
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **March 31, 2015**

OR

- TRANSITION REPORT UNDER SECTION 13 OF 15(d) OF THE EXCHANGE ACT OF 1934**

From the transition period from to .

Commission File Number **001-35798**

KALOBIOS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

77-0557236
(IRS Employer
Identification No.)

442 Littlefield Avenue, South San Francisco, CA, 94080
(Address of principal executive offices)
(Zip Code)

Registrant's telephone number, including area code: **(650) 243-3100**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 1, 2015, there were 32,992,178 shares of common stock of the issuer outstanding.

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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements**

KaloBios Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2015 (Unaudited)	December 31, 2014 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,624	\$ 10,923
Marketable securities	17,597	29,790
Prepaid expenses and other current assets	950	1,532
Total current assets	31,171	42,245
Property and equipment, net	473	414
Restricted cash	193	193
Other assets	113	125
Total assets	<u>\$ 31,950</u>	<u>\$ 42,977</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 857	\$ 1,822
Accrued compensation	1,267	1,400
Deferred rent, short term	21	16
Accrued research and clinical liabilities	3,311	3,470
Notes payable	9,677	10,928
Financing derivative	92	89
Other accrued liabilities	315	328
Total current liabilities	15,540	18,053
Deferred rent, long-term	305	311
Total liabilities	15,845	18,364
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 85,000,000 shares and 85,000,000 shares authorized at March 31, 2015 and December 31, 2014 respectively; 32,992,178 and 32,992,178 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	33	33
Additional paid-in capital	203,909	202,801
Accumulated other comprehensive income	(2)	(8)
Accumulated deficit	(187,835)	(178,213)
Total stockholders' equity	16,105	24,613
Total liabilities and stockholders' equity	<u>\$ 31,950</u>	<u>\$ 42,977</u>

See accompanying notes

KaloBios Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	<u>Three Months Ended March 31,</u>	
	<u>2015</u>	<u>2014</u>
	(unaudited)	
Operating expenses:		
Research and development	5,905	7,690
General and administrative	3,437	2,470
Total operating expenses	<u>9,342</u>	<u>10,160</u>
Loss from operations	(9,342)	(10,160)
Other (expense) income:		
Interest expense	(280)	(260)
Interest income	16	14
Other (expense) income, net	<u>(16)</u>	<u>(2)</u>
Net loss	(9,622)	(10,408)
Other comprehensive income:		
Net unrealized gains (losses) on marketable securities	6	(4)
Comprehensive loss	<u>\$ (9,616)</u>	<u>\$ (10,412)</u>
Basic and diluted net loss per common share	<u>\$ (0.29)</u>	<u>\$ (0.32)</u>
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	<u>32,992,178</u>	<u>32,966,471</u>

See accompanying notes

KaloBios Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2015	2014
	(unaudited)	
Operating activities:		
Net loss	\$ (9,622)	\$ (10,408)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	48	101
Noncash interest expense	56	45
Financing derivative	3	—
Amortization of premium on marketable securities	80	59
Stock based compensation expense	305	491
Modification of stock options related to executive retirement	389	—
Modification of stock options related to restructuring activities	414	—
Changes in operating assets and liabilities:		
Contract receivables	—	40
Prepaid expenses and other assets	583	(138)
Accounts payable	(965)	(1,563)
Accrued compensation	(133)	(454)
Accrued research and clinical liabilities	(159)	382
Other liabilities	(13)	155
Deferred rent	(1)	(8)
Net cash (used in) operating activities	(9,015)	(11,298)
Investing activities:		
Purchase of marketable securities	(3,703)	(31,005)
Proceeds from maturities of marketable securities	15,822	22,460
Purchases of property and equipment	(108)	(35)
Changes in restricted cash	—	(193)
Net cash provided by (used in) investing activities	12,011	(8,773)
Financing activities:		
Proceeds from issuance of common stock	—	59
Principal payments under notes payable	(1,295)	(811)
Net cash (used in) financing activities	(1,295)	(752)
Net increase (decrease) in cash and cash equivalents	1,701	(20,823)
Cash and cash equivalents, beginning of period	10,923	54,220
Cash and cash equivalents, end of period	\$ 12,624	\$ 33,397
Supplemental cash flow disclosure:		
Cash paid for interest	\$ 233	\$ 219

See accompanying notes.

KaloBios Pharmaceuticals, Inc.

**Notes to Condensed Consolidated Financial Statements
(Unaudited)**

1. Nature of Operations

KaloBios Pharmaceuticals, Inc. (the Company) is a biopharmaceutical company whose primary business is to develop monoclonal antibody therapeutics for diseases that represent a significant burden to society and to patients and their families. Our clinical development efforts are focused solely in oncology, including both hematologic malignancies and potentially solid tumors. The Company was incorporated on March 15, 2000 in California and reincorporated as a Delaware corporation in September 2001. All of the Company's assets are located in California.

The Company has incurred significant losses and had an accumulated deficit of \$187.8 million as of March 31, 2015. The Company has financed its operations primarily through the sale of equity securities, grants and the payments received under its agreements with Novartis Pharma AG (Novartis) and Sanofi Pasteur S.A. (Sanofi). To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. Management expects operating losses to continue for the foreseeable future. As a result, the Company will continue to require additional capital through equity offerings, debt financing and/or payments under new or existing licensing or collaboration agreements. If sufficient funds on acceptable terms are not available when needed, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of, or eliminate one or more of its development programs. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm its business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. These conditions could raise substantial doubt about the Company's ability to continue as a going concern. Therefore, the Company has classified the notes payable as current. The report of our Independent Registered Public Accounting Firm included an explanatory paragraph about the Company's ability to continue as a going concern in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and on a basis consistent with the annual consolidated financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the periods presented. These financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The December 31, 2014 Condensed Consolidated Balance Sheet was derived from the audited financial statements but does not include all disclosures required by GAAP. These interim financial results are not necessarily indicative of the results to be expected for the year ending December 31, 2015, or for any other future annual or interim period. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company's Form 10-K for the year ended December 31, 2014.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. The Company believes judgment is involved in determining the stock-based compensation and accruals. The Company evaluates estimates and assumptions as facts and circumstances

dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the consolidated financial statements.

Concentration of Credit Risk

Cash, cash equivalents, and marketable securities consist of financial instruments that potentially subject the Company to a concentration of credit risk in the event of a default by the related financial institution holding the securities, to the extent of the value recorded in the balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments with lower credit risk. The Company has established guidelines relating to the quality, diversification, and maturities of securities to enable the Company to manage its credit risk.

Cash, Cash Equivalents, and Marketable Securities

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Investments in securities with remaining maturities of less than one year, or where our intent is to use the investments to fund current operations or to make them available for current operations, are classified as short-term and available for sale. Investments in securities with remaining maturities greater than one year are classified as noncurrent and available for sale (see Note 3). Securities available for sale are carried at estimated fair value, with unrealized gains and losses reported as part of accumulated other comprehensive income (loss), a separate component of stockholders' equity. The Company has estimated the fair value amounts by using available market information. The cost of available-for-sale securities sold is based on the specific-identification method.

Research and Development Expenses

Development costs incurred in the research and development of new products are expensed as incurred, including expenses that may or may not be reimbursed under research and development collaboration agreements. Research and development costs include, but are not limited to, salaries, benefits, stock-based compensation, laboratory supplies, allocated overhead, fees for professional service providers and costs associated with product development efforts, including preclinical studies and clinical trials. Research and development expenses under collaborative agreements approximate or exceed the revenue recognized under such agreements.

The Company estimates preclinical study and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Stock-Based Compensation Expense

The Company measures employee and director stock-based compensation expense for stock awards at the grant date and employee stock purchase plan, or ESPP, based on the fair value-based measurement of the award, and the expense is recorded over the related service period, generally the vesting period, net of estimated forfeitures. The Company calculates the fair value-based measurement of stock options and ESPP using the Black-Scholes valuation model and the single-option method and recognizes expense using the straight-line attribution approach.

The Company accounts for equity instruments issued to nonemployees based on their fair values on the measurement dates using the Black-Scholes option-pricing model. The fair values of the options granted to nonemployees are remeasured as they vest. As a result, the noncash charge to operations for nonemployee options with vesting is affected each reporting period by changes in the fair value of the Company's common stock.

Comprehensive Loss

Comprehensive loss represents net loss adjusted for the change during the periods presented in unrealized gains and losses on available-for-sale securities less reclassification adjustments for realized gains or losses included in net loss. The unrealized gains or losses are reported on the Consolidated Statements of Comprehensive Loss.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

The Company's potential dilutive securities which include unvested stock options and warrants have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share and be antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following shares of outstanding potentially dilutive securities have been excluded from the computations of diluted net loss per common share as the effect of including such securities would be antidilutive:

	As of March 31,	
	2015	2014
Warrants to purchase common stock	88,545	88,545
Options to purchase common stock	4,020,821	2,548,314
	<u>4,109,366</u>	<u>2,636,859</u>

3. Investments

At March 31, 2015, the amortized cost and fair value of investments, with gross unrealized gains and losses, were as follows:

(in thousands)	Amortized	Gross	Gross	Fair Value
	Cost	Unrealized Gains	Unrealized Losses	
Money market funds	\$ 10,476	\$ —	\$ —	\$ 10,476
Federal agency securities	11,506	—	—	11,506
Corporate debt securities	6,093	—	(2)	6,091
Total investments	<u>\$ 28,075</u>	<u>\$ —</u>	<u>\$ (2)</u>	<u>\$ 28,073</u>
Reported as:				
Cash and cash equivalents				\$ 10,283
Marketable securities, current				17,597
Restricted cash				193
Total investments				<u>\$ 28,073</u>

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At December 31, 2014, the amortized cost and fair value of investments, with gross unrealized gains, were as follows:

(in thousands)	Amortized Cost	Gross	Gross	Fair Value
		Unrealized Gains	Unrealized Losses	
Money market funds	\$ 9,663	\$ —	\$ —	\$ 9,663
Federal agency securities	13,774	—	(4)	13,770
Commercial paper	1,499	1	—	1,500
Corporate debt securities	14,525	—	(5)	14,520
Total investments	<u>\$ 39,461</u>	<u>\$ 1</u>	<u>\$ (9)</u>	<u>\$ 39,453</u>
Reported as:				
Cash and cash equivalents				\$ 9,470
Marketable securities				29,790
Restricted cash				193
Total investments				<u>\$ 39,453</u>

There were no realized gains or losses from the sale of marketable securities for the three months ended March 31, 2015 and 2014.

4. Fair Value of Financial Instruments

Cash, accounts payable and accrued liabilities are carried at cost, which approximates fair value given their short-term nature. Marketable securities and cash equivalents are carried at fair value.

The fair value of financial instruments reflects the amounts that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value hierarchy is based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable, and the third is considered unobservable, as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than those included in Level 1 that are directly or indirectly observable, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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The Company measures the fair value of financial assets and liabilities using the highest level of inputs that are reasonably available as of the measurement date. The following tables summarize the fair value of financial assets and liabilities (investments) that are measured at fair value and the classification by level of input within the fair value hierarchy:

(in thousands)	Fair Value Measurements as of			
	March 31, 2015			
	Level 1	Level 2	Level 3	Total
Investments:				
Money market funds	\$ 10,476	\$ —	\$ —	\$ 10,476
Federal agency securities	—	11,506	—	11,506
Commercial paper	—	—	—	—
Corporate debt securities	—	6,091	—	6,091
Total assets measured at fair value	\$ 10,476	\$ 17,597	\$ —	\$ 28,073
Financing derivative	—	—	92	92
Total liabilities measured at fair value	\$ —	\$ —	\$ 92	\$ 92

(in thousands)	Fair Value Measurements as of			
	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Investments:				
Money market funds	\$ 9,663	\$ —	\$ —	\$ 9,663
Federal agency securities	—	13,770	—	13,770
Commercial paper	—	1,500	—	1,500
Corporate debt securities	—	14,520	—	14,520
Total assets measured at fair value	\$ 9,663	\$ 29,790	\$ —	\$ 39,453
Financing derivative	—	—	89	89
Total liabilities measured at fair value	\$ —	\$ —	\$ 89	\$ 89

The Company's Level 2 investments include U.S. government-backed securities, commercial paper and corporate debt securities that are valued based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. The average remaining maturity of the Company's Level 2 investments as of March 31, 2015 is less than three months and all of these investments are rated A3/A-/A- or P1/A1/F1, or higher by Moody's, S&P and Fitch.

In December 2014, the Company recorded a financing derivative liability resulting from an embedded derivative related to the prepayment feature of the loan and security agreement with MidCap Financial. At March 31, 2015, the Company remeasured the financing derivative liability as \$92,000 and recorded the loss of \$3,000 as other expense. The fair value of this derivative was determined using Level 3 inputs, or significant unobservable inputs. The value of the financing derivative was determined by comparing the difference between the fair value of the notes payable with and without the financing derivative by calculating the respective present values from future cash flows using a 14% discount rate, adjusted for the probability of the occurrence of an event of default under the loan and security agreement with MidCap Financial. The 14% discount rate assumption was based on an effective borrowing rate under the current circumstances considering the quoted borrowing rate for the Company and the imputed fair value of any additional financial instruments that may be required to be extended to the lender in order to obtain such debt financing. The probability of the occurrence of an event of default under the loan and security agreement with MidCap Financial was based on management's judgment. Refer to Note 5 for additional details regarding the loan and security agreement with MidCap Financial.

The following table presents changes in financial instruments measured at fair value using Level 3 inputs:

	Fair Value Measurements of Level 3 Liabilities	
	(in thousands)	
Balance at December 31, 2014	\$	89
(Gain) loss on remeasurement of the financing derivative liability		3
Balance at March 31, 2015	\$	92

The estimated fair value of the notes payable as of March 31, 2015, based on current market rates for similar borrowings, as measured using Level 3 inputs, approximates the carrying amount as presented on the condensed consolidated balance sheet.

5. Notes Payable

Loan and Security Agreement

In September 2012, the Company entered into the Agreement with MidCap Financial, providing for the borrowing of up to \$15 million, of which \$10 million was required to be drawn. The remaining \$5 million was available to be drawn at the option of the Company. The Agreement provides for the loan to be issued in three tranches: the first tranche of \$5 million was issued in September 2012; the second tranche of \$5 million was issued in December 2012; and, prior to the amendment described below, the final tranche could have been drawn at the option of the Company no later than June 2013. The loan has a monthly variable interest rate, reset each month, if applicable, as determined by adding to 600 basis points the greater of: (a) one month LIBOR or (b) 3% (the LIBOR floor). Interest on amounts outstanding are payable monthly in arrears. There was an interest only period to December 31, 2013 followed by straight-line principal payments over thirty-six months until December 31, 2016. At the time of final payment, the Company must pay an exit fee of 3% of the drawn amount. Pursuant to the Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property. In addition, the terms of the Agreement provided MidCap Financial a warrant to purchase shares of the Company's Series E convertible preferred stock (Series E Preferred) equal to 4% of the amount drawn down under the facility divided by the Series E Preferred exercise price of \$12.11 per share. The warrant expired upon the completion of the Company's IPO.

The Company has the right to prepay all or a portion of the borrowed amounts under the Agreement; however, if the Company exercises this option, the Company must pay a prepayment fee determined by multiplying the outstanding loan amount by 2% if the prepayment occurs in 2015 and 1% if the prepayment occurs in the final year. In the event of default, upon which all amounts borrowed become immediately due and payable, the Company will be subject to the prepayment fee ranging from 1% to 2% of the amount due on the loan and a step up in interest rate of 5%. An event of default includes, but is not limited to, an occurrence such as a payment default, a material adverse change, insolvency, or a change of control. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm its business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. Therefore, the Company has classified notes payable as current.

