

CYTOKINETICS INC  
Form 10-Q  
May 06, 2011

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2011**

**or**

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

**Commission file number: 000-50633**

**CYTOKINETICS, INCORPORATED**

**(Exact name of registrant as specified in its charter)**

**Delaware  
(State or other jurisdiction of  
incorporation or organization)**

**94-3291317  
(I.R.S. Employer  
Identification Number)**

**280 East Grand Avenue  
South San Francisco, California  
(Address of principal executive offices)**

**94080  
(Zip Code)**

**Registrant's telephone number, including area code: (650) 624-3000**

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 ☐

\* The registrant has not yet been phased into the interactive data requirements.

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. (Check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting  
company ☐

(Do not check if a 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 ☒

Number of shares of common stock, \$0.001 par value, outstanding as of April 29, 2011: 72,216,100.

**CYTOKINETICS, INCORPORATED**  
**TABLE OF CONTENTS FOR FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2011**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	3
<u>Item 1. Financial Statements</u>	3
<u>Unaudited Condensed Balance Sheets as of March 31, 2011 and December 31, 2010</u>	3
<u>Unaudited Condensed Statements of Operations for the three months ended March 31, 2011 and 2010, and the period from August 5, 1997 (date of inception) to March 31, 2011</u>	4
<u>Unaudited Condensed Statements of Cash Flows for the three months ended March 31, 2011 and 2010, and the period from August 5, 1997 (date of inception) to March 31, 2011</u>	5
<u>Notes to Unaudited Condensed Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	25
<u>Item 4. Controls and Procedures</u>	25
<b><u>PART II. OTHER INFORMATION</u></b>	25
<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	43
<u>Item 3. Defaults Upon Senior Securities</u>	43
<u>Item 4. Reserved</u>	43
<u>Item 5. Other Information</u>	43
<u>Item 6. Exhibits</u>	43
<b><u>SIGNATURES</u></b>	45
<b><u>EXHIBIT INDEX</u></b>	46
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	

**Table of Contents**

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

**CYTOKINETICS, INCORPORATED****(A Development Stage Enterprise)****CONDENSED BALANCE SHEETS**

(In thousands, except share and per share data)

(Unaudited)

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,452	\$ 17,514
Short-term investments	44,449	54,125
Related party accounts receivable	34	46
Prepaid and other current assets	3,019	1,813
Total current assets	62,954	73,498
Long-term investments		1,206
Property and equipment, net	2,041	2,321
Restricted cash	439	788
Other assets	228	179
Total assets	\$ 65,662	\$ 77,992
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,045	\$ 1,119
Accrued liabilities	4,279	5,372
Related party payables and accrued liabilities	11	
Short-term portion of equipment financing lines	690	833
Deferred revenue	17	
Total current liabilities	6,042	7,324
Long-term portion of equipment financing lines	34	152
Total liabilities	6,076	7,476
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock:		
Authorized: 10,000,000 shares at March 31, 2011 and December 31, 2010		
Issued and outstanding: zero shares at March 31, 2011 and December 31, 2010		
Common stock, \$0.001 par value:		
Authorized: 170,000,000 shares at March 31, 2011 and December 31, 2010		
Issued and outstanding: 66,916,100 shares at March 31, 2011 and 66,907,600 shares at December 31, 2010	67	67
Additional paid-in capital	431,872	431,103

Edgar Filing: CYTOKINETICS INC - Form 10-Q

Accumulated other comprehensive income (loss)	9	(4)
Deficit accumulated during the development stage	(372,362)	(360,650)
Total stockholders' equity	59,586	70,516
Total liabilities and stockholders' equity	\$ 65,662	\$ 77,992

The accompanying notes are an integral part of these financial statements.

3 of 49

---

Table of Contents

**CYTOKINETICS, INCORPORATED**  
**(A Development Stage Enterprise)**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)  
(Unaudited)

	<b>Three Months Ended</b>		<b>Period from</b>
	<b>March</b>	<b>March</b>	<b>August 5, 1997</b>
	<b>31,</b>	<b>31,</b>	<b>(Date of</b>
	<b>2011</b>	<b>2010</b>	<b>Inception)</b>
			<b>to March 31,</b>
			<b>2011</b>
Revenues:			
Research and development revenues from related parties	\$ 389	\$ 621	\$ 49,486
Research and development, grant and other revenues	374		4,419
License revenues from related parties			112,935
Total revenues	763	621	166,840
Operating expenses:			
Research and development	9,179	9,068	424,469
General and administrative	3,336	3,836	133,699
Restructuring charges			2,450
Total operating expenses	12,515	12,904	560,618
Operating loss	(11,752)	(12,283)	(393,778)
Interest and other, net	40	94	21,390
Loss before income taxes	(11,712)	(12,189)	(372,388)
Income tax benefit			(26)
Net loss	\$ (11,712)	\$ (12,189)	\$ (372,362)
Net loss per common share basic and diluted	\$ (0.18)	\$ (0.20)	
Weighted-average number of shares used in computing net loss per common share basic and diluted	66,911	61,995	

The accompanying notes are an integral part of these financial statements.

4 of 49

Table of Contents

**CYTOKINETICS, INCORPORATED**  
**(A Development Stage Enterprise)**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(Unaudited)

	<b>Three Months Ended</b>		<b>Period from</b>
	<b>March</b>	<b>March</b>	<b>August 5, 1997</b>
	<b>31,</b>	<b>31,</b>	<b>(Date of</b>
	<b>2011</b>	<b>2010</b>	<b>Inception)</b>
			<b>to March 31,</b>
			<b>2011</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (11,712)	\$ (12,189)	\$ (372,362)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	423	489	27,789
Loss on disposal of equipment			298
Non-cash impairment charges			103
Non-cash restructuring expenses, net of reversals			498
Non-cash interest expense			504
Non-cash forgiveness of loans to officers			434
Stock-based compensation	761	994	30,037
Non-cash warrant expense			1,626
Other non-cash expenses			141
Changes in operating assets and liabilities:			
Related party accounts receivable	12	169	(385)
Prepaid and other assets	(1,255)	394	(3,275)
Accounts payable	(33)	102	1,153
Accrued liabilities	(1,104)	(1,643)	4,068
Related party payables and accrued liabilities	11	10	11
Deferred revenue	17	(534)	17
Net cash used in operating activities	(12,880)	(12,208)	(309,343)
<b>Cash flows from investing activities:</b>			
Purchases of investments	(7,123)	(36,393)	(918,553)
Proceeds from sales and maturities of investments	18,020	40,560	854,173
Proceeds from sales of auction rate securities		250	20,025
Purchases of property and equipment	(175)	(154)	(30,768)
Proceeds from sales of property and equipment			138
(Increase) decrease in restricted cash	349	441	(439)
Issuance of related party notes receivable			(1,146)
Proceeds from repayments of notes receivable			859
Net cash provided by (used in) investing activities	11,071	4,704	(75,711)

**Cash flows from financing activities:**

Edgar Filing: CYTOKINETICS INC - Form 10-Q

Proceeds from initial public offering, sale of common stock to related party, and public offerings, net of issuance costs			206,871
Proceeds from draw down of committed equity financing facilities, net of issuance costs		3,370	52,854
Proceeds from other issuances of common stock	8	40	7,427
Proceeds from issuance of preferred stock, net of issuance costs			133,172
Repurchase of common stock			(68)
Proceeds from loan with UBS			12,441
Repayment of loan with UBS		(328)	(12,441)
Proceeds from equipment financing lines			23,696
Repayment of equipment financing lines	(261)	(424)	(23,446)
Net cash provided by (used in) financing activities	(253)	2,658	400,506
Net increase (decrease) in cash and cash equivalents	(2,062)	(4,846)	15,452
Cash and cash equivalents, beginning of period	17,514	25,561	
Cash and cash equivalents, end of period	\$ 15,452	\$ 20,715	\$ 15,452

The accompanying notes are an integral part of these financial statements.

5 of 49



**Table of Contents**

**CYTOKINETICS, INCORPORATED  
(A Development Stage Enterprise)**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**Note 1. Organization and Summary of Significant Accounting Policies**

***Overview***

Cytokinetics, Incorporated (the Company, we or our) was incorporated under the laws of the state of Delaware on August 5, 1997. The Company is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. The Company is a development stage enterprise and has been primarily engaged in conducting research, developing drug candidates and technologies, and raising capital. The Company has never generated revenues from commercial sales of its drugs and it may not have drugs to market for at least several years, if ever.

The Company's registration statement for its initial public offering (IPO) was declared effective by the Securities and Exchange Commission (SEC) on April 29, 2004. The Company's common stock commenced trading on the NASDAQ National Market, now the NASDAQ Global Market, on April 29, 2004 under the trading symbol CYTK.

The Company's financial statements contemplate the conduct of the Company's operations in the normal course of business. The Company has incurred an accumulated deficit since inception and there can be no assurance that the Company will attain profitability. The Company had a net loss of \$11.7 million and net cash used in operations of \$12.9 million for the three months ended March 31, 2011, and an accumulated deficit of \$372.4 million as of March 31, 2011. Cash, cash equivalents and investments decreased to \$59.9 million at March 31, 2011 from \$72.8 million at December 31, 2010. The Company anticipates that it will continue to have operating losses and net cash outflows in future periods. If sufficient additional capital is not available on terms acceptable to the Company, its liquidity will be impaired.

In April 2011, the Company entered into a securities purchase agreement with Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited (collectively, Deerfield), pursuant to which Deerfield purchased (i) 5,300,000 shares of the Company's common stock for a purchase price of \$1.50 per share and (ii) 8,070 shares of the Company's Series A Convertible Preferred Stock for an aggregate purchase price of approximately \$20.1 million. See Note 13, Subsequent Events for further details of this agreement.

The Company has funded its operations primarily through sales of equity securities, contract payments under its collaboration agreements, debt financing arrangements, government grants and interest income. Until it achieves profitable operations, the Company intends to continue to fund operations through payments from strategic collaborations, additional sales of equity securities, government grants and debt financings. Based on the current status of its development plans, the Company believes that its existing cash, cash equivalents and investments at March 31, 2011 will be sufficient to fund its cash requirements for at least the next 12 months. If, at any time, the Company's prospects for financing its research and development programs decline, the Company may decide to reduce research and development expenses by delaying, discontinuing or reducing its funding of one or more of its research or development programs. Alternatively, the Company might raise funds through strategic collaborations, public or private financings or other arrangements. Such funding, if needed, may not be available on favorable terms, or at all.

***Basis of Presentation***

The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim financial information and the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The financial statements include all adjustments (consisting only of normal recurring adjustments) that management believes are necessary for the fair statement of the balances and results for the periods presented. These interim financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future interim period.

The balance sheet at December 31, 2010 has been derived from the audited financial statements at that date. The financial statements and related disclosures have been prepared with the presumption that users of the interim

financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in

6 of 49

---

**Table of Contents**

conjunction with the audited financial statements and notes thereto contained in the Company's Form 10-K for the year ended December 31, 2010, as filed with the SEC on March 11, 2011.

Certain reclassifications have been made to the Condensed Financial Statements for the three months ended March 31, 2010 in order to conform to the current year presentation.

***Comprehensive Loss***

Comprehensive loss consists of net loss and other comprehensive loss. Other comprehensive loss includes certain changes in stockholders' equity that are excluded from net loss. Comprehensive loss and its components for the three months ended March 31, 2011 and 2010 were as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31, 2011</b>	<b>March 31, 2010</b>
Net loss	\$ (11,712)	\$ (12,189)
Change in unrealized gain (loss) on investments	13	(8)
Comprehensive loss	\$ (11,699)	\$ (12,197)

***Restricted Cash***

In accordance with the terms of the Company's line of credit agreements with General Electric Capital Corporation (GE Capital), the Company is obligated to maintain a certificate of deposit with the lender. In January 2011, GE Capital approved a reduction in the amount of the Company's certificate of deposit. The balance of the certificate of deposit, which the Company classifies as restricted cash, was as follows (in thousands):

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
Certificate of deposit classified as restricted cash	\$ 439	\$ 788

**Note 2. Net Loss Per Common Share**

Basic net loss per common share is computed by dividing the net loss by the weighted average number of vested common shares outstanding during the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive common shares, including outstanding stock options, unvested restricted stock, warrants, and shares issuable under the Employee Stock Purchase Plan (ESPP), by applying the treasury stock method. Following is the calculation of basic and diluted net loss per common share (in thousands, except per share data):

	<b>Three Months Ended</b>	
	<b>March 31, 2011</b>	<b>March 31, 2010</b>
Net loss	\$ (11,712)	\$ (12,189)
Weighted-average common shares outstanding	66,911	62,184
Unvested restricted stock		(189)
Weighted-average shares used in computing basic and diluted net loss per common share	66,911	61,995

Edgar Filing: CYTOKINETICS INC - Form 10-Q

Net loss per common share basic and diluted \$ (0.18) \$ (0.20)

The following instruments were excluded from the computation of diluted net loss per common share for the periods presented because their effect would have been antidilutive (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31, 2011</b>	<b>March 31, 2010</b>
Options to purchase common stock	10,075	8,361
Unvested restricted common stock		183
Warrants to purchase common stock	4,027	4,027
Shares issuable related to the ESPP	94	123
Total shares	14,196	12,694

7 of 49

**Table of Contents****Note 3. Supplemental Cash Flow Data**

Supplemental cash flow data was as follows (in thousands):

	<b>Three Months Ended</b>		<b>Period from</b>
	<b>March</b>	<b>March</b>	<b>August 5, 1997</b>
	<b>31,</b>	<b>31,</b>	<b>(date of</b>
	<b>2011</b>	<b>2010</b>	<b>inception)</b>
			<b>to March 31,</b>
			<b>2011</b>
Significant non-cash investing and financing activities:			
Deferred stock-based compensation	\$	\$	\$ 6,940
Purchases of property and equipment through accounts payable	110	30	110
Purchases of property and equipment through trade in value of disposed property and equipment			258
Penalty on restructuring of equipment financing lines			475
Conversion of convertible preferred stock to common stock			133,172
Warrants issued in registered direct equity financing			1,585

**Note 4. Related Party Research and Development Arrangements*****Amgen Inc. ( Amgen )***

Pursuant to its collaboration and option agreement with Amgen (the Amgen Agreement ), the Company has recognized research and development revenue from Amgen for reimbursements of its costs of full-time employee equivalents ( FTEs ) supporting the research and development program for omecamtiv mecarbil and related compounds, and for reimbursements of other costs related to that program. These reimbursements were recorded as research and development revenues from related parties. Revenue from Amgen was as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March</b>	<b>March 31,</b>
	<b>31,</b>	<b>2010</b>
	<b>2011</b>	
FTE reimbursements	\$ 363	\$ 415
Reimbursements of other costs	26	206
Total research and development revenues from Amgen	389	621
Total revenue from Amgen	\$ 389	\$ 621

Deferred revenue and related party accounts receivable related to Amgen were as follows (in thousands):

	<b>March</b>	<b>December</b>
	<b>31,</b>	<b>31,</b>
	<b>2011</b>	<b>2010</b>
Deferred revenue Amgen	\$ 17	\$
Related party accounts receivable Amgen	\$ 34	\$ 41

