

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended **June 30, 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**

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**KALOBIOS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**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**

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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 August 7, 2015, there were 4,123,921 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)**

	<u>June 30,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
	<u>(Unaudited)</u>	<u>(Note 2)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,122	\$ 10,923
Marketable securities	6,907	29,790
Prepaid expenses and other current assets	963	1,532
Total current assets	23,992	42,245
Property and equipment, net	447	414
Restricted cash	193	193
Other assets	116	125
Total assets	<u>\$ 24,748</u>	<u>\$ 42,977</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,329	\$ 1,822
Accrued compensation	1,400	1,400
Deferred rent, short term	26	16
Accrued research and clinical liabilities	2,279	3,470
Notes payable	8,425	10,928
Financing derivative	227	89
Other accrued liabilities	311	328
Total current liabilities	13,997	18,053
Deferred rent, long-term	298	311
Total liabilities	14,295	18,364
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 85,000,000 shares and 85,000,000 shares authorized at June 30, 2015 and December 31, 2014 respectively; 4,124,379 and 4,124,004 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	4	4
Additional paid-in capital	204,324	202,830
Accumulated other comprehensive income	—	(8)
Accumulated deficit	(193,875)	(178,213)
Total stockholders' equity	10,453	24,613
Total liabilities and stockholders' equity	<u>\$ 24,748</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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
	(unaudited)		(unaudited)	
<b>Operating expenses:</b>				
Research and development	3,332	6,721	9,237	14,411
General and administrative	2,299	2,813	5,736	5,283
Total operating expenses	<u>5,631</u>	<u>9,534</u>	<u>14,973</u>	<u>19,694</u>
Loss from operations	(5,631)	(9,534)	(14,973)	(19,694)
<b>Other (expense) income:</b>				
Interest expense	(252)	(290)	(532)	(550)
Interest income	10	31	26	45
Other (expense) income, net	<u>(167)</u>	<u>(21)</u>	<u>(183)</u>	<u>(23)</u>
Net loss	(6,040)	(9,814)	(15,662)	(20,222)
<b>Other comprehensive income:</b>				
Net unrealized gains (losses) on marketable securities	2	2	8	(2)
Comprehensive loss	<u>\$ (6,038)</u>	<u>\$ (9,812)</u>	<u>\$ (15,654)</u>	<u>\$ (20,224)</u>
Basic and diluted net loss per common share	<u>\$ (1.46)</u>	<u>\$ (2.38)</u>	<u>\$ (3.80)</u>	<u>\$ (4.91)</u>
<b>Weighted average common shares outstanding used to calculate basic and diluted net loss per common share</b>				
	<u>4,124,259</u>	<u>4,122,659</u>	<u>4,124,132</u>	<u>4,121,721</u>

*See accompanying notes*

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

	<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(unaudited)</b>	
<b>Operating activities:</b>		
Net loss	\$ (15,662)	\$ (20,222)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	91	230
Noncash interest expense	111	101
Financing derivative	138	—
Amortization of premium on marketable securities	123	217
Stock based compensation expense	642	1,018
Modification of stock options related to executive retirement	389	—
Modification of stock options related to restructuring activities	463	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	554	(351)
Accounts payable	(493)	(540)
Accrued compensation	—	(81)
Accrued research and clinical liabilities	(1,191)	(1,101)
Other liabilities	(17)	49
Deferred rent	(3)	(3)
Net cash (used in) operating activities	(14,855)	(20,683)
<b>Investing activities:</b>		
Purchase of marketable securities	(3,703)	(49,902)
Proceeds from maturities of marketable securities	26,471	22,460
Purchases of property and equipment	(125)	(287)
Changes in restricted cash	—	(193)
Net cash provided by (used in) investing activities	22,643	(27,922)
<b>Financing activities:</b>		
Proceeds from issuances of notes payable	—	5,000
Proceeds from issuance of common stock	—	59
Principal payments under notes payable	(2,589)	(1,621)
Net cash (used in) provided by financing activities	(2,589)	3,438
Net increase (decrease) in cash and cash equivalents	5,199	(45,167)
Cash and cash equivalents, beginning of period	10,923	54,220
Cash and cash equivalents, end of period	<u>\$ 16,122</u>	<u>\$ 9,053</u>
<b>Supplemental cash flow disclosure:</b>		
Cash paid for interest	\$ 442	\$ 425

*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 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 \$193.9 million as of June 30, 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 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, would 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. During the three month and six month periods ended June 30, 2015, accrued liabilities were reduced by \$312,000 related to research-related manufacturing expenses incorrectly recorded in 2014. We analyzed and assessed the effect of this adjustment on the previously reported annual and interim periods in 2014 as well as the impact of the benefit from the reversal of these expenses to the results of operations for the three and six month periods ended June 30, 2015. Following this analysis and taking into account both quantitative and qualitative factors; we believe that the uncorrected out-of-period costs are not material to the respective periods in which the errors occurred.

### **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.



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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.

### Reverse Stock Split

In July, 2015, the Company's board of directors approved the filing of an Amended Certificate of Incorporation to effectuate a reverse split of the issued and outstanding shares of the Company's common stock on a one-for-eight basis. All references to the numbers of issued and outstanding shares of our common stock, price per share and per-share amounts of stock, and shares issuable under share-based compensation arrangements and warrants in the accompanying financial statements have been adjusted retroactively to reflect the Company's one-for-eight reverse stock split effectuated on July 13, 2015. The par value per share and number of authorized shares were not adjusted as a result of the reverse stock split.

### 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 June 30,	
	2015	2014
Options to purchase common stock	491,072	331,644
Unvested restricted stock units to purchase common stock	3,750	—
ESPP contributions to purchase common stock	750	108
Warrants to purchase common stock	11,067	11,067
	<u>506,639</u>	<u>342,819</u>

### 3. Investments

At June 30, 2015, the amortized cost and fair value of investments, with gross unrealized gains and losses, were as follows:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 11,619	\$ —	\$ —	\$ 11,619
Federal agency securities	4,501	—	—	4,501
Corporate debt securities	5,460	—	(1)	5,459
Total investments	<u>\$ 21,580</u>	<u>\$ —</u>	<u>\$ (1)</u>	<u>\$ 21,579</u>
Reported as:				
Cash and cash equivalents				\$ 14,479
Marketable securities, current				6,907
Restricted cash				193
Total investments				<u>\$ 21,579</u>

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

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
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 and six months ended June 30, 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.

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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.

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			
	June 30, 2015			
	Level 1	Level 2	Level 3	Total
<b>Investments:</b>				
Money market funds	\$ 11,619	\$ —	\$ —	\$ 11,619
Federal agency securities	—	4,501	—	4,501
Corporate debt securities	—	5,459	—	5,459
<b>Total assets measured at fair value</b>	<b>\$ 11,619</b>	<b>\$ 9,960</b>	<b>\$ —</b>	<b>\$ 21,579</b>
Financing derivative	—	—	227	227
<b>Total liabilities measured at fair value</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 227</b>	<b>\$ 227</b>

(in thousands)	Fair Value Measurements as of			
	December 31, 2014			
	Level 1	Level 2	Level 3	Total
<b>Investments:</b>				
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
<b>Total assets measured at fair value</b>	<b>\$ 9,663</b>	<b>\$ 29,790</b>	<b>\$ —</b>	<b>\$ 39,453</b>
Financing derivative	—	—	89	89
<b>Total liabilities measured at fair value</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 89</b>	<b>\$ 89</b>

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 June 30, 2015 is less than one month 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 June 30, 2015, the Company remeasured the financing derivative liability as \$227,000 and recorded the loss of \$135,000 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. As compared to March 31, 2015, the probability of the occurrence of an event of default under the Loan and Security Agreement with MidCap Financial was perceived to be higher at June 30, 2015 based on management's judgment. Refer to Note 5 for additional details regarding the Loan and Security Agreement with MidCap Financial.

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

	<b>Fair Value Measurements of Level 3 Liabilities</b>
	<b>(in thousands)</b>
Balance as of December 31, 2014	\$ 89
Loss on remeasurement of the financing derivative liability	3
Balance as of March 31, 2015	92
Loss on remeasurement of the financing derivative liability	135
Balance as of June 30, 2015	\$ 227

The estimated fair value of the notes payable as of June 30, 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, would 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

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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.

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 6,193 shares of the Company's common stock with an exercise price of \$96.88 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.

In August 2015, the Company entered into an additional amendment to the Agreement, Amendment No. Two, whereby the Company agreed to maintain, in a separate account with a financial institution (held in the Company's name), an amount equal to the aggregate of the remaining future principal, interest and exit fee due under the Loan and Security Agreement, equating to \$8.3 million as of the date of this amendment. MidCap Financial can draw payments from this account under the terms of the Agreement as they become due and upon such draws there will be a corresponding reduction in the amount owed to MidCap Financial by the Company. MidCap Financial has exclusive control to withdraw funds from that account, which is to be maintained either until the debt has been repaid in full, or until MidCap Financial determines that the Company has satisfied certain capital requirements as they relate to the Company's future operating plans.

Future payments as of June 30, 2015 under the Agreement, assuming no adjustments to the variable rate of interest of 9% as of June 30, 2015, are as follows:

<b>(in thousands)</b>	
Remainder of 2015	\$ 2,915
2016	5,909
Total minimum payments	8,824
Less amount representing interest	(625)
Notes payable, gross	8,199
Discount on notes payable	(31)
Accretion of the final exit fee payment	257
Carrying value of notes payable	\$ 8,425

## **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 would 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 would 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. Based on results of the Phase 2 data released in early 2015, we have discontinued development of KB001-A in all indications.

## **7. Commitments and Contingencies**

### **Contractual Obligations and Commitments**

As of June 30, 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 6,193 shares of the Company's common stock with an exercise price of \$96.88 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 4,874 shares of common stock at \$41.04 per share which will expire on October 31, 2015.

## **9. Stockholders' Equity**

### **2012 Equity Incentive Plan**

As of June 30, 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

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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.

