

CYTOKINETICS INC  
Form 10-Q  
May 04, 2015  
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, 2015

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-50633

**CYTOKINETICS, INCORPORATED**

(Exact name of registrant as specified in its charter)

Edgar Filing: CYTOKINETICS INC - Form 10-Q

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

**280 East Grand Avenue**

**South San Francisco, California**  
(Address of principal executive offices)

**94-3291317**  
(I.R.S. Employer  
Identification No.)

**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

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  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Number of shares of common stock, \$0.001 par value, outstanding as of April 28, 2015: 38,717,139

**Table of Contents**

**CYTOKINETICS, INCORPORATED**

**TABLE OF CONTENTS FOR FORM 10-Q**

**FOR THE QUARTER ENDED MARCH 31, 2015**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014 (Unaudited)</u>	3
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014 (Unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014 (Unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
Item 4. <u>Controls and Procedures</u>	28
<b><u>PART II. OTHER INFORMATION</u></b>	<b>28</b>
Item 1. <u>Legal Proceedings</u>	28
Item 1A. <u>Risk Factors</u>	29
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	47
Item 3. <u>Defaults Upon Senior Securities</u>	47
Item 4. <u>Mine Safety Disclosures</u>	47
Item 5. <u>Other Information</u>	47
Item 6. <u>Exhibits</u>	47
<u>SIGNATURES</u>	48
<u>EXHIBIT INDEX</u>	49

**Table of Contents**

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

**CYTOKINETICS, INCORPORATED****CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share data)

	March 31, 2015 (Unaudited)	December 31, 2014 (Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 22,546	\$ 20,215
Short-term investments	85,322	63,013
Related party accounts receivable	970	46,646
Prepaid and other current assets	1,972	1,257
<b>Total current assets</b>	<b>110,810</b>	<b>131,131</b>
Property and equipment, net	1,551	1,637
Long-term investments	9,653	
Other assets	200	200
<b>Total assets</b>	<b>\$ 122,214</b>	<b>\$ 132,968</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,392	\$ 1,361
Accrued liabilities	3,981	5,400
Deferred revenue, current	19,942	17,042
Short-term portion of deferred rent	70	52
<b>Total current liabilities</b>	<b>25,385</b>	<b>23,855</b>
Deferred revenue, non-current	12,211	16,558
Long-term portion of deferred rent	466	491
<b>Total liabilities</b>	<b>38,062</b>	<b>40,904</b>
Commitments and contingencies (Note 9)		
Stockholders equity:		
Preferred stock, \$0.001 par value:		
Authorized: 10,000,000 shares;		
Issued and outstanding: Series A Convertible Preferred Stock zero shares at March 31, 2015 and December 31, 2014		
Common stock, \$0.001 par value:		
Authorized: 81,500,000 shares;		
Issued and outstanding: 38,716,905 shares at March 31, 2015 and 38,659,738 shares at December 31, 2014	39	39
Additional paid-in capital	590,234	589,272
Accumulated other comprehensive loss	(6)	(4)
Accumulated deficit	(506,115)	(497,243)

Edgar Filing: CYTOKINETICS INC - Form 10-Q

Total stockholders' equity	84,152	92,064
Total liabilities and stockholders' equity	\$ 122,214	\$ 132,968

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

Page 3

**Table of Contents****CYTOKINETICS, INCORPORATED****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(In thousands, except per share data)

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
<b>Revenues:</b>		
Research and development revenues from related parties	\$ 2,791	\$ 665
Research and development, grant and other revenues		5,232
License revenues from related parties	1,623	
License revenues		2,082
<b>Total revenues</b>	<b>4,414</b>	<b>7,979</b>
<b>Operating expenses:</b>		
Research and development	8,956	12,490
General and administrative	4,367	4,259
<b>Total operating expenses</b>	<b>13,323</b>	<b>16,749</b>
<b>Operating loss</b>	<b>(8,909)</b>	<b>(8,770)</b>
Interest and other, net	37	26
<b>Loss before income taxes</b>	<b>(8,872)</b>	<b>(8,744)</b>
Income tax benefit		
<b>Net loss</b>	<b>\$ (8,872)</b>	<b>\$ (8,744)</b>
<b>Net loss per share basic and diluted</b>	<b>\$ (0.23)</b>	<b>\$ (0.27)</b>
<b>Weighted-average number of shares used in computing net loss per share basic and diluted</b>	<b>38,675</b>	<b>32,985</b>
<b>Other comprehensive gain (loss):</b>		
Unrealized gains (losses) on available-for-sale securities, net	(1)	6
<b>Comprehensive loss</b>	<b>\$ (8,873)</b>	<b>\$ (8,738)</b>

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

**Table of Contents****CYTOKINETICS, INCORPORATED****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,872)	\$ (8,744)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	145	105
Stock-based compensation	896	694
Changes in operating assets and liabilities:		
Related party accounts receivable	45,676	(2,111)
Prepaid and other assets	(716)	(60)
Accounts payable	95	(2,113)
Accrued and other liabilities	(1,418)	(560)
Related party payables and accrued liabilities		
Deferred revenue	(1,447)	(5,033)
<b>Net cash provided by (used in) operating activities</b>	<b>34,359</b>	<b>(17,822)</b>
<b>Cash flows from investing activities:</b>		
Purchases of investments	(49,840)	(55,470)
Proceeds from sales and maturities of investments	17,877	26,943
Purchases of property and equipment	(130)	(333)
<b>Net cash used in investing activities</b>	<b>(32,093)</b>	<b>(28,860)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from public offerings of common stock, net of issuance costs		39,869
Proceeds(payments) from stock based award activities and warrants, net	65	(89)
<b>Net cash provided by financing activities</b>	<b>65</b>	<b>39,780</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>2,331</b>	<b>(6,902)</b>
Cash and cash equivalents, beginning of period	20,215	20,158
<b>Cash and cash equivalents, end of period</b>	<b>\$ 22,546</b>	<b>\$ 13,256</b>

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

---

**Table of Contents**

**CYTOKINETICS, INCORPORATED**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED 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's financial statements contemplate the conduct of the Company's operations in the normal course of business. The Company has incurred an accumulated deficit of \$506.1 million since inception and there can be no assurance that the Company will attain profitability. The Company had a net loss of \$8.9 million and net cash provided by operations of \$34.4 million for the three months ended March 31, 2015. Cash, cash equivalents and investments increased from \$83.2 million at December 31, 2014 to \$117.5 million at March 31, 2015, principally due to the receipt of \$45.0 million from Astellas in January 2015, partially offset by the use of cash to fund operations. The Company anticipates that it will continue to have operating losses and net cash outflows in future periods.

The Company is subject to risks common to clinical stage biopharmaceutical companies including, but not limited to, development of new drug candidates, dependence on key personnel, and the ability to obtain additional capital as needed to fund its future plans. The Company's liquidity will be impaired if sufficient additional capital is not available on terms acceptable to the Company. To date, the Company has funded its operations primarily through sales of its common stock and convertible preferred stock, 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, grants and debt financings. The Company has never generated revenues from commercial sales of its drugs and may not have drugs to market for at least several years, if ever. The Company's success is dependent on its ability to enter into new strategic collaborations and/or raise additional capital and to successfully develop and market one or more of its drug candidates. As a result, the Company may choose to raise additional capital through equity or debt financings to continue to fund its operations in the future. The Company cannot be certain that sufficient funds will be available from such a financing or through a collaborator when required or on satisfactory terms. Additionally, there can be no assurance that the Company's drug candidates will be accepted in the marketplace or that any future products can be developed or manufactured at an acceptable cost. These factors could have a material adverse effect on the Company's future financial results, financial position and cash flows.

Based on the current status of its research and development plans, the Company believes that its existing cash, cash equivalents and investments at March 31, 2015 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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***Basis of Presentation***

The consolidated financial statements include the accounts of Cytokinetics and its wholly owned subsidiary. The accompanying unaudited condensed consolidated 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. The financial statements include all adjustments (consisting only of normal recurring adjustments) that management believes are necessary for the fair statement of the Company's position at March 31, 2015, and the results of operations for the three months ended March 31, 2015 and the cash flows for the three months ended March 31, 2015. 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, 2014 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements. 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 conjunction with the audited financial statements and notes thereto contained in the Company's Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 6, 2015.





**Table of Contents****Comprehensive Loss**

Comprehensive loss for the three months ended March 31, 2015 was equal to net loss adjusted for unrealized gains and losses on investments.