***GlaxoSmithKline ( GSK )***

Pursuant to its collaboration and license agreement with GSK, the Company recognized revenue for patent expense reimbursements from GSK, recorded as research and development revenues from related parties, as follows (in

thousands):

	<b>Three Months Ended</b>	
	<b>March</b>	<b>March</b>
	<b>31,</b>	<b>31,</b>
	<b>2011</b>	<b>2010</b>
Patent expense reimbursements	\$	\$ 4

There were no related party accounts receivables due from GSK at March 31, 2011 or December 31, 2010. Related party payables and accrued liabilities due to GSK were as follows:

	<b>March</b>	<b>December</b>
	<b>31,</b>	<b>31,</b>
	<b>2011</b>	<b>2010</b>
Related party payables and accrued liabilities GSK	\$ 11	\$

8 of 49

---

**Table of Contents****Note 5. Grant Arrangement**

In July 2010, the National Institute of Neurological Disorders and Stroke ( NINDS ) awarded to the Company a \$2.8 million grant to support research and development of CK-2017357 directed to the potential treatment for myasthenia gravis for a period of up to three years. We have determined that the Company is the principal participant in the grant arrangement and, accordingly, the Company records amounts earned under the arrangement as revenue. The Company recognized grant revenue under this grant arrangement as follows (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31, 2011</b>	<b>March 31, 2010</b>
NINDS myasthenia gravis	\$ 374	\$

**Note 6. Cash Equivalents and Investments*****Cash Equivalents and Available for Sale Investments***

The amortized cost and fair value of cash equivalents and available for sale investments at March 31, 2011 and December 31, 2010 were as follows (in thousands):

	<b>March 31, 2011</b>				<b>Maturity Dates</b>
	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>	
Cash equivalents money market funds	\$ 13,764			\$ 13,764	
Short-term investments U.S. Treasury securities	\$ 44,440	\$ 9	\$	\$ 44,449	4/2011- 1/2012

	<b>December 31, 2010</b>				<b>Maturity Dates</b>
	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>	
Cash equivalents money market funds	\$ 16,966			\$ 16,966	
Short-term investments U.S. Treasury securities	\$ 54,129	\$ 4	\$ (8)	\$ 54,125	1/2011- 12/2011
Long-term investments U.S. Treasury securities	\$ 1,207		\$ (1)	\$ 1,206	1/2012

As of March 31, 2011, the Company's cash equivalents and short-term investments had no unrealized losses. As of December 31, 2010, the Company's cash equivalents had no unrealized losses, and its U.S. Treasury securities classified as short- and long-term investments had unrealized losses of approximately \$9,000. The unrealized losses primarily were caused by rising interest rates. The Company collected the contractual cash flows on its U.S. Treasury securities that matured from January through April 2011, and expects to be able to collect all contractual cash flows on the remaining maturities of its U.S. Treasury securities.

Interest income was as follows (in thousands):

**Period from**

	<b>Three Months Ended</b>		<b>August 5, 1997</b>
	<b>March</b>	<b>March</b>	<b>(date of</b>
	<b>31,</b>	<b>31,</b>	<b>inception)</b>
	<b>2011</b>	<b>2010</b>	<b>to March 31,</b>
			<b>2011</b>
Interest income	\$ 52	\$ 163	\$ 28,445

***Investments in Auction Rate Securities and Investment Put Option Related to Auction Rate Securities Rights***

On June 30, 2010, the Company exercised its Series C-2 Auction Rate Securities Rights issued to the Company by UBS AG (the ARS Rights), which required that UBS AG purchase the Company's remaining outstanding auction rate securities (ARS) at par value. Accordingly, on the settlement date of July 1, 2010, UBS AG deposited the proceeds of \$7.5 million into the Company's money market account. The Company recorded the ARS Rights as an investment put option, which was extinguished at the time that the ARS Rights were exercised.

The Company recognized changes in the fair value of the ARS, excluding the sale of ARS, and changes in the fair value of the ARS Rights in current period earnings in Interest and Other, net. Unrealized gains (losses) on the ARS and ARS Rights recognized in Interest and Other, net, for the quarter ended March 31, 2010 are set forth in Note 10. Interest and Other, Net.



**Table of Contents****Note 7. Fair Value Measurements**

The Company follows the fair value accounting guidance to value its financial assets and liabilities. Fair value is defined as the price that would be received for assets when sold or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company utilizes market data or assumptions that the Company believes market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated or generally unobservable.

The Company primarily applies the market approach for recurring fair value measurements and endeavors to utilize the best information reasonably available. Accordingly, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and considers the security issuers and the third-party insurers credit risk in its assessment of fair value.

The Company classifies the determined fair value based on the observability of those inputs. Fair value accounting guidance establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The three defined levels of the fair value hierarchy are as follows:

Level 1 Observable inputs, such as quoted prices in active markets for identical assets or liabilities;

Level 2 Inputs, other than the quoted prices in active markets, that are observable either directly or through corroboration with observable market data; and

Level 3 Unobservable inputs, for which there is little or no market data for the assets or liabilities, such as internally-developed valuation models.

Financial assets measured at fair value on a recurring basis as of March 31, 2011 and December 31, 2010 were classified in one of the three categories described above as follows (in thousands):

<b>March 31, 2011</b>				
<b>Fair Value Measurements Using</b>				<b>Assets</b>
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>At Fair Value</b>
Money market funds	\$ 13,764	\$	\$	\$ 13,764
U.S. Treasury securities	44,449			44,449
<b>Total</b>	<b>\$ 58,213</b>	<b>\$</b>	<b>\$</b>	<b>\$ 58,213</b>
Amounts included in:				
Cash and cash equivalents	\$ 13,764	\$	\$	\$ 13,764
Short-term investments	44,449			44,449
<b>Total</b>	<b>\$ 58,213</b>	<b>\$</b>	<b>\$</b>	<b>\$ 58,213</b>

<b>December 31, 2010</b>				
<b>Fair Value Measurements Using</b>				<b>Assets</b>
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>At Fair Value</b>
Money market funds	\$ 16,966	\$	\$	\$ 16,966
U.S. Treasury securities	55,331			55,331

Edgar Filing: CYTOKINETICS INC - Form 10-Q

Total	\$ 72,297	\$	\$	\$	72,297
Amounts included in:					
Cash and cash equivalents	\$ 16,966	\$	\$	\$	16,966
Short-term investments	54,125				54,125
Long-term investments	1,206				1,206
Total	\$ 72,297	\$	\$	\$	72,297

The valuation technique used to measure fair value for the Company's Level 1 assets is a market approach, using prices and other relevant information generated by market transactions involving identical assets.

10 of 49

## Table of Contents

As of March 31, 2011, the Company had no financial assets measured at fair value on a recurring basis using significant Level 3 inputs. The following table provides a rollforward of all assets measured at fair value using significant Level 3 inputs for the quarter ended March 31, 2010 (in thousands):

	ARS	Investment Put Option Related to ARS Rights
Balance as of December 31, 2009	\$ 15,542	\$ 2,358
Unrealized gain on ARS, included in Interest and Other, net	19	
Unrealized loss on the investment put option related to ARS Rights, included in Interest and Other, net		(19)
Sale of ARS	(250)	
Balance as of March 31, 2010	\$ 15,311	\$ 2,339

The Company recognized the unrealized gains or losses resulting from changes in the fair value of the ARS, excluding the sale of ARS, and the changes in the fair value of the ARS Rights in current period earnings in Interest and Other, net.

The Company's equipment financing line debt is not recorded at fair value, but the Company is required to disclose its fair value. The Company determined the fair value of the equipment financing line debt using a discounted cash flow model. The major inputs to the model are expected cash flows, which equal the contractual payments, and borrowing rates available to the Company for similar debt as of the applicable balance sheet dates. The fair value and the carrying value of the equipment financing line debt were as follows (in thousands):

	March 31, 2011	December 31, 2010
Carrying value equipment financing line	\$ 724	\$ 985
Fair value equipment financing line	\$ 698	\$ 947

The carrying amount of the Company's cash, accounts receivable and accounts payable approximates fair value due to the short-term nature of these instruments.

### Note 8. Loan with UBS

In connection with the settlement with UBS AG relating to the Company's ARS, in October 2008, the Company entered into a loan agreement with UBS Bank USA and UBS Financial Services Inc. On January 5, 2009, the Company borrowed approximately \$12.4 million under the loan agreement, with its ARS held in accounts with UBS Financial Services Inc. as collateral. Proceeds from sales of the ARS were first applied as repayments of the loan balance. The Company repaid the remaining balance of the loan in full during the second quarter of 2010.

Activity related to this loan during the quarter ended March 31, 2010 was as follows (in thousands):

	Three months ended March 31, 2010
Beginning balance	\$ 10,201
Interest expense incurred	29
Interest income from ARS applied to loan balance	(107)

Proceeds from sales of ARS applied to loan balance		(250)
Ending balance	\$	9,873

**Note 9. Stockholders' Equity**

*2007 Committed Equity Facility*

The 2007 committed equity financing facility with Kingsbridge Capital Limited expired on March 31, 2011, and no further shares are available to the Company for sale under the facility.

11 of 49

---

**Table of Contents***Stock Option Plans*

Stock option activity for the three months ended March 31, 2011 under the 2004 Equity Incentive Plan, as amended, and the 1997 Stock Option/Stock Issuance Plan was as follows:

	<b>Shares Available for Grant of Options or Awards</b>	<b>Stock Options Outstanding</b>	<b>Weighted Average Exercise Price per Share of Stock Options</b>
Balance at December 31, 2010	5,127,695	8,096,476	\$ 4.32
Options granted	(2,365,056)	2,365,056	\$ 1.61
Options exercised		(8,500)	\$ 1.00
Options forfeited/expired	378,165	(378,165)	\$ 4.97
Balance at March 31, 2011	3,140,804	10,074,867	\$ 3.66

**Note 10. Interest and Other, Net**

Components of Interest and Other, net were as follows (in thousands):

	<b>Three Months Ended March 31, 2011</b>	<b>March 31, 2010</b>	<b>Period from August 5, 1997 (date of inception) to March 31, 2011</b>
Unrealized gain on ARS (Note 6 and 7)	\$	\$ 19	\$
Unrealized loss on investment put option related to ARS Rights (Note 6 and 7)		(19)	
Warrant expense			(1,585)
Interest income and other income	55	163	28,922
Interest expense and other expense	(15)	(69)	(5,947)
Interest and Other, net	\$ 40	\$ 94	\$ 21,390

Investments that the Company designates as trading securities are reported at fair value, with gains or losses resulting from changes in fair value recognized in earnings and included in Interest and Other, net. The Company sold its remaining outstanding ARS on June 30, 2010.

The Company elected to measure the investment put option related to the ARS Rights at fair value to mitigate volatility in reported earnings due to its linkage to the ARS. Changes in the fair value of the ARS Rights are recognized in current period earnings in Interest and Other, net. The investment put option related to the ARS rights was extinguished on July 1, 2010, the settlement date of the sale of the remaining ARS.

Warrant expense for the period from inception to March 31, 2011, was related to the change in the fair value of the warrant liability that was recorded in connection with the Company's registered direct equity offering in May 2009.

Interest income and other income primarily consisted of interest income generated from the Company's cash, cash equivalents and investments. Interest expense and other expense primarily consisted of interest expense on borrowings

under the Company's equipment financing lines and, through June 30, 2010, on its loan agreement with UBS Bank USA and UBS Financial Services Inc.

**Note 11. Income Taxes**

The Company follows the accounting guidance established by the Financial Accounting Standards Board ( FASB ) which defines the threshold for recognizing the benefits of tax return positions in the financial statements as more-likely-than-not to be sustained by the taxing authorities based solely on the technical merits of the position. If the recognition threshold is met, the tax benefit is measured and recognized as the largest amount of tax benefit that, in the Company's judgment, is greater than 50% likely to be realized.

The Company files income tax returns with the United States Internal Revenue Service ( IRS ) and the state of California. For jurisdictions in which tax filings are made, the Company is subject to income tax examination for all fiscal years since inception. Tax

12 of 49

---

## **Table of Contents**

years 2009 and 2008 are currently under IRS examination. The Company believes that it maintains adequate reserves for uncertain tax positions.

### **Note 12. Recent Accounting Pronouncements**

#### *Recently Adopted Accounting Pronouncements*

In October 2009, the FASB issued new accounting guidance for recognizing revenue for multiple-deliverable revenue arrangements. The new guidance amends the existing guidance for separately accounting for individual deliverables in a revenue arrangement with multiple deliverables, and removes the criterion that an entity must use objective and reliable evidence of fair value to separately account for the deliverables. The new guidance also establishes a hierarchy for determining the value of each deliverable and establishes the relative selling price method for allocating consideration when vendor specific objective evidence or third party evidence of value does not exist. The Company's adoption of the new guidance prospectively for new revenue arrangements entered into or materially modified beginning on January 1, 2011 did not have a material impact on its financial position or results of operations.

In January 2010, the FASB issued new accounting guidance for improving disclosures about fair value measurements, which requires a gross presentation of Level 3 fair value rollforwards. The Company's adoption of the guidance on January 1, 2011 did not have a material impact on its financial position or results of operations.

In April 2010, the FASB issued new accounting guidance on the milestone method of revenue recognition. The new guidance codifies the milestone method as an acceptable revenue recognition model when a milestone is deemed to be substantive. The Company's adoption of the guidance effective for milestones achieved beginning on January 1, 2011 did not have a material impact on its financial position or results of operations.

### **Note 13. Subsequent Events**

On April 18, 2011, the Company entered into a securities purchase agreement with Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited (collectively, "Deerfield"), pursuant to which Deerfield purchased (i) 5,300,000 shares of the Company's common stock for a purchase price of \$1.50 per share and (ii) 8,070 shares of the Company's Series A Convertible Preferred Stock (the "Series A Preferred Stock") for a purchase price of \$1,500.00 per share, for an aggregate purchase price of approximately \$20.1 million. In connection with the securities purchase agreement, the Company issued to Deerfield warrants to purchase an aggregate of 6,685,000 shares of its common stock at an initial exercise price of \$1.65 per share. The warrants will be exercisable beginning on the date that is six months after their issuance and will remain exercisable until four years after their issuance. The holder of the warrants will be prohibited from exercising into shares of common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of the Company's common stock then issued and outstanding.

Each share of Series A Preferred Stock is convertible into 1,000 shares of the Company's common stock at any time at the holder's option. However, the holder will be prohibited from converting Series A Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of our common stock then issued and outstanding. In the event of the Company's liquidation, dissolution, or winding up, holders of our Series A Preferred Stock will receive a payment equal to \$0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of the Company's common stock. Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock. Shares of Series A Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors, and will rank:

senior to all of the Company's common stock;

senior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms junior to the Series A Preferred Stock;

on parity with any class or series of the Company's capital stock hereafter created specifically ranking by its terms on parity with the Series A Preferred Stock; and





**Table of Contents**

junior to any class or series of the Company's capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock;

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily.

The offering was made pursuant to a shelf registration statement that the Company filed with the SEC on November 10, 2008, which became effective on November 19, 2008 (File No. 333-155259). The closing of the offering took place on April 20, 2011.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included elsewhere in this report. Operating results are not necessarily indicative of results that may occur in future periods.