A summary of stock option activity for the six months ended June 30, 2015 under all of the Company's options plans is as follows:

	Options	Weighted Average Exercise Price
Outstanding at December 31, 2014	334,686	\$ 34.00
Granted	224,620	3.61
Exercised	—	—
Cancelled (forfeited)	(56,747)	31.28
Cancelled (expired)	—	—
Outstanding at March 31, 2015	502,559	\$ 20.70
Granted	20,625	4.33
Exercised	—	—
Cancelled (forfeited)	(26,221)	9.75
Cancelled (expired)	(5,891)	19.66
Outstanding at June 30, 2015	491,072	\$ 20.61

The weighted average fair value of options granted during the three months and six months ended June 30, 2015 was \$2.52 and \$2.30 per share.

In addition, 3,750 restricted stock units were issued during the three months ended June 30, 2015.

**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 21,058 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 1<sup>st</sup> and May 1<sup>st</sup> each year. There were 583 and 375 shares issued under the plan on October 31, 2014 and April 30, 2015, respectively.

**Stock-Based Compensation**

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
General and administrative	\$ 187	\$ 247	\$ 329	\$ 473
Research and development	150	280	313	545
	<u>\$ 337</u>	<u>\$ 527</u>	<u>\$ 642</u>	<u>\$ 1,018</u>

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During the three months ended June 30, 2015, the Company recorded charges of \$48,000 relating to the fair value of stock options which were modified due to restructuring activities, and classified them as general and administrative expenses. Further, during the six months ended June 30, 2015, the Company recorded charges of \$0.4 million and \$0.45 million relating to the fair value of stock options which were modified due to executive retirement and restructuring activities, and classified \$0.45 million and \$0.4 million as general and administrative expenses and research and development expenses, respectively.

At June 30, 2015, the Company had \$1.8 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 1.6 years.

## 10. Restructuring Charges

Restructuring charges incurred during the six months ended June 30, 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 and \$0.2 million in restructuring charges relating to such obligations during the three months ended March 31, 2015 and three months ended June 30, 2015, respectively. 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
Accrued	—	57	122	179
Paid	(135)	(142)	—	(277)
Balance as of June 30, 2015	\$ 571	\$ 180	\$ 204	\$ 955

As disclosed in Note 9, the Company recorded stock based compensation expense of \$0.45 million related to the fair value of stock options of former employees which were modified such that they did not expire upon termination. The Company classified \$48,000 and \$0.4 million as general and administrative expenses and research and development expenses, respectively.



## 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 and our Quarterly Report on Form 10-Q for the quarter year ended March 31, 2015, filed with the SEC on May 11, 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 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 is working to initiate a Phase 1 clinical trial in patients with chronic myelomonocytic leukemia, or CMML to assess the safety, pharmacokinetics, and clinical activity of KB003 in the second half of 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 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 June 30, 2015, we had an accumulated deficit of \$193.9 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 1,093,750 shares of common stock at an offering price of \$64.00 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 1,078,125 shares of common stock at an offering price of \$32.00 per share, resulting in net proceeds of approximately \$32.0 million, after deducting underwriting discounts, commissions and offering expenses. As of June 30, 2015, we had cash, cash equivalents, and investments of \$23.0 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 and seek regulatory approvals. Specifically, we have incurred substantial expenses in connection with our historical respiratory programs, most notably a Phase 2 clinical trial for KB003 in severe asthma patients inadequately controlled by corticosteroids, and a 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 would 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 would 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. Based on results of the Phase 2 data released in early 2015, we have discontinued development of this product in all indications.

## **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 June 30, 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 June 30, 2015, we had an accumulated deficit of \$193.9 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.

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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 2015 KB003 expenses below reflect a \$312,000 benefit relating to an out of period adjustment. The following table shows our total research and development expenses for the three and six months ended June 30, 2015 and 2014, and for the period from January 1, 2008 to June 30, 2015:

(in thousands)	For the Three Months Ended June 30,		For the Six Months Ended June 30,		For the Period from January 1, 2008 to June 30, 2015
	2015	2014	2015	2014	
External costs:					
KB004	\$ 1,469	\$ 1,420	\$ 3,480	\$ 3,459	\$ 35,120
KB003	(63)	1,598	250	3,204	40,413
KB001-A	201	1,446	1,215	3,023	33,795
Internal costs	1,725	2,257	4,292	4,724	68,368
Total research and development	\$ 3,332	\$ 6,721	\$ 9,237	\$14,410	\$ 177,696

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, commencing a Phase 1 clinical study of KB003 in CMML patients, and evaluating KB004 in potential solid tumor indications. 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 efforts going forward will be focused on our KB004 development programs, and on the KB003 Phase 1 study we are planning on commencing in CMML patients. 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 the Phase 1 study of KB003 in CMML patients.

**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 June 30, 2015 and 2014**

(in thousands)	Three Months Ended June 30,		Increase/ (Decrease)	
	2015	2014	in thousands	%
Operating expenses:				
Research and development	\$ 3,332	\$ 6,721	\$ (3,389)	-50%
General and administrative	2,299	2,813	(514)	-18%
Loss from operations	(5,631)	(9,534)	3,903	-41%
Interest expense	(252)	(290)	38	-13%
Interest income	10	31	(21)	-68%
Other (expense) income, net	(167)	(21)	(146)	695%
Net loss	\$ (6,040)	\$ (9,814)	\$ 3,774	-38%

Research and development expenses decreased \$3.4 million, from \$6.7 million for the three months ended June 30, 2014 to \$3.3 million for the three months ended June 30, 2015. The decrease was primarily attributed to a \$1.9 million decrease in contract manufacturing expenses mainly related to the KB003 program, \$1.1 million decrease in clinical activity primarily resulting from the completion of our Phase 2 study of KB001-A in CF patients with chronic *Pa*

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infections in the first quarter of 2015, and \$0.3 million decrease in personnel related expenses primarily due to the restructuring activities during the year. We expect external expenses on KB001-A will decrease 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 will continue the trial through 2016, 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 decreased \$0.5 million, from \$2.8 million for the three months ended June 30, 2014 to \$2.3 million for the three months ended June 30, 2015 due to a decrease of \$0.1 million in personnel related costs, \$0.2 million in consulting costs, \$0.1 million decrease in legal expenses and \$0.1 million decrease in facility related expenses. We do not expect an increase in general and administrative expenses in 2015.

Interest expense of \$0.3 million recognized for the three months ended June 30, 2014 and \$0.3 million recognized for the three months ended June 30, 2015, was related 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.

**Comparison of Six Months Ended June 30, 2015 and 2014**

(in thousands)	Six Months Ended June 30,		Increase/ (Decrease)	
	2015	2014	in thousands	%
Operating expenses:				
Research and development	\$ 9,237	\$ 14,411	\$ (5,174)	-36%
General and administrative	5,736	5,283	453	9%
Loss from operations	(14,973)	(19,694)	4,721	-24%
Interest expense	(532)	(550)	18	-3%
Interest income	26	45	(19)	-42%
Other (expense) income, net	(183)	(23)	(160)	696%
Net loss	\$ (15,662)	\$ (20,222)	\$ 4,560	-23%

Research and development expenses decreased \$5.2 million, from \$14.4 million for the six months ended June 30, 2014 to \$9.2 million for the six months ended June 30, 2015. The decrease was primarily attributed to a \$1.2 million decrease in clinical trial expenses related to the KB001-A program, \$0.9 million in clinical trial expenses related to the KB003 program, \$0.9 million decrease in clinical trial expenses related to the KB004 program, \$1.5 million decrease in contract manufacturing costs primarily related to KB003 program and \$0.5 million decrease due to the milestone payments for the 2014 KB004 clinical program.

We expect external expenses on KB001-A will decrease 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 will continue the trial through 2016, 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 \$0.4 million, from \$5.3 million for the six months ended June 30, 2014 to \$5.7 million for the six months ended June 30, 2015 due primarily to an increase in employee-related expenses of \$1.4 million related to severance and restructuring expenses, offset by a decrease of personnel related expenses of \$0.5 million, \$0.3 million in consulting costs, \$0.1 million in move-related costs and \$0.1 million in other general operating expenses. With the exception of the restructuring expenses, we do not expect an increase in general and administrative expenses.

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Interest expense of \$0.6 million recognized for the six months ended June 30, 2014 and \$0.5 million recognized for the six months ended June 30, 2015, was related to our Loan and Security Agreement with MidCap Financial entered into in September 2012 and amended in 2013.

Interest and other 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 equivalents, and marketable securities, borrowings against lines of credit, and receipts from agreements with Sanofi and Novartis. At June 30, 2015, we had cash and cash equivalents and investments of \$23.0 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)	Six Months Ended	
	June 30,	
	2015	2014
Net cash (used in) operating activities	\$ (14,855)	\$ (20,683)
Net cash provided by (used in) investing activities	22,643	(27,922)
Net cash (used in) provided by financing activities	(2,589)	3,438
Net increase (decrease) in cash and cash equivalents	<u>\$ 5,199</u>	<u>\$ (45,167)</u>

Net cash used in operating activities was \$14.9 million and \$20.7 million for the six months ended June 30, 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 \$14.9 million for the six months ended June 30, 2015 primarily related to our net loss of \$15.7 million, adjusted for non-cash items such as \$0.6 million of stock-based compensation expense, \$0.9 million relating to the fair value of stock options which were modified due to executive retirement and restructuring activities and net cash outflows of \$1.2 million related to changes in operating assets and liabilities. Cash used in operating activities of \$20.7 million for the six months ended June 30, 2014 primarily related to our net loss of \$20.2 million, adjusted for non-cash items such as \$1.0 million of stock-based compensation expense and net cash outflows of \$2.0 million related to changes in operating assets and liabilities.

Net cash provided by investing activities was \$22.6 million for the six months ended June 30, 2015, primarily related to proceeds from maturities of marketable securities of \$26.5 million partially offset by purchases of investments of \$3.7 million. Net cash used in investing activities was \$27.9 million for the six months ended June 30, 2014, primarily related to purchases of investments of \$49.9 million partially offset by proceeds from maturities of marketable securities of \$22.5 million.