In connection with the Agreement and the first tranche draw down of \$5 million in September 2012 and second tranche draw down of \$5 million in December 2012, the Company issued a warrant to MidCap Financial to purchase shares of the Company's Series E Preferred. Contemporaneously with the issuance of the warrant, the Company recorded a debt discount of \$79,000.

Debt issuance costs paid directly to MidCap Financial of \$114,000 (financing fees) and the fair value of the warrant issued to MidCap Financial were treated as a discount on the debt and are being accreted using the interest method. Other debt issuance costs for legal fees are included in other assets in the accompanying consolidated balance sheet and are being amortized using the interest method. The accretion of the debt discount and amortization of other debt issuance costs are recorded as non-cash interest expense in the consolidated statements of comprehensive loss.

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In June 2013, the Company entered into the Amendment to extend the draw down date for the final tranche of \$5.0 million from June 2013 to May 2014. In addition, the final tranche was changed from an optional draw down to a required draw down. In connection with the Amendment, the Company issued a warrant to purchase up to 49,548 shares of the Company's common stock with an exercise price of \$12.11 per share. The warrant expires in June 2023, on the tenth anniversary of its issuance date. The warrants issued to Midcap Financial had an initial fair value of \$130,000, which represent financing fees, and are included in other assets in the accompanying consolidated balance sheet and are being amortized as non-cash interest expense over the remaining term of the Agreement using the effective interest method. The Company estimated the fair values of these warrants using the Black-Scholes option-pricing model, based on the inputs for the estimated fair value of the underlying common stock at the valuation measurement date, the contractual term of the warrant, risk-free interest rates, expected dividend rates and expected volatility of the price of the underlying common stock. Pursuant to this Amendment, the Company drew down the final tranche of \$5.0 million in May 2014.

Future payments as of March 31, 2015 under the Agreement, assuming no adjustments to the variable rate of interest of 9% as of March 31, 2015, are as follows:

(in thousands)	
Remainder of 2015	\$ 4,418
2016	5,910
Total minimum payments	10,328
Less amount representing interest	(834)
Notes payable, gross	9,494
Discount on notes payable	(41)
Accretion of the final exit fee payment	224
Carrying value of notes payable	<u>\$ 9,677</u>

6. Past Collaborations

Sanofi

In January 2010, the Company and Sanofi entered into an agreement for the development and commercialization of KB001, the precursor to KB001-A, an investigational new biologic for the treatment and prevention of *Pseudomonas aeruginosa* (Pa) infections (the Sanofi agreement). Under the terms of the Sanofi agreement, the Company received an initial upfront non-refundable payment of \$35 million and received an additional non-refundable payment of \$5 million that represented a second installment of the upfront fees due to the Company under the agreement upon completion of a sublicense negotiation with a third party in August 2011. Sanofi was solely responsible for conducting, at its cost, the research, development, manufacture, and commercialization of the licensed products for the diagnosis, treatment and/or prevention of all human diseases and conditions caused by Pa, except that the Company retained responsibility, at the Company's cost, for developing and promoting the products for the diagnosis, treatment and/or prevention of Pa in patients with cystic fibrosis (CF) or bronchiectasis. Under the terms of the Sanofi agreement, the Company received specified research and development funding for services performed in connection with KB001-A research and development efforts and could have also received contingent payments based on the occurrence of development, regulatory or commercial events, and royalties on any product sales.

In July 2014, the Company and Sanofi executed an agreement (the Termination Agreement) under which the Sanofi agreement was terminated. As a result of the Termination Agreement, KaloBios regained full global rights to license, develop, manufacture and commercialize KB001-A in all indications, as well as a non-exclusive license to the KB001-A manufacturing process developed by Sanofi. In consideration for entering into the Termination Agreement, Sanofi will be entitled to royalties on net sales of KB001-A if approved, subject to a \$40 million cap on the aggregate royalties to be paid. In addition, Sanofi will be entitled to receive up to 10% of certain sub-license payments or other milestone payments received in the event KaloBios successfully re-partners KB001-A, subject to a separate \$40 million cap on the aggregate amount of sub-license payments to be shared with Sanofi.



7. Commitments and Contingencies

Contractual Obligations and Commitments

On May 21, 2013, the Company entered into an agreement with a third party for the manufacturing of KB003 clinical supply for future clinical trials. Despite the termination of the KB003 development program in severe asthma during the first quarter of 2014, the Company is continuing to evaluate other potential indications for KB003. Under that agreement the third party will perform a range of related services, including process development, optimization, validation, formulation development, regulatory assistance, stability testing and related activities. In addition, we had entered into an agreement with a separate third party to produce supply of KB001-A. As of December 31, 2014, there were no remaining commitments for services. In February 2015, this agreement was cancelled.

As of March 31, 2015, there were no significant and material changes to our contractual obligations from those set forth in our Form 10-K filed with the Securities and Exchange Commission (SEC) on March 16, 2015.

Guarantees and Indemnifications

The Company, as permitted under Delaware law and in accordance with its bylaws, has agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is equal to the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid.

The Company has certain agreements with service providers with which it does business that contain indemnification provisions pursuant to which the Company typically agrees to indemnify the party against certain types of third-party claims. The Company accrues for known indemnification issues when a loss is probable and can be reasonably estimated. The Company would also accrue for estimated incurred but unidentified indemnification issues based on historical activity. As the Company has not incurred any indemnification losses to date, there were no accruals for or expenses related to indemnification issues for any period presented.

8. Warrants to Purchase Common Stock

On June 19, 2013, in connection with the Amendment to its debt agreement with MidCap Financial, the Company issued a warrant to purchase up to 49,548 shares of the Company's common stock with an exercise price of \$12.11 per share. The warrant expires in June 2023. The Company recorded the initial value of the warrants in equity and other assets in the accompanying consolidated balance sheet, with the deferred other asset to be amortized over the remaining term of the debt using the effective interest method.

In addition, the Company has outstanding warrants to purchase an aggregate of 38,997 shares of common stock at \$5.13 per share which will expire on October 31, 2015.

9. Stockholders' Equity

2012 Equity Incentive Plan

As of March 31, 2015, under the 2012 Equity Incentive Plan, the Company may grant shares, stock units, stock appreciation rights, performance cash awards and/or options to employees, directors, consultants, and other service providers. For options, the per share exercise price may not be less than the fair market value of a Company common share on the date of grant. Awards generally vest over four years and expire 10 years from the date of grant. Options generally become exercisable as they vest following the date of grant.

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A summary of stock option activity for the three months ended March 31, 2015 under all of the Company's options plans is as follows:

	Options	Weighted Average Exercise Price
Outstanding at December 31, 2014	2,677,774	\$ 4.24
Granted	1,797,000	0.45
Exercised	—	—
Cancelled (forfeited)	(453,953)	3.91
Cancelled (expired)	—	—
Outstanding at March 31, 2015	4,020,821	\$ 2.59

The weighted average fair value of options granted during the three months ended March 31, 2015 was \$0.29 per share.

2012 Employee Stock Purchase Plan

The Employee Stock Purchase Plan, or ESPP, provides eligible employees with the opportunity to acquire an ownership interest in the Company through periodic payroll deductions, based on a six-month look-back period, at a price equal to the lesser of 85% of the fair market value of the ordinary shares at either the beginning or ending of the relevant offering period. The ESPP is structured as a qualified employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986. However, the ESPP is not intended to be a qualified pension, profit sharing or stock bonus plan under Section 401(a) of the Internal Revenue Code of 1986 and is not subject to the provisions of the Employee Retirement Income Security Act of 1974. The ESPP will terminate on January 15, 2033 unless sooner terminated. There were 168,469 shares initially authorized for issuance under the plan, and the first offering period commenced June 1, 2014 and ended on October 31, 2014. Subsequent offering periods will each be six months in duration and will commence on November 1st and May 1st each year.

Stock-Based Compensation

The Company recorded stock-based compensation expense in the condensed consolidated statements of comprehensive loss as follows:

(in thousands)	Three Months Ended March 31,	
	2015	2014
General and administrative	\$ 142	\$ 226
Research and development	163	265
	\$ 305	\$ 491

In addition, during the three months ended March 31, 2015, the Company recorded charges of \$0.4 million and \$0.4 million relating to the fair value of stock options which were modified due to executive retirement and restructuring activities, and classified them as general and administrative expenses and research and development expenses, respectively.

At March 31, 2015, the Company had \$2.0 million of total unrecognized stock-based compensation expense, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 1.8 years.

10. Restructuring Charges

Restructuring charges incurred during the three months ended March 31, 2015 primarily consist of severance and other post-termination benefit costs resulting from the cost reduction program implemented by the Company in January 2015. These activities primarily consisted of 20% reduction of the workforce. Per ASC 420-10-05-1, Exit or Disposal Cost Obligations, include, but are not limited to involuntary termination benefits provided to employees under the terms of a one-time benefit arrangement that, in substance, is not an ongoing benefit arrangement or a deferred compensation contract, and certain contract termination costs. Restructuring costs are expensed during the period in which the Company determines it will incur those costs and all requirements of accrual are met. The Company recorded approximately \$0.6 million in restructuring charges relating to such obligations during the first quarter, and expects to incur \$0.2 million in restructuring charges relating to such obligations during the second quarter, all of which represents costs expected to be incurred during 2015. In addition, certain contract termination costs of \$1.2 million were accrued as of December 31, 2014 relating to manufacturing activity that no longer had identifiable future benefit to the Company.

(in thousands)	Contract termination costs - R&D	Salaries and benefits - R&D	Salaries and benefits - G&A	Total
Balance as of December 31, 2014	\$ 1,185	\$ -	\$ -	\$ 1,185
Accrued	-	522	82	604
Paid	(479)	(257)	-	(736)
Balance as of March 31, 2015	\$ 706	\$ 265	\$ 82	\$ 1,053

As disclosed in Note 9, the Company recorded stock based compensation expense of \$0.4 million, classified as research and development expense, related to the fair value of stock options of a former executive which were modified such that they did not expire upon termination.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the Securities and Exchange Commission, or SEC, on March 16, 2015. This discussion contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Such forward looking statements involve risks and uncertainties. We use words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions to identify forward-looking statements. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. These statements appearing throughout this Quarterly Report on Form 10-Q are statements regarding our intent, belief, or current expectations, primarily regarding our operations. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, such as those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a biopharmaceutical company focused on monoclonal antibody therapeutics for diseases that are a significant burden to society and patients and their families. Our clinical development efforts going forward will be focused solely in oncology, including both hematologic malignancies and potentially solid tumors. Our principal pharmaceutical product candidates that we have advanced to the clinical development stage are:

- KB004, a Humaneered® anti-EphA3 monoclonal antibody that has the potential to offer a novel approach to treating both hematologic malignancies and solid tumors. In a Phase 1 dose escalation study KB004 was found to be generally safe and well tolerated and is currently enrolling patients in a Phase 2 cohort expansion study as a potential therapeutic for myelodysplastic syndrome (MDS) and myelofibrosis (MF).
- KB003 is a Humaneered®, recombinant monoclonal antibody (mAb) that neutralizes soluble granulocyte-macrophage colony-stimulating factor (GM-CSF), a critical cytokine for the growth of certain hematologic malignancies and solid tumors. KB003 is a GM-CSF antagonist with a favorable safety profile that has been studied in more than 90 subjects in clinical studies in either healthy adults or adults with autoimmune diseases. Given our strategic focus on oncology, and following discussions with clinical experts and regulatory agencies, the Company intends to initiate a Phase 1 clinical trial in CMML patients to assess the safety, pharmacokinetics, and activity of KB003 in 2015.
- KB001-A, a Humaneered®, PEGylated, anti-PcrV modified antibody fragment (Fab') antibody that was being developed for the prevention and treatment of *Pseudomonas aeruginosa* (*Pa*) infections in mechanically ventilated patients and cystic fibrosis (CF) patients with chronic *Pa* lung infections. However, based on results of the phase 2 data released in early 2015, we have discontinued development of this product in all indications.

In order to maintain adequate capital to fund the continued development of our product candidates, management continues to evaluate a number of alternatives, including but not limited to: (i) seeking additional partner(s) for our programs to provide capital for future development and to share in development costs, (ii) undertaking reductions in operating spending, and (iii) evaluating various means to raise additional capital, such as debt or equity offerings. Regardless of any actions we take to address our cash position in the near term, we will also need to raise additional capital in order to further advance our product candidates towards regulatory approval. If management is unsuccessful in these efforts, based on our current levels of operating spending our current capital may not be sufficient in some scenarios to fund our operations for the next twelve months.

From the date we commenced our operations through 2006, our efforts focused primarily on research, development, and the advancement of our Humaneered® antibody technology. In 2006, we commenced our first clinical trial. We have incurred significant losses to date and, as of March 31, 2015, we had an accumulated deficit of \$187.8 million. We have funded our operations primarily through private and public placements of our equity securities, contract revenue in connection with our collaborations, and grants and borrowings under equipment financing arrangements and our loan and security agreement. On February 5, 2013, we closed our initial public offering (IPO) of 8,750,000 shares of common stock at an offering price of \$8.00 per share, resulting in net proceeds of approximately \$61.5 million, after deducting underwriting discounts, commissions and offering expenses. On October 1, 2013 we closed a public offering of 8,625,000 shares of common stock at an offering price of \$4.00 per share, resulting in net proceeds of approximately \$32.0 million, after deducting underwriting discounts, commissions and offering expenses. As of March 31, 2015, we had cash, cash equivalents, and investments of \$30.2 million.

We expect to continue to incur net losses as we develop our drug candidates, expand clinical trials for our drug candidates currently in clinical development, expand our research and development activities, expand our systems and facilities, seek regulatory approvals, and engage in commercialization preparation activities in anticipation of Food and Drug Administration (FDA) approval of our drug candidates. Specifically, we have incurred substantial expenses in connection with our historical respiratory programs, most notably our Phase 2 clinical trial for KB003 in severe asthma patients inadequately controlled by corticosteroids, and our Phase 2 clinical trial of KB001-A in CF patients with chronic *Pa* infections. We have also incurred significant expenses on our ongoing Phase 1 and Phase 2 clinical trials for our KB004 oncology program, and expect to continue to incur significant costs on our oncology development programs going forward as we continue our current KB004 studies and as we evaluate additional potential oncology indications for both KB004 and KB003. Significant capital is required to continue to develop and to launch a product and many expenses are incurred before revenue is received, if any. We are unable to predict the extent of any future losses or when we will receive revenue or become profitable, if at all.

Past Collaborations

Sanofi

In January 2010, the Company and Sanofi entered into an agreement for the development and commercialization of KB001, the precursor to KB001-A, an investigational new biologic for the treatment and prevention of *Pseudomonas aeruginosa* (Pa) infections (the Sanofi agreement). Under the terms of the Sanofi agreement, the Company received an initial upfront non-refundable payment of \$35 million and received an additional non-refundable payment of \$5 million that represented a second installment of the upfront fees due to the Company under the agreement upon completion of a sublicense negotiation with a third party in August 2011. Sanofi was solely responsible for conducting, at its cost, the research, development, manufacture, and commercialization of the licensed products for the diagnosis, treatment and/or prevention of all human diseases and conditions caused by Pa, except that the Company retained responsibility, at the Company's cost, for developing and promoting the products for the diagnosis, treatment and/or prevention of Pa in patients with cystic fibrosis (CF) or bronchiectasis. Under the terms of the Sanofi agreement, the Company received specified research and development funding for services performed in connection with KB001-A research and development efforts and could have also received contingent payments based on the occurrence of development, regulatory or commercial events, and royalties on any product sales.