This report contains forward-looking statements that are based upon current expectations within the meaning of the Private Securities Litigation Reform Act of 1995. We intend that such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to, statements about or relating to:

guidance concerning revenues, research and development expenses and general and administrative expenses for 2011;

the sufficiency of existing resources to fund our operations for at least the next 12 months;

our capital requirements and needs for additional financing;

the initiation, design, progress, timing and scope of clinical trials and development activities for our drug candidates and potential drug candidates conducted by ourselves or our partners, such as Amgen, Inc. ( "Amgen" ), including the anticipated timing for initiation of clinical trials and anticipated dates of data becoming available or being announced from clinical trials;

the results from the clinical trials and non-clinical and pre-clinical studies of our drug candidates and other compounds, and the significance and utility of such results;

our plans to file an investigational new drug application ( "IND" ) for CK-2066260 with the U.S. Food and Drug Administration ( "FDA" );

our and our partners', such as Amgen's, plans or ability to conduct the continued research and development of our drug candidates and other compounds;

our expected roles in research, development or commercialization under our strategic alliances, such as with Amgen;

the properties and potential benefits of, and the potential market opportunities for, our drug candidates and other compounds, including the potential indications for which they may be developed;

the sufficiency of the clinical trials conducted with our drug candidates to demonstrate that they are safe and efficacious;

our receipt of milestone payments, royalties, reimbursements and other funds from current or future partners under strategic alliances, such as with Amgen;

our plans to seek strategic alternatives for our mitotic kinesin inhibitor drug candidates with third parties;

our ability to continue to identify additional potential drug candidates that may be suitable for clinical development;

our plans or ability to commercialize drugs with or without a partner, including our intention to develop sales and marketing capabilities;

14 of 49

---

**Table of Contents**

the focus, scope and size of our research and development activities and programs;

the utility of our focus on the cytoskeleton and our ability to leverage our experience in muscle contractility to other muscle functions;

our ability to protect our intellectual property and to avoid infringing the intellectual property rights of others;

expected future sources of revenue and capital;

losses, costs, expenses and expenditures;

future payments under loan and lease obligations and equipment financing lines;

potential competitors and competitive products;

retaining key personnel and recruiting additional key personnel;

expected future amortization of employee stock-based compensation; and

the potential impact of recent accounting pronouncements on our financial position or results of operations.

Such forward-looking statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to:

Amgen's decisions with respect to the timing, design and conduct of development activities for omecamtiv mecarbil, including decisions to postpone or discontinue research or development activities relating to omecamtiv mecarbil;

our ability to obtain additional financing;

our receipt of funds and access to other resources under our current or future strategic alliances;

difficulties or delays in the development, testing, production or commercialization of our drug candidates;

difficulties or delays in or slower than anticipated patient enrollment in our or our partners' clinical trials;

adverse side effects, including potential drug-drug interactions, or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product approval (including the risk that current and past results of preclinical research or non-clinical or clinical development may not be indicative of future clinical trials results);

results from non-clinical studies that may adversely impact the timing or the further development of our drug candidates and potential drug candidates;

the possibility that the FDA or foreign regulatory agencies may delay or limit our or our partners' ability to conduct clinical trials or may delay or withhold approvals for the manufacture and sale of our products;

activities and decisions of, and market conditions affecting, current and future strategic partners;

our ability to enter into partnership agreements for any of our programs on acceptable terms and conditions or in accordance with our planned timelines;

the availability of funds under our grant from the National Institute of Neurological Disorders and Stroke in future periods;

changing standards of care and the introduction of products by competitors or alternative therapies for the treatment of indications we target that may make our drug candidates commercially unviable;

15 of 49

---

## **Table of Contents**

the uncertainty of protection for our intellectual property, whether in the form of patents, trade secrets or otherwise; and

potential infringement or misuse by us of the intellectual property rights of third parties.

In addition such statements are subject to the risks and uncertainties discussed in the Risk Factors section and elsewhere in this document. Operating results reported are not necessarily indicative of results that may occur in future periods.

When used in this report, unless otherwise indicated, Cytokinetics, the Company, we, our and us refers to Cytokinetics, Incorporated.

CYTOKINETICS, and our logo used alone and with the mark CYTOKINETICS, are registered service marks and trademarks of Cytokinetics. Other service marks, trademarks and trade names referred to in this report are the property of their respective owners.

## **Overview**

We are a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Our research and development activities relating to the biology of muscle function have evolved from our knowledge and expertise regarding the cytoskeleton, a complex biological infrastructure that plays a fundamental role within every human cell. Our current research and development programs relating to the biology of muscle function are directed to small molecule modulators of the contractility of cardiac, skeletal and smooth muscle. We have, and intend to continue, to leverage our experience in muscle contractility in order to expand our current pipeline into new therapeutic areas, and expect to continue to be able to identify additional potential drug candidates that may be suitable for clinical development. To date, five drug candidates arising from our research activities have been progressed into clinical development.

Our drug candidates currently in clinical development include omecamtiv mecarbil for the potential treatment of heart failure and CK-2017357 for the potential treatment of diseases or medical conditions associated with skeletal muscle weakness or wasting. We are also advancing a second, structurally distinct, fast skeletal muscle sarcomere activator, CK-2066260, in non-clinical studies intended to enable the filing of an IND with the FDA in 2011. Both CK-2017357 and CK-2066260 selectively activate the fast skeletal muscle troponin complex, which is a set of regulatory proteins that modulates the contractility of the fast skeletal muscle sarcomere. We are also conducting non-clinical development of compounds that inhibit smooth muscle contractility. These compounds may be useful as potential treatments for diseases and conditions such as bronchoconstriction and chronic obstructive pulmonary disease. We are evaluating strategic alternatives for the further clinical development of the three drug candidates from our discontinued oncology program: ispinesib, SB-743921 and GSK-923295.

## **Muscle Contractility Programs**

### ***Cardiac Muscle Contractility***

Our lead drug candidate from this program is omecamtiv mecarbil, a novel cardiac muscle myosin activator. In December 2006, we entered into a collaboration and option agreement with Amgen to discover, develop and commercialize novel small molecule therapeutics that activate cardiac muscle contractility for potential applications in the treatment of heart failure, including omecamtiv mecarbil. In May 2009, Amgen exercised its option under this agreement to obtain an exclusive license worldwide, except Japan, to develop and commercialize omecamtiv mecarbil and other drug candidates arising from the collaboration, and subsequently paid us an option exercise fee of \$50.0 million. As a result, Amgen is now responsible for the development and commercialization of omecamtiv mecarbil and related compounds, at its expense worldwide, except Japan, subject to our development and commercialization participation rights. Under the agreement, Amgen will reimburse us for agreed research and development activities we perform. The agreement provides for potential pre-commercialization and commercialization milestone payments of up to \$600.0 million in the aggregate on omecamtiv mecarbil and other potential products arising from research under the collaboration, and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. The agreement also provides for us to receive increased royalties by co-funding Phase III development costs of drug candidates under the collaboration. If we elect to co-fund such costs, we would be entitled to co-promote omecamtiv mecarbil in North America and participate in agreed commercialization activities in

institutional care settings, at Amgen's expense.

16 of 49

---

## **Table of Contents**

We expect omecamtiv mecarbil to be developed as a potential treatment across the continuum of care in heart failure both as an intravenous formulation for use in the hospital setting and as an oral formulation for use in the outpatient setting. We are also conducting joint research activities with Amgen under an agreed research plan directed to potential next-generation compounds in our cardiac muscle contractility program.

In April 2011, we announced that Amgen opened to enrollment an international, randomized, double-blind, placebo-controlled Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil in patients with left ventricular systolic dysfunction hospitalized with acute heart failure. This trial is being conducted by Amgen in collaboration with Cytokinetics.

We are discussing with Amgen the development strategy for oral formulations of omecamtiv mecarbil, including plans regarding the initiation of a Phase I study designed to investigate the safety, tolerability and pharmacokinetics of multiple oral formulations of omecamtiv mecarbil in healthy volunteers which may occur in the second half of 2011.

The clinical trials program for omecamtiv mecarbil may proceed for several years, and we will not be in a position to generate any revenues or material net cash flows from sales of this drug candidate until the program is successfully completed, regulatory approval is achieved, and the drug is commercialized. Omecamtiv mecarbil is at too early a stage of development for us to predict if or when this may occur. We funded all research and development costs associated with this program prior to Amgen's option exercise in May 2009. We recorded research and development expenses for activities relating to our cardiac muscle contractility program of approximately \$0.4 million and \$0.5 million in the three months ended March 31, 2011 and 2010, respectively. We recognized research and development revenue from Amgen of \$0.4 million and \$0.6 million in the three months ended March 31, 2011 and 2010, respectively, consisting of reimbursements of full-time employee equivalent ( FTE ) and other expenses.

We anticipate that our expenditures relating to the research and development of compounds in our cardiac muscle contractility program will increase if we participate in the future advancement of omecamtiv mecarbil through clinical development. Our expenditures will also increase if Amgen terminates development of omecamtiv mecarbil or related compounds and we elect to develop them independently, or if we elect to co-fund later-stage development of omecamtiv mecarbil or other compounds in our cardiac muscle contractility program under our collaboration and option agreement with Amgen.

### ***Skeletal Muscle Contractility***

CK-2017357 is the lead drug candidate from this program. We are also advancing another compound from this program, CK-2066260, in non-clinical studies intended to enable the filing of an IND in mid-year 2011. CK-2017357 and CK-2066260 are structurally distinct and selective small molecule activators of the fast skeletal sarcomere. These compounds act on fast skeletal muscle troponin. Activation of troponin increases its sensitivity to calcium, leading to an increase in skeletal muscle contractility. We are evaluating the potential indications for which CK-2017357 and CK-2066260 may be useful.

Each of CK-2017357 and CK-2066260 has demonstrated encouraging pharmacological activity in preclinical models and, with respect to CK-2017357, in healthy volunteers and patients with amyotrophic lateral sclerosis ( ALS ). In a recent Phase IIa clinical trial of CK-2017357 in ALS patients, evidence of potentially clinically relevant pharmacodynamic effects was observed. CK-2017357 has received an orphan drug designation from the FDA for the treatment of ALS. In July 2010, we were awarded a grant in the amount of \$2.8 million by the National Institute of Neurological Disorders and Stroke, which is intended to support research and development of CK-2017357 for the potential treatment of myasthenia gravis for three years. The grant was awarded under the American Recovery and Reinvestment Act of 2009. We recognized revenue of \$0.4 million under this grant arrangement in the first quarter of 2011, which we recorded as research and development, grant and other revenues.

We have initiated three evidence of effect Phase IIa clinical trials of CK-2017357: one trial in patients with ALS, which was completed in December 2010, one ongoing trial in patients with symptoms of claudication associated with peripheral artery disease ( PAD ), and one ongoing trial in patients with generalized myasthenia gravis. Our evidence of effect clinical trials are randomized, double-blind, placebo-controlled, three-period cross-over studies of single doses of CK-2017357 intended to translate the mechanism of action of CK-2017357, as demonstrated pharmacodynamically in healthy volunteers, to patients with impaired muscle function and potentially to establish statistically significant and clinically relevant evidence of pharmacodynamic effects. These trials may then form the basis for larger clinical trials

designed to demonstrate proof of concept.

In December 2010, we completed a Phase IIa evidence of effect clinical trial of CK-2017357 in ALS patients. 67 patients were enrolled in this trial. Results from this trial were presented in December 2010 at the Clinical Trials Session at the 21st International Symposium on ALS/Motor Neurone Diseases. Increases in multiple clinically relevant pharmacodynamic assessments were observed, and the two doses of CK-2017357 administered (250 mg and 500 mg) exhibited dose-proportional pharmacokinetics. The

17 of 49

---



**Table of Contents**

investigators also concluded that these single doses of CK-2017357 appeared to be safe and generally well-tolerated by the patients in this trial. There were no serious adverse events judged to have been drug-related, and most adverse events were classified by the investigators as mild. In April 2011, additional analyses of the data were presented from this trial during a Clinical Trials Session at the 63rd Annual Meeting of the American Academy of Neurology in Honolulu, Hawaii.

In June 2010, we initiated a Phase IIa evidence of effect clinical trial of CK-2017357 in patients with symptoms of claudication associated with PAD. The primary objective of this trial is to evaluate the pharmacodynamic effects of single doses of CK-2017357 on measures of skeletal muscle function and fatigability in these patients. The secondary objectives of this trial are to evaluate and characterize the relationship, if any, between the doses and plasma concentrations of CK-2017357 and its pharmacodynamic effects and to evaluate the safety and tolerability of CK-2017357 administered as single oral doses to these patients. We have completed enrollment and the dosing of patients in this trial. The dose levels originally administered in this trial were 375 mg and 750 mg. In October 2010, we conducted an interim review of data from this trial that suggested potential pharmacodynamic activity of CK-2017357 to increase skeletal muscle performance in these patients. In addition, this review suggested that single oral doses of CK-2017357 were generally well-tolerated by most patients in this trial. However, serious adverse events were reported by two patients: dizziness and mental confusion in one and dizziness and dyskinesia (or abnormal movements) in the other. Both patients required inpatient observation until their symptoms resolved. These events were not life-threatening and appeared to resolve spontaneously and completely without any additional treatment. Following these observations, the protocol was amended to lower the 750 mg dose to 500 mg. We plan to present two abstracts from this clinical trial in June 2011 at the 22nd Annual Sessions of the Society of Vascular Medicine in Boston, Massachusetts.

In January 2011, we initiated our third Phase IIa evidence of effect clinical trial of CK-2017357 in patients with generalized myasthenia gravis. At least 36 and up to 78 patients may be enrolled in this trial, and we continue to enroll and dose patients in this trial. Patients receive a single oral dose of placebo or 250 mg or 500 mg of CK-2017357. The primary objective of this trial is to assess the effects of CK-2017357 on measures of muscle strength, muscle fatigue and pulmonary function in these patients. The secondary objectives of this clinical trial are to evaluate and characterize the relationship, if any, between the doses and plasma concentrations of CK-2017357 and its pharmacodynamic effects; to evaluate the safety and tolerability of CK-2017357 administered as single doses to patients with myasthenia gravis; and to evaluate the effect of CK-2017357 on investigator- and patient-determined global functional assessment and the Modified MG Symptom Score, an assessment combining patient reports and physician evaluations to assess the severity of symptoms due to myasthenia gravis. We anticipate that data from this clinical trial will be available by the end of 2011.

In the first quarter of 2011, we initiated a Phase I drug-drug interaction clinical trial of CK-2017357 administered orally to healthy volunteers. This trial is intended to evaluate the effects of CK-2017357 on the pharmacokinetics of riluzole and other drugs as well as the pharmacokinetics of CK-2017357 when administered after a meal and when fasting. We anticipate that data from this trial will be available in the second half of 2011.

By mid-year 2011, we anticipate initiating a Phase II multi-dose, safety, tolerability, pharmacokinetic and pharmacodynamic clinical trial of CK-2017357 in ALS patients. This trial is expected to evaluate patients receiving daily oral doses of CK-2017357 for up to 14 days. The primary objective of this trial will be to evaluate the safety and tolerability of multiple doses of CK-2017357 in patients with ALS. In addition, patients will be asked to report their ALS symptoms using the ALS Functional Rating Scale-Revised (ALSFRS-R). Patients will also undergo tests of muscle fatigability, certain indices of pulmonary function, and patients and investigators global status assessments.