Net cash used in financing activities was \$2.6 million for the six months ended June 30, 2015 relating to the payments on our borrowings. Net cash provided by financing activities was \$3.4 million for the six months ended June 30, 2014, and consisted primarily of proceeds from issuance of debt of \$5.0 million partially offset by payments on our borrowings of \$1.6 million.

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. 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. We also expect to incur significant costs as a result of the Phase 1 clinical trial we are preparing to commence to evaluate safety, pharmacokinetics and clinical activity of KB003 in CMML patients.

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

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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 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, would 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.

In August 2015, we entered into an additional amendment, Amendment No. Two, to our Agreement with MidCap Financial as explained in Note 5 to the financial statements, whereby we agreed to maintain, in a separate account with a financial institution (held in our name), an amount equal to the aggregate of the remaining future principal, interest and exit fee due under the Loan and Security Agreement, equating to \$8.3 million as of the date of this amendment. MidCap Financial can draw payments from this account under the terms of the Agreement as they become due and upon such draws there will be a corresponding reduction in the amount owed by us. MidCap Financial has exclusive control to withdraw funds from that account, which is to be maintained either until the debt has been repaid in full, or until MidCap Financial determines that we have satisfied certain capital requirements as they relate to our future operating plans.

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 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**

As of June 30, 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 \$21.4 million and \$39.3 million as of June 30, 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 June 30, 2015, we had \$23.0 million in cash, cash equivalents, and investments. We utilized \$14.9 million of cash in operating activities during the six months ended June 30, 2015. Additionally, in August 2015 under the Amendment No. Two to the Loan and Security Agreement with MidCap Financial, we transferred an amount equal to the aggregate of the remaining future payments under the Loan and Security Agreement, equating to \$8.3 million, in a segregated deposit account. While these funds will be used to make the MidCap loan payments as they become due, we cannot use these funds for other business purposes, including the operations of our business. Therefore, a substantial amount of our cash cannot be used without the consent of MidCap Financial.

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 prior partnering agreements. 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, would 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 June 30, 2015, we had an accumulated deficit of \$193.9 million, and for the six months ended June 30, 2015, we incurred a net loss of \$15.7 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 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

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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 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.

***Our business is highly dependent on the success of two oncology product candidates, KB004 and KB003. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, either KB004 or KB003.***

We have recently made the strategic decision to focus our efforts on oncology. We have only one product candidate in Phase 2 clinical trials: KB004, our Humaneered® anti-EphA3 monoclonal antibody being developed to treat both hematologic malignancies and potentially in solid tumors. We have a very limited pipeline of product candidates other than KB004, currently consisting of KB003 in development for CMML, an oncological indication. We are not conducting active research at this time for discovery of new molecules or antibodies.

We are therefore dependent on the successful continued development and regulatory approval of KB004 and KB003 for our future business success. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of KB004 and will undertake development efforts for KB003. We will need to successfully enroll and complete clinical trials of KB004 and KB003, and obtain regulatory approvals to market those products, if clinical trials are successful. The future clinical, regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not be able to enroll adequate numbers of eligible patients in the clinical trials we propose to conduct;
- we may not have sufficient financial and other resources to complete the clinical trials;
- we may not be able to provide acceptable evidence of safety and efficacy for KB004;
- the results of our clinical trials may not meet the level of statistical or clinical significance, or product safety, required by the FDA for marketing approval;
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and
- we may not be able to obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities.

Furthermore, even if we do receive regulatory approval to market KB004, any such approval may be subject to limitations on the indicated uses for which we may market the product. If either or both of KB004 and KB003 are unsuccessful, that could have a substantial negative impact on 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.***

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. Even if we are successful in securing a development partnership, we may not be able to continue it. For example, in July 2014, we announced our mutual agreement with Sanofi to terminate our prior development partnership for KB001-A. 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

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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 and a substantial amount of our cash is controlled by MidCap Financial and cannot be used for our business operations without the consent of MidCap Financial.***

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, as amended, 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;
- 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,

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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.

Additionally, in August 2015 under the Amendment No. Two, we transferred an amount equal to the aggregate of the remaining future payments under the Loan and Security Agreement, equating to \$8.3 million, in a segregated deposit account. While these funds will be used to make the MidCap loan payments as they become due, we cannot use these funds for other business purposes, including the operations of our business. Therefore, a substantial amount of our cash cannot be used without the consent of MidCap Financial.

***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. In particular, we have recently shifted our focus to oncological indications.***

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, due to our recent shift in focus to oncology product candidates, we have limited background and experience in developing an oncology drug, and we are heavily dependent at this time on external consultants for medical and scientific expertise. 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

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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 chief medical officer, 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;
- 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 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 future development partners experience delays in the completion of, or if we or any 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 future development partners' clinical trials;
- we or any 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 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;
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any 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 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 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 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 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 hire and effectively integrate a new executive officer, our business will likely be harmed.***

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 on our ability to successfully integrate a new 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.

***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 heavily affected by turnover and highly dependent on the expertise of the members of our senior management. In January 2015, we announced the retirement of David W. Pritchard, our former president and chief executive officer, and in a subsequent reduction in force we announced the elimination of our chief medical officer position. Although we have recently announced the hiring of Ronald Martell, a member of our Board of Directors, as Executive Chairman, and continue to fill the vacant CEO position with Herb Cross, our Chief Financial Officer, as interim CEO, 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, and intense competition from biotechnology and pharmaceutical companies, universities, and research organizations for qualified personnel. Many of these competitors have substantially greater financial, technical and human resources than we do. 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.

***Any product candidate we or any 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 future development partners are unable to establish sales and

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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 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 any 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 any 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 future development partners are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and any 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 future development partners may fail to report adverse events we become aware of within the prescribed timeframe. We and any 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 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. From time to time, we experience delays from our drug substance suppliers. To date, such delays have been manageable. However, 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, including affecting our ability

to enroll in and timely progress clinical trials. Furthermore, if any of our contract 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 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 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 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 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 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 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. 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 our ability to continue as a going concern in our 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 December 31, 2014, as indicated in our Management Report on Internal Control over Financial Reporting, included in our Annual Report on Form 10-K for the year ended December 31, 2014, 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 August 7, 2015, our stock had high and low sales prices in the range of \$66.00 to \$1.83 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 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. We effectuated a one-for-eight reverse stock split of our issued and outstanding common stock on July 13, 2015 to regain compliance with the NASDAQ listing requirements. The par value and number of authorized shares were not adjusted as a result of the reverse stock split. Since the reverse stock split was effectuated, our stock price has closed higher than \$1.00 for the minimum 10 day period mandated under the NASDAQ listing requirements, and NASDAQ has confirmed that we are in compliance with the minimum bid price listing requirements.

### ***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 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 June 30, 2015, we had 4,124,379 shares of common stock outstanding. In addition, as of June 30, 2015, we have also registered 646,031 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.

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 30% of our common stock as of June 30, 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**

On August 7, 2015, KaloBios Pharmaceuticals, Inc. (the "Company") entered into Amendment No. Two to Loan and Security Agreement ("Amendment No. Two"), by and among the Company, as borrower, MidCap Financial Trust, a Delaware statutory trust (as Agent for Lenders, "Agent"), and the entities shown as parties to the Loan Agreement referenced below, each as a Lender.

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Pursuant to the Loan and Security Agreement dated as of September 5, 2012 by and among Borrower, Agent and Lenders (as amended by Amendment No. One to Loan and Security Agreement, dated as of June 19, 2013, and by Amendment No. Two, the “Loan Agreement”), Agent and Lenders agreed to make available to the Company a secured term loan in the original principal amount of \$15,000,000 (the “Loan”). That amount has been drawn in full by the Company. The Company is in compliance with its obligations under the Loan Agreement and is in the process of repaying the Loan according to its terms, which matures in full on December 31, 2016.

Under the Loan Agreement, Lenders have a pre-existing security interest in substantially all of the Company’s assets, including cash collateral (but excluding any intellectual property owned or controlled by the Company). In order to provide Lenders with additional security for the fulfillment of the Company’s obligations under the Loan, the Company has agreed to deposit an amount equal to the aggregate of the remaining future payments under the Loan Agreement, equating to \$8.3 million, in a segregated deposit account from which Agent can draw such payments as they become due. The Company has simultaneously entered into a Deposit Account Control Agreement establishing Agent’s exclusive control to withdraw funds from that account, which is to be maintained either until the Loan has been repaid in full, or until Agent determines that the Company has satisfied certain capital requirements.

**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: August 10, 2015

By: /s/ Herb C. Cross

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

Date: August 10, 2015

By: /s/ Herb C. Cross

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

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company.
10.1*	Employment Offer Letter, dated May 28, 2015, by and between the Registrant and Ronald A. Martell.
10.2	2012 Equity Incentive Plan, as amended
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

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\* Indicates management contract or compensatory plan.

† 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.

**CERTIFICATE OF AMENDMENT TO THE  
AMENDED AND restated CERTIFICATE OF INCORPORATION of  
KALOBIOS PHARMACEUTICALS, INC.**

KaloBios Pharmaceuticals, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "Corporation"),

DOES HEREBY CERTIFY:

FIRST: The name of the Corporation is KaloBios Pharmaceuticals, Inc.

SECOND: The date on which the Certificate of Incorporation of the Corporation was originally filed with the Secretary of State of the State of Delaware is September 19, 2001 under the name Horizon Biotechnologies, Inc.

THIRD: That the Board of Directors of the Corporation adopted resolutions setting forth a proposed amendment of the Corporation's Amended and Restated Certificate of Incorporation, declaring said amendment to be advisable and in the best interests of the Corporation and its stockholders and authorizing the appropriate officers of the Corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment is as follows:

RESOLVED, that Article IV of the Amended and Restated Certificate of Incorporation of the Corporation be amended to read in its entirety as follows:

"The Corporation is authorized to issue one class of stock to be designated common stock ("Common Stock"). The number of shares of Common Stock authorized to be issued is Eighty Five Million (85,000,000), par value \$0.001 per share.

Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote.