In July 2014, the Company and Sanofi executed an agreement (the Termination Agreement) under which the Sanofi agreement was terminated. As a result of the Termination Agreement, KaloBios regained full global rights to license, develop, manufacture and commercialize KB001-A in all indications, as well as a non-exclusive license to the KB001-A manufacturing process developed by Sanofi. In consideration for entering into the Termination Agreement, Sanofi will be entitled to royalties on net sales of KB001-A if approved, subject to a \$40 million cap on the aggregate royalties to be paid. In addition, Sanofi will be entitled to receive up to 10% of certain sub-license payments or other milestone payments received in the event KaloBios successfully re-partners KB001-A, subject to a separate \$40 million cap on the aggregate amount of sub-license payments to be shared with Sanofi.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of our financial statements in conformity with GAAP requires our management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. Our management believes judgment is involved in determining revenue recognition, the fair value-based measurement of stock-based compensation, accruals and warrant valuations. Our management evaluates estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the consolidated financial statements. If our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our statements of operations, liquidity and financial condition.

We are an emerging growth company under the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

There have been no significant and material changes in our critical accounting policies and use of estimates during the three months ended March 31, 2015, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" in our 2014 Annual Report on Form 10-K (File No. 001-35798), filed with the Securities and Exchange Commission (SEC) on March 16, 2015.

Results of Operations**General**

We have not generated net income from operations, except for the year ended December 31, 2007 during which we recognized a one-time license payment from Novartis. At March 31, 2015, we had an accumulated deficit of \$187.8 million primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, and research and development payments in connection with strategic partnerships, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Research and Development Expenses

Conducting research and development is central to our business model. We expense both internal and external research and development costs as incurred. We currently track external research and development costs incurred by project for each of our clinical programs (KB004, KB003, and KB001-A). We began tracking our external costs by project beginning January 1, 2008, and we have continued to refine our systems and our methodology in tracking external research and development costs. Our external research and development costs consist primarily of:

- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring and manufacturing clinical trial and other materials; and
- other costs associated with development activities, including additional studies.

Other research and development costs consist primarily of internal research and development costs such as salaries and related fringe benefit costs for our employees (such as workers compensation and health insurance premiums), stock-based compensation charges, travel costs, lab supplies, overhead expenses such as rent and utilities, and external costs not allocated to one of our clinical programs. Internal research and development costs generally benefit multiple projects and are not separately tracked per project. The following table shows our total research and development expenses for the three months ended March 31, 2015 and 2014, and for the period from January 1, 2008 to March 31, 2015:

(in thousands)	For the Three Months Ended March 31,		For the Period from January 1, 2008 to March 31, 2015
	2015	2014	
External costs:			
KB004	\$ 2,011	\$ 2,039	\$ 33,651
KB003	313	1,606	40,476
KB001-A	1,014	1,578	33,594
Internal costs	2,567	2,467	66,643
Total research and development	\$ 5,905	\$ 7,690	\$ 174,364

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development including continuing the Phase 2 expansion portion of our KB004 trial in hematologic malignancies, evaluating KB004 in potential solid tumor indications and evaluating KB003 in certain orphan oncology indications such as CMML. We also expect to continue to incur some costs in the first half of 2015 associated with concluding our Phase 2 clinical trial for our KB001-A CF program completed in January 2015. Historically, we have incurred significant costs related to our respiratory programs for KB001-A and KB003 and oncology for KB004. However, due to the termination of our respiratory programs, we expect our clinical development

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efforts going forward will be focused on the KB004 program, while we will continue to evaluate KB003 in certain orphan oncology indications such as CMML. As a result, we expect our research and development expenses will decrease in 2015 as compared to 2014. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential clinical trials and activities beyond the ongoing Phase 2 trial for KB004 and any trials we commence to evaluate KB003 in oncology indications such as CMML.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development.

Comparison of Three Months Ended March 31, 2015 and 2014

(in thousands)	Three Months Ended March 31,		Increase/ (Decrease)	
	2015	2014	in thousands	%
Operating expenses:				
Research and development	\$ 5,905	\$ 7,690	\$ (1,785)	-23%
General and administrative	3,437	2,470	967	39%
Loss from operations	(9,342)	(10,160)	818	-8%
Interest expense	(280)	(260)	(20)	8%
Interest income	16	14	2	14%
Other (expense) income, net	(16)	(2)	(14)	700%
Net loss	<u>\$ (9,622)</u>	<u>\$ (10,408)</u>	<u>\$ 786</u>	<u>-8%</u>

Research and development expenses decreased \$1.8 million, from \$7.7 million for the three months ended March 31, 2014 to \$5.9 million for the three months ended March 31, 2015. The decrease was primarily attributed to a \$1.3 million decrease in clinical trial expenses related to the completion of KB003 in severe asthma, \$0.6 million decrease resulting from the completion of our Phase 2 study of KB001-A in CF patients with chronic *Pa* infections in the first quarter of 2015, \$0.5 million decrease in milestone payments from the initiation of the Phase 2 KB004 program in Q1 2014, and \$0.2 million decrease in personnel related expenses, offset by \$0.9 million in restructuring charges which consisted of a 20% reduction in force. We expect external expenses on KB001-A will decrease significantly in 2015 as a result of the trial being completed in the first quarter of 2015 and our discontinuing development of KB001-A for CF patients with chronic *Pa* infections. In addition, we began enrollment of patients in a Phase 2 clinical trial in hematologic malignancies of KB004 in the first half of 2014, and as a result, we expect external costs for our KB004 program to increase in 2015. Overall, we expect a decrease in total research and development expense in 2015 as we focus our efforts on our oncology programs with KB004 and KB003.

General and administrative expenses increased \$1.0 million, from \$2.5 million for the three months ended March 31, 2014 to \$3.4 million for the three months ended March 31, 2015 due primarily to one-time charges of \$1.1 million for costs incurred due to the retirement of the CEO, and \$0.1 million in restructuring expenses, offset by a decrease of \$0.2 million in personnel related costs. With the exception of the one-time executive retirement and restructuring costs, we do not expect an increase in general and administrative expenses in 2015.

Interest expenses relate to our loan and security agreement with MidCap Financial entered into in September 2012 and amended in 2013. Interest income and other (expense) income, net, primarily consists of interest earned on our cash and cash equivalents, foreign currency gains and losses and realized gains and losses on the sale of investments.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through proceeds from the public offerings of our common stock, private placements of our preferred stock, debt financings, interest income earned on cash, and cash

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equivalents, and marketable securities, borrowings against lines of credit, and receipts from agreements with Sanofi and Novartis. At March 31, 2015, we had cash and cash equivalents and investments of \$30.2 million.

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

(in thousands)	Three Months Ended	
	March 31,	
	2015	2014
Net cash (used in) operating activities	\$ (9,015)	\$ (11,298)
Net cash provided by (used in) investing activities	12,011	(8,773)
Net cash (used in) financing activities	(1,295)	(752)
Net increase (decrease) in cash and cash equivalents	\$ 1,701	\$ (20,823)

Net cash used in operating activities was \$9.0 million and \$11.3 million for the three months ended March 31, 2015 and 2014, respectively. The primary use of cash in each of the periods was to fund our operations related to the development of our product candidates. Cash used in operating activities of \$9.0 million for the three months ended March 31, 2015 primarily related to our net loss of \$9.6 million, adjusted for non-cash items such as \$0.3 million of stock-based compensation expense, \$0.8 million relating to the fair value of stock options which were modified due to executive retirement and restructuring activities and net cash outflows of \$0.7 million related to changes in operating assets and liabilities. Cash used in operating activities of \$11.3 million for the three months ended March 31, 2014 primarily related to our net loss of \$10.4 million, adjusted for non-cash items such as \$0.5 million of stock-based compensation expense and net cash outflows of \$1.6 million related to changes in operating assets and liabilities..

Net cash provided by investing activities was \$12.0 million for the three months ended March 31, 2015, primarily related to proceeds from maturities of marketable securities of \$15.8 million partially offset by purchases of investments of \$3.7 million. Net cash used in investing activities was \$8.8 million for the three months ended March 31, 2014, primarily related to purchases of marketable securities of \$31.0 million offset by proceeds from maturities of marketable securities of \$22.5 million.

Net cash used in financing activities was \$1.3 million for the three months ended March 31, 2015, and \$0.8 million for the three months ended March 31, 2014, and consisted primarily of payments on our borrowings.

We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates. Specifically, we have incurred substantial expenses in connection with our Phase 2 clinical trial for KB001-A in CF patients with chronic *Pa* infections and expect to continue to incur additional costs as we wind that program down. In addition, we have incurred and expect to continue to incur significant costs as a result of our ongoing Phase 2 clinical trials for our KB004 development program in hematologic malignancies, as well as for any clinical trials we initiate to evaluate KB004 in other indications including potentially solid tumors and any trials we may initiate to evaluate KB003 as an oncology therapeutic.

In order to maintain adequate capital to fund the continued development of our product candidates, management continues to evaluate a number of alternatives, including but not limited to: (i) seeking additional partner(s) for our programs to provide capital for future development and to share in development costs, (ii) undertaking reductions in operating spending, and (iii) evaluating various means to raise additional capital, such as debt or equity offerings. Regardless of any actions we take to address our cash position in the near term, we will also need to raise additional capital in order to further advance our product candidates towards regulatory approval. If management is unsuccessful in these efforts, based on our current levels of operating spending our current capital may not be sufficient in some scenarios to fund our operations for the next twelve months. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm our business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. These conditions could raise substantial doubt about our ability to continue as a going concern. The report of our Independent Registered Public Accounting Firm included an explanatory paragraph about the Company's ability to continue as a going concern as included in our Annual Report on Form 10-K for the year ended December 31, 2014.

We will continue to require additional financing to develop our products and fund operations. We will seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- the scope, progress, expansion, costs, and results of our clinical trials;
- the timing of and costs involved in obtaining regulatory approvals;
- our ability to establish and maintain development partnering arrangements;
- the timing, receipt and amount of contingent, royalty, and other payments from Sanofi or any of our future development partners;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- our ability to draw funds from our current or any future loan and security agreement; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

Contractual Obligations and Commitments

On May 21, 2013, we entered into an agreement with a third party for the manufacturing of KB003 clinical supply for future clinical trials. Despite the termination of the KB003 development program in severe asthma during the first quarter of 2014, we are continuing to evaluate other potential indications for KB003. Under that agreement the third party will perform a range of related services, including process development, optimization, validation, formulation development, regulatory assistance, stability testing and related activities. In addition, we had entered into an agreement with a separate third party to produce supply of KB001-A. As of December 31, 2014, there were no remaining commitments for services and in February 2015, this agreement was cancelled.

As of March 31, 2015, there were no significant and material changes to our contractual obligations from those set forth in our Form 10-K filed with the Securities and Exchange Commission (SEC) on March 16, 2015.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

In accordance with our amended and restated certificate of incorporation and our amended and restated bylaws, we have indemnification obligations to our officers and directors for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. We have also entered into indemnification agreements with our directors, executive officers, and key employees. There have been no claims to date, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities or variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, since a majority of our investments are in short-term FDIC-insured government securities, and money market funds, we do not believe we are subject to any material market risk exposure. The fair value of our investments included in cash equivalents and marketable securities was \$27.9 million and \$39.3 million as of March 31, 2015 and December 31, 2014, respectively.

Our investment policy is to limit credit exposure through diversification and investment in highly rated securities. We, along with our investment advisors, actively review current investment ratings, company specific events, and general economic conditions in managing our investments and in determining whether there is a significant decline in fair value that is other-than-temporary. We monitor and evaluate our investment portfolio on a quarterly basis for other-than-temporary impairment charges.

We are also exposed to market risk related to fluctuations in interest rates indexed to LIBOR, which determines the variable interest payments made on our notes payable. However, we do not believe we are subject to any material market risk exposure related to this obligation.

We are also exposed to foreign currency exchange rate risk inherent in our contracts with research institutions and contract research organizations as certain services are performed by them outside the United States. While billed in US dollars by our vendors, our estimate of the amount owed may change until the vendor invoices us for the services rendered. We make our estimates for those services using our best estimate of costs incurred including the impact of foreign currency.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Management, including our Interim Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. Based upon the evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports we file and submit under the Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including our Interim Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

Risk Related to Our Business and the Development, Regulatory Approval, and Commercialization of Our Product Candidates

We will need substantial additional capital to develop and commercialize our product candidates, and we may be unable to raise additional capital when needed, or at all, which would force us to reduce or discontinue operations.

As of March 31, 2015, we had \$30.2 million in cash, cash equivalents, and investments. We utilized \$9.0 million of cash in operating activities during the three months ended March 31, 2015.

Our spending levels vary based on new and ongoing development and corporate activities. As a result, our cash used in operating activities will also fluctuate from period to period. We have not sold and do not expect to sell any product candidates or derive royalty revenue from product candidate sales for the foreseeable future, if ever. In order to develop and bring product candidates through approval for marketing, we must commit substantial resources to costly and time-consuming clinical trials. As such, we anticipate that we will need to raise substantial additional capital, primarily to advance our lead program, KB004, in clinical trials. The amount of capital we will require and the timing of our need for additional capital will depend on many other factors, including:

- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- the scope, progress, expansion, costs, and results of, or delays in, our clinical trials;
- the timing of and costs involved in obtaining regulatory approvals;
- our ability to establish and maintain development partnering arrangements and any associated funding;
- the timing, receipt and amount of contingent, royalty, and other payments from any future development partners;
- the emergence of competing products or technologies and other adverse market developments;
- the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the sourcing, timing, scope, progress, expansion, and costs of manufacturing our product candidates;
- the timing of repayment of current loans, and our ability to draw funds from any future loan and security agreement; and
- the costs associated with being a public company.

Since our inception, we have been financing our operations primarily through private placements and our initial and secondary public offerings of our equity securities, interest income earned on cash, cash equivalents, and marketable securities, borrowings from lines of credit, and payments under agreements with Sanofi and Novartis International

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Pharmaceutical Ltd. (together with its affiliates, Novartis), a licensee of our Humaneered® technology. Our future capital requirements are substantial and in order to fund our future needs, we may seek additional funding through equity or debt financings, development partnering arrangements, borrowings from lines of credit, or other sources. In order to maintain adequate capital to fund the continued development of our product candidates, management continues to evaluate a number of alternatives, including but not limited to: (i) seeking additional partner(s) for our programs to provide capital for future development and to share in development costs, (ii) undertaking reductions in operating spending, and (iii) evaluating various means to raise additional capital, such as debt or equity offerings. Regardless of any actions we take to address our cash position in the near term, we will also need to raise additional capital in order to further advance our product candidates towards regulatory approval. If management is unsuccessful in these efforts, based on our current levels of operating spending our current capital may not be sufficient in some scenarios to fund our operations for the next twelve months. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, could materially harm our business, financial condition and results of operations. Further, any failure to raise capital could be deemed a material adverse change under our loan and security agreement with MidCap Financial and that may, in turn, result in the lender declaring the loan in default and demanding repayment of the principal, accrued interest, the exit fee and a prepayment fee. These conditions could raise substantial doubt about our ability to continue as a going concern. The Report of Independent Registered Public Accounting Firm at the beginning of the Consolidated Financial Statements section of the Annual Report for the year ended December 31, 2014 on Form 10-K filed on March 16, 2015 included an explanatory paragraph about the Company's ability to continue as a going concern.

Our expectations are based on management's current assumptions and clinical development plans, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. We will require substantial additional capital to support clinical trials, regulatory approvals, and, if approved, the commercialization of our product candidates. Additional funding may not be available to us on a timely basis or at acceptable terms, if at all.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others our technologies, product candidates, or development programs that we would have preferred to develop and commercialize ourselves on less than favorable terms, if at all.

We have a history of operating losses, we expect to continue to incur losses, and we may never become profitable.