We anticipate that by mid-year 2011, we will file an IND for CK-2066260 with the FDA and anticipate initiating a Phase I, first-time-in-humans clinical trial of this drug candidate in healthy volunteers in the second half of 2011.

CK-2017357 and CK-2066260 are at too early a stage of development for us to predict if or when we will be in a position to generate any revenues or material net cash flows from their commercialization. We currently fund all research and development costs associated with this program. We recorded research and development expenses for activities relating to our skeletal muscle contractility program of approximately \$5.9 million and \$6.4 million in the three months ended March 31, 2011 and 2010, respectively. We anticipate that our expenditures relating to the

research and development of compounds in our skeletal muscle contractility program will increase significantly if and as we advance CK-2017357, CK-2066260 or other compounds from this program into and through development.

18 of 49

---

## **Table of Contents**

### ***Smooth Muscle Contractility***

Our smooth muscle contractility program is focused on the discovery and development of small molecule smooth muscle myosin inhibitors, which may be useful as potential treatments for diseases and conditions associated with excessive smooth muscle contraction, and leverages our expertise in muscle function and its application to drug discovery. Our inhaled smooth muscle myosin inhibitors have demonstrated pharmacological activity in preclinical models of bronchoconstrictive diseases and may have applications for indications such as asthma or chronic obstructive pulmonary disease. Our smooth muscle myosin inhibitors, administered orally or intravenously, have also demonstrated pharmacological activity in preclinical models of vascular constriction. We intend to continue to conduct non-clinical development of compounds from this program.

Our smooth muscle myosin inhibitors are at too early a stage of development for us to predict if or when we will be in a position to generate any revenues or material net cash flows from their commercialization. We currently fund all research and development costs associated with this program. We recorded research and development expenses for activities relating to our smooth muscle contractility program of approximately \$1.3 million and \$0.6 million in the three months ended March 31, 2011 and 2010, respectively. We anticipate that our expenditures relating to the research and development of compounds in our smooth muscle contractility program will increase significantly if and as we advance compounds from this program into and through development

### **Oncology Program: Mitotic Kinesin Inhibitors**

We currently have three drug candidates for the potential treatment of cancer: ispinesib, SB-743921 and GSK-923295. All of these arose from our earlier research activities directed to the role of the cytoskeleton in cell division and were progressed under our strategic alliance with GlaxoSmithKline ( GSK ), established in 2001. We agreed with GSK to terminate our strategic alliance effective February 2010. We have retained all rights to ispinesib, SB-743921 and GSK-923295, subject to certain royalty obligations to GSK. GSK remains responsible for completing its Phase I clinical trial of GSK-923295 in cancer patients, at its expense. Following GSK's completion of its Phase I clinical trial of GSK-923295, we will be responsible for any further research and development costs associated with GSK-923295.

Each of ispinesib, SB-743921 and GSK-923295 is at too early a stage of development for us to predict if or when we will be in a position to generate any revenues or material net cash flows from its commercialization. We currently are responsible for all research and development costs associated with ispinesib and SB-743921. We recorded research and development expenses for activities relating to our mitotic kinesin inhibitors program of approximately zero and \$0.5 million in the three months ended March 31, 2011 and 2010, respectively. We have completed the Phase I portion of each of the Phase I/II clinical trials for ispinesib and SB-743921. GSK is completing the current Phase I clinical trial of GSK-923295, at its expense. We do not currently intend to conduct any further development of these drug candidates ourselves in oncology. We are evaluating strategic alternatives for the future development and commercialization of ispinesib, SB-743921 and GSK-923295 with third parties. We may not be able to enter into an agreement regarding such a strategic alternative on acceptable terms, if it all.

### **Development Risks**

The successful development of any of our drug candidates is highly uncertain. We cannot estimate with certainty or know the exact nature, timing and costs of the activities necessary to complete the development of any of our drug candidates or the date of completion of these development activities due to numerous risks and uncertainties, including, but not limited to:

decisions made by Amgen with respect to the development of omecamtiv mecarbil;

the uncertainty of the timing of the initiation and completion of patient enrollment and treatment in our clinical trials;

the possibility of delays in the collection of clinical trial data and the uncertainty of the timing of the analyses of our clinical trial data after these trials have been initiated and completed;

safety issues that may arise at any time during clinical trials and preclinical studies;

our potential inability to obtain additional funding and resources for our development activities on acceptable terms, if at all, including, but not limited to, our potential inability to obtain or retain partners to assist in the design, management, conduct and funding of clinical trials;

delays or additional costs in manufacturing of our drug candidates for clinical trial use, including developing appropriate formulations of our drug candidates;

19 of 49

---

**Table of Contents**

the uncertainty of clinical trial results, including variability in patient response;

the uncertainty of obtaining FDA or other foreign regulatory agency approval required for the clinical investigation of our drug candidates;

the uncertainty related to the development of commercial scale manufacturing processes and qualification of a commercial scale manufacturing facility; and

possible delays in the characterization, formulation and manufacture of potential drug candidates.

If we fail to complete the development of any of our drug candidates in a timely manner, it could have a material adverse effect on our operations, financial position and liquidity. In addition, any failure by us or our partners to obtain, or any delay in obtaining, regulatory approvals for our drug candidates could have a material adverse effect on our results of operations. A further discussion of the risks and uncertainties associated with completing our programs on schedule, or at all, and certain consequences of failing to do so are discussed further in the risk factors entitled "We have never generated, and may never generate, revenues from commercial sales of our drugs and we may not have drugs to market for at least several years, if ever," "Clinical trials may fail to demonstrate the desired safety and efficacy of our drug candidates, which could prevent or significantly delay completion of clinical development and regulatory approval" and "Clinical trials are expensive, time-consuming and subject to delay," and other risk factors.

**Results of Operations**

***Revenues***

We recorded total revenues of \$0.8 million and \$0.6 million for the first quarter of 2011 and 2010, respectively.

Research and development revenues from related parties for the first quarter of 2011 and 2010 primarily include research and development revenues from our strategic alliance with Amgen. Research and development revenues from Amgen were \$0.4 million and \$0.6 million in the first quarter of 2011 and 2010, respectively. Research and development revenues from Amgen for the first quarter of 2011 consisted of \$0.4 million for reimbursements of FTE expenses and \$26,000 for reimbursements of other research and development expenses. Research and development revenues from Amgen for the first quarter of 2010 consisted of reimbursements of \$0.4 million for FTE costs and \$0.2 million for other out of pocket expenses.

In July 2010, the National Institute of Neurological Disorders and Strokes awarded us a grant to support research and development of CK-2017357 directed to the potential treatment for myasthenia gravis for a period of up to three years. In the first quarter of 2011, we recognized grant revenue of \$0.4 million under this arrangement.

The deferred revenue balance related to Amgen was \$17,000 at March 31, 2011 and zero at December 31, 2010. The deferred revenue balance at March 31, 2011 consisted of Amgen's prepayment of FTE reimbursements.

***Research and Development Expenses***

Research and development expenses were \$9.2 million and \$9.1 million in the first quarter of 2011 and 2010, respectively. The increase in research and development expenses in the first quarter of 2011 compared to the same period in 2010 was primarily due to an increase of \$0.5 million in laboratory expenses and \$0.2 million in clinical and pre-clinical outsourcing costs, partially offset by a decrease of \$0.6 million in personnel and facility-related costs.

From a program perspective, the \$0.1 million increase in spending in the first quarter of 2011 compared to the first quarter of 2010 was due to increased spending of \$0.7 million for our smooth muscle contractility program and \$0.6 million for our other research programs, partially offset by decreases of \$0.5 million for our skeletal muscle contractility program, \$0.5 million for our mitotic kinesin inhibitors program, \$0.1 million for our cardiac muscle contractility program and \$0.1 million for our propriety technologies.

**Table of Contents**

Research and development expenses incurred were related to the following programs (in millions):

	<b>Three Months Ended</b>	
	<b>March</b>	
	<b>31,</b>	<b>March 31,</b>
	<b>2011</b>	<b>2010</b>
Cardiac muscle contractility	\$ 0.4	\$ 0.5
Skeletal muscle contractility	5.9	6.4
Smooth muscle contractility	1.3	0.6
Mitotic kinesin inhibitors		0.5
Proprietary technologies		0.1
All other research programs	1.6	1.0
Total research and development expenses	\$ 9.2	\$ 9.1

Clinical development timelines, likelihood of success and total completion costs vary significantly for each drug candidate and are difficult to estimate. We anticipate that we will determine on an ongoing basis which research and development programs to pursue and how much funding to direct to each program, taking into account the scientific and clinical success of each drug candidate. The lengthy process of seeking regulatory approvals and subsequent compliance with applicable regulations requires the expenditure of substantial resources. Any failure by us to obtain and maintain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, could have a material adverse effect on our results of operations.

We expect our research and development expenditures to increase in 2011 compared to 2010. As part of our strategic alliance with Amgen, we expect to continue development of our drug candidate omecamtiv mecarbil for the potential treatment of heart failure. We expect to continue development of our drug candidate CK-2017357 and our potential drug candidate CK-2066260 for the potential treatment of diseases and medical conditions associated with muscle weakness or wasting. We expect to continue research and development of our smooth muscle myosin inhibitor compounds, which may be useful for the potential treatment of diseases and medical conditions associated with bronchoconstriction or vasoconstriction. We anticipate that research and development expenses for 2011 will be in the range of \$42.0 million to \$47.0 million. Non-cash expenses such as stock-based compensation and depreciation of approximately \$2.5 million are included in our estimate of 2011 research and development expenses.

**General and Administrative Expenses**

General and administrative expenses were \$3.3 million and \$3.8 million in the first quarter of 2011 and 2010, respectively. The decrease in the first quarter of 2011 compared to the same period in 2010 was primarily due to decreases of \$0.3 million in personnel expenses and \$0.2 million in legal and outside services.

We expect that general and administrative expenses will increase in 2011 compared to 2010. We anticipate general and administrative expenses to be in the range of \$15.0 million to \$17.0 million. Non-cash expenses such as stock-based compensation and depreciation of approximately \$2.3 million are included in our estimate of 2011 general and administrative expenses.

**Interest and Other, Net**

Components of Interest and Other, net were as follows (in millions):

	<b>Three Months Ended</b>	
	<b>March</b>	
	<b>31,</b>	<b>March 31,</b>
	<b>2011</b>	<b>2010</b>
Interest income and other income		0.2
Interest expense and other expense		(0.1)

Interest and Other, net	\$	\$	0.1
-------------------------	----	----	-----

Interest income and other income decreased in the first quarter of 2011 compared to the first quarter of 2010, due to lower average invested balances and lower average effective interest rates.

Interest expense and other expense primarily consisted of interest expense on our equipment financing debt and, through the second quarter of 2010, our loan with UBS Bank USA.

21 of 49

---

## **Table of Contents**

### ***Income Taxes***

We follow the accounting guidance established by the Financial Accounting Standards Board ( FASB ) which defines the threshold for recognizing the benefits of tax return positions in the financial statements as more-likely-than-not to be sustained by the taxing authorities based solely on the technical merits of the position. If the recognition threshold is met, the tax benefit is measured and recognized as the largest amount of tax benefit that, in our judgment, is greater than 50% likely to be realized.

We file income tax returns with the United States Internal Revenue Service ( IRS ) and the state of California. For jurisdictions in which tax filings are made, we are subject to income tax examination for all fiscal years since inception. Tax years 2009 and 2008 are currently under IRS examination. We believe that we maintain adequate reserves for uncertain tax positions.

### **Critical Accounting Policies**

The accounting policies that we consider to be our most critical (i.e., those that are most important to the portrayal of our financial condition and results of operations and that require our most difficult, subjective or complex judgments), the effects of those accounting policies applied and the judgments made in their application are summarized in *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

### **Recent Accounting Pronouncements**

See Note 12, Recent Accounting Pronouncements in the Notes to Unaudited Condensed Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected impact on our financial position and results of operations.

### **Liquidity and Capital Resources**

From August 5, 1997, our date of inception, through March 31, 2011, we funded our operations through the sale of equity securities, equipment financings, non-equity payments from collaborators, government grants and interest income.

Our cash, cash equivalents and investments, excluding restricted cash, totaled \$59.9 million at March 31, 2011, down from \$72.8 million at December 31, 2010. The decrease of \$12.9 million was primarily due to the use of cash to fund operations.

Net cash used in operating activities was \$12.9 million in the first quarter of 2011 and primarily resulted from the net loss of \$11.7 million. Net cash used in operating activities in the first quarter of 2010 was \$12.2 million and primarily resulted from net loss of \$12.2 million.

Net cash provided by investing activities was \$11.1 million in the first quarter of 2011 and primarily consisted of proceeds from the maturity of investments, net of cash used to purchase investments, of \$10.9 million. Net cash provided by investing activities in the first quarter of 2010 was \$4.7 million and primarily consisted of proceeds from the maturity of investments, net of cash used to purchase investments, of \$4.2 million, and proceeds of \$0.3 million from sales of our auction rate securities.

Net cash used in financing activities was \$0.3 million in the first quarter of 2011 and primarily consisted of repayments of \$0.3 million on our equipment financing debt. Net cash provided by financing activities in the first quarter of 2010 was \$2.7 million and primarily consisted of proceeds from drawdowns under our 2007 committed equity financing facility with Kingsbridge of \$3.4 million. The 2007 committed financing facility with Kingsbridge expired on March 31, 2011 and no further shares are available to us for sale under the facility.

On April 18, 2011, we entered into a securities purchase agreement with Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited (collectively, Deerfield ), pursuant to which Deerfield purchased (i) 5,300,000 shares of our common stock for a purchase price of \$1.50 per share and (ii) 8,070 shares of our Series A Convertible Preferred Stock (the Series A Preferred Stock ) for a purchase price of \$1,500.00 per share, for an aggregate purchase price of approximately \$20.1 million. In connection with the securities purchase agreement, we issued to Deerfield warrants to purchase an aggregate of 6,685,000 shares of our common stock at





**Table of Contents**

an initial exercise price of \$1.65 per share. The warrants will be exercisable beginning on the date that is six months after their issuance and will remain exercisable until four years after their issuance.

The rights, preferences and privileges of the Series A Preferred Stock are set forth in a Certificate of Designation of Series A Convertible Preferred Stock. Each share of Series A Preferred Stock is convertible into 1,000 shares of our common stock at any time at the holder's option. However, the holder will be prohibited from converting Series A Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.98% of the total number of shares of our common stock then issued and outstanding. In the event of our liquidation, dissolution, or winding up, holders of our Series A Preferred Stock will receive a payment equal to \$0.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of our common stock. Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock. Shares of Series A Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors, and will rank:

senior to all of our common stock;

senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A Preferred Stock;

on parity with any class or series of our capital stock hereafter created specifically ranking by its terms on parity with the Series A Preferred Stock; and

junior to any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock;

in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

The offering was made pursuant to a shelf registration statement we filed with the Securities and Exchange Commission (SEC) on November 10, 2008, which became effective on November 19, 2008 (File No. 333-155259). The closing of the offering took place on April 20, 2011.