Effective as of 5:00 p.m., Eastern time, on the date this Certificate of Amendment to the Amended and Restated Certificate of Incorporation is filed with the Secretary of State of the State of Delaware, each eight (8) shares of the Corporation's Common Stock, par value \$0.001 per share, issued and outstanding shall, automatically and without any action on the part of the respective holders thereof, be combined and converted into one (1) share of Common Stock, par value \$0.001 per share, of the Corporation. No fractional shares shall be issued and, in lieu thereof, any holder of less than one (1) share of Common Stock shall be entitled to receive cash for such holder's fractional share based upon the closing sales price of the Corporation's Common Stock as reported on the Nasdaq Global Market, as of the date this Certificate of Amendment is filed with the Secretary of State of the State of Delaware."

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**FOURTH:** This Certificate of Amendment of the Amended and Restated Certificate of Incorporation has been duly adopted by the stockholders of the Corporation in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

**IN WITNESS WHEREOF**, this Corporation has caused this Certificate of Amendment of the Amended and Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this 13th day of July, 2015.

/s/ Herb C. Cross

\_\_\_\_\_  
Herb C. Cross

Interim Chief Executive Officer and  
Chief Financial Officer

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May \_\_, 2015

Ronald A. Martell  
40 San Andreas Way  
San Francisco, CA 94127

Dear Ron:

KaloBios Pharmaceuticals, Inc. (the "Company") is pleased to offer you employment on the following terms:

1. **Position.** Your title will be Executive Chairman, and you will report to the Company's Board of Directors. This is a full-time position, which we will reassess from time to time, and in particular upon the hiring of a full-time Chief Executive Officer. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company. Your primary duties shall include (a) leading the Company's financing and strategic planning efforts, in coordination with Herb Cross, CFO and interim CEO; (b) leading the Company's search for a permanent CEO, also in coordination with Herb; (c) providing strategy and leadership on execution of the Company's other 2015 corporate objectives, as approved by the Board; and (d) assuming the duties of Chairman, as described in the Company's Bylaws. You may have other duties as specified by the Board from time to time. You will have no direct reports other than Herb. Your start date will be as soon as possible upon the execution of this letter agreement, as mutually agreed.

2. **Cash Compensation.** Your salary will be at the rate of \$41,667 per month, payable in accordance with the Company's standard payroll schedule. This salary will be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time. You are eligible to participate in the Company's annual bonus plan. Your maximum bonus (if any) will be equal to 50% of your base salary for the bonus period, prorated for part year service. The bonus (if any) is determined by the Board, and will be awarded based on the achievement of Company objectives established by the Board. The determinations of the Board with respect to your bonus will be final and binding. In the event that there is any conflict between this letter agreement and the Company's Bonus Plan, the Bonus Plan, as interpreted and administered by the Company, will govern. You also understand and agree that upon the effective date of this letter agreement, you will no longer receive or be eligible for compensation as a director of the Company.

3. **Employee Benefits.** As a regular employee of the Company, you will be eligible to participate in a number of Company-sponsored benefits, including medical and dental benefits, flexible spending account and 401(k) plan. In addition, you will be entitled to paid vacation in accordance with the Company's vacation policy as in effect from time to time.

4. **Stock Options.** Subject to the approval of the Board, you will be granted options to purchase 25,000 shares of the Company's Common Stock, to be granted each month over the shorter of a one-year period, or until the date you are no longer serving as Executive Chairman.

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The exercise price per share will be determined by the Board or its Compensation Committee on the date of each option grant. The options will be subject to the terms and conditions applicable to options granted under the Company's 2012 Equity Incentive Plan (the "Plan"), as described in the Plan and the applicable Stock Option Agreement. Each monthly option grant will vest on the first year anniversary of that grant date, as described in the applicable Stock Option Agreement, subject to your ongoing status as a service provider to the Company, as defined in the Plan. You will be responsible for ensuring compliance with Section 16 securities ownership reporting requirements, although if desired we will request that our outside counsel assist you in that regard.

**5. Proprietary Information and Inventions Agreement.** Like all Company employees, you will be required, as a condition of your employment with the Company, to sign the Company's standard Proprietary Information and Inventions Agreement, a copy of which is attached hereto as **Exhibit A**.

**6. Employment Relationship.** Employment with the Company is for no specific period of time. Your employment with the Company will be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without cause. Any contrary representations that may have been made to you are superseded by this letter agreement. This is the full and complete agreement between you and the Company on this term. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

**7. Outside Activities.** While you render services to the Company, you agree that you will not engage in any other significant employment, consulting or other business activity without the prior written consent of the Board. While you render services to the Company, you also will not assist any person or entity in competing with the Company, in preparing to compete with the Company or in hiring any employees or consultants of the Company.

**8. Taxes.** All forms of compensation referred to in this letter agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You agree that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or its Board of Directors related to tax liabilities arising from your compensation.

**9. Interpretation, Amendment and Enforcement.** This letter agreement and Exhibit A constitute the complete agreement between you and the Company regarding your employment, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company. The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by California law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in San Mateo County in connection with any Dispute or any claim related to any Dispute.

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10. **Arbitration.** Any controversy or claim arising out of this letter agreement and any and all claims relating to your employment with the Company will be settled by final and binding arbitration. The arbitration will take place in San Mateo County. The arbitration will be administered by the American Arbitration Association under its National Rules for the Resolution of Employment Disputes. Any award or finding will be confidential. You and the Company agree to provide one another with reasonable access to documents and witnesses in connection with the resolution of the dispute. You and the Company will share the costs of arbitration equally, except that the Company will bear the cost of the arbitrator's fee and any other type of expense or cost that you would not be required to bear if you were to bring the dispute or claim in court. Each party will be responsible for its own attorneys' fees, and the arbitrator may not award attorneys' fees unless a statute or contract at issue specifically authorizes such an award. This Section does not apply to claims for workers' compensation benefits or unemployment insurance benefits.

\* \* \* \* \*

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Proprietary Information and Inventions Agreement and returning them to Don Joseph, Chief Legal Officer, at the Company. As required by law, your employment with the Company is contingent upon your providing legal proof of your identity and authorization to work in the United States.

Ron, we are very excited for you to take on this new role with the Company. If you have any questions about the position or this letter agreement, please call me.

Very truly yours,

KaloBios Pharmaceuticals, Inc.

By: \_\_\_\_\_  
Title: \_\_\_\_\_ Chairman

I have read and accept this employment offer:

\_\_\_\_\_  
Ronald A. Martell

Dated: \_\_\_\_\_

**Attachment:** Exhibit A--Proprietary Information and Inventions Agreement

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**KaloBios Pharmaceuticals, Inc.**

**2012 Equity Incentive Plan**

**(As Amended and Restated July 14, 2015)**

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# KaloBios Pharmaceuticals, Inc.

## 2012 Equity Incentive Plan

### ARTICLE 1. INTRODUCTION.

The Board adopted the Plan to become effective immediately, although no Awards were eligible to be granted prior to the Registration Date. The Plan was amended and restated by the Board on May 8, 2015, subject to approval by the Company's stockholders at the 2015 Annual Meeting. All share numbers herein have been adjusted to reflect the 1-for-8 reverse split of the Common Shares effected on July 14, 2015.

The purpose of the Plan is to promote the long-term success of the Company and the creation of stockholder value by (a) encouraging Service Providers to focus on critical long-range corporate objectives, (b) encouraging the attraction and retention of Service Providers with exceptional qualifications and (c) linking Service Providers directly to stockholder interests through increased stock ownership. The Plan seeks to achieve this purpose by providing for Awards in the form of Options (which may constitute ISOs or NSOs), SARs, Restricted Shares, Stock Units and Performance Cash Awards.

### ARTICLE 2. ADMINISTRATION.

**2.1 General.** The Plan may be administered by the Board or one or more Committees. Each Committee shall have the authority and be responsible for such functions as have been assigned to it.

**2.2 Section 162(m).** To the extent an Award is intended to qualify as "performance-based compensation" within the meaning of Code Section 162(m), the Plan will be administered by a Committee of two or more "outside directors" within the meaning of Code Section 162(m).

**2.3 Section 16.** To the extent desirable to qualify transactions hereunder as exempt under Exchange Act Rule 16b-3, the transactions contemplated hereunder will be approved by the entire Board or a Committee of two or more "non-employee directors" within the meaning of Exchange Act Rule 16b-3.

**2.4 Powers of Administrator.** Subject to the terms of the Plan, and in the case of a Committee, subject to the specific duties delegated to the Committee, the Administrator shall have the authority to (a) select the Service Providers who are to receive Awards under the Plan, (b) determine the type, number, vesting requirements and other features and conditions of such Awards, (c) determine whether and to what extent any Performance Goals have been attained, (d) interpret the Plan and Awards granted under the Plan, (e) make, amend and rescind rules relating to the Plan and Awards granted under the Plan, including rules relating to sub-plans established for the purposes of satisfying applicable foreign laws or for qualifying for favorable tax treatment under applicable foreign laws, (f) impose such restrictions, conditions or limitations as it determines appropriate as to the timing and manner of any resales by a Participant of any Common Shares issued pursuant to an Award, including restrictions under an

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insider trading policy and restrictions as to the use of a specified brokerage firm for such resales, and (g) make all other decisions relating to the operation of the Plan and Awards granted under the Plan.

**2.5 Effect of Administrator's Decisions .** The Administrator's decisions, determinations and interpretations shall be final and binding on all Participants and any other holders of Awards.

**2.6 Governing Law.** The Plan shall be governed by, and construed in accordance with, the laws of the State of Delaware (except its choice-of-law provisions).

### **ARTICLE 3. SHARES AVAILABLE FOR GRANTS.**

**3.1 Basic Limitation.** Common Shares issued pursuant to the Plan may be authorized but unissued shares or treasury shares. The aggregate number of Common Shares<sup>1</sup> issued under the Plan shall not exceed 810,498. Such number consists of (a) 140,391 Common Shares initially reserved under the Plan; (b) 133,371 Common Shares reserved under the Predecessor Plan that were not issued or subject to outstanding awards on the Registration Date plus Common Shares subject to outstanding awards under the Predecessor Plan that subsequently expired or lapsed unexercised, or were forfeited to or repurchased by the Company; (c) an aggregate of 224,236 Common Shares added on the first business day in 2013, 2014, and 2015 pursuant to an automatic share increase provision; and (d) an additional 312,500 Common Shares approved by the stockholders at the 2015 Annual Meeting. The number of Common Shares that are subject to Stock Awards outstanding at any time under the Plan may not exceed the number of Common Shares that then remain available for issuance under the Plan. The numerical limitations in this Article 3.1 shall be subject to adjustment pursuant to Article 9.