As of March 31, 2015, we had an accumulated deficit of \$187.8 million, and for the three months ended March 31, 2015, we incurred a net loss of \$9.6 million. We have incurred net losses each year since our inception except for the year ended December 31, 2007. To date, we have only recognized revenue from payments for funded research and development and for license or collaboration fees. We expect to make substantial expenditures and incur additional operating losses in the future to further develop and commercialize our product candidates. Our accumulated deficit is expected to increase significantly as we continue our development and clinical trial efforts. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our product candidates, either alone or with third parties. We do not currently have the required approvals to market any of our product candidates and we may never receive them. We may not be profitable even if we or any of our future development partners succeed in commercializing any of our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our product candidates are at an early stage of development and may not be successfully developed or commercialized. We have had to discontinue the development of prior product candidates.

Our product candidates are in the early stage of development and will require substantial clinical development, testing, and regulatory approval prior to commercialization. We currently only have one product candidate in Phase 2 clinical trials, KB004, and we have recently discontinued development of KB001-A in CF patients with Pa lung infections and KB003 in severe asthma. None of our product candidates have advanced into a pivotal study and it may be years before such a study is initiated, if at all. Of the large number of drugs in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that our product

candidates will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain regulatory approval for or, if approved, successfully commercialize, one or more of our product candidates, we may not be able to generate sufficient revenue to continue our business.

We may not be successful in establishing and maintaining additional development partnerships, which could adversely affect our ability to develop and commercialize product candidates.

We have recently announced our mutual agreement with Sanofi to terminate our prior development partnership for KB001-A. In addition to our prior partnership with Sanofi, a part of our strategy is to enter into development partnerships in the future, including collaborations with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate development partners and the negotiation process is time consuming and complex. Although our decision with Sanofi was mutual, we cannot predict the impact of that decision on the likelihood of our ability to enter into future partnerships for KB001-A or for our other programs. Moreover, we may not be successful in our efforts to establish a development partnership or other alternative arrangements for any of our other existing or future product candidates and programs because, among other reasons, our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new development partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into new development partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

Moreover, if we fail to establish and maintain additional development partnerships related to our product candidates:

- the development of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

Our loan and security agreement contains restrictions that limit our flexibility in operating our business.

In September 2012, we entered into a loan and security agreement with MidCap Financial and drew down \$5.0 million under the facility. In December 2012, we drew down an additional \$5.0 million under the facility, and in May 2014, we drew down the final \$5.0 million available under the facility. The agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur or assume certain debt;
- merge or consolidate;
- change the nature of our business;
- change our organizational structure or type;
- dispose of certain assets;

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- grant liens on our assets;
- make certain investments;
- pay dividends; and
- enter into material transactions with affiliates.

A breach of any of these covenants or a material adverse change to our business, operations, or condition (financial or otherwise) could result in a default under the loan. A material adverse change means a material impairment in the perfection or priority of the lender's lien in the collateral or in the value of the collateral; a material adverse change in the business, operations, or condition (financial or otherwise) of the Company, taken as a whole; or a material impairment of the prospect of repayment of any portion of the obligations. In the case of a continuing event of default under the loan, MidCap Financial could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to MidCap Financial under the loan. Amounts outstanding under the term loan are secured by all of our existing and future assets (excluding intellectual property, which is subject to a negative pledge arrangement). A default and any accompanying repayment could have a material adverse effect on our business, operating results and financial condition.

Because we have a short operating history developing clinical-stage antibodies, there is a limited amount of information about us upon which you can evaluate our product candidates and business prospects.

We commenced our first clinical trial in 2006, and we have a limited operating history developing clinical-stage antibodies upon which you can evaluate our business and prospects. In addition, as an early-stage clinical development company, we have limited experience in conducting clinical trials, and we have never conducted clinical trials of a size required for regulatory approvals. Further, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. For example, to execute our business plan we will need to successfully:

- execute our product candidate development activities, including successfully completing our clinical trial programs;
- obtain required regulatory approvals for the development and commercialization of our product candidates;
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals, manufacturing and commercialization;
- secure substantial additional funding;
- develop and maintain successful strategic relationships;
- build and maintain a strong intellectual property portfolio;
- build and maintain appropriate clinical, sales, distribution, and marketing capabilities on our own or through third parties; and
- gain market acceptance and favorable reimbursement status for our product candidates.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop product candidates, raise capital, expand our business, or continue our operations.

We have and may continue to experience delays in commencing or conducting our clinical trials, in receiving data from third parties or in the continuation or completion of clinical testing, which could result in increased costs to us and delay our ability to generate product candidate revenue.

Before we can initiate clinical trials in the United States for any new product candidates, we are required to submit the results of preclinical testing to the FDA as part of an Investigational New Drug (IND) application, along with other information including information about product candidate chemistry, manufacturing, and controls and our proposed clinical trial protocol. In doing so, we rely in part on preclinical, clinical, and quality data previously generated by other third parties for regulatory submissions. In addition, for our programs already underway, we are required to report or provide information to appropriate regulatory authorities in order to continue with our testing programs. If we are unable to make timely regulatory submissions for any of our programs, it will delay our plans for our clinical trials. If those third parties do not make the required data available to us, we will likely have to identify and contract with another CMO, and/or develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development. Moreover, despite the presence of an active IND for a product candidate, clinical trials can be delayed for a variety of reasons, including delays in:

- identifying, recruiting, and enrolling qualified subjects to participate in a clinical trial;
- identifying, recruiting, and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs) and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time, and may vary significantly among different CROs and trial sites;
- obtaining and maintaining sufficient quantities of a product candidate for use in clinical trials, either as a result of transferring the manufacturing of a product candidate to another site or manufacturer, deferring ordering or production of product in order to conserve resources or mitigate risk, having product in inventory become no longer suitable for use in humans, or other reasons that reduce or delay availability of drug supply;
- obtaining and maintaining institutional review board (IRB) or ethics committee approval to conduct a clinical trial at an existing or prospective site;
- retaining or replacing participants who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, or personal issues; readiness of any companion diagnostic necessary to ensure that the study enrolls the target population; or
- undergoing a clinical trial put on clinical hold at any time by the FDA during product candidate development.

Once a clinical trial has begun, recruitment and enrollment of subjects may be slower than we anticipate. Numerous companies and institutions are conducting clinical studies in similar patient populations which can result in competition for qualified patients. In addition, clinical trials will take longer than we anticipate if we are required, or believe it is necessary, to enroll additional subjects. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an Institutional Review Board (IRB), an ethics committee, or a data safety monitoring committee overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities;
- inability to provide timely supply of drug product;

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- unforeseen safety issues, known safety issues that occur at a greater frequency or severity than we anticipate, or any determination that the clinical trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial.

Additionally, if any of our future development partners do not develop the licensed product candidates in the time and manner that we expect, or at all, the clinical development efforts related to these licensed product candidates could be delayed or terminated. In addition, our ability to enforce our partners' obligations under any future collaboration efforts may be limited due to time and resource constraints, competing corporate priorities of our future partners, and other factors.

Any delays in the commencement of our clinical trials may delay or preclude our ability to further develop or pursue regulatory approval for our product candidates. Changes in U.S. and foreign regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may affect the costs, timing, and likelihood of a successful completion of a clinical trial. If we or any of our future development partners experience delays in the completion of, or if we or any of our future development partners must terminate, any clinical trial of any product candidate our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

Our product candidates are subject to extensive regulation, compliance with which is costly and time consuming, may cause unanticipated delays, or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, approval, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indications. Approval policies or regulations may change and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit, or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or other comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our or any of our future development partners' clinical trials;
- we or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the use of results from antibody studies that served as precursors to our current drug candidates;

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- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any of our future development partners contract for clinical and commercial supplies;
- we may not be successful in developing any companion diagnostic necessary to demonstrate efficacy in our desired target populations for KB004;
- such authorities may delay approval or clearance of any companion diagnostic for KB004; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary widely among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods, and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased caution by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us, or any of our future development partners from commercializing our product candidates.

The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate we or any of our future development partners advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Drug development has substantial inherent risk. We or any of our future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy for approval by regulatory authorities in larger patient populations. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of a New Drug Application (NDA) or BLA to the FDA and even fewer are approved for commercialization.

For example, we recently announced the termination of development in *Pa* lung infections in CF patients of KB001-A, our most advanced product candidate, because the Phase 2 study we were conducting did not meet its primary or secondary endpoints, despite promising results in prior studies of a precursor molecule, KB001. In early 2014, we announced termination of development in severe asthma of KB003, also based on negative Phase 2 results despite earlier positive data from studies of KB002, a precursor molecule.

Furthermore, our Phase 2 expansion trial for KB004, currently enrolling and underway, may not be successful.

If we fail to attract and retain key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to effectively manage our managerial, operational, financial, and other resources in order to successfully pursue our clinical development and commercialization efforts. As a company with a limited number of personnel, we are highly dependent on the expertise of the members of our senior management. We recently announced the retirement of David W. Pritchard, our president and chief executive officer, and in a subsequent reduction in force we announced the elimination of our chief medical officer position. We cannot predict the impact of the loss of such individuals or the loss of services of any of our other senior management, should they occur. Such losses could delay or

prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business.

Our success also depends on our continued ability to attract, retain, and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to recent events, intense competition among biotechnology and pharmaceutical companies, universities, and research organizations for qualified personnel. We have initiated a search for permanent chief executive officer and at this time do not plan to replace the chief medical officer position, although we are actively recruiting for additional senior staff with oncology expertise in light of our dedication to oncology. If we are unable to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

If we fail to effectively integrate any new executive officers into our organization, the future development and commercialization of our product candidates may suffer, harming future regulatory approvals, sales of our product candidates or our results of operations.

We are currently conducting a search for a permanent chief executive officer. There can be no assurance that we can identify and hire such a candidate on a timely basis, or at all. Even if we are successful in locating a permanent chief executive officer, that person will not have worked with our senior executive team. Our future performance will depend, in part, on our ability to successfully integrate any newly hired chief executive officer into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate this individual and create effective working relationships among the members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

Any product candidate we or any of our future development partners advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent its regulatory approval or commercialization or limit its commercial potential.

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn could prevent us from completing development or commercializing the affected product candidate and generating revenue from its sale. For example, we observed fatal intracranial hemorrhages in two subjects deemed possibly related to the study drug by the study investigator in our KB004 Phase 1 clinical trial and, as a result, we amended our clinical protocol, which caused a delay in our program.

We have not yet successfully completed testing of any of our product candidates for the treatment of the indications for which we intend to seek approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in individuals who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product candidate.

If we pursue development of a companion diagnostic intended to identify patients who are likely to benefit from treatment with KB004, failure to obtain approval for the diagnostic may prevent or delay approval of KB004.

We are in the initial phases of developing an in vitro EphA3 diagnostic, currently in the CLIA validated laboratory format, which is intended to identify patients who are likely to benefit from KB004. We have amended our study protocol prior to initiation of the Phase 2 expansion phase to include EphA3 positive tumor status as an inclusion criterion.

The FDA regulates companion diagnostics such as the one we are developing as medical devices. FDA regulations pertaining to medical devices govern, among other things, the research, design, development, pre-clinical and clinical testing, manufacture, safety, efficacy, storage, record-keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution, and import and export of medical devices. Pursuant to the Federal Food, Drug, and

Cosmetic Act (FDC Act), medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the controls the FDA determines necessary to reasonably ensure their safety and efficacy. In July 2011, the FDA issued a draft guidance that stated that if safe and effective use of a therapeutic depends on an in vitro diagnostic, then the FDA generally will not approve the therapeutic product until it is ready to approve or clear the in vitro companion diagnostic device. It is possible that KB004 may not be approved until the FDA has sufficient information to also approve or clear our companion device. Moreover, the FDA's expectations for in vitro companion diagnostics are evolving and some aspects of the FDA's regulatory approach remain unclear. The FDA's developing expectations will affect, among other things, the development, testing and review of any in vitro companion diagnostics.

Because our companion diagnostic candidate is at an early stage of development, and because we have not yet decided whether to pursue a reference lab-based test or a kit, we have yet to seek a meeting with the FDA to discuss our companion diagnostic test in development. We therefore do not yet know what the FDA will require for this test. We may not be able to develop or obtain approval or clearance for the companion diagnostic, and any delay or failure to obtain regulatory approval or clearance could delay development or prevent approval of KB004.

If our competitors develop treatments for the target indications of our product candidates that are approved more quickly, marketed more successfully or demonstrated to be safer or more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies as well as with new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product candidate development, manufacturing, and marketing resources than we do. Large pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists, and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites, and registering subjects for clinical trials, and in identifying and in-licensing new product candidates.

Competition in cancer drug development including hematology/oncology is intense, with more than 250 compounds in clinical trials by large pharmaceutical and biotechnology companies. Many of these companies are focused on targeted therapies. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available. In addition, the development program that we undertake may change from time to time due to clinical or non-clinical results, competitive developments, regulatory changes, recruitment, resource or other constraints in running clinical studies and other factors.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

We are, and will for the foreseeable future continue to be, wholly dependent on third party contract manufacturers for the timely supply of adequate quantities of our products which meet or exceed requisite quality and production standards for use in clinical and nonclinical studies. Given the extensive risks, scope, complexity, cost, regulatory requirements and commitment of resources associated with developing the capabilities to manufacture one or more of our products, we have no present plan or intention of developing in-house manufacturing capabilities for nonclinical, clinical or commercial scale production, beyond our current supervision and management of our third party contract manufacturers. In addition, in order to balance risk and conserve financial and human resources, we have and may continue from time to time to defer commitment to production of product, which could result in delays to the continued progress of our clinical and nonclinical testing.

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In addition to the foregoing, the process of manufacturing our products is complex, highly regulated and subject to several risks, including but not limited to the following:

- The process of manufacturing biologics is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.
- The manufacturing facilities in which our products are made could be adversely affected by equipment failures, plant closures, capacity constraints, competing customer priorities or changes in corporate strategy or priorities, process changes or failures, changes in business models or operations, materials or labor shortages, natural disasters, power failures and numerous other factors.
- We are wholly dependent upon third party CMOs for the timely supply of adequate quantities of requisite quality product for our nonclinical, clinical and, if approved by regulatory authorities, commercial scale production.
- We, and our contract manufacturers, must comply with the FDA's current Good Manufacturing Practice (cGMP) regulations and guidelines. We, and our contract manufacturers, may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We, and our contract manufacturers, are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.
- Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business will be limited.

A substantial amount of our effort is focused on the continued clinical testing and potential approval of our current product candidates and expanding our product candidates to serve other indications of unmet medical needs. Research programs to identify other indications require substantial technical, financial and human resources, whether or not any product candidates for other indications are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;

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- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- A product candidate may not be accepted as safe and effective by patients, the medical community or third-party payers, if applicable.

If we do not successfully develop and commercialize product candidates for other indications, our business and future prospects may be limited and our business will be more vulnerable to problems that we encounter in developing and commercializing our current product candidates.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenue that it generates may be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved product candidates will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians, major operators of hospitals and clinics, and patients of the product candidate as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, and patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Market acceptance and sales of our product candidates will depend significantly on the availability of adequate insurance coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product candidate is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product candidate from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical, and cost effectiveness data for the use of our product candidates to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. If reimbursement is not available or is available only to limited levels or with restrictions, we may not be able to commercialize certain of our product candidates profitably, or at all, even if approved.

In the United States and in certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could affect our ability to sell our product candidates profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methods for many product candidates under Medicare. This has resulted in lower rates of reimbursement. There have been numerous other federal and state initiatives designed to reduce payment for pharmaceuticals.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide coverage of approved product candidates for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations, and additional legislative proposals as well as country, regional, or local healthcare budget limitations.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any product candidates we may successfully develop, we may not be able to effectively market and sell any such product candidates.

