

KaloBios Reports Third Quarter Financial Results

SOUTH SAN FRANCISCO, Calif., Nov. 6, 2014 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today reported its financial results for the third quarter of 2014.



Net loss for the three months ended September 30, 2014 was \$8.1 million or \$0.24 per common share, as compared to \$11.3 million or \$0.47 per common share for the same period in 2013.

No contract revenue was reported for the third quarter of 2014 as compared to \$9,000 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 collaboration agreement with Sanofi Pasteur.

Research and development (R&D) expenses were \$5.1 million for the three months ended September 30, 2014 as compared to \$9.0 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 \$2.6 million for the third quarter of 2014 compared to \$2.1 million for the same period in 2013. The increase in G&A expenses was due primarily to costs resulting from our move into a new facility in 2014 as well as higher legal, accounting and consulting costs.

As of September 30, 2014, KaloBios had cash, cash equivalents and investments totaling \$49.3 million, compared to \$76.7 million at December 31, 2013.

"The third quarter was a very productive one for us on a number of fronts," said David Pritchard, KaloBios' President and Chief Executive Officer. "Most notably for the completion of enrollment in our 180 patient Phase 2 KB001-A study targeting *Pseudomonas aeruginosa* infections in cystic fibrosis (CF) patients, which will enable us to provide top-line data on that study in January 2015. In addition, we completed the Phase 1 dose escalation portion of our KB004 study in hematologic malignancies, data on which will be presented at the American Society of Hematology Annual Meeting in December 2014. Completion of the Phase 1 portion of that study enabled us to commence enrolling patients in the Phase 2 high-dose cohorts during the quarter."

Key Milestones for 2014-2015

2H 2014: Full enrollment of 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

December KB004 Phase 1 study poster presentation at the American Society of Hematology Annual Meeting

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

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 FEV₁ 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 Humaneere® 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. Forwardlooking 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. Forwardlooking 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 August 7, 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.

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Consolidated Balance Sheets

September 30, 2014 and December 31, 2013

(in thousands, except share and per share data)

September	December
30,	31,

2014 2013

(Unaudited)

Assets

Current assets:

Cash and cash equivalents

\$ 11,270\$

54,220

Marketable securities	37,844		22,51	1
Prepaid expenses and other current assets	1,322		786	
Restricted cash, current	-		205	
Total current assets	50,436		77,72	2
Restricted cash, non current	193		-	
Property and equipment, net	339		276	
Other assets	139		706	
Total assets	\$	51,10	7\$	78,704

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$	92 \$	3,197
Accrued compensation	1,380	1,091	
Deferred rent, short-term	10	160	
Accrued research and clinical liabilities	1,984	3,309	
Notes payable, short-term	5,134	3,182	
Other accrued liabilities	526	443	
Total current liabilities	9,954	11,382	

Deferred rent, long-term	318	-
Notes payable, long-term	7,042	6,786
Total liabilities	17,314	18,168
Stockholders' equity:		
Common stock, \$0.001 par value: 85,000,000 shares and 47,500,000 shares authorized at September 30, 2014 and December 31, 2013, respectively; 32,981,817 and 32,931,09 shares issued and outstanding at September 30, 2014, and December 31, 2013, respectively	33	
Additional paid-in capital	202,259	200,715
Accumulated other comprehensive income	1	3
Accumulated deficit	(168,500)	(140,215)
Total stockholders' equity	33,793	60,536
		-

Consolidated Statements of Operations

Total liabilities and stockholders' equity

Three and Nine Months Ended September 30, 2014 and 2013

(in thousands, except share and per share information)

Three Months Ended September 30,

Nine Months Ended September 30,

51,107\$

78,704

\$

	2014	2013	2014	2013			
	(unaudited)						
Contract revenue	\$	- \$	\$	- \$ 40			
Operating expenses:							
Research and development	5,085	8,995	19,496	24,961			
General and administrative	2,624	2,101	7,907	6,060			
Total operating expenses	7,709	11,096	27,403	31,021			
Loss from operations	(7,709)	(11,087)	(27,403)	(30,981)			
Other income (expense):							
Interest expense	(348)	(278)	(898)	(807)			
Other income (expense), net	(6)	36	16	76			
Net loss	(8,063)	(11,329)	(28,285)	(31,712)			
Other comprehensive income (loss):							
Net unrealized gains (losses) on marketable securities	-	(7)	(2)	10			
Comprehensive loss	\$ (8,06	3)\$ (11,33	6)\$ (28,28	7)\$ (31,702)			

Basic and diluted net loss per common (0.24) (0.47) (0.86) (1.48) share

Weighted average common shares outstanding used to calculate basic 32,981,725 24,263,745 32,976,532 21,385,478 and diluted net loss per common share

Stock Based Compensation Expense

Three and Nine Months Ended September 30, 2014 and 2013

(in thousands)

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

	Three Months Ended September 30,			Nine Months Ended September30,				
	2014		2013		201	4	2013	3
Research and development	\$	184	\$	213	\$	729	\$	508
General and administrative	282		241		755		500	
Total stock-based compensation expense	\$	466	\$	454	\$	1,484	\$	1,008

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