#### **3.2 Shares Returned to Reserve .**

(a) To the extent that Options, SARs or Stock Units granted under this Plan or under the Predecessor Plan are forfeited or expire for any other reason before being exercised or settled in full, the Common Shares subject to such Options, SARs or Stock Units shall again become available for issuance under the Plan. If Restricted Shares or Common Shares issued upon the exercise of Options or otherwise under the Plan or the Predecessor Plan are reacquired by the Company pursuant to a forfeiture provision, repurchase right at no greater than their original exercise price or purchase price (if any) or for any other reason prior to the shares having become vested, then such Common Shares shall again become available for issuance under the Plan. To the extent that an Award is settled in cash rather than Common Shares, the cash settlement shall not reduce the number of Shares available for issuance under the Plan.

(b) Prior to the date of the 2015 Annual Meeting, the following Common Shares shall again become available for issuance under this Article 3.2: (i) Common Shares subject to an Award not delivered to a Participant because the Award is exercised through a reduction in the Common Shares subject to the Award (*i.e.*, "net exercised"); (ii) if a SAR is

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1 All share numbers have been adjusted to reflect the 1-for-3.56147 reverse split of the Common Shares effected on January 15, 2013, and the 1-for-8 reverse split of the Common Shares effected on July 13, 2015.

settled in Common Shares, the number of Common Shares subject to the SAR that are not delivered to the Participant upon such settlement; (iii) Common Shares subject to an Award not delivered to the Participant because such Common Shares are withheld to satisfy tax withholding obligations related to the Award or are applied to pay the Exercise Price of an Option or SAR; (iv) Common Shares tendered by a Participant (either through actual delivery or attestation) to pay the Exercise Price of an Option or SAR; or (v) Common Shares reacquired by the Company, on the open market or otherwise, using cash proceeds from the exercise of an Option.

(c) Beginning on the date of the 2015 Annual Meeting and thereafter, the Common Shares specified in Article 3.2(b) shall no longer become available for issuance under this Article 3.2.

**3.3 Awards Not Reducing Share Reserve in Article 3.1** . Any dividend equivalents paid or credited under the Plan with respect to Stock Units shall not be applied against the number of Common Shares that may be issued under the Plan, whether or not such dividend equivalents are converted into Stock Units. In addition, Common Shares subject to Substitute Awards granted by the Company shall not reduce the number of Common Shares that may be issued under Article 3.1, nor shall shares subject to Substitute Awards again be available for Awards under the Plan in the event of any forfeiture, expiration or cash settlement of such Substitute Awards.

**3.4 Plan Limits.** Subject to adjustment in accordance with Article 9:

(a) The maximum aggregate number of Common Shares subject to Options and SARs that may be granted under this Plan during any calendar year to any one Participant shall not exceed 125,000, except that the Company may grant to a new Employee in the calendar year in which his or her Service as an Employee first commences Options and/or SARs that cover (in the aggregate) up to an additional 125,000 Common Shares;

(b) The maximum aggregate number of Common Shares subject to Restricted Share awards and Stock Units that may be granted under this Plan during any calendar year to any one Participant shall not exceed 125,000, except that the Company may grant to a new Employee in the calendar year in which his or her Service as an Employee first commences Restricted Share awards and Stock Units that cover (in the aggregate) up to an additional 125,000 Common Shares;

(c) No Participant shall be paid more than \$2 million in cash in any calendar year pursuant to Performance Cash Awards granted under the Plan; and

(d) No more than 810,498 Common Shares may be issued under the Plan upon the exercise of ISOs.

#### **ARTICLE 4. ELIGIBILITY.**

**4.1 Incentive Stock Options.** Only Employees who are common-law employees of the Company, a Parent or a Subsidiary shall be eligible for the grant of ISOs. In addition, an Employee who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company or any of its Parents or Subsidiaries shall not be eligible for

the grant of an ISO unless the additional requirements set forth in Code Section 422(c)(5) are satisfied.

**4.2 Other Awards .** Awards other than ISOs may only be granted to Service Providers.

## **ARTICLE 5. OPTIONS.**

**5.1 Stock Option Agreement .** Each grant of an Option under the Plan shall be evidenced by a Stock Option Agreement between the Optionee and the Company. Such Option shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The Stock Option Agreement shall specify whether the Option is intended to be an ISO or an NSO. The provisions of the various Stock Option Agreements entered into under the Plan need not be identical.

**5.2 Number of Shares .** Each Stock Option Agreement shall specify the number of Common Shares subject to the Option, which number shall adjust in accordance with Article 9.

**5.3 Exercise Price .** Each Stock Option Agreement shall specify the Exercise Price, which shall not be less than 100% of the Fair Market Value of a Common Share on the date of grant. The preceding sentence shall not apply to an Option that is a Substitute Award granted in a manner that would satisfy the requirements of Code Section 409A and, if applicable, Code Section 424(a).

**5.4 Exercisability and Term .** Each Stock Option Agreement shall specify the date or event when all or any installment of the Option is to become vested and/or exercisable. The Stock Option Agreement shall also specify the term of the Option; provided that, except to the extent necessary to comply with applicable foreign law, the term of an Option shall in no event exceed 10 years from the date of grant. A Stock Option Agreement may provide for accelerated vesting and/or exercisability upon certain specified events and may provide for expiration prior to the end of its term in the event of the termination of the Optionee's Service.

**5.5 Death of Optionee .** After an Optionee's death, any vested and exercisable Options held by such Optionee may be exercised by his or her beneficiary or beneficiaries. Each Optionee may designate one or more beneficiaries for this purpose by filing the prescribed form with the Company. A beneficiary designation may be changed by filing the prescribed form with the Company at any time before the Optionee's death. If no beneficiary was designated or if no designated beneficiary survives the Optionee, then any vested and exercisable Options held by the Optionee may be exercised by his or her estate.

**5.6 Modification or Assumption of Options .** Within the limitations of the Plan, the Administrator may modify, extend or assume outstanding Options, provided that no modification of an Option shall, without the consent of the Optionee, impair his or her rights or obligations under such Option. Notwithstanding anything in this Plan to the contrary, and except for the adjustments provided in Article 9, neither the Administrator nor any other person may: (a) decrease the Exercise Price of any outstanding Option after the date of grant, (b) cancel or allow an Optionee to surrender an outstanding Option to the Company in exchange for cash or as consideration for the grant of a new Option with a lower Exercise Price or the grant of another

Award the effect of which is to reduce the Exercise Price of any outstanding Option, or (c) take any other action with respect to an Option that would be treated as a repricing under the rules and regulations of the Nasdaq Global Market (or such other principal U.S. national securities exchange on which the Common Shares are traded), unless the Company's stockholders have approved such an action within twelve (12) months prior to such an event.

**5.7 Buyout Provisions.** Except to the extent prohibited by Article 5.6, the Administrator may at any time (a) offer to buy out for a payment in cash or cash equivalents an Option previously granted or (b) authorize an Optionee to elect to cash out an Option previously granted, in either case at such time and based upon such terms and conditions as the Administrator shall establish.

**5.8 Payment for Option Shares.** The entire Exercise Price of Common Shares issued upon exercise of Options shall be payable in cash or cash equivalents at the time when such Common Shares are purchased. In addition, the Administrator may, in its sole discretion and to the extent permitted by applicable law, accept payment of all or a portion of the Exercise Price through any one or a combination of the following forms or methods:

(a) Subject to any conditions or limitations established by the Administrator, by surrendering, or attesting to the ownership of, Common Shares that are already owned by the Optionee with a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Common Shares as to which such Option will be exercised;

(b) By delivering (on a form prescribed by the Company) an irrevocable direction to a securities broker approved by the Company to sell all or part of the Common Shares being purchased under the Plan and to deliver all or part of the sales proceeds to the Company;

(c) Subject to such conditions and requirements as the Administrator may impose from time to time, through a net exercise procedure;

(d) By delivering a full-recourse promissory note, on such terms approved by the Administrator; or

(e) Through any other form or method consistent with applicable laws, regulations and rules.

## **ARTICLE 6. STOCK APPRECIATION RIGHTS.**

**6.1 SAR Agreement.** Each grant of a SAR under the Plan shall be evidenced by a SAR Agreement between the Optionee and the Company. Such SAR shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various SAR Agreements entered into under the Plan need not be identical.

**6.2 Number of Shares.** Each SAR Agreement shall specify the number of Common Shares to which the SAR pertains, which number shall adjust in accordance with Article 9.

**6.3 Exercise Price.** Each SAR Agreement shall specify the Exercise Price, which shall in no event be less than 100% of the Fair Market Value of a Common Share on the date of grant. The preceding sentence shall not apply to a SAR that is a Substitute Award granted in a manner that would satisfy the requirements of Code Section 409A.

**6.4 Exercisability and Term.** Each SAR Agreement shall specify the date when all or any installment of the SAR is to become vested and exercisable. The SAR Agreement shall also specify the term of the SAR; provided that except to the extent necessary to comply with applicable foreign law, the term of a SAR shall not exceed 10 years from the date of grant. A SAR Agreement may provide for accelerated vesting and exercisability upon certain specified events and may provide for expiration prior to the end of its term in the event of the termination of the Optionee's Service.

**6.5 Exercise of SARs.** Upon exercise of a SAR, the Optionee (or any person having the right to exercise the SAR after his or her death) shall receive from the Company (a) Common Shares, (b) cash or (c) a combination of Common Shares and cash, as the Administrator shall determine. The amount of cash and/or the Fair Market Value of Common Shares received upon exercise of SARs shall, in the aggregate, not exceed the amount by which the Fair Market Value (on the date of surrender) of the Common Shares subject to the SARs exceeds the Exercise Price. If, on the date when a SAR expires, the Exercise Price is less than the Fair Market Value on such date but any portion of such SAR has not been exercised or surrendered, then such SAR shall automatically be deemed to be exercised as of such date with respect to such portion. A SAR Agreement may also provide for an automatic exercise of the SAR on an earlier date.