We do not currently have any infrastructure for the sale, marketing, and distribution of any of our product candidates once approved, if at all, and we must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any product candidates for which we may obtain approval. The establishment and development of a sales force, either by us or jointly with a development partner, or the establishment of a contract sales force to market any product candidates we may develop will be expensive and time consuming and could delay any product candidate launch. If we or any of our future development partners are unable to establish sales and marketing

capabilities or any other nontechnical capabilities necessary to commercialize any product candidates we may successfully develop, we will need to contract with third parties to market and sell such product candidates. We may not be able to establish arrangements with third parties on acceptable terms, if at all.

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any product candidates for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or any of our future development partners by participants enrolled in our clinical trials, patients, health care providers, or others using, administering, or selling our product candidates. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to trial participants or other claimants;
- decreased demand for our product candidates and loss of revenue;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials domestically and in selected foreign countries where we are conducting clinical trials. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for product candidates to include the sale of commercial products if we obtain marketing approval for our product candidates in development; however, we may be unable to obtain commercially reasonable product liability insurance for any product candidates approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our working capital and adversely affect our business.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability, and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Our recent history may result in an increase in premium costs or otherwise affect the terms of coverage available to us. Any significant, uninsured liability may require us to pay substantial amounts, which would adversely affect our working capital and results of operations.

Our employees may engage in misconduct or other improper activities including noncompliance with regulatory standards and requirements and insider trading.

As with any business, we are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to regulatory authorities, comply with manufacturing standards we have established, comply with federal and state health care fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

In addition, during the course of our operations our directors, executives, and employees may have access to material, nonpublic information regarding our business, our results of operations, or potential transactions we are considering. We may not be able to prevent a director, executive, or employee from trading in our common stock on the basis of, or while having access to, material, non-public information. If a director, executive, or employee was to be investigated or an action was to be brought against a director, executive, or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials we will need to expand our development, regulatory, manufacturing, marketing, and sales capabilities, and contract with third parties to provide these capabilities for us. As our operations expand we expect that we will need to manage additional relationships with various development partners, suppliers, and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend in part on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively. We may not be able to accomplish these tasks and our failure to accomplish any of them could prevent us from successfully growing our company.

We and our future development partners, third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time consuming or costly.

We and our future development partners, third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations and the operations of our development partner, third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling, and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Our internal computer systems, or those of our future development partner, third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our development partner, third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

Healthcare reform measures, when implemented, could hinder or prevent our commercial success.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of health care and containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- the demand for any drug products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Governments may impose price controls, which may adversely affect our future profitability.

We intend to seek approval to market our future product candidates in both the United States and in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product candidates. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We and any of our future development partners will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we and any of our future development partners are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and any of our future development partners report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our future development partners may fail to report adverse events we become aware of within the prescribed timeframe. We and any of our future development partners may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an

adverse event that is unexpected or removed in time from the use of our products. If we and any of our future development partners fail to comply with our reporting obligations, the FDA or a foreign regulatory authority could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as part of the Affordable Care Act, an abbreviated pathway for the approval of dissimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Finally, there is a risk that the 12-year exclusivity period could be reduced which could negatively affect our products.

In addition, foreign regulatory authorities may also provide for exclusivity periods for approved biological products. For example, biological products in Europe may be eligible for a 10-year period of exclusivity. However, biosimilar products have been approved under a sub-pathway of the centralized procedure since 2006. The pathway allows sponsors of a biosimilar product to seek and obtain regulatory approval based in part on the clinical trial data of an originator product to which the biosimilar product has been demonstrated to be “similar.” In many cases, this allows biosimilar products to be brought to market without conducting the full suite of clinical trials typically required of originators. It is unclear whether we and our development partner would face competition to our products in European markets sooner than anticipated.

We may in the future be subject to various U.S. federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

If one or more of our product candidates is approved, we will likely be subject to the various U.S. federal and state laws intended to prevent health care fraud and abuse. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The False Claims Act (FCA) imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or

other arrangements were determined to violate the FCA or anti-kickback or related laws, then our revenue could be adversely affected, which would likely harm our business, financial condition, and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans or Corporate Integrity Agreements, and have often become subject to consent decrees severely restricting the manner in which they conduct their business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

Also, the Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties, or prosecution and have a negative impact on our business, results of operations and reputation.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market, and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our current product candidates or any future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- additional studies, including clinical studies;
- recall, replacement, or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory approvals for any future products would harm our business, financial condition, and results of operations.

Even if we are able to obtain regulatory approval for our product candidates, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, such as continued safety reporting requirements, and we may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls or seizures.

If the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for our products will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the products, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the foreseeable future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these losses to offset income before such unused losses expire. Under Section 382 of the Internal Revenue Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have in the past experienced ownership changes that have resulted in limitations on the use of a portion of our net operating loss carryforwards. If we experience further ownership changes our ability to utilize our net operating loss carryforwards could be further limited.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. Therefore, the timing of the initiation and completion of these trials is uncertain and may occur on substantially different timing from our estimates. We also use clinical research organizations (CROs) to conduct our clinical trials and rely on medical institutions, clinical investigators, CROs, and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Our CROs, investigators, and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data.

There is no guarantee that any CROs, investigators, or other third parties on which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed, or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer those subjects to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

We rely completely on third parties, most of which are sole source suppliers, to supply drug substance and manufacture drug product for our clinical trials and preclinical studies and intend to rely on other third parties to produce commercial supplies of product candidates, and our dependence on third parties could adversely impact our business.

We are completely dependent on third-party suppliers, most of which are sole source suppliers of the drug substance and drug product for our product candidates. We are continually evaluating potential alternate sources of supply but there can be no assurance that any such suppliers would be available, acceptable or successful. If these third-party suppliers do not supply sufficient quantities for product candidates to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there could be a significant interruption of our supplies, which would adversely affect clinical development of the product candidate. Furthermore, if any of our contract

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manufacturers cannot successfully manufacture material that conforms to our specifications and with regulatory requirements, we will not be able to secure and/or maintain regulatory approval, if any, for our product candidates.

We will also rely on our contract manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials used to manufacture our product candidates. We do not have any control over the process or timing of the acquisition of these raw materials by our contract manufacturers. Moreover, we currently do not have agreements in place for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial could considerably delay completion of that clinical trial, product candidate testing, and potential regulatory approval of that product candidate.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed product candidates if approved, and will likely continue to be dependent on third-party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved product candidates may adversely affect our ability to develop and commercialize our product candidates on a timely basis.

Having recently terminated our development partnership with Sanofi, we will not continue development or commercialization of KB001-A without a future development partner. Our development and/or commercialization of KB004, KB003 and any other future products may also depend in whole or in part on a future development partner. Our inability to successfully identify and enter into a development partnership, or the failure of any new partner to develop and/or commercialize one or more of our products, could result in a material adverse effect on our business and operating results.

In 2014, we announced the mutual termination of our exclusive license to Sanofi of KB001, KB001-A and other antibodies directed against the PerV protein of *Pa* for all indications for most aspects of their development and commercialization. Before that termination, we were dependent on Sanofi to carry out its contractual obligations, and did not have significant control over their efforts or the outcome of those efforts. Now that our development partnership with Sanofi on KB001-A or other antibodies has terminated, we will not continue further development of KB001-A unless we enter into a new partnership(s) for that further development of KB001-A. We also intend to explore development and/or commercial partnerships for KB004 and any other of our future products. Any new partnership for one or more of our products, assuming we are able to successfully identify and enter into such a transaction(s), may not be scientifically, medically, technically or commercially successful due to a number of important factors, including the following:

- Regardless of the standard of effort required under any new partnership agreement, any new partner will likely have significant discretion in determining the efforts and resources that it will apply to the development and commercialization of our product;
- The timing and amount of any contingent, royalty or other payments we may receive under any new agreement have yet to be determined and will depend on, among other things, the efforts, allocation of resources, and successful development and commercialization of our product candidate by the new partner under any such agreement;
- A new partner, if any, may change the focus of its development and commercialization efforts or pursue higher- priority programs;
- A new partner, if any, may not make timely regulatory submissions;
- The terms of any new partnership agreement have yet to be identified, and may not be optimal for us in any number of respects, including but not limited to the amount, timing and contingencies associated with any payments or funding to us; the degree of control or influence we may have over any partners' efforts; the indications, territories, responsibilities, rights, obligations and recourse available to us under any partnership agreement; and the other economic and non-economic terms of any partnership agreement;

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- If a new partner negotiates for clinical supply manufacturing rights, such partner may fail to manufacture or supply sufficient drug substance of our product for our clinical use, which could result in program delays;
- If a new partner negotiates for commercial supply manufacturing rights, such partner may fail to manufacture or supply sufficient drug substance of our product for our commercial use, if approved, which could result in delays and lost revenue;
- Any new partner may utilize our intellectual property rights or take actions related to licensed products in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- Any new partner may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- If a new partner were to breach or terminate any agreement with us, the development and commercialization of our product could be delayed. We would need to either use our own resources and capabilities to continue the development and commercialization of our product or grant rights to another development or commercial partner, which may not be available on reasonable terms, or at all;
- If any new partner were to terminate any future partnership arrangements with us, our potential revenue under such an agreement, including from potential development and commercial contingent payments and royalties on net sales of licensed products, would be significantly reduced or eliminated; and
- Any new partner may not dedicate the resources that would be necessary to carry the product candidate through clinical development or may not obtain the necessary regulatory approvals to market our product.

Our or any new partner's failure to develop, manufacture or effectively commercialize our product would result in a material adverse effect on our business and results of operations and would likely cause our stock price to decline.

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, we may not have adequate resources to devote to the substantial costs of enforcing intellectual property rights in affected jurisdictions. Any failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Composition-of-matter patents on the biological or chemical active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. Although we have received issued patents providing composition of matter protection, we cannot be certain that the claims in our pending or future patent applications covering composition-of-matter of our product candidates will be considered patentable by the U.S. Patent and Trademark Office (USPTO) and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Method-of-use patents protect the use of a product for the specified method. This type of patent does not

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prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued, with or without oppositions being filed by competitors or other third parties;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates.

Furthermore, we and our development partners rely on the protection of our trade secrets and proprietary know-how. For example, we rely on Novartis, to whom we have licensed our Humaneered® platform, to protect our trade secrets and proprietary know-how that has been licensed to them. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants, and advisors, third parties may still obtain this information or may come upon this or similar information independently. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

Additionally, in the U.S., the central provisions of the Leahy-Smith America Invents Act (AIA) became effective on March 16, 2013. Among other things, this law will switch U.S. patent rights from the present “first-to-invent” system to a “first inventor-to-file” system. This may result in inventors and companies having to file patent applications more frequently to preserve rights in their inventions. This may favor larger competitors that have greater resources to file more patent applications.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over

the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

If we or any of our future development partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability and the ability of any of our future development partners to develop, manufacture, market, and sell our product candidates without infringing upon the proprietary rights of third parties. Numerous U.S.-issued and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing product candidates, some of which may contain claims that overlap with the subject matter of our intellectual property or are directed at our product candidates. When we become aware of patents held by third parties that may implicate the manufacture, development or commercialization of our product candidates, we evaluate our need to license rights to such patents. For example, we have entered into several licenses for the right to use third-party intellectual property, including with UCSF and LICR. If we need to license rights from third parties to manufacture, develop or commercialize our product candidates, there can be no assurance that we will be able to obtain a license on commercially reasonable terms or at all.

Because patent applications can take many years to issue there may be currently pending applications, unknown to us, that may later result in issued patents upon which our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers, or development partners infringe upon a third party's intellectual property rights, we may have to:

- seek to obtain licenses that may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages including, in an exceptional case, treble damages and attorneys' fees, which we may have to pay if a court decides that the product candidate or proprietary technology at issue infringes upon or violates the third party's rights;
- pay substantial royalties or fees and/or grant cross-licenses to our technology; and/or
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Any such claims against us could also be deemed to constitute an event of default under our loan and security agreement with MidCap Financial. In the case of a continuing event of default under the loan, MidCap Financial could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, commence and prosecute bankruptcy and/or other insolvency proceedings, or proceed against the collateral granted to MidCap Financial under the loan.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe upon our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology, or enter into development partnerships that would help us bring our product candidates to market.

In addition, any future patent litigation, interference, or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us, or any of our future development partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all.

Our issued patents could be found invalid or unenforceable if challenged in court.

If we or any of our future development partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

We may fail to comply with any of our obligations under existing agreements pursuant to which we license rights or technology, which could result in the loss of rights or technology that are material to our business.

We are a party to technology licenses that are important to our business and we may enter into additional licenses in the future. We currently hold licenses from the Medical College of Wisconsin, UCSF, LICR, BioWa, Lonza, and Sanofi. These licenses impose various commercial, contingent payments, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we would lose valuable rights under our collaboration agreements and our ability to develop product candidates.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to us.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, or may have previously or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that our company or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming, and inherently

uncertain. In addition, Congress may pass patent reform legislation. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and we intend to seek patent protection only in selected countries. Our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Common Stock

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. For example, on September 3, 2013 we entered into an At-the-Market Issuance Sales Agreement with MLV & Co. LLC (MLV) under which, subject to certain conditions, we may offer and sell shares of our common stock having an aggregate offering price of up to \$50,000,000 from time to time through MLV, acting as agent. On October 1, 2013, we completed a secondary offering of common stock which resulted in dilution of our existing shareholders. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance could result in further dilution to our stockholders.

Any future debt financing may involve covenants that restrict our operations, including, among other restrictions, limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to grant potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements.

The report of our Independent Registered Public Accounting Firm included an explanatory paragraph about the Company's ability to continue as a going concern in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 stating that our recurring net losses at December 31, 2014 raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. We may also be forced to make reductions in spending, including delaying or curtailing our ongoing or future clinical programs. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

We previously identified and have remediated a material weakness in our internal control over financial reporting. Any failure to maintain effective internal control over financial reporting could result in our failure to meet our reporting obligations and cause investors to lose confidence in our reported financial information, which in turn could cause the trading price of our common stock to decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, our management was required to report upon the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014. When and if we are no longer an "emerging growth company," as defined in the Securities Exchange Act of 1934, as amended (the Exchange Act), our independent registered public accounting firm will also be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting.

Although we have determined that our internal control over financial reporting was effective as of March 31, 2015, as indicated in our Management Report on Internal Control over Financial Reporting, included in our Quarterly Report on Form 10-Q for the three months ended March 31, 2015, we must continue to monitor and assess our internal control over financial reporting. If our management identifies one or more material weaknesses in our internal control over financial reporting in the future and such weakness remains uncorrected at fiscal year-end, we will be unable to assert such internal control is effective at fiscal year-end. If we are unable to assert that our internal control over financial reporting is effective at fiscal year-end (or if our independent registered public accounting firm concludes that we have a material weakness in our internal controls or, after we are no longer an emerging growth company, is unable to express an opinion on the effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports, which would likely have an adverse effect on our business and stock price.

Our stock price is volatile and purchasers of our common stock could incur substantial losses.