**Recent Accounting Pronouncements**

In April 2015, the FASB issued ASU 2015-03, *Interest Imputation of Interest (Subtopic 835-30)*. ASU 2015-03 simplifies the presentation of debt issuance costs. ASU 2015-03 is effective for annual and interim periods beginning on or after December 15, 2015 and early adoption is permitted. The Company does not expect the adoption of ASU 2015-03 to have a material effect upon its financial statements.

In February 2015, the FASB issued ASU 2015-02, *Amendments to the Consolidation Analysis (Topic 810)*. ASU 2015-02 improves targeted areas of the consolidation guidance and reduces the number of consolidation models. ASU 2015-02 is effective for annual and interim periods beginning on or after December 15, 2015 and early adoption is permitted. The Company does not expect the adoption of ASU 2015-02 to have a material effect upon its financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*. ASU 2014-15 requires management to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. ASU 2014-15 is effective for annual and interim reporting periods beginning on or after December 15, 2016 and early adoption is permitted. The Company does not expect the adoption of ASU 2014-15 to have a material effect upon its financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes the revenue recognition requirements in Accounting Standards Codification 605, Revenue Recognition. ASU 2014-09 stipulates that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In April 2015, the FASB decided to defer the effective date of ASU 2014-09 by one year. ASU 2014-09 is effective for annual and interim reporting periods beginning on or after December 15, 2017, and early adoption is permitted, but not before the original public entity effective date of annual periods beginning after December 31, 2016. ASU 2014-09 permits the use of two transition methods, either retrospectively to each prior reporting period presented or as a cumulative-effect adjustment as of the date of adoption. The Company has not yet selected a transition method, and is currently evaluating the impact of the adoption of ASU 2014-09 on its consolidated financial statements.

**Note 2 Net Loss Per Share**

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

	<b>Three Months Ended</b>	
	<b>March 31, 2015</b>	<b>March 31, 2014</b>
Net loss	\$ (8,872)	\$ (8,744)
Weighted-average common shares outstanding (weighted average number of shares used in computing net loss per share) – basic and diluted	38,675	32,985
Net loss per share – basic and diluted	\$ (0.23)	\$ (0.27)



**Table of Contents**

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

	Three Months Ended	
	March 31, 2015	March 31, 2014
Options to purchase common stock	4,556	3,249
Warrants to purchase common stock	6,691	7,691
Restricted stock units	73	64
Shares issuable related to the ESPP	36	31
<b>Total shares</b>	<b>11,356</b>	<b>11,035</b>

**Note 3 Supplemental Cash Flow Data**

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

	Three Months Ended	
	March 31, 2015	March 31, 2014
Cash paid for income taxes	\$ 1	\$
Significant non-cash investing and financing activities:		
Purchases of property and equipment through accounts payable	63	(93)
Purchases of property and equipment through accrued liabilities	8	33

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

In December 2006, the Company entered into a collaboration and option agreement with Amgen to discover, develop and commercialize novel small molecule therapeutics, including omecamtiv mecarbil, that activate cardiac muscle contractility for potential applications in the treatment of heart failure (the Amgen Agreement). The agreement granted Amgen an option to obtain an exclusive license worldwide, except Japan, to develop and commercialize omecamtiv mecarbil and other drug candidates arising from the collaboration. In May 2009, Amgen exercised its option. As a result, Amgen became responsible for the development and commercialization of omecamtiv mecarbil and related compounds at its expense worldwide (excluding Japan), subject to the Company's development and commercialization participation rights. Amgen reimburses the Company for certain research and development activities it performs under the collaboration.

In June 2013, Cytokinetics and Amgen executed an amendment to the Amgen Agreement to include Japan, resulting in a worldwide collaboration (the Amgen Agreement Amendment). Under the terms of the Amgen Agreement Amendment, the Company received a non-refundable upfront license fee of \$15.0 million in June 2013. Under the Amgen Agreement Amendment, the Company conducted a Phase I pharmacokinetic study intended to support inclusion of Japan in a potential Phase III clinical development program and potential global registration dossier for omecamtiv mecarbil. Amgen reimbursed the Company for the costs of this study. In addition, the Company is eligible to receive additional pre-commercialization milestone payments relating to the development of omecamtiv mecarbil and royalties on sales of omecamtiv mecarbil in Japan.

In conjunction with the Amgen Agreement Amendment, the Company also entered into a common stock purchase agreement which provided for the sale of 1,404,100 shares of its common stock to Amgen at a price per share of \$7.12 and an aggregate purchase price of \$10.0 million, which was received in June 2013. The Company determined the fair value of the stock issued to Amgen to be \$7.5 million. The excess of cash received over fair value of \$2.5 million was initially deferred and allocated between the license and services based on their relative selling prices using best estimate of selling price. The allocated consideration was recognized as revenue as revenue criteria were satisfied, or as services were performed over approximately 12 months. Pursuant to this agreement, Amgen agreed to certain trading and other restrictions with respect to the Company's common stock.

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

The Company determined that the license to the Japan territory granted under the Amgen Agreement Amendment was a separate, non-contingent deliverable under the amendment. The Company determined that the license has stand-alone value based on Amgen's internal product development capabilities since all relevant manufacturing know-how related to omecamtiv mecarbil was previously delivered to Amgen.

Page 8

**Table of Contents**

In October 2013, the Company determined that the revenue recognition requirements under ASC 605-10 had been met and accordingly, recognized \$17.2 million in license revenue attributable to the Amgen Agreement Amendment in the fourth quarter of 2013. In year ended December 31, 2014, the Company recognized the remaining \$0.3 million of the previously deferred consideration attributable to the Amgen Agreement Amendment as research and development revenues from related parties.

In March 2015, Amgen and the Company agreed to extend the term of the research program through December 2015. Under the amended Amgen Agreement, the Company is entitled to receive reimbursements of internal costs of certain full-time employee equivalents during 2015, as well as potential additional milestone payments related to the research activities.

Under the Amgen Agreement, as amended, the Company is eligible to receive over \$350.0 million in development milestone payments which are based on various clinical milestones, including the initiation of certain clinical studies, the submission of a drug candidate to certain regulatory authorities for marketing approval and the receipt of such approvals. Additionally, the Company is eligible to receive up to \$300.0 million in commercial milestone payments provided certain sales targets are met. Due to the nature of drug development, including the inherent risk of development and approval of drug candidates by regulatory authorities, it is not possible to estimate if and when these milestone payments would become due. The achievement of each of these milestones is dependent solely upon the results of Amgen's development and commercialization activities and therefore none of these milestones was deemed to be substantive. During the three months ended March 31, 2015, no revenues were recognized for milestones achieved under the Amgen Agreement.

The Amgen Agreement also provides for the Company to receive increased royalties by co-funding Phase III development costs of omecantiv mecarbil and other drug candidates under the collaboration. If the Company elects to co-fund such costs, it would be entitled to co-promote the co-funded drug in North America and participate in agreed commercialization activities in institutional care settings, at Amgen's expense.

Pursuant to the Amgen Agreement, the Company has recognized research and development revenue from Amgen for reimbursements of internal costs of certain full-time employee equivalents, supporting a collaborative research program directed to the discovery of next-generation cardiac sarcomere activator compounds and of other costs related to that research program. These reimbursements are recorded as research and development revenues from related parties.

Revenue from Amgen was as follows (in thousands):

	Three Months Ended	
	March 31, 2015	March 31, 2014
Research and development revenues from related parties		
Reimbursement of internal costs	\$ 688	\$ 665
<b>Total revenues from Amgen</b>	<b>\$ 688</b>	<b>\$ 665</b>

Related party accounts receivable from Amgen were as follows (in thousands):

	March 31, 2015	December 31, 2014
Related party accounts receivable - Amgen	\$ 948	\$ 1,642

**Astellas Pharma Inc. ( Astellas )***Original Astellas Agreement (Non-neuromuscular license)*

In June 2013, the Company entered into a license and collaboration agreement with Astellas (the Original Astellas Agreement). The primary objective of the collaboration with Astellas is to advance novel therapies for diseases and medical conditions associated with muscle weakness.

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

Under the Original Astellas Agreement, the Company granted Astellas an exclusive license to co-develop and jointly commercialize CK-2127107, a fast skeletal troponin activator, for potential application in non-neuromuscular indications worldwide. The Company was primarily responsible for the conduct of Phase I clinical trials and certain Phase II readiness activities for CK-2127107 and Astellas was primarily responsible for the conduct of subsequent development and commercialization activities for CK-2127107.