**6.6 Death of Optionee.** After an Optionee's death, any vested and exercisable SARs held by such Optionee may be exercised by his or her beneficiary or beneficiaries. Each Optionee may designate one or more beneficiaries for this purpose by filing the prescribed form with the Company. A beneficiary designation may be changed by filing the prescribed form with the Company at any time before the Optionee's death. If no beneficiary was designated or if no designated beneficiary survives the Optionee, then any vested and exercisable SARs held by the Optionee at the time of his or her death may be exercised by his or her estate.

**6.7 Modification or Assumption of SARs.** Within the limitations of the Plan, the Administrator may modify, extend or assume outstanding SARs, provided that no modification of a SAR shall, without the consent of the Optionee, impair his or her rights or obligations under such SAR. Notwithstanding anything in this Plan to the contrary, and except for the adjustments provided in Article 9, neither the Administrator nor any other person may: (a) decrease the Exercise Price of any outstanding SAR after the date of grant, (b) cancel or allow an Optionee to surrender an outstanding SAR to the Company in exchange for cash or as consideration for the grant of a new SAR with a lower Exercise Price or the grant of another Award the effect of which is to reduce the Exercise Price of any outstanding SAR, or (c) take any other action with respect to a SAR that would be treated as a repricing under the rules and regulations of the Nasdaq Global Market (or such other principal U.S. national securities exchange on which the Common Shares are traded), unless the Company's stockholders have approved such an action within twelve (12) months prior to such an event.

## **ARTICLE 7. RESTRICTED SHARES.**

**7.1 Restricted Stock Agreement.** Each grant of Restricted Shares under the Plan shall be evidenced by a Restricted Stock Agreement between the recipient and the Company. Such Restricted Shares shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various Restricted Stock Agreements entered into under the Plan need not be identical.

**7.2 Payment for Awards.** Restricted Shares may be sold or awarded under the Plan for such consideration as the Administrator may determine, including (without limitation) cash, cash equivalents, property, cancellation of other equity awards, full-recourse promissory notes, past services and future services, and such other methods of payment as are permitted by applicable law.

**7.3 Vesting Conditions.** Each Award of Restricted Shares may or may not be subject to vesting and/or other conditions as the Administrator may determine. Vesting shall occur, in full or in installments, upon satisfaction of the conditions specified in the Restricted Stock Agreement. Such conditions, at the Administrator's discretion, may include one or more Performance Goals. A Restricted Stock Agreement may provide for accelerated vesting upon certain specified events.

**7.4 Voting and Dividend Rights.** The holders of Restricted Shares awarded under the Plan shall have the same voting, dividend and other rights as the Company's other stockholders, unless the Administrator otherwise provides. A Restricted Stock Agreement, however, may require that any cash dividends paid on Restricted Shares (a) be accumulated and paid when such Restricted Shares vest, or (b) be invested in additional Restricted Shares. Such additional Restricted Shares shall be subject to the same conditions and restrictions as the shares subject to the Stock Award with respect to which the dividends were paid. In addition, unless the Administrator provides otherwise, if any dividends or other distributions are paid in Common Shares, such Common Shares shall be subject to the same restrictions on transferability and forfeitability as the Restricted Shares with respect to which they were paid.

## **ARTICLE 8. STOCK UNITS.**

**8.1 Stock Unit Agreement.** Each grant of Stock Units under the Plan shall be evidenced by a Stock Unit Agreement between the recipient and the Company. Such Stock Units shall be subject to all applicable terms of the Plan and may be subject to any other terms that are not inconsistent with the Plan. The provisions of the various Stock Unit Agreements entered into under the Plan need not be identical.

**8.2 Payment for Awards.** To the extent that an Award is granted in the form of Stock Units, no cash consideration shall be required of the Award recipients.

**8.3 Vesting Conditions.** Each Award of Stock Units may or may not be subject to vesting, as determined by the Administrator. Vesting shall occur, in full or in installments, upon satisfaction of the conditions specified in the Stock Unit Agreement. Such conditions, at the Administrator's discretion, may include one or more Performance Goals. A Stock Unit Agreement may provide for accelerated vesting upon certain specified events.



**8.4 Voting and Dividend Rights.** The holders of Stock Units shall have no voting rights. Prior to settlement or forfeiture, Stock Units awarded under the Plan may, at the Administrator's discretion, provide for a right to dividend equivalents. Such right entitles the holder to be credited with an amount equal to all cash dividends paid on one Common Share while the Stock Unit is outstanding. Dividend equivalents may be converted into additional Stock Units. Settlement of dividend equivalents may be made in the form of cash, in the form of Common Shares, or in a combination of both. Prior to distribution, any dividend equivalents shall be subject to the same conditions and restrictions as the Stock Units to which they attach.

**8.5 Form and Time of Settlement of Stock Units.** Settlement of vested Stock Units may be made in the form of (a) cash, (b) Common Shares or (c) any combination of both, as determined by the Administrator. The actual number of Stock Units eligible for settlement may be larger or smaller than the number included in the original Award, based on predetermined performance factors, including Performance Goals. Methods of converting Stock Units into cash may include (without limitation) a method based on the average Fair Market Value of Common Shares over a series of trading days. Vested Stock Units shall be settled in such manner and at such time(s) as specified in the Stock Unit Agreement. Until an Award of Stock Units is settled, the number of such Stock Units shall be subject to adjustment pursuant to Article 9.

**8.6 Death of Recipient.** Any Stock Units that become payable after the recipient's death shall be distributed to the recipient's beneficiary or beneficiaries. Each recipient of Stock Units under the Plan may designate one or more beneficiaries for this purpose by filing the prescribed form with the Company. A beneficiary designation may be changed by filing the prescribed form with the Company at any time before the Award recipient's death. If no beneficiary was designated or if no designated beneficiary survives the Award recipient, then any Stock Units that become payable after the recipient's death shall be distributed to the recipient's estate.

**8.7 Modification or Assumption of Stock Units.** Within the limitations of the Plan, the Administrator may modify or assume outstanding stock units or may accept the cancellation of outstanding stock units (whether granted by the Company or by another issuer) in return for the grant of new Stock Units for the same or a different number of shares or in return for the grant of a different type of Award. The foregoing notwithstanding, no modification of a Stock Unit shall, without the consent of the Participant, impair his or her rights or obligations under such Stock Unit.

**8.8 Creditors' Rights.** A holder of Stock Units shall have no rights other than those of a general creditor of the Company. Stock Units represent an unfunded and unsecured obligation of the Company, subject to the terms and conditions of the applicable Stock Unit Agreement.

## **ARTICLE 9. ADJUSTMENTS; DISSOLUTIONS AND LIQUIDATIONS; CORPORATE TRANSACTIONS.**

**9.1 Adjustments.** In the event of a subdivision of the outstanding Common Shares, a declaration of a dividend payable in Common Shares or a combination or consolidation of the outstanding Common Shares (by reclassification or otherwise) into a lesser number of Common

Shares or any other increase or decrease in the number of issued Common Shares effected without receipt of consideration by the Company, corresponding proportionate adjustments shall automatically be made in each of the following:

(a) The number and kind of shares available for issuance under Article 3, including the numerical share limits in Articles 3.1 and 3.4;

(b) The number and kind of shares covered by each outstanding Option, SAR and Stock Unit; and

(c) The Exercise Price applicable to each outstanding Option and SAR, and the repurchase price, if any, applicable to Restricted Shares.

In the event of a declaration of an extraordinary dividend payable in a form other than Common Shares in an amount that has a material effect on the price of Common Shares, a recapitalization, a spin-off or a similar occurrence, the Administrator shall make such adjustments as it, in its sole discretion, deems appropriate in one or more of the foregoing. Any adjustment in the number of and kind of shares subject to an Award under this Article 9.1 shall be rounded down to the nearest whole share, although the Administrator in its sole discretion may make a cash payment in lieu of a fractional share. Except as provided in this Article 9, a Participant shall have no rights by reason of any issuance by the Company of stock of any class or securities convertible into stock of any class, any subdivision or consolidation of shares of stock of any class, the payment of any stock dividend or any other increase or decrease in the number of shares of stock of any class.

**9.2 Dissolution or Liquidation.** To the extent not previously exercised or settled, Options, SARs and Stock Units shall terminate immediately prior to the dissolution or liquidation of the Company.