We are eligible to request up to \$2.0 million in future grant payments from the National Institute of Neurological Disorders and Stroke, provided we incur eligible research and development costs for CK-2017357 directed to the potential treatment for myasthenia gravis for three years.

*Shelf Registration Statement.* In November 2008, we filed a shelf registration statement with the SEC, which was declared effective in November 2008. The shelf registration statement allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to \$100 million. As of May 6, 2011, \$45.1 million remains available to us under this shelf registration statement, assuming all outstanding warrants are exercised in cash. The specific terms of offerings, if any, under the shelf registration statement would be established at the time of such offerings.

As of March 31, 2011, future minimum payments under our loan and lease obligations were as follows (in thousands):

	<b>Within One Year</b>	<b>One to Three Years</b>	<b>Three to Five Years</b>	<b>After Five Years</b>	<b>Total</b>
Operating leases (1)	\$ 2,930	\$ 5,958	\$ 6,608	\$ 7,974	\$ 23,470
Equipment financing line	690	34			724
<b>Total</b>	<b>\$ 3,620</b>	<b>\$ 5,992</b>	<b>\$ 6,608</b>	<b>\$ 7,974</b>	<b>\$ 24,194</b>

- (1) Our long-term commitment under operating lease relates to payments under our facility lease in South San Francisco, California, which expires in 2018.

In future periods, we expect to incur substantial costs as we continue to expand our research programs and related research and development activities. We plan to continue to support the clinical development of our cardiac muscle myosin activator omecamtiv mecarbil for the potential treatment of heart failure and research of potential next-generation compounds as part of our strategic alliance with Amgen. We plan to continue clinical development of our fast skeletal troponin activator CK-2017357 for the potential treatment of diseases and conditions related to skeletal muscle weakness or wasting. We plan to continue to conduct non-clinical

23 of 49

---

**Table of Contents**

development of our fast skeletal troponin activator CK-2066260 and, following clearance of an IND, clinical development. We plan to progress one or more of our smooth muscle myosin inhibitor compounds through non-clinical and clinical development. We expect to incur significant research and development expenses as we advance the research and development of our other compounds from our muscle contractility programs through research to candidate selection.

Our future capital uses and requirements depend on numerous factors. These factors include, but are not limited to, the following:

- the initiation, progress, timing, scope and completion of preclinical research, non-clinical development and clinical trials for our drug candidates and potential drug candidates;

- the time and costs involved in obtaining regulatory approvals;

- delays that may be caused by requirements of regulatory agencies;

- Amgen's decisions with regard to funding of development and commercialization of omecamtiv mecarbil or other compounds for the potential treatment of heart failure under our collaboration;

- our level of funding for the development of current or future drug candidates;

- the number of drug candidates we pursue;

- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;

- our ability to establish and maintain selected strategic alliances required for the development of drug candidates and commercialization of our potential drugs;

- our plans or ability to expand our drug development capabilities, including our capabilities to conduct clinical trials for our drug candidates;

- our plans or ability to establish sales, marketing or manufacturing capabilities and to achieve market acceptance for potential drugs;

- the expansion and advancement of our research programs;

- the hiring of additional employees and consultants;

- the expansion of our facilities;

- the acquisition of technologies, products and other business opportunities that require financial commitments; and

- our revenues, if any, from successful development of our drug candidates and commercialization of potential drugs.

We believe that our existing cash and cash equivalents, investments and interest earned on investments will be sufficient to meet our projected operating requirements for at least the next 12 months.

If, at any time, our prospects for internally financing our research and development programs decline, we may decide to reduce research and development expenses by delaying, discontinuing or reducing our funding of development of one or more of our drug candidates or potential drug candidates or of other research and development programs. Alternatively, we might raise funds through strategic relationships, public or private financings or other

arrangements. There can be no assurance that funding, if needed, will be available on attractive terms, or at all, or in accordance with our planned timelines. Furthermore, financing obtained through future strategic relationships may require us to forego certain commercialization and other rights to our drug candidates. Similarly, any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategy.

24 of 49

---

## **Table of Contents**

### **Off-Balance Sheet Arrangements**

As of March 31, 2011, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. Therefore, we are not materially exposed to financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk has not changed materially since our disclosures in Item 7A, Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2010.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **(a) Evaluation of disclosure controls and procedures**

Our management evaluated, with the participation and under the supervision of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded, subject to the limitations described below, that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

#### **(b) Changes in internal control over financial reporting**

There was no change in our internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **(c) Limitations on the Effectiveness of Controls**

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the controls are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

None.

### **ITEM 1A. RISK FACTORS**

*In evaluating our business, you should carefully consider the following risks in addition to the other information in this report. Any of the following risks could materially and adversely affect our business, results of operations, financial condition or your investment in our securities, and many are beyond our control. It is not possible to predict or identify all such factors and, therefore, you should not consider any of these risk factors to be a complete statement of all the potential risks or uncertainties that we face.*

#### **Risks Related To Our Business**

***We have a history of significant losses and may not achieve or sustain profitability and, as a result, you may lose all or part of your investment.***

## **Table of Contents**

We have generally incurred operating losses in each year since our inception in 1997, due to costs incurred in connection with our research and development activities and general and administrative costs associated with our operations. Our drug candidates are all in early and mid-stage clinical testing, and we and our partners must conduct significant additional clinical trials before we and our partners can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur increasing losses for at least several more years, as we continue our research activities and conduct development of, and seek regulatory approvals for, our drug candidates, and commercialize any approved drugs. If our drug candidates fail or do not gain regulatory approval, or if our drugs do not achieve market acceptance, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, you could lose all or part of your investment.

### ***We will need substantial additional capital in the future to sufficiently fund our operations.***

We have consumed substantial amounts of capital to date, and our operating expenditures will increase over the next several years if we expand our research and development activities. We have funded all of our operations and capital expenditures with proceeds from private and public sales of our equity securities, strategic alliances with Amgen, GSK and others, equipment financings, interest on investments and government grants. We believe that our existing cash and cash equivalents, short-term investments and interest earned on investments should be sufficient to meet our projected operating requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our drug candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of capital outlays and operating expenditures associated with these activities.

For the foreseeable future, our operations will require significant additional funding, in large part due to our research and development expenses and the absence of any revenues from product sales. Until we can generate a sufficient amount of product revenue, we expect to raise future capital through strategic alliance and licensing arrangements, public or private equity offerings and debt financings. We do not currently have any commitments for future funding other than grant funding for our myasthenia gravis preclinical and clinical activities, and reimbursements, milestone and royalty payments that we may receive under our collaboration and option agreement with Amgen. We may not receive any further funds under that agreement. Our ability to raise funds may be adversely impacted by current economic conditions, including the effects of the recent disruptions to the credit and financial markets in the United States and worldwide. In particular, the pool of third-party capital that in the past has been available to development-stage companies such as ours has decreased significantly in recent years, and such decreased availability may continue for a prolonged period. As a result of these and other factors, we do not know whether additional financing will be available when needed, or that, if available, such financing would be on terms favorable to our stockholders or us.

To the extent that we raise additional funds through strategic alliances or licensing and other arrangements with third parties, we will likely have to relinquish valuable rights to our technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. To the extent that we raise additional funds by issuing equity securities, our stockholders will experience additional dilution. To the extent that we raise additional funds through debt financing, the financing may involve covenants that restrict our business activities. In addition, funding from any of these sources, if needed, may not be available to us on favorable terms, or at all, or in accordance with our planned timelines.

If we can not raise the funds we need to operate our business, we will need to discontinue certain research and development activities and our stock price likely would be negatively affected.

### ***We depend on Amgen for the conduct, completion and funding of the clinical development and commercialization of omecamtiv mecarbil (formerly known as CK-1827452).***

In May 2009, Amgen exercised its option to acquire an exclusive license to our drug candidate omecamtiv mecarbil worldwide, except for Japan. As a result, Amgen is responsible for the clinical development and obtaining and maintaining regulatory approval of omecamtiv mecarbil for the potential treatment of heart failure worldwide, except Japan.

We do not control the clinical development activities being conducted or that may be conducted in the future by Amgen, including, but not limited to, the timing of initiation, termination or completion of clinical trials, the analysis of data arising out of those clinical trials or the timing of release of data concerning those clinical trials, which may impact our ability to report on Amgen's results. Amgen may conduct these activities more slowly or in a different manner than we would if we controlled the clinical development of omecamtiv mecarbil. Amgen is responsible for filing future applications with the FDA or other regulatory authorities for approval of

26 of 49

---



**Table of Contents**

omecamtiv mecarbil and will be the owner of any marketing approvals issued by the FDA or other regulatory authorities for omeclamtiv mecarbil. If the FDA or other regulatory authorities approve omeclamtiv mecarbil, Amgen will also be responsible for the marketing and sale of the resulting drug, subject to our right to co-promote omeclamtiv mecarbil in North America if we exercise our option to co-fund Phase III development costs of omeclamtiv mecarbil under the collaboration. However, we cannot control whether Amgen will devote sufficient attention and resources to the clinical development of omeclamtiv mecarbil or will proceed in an expeditious manner, even if we do exercise our option to co-fund the development of omeclamtiv mecarbil. Even if the FDA or other regulatory agencies approve omeclamtiv mecarbil, Amgen may elect not to proceed with the commercialization of the resulting drug in one or more countries.

Amgen generally has discretion to elect whether to pursue or abandon the development of omeclamtiv mecarbil and may terminate our strategic alliance for any reason upon six months prior notice. If the initial results of one or more clinical trials with omeclamtiv mecarbil do not meet Amgen's expectations, Amgen may elect to terminate further development of omeclamtiv mecarbil or certain of the potential clinical trials for omeclamtiv mecarbil, even if the actual number of patients treated at that time is relatively small. If Amgen abandons omeclamtiv mecarbil, it would result in a delay in or could prevent us from commercializing omeclamtiv mecarbil, and would delay and could prevent us from obtaining revenues for this drug candidate. Disputes may arise between us and Amgen, which may delay or cause the termination of any omeclamtiv mecarbil clinical trials, result in significant litigation or cause Amgen to act in a manner that is not in our best interest. If development of omeclamtiv mecarbil does not progress for these or any other reasons, we would not receive further milestone payments or royalties on product sales from Amgen with respect to omeclamtiv mecarbil. If Amgen abandons development of omeclamtiv mecarbil prior to regulatory approval or if it elects not to proceed with commercialization of the resulting drug following regulatory approval, we would have to seek a new partner for clinical development or commercialization, curtail or abandon that clinical development or commercialization, or undertake and fund the clinical development of omeclamtiv mecarbil or commercialization of the resulting drug ourselves. If we seek a new partner but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of omeclamtiv mecarbil ourselves, we would have to curtail or abandon that development or commercialization, which could harm our business.

***We have never generated, and may never generate, revenues from commercial sales of our drugs and we will not have drugs to market for at least several years, if ever.***

We currently have no drugs for sale and we cannot guarantee that we will ever develop or obtain approval to market any drugs. To receive marketing approval for any drug candidate, we must demonstrate that the drug candidate satisfies rigorous standards of safety and efficacy to the FDA in the United States and other regulatory authorities abroad. We and our partners will need to conduct significant additional research and preclinical and clinical testing before we or our partners can file applications with the FDA or other regulatory authorities for approval of any of our drug candidates. In addition, to compete effectively, our drugs must be easy to use, cost-effective and economical to manufacture on a commercial scale, compared to other therapies available for the treatment of the same conditions. We may not achieve any of these objectives. Currently, our only drug candidates that have progressed into clinical development are: omeclamtiv mecarbil, our drug candidate for the potential treatment of heart failure; CK-2017357, our drug candidate for the potential treatment of diseases associated with aging, muscle wasting and neuromuscular dysfunction; and ispinesib, SB-743921 and GSK-923295, our drug candidates for the potential treatment of cancer. We cannot be certain that the clinical development of these or any future drug candidates will be successful, that they will receive the regulatory approvals required to commercialize them, or that any of our other research programs will yield a drug candidate suitable for clinical testing or commercialization. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially marketed for at least several years, if at all. The development of any one or all of these drug candidates may be discontinued at any stage of our clinical trials programs and we may not generate revenue from any of these drug candidates.

***Clinical trials may fail to demonstrate the desired safety and efficacy of our drug candidates, which could prevent or significantly delay completion of clinical development and regulatory approval.***

Prior to receiving approval to commercialize any of our drug candidates, we or our partners must adequately demonstrate to the FDA and foreign regulatory authorities that the drug candidate is sufficiently safe and effective with substantial evidence from well-controlled clinical trials. In clinical trials we or our partners will need to demonstrate efficacy for the treatment of specific indications and monitor safety throughout the clinical development process and following approval. None of our drug candidates have yet been demonstrated to be safe and effective in clinical trials and they may never be. In addition, for each of our current preclinical compounds, we or our partners must adequately demonstrate satisfactory chemistry, formulation, stability and toxicity in order to submit an IND to the FDA, or an equivalent application in foreign jurisdictions, that would allow us to advance that compound into clinical trials. Furthermore, we or our partners may need to submit separate INDs (or foreign equivalent) to different divisions within the FDA (or foreign regulatory authorities) in order to pursue clinical trials in different therapeutic areas. Each new IND (or foreign equivalent) must be reviewed by the new division before the clinical trial under its jurisdiction can proceed, entailing all the risks of delay inherent to regulatory review. If our or our partners' current or future preclinical studies or clinical trials are unsuccessful, our business will be significantly harmed and our stock price could be negatively affected.

27 of 49

---

**Table of Contents**

All of our drug candidates are prone to the risks of failure inherent in drug development. Preclinical studies may not yield results that would adequately support the filing of an IND (or a foreign equivalent) with respect to our potential drug candidates. Even if the results of preclinical studies for a drug candidate are sufficient to support such a filing, the results of preclinical studies do not necessarily predict the results of clinical trials. As an example, because the physiology of animal species used in preclinical studies may vary substantially from other animal species and from humans, it may be difficult to assess with certainty whether a finding from a study in a particular animal species will result in similar findings in other animal species or in humans. For any of our drug candidates, the results from Phase I clinical trials in healthy volunteers and clinical results from Phase I and II trials in patients are not necessarily indicative of the results of larger Phase III clinical trials that are necessary to establish whether the drug candidate is safe and effective for the applicable indication. Likewise, interim results from a clinical trial may not be indicative of the final results from that trial.

In addition, while the clinical trials of our drug candidates are designed based on the available relevant information, in view of the uncertainties inherent in drug development, such clinical trials may not be designed with focus on indications, patient populations, dosing regimens, safety or efficacy parameters or other variables that will provide the necessary safety or efficacy data to support regulatory approval to commercialize the resulting drugs. For example, in previously conducted two-stage Phase II clinical trials designed to evaluate the safety and efficacy of ispinesib as monotherapy in the first- or second-line treatment of patients with different forms of cancer, ispinesib did not satisfy the criteria for advancement to Stage 2. In addition, individual patient responses to the dose administered of a drug may vary in a manner that is difficult to predict. Also, the methods we select to assess particular safety or efficacy parameters may not yield the same statistical precision in estimating our drug candidates' effects as may other alternative methodologies. Even if we believe the data collected from clinical trials of our drug candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval.