In July 2013, the Company received an upfront, non-refundable license fee of \$16.0 million in connection with the execution of the Original Astellas Agreement. Under the agreement, the Company was eligible to potentially receive approximately \$25.4 million in reimbursement of sponsored research and development activities during the initial two years of the collaboration. The agreement

---

**Table of Contents**

also provided for research and early and late stage development milestone payments based on various research and clinical milestones, including the initiation of certain clinical studies, the submission for approval of a drug candidate to certain regulatory authorities for marketing approval and the commercial launch of collaboration products, and royalties on sales of commercialized products.

At the inception of the Original Astellas Agreement, the Company deferred revenue related to the Original Astellas Agreement in accordance with ASC 605-25. The Company evaluated whether the delivered elements under the arrangement have value on a stand-alone basis. Upfront, non-refundable licensing payments are assessed to determine whether or not the licensee is able to obtain stand-alone value from the license. Where this is not the case, the Company does not consider the license deliverable to be a separate unit of accounting, and the revenue for the license fee is deferred and recognized in conjunction with the other deliverables that constitute the combined unit of accounting.

The Company determined that the license and the research and development services are a single unit of accounting as the license was determined to not have stand-alone value. Accordingly, the Company is recognizing this revenue using the proportional performance model over the initial research term of the Original Astellas Agreement. During the three months ended March 31, 2015, the Company recorded \$1.2 million in license revenue based on the proportional performance model. As of March 31, 2015, the Company has recognized \$14.9 million of the \$16.0 million upfront license fee as license revenue, and has \$1.1 million of deferred license revenue under the Original Astellas Agreement.

Pursuant to the Original Astellas Agreement, the Company has recognized research and development revenue from Astellas for reimbursements of internal costs of certain full-time employee equivalents, supporting collaborative research and development programs, and of other costs related to those programs. During the three months ended March 31, 2015, the Company recorded research and development revenue from Astellas of \$0.8 million related to the reimbursement of internal costs and \$1.1 million related to the reimbursement of other costs.

*Amended Astellas Agreement (Expansion to include neuromuscular indications)*

On December 22, 2014, the Company entered into an amended and restated license and collaboration agreement with Astellas (the Amended Astellas Agreement). This agreement superseded the Original Astellas Agreement. The Amended Astellas Agreement expanded the objective of the collaboration of advancing novel therapies for diseases and medical conditions associated with muscle weakness to include spinal muscular atrophy (SMA) and potentially other neuromuscular indications, in addition to the non-neuromuscular indications provided for in the Original Astellas Agreement. Under the terms of the Amended Astellas Agreement, we received a non-refundable upfront license fee of \$30.0 million in January 2015. Concurrently, the Company received \$15.0 million as a milestone payment relating to Astellas' decision to advance CK-2127107 into Phase II clinical development. The Company is also eligible to potentially receive over \$20.0 million in reimbursement of sponsored research and development activities through December 2016. Under the Amended Astellas Agreement, the Company plans to conduct the initial Phase II clinical trial of CK-2127107 in patients with SMA. In addition, the Company is entitled to receive additional pre-commercialization milestone payments related to the development of CK-2127107 in neuromuscular indications, and royalties on sales of CK-2127107 in neuromuscular indications.

The Company determined that the license and the research and development services relating to the Amended Astellas Agreement are a single unit of accounting as the license was determined to not have stand-alone value. Accordingly, the Company is recognizing this revenue over the initial research term of the Amended Astellas Agreement using the proportional performance model. As of March 31, 2015, the Company has recognized \$0.4 million of the \$30.0 million upfront license fee as license revenue and deferred the remaining amount.

The Company believes that each of the milestones related to research and early development under the Amended Astellas Agreement is substantive and can only be achieved with the Company's past and current performance and each milestone will result in additional payments to the Company. During the three months ended March 31, 2015, no milestone revenue for early development was recognized under this agreement. The Company is eligible to receive up to \$2.0 million in research milestone payments for each future collaboration product candidate.

The achievement of each of the late stage development milestones and the commercialization milestones are dependent solely upon the results of Astellas' development activities and therefore these milestones were not deemed to be substantive.

Under the Amended Astellas Agreement, additional research and early and late state development milestone payments which are based on various research and clinical milestones, including the initiation of certain clinical studies, the submission for approval of a drug candidate to certain regulatory authorities for marketing approval and the commercial launch of collaboration products could total over \$600.0 million, including up to \$95.0 million relating to CK-2127107 in non-neuromuscular indications, and over \$100.0 million related to CK-2127107 in each of SMA and other neuromuscular indications. Additionally, \$200.0 million in commercial milestones could be received under the Amended Astellas Agreement provided certain sales targets are met. Due to the nature of drug development, including the inherent risk of development and approval of drug candidates by regulatory authorities, it is not possible to estimate if and when these milestone payments could become due.





**Table of Contents**

In the event Astellas commercializes any collaboration products, the Company will receive royalties on sales of such collaboration products, including royalties ranging from the high single digits to the high teens on sales of products containing CK-2127107. Cytokinetics also holds an option to co-fund certain development costs for CK-2127107 and other compounds in exchange for increased milestone payments and royalties; such royalties may increase under certain scenarios to exceed twenty percent. Under the Amended Astellas Agreement, Cytokinetics retains an option to co-promote collaboration products containing fast skeletal muscle activators for neuromuscular indications in the U.S., Canada and Europe, in addition to its option to co-promote other collaboration products in the U.S. and Canada as provided for in the Original Astellas Agreement. Astellas will reimburse Cytokinetics for certain expenses associated with its co-promotion activities. The Amended Astellas Agreement also provides for Cytokinetics to lead certain activities relating to the commercialization of collaboration products for neuromuscular indications in the U.S., Canada and Europe under particular scenarios.

In conjunction with the Amended Astellas Agreement, the Company also entered into a common stock purchase agreement which provided for the sale of 2,040,816 shares of its common stock to Astellas at a price per share of \$4.90 and an aggregate purchase price of \$10.0 million which was received in December 2014. Pursuant to this agreement, Astellas agreed to certain trading and other restrictions with respect to the Company's common stock. The Company determined the fair value of the stock issued to Astellas to be \$9.1 million. The excess of cash received over fair value of \$0.9 million was deferred along with the license and research and development services. Allocated consideration will be recognized as revenue for the single unit of accounting above, as services are performed following the proportional performance model over the initial research term of the Amended Astellas Agreement.

Following the common stock purchase, Astellas was determined to be a related party. As such, all revenue earned following the common stock purchase will be classified as related party revenue.

Research and development revenue from Astellas was as follows (in thousands):

	<b>Three Months Ended March 31, 2015</b>	<b>Three Months Ended March 31, 2014</b>
Research and development revenues with related parties:		
Reimbursement of internal costs	\$ 909	\$
Reimbursement of other costs	1,194	
Research and development revenues:		
Reimbursement of internal costs		1,720
Reimbursement of other costs		1,467
Research and development milestone fees		2,000
Total research and development revenue from Astellas	\$ 2,103	\$ 5,187

Related party accounts receivable from Astellas were as follows (in thousands):

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Related party accounts receivable - Astellas	\$ 4	\$ 45,000

At March 31, 2015, the Company had \$32.2 million of deferred revenue under the Amended Astellas Agreement, reflecting the unrecognized portion of the license revenue and prepayment on expenses expected to be incurred in the second quarter of 2015.

**Table of Contents****Note 5 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, 2015 and December 31, 2014 were as follows (in thousands):

		March 31, 2015				
		Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Maturity Dates
Cash equivalents	money market funds	\$ 20,436	\$	\$	\$ 20,436	
Short-term investments	U.S. Treasury securities	\$ 85,322	\$ 1	\$ (1)	\$ 85,322	4/2015-12/2015
Long-term investments	U.S. Treasury securities	\$ 9,659	\$	\$ (6)	\$ 9,653	4/2016-6/2016

		December 31, 2014				
		Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Maturity Dates
Cash equivalents	money market funds	\$ 16,932	\$	\$	\$ 16,932	
Short-term investments	U.S. Treasury securities	\$ 63,017	\$ 3	\$ (7)	\$ 63,013	1/2015-12/2015
Long-term investments	U.S. Treasury securities	\$	\$	\$	\$	

At March 31, 2015 there were no investments that had been in a continuous unrealized loss position for 12 months or longer. The Company collected the contractual cash flows on its U.S. Treasury securities that matured from April 1, 2015 through April 28, 2015 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):

	Three Months Ended	
	March 31, 2015	March 31, 2014
Interest income	\$ 37	\$ 26

**Note 6 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.

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

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.