**9.3 Corporate Transactions.** In the event that the Company is a party to a merger, consolidation, or a Change in Control (other than one described in Article 14.6(d)), all Common Shares acquired under the Plan and all Awards outstanding on the effective date of the transaction shall be treated in the manner described in the definitive transaction agreement (or, in the event the transaction does not entail a definitive agreement to which the Company is party, in the manner determined by the Administrator, with such determination having final and binding effect on all parties), which agreement or determination need not treat all Awards (or portions thereof) in an identical manner. Unless an Award Agreement provides otherwise, the treatment specified in the transaction agreement or by the Administrator shall include (without limitation) one or more of the following with respect to each outstanding Award:

(a) The continuation of such outstanding Awards by the Company (if the Company is the surviving entity);

(b) The assumption of such outstanding Awards by the surviving entity or its parent, provided that the assumption of an Option or a SAR shall comply with applicable tax requirements;

(c) The substitution by the surviving entity or its parent of an equivalent award for outstanding Awards (including, but not limited to, an award to acquire the same consideration paid to the holders of Common Shares in the transaction), provided that the substitution of an Option or a SAR shall comply with applicable tax requirements;

(d) The cancellation of outstanding Options and SARs without payment of any consideration. The Optionees shall be able to exercise such Options and SARs (to the extent the Options and SARs are vested or become vested as of the effective date of the transaction) during a period of not less than five full business days preceding the closing date of the transaction, unless (i) a shorter period is required to permit a timely closing of the transaction and (ii) such shorter period still offers the Optionees a reasonable opportunity to exercise such Options and SARs. Any exercise of such Options and SARs during such period may be contingent on the closing of the transaction;

(e) Full exercisability of outstanding Options and SARs and full vesting of the Common Shares subject to Options and SARs, followed by cancellation of such Options and SARs. The full exercisability of such Options and SARs and full vesting of such Common Shares may be contingent on the closing of the transaction. The Optionees shall be able to exercise such Options and SARs during a period of not less than five full business days preceding the closing date of such merger or consolidation, unless (i) a shorter period is required to permit a timely closing of such merger or consolidation and (ii) such shorter period still offers the Optionees a reasonable opportunity to exercise such Options and SARs. Any exercise of such Options and SARs during such period may be contingent on the closing of such merger or consolidation;

(f) The cancellation of the Options and SARs and a payment to the Optionee with respect to each Share subject to the portion of the Award that is vested as of the transaction date equal to the excess of (A) the value, as determined by the Administrator in its absolute discretion, of the property (including cash) received by the holder of a Common Share as a result of the transaction, over (B) the per-share Exercise Price of the Option or SAR (such excess, the “**Spread**”). Such payment shall be made in the form of cash, cash equivalents, or securities of the surviving entity or its parent having a value equal to the Spread. In addition, any escrow, holdback, earn-out or similar provisions in the transaction agreement may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of Common Shares, but only to the extent the application of such provisions does not adversely affect the status of the Option or SAR as exempt from Code Section 409A. If the Spread applicable to an Option or SAR is zero or a negative number, then the Option or SAR may be cancelled without making a payment to the Optionee;

(g) The cancellation of outstanding Stock Units and a payment to the holder thereof with respect to each Common Share subject to the Stock Unit equal to the value, as determined by the Administrator in its absolute discretion, of the property (including cash) received by the holder of a Common Share as a result of the transaction (the “**Transaction Value**”). Such payment shall be made in the form of cash, cash equivalents, or securities of the surviving entity or its parent having a value equal to the Transaction Value. In addition, such payment may be subject to vesting based on the Participant’s continuing Service, provided that the vesting schedule shall not be less favorable to the Participant than the schedule under which

such Stock Units would have vested, and if required under applicable tax rules, such payment may be deferred until the settlement date specified in the Stock Unit Agreement.

In addition, any escrow, holdback, earn-out or similar provisions in the transaction agreement may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of Common Shares. In the event that a Stock Unit is subject to Code Section 409A, the payment described in this clause (g) shall be made on the settlement date specified in the applicable Stock Unit Agreement, provided that settlement may be accelerated in accordance with Treasury Regulation Section 1.409A-3(j)(4); or

(h) The assignment of any reacquisition or repurchase rights held by the Company in respect of an Award of Restricted Shares to the surviving entity or its parent, with corresponding proportionate adjustments made to the price per share to be paid upon exercise of any such reacquisition or repurchase rights.

For avoidance of doubt, the Administrator shall have the discretion, exercisable either at the time an Award is granted or at any time while the Award remains outstanding, to provide for the acceleration of vesting upon the occurrence of a Change in Control, whether or not the Award is to be assumed or replaced in the transaction, or in connection with a termination of the Participant's Service following a transaction.

Any action taken under this Article 9.3 shall either preserve an Award's status as exempt from Code Section 409A or comply with Code Section 409A.

## **ARTICLE 10. OTHER AWARDS.**

**10.1 Performance Cash Awards .** A Performance Cash Award is a cash award that may be granted subject to the attainment of specified Performance Goals during a Performance Period. A Performance Cash Award may also require the completion of a specified period of continuous Service. The length of the Performance Period, the Performance Goals to be attained during the Performance Period, and the degree to which the Performance Goals have been attained shall be determined conclusively by the Administrator. Each Performance Cash Award shall be set forth in a written agreement or in a resolution duly adopted by the Administrator which shall contain provisions determined by the Administrator and not inconsistent with the Plan. The terms of various Performance Cash Awards need not be identical.

**10.2 Awards Under Other Plans .** The Company may grant awards under other plans or programs. Such awards may be settled in the form of Common Shares issued under this Plan. Such Common Shares shall be treated for all purposes under the Plan like Common Shares issued in settlement of Stock Units and shall, when issued, reduce the number of Common Shares available under Article 3.

## **ARTICLE 11. LIMITATION ON RIGHTS.**

**11.1 Retention Rights.** Neither the Plan nor any Award granted under the Plan shall be deemed to give any individual a right to remain a Service Provider. The Company and its Parents, Subsidiaries and Affiliates reserve the right to terminate the Service of any Service Provider at any time, with or without cause, subject to applicable laws, the Company's certificate of incorporation and by-laws and a written employment agreement (if any).

**11.2 Stockholders' Rights.** Except as set forth in Article 7.4 or 8.4 above, a Participant shall have no dividend rights, voting rights or other rights as a stockholder with respect to any Common Shares covered by his or her Award prior to the time when a stock certificate for such Common Shares is issued or, if applicable, the time when he or she becomes entitled to receive such Common Shares by filing any required notice of exercise and paying any required Exercise Price. No adjustment shall be made for cash dividends or other rights for which the record date is prior to such time, except as expressly provided in the Plan.

**11.3 Regulatory Requirements.** Any other provision of the Plan notwithstanding, the obligation of the Company to issue Common Shares under the Plan shall be subject to all applicable laws, rules and regulations and such approval by any regulatory body as may be required. The Company reserves the right to restrict, in whole or in part, the delivery of Common Shares pursuant to any Award prior to the satisfaction of all legal requirements relating to the issuance of such Common Shares, to their registration, qualification or listing or to an exemption from registration, qualification or listing. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed necessary by the Company's counsel to be necessary to the lawful issuance and sale of any Common Shares hereunder, will relieve the Company of any liability in respect of the failure to issue or sell such Common Shares as to which such requisite authority will not have been obtained.

**11.4 Transferability of Awards.** The Administrator may, in its sole discretion, permit transfer of an Award in a manner consistent with applicable law. Unless otherwise determined by the Administrator, Awards shall be transferable by a Participant only by (a) beneficiary designation, (b) a will or (c) the laws of descent and distribution. An ISO may only be transferred by will or by the laws of descent and distribution and may be exercised during the lifetime of the Optionee only by the Optionee or by the Optionee's guardian or legal representative.

**11.5 Other Conditions and Restrictions on Common Shares.** Any Common Shares issued under the Plan shall be subject to such forfeiture conditions, rights of repurchase, rights of first refusal, other transfer restrictions and such other terms and conditions as the Administrator may determine. Such conditions and restrictions shall be set forth in the applicable Award Agreement and shall apply in addition to any restrictions that may apply to holders of Common Shares generally. In addition, Common Shares issued under the Plan shall be subject to such conditions and restrictions imposed either by applicable law or by Company policy, as adopted from time to time, designed to ensure compliance with applicable law or laws with which the Company determines in its sole discretion to comply including in order to maintain any statutory, regulatory or tax advantage.

**11.6 Repayment of Awards as a Result of Certain Improper Conduct .** If an Award has been paid to an Participant who is an "executive officer" within the meaning of Exchange Act Rule 3b-7 (an "**Executive Participant**") or to such individual's spouse or beneficiary, and the Administrator later determines that financial results used to determine the amount of such Award are materially restated and that the Executive Participant engaged in fraud or intentional misconduct, the Company may seek repayment or recovery of the Award, as appropriate, notwithstanding any contrary provision of the Plan. In addition, the Administrator may provide that any Participant and/or any Award, including any Common Shares subject to or issued under

an Award, are subject to any other recovery, recoupment, clawback and/or other forfeiture policy maintained by the Company from time to time, including as required by Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

## **ARTICLE 12. TAXES.**

**12.1 General.** As a condition to an Award under the Plan, a Participant or his or her successor shall make arrangements satisfactory to the Company for the satisfaction of any federal, state, local or foreign withholding tax obligations that arise in connection with any Award granted under the Plan. The Company shall not be required to issue any Common Shares or make any cash payment under the Plan until such obligations are satisfied.

**12.2 Share Withholding.** To the extent that applicable law subjects a Participant to tax withholding obligations, the Administrator may permit such Participant to satisfy all or part of such obligations by having the Company withhold all or a portion of any Common Shares that otherwise would be issued to him or her or by surrendering all or a portion of any Common Shares that he or she previously acquired. Such Common Shares shall be valued at their Fair Market Value on the date when they are withheld or surrendered. Any payment of taxes by assigning Common Shares to the Company may be subject to restrictions including any restrictions required by SEC, accounting or other rules.

**12.3 Section 162(m) Matters** The Administrator, in its sole discretion, may determine whether an Award is intended to qualify as “performance-based compensation” within the meaning of Code Section 162(m). The Administrator may grant Awards that are based on Performance Goals but that are not intended to qualify as performance-based compensation. With respect to any Award that is intended to qualify as performance-based compensation, the Administrator shall designate the Performance Goal(s) applicable to, and the formula for calculating the amount payable under, an Award within 90 days following commencement of the applicable Performance Period (or such earlier time as may be required under Code Section 162(m)), and in any event at a time when achievement of the applicable Performance Goal(s) remains substantially uncertain. Prior to the payment of any Award that is intended to constitute performance-based compensation, the Administrator shall certify in writing whether and the extent to which the Performance Goal(s) were achieved for such Performance Period. The Administrator shall have the right to reduce or eliminate (but not to increase) the amount payable under an Award that is intended to constitute performance-based compensation.

**12.4 Section 409A Matters.** Except as otherwise expressly set forth in an Award Agreement, it is intended that Awards granted under the Plan either be exempt from, or comply with, the requirements of Code Section 409A. To the extent an Award is subject to Code Section 409A (a “**409A Award**”), the terms of the Plan, the Award and any written agreement governing the Award shall be interpreted to comply with the requirements of Code Section 409A so that the Award is not subject to additional tax or interest under Code Section 409A, unless the Administrator expressly provides otherwise. A 409A Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order for it to comply with the requirements of Code Section 409A. In this regard, if any amount under a 409A Award is payable upon a “separation from service” to an individual who is considered a “specified employee” (as each term is defined under Code Section 409A), then no such payment

shall be made prior to the date that is the earlier of (i) six months and one day after the Participant's separation from service or (ii) the Participant's death, but only to the extent such delay is necessary to prevent such payment from being subject to Code Section 409A(a) (1).