Administering any of our drug candidates or potential drug candidates may produce undesirable side effects, also known as adverse effects. Toxicities and adverse effects observed in preclinical studies for some compounds in a particular research and development program may also occur in preclinical studies or clinical trials of other compounds from the same program. Potential toxicity issues may arise from the effects of the active pharmaceutical ingredient itself or from impurities or degradants that are present in the active pharmaceutical ingredient or could form over time in the formulated drug candidate or the active pharmaceutical ingredient. These toxicities or adverse effects could delay or prevent the filing of an IND (or a foreign equivalent) with respect to our drug candidates or potential drug candidates or cause us or our partners to modify, suspend or terminate clinical trials with respect to any drug candidate at any time during the development program. The FDA, other regulatory authorities, our partners or we may modify, suspend or terminate clinical trials with our drug candidates at any time. If these or other adverse effects are severe or frequent enough to outweigh the potential efficacy of a drug candidate, the FDA or other regulatory authorities could deny approval of that drug candidate for any or all targeted indications. Even if one or more of our drug candidates were approved for sale as drugs, the occurrence of even a limited number of toxicities or adverse effects when used in large populations may cause the FDA to impose restrictions on, or stop, the further marketing of those drugs. Indications of potential adverse effects or toxicities which do not seem significant during the course of clinical trials may later turn out to actually constitute serious adverse effects or toxicities when a drug is used in large populations or for extended periods of time.

We have observed certain adverse effects in the clinical trials conducted with our drug candidates. For example, in clinical trials of omecamtiv mecarbil, doses that exceeded the maximum tolerated dose were associated with complaints of chest discomfort, palpitations, dizziness and feeling hot, increases in heart rate, declines in blood pressure, electrocardiographic changes consistent with acute myocardial ischemia and transient rises in the MB fraction of creatine kinase and cardiac troponins I and T, which are indicative of myocardial infarction. In Phase IIa clinical trials of CK-2017357, adverse events of dizziness, fatigue, headache, somnolence (sleepiness), euphoric mood, muscle spasms, gait disturbance, muscular weakness, nausea, balance disorder, asthenia (loss of strength and

energy), abnormal coordination and dysarthria (difficulty speaking) appeared to increase in frequency with increasing doses of CK-2017357. In clinical trials of ispinesib, the most commonly observed dose-limiting toxicity was neutropenia, a decrease in the number of a certain type of white blood cell that results in an increase in susceptibility to infection.

Further, the administration of two or more drugs contemporaneously can lead to interactions between them, and in clinical trials, our drug candidates may interact with other drugs that the trial subjects are taking. For example, many ALS patients take riluzole, a commercially available treatment for ALS. In a Phase IIa clinical trial of CK-2017357 in ALS patients, we observed in the patients taking riluzole increases in the blood plasma concentration of riluzole associated with the administration of CK-2017357.

28 of 49

---

## **Table of Contents**

Accordingly, we are conducting a Phase I drug-drug interaction clinical trial intended to evaluate the effects of CK-2017357 on the pharmacokinetics of riluzole and other drugs to better understand the significance of this finding. If this drug-drug interaction trial produces materially adverse findings, it may call into question the feasibility of developing CK-2017357 as a treatment for ALS.

In addition, clinical trials of omecamtiv mecarbil and CK-2017357 enroll patients who typically suffer from serious diseases which put them at increased risk of death. These patients may die while receiving our drug candidates. In such circumstances, it may not be possible to exclude with certainty a causal relationship to our drug candidate, even though the responsible clinical investigator may view such an event as not study drug-related. For example, in a Phase IIa clinical trial designed to evaluate and compare the oral pharmacokinetics of both modified and immediate release formulations of omecamtiv mecarbil in patients with stable heart failure, a patient died suddenly after receiving the immediate release formulation of omecamtiv mecarbil, without having reported any preceding adverse events. The clinical investigator assessed the patient's death as not related to omecamtiv mecarbil. However, the event was reported to the appropriate regulatory authorities as possibly related to omecamtiv mecarbil because the immediate cause of the patient's death could not be determined, and therefore, a relationship to omecamtiv mecarbil could not be excluded definitively.

Any failure or significant delay in completing preclinical studies or clinical trials for our drug candidates, or in receiving and maintaining regulatory approval for the sale of any resulting drugs, may significantly harm our business and negatively affect our stock price.

### ***Clinical trials are expensive, time-consuming and subject to delay.***

Clinical trials are subject to rigorous regulatory requirements and are very expensive, difficult and time-consuming to design and implement. The length of time and number of trial sites and patients required for clinical trials vary substantially based on the type, complexity, novelty, intended use of the drug candidate and safety concerns. We estimate that the clinical trials of our current drug candidates will each continue for several more years. However, the clinical trials for all or any of these drug candidates may take significantly longer to complete. The commencement and completion of our clinical trials could be delayed or prevented by many factors, including, but not limited to:

- delays in obtaining, or inability to obtain, regulatory or other approvals to commence and conduct clinical trials in the manner we or our partners deem necessary for the appropriate and timely development of our drug candidates and commercialization of any resulting drugs;

- delays in identifying and reaching agreement, or inability to identify and reach agreement, on acceptable terms, with prospective clinical trial sites and other entities involved in the conduct of our clinical trials;

- delays or additional costs in developing, or inability to develop, appropriate formulations of our drug candidates for clinical trial use, including an appropriate modified release oral formulation for omecamtiv mecarbil;

- slower than expected rates of patient recruitment and enrollment, including as a result of competition for patients with other clinical trials; limited numbers of patients that meet the enrollment criteria; patients', investigators' or trial sites' reluctance to agree to the requirements of a protocol; or the introduction of alternative therapies or drugs by others;

- for those drug candidates that are the subject of a strategic alliance, delays in reaching agreement with our partner as to appropriate development strategies;

- a regulatory authority may require changes to a protocol for a clinical trial that then may require approval from regulatory agencies in other jurisdictions where the trial is being conducted;

- an institutional review board (IRB) or its foreign equivalent may require changes to a protocol that then require approval from regulatory agencies and other IRBs and their foreign equivalents, or regulatory authorities may

require changes to a protocol that then require approval from the IRBs or their foreign equivalents;

for clinical trials conducted in foreign countries, the time and resources required to identify, interpret and comply with foreign regulatory requirements or changes in those requirements, and political instability or natural disasters occurring in those countries;

lack of effectiveness of our drug candidates during clinical trials;

29 of 49

---

**Table of Contents**

unforeseen safety issues;

inadequate supply of clinical trial materials;

uncertain dosing issues;

failure by us, our partners, or clinical research organizations, investigators or site personnel engaged by us or our partners to comply with good clinical practices and other applicable laws and regulations, including those concerning informed consent;

inability or unwillingness of investigators or their staffs to follow clinical protocols;

inability to monitor patients adequately during or after treatment;

introduction of new therapies or changes in standards of practice or regulatory guidance that render our drug candidates or their clinical trial endpoints obsolete; and

results from non-clinical studies that may adversely impact the timing or further development of our drug candidates.

We do not know whether planned clinical trials will begin on time, or whether planned or currently ongoing clinical trials will need to be restructured or will be completed on schedule, if at all. Significant delays in clinical trials will impede our ability to commercialize our drug candidates and generate revenue and could significantly increase our development costs.

***If we fail to enter into and maintain successful strategic alliances for our drug candidates, potential drug candidates or research and development programs, we will have to reduce, delay or discontinue our advancement of those drug candidates, potential drug candidates and programs or expand our research and development capabilities and increase our expenditures.***

Drug development is complicated and expensive. We currently have limited financial and operational resources to carry out drug development. Our strategy for developing, manufacturing and commercializing our drug candidates and potential drug candidates currently requires us to enter into and successfully maintain strategic alliances with pharmaceutical companies or other industry participants to advance our programs and reduce our expenditures on each program. Accordingly, the success of our development activities depends in large part on our current and future strategic partners' performance, over which we have little or no control.

We have retained all rights to develop and commercialize CK-2017357, CK-2066260, ispinesib, SB-743921 and GSK-923295. We currently do not have a strategic partner for these drug candidates. We are relying on GSK to complete its Phase I clinical trial for GSK-923295. We expect to rely on one or more strategic partners or other arrangements with third parties to advance and develop each of CK-2017357, CK-2066260 and other compounds from our skeletal muscle contractility program; ispinesib, SB-743921 and GSK-923295; and our smooth muscle myosin inhibitors. However, we may not be able to negotiate and enter into such strategic alliances or arrangements on acceptable terms, if at all, or in accordance with our planned timelines.

We rely on Amgen to conduct non-clinical and clinical development for omecamtiv mecarbil for the potential treatment of heart failure. If Amgen elects to terminate its development activities with respect to omecamtiv mecarbil, we currently do not have an alternative strategic partner for this drug candidate.

Our ability to commercialize drugs that we develop with our partners and that generate royalties from product sales depends on our partners' abilities to assist us in establishing the safety and efficacy of our drug candidates, obtaining and maintaining regulatory approvals and achieving market acceptance of the drugs once commercialized. Our partners may elect to delay or terminate development of one or more drug candidates, independently develop drugs that could compete with ours or fail to commit sufficient resources to the marketing and distribution of drugs developed through their strategic alliances with us. Our partners may not proceed with the development and

commercialization of our drug candidates with the same degree of urgency as we would because of other priorities they face. In addition, new business combinations or changes in a partner's business strategy may adversely affect its willingness or ability to carry out its obligations under a strategic alliance.

If we are not able to successfully maintain our existing strategic alliances or establish and successfully maintain additional strategic alliances, we will have to limit the size or scope of, or delay or discontinue, one or more of our drug development programs or research programs, or undertake and fund these programs ourselves. Alternatively, if we elect to continue to conduct any of these drug

30 of 49

---



**Table of Contents**

development programs or research programs on our own, we will need to expand our capability to conduct clinical development by bringing additional skills, technical expertise and resources into our organization. This would require significant additional funding, which may not be available to us on acceptable terms, or at all.

***We depend on contract research organizations to conduct our clinical trials and have limited control over their performance.***

We have used and intend to continue to use contract research organizations ( CROs ) within and outside of the United States to conduct clinical trials of our drug candidates, such as CK-2017357. We do not have control over many aspects of our CROs' activities, and cannot fully control the amount, timing or quality of resources that they devote to our programs. CROs may not assign as high a priority to our programs or pursue them as diligently as we would if we were undertaking these programs ourselves. The activities conducted by our CROs therefore may not be completed on schedule or in a satisfactory manner. CROs may also give higher priority to relationships with our competitors and potential competitors than to their relationships with us. Outside of the United States, we are particularly dependent on our CROs' expertise in communicating with clinical trial sites and regulatory authorities and ensuring that our clinical trials and related activities and regulatory filings comply with applicable laws. Our CROs' failure to carry out development activities on our behalf according to our and the FDA's or other regulatory agencies' requirements and in accordance with applicable U.S. and foreign laws, or our failure to properly coordinate and manage these activities, could increase the cost of our operations and delay or prevent the development, approval and commercialization of our drug candidates. In addition, if a CRO fails to perform as agreed, our ability to collect damages may be contractually limited. If we fail to effectively manage the CROs carrying out the development of our drug candidates or if our CROs fail to perform as agreed, the commercialization of our drug candidates will be delayed or prevented.

***We have no manufacturing capacity and depend on our strategic partners and contract manufacturers to produce our clinical trial drug supplies for each of our drug candidates and potential drug candidates, and anticipate continued reliance on contract manufacturers for the development and commercialization of our potential drugs.***

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates or potential drug candidates. We have limited experience in drug formulation and manufacturing, and we lack the resources and the capabilities to manufacture any of our drug candidates or potential drug candidates on a clinical or commercial scale. Amgen has assumed responsibility to conduct these activities for the ongoing clinical development of omecamtiv mecarbil worldwide, except Japan. We have relied on GSK to conduct these activities for the clinical development of GSK-923295. For CK-2017357, CK-2066260 and our other drug candidates and potential drug candidates, we rely (and for omecamtiv mecarbil, ispinosib and SB-743921, we have relied) on a limited number of contract manufacturers. In particular, we rely on single-source contract manufacturers for the active pharmaceutical ingredient and the drug product supply for our clinical trials. We expect to rely on contract manufacturers to supply all future drug candidates for which we conduct clinical development. If any of our existing or future contract manufacturers fail to perform satisfactorily, it could delay clinical development or regulatory approval of our drug candidates or commercialization of our drugs, producing additional losses and depriving us of potential product revenues. In addition, if a contract manufacturer fails to perform as agreed, our ability to collect damages may be contractually limited.

Our drug candidates and potential drug candidates require precise high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including failure to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in patient injury or death, discontinuance or delay of ongoing or planned clinical trials, delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals and other problems that could seriously hurt our business. Contract drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance and shortages of qualified personnel. These manufacturers are subject to stringent regulatory requirements, including the FDA's current good manufacturing practices regulations and similar foreign laws and standards. Each contract manufacturer must pass a pre-approval inspection before we can obtain marketing approval for any of our drug candidates and following approval will be subject to ongoing periodic unannounced inspections by the FDA, the U.S. Drug Enforcement Agency and other regulatory agencies, to ensure strict compliance with current good manufacturing practices and

other applicable government regulations and corresponding foreign laws and standards. We seek to ensure that our contract manufacturers comply fully with all applicable regulations, laws and standards. However, we do not have control over our contract manufacturers' compliance with these regulations, laws and standards. If one of our contract manufacturers fails to pass its pre-approval inspection or maintain ongoing compliance at any time, the production of our drug candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and potentially lost revenues. In addition, failure of any third party manufacturers or us to comply with applicable regulations, including pre-or post-approval inspections and the current good manufacturing practice requirements of the FDA or other comparable regulatory agencies, could result in sanctions being imposed on us. These sanctions could include fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation,

31 of 49

---

**Table of Contents**

product seizures or recalls, operational restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

In addition, our existing and future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our drug candidates. If a natural disaster, business failure, strike or other difficulty occurs, we may be unable to replace these contract manufacturers in a timely or cost-effective manner and the production of our drug candidates would be interrupted, resulting in delays and additional costs.

Switching manufacturers or manufacturing sites would be difficult and time-consuming because the number of potential manufacturers is limited. In addition, before a drug from any replacement manufacturer or manufacturing site can be commercialized, the FDA and, in some cases, foreign regulatory agencies, must approve that site. These approvals would require regulatory testing and compliance inspections. A new manufacturer or manufacturing site also would have to be educated in, or develop substantially equivalent processes for, production of our drugs and drug candidates. It may be difficult or impossible to transfer certain elements of a manufacturing process to a new manufacturer or for us to find a replacement manufacturer on acceptable terms quickly, or at all, either of which would delay or prevent our ability to develop drug candidates and commercialize any resulting drugs.

***We may not be able to successfully scale-up manufacturing of our drug candidates in sufficient quality and quantity, which would delay or prevent us from developing our drug candidates and commercializing resulting approved drugs, if any.***

To date, our drug candidates have been manufactured in small quantities for preclinical studies and early-stage clinical trials. In order to conduct larger scale or late-stage clinical trials for a drug candidate and for commercialization of the resulting drug if that drug candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity for any of our drug candidates, whether in collaboration with third-party manufacturers or on our own, in a timely or cost-effective manner or at all. If a contract manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to those improvements. Significant scale-up of manufacturing may require additional validation studies, which are costly and which the FDA must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a drug candidate itself or of a drug candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up manufacture of any of our drug candidates in sufficient quality and quantity, the development of that drug candidate and regulatory approval or commercial launch for any resulting drugs may be delayed or there may be a shortage in supply, which could significantly harm our business.