**Table of Contents**

Financial assets measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014 are classified in the table below in one of the three categories described above (in thousands):

	March 31, 2015			Assets At Fair Value
	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	
Money market funds	\$ 20,436	\$	\$	\$ 20,436
U.S. Treasury securities	94,975			94,975
<b>Total</b>	<b>\$ 115,411</b>	<b>\$</b>	<b>\$</b>	<b>\$ 115,411</b>
Amounts included in:				
Cash and cash equivalents	\$ 20,436	\$	\$	\$ 20,436
Short-term investments	85,322			85,322
Long-term investments	9,653			9,653
<b>Total</b>	<b>\$ 115,411</b>	<b>\$</b>	<b>\$</b>	<b>\$ 115,411</b>

	December 31, 2014			Assets At Fair Value
	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	
Money market funds	\$ 16,932	\$	\$	\$ 16,932
U.S. Treasury securities	63,013			63,013
<b>Total</b>	<b>\$ 79,945</b>	<b>\$</b>	<b>\$</b>	<b>\$ 79,945</b>
Amounts included in:				
Cash and cash equivalents	\$ 16,932	\$	\$	\$ 16,932
Short-term investments	63,013			63,013
Long-term investments				
<b>Total</b>	<b>\$ 79,945</b>	<b>\$</b>	<b>\$</b>	<b>\$ 79,945</b>

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. As of March 31, 2015 and December 31, 2014, the Company had no financial assets measured at fair value on a recurring basis using significant Level 2 or Level 3 inputs. The carrying amount of the Company's accounts receivable and accounts payable approximates fair value due to the short-term nature of these instruments.

**Note 7 Stockholders' Equity (Deficit)***Accumulated Other Comprehensive Income*

In the first three months of 2015, the Company did not reclassify any unrealized gains on investments from accumulated other comprehensive income into net loss.

*Warrants*

As of March 31, 2015, the Company had warrants outstanding to purchase 6.7 million shares of the Company's common stock. These warrants were issued pursuant to an April 2011 securities purchase agreement (the "Deerfield 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"); and pursuant to the June 2012 underwriting agreements the Company entered into in connection with two

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

separate, concurrent offerings for our securities (the June 2012 Public Offerings ). During the three months ended March 31, 2015, no warrants were exercised.

Page 13

**Table of Contents**

Outstanding warrants as of March 31, 2015 were as follows:

	Number of Shares	Exercise Price	Expiration Date
Issued pursuant to the Deerfield Agreement	1,114,168	\$ 9.90	04/20/15
Issued pursuant to the June 2012 Public Offerings	5,576,928	\$ 5.28	06/25/17

The 1,114,168 warrants issued pursuant to the Deerfield Agreement expired unexercised on April 20, 2015.

*Equity Incentive Plans*

Stock option activity for the three months ended March 31, 2015 under the Company's 2004 Equity Incentive Plan, as amended, and the Company's 1997 Stock Option/Stock Issuance Plan was as follows:

	Shares Available for Grant of Options or Awards	Stock Options Outstanding	Weighted Average Exercise Price per Share of Stock Options
Balance at December 31, 2014	1,270,478	3,297,826	\$ 12.62
Options granted	(879,530)	879,530	7.93
Options exercised		(33,442)	6.24
Options forfeited	58,800	(58,800)	7.75
Options expired	32,402	(32,402)	46.56
Restricted stock units granted	(54,000)		
Balance at March 31, 2015	428,150	4,052,712	\$ 11.45

Restricted stock unit activity for the three months ended March 31, 2015 was as follows:

	Number of Shares	Weighted Average Award Date Fair Value per Share
Restricted stock units outstanding at December 31, 2014	63,330	\$ 8.51
Restricted stock units granted	54,000	7.96
Restricted stock units released	(42,078)	7.82
Restricted stock units forfeited	(2,000)	7.96
Unvested restricted stock units outstanding at March 31, 2015	73,252	\$ 8.51

Restricted stock activities were limited to non-executive employees for the three months ended March 31, 2015.

Total employee stock-based compensation expenses were \$0.9 million and \$0.7 million for the three months ended March 31, 2015 and 2014, respectively.

**Note 8 Interest and Other, Net**

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

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

### **Note 9 Commitments and Contingencies**

#### *Commitments*

The Company leases office space and equipment under a non-cancelable operating lease that expires in 2018, with an option to extend the lease for an additional three-year period. The lease terms provide for rental payments on a graduated scale and the Company's payment of certain operating expenses. The Company recognizes rent expense on a straight-line basis over the lease period. Rent expense for the three months ended March 31, 2015 and 2014 was \$0.8 million, respectively.

#### *Contingencies*

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters, including, but not limited to, losses arising out of the Company's breach of such agreements, services to be provided by or on behalf of the Company, or from intellectual property infringement claims



## **Table of Contents**

made by third parties. In addition, the Company has entered into indemnification agreements with its directors and certain of its officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. The Company maintains director and officer insurance, which may cover certain liabilities arising from its obligation to indemnify its directors and certain of its officers and employees, and former officers and directors in certain circumstances. The Company maintains product liability insurance and comprehensive general liability insurance, which may cover certain liabilities arising from its indemnification obligations. It is not possible to determine the maximum potential amount of exposure under these indemnification obligations due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular indemnification obligation. Such indemnification obligations may not be subject to maximum loss clauses. Management is not currently aware of any matters that could have a material adverse effect on the financial position, results of operations or cash flows of the Company.

In December 2014, the Company filed a lawsuit alleging fraudulent inducement, breach of contract and negligence on the part of a data management vendor for a clinical trial. The Company is seeking monetary damages. As this is a contingency that may result in a gain, no provision has been made in the financial statements.

### **Note 10 Income Taxes**

During the three months ended March 31, 2015 the Company did not record a provision for income taxes because it expected to generate a net operating loss for the year ending December 31, 2015.

The Company 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 significant jurisdictions in which the Company files income tax returns are the United States 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. The IRS's Large Business and International Division concluded its audit of the 2009 tax year with no material adjustments. However, in general, the statute of limitations for tax liabilities for these years remains open for the purpose of adjusting the amounts of the losses and credits carried forward from those years. The Company believes that it maintains adequate reserves for uncertain tax positions.

In general, under section 382 of the Internal Revenue Code ( *Section 382* ), a corporation that undergoes an *ownership change* is subject to limitations on its ability to utilize its pre-change net operating losses ( *NOLs* ) and tax credits to offset future taxable income. The Company has performed a *Section 382* analysis and does not believe that it has experienced an ownership change since 2006. A portion of the Company's existing *NOLs* and tax credits are subject to limitations arising from previous ownership changes. Future changes in the Company's stock ownership, some of which are outside of our control, could result in an ownership change under *Section 382* and result in additional limitations.

**Table of Contents**

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 indicating expectations about future performance and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. 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 2015;

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, conduct, enrollment, progress, timing and scope of clinical trials and development activities for our drug candidates conducted by ourselves or our partners, Amgen Inc. and Astellas Pharma Inc. (Astellas), including the anticipated timing for initiation of clinical trials, anticipated rates of enrollment for clinical trials and anticipated timing of results becoming available or being announced from clinical trials;

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

the potential further development of tirasemtiv for the potential treatment of amyotrophic lateral sclerosis (ALS);

the expected acceptability by regulatory authorities of the effects of tirasemtiv on Slow Vital Capacity or other measures of clinical benefit related to respiratory function in patients with ALS as a Phase III clinical trial endpoint to support the registration of tirasemtiv as a treatment for ALS;

our and our partners' 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 with Amgen and Astellas;

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 or Astellas;

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;

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

the utility of our focus on the biology of muscle function, 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;

potential competitors and competitive products;

retaining key personnel and recruiting additional key personnel;

expected timing for recognition of compensation cost related to unvested stock options; and

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

**Table of Contents**

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

further clinical development of tirasemtiv for the potential treatment of ALS will require significant additional funding and we may be unable to obtain such additional funding on acceptable terms, if at all;

the U.S. Food and Drug Administration ( FDA ) and/or other regulatory authorities may not accept Slow Vital Capacity or other measures of clinical benefit related to respiratory function as an appropriate clinical trial endpoint to support the registration of tirasemtiv for the treatment of ALS;

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

Astellas' decisions with respect to the timing, design and conduct of research and development activities for CK-2127107 and other skeletal muscle activators, including decisions to postpone or discontinue research or development activities relating to CK-2127107 and other skeletal muscle activators;

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

our ability to obtain additional financing on acceptable terms, if at all;

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

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

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

difficulties or delays in the manufacture and supply of clinical trial materials;

failure by our contract research organizations, contract manufacturing organizations and other vendors to properly fulfill their obligations or otherwise perform as expected;

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

the possibility that the U.S. Food and Drug Administration ( 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;

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

difficulties or delays in achieving market access and reimbursement for our drug candidates and the potential impacts of health care reform;

changes in laws and regulations applicable to drug development, commercialization or reimbursement;

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

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

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

accrual information provided by our contract research organizations and other vendors;

potential ownership changes under Internal Revenue Code Section 382; and

the timeliness and accuracy of information filed with the U.S. Securities and Exchange Commission (the "SEC") by third parties. In addition such statements are subject to the risks and uncertainties discussed in the "Risk Factors" section and elsewhere in this document. Such statements speak only as of the date on which they are made, and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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.

