:		
Research and development	32,640	24,519
General and administrative	8,313	5,061
Total operating expenses	<u>40,953</u>	<u>29,580</u>
Loss from operations	(40,909)	(23,482)
Other income (expense):		
Interest income	86	44
Interest expense	(1,086)	(184)
Other income (expense), net	(39)	113
Net loss	<u>(41,948)</u>	<u>(23,509)</u>
Other comprehensive income (loss):		
Net unrealized gains (losses) on marketable securities	<u>(1)</u>	<u>5</u>
Comprehensive loss	<u>\$ (41,949)</u>	<u>\$ (23,504)</u>
Basic and diluted net loss per common share	<u>\$ (1.73)</u>	<u>\$ (11.22)</u>
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	<u>24,270,407</u>	<u>2,095,950</u>

Stock Based Compensation Expense
Year Ended December 31, 2013 and 2012
(in thousands)

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

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2012</u>
Research and development	\$ 709	\$ 398
General and Administrative	731	423
Total stock-based compensation expense	<u>\$ 1,440</u>	<u>\$ 821</u>



Photo - <http://photos.prnewswire.com/prnh/20130225/MM66380LOGO>

SOURCE KaloBios Pharmaceuticals, Inc.

News Provided by Acquire Media