***The mechanisms of action of our drug candidates and potential drug candidates are unproven, and we do not know whether we will be able to develop any drug of commercial value.***

We have discovered and are currently developing drug candidates and potential drug candidates that have what we believe are novel mechanisms of action directed against cytoskeletal targets, and intend to continue to do so. Because no currently approved drugs appear to operate via the same biochemical mechanisms as our compounds, we cannot be certain that our drug candidates and potential drug candidates will result in commercially viable drugs that safely and effectively treat the indications for which we intend to develop them. The results we have seen for our compounds in preclinical models may not translate into similar results in humans, and results of early clinical trials in humans may not be predictive of the results of larger clinical trials that may later be conducted with our drug candidates. Even if we are successful in developing and receiving regulatory approval for a drug candidate for the treatment of a particular disease, we cannot be certain that we will also be able to develop and receive regulatory approval for that or other drug candidates for the treatment of other diseases. If we or our partners are unable to successfully develop and commercialize our drug candidates, our business will be materially harmed.

***Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our drug candidates, potential drug candidates and research technologies.***

We own, or hold exclusive licenses to, a number of U.S. and foreign patents and patent applications directed to our drug candidates, potential drug candidates and research technologies. Our success depends on our ability to obtain

patent protection both in the United States and in other countries for our drug candidates and potential drug candidates, their methods of manufacture and use, and our technologies. Our ability to protect our drug candidates, potential drug candidates and technologies from unauthorized or infringing use by third parties depends substantially on our ability to obtain and enforce our patents. If our issued patents and patent applications, if granted, do not adequately describe, enable or otherwise provide coverage of our technologies and drug candidates and potential drug candidates, including omecamtiv mecarbil, CK-2017357, CK-2066260, ispinesib, SB-743921 and GSK-923295, we or our

32 of 49

---

**Table of Contents**

licensees would not be able to exclude others from developing or commercializing these drug candidates. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the claim scope of these patents, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards which the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents. Thus, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. In particular:

we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;

we or our licensors might not have been the first to file patent applications for the inventions covered by our pending patent applications and issued patents;

others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

some or all of our or our licensors' pending patent applications may not result in issued patents or the claims that issue may be narrow in scope and not provide us with competitive advantages;

our and our licensors' issued patents may not provide a basis for commercially viable drugs or therapies or may be challenged and invalidated by third parties;

our or our licensors' patent applications or patents may be subject to interference, opposition or similar administrative proceedings that may result in a reduction in their scope or their loss altogether;

we may not develop additional proprietary technologies or drug candidates that are patentable; or

the patents of others may prevent us or our partners from discovering, developing or commercializing our drug candidates.

Patent protection is afforded on a country-by-country basis. Some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending intellectual property rights in foreign jurisdictions. Some of our development efforts are performed in countries outside of the United States through third party contractors. We may not be able to effectively monitor and assess intellectual property developed by these contractors. We therefore may not be able to effectively protect this intellectual property and could lose potentially valuable intellectual property rights. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective of intellectual property rights as in the United States. Therefore, we may be unable to acquire and protect intellectual property developed by these contractors to the same extent as if these development activities were being conducted in the United States. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

We rely on intellectual property assignment agreements with our corporate partners, employees, consultants, scientific advisors and other collaborators to grant us ownership of new intellectual property that is developed. These agreements may not result in the effective assignment to us of that intellectual property. As a result, our ownership of

key intellectual property could be compromised.

Changes in either the patent laws or their interpretation in the United States or other countries may diminish the value of our intellectual property or our ability to obtain patents. For example, the U.S. Congress is currently considering bills that could change U.S. law regarding, among other things, post-grant review of issued patents and the calculation of damages once patent infringement has been determined by a court of law. If enacted into law, these provisions could severely weaken patent protection in the United States.

33 of 49

---

**Table of Contents**

If one or more products resulting from our drug candidates is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate them for approval and sale in the United States without repeating the extensive testing required of us or our partners to obtain FDA approval. Regardless of any patent protection, under current law, an application for a generic version of a new chemical entity cannot be approved until at least five years after the FDA has approved the original product. When that period expires, or if that period is altered, the FDA could approve a generic version of our product regardless of our patent protection. An applicant for a generic version of our product may only be required to conduct a relatively inexpensive study to show that its product is bioequivalent to our product, and may not have to repeat the lengthy and expensive clinical trials that we or our partners conducted to demonstrate that the product is safe and effective. In the absence of adequate patent protection for our products in other countries, competitors may similarly be able to obtain regulatory approval in those countries of generic versions of our products.

We also rely on trade secrets to protect our technology, particularly where we believe patent protection is not appropriate or obtainable. However, trade secrets are often difficult to protect, especially outside of the United States. While we endeavor to use reasonable efforts to protect our trade secrets, our or our partners' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our information to competitors. In addition, confidentiality agreements, if any, executed by those individuals may not be enforceable or provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. Pursuing a claim that a third party had illegally obtained and was using our trade secrets would be expensive and time-consuming, and the outcome would be unpredictable. Even if we are able to maintain our trade secrets as confidential, if our competitors independently develop information equivalent or similar to our trade secrets, our business could be harmed.

If we are not able to defend the patent or trade secret protection position of our technologies and drug candidates, then we will not be able to exclude competitors from developing or marketing competing drugs, and we may not generate enough revenue from product sales to justify the cost of development of our drugs or to achieve or maintain profitability.

***If we are sued for infringing third party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business.***

Our ability to commercialize drugs depends on our ability to use, manufacture and sell those drugs without infringing the patents or other proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the therapeutic areas in which we are developing drug candidates and seeking new potential drug candidates. In addition, because patent applications can take several years to issue, there may be currently pending applications, unknown to us, which could later result in issued patents that our activities with our drug candidates could infringe. There may also be existing patents, unknown to us, that our activities with our drug candidates could infringe.

Currently, we are aware of an issued U.S. patent and at least one pending U.S. patent application assigned to Curis, Inc., relating to certain compounds in the quinazolinone class. Ispinesib falls into this class of compounds. The Curis U.S. patent claims a method of inhibiting signaling by what is called the hedgehog pathway using certain quinazolinone compounds. Curis also has pending applications in Europe, Japan, Australia and Canada with claims covering certain quinazolinone compounds, compositions thereof and methods of their use. Two of the Australian applications have been allowed and two of the European applications have been granted. We have opposed the granting of certain of these patents to Curis in Europe and in Australia. Curis has withdrawn one of the Australian applications. One of the European patents that we opposed was recently revoked and is no longer valid in Europe. Curis has appealed this decision.

Curis or a third party may assert that the manufacture, use, importation or sale of ispinesib may infringe one or more of its patents. We believe that we have valid defenses against the issued U.S. patent owned by Curis if it were to be asserted against us. However, we cannot guarantee that a court would find these defenses valid or that any additional defenses would be successful. We have not attempted to obtain a license to these patents. If we decide to seek a license to these patents, we cannot guarantee that such a license would be available on acceptable terms, if at all.

Other future products of ours may be impacted by patents of companies engaged in competitive programs with significantly greater resources (such as Merck & Co., Inc., Eli Lilly and Company, Bristol-Myers Squibb Company, Novartis and AstraZeneca AB). Further development of these products could be impacted by these patents and result in significant legal fees.

If a third party claims that our actions infringe its patents or other proprietary rights, we could face a number of issues that could

34 of 49

---



## **Table of Contents**

seriously harm our competitive position, including, but not limited to:

infringement and other intellectual property claims that, even if meritless, can be costly and time-consuming to litigate, delay the regulatory approval process and divert management's attention from our core business operations;

substantial damages for past infringement which we may have to pay if a court determines that our drugs or technologies infringe a third party's patent or other proprietary rights;

a court prohibiting us from selling or licensing our drugs or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do; and

if a license is available from a holder, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

If any of these events occur, it could significantly harm our business and negatively affect our stock price.

***We may undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.***

Third parties may infringe our patents. To prevent infringement or unauthorized use, we may need to file infringement suits, which are expensive and time-consuming. In an infringement proceeding, a court may decide that one or more of our patents is invalid, unenforceable, or both. In this case, third parties may be able to use our technology without paying licensing fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party's activities are not covered by our patents. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. In addition, third parties may affirmatively challenge our rights to, or the scope or validity of, our patent rights.

***We may become involved in disputes with our strategic partners over intellectual property ownership, and publications by our research collaborators and clinical investigators could impair our ability to obtain patent protection or protect our proprietary information, either of which would have a significant impact on our business.***

Inventions discovered under our current or future strategic alliance agreements may become jointly owned by our strategic partners and us in some cases, and the exclusive property of one of us in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention or whether it is jointly owned, and disputes could arise regarding ownership or use of those inventions. These disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions. In addition, our research collaborators and clinical investigators generally have contractual rights to publish data arising from their work. Publications by our research collaborators and clinical investigators relating to our research and development programs, either with or without our consent, could benefit our current or potential competitors and may impair our ability to obtain patent protection or protect our proprietary information, which could significantly harm our business.

***We may be subject to claims that we or our employees have wrongfully used or disclosed trade secrets of their former employers.***

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending these claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to develop and commercialize certain potential drugs, which could significantly harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management.

*Our competitors may develop drugs that are less expensive, safer or more effective than ours, which may diminish or eliminate the commercial success of any drugs that we may commercialize.*

35 of 49

---

## **Table of Contents**

We compete with companies that have developed drugs or are developing drug candidates for cardiovascular diseases, cancer and other diseases for which our drug candidates may be useful treatments. For example, if omecamtiv mecarbil is approved for marketing by the FDA for heart failure, that drug candidate would compete against other drugs used for the treatment of heart failure. These include generic drugs, such as milrinone, dobutamine or digoxin and newer marketed drugs such as nesiritide. Omecamtiv mecarbil could also potentially compete against other novel drug candidates in development, such as bucindolol, which is being developed by ARCA biopharma, Inc.; relaxin, which is being developed by Novartis; CD-NP, which is being developed by Nile Therapeutics, Inc., and glial growth factor (GGF-2) which is being developed by Acorda Therapeutics, Inc. In addition, there are a number of medical devices being developed for the potential treatment of heart failure.

With respect to CK-2017357, CK-2066260 and other compounds that may arise from our skeletal muscle contractility program, potential competitors include Ligand Pharmaceuticals, Inc., which is developing LGD-4033, a selective androgen receptor modulator, for muscle wasting; and GTx, Inc., which is developing ostarine, a selective androgen receptor modulator, for cancer cachexia. Acceleron Pharma, Inc. is conducting clinical development with ACE-031, a myostatin inhibitor, and related compounds to evaluate their ability to treat diseases involving the loss of muscle mass, strength and function. We are aware that other companies are developing potential new therapies for ALS, such as Biogen Idec, Inc., Mitsubishi Tanabe Pharma Corporation, Eisai Inc., Trophos SA, and Isis Pharmaceuticals, Inc. If CK-2017357 or other of our skeletal muscle sarcomere activators are approved for the treatment of claudication associated with peripheral artery disease, they will compete with currently approved therapies for the treatment of peripheral artery disease. We are also aware that a number of companies are developing potential new treatments for peripheral artery disease or associated symptoms of claudication. If CK-2017357 or other of our skeletal muscle sarcomere activators are approved for the treatment of myasthenia gravis, they will compete with currently approved therapies for the treatment of myasthenia gravis, including but not limited to anticholinesterase agents, such as pyridostigmine bromide and neostigmine bromide, corticosteroids, such as prednisone, and immunomodulatory drugs, such as azathioprine and cyclosporine. We are also aware that a number of companies are developing or commercializing in certain markets potential new treatments for myasthenia gravis, such as Benesis Corp. (GB-0998), Alexion Pharmaceuticals, Inc. (eculizumab) and Astellas (tacrolimus).

Our competitors may:

- develop drug candidates and market drugs that are less expensive or more effective than our future drugs;

- commercialize competing drugs before we or our partners can launch any drugs developed from our drug candidates;

- hold or obtain proprietary rights that could prevent us from commercializing our products;

- initiate or withstand substantial price competition more successfully than we can;

- more successfully recruit skilled scientific workers and management from the limited pool of available talent;

- more effectively negotiate third-party licenses and strategic alliances;

- take advantage of acquisition or other opportunities more readily than we can;

- develop drug candidates and market drugs that increase the levels of safety or efficacy that our drug candidates will need to show in order to obtain regulatory approval; or

- introduce therapies or market drugs that render the market opportunity for our potential drugs obsolete.

We will compete for market share against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or

together with their partners, may develop new drug candidates that will compete with ours. These competitors may, and in certain cases do, operate larger research and development programs or have substantially greater financial resources than we do. Our competitors may also have significantly greater experience in:

developing drug candidates;

undertaking preclinical testing and clinical trials;

36 of 49

---

## **Table of Contents**

building relationships with key customers and opinion-leading physicians;

obtaining and maintaining FDA and other regulatory approvals of drug candidates;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

If our competitors market drugs that are less expensive, safer or more efficacious than our potential drugs, or that reach the market sooner than our potential drugs, we may not achieve commercial success. In addition, the life sciences industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by improving existing technological approaches or developing new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies.

***Our failure to attract and retain skilled personnel could impair our drug development and commercialization activities.***

Our business depends on the performance of our senior management and key scientific and technical personnel. The loss of the services of any member of our senior management or key scientific or technical staff may significantly delay or prevent the achievement of drug development and other business objectives by diverting management's attention to transition matters and identifying suitable replacements. We also rely on consultants and advisors to assist us in formulating our research and development strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us. In addition, if and as our business grows, we will need to recruit additional executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. Our inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development activities, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

***Any future workforce and expense reductions may have an adverse impact on our internal programs and our ability to hire and retain skilled personnel.***

In light of our continued need for funding and cost control, we may be required to implement future workforce and expense reductions, which may negatively affect our productivity and limit our research and development activities. For example, as part of our strategic restructuring and workforce reduction in 2008, we discontinued our early research activities in oncology. Our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce reductions. In addition, the implementation of workforce or expense reduction programs may divert the efforts of our management team and other key employees, which could adversely affect our business.

***We may expand our development and clinical research capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We may have growth in our expenditures, the number of our employees and the scope of our operations, in particular with respect to those drug candidates that we elect to develop or commercialize independently or together with a partner. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***We currently have no sales or marketing staff and, if we are unable to enter into or maintain strategic alliances with marketing partners or to develop our own sales and marketing capabilities, we may not be successful in commercializing our potential drugs.***



## **Table of Contents**

We currently have no sales, marketing or distribution capabilities. We plan to commercialize drugs that can be effectively marketed and sold in concentrated markets that do not require a large sales force to be competitive. To achieve this goal, we will need to establish our own specialized sales force and marketing organization with technical expertise and supporting distribution capabilities. Developing such an organization is expensive and time-consuming and could delay a product launch. In addition, we may not be able to develop this capacity efficiently, cost-effectively or at all, which could make us unable to commercialize our drugs. If we determine not to market our drugs on our own, we will depend on strategic alliances with third parties, such as Amgen, which have established distribution systems and direct sales forces to commercialize them. If we are unable to enter into such arrangements on acceptable terms, we may not be able to successfully commercialize these drugs. To the extent that we are not successful in commercializing any drugs ourselves or through a strategic alliance, our product revenues and business will suffer and our stock price would decrease.