## **Table of Contents**

### **Overview**

We were incorporated in Delaware in August 1997 as Cytokinetics, Incorporated. 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 most advanced research and development programs relate to the biology of muscle function and are directed to small molecule modulators of the contractility of skeletal or cardiac muscle. Our earlier-stage research is directed to other compounds with the potential to modulate muscle contractility and other muscle functions, such as growth, energetics and metabolism.

Our drug candidates currently in clinical development are our skeletal muscle activators tirasemtiv and CK-2127107, and our cardiac muscle activator omecamtiv mecarbil. Cytokinetics retains exclusive rights to tirasemtiv, which is being evaluated for the potential treatment of ALS. CK-2127107 is being evaluated for the potential treatment of spinal muscle atrophy ( SMA ) and for potential use in other indications associated with muscle weakness under a strategic alliance with Astellas established in June 2013 and expanded in December 2014. Omecamtiv mecarbil is being evaluated for the potential treatment of heart failure under a strategic alliance with Amgen established in 2006.

### **Muscle Contractility Programs**

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

Tirasemtiv is the lead drug candidate from this program. We retain exclusive rights to tirasemtiv. We have conducted a Phase II clinical development program for tirasemtiv, and are planning to initiate a Phase III clinical development program for this drug candidate in patients with ALS. We are also developing another drug candidate from this program, CK-2127107, which has been evaluated in Phase I clinical trials in collaboration with Astellas for potential indications associated with muscle weakness. We are planning to conduct a Phase II clinical trial for CK-2127107 in patients with SMA. Tirasemtiv and CK-2127107 are structurally distinct and selective small molecules that activate the fast skeletal muscle troponin complex in the sarcomere by increasing its sensitivity to calcium, leading to an increase in skeletal muscle contractility. Each of tirasemtiv and CK-2127107 has demonstrated pharmacological activity in preclinical models and evidence of potentially clinically relevant pharmacodynamic effects in humans. We are evaluating other potential indications for which tirasemtiv and CK-2127107 may be useful.

#### **Tirasemtiv.**

Tirasemtiv, a fast skeletal troponin activator, is the lead drug candidate from our skeletal muscle contractility program. We have conducted three evidence of effect Phase IIa clinical trials of tirasemtiv. These evidence of effect clinical trials were randomized, double-blind, placebo-controlled, three-period cross-over studies of single doses of tirasemtiv administered to patients with impaired muscle function. These studies were intended to translate the mechanism of action of tirasemtiv into potentially clinically relevant pharmacodynamic effects. The first of these trials was conducted in patients with ALS, a chronic and progressive disease in which the motor neurons die, thus denervating skeletal muscles and causing them to atrophy. This leads to weakness, fatigue, and eventually complete paralysis and death, primarily from respiratory complications. The second of these trials was conducted in patients with myasthenia gravis, a chronic, autoimmune, neuromuscular disease which is the most common primary disorder of neuromuscular transmission. The third of these trials was conducted in patients with symptoms of claudication, which is pain or cramping in the leg muscles due to inadequate blood flow during exercise, associated with peripheral artery disease. Evidence of potentially clinically relevant pharmacodynamic effects was observed in each of these trials.

In 2014, we completed BENEFIT-ALS (Blinded Evaluation of Neuromuscular Effects and Functional Improvement with Tirasemtiv in ALS), a Phase IIb clinical trial of tirasemtiv in patients with ALS. We have previously reported the results from BENEFIT-ALS. We have concluded that in this trial effects observed on slow vital capacity (SVC), a measure of the strength of the skeletal muscles responsible for breathing, in patients treated with tirasemtiv were robust and potentially clinically meaningful. We have engaged with regulatory authorities in the U.S. and Europe regarding the results from BENEFIT-ALS and plan to advance tirasemtiv into Phase III clinical development. While regulatory interactions are ongoing, we believe that current feedback from these regulatory authorities informs advancement of tirasemtiv to a Phase III clinical development program that is intended to potentially confirm and extend results from BENEFIT-ALS. Key clinical endpoints in the Phase III program will include measures of respiratory function after longer durations of treatment in patients with ALS, including effects on SVC. We have initiated non-clinical and clinical development activities to prepare for this Phase III program and anticipate initiating the program in the second quarter of 2015.

During the quarter, a manuscript titled *A Double-Blinded, Randomized, Placebo-Controlled Trial to Evaluate Efficacy, Safety, and Tolerability of Single Doses of Tirasemtiv in Patients with Acetylcholine Receptor-Binding Antibody-Positive Myasthenia Gravis* was published in the

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

journal Neurotherapeutics. This publication summarized results from a Phase IIa clinical trial which evaluated two doses of tirasemtiv in patients with generalized myasthenia gravis (MG). The authors concluded that tirasemtiv may improve muscle function in patients with MG and that the results support further development of tirasemtiv in neuromuscular diseases.

Page 18

## Table of Contents

The clinical trials program for tirasemtiv 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. Tirasemtiv is at too early a stage of development for us to predict if or when this may occur. Our expenditures will increase if and as we move tirasemtiv into later stage development.

### CK-2127107 and Other Skeletal Muscle Activators

*Astellas Strategic Alliance.* CK-2127107 is being developed jointly by Cytokinetics and Astellas. In December 2014, we entered into an Amended and Restated License and Collaboration Agreement with Astellas (the Amended Astellas Agreement). This agreement superseded the License and Collaboration Agreement between Cytokinetics and Astellas of June 2013 (the Original Astellas Agreement). The Amended Astellas Agreement expanded the objective of the collaboration of advancing novel therapies for diseases and medical conditions associated with muscle weakness to include SMA and potentially other neuromuscular indications, in addition to the non-neuromuscular indications provided for in the Original Astellas Agreement.

Under the Amended Astellas Agreement, we expanded the exclusive license previously granted Astellas under the Original Astellas Agreement to co-develop and commercialize CK-2127107 for potential application in non-neuromuscular indications worldwide to include certain neuromuscular indications as well. Concurrent with the expanded collaboration, the companies agreed to advance CK-2127107 into Phase II clinical development. Cytokinetics will conduct the initial Phase II clinical trial in patients with SMA. We anticipate initiating this trial in the second half of 2015. The development program may include other neuromuscular indications as the companies may agree. Cytokinetics and Astellas will jointly develop and may jointly commercialize CK-2127107 and other fast skeletal troponin activators in neuromuscular indications. Astellas will be responsible for the costs associated with the development of all collaboration products, including CK-2127107, subject to Cytokinetics' option to co-fund certain development costs as described below.

Under the Amended Astellas Agreement, the parties extended through 2016 their joint research program to identify next-generation skeletal muscle activators to be nominated as potential drug candidates. This research will be conducted at Astellas' expense. Under the Amended Astellas Agreement, Astellas has exclusive rights to co-develop and commercialize CK-2127107 and other fast skeletal troponin activators in SMA and potentially other indications and other novel mechanism skeletal muscle activators in all indications, subject to certain Cytokinetics development and commercialization rights. Cytokinetics may co-promote and conduct certain commercial activities in the U.S., Canada and Europe under agreed scenarios.

Cytokinetics retains an option to conduct early-stage development for certain agreed indications at its initial expense, subject to reimbursement if development continues under the collaboration. Under the Amended Astellas Agreement, Cytokinetics also retains an option to co-promote collaboration products containing fast skeletal muscle activators for neuromuscular indications in the U.S., Canada and Europe, in addition to its option to co-promote other collaboration products in the U.S. and Canada as provided for in the Original Astellas Agreement. Astellas will reimburse Cytokinetics for certain expenses associated with its co-promotion activities. The Amended Astellas Agreement also provides for Cytokinetics to lead certain activities relating to the commercialization of collaboration products for neuromuscular indications in the U.S., Canada and Europe under particular scenarios.