**12.5 Limitation on Liability.** Neither the Company nor any person serving as Administrator shall have any liability to a Participant in the event an Award held by the Participant fails to achieve its intended characterization under applicable tax law.

#### **ARTICLE 13. FUTURE OF THE PLAN.**

**13.1 Term of the Plan.** The Plan, as set forth herein, shall become effective on the Registration Date. The Plan shall remain in effect until the earlier of (a) the date when the Plan is terminated under Article 13.2 or (b) the 10th anniversary of the date when the Board adopted the Plan.

**13.2 Amendment or Termination.** The Board may, at any time and for any reason, amend or terminate the Plan. No Awards shall be granted under the Plan after the termination thereof. The termination of the Plan, or any amendment thereof, shall not affect any Award previously granted under the Plan.

**13.3 Stockholder Approval.** An amendment of the Plan shall be subject to the approval of the Company's stockholders only to the extent required by applicable laws, regulations or rules.

#### **ARTICLE 14. DEFINITIONS.**

14.1 **"Administrator"** means the Board or any Committee administering the Plan in accordance with Article 2.

14.2 **"Affiliate"** means any entity other than a Subsidiary, if the Company and/or one or more Subsidiaries own not less than 50% of such entity.

14.3 **"Award"** means any award granted under the Plan, including as an Option, a SAR, a Restricted Share, a Stock Unit or a Performance Cash Award.

14.4 **"Award Agreement"** means a Stock Option Agreement, an SAR Agreement, a Restricted Stock Agreement, a Stock Unit Agreement or such other agreement evidencing an Award granted under the Plan.

14.5 **"Board"** means the Company's Board of Directors, as constituted from time to time.

14.6 **"Change in Control"** means:

(a) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then-outstanding voting securities;

(b) The consummation of the sale or disposition by the Company of all or substantially all of the Company's assets;

(c) The consummation of a merger or consolidation of the Company with or into any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or

(d) Individuals who are members of the Board (the “**Incumbent Board**”) cease for any reason to constitute at least a majority of the members of the Board over a period of 12 months; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

A transaction shall not constitute a Change in Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In addition, if a Change in Control constitutes a payment event with respect to any Award which provides for a deferral of compensation and is subject to Code Section 409A, then notwithstanding anything to the contrary in the Plan or applicable Award Agreement the transaction with respect to such Award must also constitute a “change in control event” as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Code Section 409A.

14.7 “**Code**” means the Internal Revenue Code of 1986, as amended.

14.8 “**Committee**” means a committee of one or more members of the Board, or of other individuals satisfying applicable laws, appointed by the Board to administer the Plan.

14.9 “**Common Share**” means one share of the common stock of the Company.

14.10 “**Company**” means KaloBios Pharmaceuticals, Inc., a Delaware corporation.

14.11 “**Consultant**” means a consultant or adviser who provides *bona fide* services to the Company, a Parent, a Subsidiary or an Affiliate as an independent contractor and who qualifies as a consultant or advisor under Instruction A.1.(a)(1) of Form S-8 under the Securities Act.

14.12 “**Employee**” means a common-law employee of the Company, a Parent, a Subsidiary or an Affiliate.

14.13 “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.



14.14 “**Exercise Price**,” in the case of an Option, means the amount for which one Common Share may be purchased upon exercise of such Option, as specified in the applicable Stock Option Agreement. “Exercise Price,” in the case of a SAR, means an amount, as specified in the applicable SAR Agreement, which is subtracted from the Fair Market Value of one Common Share in determining the amount payable upon exercise of such SAR.

14.15 “**Fair Market Value**” means the closing price of a Common Share on any established stock exchange or a national market system on the applicable date or, if the applicable date is not a trading day, on the last trading day prior to the applicable date, as reported in a source that the Administrator deems reliable. If Common Shares are no longer traded on an established stock exchange or a national market system, the Fair Market Value shall be determined by the Administrator in good faith on such basis as it deems appropriate. The Administrator’s determination shall be conclusive and binding on all persons.

14.16 “**ISO**” means an incentive stock option described in Code Section 422(b).

14.17 “**NSO**” means a stock option not described in Code Sections 422 or 423.

14.18 “**Option**” means an ISO or NSO granted under the Plan and entitling the holder to purchase Common Shares.

14.19 “**Optionee**” means an individual or estate holding an Option or SAR.

14.20 “**Outside Director**” means a member of the Board who is not an Employee.

14.21 “**Parent**” means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company, if each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Parent on a date after the adoption of the Plan shall be considered a Parent commencing as of such date.

14.22 “**Participant**” means an individual or estate holding an Award.

14.23 “**Performance Cash Award**” means an award of cash granted under Article 10.1 of the Plan.

14.24 “**Performance Goal**” means a goal established by the Administrator for the applicable Performance Period based on one or more of the performance criteria set forth in **Appendix A**. Depending on the performance criteria used, a Performance Goal may be expressed in terms of overall Company performance or the performance of a business unit, division, Subsidiary, Affiliate or an individual. A Performance Goal may be measured either in absolute terms or relative to the performance of one or more comparable companies or one or more relevant indices. The Administrator may adjust the results under any performance criterion to exclude any of the following events that occurs during a Performance Period: (a) asset write-downs, (b) litigation, claims, judgments or settlements, (c) the effect of changes in tax laws, accounting principles or other laws or provisions affecting reported results, (d) accruals for

reorganization and restructuring programs, (e) extraordinary, unusual or non-recurring items, (f) exchange rate effects for non-U.S. dollar denominated net sales and operating earnings, or (g) statutory adjustments to corporate tax rates; provided, however, that if an Award is intended to qualify as “performance-based compensation” within the meaning of Code Section 162(m), such adjustment(s) shall only be made to the extent consistent with Code Section 162(m)..

14.25 “**Performance Period**” means a period of time selected by the Administrator over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to a Performance Cash Award or an Award of Restricted Shares or Stock Units that vests based on the achievement of Performance Goals. Performance Periods may be of varying and overlapping duration, at the discretion of the Administrator.

14.26 “**Plan**” means this KaloBios Pharmaceuticals, Inc. 2012 Equity Incentive Plan, as amended from time to time.

14.27 “**Predecessor Plan**” means the Company’s 2001 Stock Plan, as amended.

14.28 “**Registration Date**” means the effective date of the registration statement filed by the Company with the Securities and Exchange Commission pursuant to Form 10.

14.29 “**Restricted Share**” means a Common Share awarded under the Plan.

14.30 “**Restricted Stock Agreement**” means the agreement between the Company and the recipient of a Restricted Share that contains the terms, conditions and restrictions pertaining to such Restricted Share.

14.31 “**SAR**” means a stock appreciation right granted under the Plan.

14.32 “**SAR Agreement**” means the agreement between the Company and an Optionee that contains the terms, conditions and restrictions pertaining to his or her SAR.

14.33 “**Service**” means service as an Employee, Outside Director or Consultant.

14.34 “**Service Provider**” means any individual who is an Employee, Outside Director or Consultant.

14.35 “**Stock Award**” means any award of an Option, a SAR, a Restricted Share or a Stock Unit under the Plan.

14.36 “**Stock Option Agreement**” means the agreement between the Company and an Optionee that contains the terms, conditions and restrictions pertaining to his or her Option.

14.37 “**Stock Unit**” means a bookkeeping entry representing the equivalent of one Common Share, as awarded under the Plan.

14.38 “**Stock Unit Agreement**” means the agreement between the Company and the recipient of a Stock Unit that contains the terms, conditions and restrictions pertaining to such Stock Unit.

14.39 “**Subsidiary**” means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Subsidiary on a date after the adoption of the Plan shall be considered a Subsidiary commencing as of such date

14.40 “**Substitute Awards**” means Awards or Common Shares issued by the Company in assumption of, or substitution or exchange for, Awards previously granted, or the right or obligation to make future awards, in each case by a corporation acquired by the Company or any Affiliate or with which the Company or any Affiliate combines to the extent permitted by Nasdaq Marketplace Rule 5635 or any successor thereto.

# Appendix A

## Performance Criteria

The Administrator may establish Performance Goals derived from one or more of the following criteria when it makes Awards of Restricted Shares or Stock Units that vest entirely or in part on the basis of performance or when it makes Performance Cash Awards:

- ⌚ Earnings (before or after taxes)
  - ⌚ Sales or revenue (using a measure thereof that complies with Section 162(m))
  - ⌚ Earnings per share
  - ⌚ Expense or cost reduction
  - ⌚ Earnings before interest, taxes and depreciation
  - ⌚ Working capital
  - ⌚ Earnings before interest, taxes, depreciation and amortization
  - ⌚ Economic value added (or an equivalent metric)
  - ⌚ Total stockholder return
  - ⌚ Market share
  - ⌚ Return on equity or average stockholders' equity
  - ⌚ Cash measures including cash flow and cash balance
  - ⌚ Return on assets, investment or capital employed
  - ⌚ Operating cash flow
  - ⌚ Operating income
  - ⌚ Cash flow per share
  - ⌚ Gross margin
  - ⌚ Share price
  - ⌚ Operating margin
  - ⌚ Debt reduction
  - ⌚ Net operating income
  - ⌚ Customer satisfaction
  - ⌚ Net operating income after tax
  - ⌚ Stockholders' equity
  - ⌚ Return on operating revenue
  - ⌚ Contract awards or backlog
  - ⌚ Objective corporate or individual strategic goals
  - ⌚ Objective individual performance goals
  - ⌚ To the extent that an Award is not intended to comply with Code Section 162(m), other measures of performance selected by the Administrator
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**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.

August 10, 2015

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

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**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.

August 10, 2015

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

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**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 June 30, 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.

August 10, 2015

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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.

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**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 June 30, 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.

August 10, 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.

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