### **Risks Related To Our Industry**

***The regulatory approval process is expensive, time-consuming and uncertain and may prevent our partners or us from obtaining approvals to commercialize some or all of our drug candidates.***

The research, testing, manufacturing, selling and marketing of drugs are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Neither we nor our partners are permitted to market our potential drugs in the United States until we receive approval of a new drug application ( NDA ) from the FDA. Neither we nor our partners have received marketing approval for any of Cytokinetics' drug candidates.

Obtaining NDA approval is a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production, and refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is never guaranteed, and the approval process typically takes several years and is extremely expensive. The FDA and foreign regulatory agencies also have substantial discretion in the drug approval process. Despite the time and efforts exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical testing and clinical trials. The number and focus of preclinical studies and clinical trials that will be required for approval by the FDA and foreign regulatory agencies varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. In addition, the FDA may require that a proposed Risk Evaluation and Mitigation Strategy, also known as a REMS, be submitted as part of an NDA if the FDA determines that it is necessary to ensure that the benefits of the drug outweigh its risks. The FDA and foreign regulatory agencies can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

they might determine that a drug candidate is not safe or effective;

they might not find the data from preclinical testing and clinical trials sufficient and could request that additional trials be performed;

they might not approve our, our partner's or the contract manufacturer's processes or facilities; or

they might change their approval policies or adopt new regulations.

Even if we receive regulatory approval to manufacture and sell a drug in a particular regulatory jurisdiction, other jurisdictions' regulatory authorities may not approve that drug for manufacture and sale. If we or our partners fail to receive and maintain regulatory approval for the sale of any drugs resulting from our drug candidates, it would significantly harm our business and negatively affect our stock price.

***If we or our partners receive regulatory approval for our drug candidates, we or they will be subject to ongoing obligations to and continued regulatory review by the FDA and foreign regulatory agencies, and may be subject to***

***additional post-marketing obligations, all of which may result in significant expense and limit commercialization of our potential drugs.***

Any regulatory approvals that we or our partners receive for our drug candidates may be subject to limitations on the indicated uses for which the drug may be marketed or require potentially costly post-marketing follow-up studies or compliance with a REMS. In addition, if the FDA or foreign regulatory agencies approves any of our drug candidates, the labeling, packaging, adverse event

38 of 49

---



## **Table of Contents**

reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, or the discovery that adverse effects or toxicities observed in preclinical research or clinical trials that were believed to be minor actually constitute much more serious problems, may result in restrictions on the marketing of the drug or withdrawal of the drug from the market.

The FDA and foreign regulatory agencies may change their policies and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business would suffer.

***If physicians and patients do not accept our drugs, we may be unable to generate significant revenue, if any.***

Even if our drug candidates obtain regulatory approval, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare payors, patients and the medical community. Even if the clinical safety and efficacy of drugs developed from our drug candidates are established for purposes of approval, physicians may elect not to recommend these drugs for a variety of reasons including, but not limited to:

introduction of competitive drugs to the market;

clinical safety and efficacy of alternative drugs or treatments;

cost-effectiveness;

availability of coverage and reimbursement from health maintenance organizations and other third-party payors;

convenience and ease of administration;

prevalence and severity of adverse side effects;

other potential disadvantages relative to alternative treatment methods; or

insufficient marketing and distribution support.

If our drugs fail to achieve market acceptance, we may not be able to generate significant revenue and our business would suffer.

***The coverage and reimbursement status of newly approved drugs is uncertain and failure to obtain adequate coverage and reimbursement could limit our ability to market any drugs we may develop and decrease our ability to generate revenue.***

Even if one or more of our drug candidates is approved for sale, the commercial success of our drugs in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for our drugs by the medical profession for use by their patients, which is highly uncertain. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. As a result, they may not cover or provide adequate payment for our drugs. They may not view our drugs as cost-effective and reimbursement may not be available to consumers or may be insufficient to allow our drugs to be marketed on a competitive basis. If we are unable to obtain adequate coverage and reimbursement for our drugs, our ability to generate revenue will be adversely affected. Likewise, current and future legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs, such as the Patient Protection Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, could result in lower prices or rejection of coverage and reimbursement for our potential drugs. Changes in coverage and reimbursement policies or healthcare cost containment initiatives that limit or restrict reimbursement for any of our drug candidates that are approved could

cause our potential future revenues to decline.

***We may be subject to costly product liability or other liability claims and may not be able to obtain adequate insurance.***

The use of our drug candidates in clinical trials may result in adverse effects. We cannot predict all the possible harms or adverse effects that may result from our clinical trials. We currently maintain limited product liability insurance. We may not have sufficient

39 of 49

---

## **Table of Contents**

resources to pay for any liabilities resulting from a personal injury or other claim excluded from, or beyond the limit of, our insurance coverage. Our insurance does not cover third parties' negligence or malpractice, and our clinical investigators and sites may have inadequate insurance or none at all. In addition, in order to conduct clinical trials or otherwise carry out our business, we may have to contractually assume liabilities for which we may not be insured. If we are unable to look to our own or a third party's insurance to pay claims against us, we may have to pay any arising costs and damages ourselves, which may be substantial.

In addition, if we commercially launch drugs based on our drug candidates, we will face even greater exposure to product liability claims. This risk exists even with respect to those drugs that are approved for commercial sale by the FDA and foreign regulatory agencies and manufactured in licensed and regulated facilities. We intend to secure additional limited product liability insurance coverage for drugs that we commercialize, but may not be able to obtain such insurance on acceptable terms with adequate coverage, or at reasonable costs. Even if we are ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which would impair our ability to generate sales of the affected product and our other potential drugs. Moreover, product recalls may be issued at our discretion or at the direction of the FDA and foreign regulatory agencies, other governmental agencies or other companies having regulatory control for drug sales. Product recalls are generally expensive and often have an adverse effect on the reputation of the drugs being recalled and of the drug's developer or manufacturer.

We may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which could be costly and time-consuming and distract management. If third parties that have agreed to indemnify us against damages and other liabilities arising from their activities do not fulfill their obligations, then we may be held responsible for those damages and other liabilities.

***To the extent we elect to fund the development of a drug candidate or the commercialization of a drug at our expense, we will need substantial additional funding.***

The discovery, development and commercialization of new drugs is costly. As a result, to the extent we elect to fund the development of a drug candidate or the commercialization of a drug, we will need to raise additional capital to:

- expand our research and development capabilities;

- fund clinical trials and seek regulatory approvals;

- build or access manufacturing and commercialization capabilities;

- implement additional internal systems and infrastructure;

- maintain, defend and expand the scope of our intellectual property; and

- hire and support additional management and scientific personnel.

Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and costs of our clinical trials and other research and development activities;

- the costs and timing of seeking and obtaining regulatory approvals;

- the costs associated with establishing manufacturing and commercialization capabilities;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the costs of acquiring or investing in businesses, products and technologies;

the effect of competing technological and market developments; and

the status of, payment and other terms, and timing of any strategic alliance, licensing or other arrangements that we have entered into or may establish.

40 of 49

---

## **Table of Contents**

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to continue to finance our future cash needs primarily through strategic alliances, public or private equity offerings and debt financings. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or future commercialization initiatives.

***Responding to any claims relating to improper handling, storage or disposal of the hazardous chemicals and radioactive and biological materials we use in our business could be time-consuming and costly.***

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our or third parties' use of these materials. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production activities.

***Our facilities in California are located near an earthquake fault, and an earthquake or other types of natural disasters, catastrophic events or resource shortages could disrupt our operations and adversely affect our results.***

All of our facilities and our important documents and records, such as hard copies of our laboratory books and records for our drug candidates and compounds and our electronic business records, are located in our corporate headquarters at a single location in South San Francisco, California near active earthquake zones. If a natural disaster, such as an earthquake or flood, a catastrophic event such as a disease pandemic or terrorist attack, or a localized extended outage of critical utilities or transportation systems occurs, we could experience a significant business interruption. Our partners and other third parties on which we rely may also be subject to business interruptions from such events. In addition, California from time to time has experienced shortages of water, electric power and natural gas. Future shortages and conservation measures could disrupt our operations and cause expense, thus adversely affecting our business and financial results.

## **Risks Related To an Investment in Our Securities**

***We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or at or above your investment price.***

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks, which often does not relate to the operating performance of the companies represented by the stock. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- announcements concerning any of the clinical trials for our compounds, such as omecamtiv mecarbil for heart failure and CK-2017357 and CK-2066260 for the potential treatment of diseases associated with aging, muscle wasting and neuromuscular dysfunction (including, but not limited to, the timing of initiation or completion of such trials and the results of such trials, and delays or discontinuations of such trials, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical end-points);

- announcements concerning our strategic alliance with Amgen or future strategic alliances;

- failure or delays in entering additional drug candidates into clinical trials;

- failure or discontinuation of any of our research programs;

- issuance of new or changed securities analysts' reports or recommendations;

- failure or delay in establishing new strategic alliances, or the terms of those alliances;

market conditions in the pharmaceutical, biotechnology and other healthcare-related sectors;  
41 of 49

---

**Table of Contents**

actual or anticipated fluctuations in our quarterly financial and operating results;

developments or disputes concerning our intellectual property or other proprietary rights;

introduction of technological innovations or new products by us or our competitors;

issues in manufacturing our drug candidates or drugs;

market acceptance of our drugs;

third-party healthcare coverage and reimbursement policies;

FDA or other U.S. or foreign regulatory actions affecting us or our industry;

litigation or public concern about the safety of our drug candidates or drugs;

additions or departures of key personnel;

substantial sales of our common stock by our existing shareholders, whether or not related to our performance; and

volatility in the stock prices of other companies in our industry or in the stock market generally.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert our management's time and attention.

***If the ownership of our common stock continues to be highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.***

As of April 29, 2011, our executive officers, directors and their affiliates beneficially owned or controlled approximately 12.6% of the outstanding shares of our common stock (after giving effect to the exercise of all outstanding vested and unvested options and warrants). Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

***Volatility in the stock prices of other companies may contribute to volatility in our stock price.***

The stock market in general, and the NASDAQ Global Market ( NASDAQ ) and the market for technology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of early stage and development stage life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources, and could harm our reputation and business.

***Our common stock is thinly traded and there may not be an active, liquid trading market for our common stock.***

## Edgar Filing: CYTOKINETICS INC - Form 10-Q

There is no guarantee that an active trading market for our common stock will be maintained on NASDAQ, or that the volume of trading will be sufficient to allow for timely trades. Investors may not be able to sell their shares quickly or at the latest market price if trading in our stock is not active or if trading volume is limited. In addition, if trading volume in our common stock is limited, trades of relatively small numbers of shares may have a disproportionate effect on the market price of our common stock.

42 of 49

---



**Table of Contents*****Evolving regulation of corporate governance and public disclosure may result in additional expenses, use of resources and continuing uncertainty.***

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and new Securities and Exchange Commission ( SEC ) regulations and NASDAQ Stock Market LLC rules are creating uncertainty for public companies. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of these costs. For example, compliance with the internal control requirements of Section 404 of the Sarbanes-Oxley Act has to date required the commitment of significant resources to document and test the adequacy of our internal control over financial reporting. We can provide no assurance as to conclusions of management or by our independent registered public accounting firm with respect to the effectiveness of our internal control over financial reporting in the future. In addition, the SEC has adopted regulations that will require us to file corporate financial statement information in a new interactive data format known as XBRL beginning in 2011. We may incur significant costs and need to invest considerable resources to implement and to remain in compliance with these new requirements.

These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to maintain high standards of corporate governance and public disclosure. As a result, we intend to invest the resources necessary to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, due to ambiguities related to practice or otherwise, regulatory authorities may initiate legal proceedings against us, which could be costly and time-consuming, and our reputation and business may be harmed.

***We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.***

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. In addition, the terms of existing or any future debts may preclude us from paying these dividends.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. RESERVED****ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(2)	Specimen Common Stock Certificate.
4.2(3)	Warrant for the purchase of shares of common stock, dated October 28, 2005, issued by the Company to Kingsbridge Capital Limited.

- 4.3(4) Registration Rights Agreement, dated as of December 29, 2006, by and between the Company and Amgen Inc.

43 of 49

---

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
4.4(5)	Warrant for the purchase of shares of common stock, dated October 15, 2007, issued by the Company to Kingsbridge Capital Limited.
4.5(5)	Registration Rights Agreement, dated October 15, 2007, by and between the Company and Kingsbridge Capital Limited.
4.6(6)	Form of Certificate of Designation of Series A Convertible Preferred Stock of Cytokinetics, Inc.
10.67(6)	Securities Purchase Agreement, dated April 18, 2011, between Cytokinetics, Inc. and Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited.
10.68(6)	Form of Warrant to Purchase Common Stock of Cytokinetics, Inc.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
(1)	Incorporated by reference from our registration statement on Form S-1, registration number 333-112261, declared effective by the Securities and Exchange Commission on April 29, 2004.
(2)	Incorporated by reference from our Quarterly Report on Form 10-Q, filed with the Security and Exchange Commission on May 9, 2007.
(3)	Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 20, 2006.
(4)	Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 3, 2007.
(5)	Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 15, 2007.
(6)	Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 18, 2011.

**Table of Contents**

**SIGNATURES**

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

Dated: May 6, 2011

CYTOKINETICS, INCORPORATED  
(Registrant)

/s/ Robert I. Blum  
Robert I. Blum  
President and Chief Executive Officer  
(Principal Executive Officer)

/s/ Sharon A. Barbari  
Sharon A. Barbari  
Executive Vice President, Finance and  
Chief Financial Officer  
(Principal Financial Officer)

45 of 49

---

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(2)	Specimen Common Stock Certificate.
4.2(3)	Warrant for the purchase of shares of common stock, dated October 28, 2005, issued by the Company to Kingsbridge Capital Limited.
4.3(4)	Registration Rights Agreement, dated as of December 29, 2006, by and between the Company and Amgen Inc.
4.4(5)	Warrant for the purchase of shares of common stock, dated October 15, 2007, issued by the Company to Kingsbridge Capital Limited.
4.5(5)	Registration Rights Agreement, dated October 15, 2007, by and between the Company and Kingsbridge Capital Limited.
4.6(6)	Form of Certificate of Designation of Series A Convertible Preferred Stock of Cytokinetics, Inc.
10.67(6)	Securities Purchase Agreement, dated April 18, 2011, between Cytokinetics, Inc. and Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited.
10.68(6)	Form of Warrant to Purchase Common Stock of Cytokinetics, Inc.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
(1)	Incorporated by reference from our registration statement on Form S-1, registration number 333-112261, declared effective by the Securities and Exchange Commission on April 29, 2004.
(2)	Incorporated by reference from our Quarterly Report on Form 10-Q, filed with the Security and Exchange Commission on May 9, 2007.
(3)	Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 20, 2006.
(4)	Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 3, 2007.

Edgar Filing: CYTOKINETICS INC - Form 10-Q

- (5) Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 15, 2007.
- (6) Incorporated by reference from our Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 18, 2011.

46 of 49