Cytokinetics received an upfront payment of \$30.0 million in connection with the execution of the Amended Astellas Agreement. Also, in conjunction with the execution of the Amended Astellas Agreement, we also entered into a common stock purchase agreement which provided for the sale of 2,040,816 shares of our common stock to Astellas at a price per share of \$4.90 and an aggregate purchase price of \$10.0 million, which was received in December 2014. Pursuant to this agreement, Astellas agreed to certain trading and other restrictions with respect to our common stock. Concurrently, Cytokinetics earned a \$15.0 million milestone payment relating to Astellas' decision to advance CK-2127107 into Phase II clinical development. Cytokinetics is also eligible to potentially receive over \$20.0 million in reimbursement of sponsored research and development activities through December 2016. Based on the achievement of pre-specified criteria, Cytokinetics may receive over \$600.0 million in milestone payments relating to the development and commercial launch of collaboration products, including up to \$112.0 million (of which Cytokinetics has now received \$17.0 million) relating to early development of CK-2127107 and for later-stage development and commercial launch milestones for CK-2127107 in non-neuromuscular indications, and over \$100.0 million in development and commercial launch milestones for CK-2127107 in each of SMA and other neuromuscular indications. Cytokinetics may also receive up to \$200.0 million in payments for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Amended Astellas Agreement. If Astellas commercializes any collaboration products, Cytokinetics will also receive royalties on sales of such collaboration products, including royalties ranging from the high single digits to the high teens on sales of products containing CK-2127107. Cytokinetics also holds an option to co-fund certain development costs for CK-2127107 and other compounds in exchange for increased milestone payments and royalties; such royalties may increase under certain scenarios to exceed twenty percent. In addition to the foregoing development, commercial and sales milestones, Cytokinetics may also receive payments for the achievement of pre-specified milestones relating to the joint research program.





---

## **Table of Contents**

Cytokinetics retains the exclusive right to develop and commercialize tirasemtiv for the potential treatment of ALS and certain other neuromuscular disorders independently from the Amended Astellas Agreement.

During the three months ended March 31, 2015, we recorded \$1.6 million of license revenue and \$2.1 million in reimbursement of sponsored research and development activities in connection with our strategic alliance with Astellas. See our unaudited condensed consolidated financial statements for a further discussion of our revenue recognition policy under our agreement with Astellas.

The clinical trials programs for CK-2127107 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. CK-2127107 is at too early a stage of development for us to predict if or when this may occur. Our expenditures will increase if Astellas terminates development of CK-2127107 or related compounds and we elect to develop them independently, or if we conduct early-stage development for certain agreed indications at our initial expense, subject to reimbursement if development continues under the collaboration.

### **Ongoing Research in Skeletal Muscle Activators.**

Our research on the direct activation of skeletal muscle continues in two areas. We are conducting translational research in preclinical models of disease and muscle function with fast skeletal muscle troponin activators to explore the potential clinical applications of this novel mechanism in diseases or conditions associated with skeletal muscle dysfunction. We also intend to conduct preclinical research on other chemically and pharmacologically distinct mechanisms to activate the skeletal sarcomere. We are conducting a joint research program with Astellas directed to the discovery of next-generation skeletal muscle activators. Under the Amended Astellas Agreement, the joint research program will continue through 2016 and Astellas will reimburse us for certain research activities we perform.

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

Our lead drug candidate from this program is omecamtiv mecarbil, a novel cardiac muscle myosin activator. 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.

**Amgen Strategic Alliance.** In December 2006, we entered into a collaboration and option agreement with Amgen to discover, develop and commercialize novel small molecule therapeutics, including omecamtiv mecarbil, that activate cardiac muscle contractility for potential applications in the treatment of heart failure (the Amgen Agreement). The agreement granted Amgen an option to obtain an exclusive license worldwide, except Japan, to develop and commercialize omecamtiv mecarbil and other drug candidates arising from the collaboration. In May 2009, Amgen exercised its option. As a result, Amgen became responsible for the development and commercialization of omecamtiv mecarbil and related compounds at its expense worldwide (excluding Japan), subject to our development and commercialization participation rights. Amgen will reimburse us for certain research and development activities we perform under the collaboration.

In June 2013, Cytokinetics and Amgen executed an amendment to the Amgen Agreement to include Japan, resulting in a worldwide collaboration (the Amgen Agreement Amendment). Under the terms of the Amgen Agreement Amendment, we received a non-refundable upfront license fee of \$15.0 million in June 2013. Under the Amgen Agreement Amendment, we conducted a Phase I pharmacokinetic study intended to support inclusion of Japan in a potential Phase III clinical development program and potential global registration dossier for omecamtiv mecarbil. Amgen reimbursed us for the costs of this study. In addition, we are eligible to receive additional pre-commercialization milestone payments relating to the development of omecamtiv mecarbil in Japan of up to \$50.0 million, and royalties on sales of omecamtiv mecarbil in Japan. In conjunction with the Amgen Agreement Amendment, we also entered into a common stock purchase agreement which provided for the sale of 1,404,100 shares of our common stock to Amgen at a price per share of \$7.12 and an aggregate purchase price of \$10.0 million which was received in June 2013. Pursuant to this agreement, Amgen agreed to certain trading and other restrictions with respect to our common stock.

In March 2015, Amgen and the Company agreed to extend the term of the research program through December 2015. Under the amended Amgen Agreement, we are entitled to receive reimbursements of internal costs of certain full-time employee equivalents during 2015, as well as potential additional milestone payments related to the research activities.

Under the Amgen Agreement as amended, we are eligible for potential pre-commercialization and commercialization milestone payments of up to \$650.0 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 Amgen Agreement also provides for us to receive increased royalties by co-funding Phase III development costs of omecamtiv mecarbil and other drug candidates under the collaboration. If we elect to co-fund such costs, we would be entitled to co-promote the co-funded drug in North America and

participate in agreed commercialization activities in institutional care settings, at Amgen's expense.

---

## **Table of Contents**

In July 2013, Amgen announced that it had granted an option to commercialize omecamtiv mecarbil in Europe to Servier, with Cytokinetics consent. The option and, if the option is exercised, the resulting commercialization sublicense to Servier, is subject to the terms and conditions of the Amgen Agreement. Amgen remains responsible for the performance of its obligations under the Amgen Agreement relating to Europe, including the payment of milestones and royalties relating to the development and commercialization of omecamtiv mecarbil in Europe.

During the three months ended March 31, 2015 and 2014, we recorded \$0.7 million, respectively in reimbursement of sponsored research and development activities in connection with our strategic alliance with Amgen. See our unaudited condensed consolidated financial statements for a further discussion of our revenue recognition policy under our agreement with Amgen.

### **Omecamtiv Mecarbil: Current Clinical Development**

In March 2013, we announced the initiation of dosing of patients in COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure). COSMIC-HF is a Phase II, double-blind, randomized, placebo-controlled, multicenter, clinical trial designed to assess the pharmacokinetics and tolerability of *omecamtiv mecarbil* dosed orally in patients with heart failure and left ventricular systolic dysfunction as well as its effects on echocardiographic measures of cardiac function. COSMIC-HF is being conducted by Amgen in collaboration with Cytokinetics. Cytokinetics and Amgen reviewed results from the dose escalation phase of COSMIC-HF and selected an oral formulation of omecamtiv mecarbil for evaluation in the expansion phase of the trial.

The expansion phase of COSMIC-HF has concluded enrollment. Approximately 450 patients from approximately 93 clinical sites internationally have been enrolled; over 275 of these patients have concluded dosing. Patients are randomized 1:1:1 to receive placebo, 25 mg, or 50 mg twice daily of omecamtiv mecarbil. Escalation to the 50 mg dose will depend on the plasma concentration of omecamtiv mecarbil following 2 weeks of oral dosing at 25 mg twice daily. The primary objective of the expansion phase of this trial is to characterize the safety, tolerability, and pharmacokinetics of omecamtiv mecarbil dosed orally during 20 weeks of treatment. The secondary objectives are to assess the changes from baseline in systolic ejection time, stroke volume, left ventricular end-systolic diameter, left ventricular end-diastolic diameter, heart rate and N-terminal pro-brain natriuretic peptide (a biomarker associated with the severity of heart failure) during 20 weeks of treatment. We anticipate that results from COSMIC-HF will be available in the second half of 2015.

During the three months ended March 31, 2015, Cytokinetics collaborated with Amgen on clinical and non-clinical development, regulatory planning and other activities directed to the potential advancement of omecamtiv mecarbil to a Phase III program.

**Ongoing Research in Cardiac Muscle Contractility.** We have agreed with Amgen on additional research activities intended to be conducted through 2015 under the research plan directed to next-generation compounds in our cardiac muscle contractility program. Under the Amgen Agreement, Amgen will reimburse us for certain activities we perform. We are also eligible to receive research-related milestones.