Our stock price is volatile and from January 31, 2013, the first day of trading of our common stock, to May 1, 2015, our stock had high and low sales prices in the range of \$8.25 to \$0.36 per share. The market price of our common stock may fluctuate significantly in response to a number of factors. These factors include those discussed in this "Risk Factors" section of this report and others such as:

- delay or failure in initiating or completing preclinical studies or clinical trials, or unsatisfactory results of these trials and the resulting impact on ongoing product development;

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- announcements regarding equity or debt financing transactions;
- sales or potential sales of substantial amounts of our common stock;
- announcements about us or about our competitors including clinical trial results, regulatory approvals, or new product candidate introductions;
- developments concerning our development partner, licensors or product candidate manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries and the economy as a whole;
- governmental regulation and legislation;
- recruitment or departure of members of our board of directors, management team or other key personnel;
- changes in our operating results;
- any financial projections we may provide to the public, any changes in these projections, our failure to meet these projections, or changes in recommendations by any securities analysts that elect to follow our common stock;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations; and
- price and volume fluctuations in the overall stock market or resulting from inconsistent trading volume levels of our shares.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnological companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

In a particular case, following the announcement of our failed Phase 2 study of KB001-A, on February 23, 2015, we received a notice of possible delisting from The NASDAQ Stock Market LLC ("NASDAQ") indicating that, based on the our closing bid price for the last 30 consecutive business days, we were not compliant with the minimum bid price requirement of \$1.00 per share, as set forth in NASDAQ Listing Rule 5550(a)(2). In order to regain compliance, the minimum closing bid price per share of our common stock must be at least \$1.00 for a minimum of ten consecutive business days. We are evaluating possible measures to return our share price to above \$1.00 for this period so that our listing will not be affected. We have a grace period of 180 calendar days, or until August 19, 2015, to regain compliance with the minimum closing bid price requirement for continued listing. There can be no assurance that we will be successful in regaining compliance with the NASDAQ listing requirements. Any delisting of our shares could affect the liquidity of our stock.

An active trading market for our common stock may not develop or be sustained or may be volatile.

We have a limited number of shares publicly available for purchase. An active trading market may not develop or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. In addition, the public market for our shares may be extremely volatile in light of the results of our

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operations, our limited resources, the number of products we may have in development at any given time, and numerous other factors.

Substantial future sales of shares by existing stockholders, or the perception that such sales may occur, could cause our stock price to decline.

If our existing stockholders, particularly our directors and executive officers and the venture capital funds affiliated with our current and former directors, sell substantial amounts of our common stock in the public market, or are perceived by the public market as intending to sell substantial amounts of our common stock, the trading price of our common stock could decline significantly. As of March 31, 2015, we had 32,992,178 shares of common stock outstanding. In addition, as of March 31, 2015, we have also registered 5,168,260 shares of our common stock that we may issue under our equity plans. Once we issue these shares, they can be freely sold in the public market upon issuance, subject to any vesting restriction or Rule 144 transfer restrictions applicable to affiliates.

Certain holders of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for our stockholders or ourselves. These shares will be able to be sold freely in the public market upon issuance.

If securities analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities and industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes unfavorable research about our business, or if our clinical trials or operating results fail to meet the analysts' expectations, as recently occurred with respect to KB001-A and KB003 and their respective Phase 2 study results, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Requirements associated with being a public reporting company will continue to increase our costs significantly, as well as divert significant company resources and management attention.

We have only been subject to the reporting requirements of the Exchange Act and the other rules and regulations of the Securities and Exchange Commission (SEC) since August 2012. We are working with our legal, independent accounting, and financial advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public reporting company. These areas include corporate governance, corporate control, disclosure controls and procedures, and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. Compliance with the various reporting and other requirements applicable to public reporting companies will require considerable time, attention of management, and financial resources. In addition, the changes we make may not be sufficient to allow us to satisfy our obligations as a public reporting company on a timely basis.

Further, the listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

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In addition, being a public company could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

We have never paid and do not intend to pay cash dividends and, consequently, your ability to achieve a return on your investment in our common stock will depend on appreciation in the price of our common stock.

We have never paid cash dividends on any of our capital stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our business. Additionally, our loan and security agreement with MidCap Financial contains covenants that restrict our ability to pay dividends. Therefore, you are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on an investment in our common stock will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which you purchased it.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our directors, executive officers, and the holders of more than 5% of our common stock together with their affiliates beneficially own approximately 31% of our common stock as of March 31, 2015. These stockholders, acting together, may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

As a public company, our stock price has been volatile, and securities class action litigation has often been instituted against companies following periods of volatility of their stock price. Any such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

In the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has sometimes been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Anti-takeover provisions in our charter documents and Delaware law, could discourage, delay, or prevent a change in control of our company and may affect the trading price of our common stock.

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay, or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and amended and restated bylaws:

- provide that vacancies on our board of directors, including newly created directorships, may be filled only by a majority vote of directors then in office;
- do not provide stockholders with the ability to cumulate their votes; and
- require advance notification of stockholder nominations and proposals.

We are an emerging growth company and the extended transition period for complying with new or revised financial accounting standards and reduced disclosure and governance requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). If we do, the information that we provide stockholders may be different than what is available with respect to other public companies.

Investors could find our common stock less attractive because we will rely on these exemptions, which may make it more difficult for investors to compare our business with other companies in our industry. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, it may be difficult for us to raise additional capital as and when we need it. If we are unable to do so, our financial condition and results of operations could be materially and adversely affected.

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenue of \$1 billion or more during such fiscal year, (iii) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period or (iv) December 31, 2017, the end of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement filed under the Securities Act.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

Not Applicable.

Item 6. Exhibits

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q, and is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KALOBIOUS PHARMACEUTICALS, INC.

Date: May 11, 2015

By: /s/ Herb C. Cross

Herb C. Cross
Interim Chief Executive Officer
(Principal Executive Officer)

Date: May 11, 2015

By: /s/ Herb C. Cross

Herb C. Cross
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit No.	Description
10.1**	Amendment to Termination Agreement, by and between KaloBios Pharmaceuticals Inc. and Sanofi Pasteur S.A., dated as of July 24, 2014.
31.1	Certification of Chief Executive Officer of the Registrant, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer of the Registrant, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification by the Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).
32.2†	Certification by the Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

** Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. Omitted portions have been submitted separately to the Securities and Exchange Commission.

† The Certifications attached as Exhibits 32.1 and 32.2 that accompanies this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of KaloBios Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

CONFIDENTIAL TREATMENT REQUESTED
TERMINATION AGREEMENT

This Termin **CONFIDENTIAL PORTIONS OF THIS DOCUMENT
REDACTED AND SEPARATELY FILED WITH THE**

COMMISSION.ation Agreement (the “Termination Agreement”) is made effective as of July 24, 2014 (the “Termination Agreement Effective Date”) between **KaloBios Pharmaceuticals, Inc.**, a Delaware corporation, with its principal place of business at 442 Littlefield Ave., South San Francisco, California, U.S.A. 94080 (“**KaloBios**”), and **Sanofi Pasteur S.A.**, a company organized and existing under the laws of the Republic of France, having offices located at 2, avenue Pont Pasteur, 69007 Lyon, France (“**Sanofi**”). KaloBios and Sanofi are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties.**”

RECITALS

WHEREAS, Sanofi and KaloBios entered into a Development, Commercialization Collaboration and License Agreement effective as of January 8, 2010, which was amended by Amendment No. 1 made effective January 1, 2012, and by Amendment No. 2 made effective July 1, 2012, (collectively the “Agreement”) pursuant to which the Parties agreed to collaborate to develop products to treat or prevent *Pseudomonas aeruginosa* infections and related indications, including ventilator associated pneumonia, cystic fibrosis, and bronchiectasis; and

WHEREAS, Sanofi has determined that it desires to terminate the Agreement at will, as it is entitled to do under Section 13.3 of the Agreement; and

WHEREAS, the Parties desire to confirm and agree on certain aspects of the termination of the Agreement as set forth below.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Termination Agreement, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

The following terms shall have the meanings provided, whether in the singular or plural form. Capitalized terms not defined below shall have the meanings given in the Agreement. In the event of any inconsistency between any terms defined in this Termination Agreement and those defined in the Agreement, the terms set out in this Termination Agreement shall prevail and govern.

1.1 “**Collaboration Term**” refers to that period of time beginning on January 8, 2010 and ending on the Termination Agreement Effective Date.

1.2 “**Field**” means the diagnosis, treatment and/or prophylaxis of all human diseases and conditions caused by *Pseudomonas aeruginosa* or otherwise associated with *Pseudomonas aeruginosa* infections.

1.3 “**First Commercial Sale**” means the first sale to a Third Party of a Licensed Product by KaloBios (including its Affiliates and any successor(s)), or its licensees or sub-licensees or any of their respective agents or distributors, in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction.

1.4 “**KaloBios Field**” means the diagnosis, treatment and/or prophylaxis of *Pseudomonas aeruginosa* in patients with either Cystic Fibrosis or Bronchiectasis.

**CONFIDENTIAL PORTIONS OF THIS DOCUMENT REDACTED AND
SEPARATELY FILED WITH THE COMMISSION.**

CONFIDENTIAL TREATMENT REQUESTED

1.5 “**KaloBios Know-How**” means all Know-How that is Controlled by KaloBios or its Affiliates, which is necessary for the Development, manufacture and/or Commercialization of a Licensed Product.

1.6 “**KaloBios Patent**” means any Patent that (a) is Controlled by KaloBios or its Affiliates and (b) claims the composition of matter, manufacture or use of a Licensed Product, which would be infringed by the manufacture, use or sale of such Licensed Product by a Third Party. KaloBios Patents existing as of the Termination Agreement Effective Date are set forth on **Exhibit B** to be incorporated by reference.

1.7 “**Licensed Product**” means any Antibody incorporating any KaloBios Technology that (a) has been raised, engineered or otherwise targeted or optimized to bind specifically and directly to PcrV (whether exclusively or in addition to any other target such Antibody may modulate) and (b) competes for binding to PcrV with a naturally occurring receptor of PcrV, or, once bound to the PcrV, exhibits antagonistic activity against PcrV, agonist activity against PcrV, ADCC (antibody dependent cellular cytotoxicity) and/or other [***], including [***] KB001, KB001-A or another anti-*Pa* Antibody targeting PcrV.

1.8 “**Net Sales**” means the gross amount invoiced by KaloBios (including its Affiliates and any successor(s)), or its licensees, sub-licensees, or any of their respective agents or distributors on account of sales of Licensed Product to Third Parties (including without limitation Third Party distributors and wholesalers), less the total of each of the following, in each case to the extent actually incurred or allowed and not already deducted, credited or otherwise reflected in the amount invoiced:

- (a) trade, cash and/or quantity discounts, credits, allowances, rebates and returns (including, but not limited to, wholesaler and retailer returns);
- (b) excise, sales and other consumption taxes and customs duties and other compulsory payments made to government authorities to the extent included in the invoice price;
- (c) amounts repaid or credited by reason of rejections, defects, recalls or returns or because of charge-backs, retroactive price reductions, refunds or billing errors; and
- (d) sales commissions actually paid to any Third Party and non-employee wholesalers and distributors.

Each of the deductions set forth above shall be reasonable and customary, and shall be determined on an accrual basis in accordance with applicable generally acceptable accounting standards or US GAAP, consistently applied and as applicable to the booking of such sales for a particular country.

1.9 “[***] **Milestones**” shall have the meaning given in Section [***] below.

1.10 “**Royalty Cap**” means Forty Million United States Dollars (US\$40,000,000).

1.11 “**Royalties**” shall have the meaning given in Section 3.1(a) below.

1.12 “**Sanofi Field**” means the Field, but excluding the KaloBios Field.

1.13 “**Sanofi Know-How**” means all Know-How that is Controlled by Sanofi or its Affiliates as of the Termination Agreement Effective Date and is necessary for the Development, manufacture and/or Commercialization of a Licensed Product.

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1.14 “**Sanofi Patent**” means any Patent that (a) is Controlled by Sanofi or its Affiliates as of the Termination Agreement Effective Date (including Sanofi’s interest in any Joint Patents), and (B) claims the composition of matter, manufacture or use of a Licensed Product.

1.15 “**Sanofi Technology**” means the Sanofi Patents and Sanofi Know-How.

1.16 “**Sublicense[***] Cap**” means Forty Million United States Dollars (US\$40,000,000).

1.17 “**Sublicense Revenue**” shall have the meaning given in Section 3.2 below.

1.18 “**Successful Completion**” shall have the meaning given in Section 3.3 below.

1.19 “**Third Party Agreements**” means any or all agreements between Sanofi, its Affiliates and Third Parties, relating solely to the Development, manufacture or Commercialization of Licensed Products as listed in **Exhibit A** attached hereto.

1.20 “**Transition Completion Date**” [***]

ARTICLE 2

TERMINATION; TIMING; EFFECT

2.1 Termination. Pursuant to Section 13.3 of the Agreement, Sanofi hereby notifies KaloBios that it is terminating the Agreement at will. The Parties agree that the effective date of such termination shall be the Termination Agreement Effective Date, as stated on the first page hereof, and KaloBios hereby waives any further notice of such termination.

2.2 Consequences of Termination By Sanofi. The Parties intend and agree that Section 13.4 and 13.9 of the Agreement are superseded in their entirety by Sections 2.2 and 2.3 hereof. The Parties further agree to use reasonable efforts to accomplish the transitions called for in this Section 2.2 and elsewhere in this Termination Agreement as soon as reasonably possible, but in any event by the Transition Completion Date.

(a) Regulatory Filings; Data. Sanofi shall transfer, assign or otherwise make available to KaloBios all Regulatory Filings, Regulatory Approvals, and related preclinical, analytical, and clinical data and all Materials generated by or on behalf of Sanofi, its Affiliates (or its licensees and sublicensees) developed pursuant to the Agreement during the Collaboration Term and, in the case of the license to Sanofi Technology granted to KaloBios under subsection (e) below, necessary for the Development, manufacture and/or Commercialization of Licensed Products throughout the Territory. Sanofi agrees that it will, effective as of the date hereof, begin to transfer, assign or otherwise make available to KaloBios that specific data and Materials required to be transferred, assigned or otherwise made available to KaloBios under this Section 2.2(a) of this Termination Agreement and otherwise as agreed by the Parties through the transition process. Sanofi will prepare and provide as soon as practical following the Termination Agreement Effective Date, a complete list of such data and Materials by the Transition Completion Date, which list shall be incorporated by reference herein. Sanofi shall expressly indicate on the lists it provides to KaloBios which information and/or materials are assigned to KaloBios (i.e. the ownership is transferred and Sanofi will no longer utilize) and which information and/or materials are made available to KaloBios (i.e. the ownership in which is retained by Sanofi, but KaloBios may use for Development and Commercialization of Licensed Product in accordance with this Termination Agreement). KaloBios agrees that Sanofi (i) shall provide, on request, copies of records, data and materials supporting summaries or slides previously provided, but (ii) shall have

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no obligation to transfer any original records, data and materials already delivered to KaloBios during the Collaboration Term.

(b) Manufacturing Process. Sanofi shall make available, through the non-exclusive license granted to KaloBios pursuant to section 2.2(e) below, the manufacturing process for the Licensed Products to KaloBios or its designee (which will be designated as soon as reasonably practical but in no event later than the Transition Completion Date). The Parties will develop and agree on a written technology transfer plan, with scope, deliverables and timelines. For greater certainty, the term "technology transfer" as used herein means a transfer of documents and Materials and does not include hands-on training or assistance other than being reasonably available to respond to questions. Further, Sanofi shall indicate which information and/or Materials are assigned to KaloBios and which information and/or Materials may be accessed by KaloBios through the non-exclusive license granted to it pursuant to section 2.2(e) below. The Parties agree that they will begin the manufacturing process technology transfer called for under this Section 2.2(b) immediately following the Termination Agreement Effective Date, such transfer to be completed by the Transition Completion Date [***]. For greater certainty, Sanofi shall have no obligation to transfer any information regarding the manufacturing process that Sanofi was granted access to under any agreement with [***].