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 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.

### **Beyond Muscle Contractility**

We have developed preclinical expertise in the mechanics of skeletal, cardiac and smooth muscle that extends from proteins to tissues to intact animal models. Our translational research in muscle contractility has enabled us to better understand the potential impact of small molecule compounds that increase skeletal or cardiac muscle contractility and to apply those findings to the further evaluation of our drug candidates in clinical populations. In addition to contractility, the other major functions of muscle include metabolism, growth and energetics, with each of these functions playing a role in certain diseases that could benefit from novel mechanism treatments. Accordingly, our knowledge of muscle contractility may serve as an entry point to the discovery of novel treatments for disorders involving muscle functions other than muscle contractility. We are leveraging our current understandings of muscle biology to investigate new ways of modulating these other aspects of muscle function for other potential therapeutic applications. For example, we are conducting research with compounds that affect muscle growth and that may have applications for serious diseases and medical conditions such as cachexia. Cachexia is a condition that can be associated with cancer, heart failure, chronic obstructive pulmonary disease or other conditions. This syndrome is characterized by the loss of muscle mass and may lead to weakness and disability. We are performing research on compounds that may increase muscle mass and which may impact patient

functionality or potentially alter the course of diseases associated with muscle wasting.

## Table of Contents

### **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:

the results of clinical trials of our drug candidates conducted by us or our partners may not support the further clinical development of those drug candidates;

further clinical development of tirasemtiv for the potential treatment of ALS will require significant additional funding and we may be unable to obtain such additional funding on acceptable terms, if at all;

the FDA and/or other regulatory authorities may not accept effects of tirasemtiv on SVC or other measures of clinical benefit related to respiratory function, as an appropriate clinical trial endpoint to support the registration of tirasemtiv for the treatment of ALS;

decisions made by Amgen with respect to the development of omecantiv mecarbil and by Astellas with respect to the development of CK-2127107;

the uncertainty of the timing of the initiation and completion of patient enrollment and treatment in our or our partners' 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;

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;

failure by our clinical trial sites, clinical research organizations, clinical manufacturing organizations and other third parties supporting our or our partners' clinical trials to fulfill their obligations or otherwise perform as expected;

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

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;

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

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

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 as planned, or at all, and certain consequences of failing to do so are discussed further in the risk factors entitled "We will need substantial additional capital in the future to sufficiently fund our operations," "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.

**Table of Contents****Results of Operations****Revenues**

We recorded total revenues of \$4.4 million and \$8.0 million for the first quarter of 2015 and 2014, respectively.

Total revenues were as follows (in thousands):

	<b>Three Months Ended</b>		
	<b>March 31, 2015</b>	<b>March 31, 2014</b>	<b>Increase (Decrease)</b>
Research and development revenues from related parties	\$ 2,791	\$ 665	\$ 2,126
Research and development, grant and other revenues		5,232	(5,232)
License revenues from related parties	1,623		1,623
License revenues		2,082	(2,082)
<b>Total revenues</b>	<b>\$ 4,414</b>	<b>\$ 7,979</b>	<b>\$ (3,565)</b>

Research and development revenues from related parties refers to research and development revenues from our strategic alliances with Astellas and Amgen. Revenues from Astellas, which became a related party in December 2014, were \$2.1 million in the first quarter of 2015 and consisted of reimbursements of internal costs of certain full-time employee equivalents, and other research and development expenses. All research and development revenues from Astellas, prior to it becoming a related party are classified in research and development, grant and other revenues. Research and development revenue from Astellas decreased by \$3.1 million when compared to the first quarter of 2014 primarily due to the \$2.0 million milestone payment related to research activities recognized in the first quarter of 2014. Revenues from Amgen were \$0.7 million for the first quarter of 2015 and 2014, respectively and consisted of reimbursements of internal costs of certain full-time employee equivalents, and recognition of allocated consideration related to the execution of the Amgen Agreement Amendment in June 2013.

Research and development, grant and other revenues in the first quarter of 2014 included Revenues from Astellas, prior to becoming a related party, including reimbursement of internal costs of certain full-time employee equivalents from Astellas of \$1.7 million, reimbursement of third party costs from Astellas of \$1.5 million and milestone revenues from Astellas of \$2.0 million.

License revenues from related parties refers to license revenues from our strategic alliance with Astellas. License revenues from Astellas, which became a related party in December 2014, were \$1.6 million in the first quarter of 2015 and consisted of recognition of a portion of the \$16.0 million upfront license fee received from Astellas in July 2013, using the proportional performance model and recognition of a portion of the \$30.0 million upfront license fee received from Astellas in January 2015, also using the proportional performance model.

License revenues refers to license revenues from our collaboration with Astellas prior to it becoming a related party in December 2014. License revenues were \$2.1 million in the first quarter of 2014 and consisted of recognition of a portion of the \$16.0 million upfront license fee received from Astellas in July 2013, using the proportional performance model. The research activities with Astellas are anticipated to continue through December 2016 under the current agreement as amended.

We anticipate that revenue for the full year 2015 will be in the range of \$23 million to \$27 million.

**Research and Development Expenses**

Research and development expenses were \$9.0 million and \$12.5 million in the first quarter of 2015 and 2014, respectively.

Total research and development expenses were as follows (in thousands):

**Three Months Ended**



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

	<b>March 31, 2015</b>	<b>March 31, 2014</b>	<b>Increase (Decrease)</b>
Research and development expenses	\$ 8,956	\$ 12,490	\$ (3,534)

The decrease of \$3.5 million in research and development expenses in 2015, compared to the same period in 2014, was primarily due to decreased spending of \$3.9 million for outsourced clinical and preclinical costs mainly due to the completion of the BENEFIT-ALS clinical trial in 2014, partially offset by increased spending of \$0.2 million personnel-related costs due to increased headcount.

**Table of Contents**

From a program perspective, the \$3.5 million decrease in research and development spending in the first quarter of 2015, compared to the same period in 2014, was primarily due to reduced spending in 2015 for our skeletal muscle contractility program, tirasemtiv, for the treatment of ALS and our collaboration agreement with Astellas.

The following presents our research and development expenses by program:

	Three Months Ended		Increase (Decrease)
	March 31, 2015	March 31, 2014 (In millions)	
Cardiac muscle contractility	\$ 1.4	\$ 1.3	\$ 0.1
Skeletal muscle contractility	6.4	10.3	(3.9)
All other research programs	1.2	0.9	0.3
Total research and development expenses	\$ 9.0	\$ 12.5	\$ (3.5)

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 2015 compared to 2014 and that they will be in the range of \$56.0 million to \$59.0 million. We expect to continue development of our drug candidate tirasemtiv for the potential treatment of ALS. As part of our strategic alliance with Astellas, we expect to continue development of our drug candidate CK-2127107 for the potential treatment of SMA and potentially other diseases and medical conditions associated with muscle weakness or wasting. 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. Non-cash expenses such as stock-based compensation and depreciation of approximately \$1.5 million are included in our estimate of 2015 research and development expenses.

**General and Administrative Expenses**

General and administrative expenses were \$4.4 million and \$4.3 million in the first quarter of 2015 and 2014, respectively.

Total general and administrative expenses were as follows (in thousands):

	Three Months Ended		Increase (Decrease)
	March 31, 2015	March 31, 2014	
General and Administrative expenses	\$ 4,367	\$ 4,259	\$ 108

The increase in the first quarter of 2015, compared to the same period in 2014, was primarily due to increased spending of \$0.3 million for personnel-related costs due to increased headcount, partially offset by decreased spending of \$0.3 million for outside services mainly related to commercial development and market access assessment activities.

We anticipate that general and administrative expenses in 2015 will increase compared to 2014 and will be in the range of \$18 million to \$20 million. Non-cash expenses such as stock-based compensation and depreciation of approximately \$2.1 million are included in our estimate of 2015 general and administrative expenses.

**Interest and Other, Net**

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

Interest income and other income increased in the first quarter of 2015 compared to the same period in 2014, due to higher interest rates and higher average invested balances in the current year period.

### **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, 2014. There has been no material change to our critical accounting policies since then.

---

## **Table of Contents**

### **Recent Accounting Pronouncements**

See Note 1, *Recent Accounting Pronouncements* in the Notes to Unaudited Condensed Consolidated 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, 2015, we funded our operations through the sale of equity securities, equipment financings, non-equity payments from collaborators, grants and interest income.