(c) Third Party Agreements. Sanofi shall, at the request of KaloBios, assign to KaloBios any or all Third Party Agreements, to the extent permissible under the terms of such agreements. Sanofi represents and warrants that attached hereto as Exhibit A is an initial list of all Third Party Agreements, for KaloBios review and decision on whether to accept assignment of one or more of those Third Party Agreements, to the extent permissible under the respective Third Party Agreement. Sanofi will provide an update to Exhibit A, if any, by the Transition Completion Date. Upon receiving any necessary consent to do so, Sanofi will provide KaloBios with copies of all such Third Party Agreements. For greater certainty, KaloBios acknowledges that it will not receive copies of any such agreements until the Third Party in question has consented to such disclosure if required under the terms of the applicable agreement. Sanofi will take reasonable steps to provide or pass through any services to KaloBios under Third Party Agreements, consistent with their terms, until any requested consent to assignment has been received or a new, direct agreement with KaloBios is in place; provided however that KaloBios shall reimburse Sanofi for the cost of any such Third Party services engaged on their behalf and approved in advance by KaloBios for services during the period beginning on the Termination Agreement Effective Date and ending on the Transition Completion Date.

(d) Marks; Other Intellectual Property. As of the Termination Agreement Effective Date, Sanofi represents and warrants that there are no Marks relating solely to Licensed Products existing and available to transfer to KaloBios.

(e) Sanofi License. Sanofi hereby grants to KaloBios, effective on the Termination Agreement Effective Date, a [***] license under Sanofi Technology to Develop, make, have made, use, sell, offer for sale, have sold, import and otherwise Commercialize Licensed Products in the Sanofi Field or in the KaloBios Field, as the case may be, in the Territory. The Parties agree and acknowledge that the economic terms of the license provided under this Subsection 2.2(e) are provided for in Article 3 of this Termination Agreement.

(f) Interim Supply. The Parties agree that any inventories of KB001-A and/or [***] (as defined in the Agreement) in Sanofi's or its Affiliates or subcontractors' possession are hereby assigned to KaloBios and Sanofi shall cooperate with KaloBios to transfer such inventories to KaloBios or its designee as soon as KaloBios or its designee confirms that it is ready to receive such Materials following the Termination Agreement Effective Date. The Parties agree that Sanofi's obligations regarding supply of Licensed Product under the Agreement are terminated as of the Termination Agreement Effective Date and no further notice of termination, for example, of the Supply Agreement between the Parties dated as of October 10, 2010, as amended, is necessary, and that KaloBios waives the right to any such notice under that Supply Agreement.

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(g) **Transition Assistance.** Sanofi shall provide such assistance, at no cost to KaloBios, as may be reasonably necessary or useful for KaloBios to commence or continue Developing or Commercializing Licensed Products in the Sanofi Field in the Territory, to the extent Sanofi is then performing or having performed such activities, including transferring or amending as appropriate, upon request of KaloBios, any agreements or arrangements with Third Party vendors with respect to Licensed Products. To the extent that any such contract between Sanofi and a Third Party is not assignable to KaloBios, then Sanofi shall reasonably cooperate with KaloBios to arrange to continue to and provide such services from such entity. In no event shall Sanofi be required to perform any transition assistance after the Transition Completion Date.

(h) **Confidential Information.** With the exception of Sanofi's Confidential Information transferred, assigned or licensed to KaloBios pursuant to Sections 2.2(a) and 2.2(e), each Party agrees to destroy all written copies of the other Party's Confidential Information (as that term is defined in the Agreement) acquired from the Party during the Collaboration Term, provided that each Party shall be entitled to retain a complete copy of all such Confidential Information for purpose of ensuring compliance with its obligations herein, and further provided that neither Party shall be required to delete from any servers or other electronic archiving devices any Confidential Information from the other Party. The Parties agree that as of the Termination Agreement Effective Date, neither of them shall use the Confidential Information (as that term is defined in the Agreement) of the other Party except as expressly permitted under surviving clauses of the Agreement and this Termination Agreement.

(i) **Transfer Costs; Permits.** With regard to the physical transfer of any information and/or Materials pursuant to this Section 2.2, the Parties will agree in advance on shipping or transfer method, timing, destination and an estimate of out-of-pocket costs to do so. KaloBios will pay directly or reimburse Sanofi for all out-of-pocket shipping costs approved in advance by KaloBios, and will be responsible at its cost for obtaining any necessary permits to allow such transfer. Sanofi shall cooperate reasonably in any such permitting process.

2.3 Survival. The Parties confirm that except as expressly provided for in this Termination Agreement, only the following provisions of the Agreement shall survive termination of the Agreement Articles 1, 11, 12 (as modified herein), 14 and 15; Sections 8.10, 9.1, 10.3, 10.4, 13.7, and 13.8.

ARTICLE 3

PAYMENTS; PAYMENT CAPS

3.1 Royalties.

(a) As a consequence of termination of the Agreement, including the license to Sanofi Technology granted under Section 2.2(e) hereof, KaloBios shall pay Sanofi tiered royalties on Net Sales of Licensed Product in the Territory, as follows (the "**Royalties**"), subject to the Royalty Cap: (i) [***] percent ([***]%) of the first \$[***] in cumulative Net Sales of Licensed Products in the Territory; and (ii) [***] percent ([***]%) of cumulative Net Sales of Licensed Products in excess of \$[***].

(b) The Royalties shall be payable upon First Commercial Sale on a country-by-country basis, until [***] ([***]) years from First Commercial Sale. Such royalties shall be reduced, on a country-by-country basis, by [***] percent ([***]%) in the event and for so long as KaloBios's total royalty obligations for sales of Licensed Product in that country exceed [***] percent ([***]%).

3.2 Sublicense Revenue. In addition to the Royalty payments described above, subject to the Sublicense [***] Cap, KaloBios shall pay to Sanofi (a) [***] percent ([***]%) of all [***] actually received by KaloBios for the license, sublicense, transfer (other than by Acquisition) or assignment of the right to sell or

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otherwise distribute Licensed Product [***] anywhere in the Territory, and (b) [***] percent ([***]%) of all [***] actually received by KaloBios for the license, sublicense, transfer (other than by Acquisition) or assignment of the right to sell or otherwise distribute Licensed Product [***] anywhere in the Territory (collectively, “**Sublicense Revenue**”). Sublicense Revenue shall mean any [***] payments actually made to KaloBios, but shall not include [***] of Licensed Products [***] to the extent made in return for [***] including but not limited to [***].

3.3 [*] Milestones.** [***] while this Termination Agreement is in effect, and [***] entered into a [***] (“**[***] Milestones**”) to [***] for any [***] occurring after the [***] of such [***]. Each [***] by [***] to [***] hereunder shall be [***] only on the [***] of such [***]. For purposes of this Section, “**Successful Completion**” means, for any applicable [***] achievement of the [***] for such [***] as specified in the applicable [***]. If in a calendar year, [***] achieves more than [***] milestone, then the [***] shall be [***]. For example, if the [***] occurrence of [***] in a single calendar year are [***] (and [***] were not achieved in any previous year), then [***] and [***] shall be [***] in a [***].

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(c) Notwithstanding any other provision of this Termination Agreement, (i) the total payments of Royalties that KaloBios or its Affiliates (or any successor thereof) shall be obligated to pay to Sanofi will not in any event exceed the Royalty Cap, and (ii) the total payments of Sublicense Revenue [***] that KaloBios shall be obligated to pay to Sanofi shall not exceed the Sublicense[***] Cap.

(d) The first Royalty payment shall be made within [***] days following the end of the calendar quarter in which any event triggering a Royalty payment first occurs (e.g. if First Commercial Sale of a Licensed Product occurs on January 30th in a given year, Sanofi shall receive the corresponding Royalty payment by no later than May 30th of the same year). For all subsequent Royalty payments, payment shall be made within [***] days following the end of the calendar quarter in which the Net Sales for such quarter have been earned by KaloBios (e.g. for KaloBios' Net Sales earned from January 1st to March 31 in a given year, Sanofi shall receive the corresponding Royalty payment by no later than May 30th of the same year). Royalty payments shall be made by KaloBios to Sanofi to such account as Sanofi may direct in writing. Each Royalty payment shall be accompanied by an itemized written report showing the basis on which the Royalty payment amount(s) were calculated. If no Royalty payment is due to Sanofi for such reporting period, the report shall state this. In respect of all payments due to Sanofi hereunder, except for Royalty payments or service payment reimbursements, KaloBios shall remit such payments to Sanofi, to such account as Sanofi may direct in writing, within [***] days of the occurrence of any event under Article 3 obligating KaloBios to make a payment to Sanofi (other than Royalty payments) without having received any invoice from Sanofi. With regard to payments by KaloBios to Sanofi as reimbursement for services engaged by Sanofi on KaloBios' behalf in accordance with Sub-section 2.2(c) hereof, KaloBios shall remit such payments to Sanofi, to such account as Sanofi may direct in writing, within fourteen (14) days of receipt of Sanofi's invoices for such services.

All payments due to Sanofi hereunder shall be paid in Dollars and made by wire transfer of immediately available funds into an account designated by Sanofi. Any payments or portions thereof due hereunder that are not received by Sanofi on the date such payments are due under this Termination Agreement shall bear interest at a rate equal to the lesser of: (a) [***], or any successor thereto, at 12:01 a.m. on the first day of each calendar quarter in which such payments are overdue; or (b) the [***], in each case calculated on the number of days such payment is delinquent, compounded monthly.

To the extent a Party disputes any amount hereunder it shall immediately notify the other Party. If a payment is found to be in error due to the accounting of KaloBios, interest shall be payable as set out above from the period of the initial due date until the dispute is resolved.

(e) The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be made at the average of the daily closing exchange rates reported in *The Wall Street Journal* (U.S., Western Edition) over the applicable reporting period for the payment due.

(f) KaloBios will maintain complete and accurate records in sufficient detail to permit Sanofi to confirm the correct amount of all payments owed under this Termination Agreement including all Royalty, Sublicense Revenue and [***]. Upon reasonable prior notice, such records shall be available during regular business hours for a period of [***] from the end of the calendar year to which they pertain for examination at the expense of Sanofi, and not more often than once each calendar year, by an independent certified public accountant selected by Sanofi and reasonably acceptable to KaloBios, for the sole purpose of verifying the correct amount of the [***] Sublicense Revenue and Royalty payments owed by KaloBios pursuant to this Termination Agreement. Any such auditor shall not disclose KaloBios' Confidential Information to Sanofi or any Third Party, except to the extent such disclosure is necessary to accomplish such purpose. Any amounts shown to be owed but unpaid shall be paid by KaloBios in accordance with Subsection 3.5(d) following receipt of the accountant's report. Sanofi shall be responsible for the full cost of such audit unless such audit discloses an underpayment by KaloBios of more than [***] percent ([***]%) of the amount due, in which case KaloBios shall be responsible for the full cost of such audit.

3.6 Taxes.

(a) **Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes it is liable for.

(b) **Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by KaloBios to Sanofi under this Termination Agreement. To the extent KaloBios is required to deduct and withhold taxes on any payment to Sanofi, KaloBios shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner, deduct this amount from the payment due to Sanofi and promptly transmit to Sanofi evidence of such withholding sufficient to enable Sanofi to claim any amount allowed by its own tax authorities. In order to benefit from the provisions of the double tax treaty between France and the United States, Sanofi will complete and sign the Certificate of Residence and Application for a Reduction of Withholding Tax on Royalties forms or such other applicable forms and send them to KaloBios immediately upon the Termination Agreement Effective Date and every January thereafter. In the event Sanofi fails to promptly provide such forms duly completed and signed, KaloBios will notify Sanofi in writing to the address listed in Section 6.5, that it must send such forms to KaloBios. If, after thirty (30) days of such written notice to Sanofi, KaloBios has not received such documents, KaloBios will declare and pay withholding tax at the common rate of the applicable corporate income tax, and such tax will then be deducted from the corresponding payment by KaloBios to Sanofi, and proof of payment will be sent to Sanofi as evidence of such payment.

3.7 Non-Monetary Consideration. In the event KaloBios receives any non-monetary consideration in connection with the sale of a Licensed Product, KaloBios's payment obligations under this Article 3 shall be based on the fair market value of such other consideration. In such case, KaloBios shall disclose the terms of such arrangement to Sanofi and the Parties shall endeavor in good faith to agree on such fair market value.

3.8 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country, royalties accrued in that country shall be paid to Sanofi in Dollars based on the Dollar reported sales for the quarter in accordance with applicable Laws and accounting standards, unless otherwise mutually agreed.

ARTICLE 4

INTELLECTUAL PROPERTY

4.1 Ownership of Inventions. Each Party represents and warrants that lists of the Sole Inventions of that Party, of any Joint Inventions and any Joint Patents, each as of the Termination Agreement Effective Date, will be provided to the other Party as soon as practical following the Termination Agreement Effective Date but in any event not later than the Transition Completion Date, and will be attached hereto as Exhibits C (KaloBios' Sole Inventions), D (Sanofi's Sole Inventions), E (Joint Inventions) and F (Joint Patents), respectively, and are incorporated by this reference. Each Party may practice any Joint Inventions listed in Exhibit D in any field on a cost-free, non-exclusive basis in the Territory, without obligation to report to the other Party.

4.2 Notification. KaloBios shall promptly notify Sanofi in writing if it becomes aware of any (1) existing or threatened misuse of any Sanofi Technology, or (2) any allegation of infringement or misappropriation made by a Third Party in connection with the manufacture, use, sale or importation of a Licensed Product made

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under the license granted by Sanofi herein, and shall share with Sanofi any available information relating to such notice.

4.3 Publications.

(a) Sanofi and KaloBios may jointly or separately publish data generated by them collectively or individually during Collaboration Term, provided that the Party wishing to publish provides the other Party a draft copy of any proposed public disclosure at least [***] in advance of the proposed submission date and the receiving Party shall have the right to require modifications of the proposed public disclosure in order to (a) to protect KaloBios' Confidential Information and/or Sanofi Confidential Information, as the case may be; (b) for [***] reasons or [***] reasons; and/or (c) to delay such submission for an additional [***] as may be reasonably necessary to seek patent protection for the information disclosed in such proposed public disclosure (if applicable).

(b) KaloBios shall have the right to publish data generated by KaloBios using the Sanofi Technology following the Termination Agreement Effective Date, provided that KaloBios provides a draft copy of any proposed public disclosure to Sanofi [***] in advance of the proposed submission date and Sanofi shall have the right to require modifications of the proposed public disclosure in order to (a) to protect Sanofi's Confidential Information; (b) for [***] reasons or [***] reasons; and/or (c) to delay such submission for an additional [***] as may be reasonably necessary to seek patent protection for the information disclosed in such proposed public disclosure (if applicable).

ARTICLE 5

MUTUAL RELEASES

5.1 Mutual General Release.

(a) In consideration for the release provided in Section 5.1(b) of this Termination Agreement, and effective upon the Termination Agreement Effective Date, KaloBios, for itself and its Affiliates, predecessors, successors, assigns, officers, directors, shareholders, agents, employees, and representatives, past or present, and all persons acting under, by, through, or with any of them (collectively, the "KaloBios Releasers"), hereby releases and forever discharges Sanofi and its Affiliates, predecessors, successors, assigns, officers, directors, shareholders, agents, employees, and representatives, past or present, and all persons acting under, by, through, or with any of them (collectively, the "Sanofi Releasees") from any and all actions, causes of action, obligations, costs, expenses, damages, losses, claims, liabilities, suits, debts, demands, and benefits (including attorneys' fees and costs) of whatever character, in law or in equity, known or unknown, suspected or unsuspected, of any kind or nature whatsoever, based on any act, omission, event, occurrence, or nonoccurrence from the beginning of the world to the day of the Termination Agreement Effective Date, including but not limited to any claims or causes of action arising out of or in any way relating to the Agreement, the Parties' entering into the Agreement, and the Parties' respective performance of their obligations under the Agreement, excluding only any claims or rights arising out of the performance of the Parties' respective obligations under this Termination Agreement including any provisions of the Agreement surviving in accordance with the terms of Section 2.3 hereof.

(b) In consideration for the release provided in Section 5.1(a) of this Termination Agreement, and effective upon the Termination Agreement Effective Date, Sanofi, for itself and its Affiliates, predecessors, successors, assigns, officers, directors, shareholders, agents, employees, and representatives, past or present, and all persons acting under, by, through, or with any of them (collectively, the "Sanofi Releasers"), hereby releases and forever discharges KaloBios and its Affiliates, predecessors, successors, assigns, officers, directors, shareholders, agents, employees, and representatives, past or present, and all persons acting under, by, through, or with any of them (collectively, the "KaloBios Releasees") from any and all actions, causes of action, obligations, costs,

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expenses, damages, losses, claims, liabilities, suits, debts, demands, and benefits (including attorneys' fees and costs) of whatever character, in law or in equity, known or unknown, suspected or unsuspected, of any kind or nature whatsoever, based on any act, omission, event, occurrence, or nonoccurrence from the beginning of the world to the day of the Termination Agreement Effective Date, including but not limited to any claims or causes of action arising out of or in any way relating to the Agreement, the Parties' entering into the Agreement, and the Parties' respective performance of their obligations under the Agreement, excluding only any claims or rights arising out of the performance of the Parties' respective obligations under this Termination Agreement including any provisions of the Agreement surviving in accordance with the terms of Section 2.3 hereof.

(c) In addition to the provisions of Sections 5.1(a) and 5.1(b) of this Termination Agreement, KaloBios hereby expressly waives and releases any and all defenses, rights, and benefits that it or any of the other KaloBios Releasers might have in relation to any of the Sanofi Releasees, and Sanofi hereby expressly waives and releases any and all defenses, rights, and benefits that it or any of the other Sanofi Releasers might have in relation to any of the KaloBios Releasees, under or by virtue of any laws or statutes relating to the release of unknown claims, such as or similar to § 1542 of the California Civil Code, which reads:

Section 1542 Certain Claims Not Affected by General Release A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his settlement with the debtor.

KaloBios or Sanofi may hereafter discover facts other than or different from those that it now knows or believes to be true with respect to the subject matter of the releases in this section, but each of KaloBios and Sanofi hereby expressly waives and fully, finally, and forever settles and releases any known or unknown, suspected or unsuspected, contingent or non-contingent claim against the Sanofi Releasees and the KaloBios Releasees, respectively, whether or not concealed or hidden, without regard to the subsequent discovery or existence of such different or additional facts.

ARTICLE 6

CONFIDENTIALITY

6.1 Confidential Information under this Termination Agreement. Except to the extent expressly authorized by this Termination Agreement or otherwise agreed in writing by the Parties, each Party agrees it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Termination Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Termination Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

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(d) is subsequently disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure; or

(e) is subsequently independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of the disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

6.2 Definition. The Parties agree that the term "Confidential Information" as used in this Termination Agreement means any and all information communicated in writing, orally or visually or in any tangible or electronic form or media, and any full or partial copies thereof, disclosed by the disclosing Party relating to, but not limited to, business plans and strategy, research and development (including but not limited to pre-clinical studies and current and future clinical trials), relationships with Third Parties, technology, trade secrets, Know-How, proprietary information, inventions (whether or not patentable), unpublished Patent applications, licenses, software, programs, prototypes, designs, analysis codes, discoveries, techniques, methods, ideas, concepts, data, engineering and manufacturing information, procedures, specifications, diagrams, drawings, schematics, blue prints, parts lists, and samples, and financial information including sales and royalties, and also the confidential information of any Third Party which is disclosed to the disclosing Party and is in turn disclosed to the receiving Party or otherwise learned by visual or other inspection. The Parties agree that the information in any technology transfer plan or other document disclosing Sanofi Technology is also Confidential Information under this Termination Agreement.

6.3 Confidential Information under the Agreement. The Parties agree that the term "Confidential Information" as defined in the Agreement shall apply to information exchanged between the Parties during the Collaboration Term and also includes all Confidential Information disclosed under the Non-Disclosure or Confidentiality Agreements dated March 30, 2009 and August 1, 2009 between the Parties. Such Confidential Information under the Agreement shall be subject to the Agreement's requirements of confidentiality as contained in Article 12 of the Agreement, for a period of [***] from the Termination Agreement Effective Date (except with regard to any Confidential Information which is a trade secret of either Party, in which case, the receiving Party's obligation to hold such information in confidence shall be of indefinite duration or unless and until such information is no longer a trade secret).

ARTICLE 7

MISCELLANEOUS

7.1 Entire Agreement; Amendment. This Termination Agreement, including the Exhibits hereto or incorporated by reference herein, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Termination Agreement Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein, with respect to the subject matter of this Agreement. No subsequent alteration, amendment, change or addition to this Termination Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

7.2 Publicity; Terms of Agreement.

(a) The Parties agree that the terms of this Termination Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 7.2 and Section 7.3. The Parties shall communicate and use reasonable efforts to agree on key messages associated with this

CONFIDENTIAL TREATMENT REQUESTED

Termination Agreement. If either Party desires to make a public announcement or news release concerning this Termination Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and comment (except as otherwise provided herein), which the disclosing Party will consider in good faith. The Parties agree that the public announcement of the execution of this Termination Agreement will be made by a KaloBios press release immediately following such execution. In the case of a public disclosure required by Law, the disclosing Party shall provide the other Party with a reasonable time to review and comment on such proposed disclosure, and in any event the reviewing Party shall not unreasonably withhold its approval of such proposed disclosure. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Termination Agreement that have already been publicly disclosed by such Party, or by the other Party, in accordance with this Section.

(b) The Parties acknowledge that either or both Parties may be obligated to file a copy of this Termination Agreement (and/or provide a summary disclosure thereof) with the United States Securities and Exchange Commission or other Government Authorities, including but not limited to tax authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of any such summary thereof and/or this Termination Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.

7.3 Authorized Disclosure. Notwithstanding the obligations set forth in Section 7.2 and the Agreement, a Party **may** disclose the other Party's Confidential Information and the terms of this Termination Agreement to the extent:

(a) such disclosure is reasonably necessary: (i) to such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to the receiving Party, provided that in each such case on the condition that such directors, attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with those contained in this Termination Agreement; or (ii) to actual or potential investors, licensees, sub-licensees and/or acquirers solely for the purpose of evaluating an actual or potential investment or acquisition; provided that in each such case on the condition that such actual or potential investors and/or acquirers are bound by confidentiality and non-use obligations consistent with those contained in this Termination Agreement and having a minimum duration of at least [***] (and of indefinite duration with regard to disclosure of any trade secrets, unless and until such information is no longer a trade secret); or

(b) such disclosure is required by Law or judicial or administrative process, provided that in such event such Party shall promptly inform the other Party such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed as required by Law or judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article, and the Party disclosing Confidential Information pursuant to Law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order to ensure the continued confidential treatment of such Confidential Information.

7.4 Force Majeure. Each Party shall be excused from the performance of its obligations under this Termination Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition **constituting** force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Termination Agreement, force majeure shall include conditions beyond the reasonable control of the nonperforming Party, including an act of God or terrorism, voluntary or involuntary

CONFIDENTIAL TREATMENT REQUESTED

and not to any particular provision hereof and (d) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Termination Agreement.

7.7 Assignment. Neither Party may assign or transfer this Termination Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment **without** the other Party's consent to an Affiliate or Acquirer of such Party or to a successor to substantially all of the business of such Party. Any permitted successor or assignee of rights and/or obligations hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section shall be null, void and of no legal effect.

7.8 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Termination Agreement, and shall cause its Affiliates to comply with the provisions of this Termination Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Termination Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

7.9 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and **to** do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Termination Agreement.

7.10 Severability. If any one or more of the provisions of this Termination Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall **be** considered severed from this Termination Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Termination Agreement may be realized.

7.11 No Waiver. Any delay in enforcing a Party's rights under this Termination Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of **its** rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

7.12 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Termination Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the **other** Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

7.13 English Language; Governing Law. This Termination Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Termination Agreement. This Termination Agreement and all disputes arising out of or related to this Termination Agreement or any breach **hereof** shall be governed by and construed under the Laws of the State of New York, USA, without giving effect to any choice of law principles that would require the application of the Laws of a different jurisdiction.

7.14 Compliance. In carrying out its rights and obligations hereunder, each Party shall comply with all applicable **Laws**.

7.15 Counterparts. This Termination Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

CONFIDENTIAL TREATMENT REQUESTED

7.16 Dispute Resolution. In the event of a dispute arising out of, relating to, or in connection with this Termination Agreement, including disputes over the interpretation or enforcement of this Termination Agreement, the Parties **shall** follow the dispute resolution provisions of Article 14 of the Agreement, which are incorporated herein by this reference as if set out in full.

7.17 Specific Performance

(a) KaloBios acknowledges and agrees that Sanofi would be damaged irreparably in the event of an unauthorized use by KaloBios, its Affiliates, licensees, sub-licensees or agents, of the Sanofi Technology outside the scope of the license contained in Section 2.2(e) of this Termination Agreement in accordance with its specific terms. In such event, KaloBios agrees that Sanofi shall be entitled to injunctive relief to prevent breaches of this Termination Agreement and to enforce specifically this Termination Agreement. Such remedies shall not be deemed to be the exclusive remedies for such a breach of this Termination Agreement but shall be in addition to all other remedies available to Sanofi at law or equity. KaloBios shall not oppose the granting of an injunction, specific performance or other equitable relief sought in accordance with this section on the basis that Sanofi has an adequate remedy at law or that any award of equitable relief is not an appropriate remedy for any reason at law or in equity. In seeking an injunction or injunctions in connection with this section, Sanofi shall not be required to provide any bond or other security in connection with any such injunction or order.

(b) KaloBios shall, with regard to any sub-licensee of the Sanofi Technology, include a requirement for specific performance similar to that set out in paragraph 7.17(a) as one of the terms of any such sub-license.

In Witness Whereof, the Parties have executed this Termination Agreement in duplicate originals by their duly authorized officers.

Sanofi Pasteur S.A.

KaloBios Pharmaceuticals, Inc.

By: _____

By: _____

Name: Olivier Charmeil

Name: David Pritchard

Title: Chief Executive Officer

Title: President and Chief Executive Officer

Date: _____

Date: _____

CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT A

INITIAL LIST OF THIRD PARTY AGREEMENTS

***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***

**CONFIDENTIAL PORTIONS OF THIS DOCUMENT REDACTED AND
SEPARATELY FILED WITH THE COMMISSION.**

CONFIDENTIAL TREATMENT REQUESTED

ADDITIONAL EXHIBITS INCORPORATED BY REFERENCE

EXHIBIT B: KaloBios Patents existing as of the Termination Agreement Effective Date

EXHIBIT C: KaloBios' Sole Inventions existing as of the Termination Agreement Effective Date

EXHIBIT D: Sanofi's Sole Inventions existing as of the Termination Agreement Effective Date

EXHIBIT E: Joint Inventions existing as of the Termination Agreement Effective Date

EXHIBIT F: Joint Patents existing as of the Termination Agreement Effective Date

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EXHIBIT B

**KALOBIOUS PATENTS AS OF TERMINATION AGREEMENT EFFECTIVE DATE –
KB001/KB001-A****CONFIDENTIAL**

Patent or Application Title	Applicant/ Assignee(s)	Geography	Utility Filing Date	Status	Patent or Application Publication No.** #:Application No.
KB001/1-A					
Method of and Compositions for Immunization with the <i>Pseudomonas</i> V Antigen*	Med. Coll. Wisconsin; Univ. of Calif.	CA EP [***] JP ¹	23 Nov 1999	Issued: EP(2), CA, JP	EP 1049488B1 EP1666058B1 CA 2,318,536C JP04707234B2
Method of and Compositions for Immunization with the <i>Pseudomonas</i> V Antigen*	Med. Coll. Wisc.; Univ. of Calif.	US (CIP)	26 Jan 2001 (subject to TD)	Issued: US	US 6,827,935
Method and Compositions for Immunization with the <i>Pseudomonas</i> V Antigen*	Med. Coll. Wisconsin Res. Fdn; Regents Univ. of Calif.	US EP [***] AU, JP	25 Jan 2002 (subject to TD)	Issued: US (2), EP, AU, JP	US 7,494,653 US 8,101,347 EP 1353688B1 AU2007231760(B2) JP 4355786B2
Antibodies to the PcrV Antigen of <i>Pseudomonas aeruginosa</i> * (composition of matter) [***]	KaloBios	US AU, [***], CA, CN, EA, EP, HK, [***], IN, KR, MX, JP, NZ, SG, [***]	1 Dec 2008	Issued: US, MX, NZ Pending: See Geography (left); +US CON	US 8,044,181 AU2008333985 #[***] CA2,706,732 CN 101910197 EA201000903 EP 2220117(A2) HK1142343A #[***] IN 45/2011 JP 2011505381 KR 20100097719 MX301710 NZ586357 SG186017 US 2012-0020986 #[***]

** **Boldface**: issued or granted patents; Publication numbers provided when possible; # indicates patent application number for unpublished applications

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EXHIBIT B

**KALOBIOUS PATENTS AS OF TERMINATION AGREEMENT EFFECTIVE DATE –
KB001/KB001-A**

CONFIDENTIAL

Patent or Application Title	Applicant/ Assignee(s)	Geography	Utility Filing Date	Status	Patent or Application Publication No.** #:Application No.
Combination Antibiotic and Antibody Therapy for the Treatment of <i>Pseudomonas aeruginosa</i> Infection* [***]	KaloBios/ UCSF	US CA, EP, JP	4 Feb 2010	Pending: US, CA, EP, JP	US 2010-0272736 CA 2,751,433 EP2393515 (A1) JP 2012516897
A Method of Treating a <i>Staphylococcus</i> Infection in a Patient having a Low-level pathogenic <i>Pseudomonas aeruginosa</i> Infection* [***]	KaloBios	US CA, EP, JP	21 Dec 2010	Pending: US, EP, CA, JP	US 8,642,039 CA 2,784,033 EP 2515935(A1) JP 2013515079

** **Boldface:** issued or granted patents; Publication numbers provided when possible; # indicates patent application number for unpublished applications

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EXHIBIT C

KALOBIOS' SOLE INVENTIONS

Inventions KaloBios Intends to Maintain as Trade Secrets:

[***]

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WITH THE COMMISSION.**

CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT D

SANOFI'S SOLE INVENTIONS

Inventions Sanofi Intends to Maintain as Trade Secrets:

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WITH THE COMMISSION.**

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EXHIBIT E
JOINT INVENTIONS

None

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WITH THE COMMISSION.**

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EXHIBIT F
JOINT PATENTS

None

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WITH THE COMMISSION.**

**Certification of Chief Executive Officer Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Herb C. Cross, certify that:

1. I have reviewed this quarterly report on Form 10-Q of KaloBios Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 11, 2015

/s/ Herb C. Cross
Herb C. Cross
Interim Chief Executive Officer
(Principal Executive Officer)

**Certification of Chief Financial Officer Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Herb C. Cross, certify that:

1. I have reviewed this quarterly report on Form 10-Q of KaloBios Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 11, 2015

/s/ Herb C. Cross
Herb C. Cross
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of KaloBios Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Herb C. Cross, the Interim Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 11, 2015

/s/ Herb C. Cross

Herb C. Cross

Interim Chief Executive Officer

(Principal Executive Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to KaloBios Pharmaceuticals, Inc. and will be retained by KaloBios Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of KaloBios Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of KaloBios Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Herb C. Cross, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 11, 2015

/s/ Herb C. Cross

Herb C. Cross

Chief Financial Officer

(Principal Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to KaloBios Pharmaceuticals, Inc. and will be retained by KaloBios Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of KaloBios Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.