#### *Original Astellas Agreement*

In June 2013, we entered into the Original Astellas Agreement (see Note 4, *Related Party Research and Development Arrangements* in the Notes to Unaudited Condensed Consolidated Financial Statements). In July 2013, we received an upfront non-refundable license payment of \$16.0 million in connection with the execution of the Original Astellas Agreement. Pursuant to that agreement we were eligible to potentially receive approximately \$25.4 million in reimbursement of sponsored research and development activities during the initial two years of the collaboration. In addition, the agreement also provided for payments for the achievement of pre-specified milestones relating to the joint research and development program. In 2014, we recognized revenue of \$17.0 million relating to milestones under the Original Astellas Agreement, including a \$15.0 million milestone payment which was paid in January 2015.

#### *Amended Astellas Agreement*

In December 2014, we entered into the Amended Astellas Agreement, which superseded the Original Astellas Agreement (see Note 4, *Related Party Research and Development Arrangements* in the Notes to Unaudited Condensed Consolidated Financial Statements). Under the terms of the Amended Astellas Agreement, we received a non-refundable upfront license fee of \$30.0 million in January 2015. In conjunction with the Amended Astellas Agreement, we also entered into a common stock purchase agreement pursuant to which we sold 2,040,816 shares common stock to Astellas at a price per share of \$4.90. The aggregate purchase price of \$10.0 million was received in December 2014.

Under the Amended Astellas Agreement, we are eligible to potentially receive over \$20.0 million in reimbursement of sponsored research and development activities through December 2016. In addition, we may also receive payments for the achievement of pre-specified milestones relating to the Amended Astellas Agreement.

Based on the achievement of pre-specified criteria, Cytokinetics may receive over \$600.0 million in milestone payments relating to the development and commercial launch of collaboration products, including up to \$112.0 million (of which Cytokinetics has now received \$17.0 million) relating to early development of CK-2127107 and for later-stage development and commercial launch milestones for CK-2127107 in non-neuromuscular indications, and over \$100.0 million in development and commercial launch milestones for CK-2127107 in each of SMA and other neuromuscular indications. Cytokinetics may also receive up to \$200.0 million in payments for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Amended Astellas Agreement. If Astellas commercializes any collaboration products, Cytokinetics will also receive royalties on sales of such collaboration products, including royalties ranging from the high single digits to the high teens on sales of products containing CK-2127107.

#### *February 2014 Public Offering*

On February 25, 2014, we closed an underwritten public offering for the issuance and sale of 5,031,250 shares of our common stock. The gross proceeds from this public offering were \$40.3 million and net proceeds were \$37.5 million, after deducting the underwriting discount and offering expenses.

#### *Amgen Agreement Amendment*

In June 2013, we entered into the Amgen Agreement Amendment, which expanded our strategic alliance to include Japan (see Note 4, *Related Party Research and Development Arrangements* in the Notes to Unaudited Condensed Consolidated Financial Statements). Under the terms of the Amgen Agreement Amendment, we received a non-refundable upfront license fee of \$15 million in June 2013. In conjunction with the Amgen Agreement Amendment, we also entered into a common stock purchase agreement pursuant to which we sold 1,404,100 shares common stock to Amgen at a price per share of \$7.12. The aggregate purchase price of \$10.0 million was received in June 2013.



**Table of Contents**

In March 2015, Amgen and the Company agreed to extend the term of the research program through December 2015. Under the amended Amgen Agreement, we are entitled to receive reimbursements of internal costs for certain full-time employee equivalents during 2015, as well as potential additional milestone payments related to the research activities.

Under the Amgen Agreement as amended, we are eligible for potential pre-commercialization and commercialization milestone payments of up to \$650.0 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.

*MLV*

On June 10, 2011, we entered into an At-The-Market Issuance Sales Agreement (the *MLV Agreement*) with McNicoll, Lewis & Vlak LLC (*MLV*), pursuant to which we issued and sold, through January 2014, 2,397,278 shares for total net proceeds of approximately \$15.2 million. Sales of our common stock through *MLV* in 2014 were 364,103 shares for net proceeds of approximately \$2.4 million. No shares remain available to us for sale through the *MLV Agreement*.

*Sources and Uses of Cash*

Our cash, cash equivalents and investments totaled \$117.5 million at March 31, 2015, compared to \$83.2 million at December 31, 2014. The increase of \$34.3 million was primarily due to the receipt of \$45.0 million from Astellas in January 2015, partially offset by the use of cash to fund operations. Cash received from Astellas in January 2015 was in payment of a non-refundable upfront license fee of \$30.0 million and a milestone payment of \$15.0 million.

Net cash provided by operating activities was \$34.4 million in the three months ended March 31, 2015 and was largely due to the receipt of \$45.0 million from Astellas in January 2015, partially offset by cash used by operations. The net loss for the three months ended March 31, 2015 included non-cash stock based compensation of \$0.9 million. At March 31, 2015, deferred revenue of \$32.2 million related largely to the deferral of revenue for Astellas based on the proportional performance model. Net cash used in operating activities was \$17.8 million in the first three months of 2014 and was largely due to ongoing research and development activities.

Net cash used in investing activities was \$32.1 million in the first three months of 2015 was primarily due to purchases of investments, exceeding proceeds from the maturity of investments, by \$32.0 million. Net cash used in investing activities was \$28.9 million in the first three months of 2014 and primarily consisted cash used to purchase investments, net of proceeds from the maturity of investments, of \$28.5 million.

Net cash provided by financing activities was \$0.1 million in the first three months of 2015 and consisted of net proceeds from issuances of restricted stock to employees and proceeds from employee stock option exercises. Net cash provided by financing activities was \$39.8 million in the first three months of 2014 and primarily consisted of the net proceeds of \$37.5 million from the February 2014 public offering and \$2.4 million from sales of our common stock through the *MLV Agreement*. As of January 8, 2014, no shares remain available to the Company for sale through *MLV*.

*Shelf Registration Statements.* In November 2013 we filed a shelf registration statement with the SEC, which was declared effective in December 2013 (the *December 2013 Shelf*). The *December 2013 Shelf* allowed us to issue common stock and preferred stock, and/or warrants to purchase any of such securities with a total value of up to \$150.0 million. As of April 28, 2015, \$109.7 million remains available to us under the *December 2013 Shelf*. The specific terms of offerings, if any, under the *December 2013 Shelf* will be established at the time of such offerings.

As of March 31, 2015, future minimum payments under our lease obligations were as follows (in thousands):

	<b>Remainder of 2015</b>	<b>2016 and 2017</b>	<b>2018 and 2019</b>	<b>2020 and beyond</b>	<b>Total</b>
Operating leases (1)	\$ 2,549	\$ 7,130	\$ 1,860	\$	\$ 11,539

(1)

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

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 development of our fast skeletal muscle troponin activator tirasemtiv for the potential treatment of ALS. We plan to continue development of our fast skeletal muscle troponin activator CK-2127107 for the potential treatment of SMA and potentially other diseases and conditions related to skeletal muscle weakness or wasting and research of potential next-generation compounds as part of our strategic alliance with Astellas. We plan to continue to support the development of our cardiac muscle myosin activator omecamtiv mecarbil for the potential treatment of heart failure and the research of potential next-generation compounds as part of our strategic alliance with Amgen. We expect to incur significant research and development expenses as we advance the research and development of compounds from our other muscle biology programs through research to candidate selection.

**Table of Contents**

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 other compounds;

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;

Astellas' decisions with regard to funding of development and commercialization of CK-2127107 or other skeletal muscle activators 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 engage third party manufacturers for our drug candidates and potential drugs;

our plans or ability to build or access sales and marketing 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 have incurred an accumulated deficit of \$506.1 million since inception and there can be no assurance that we will attain profitability. We are subject to risks common to clinical-stage companies including, but not limited to, development of new drug candidates, dependence on key personnel, and the ability to obtain additional capital as needed to fund our future plans. Our liquidity will be impaired if sufficient additional capital is not available on terms acceptable to us, if at all. To date, we have funded our operations primarily through sales of our common stock and convertible preferred stock, contract payments under our collaboration agreements, debt financing arrangements, grants and interest income. Until we achieve profitable operations, we intend to continue to fund operations through payments from strategic collaborations, additional sales of equity securities, grants and debt financings. We have never generated revenues from commercial sales of our drugs and may not have drugs to market for at least several years, if ever. Our success is dependent on our ability to obtain additional capital by entering into new strategic collaborations and/or through equity or debt financings, and ultimately on our and our collaborators' ability to successfully develop and market one or more of our drug candidates. We cannot be certain that sufficient funds will be available from such collaborators or financings when needed or on satisfactory terms. Additionally, there can be no assurance that any of drugs based on our drug candidates will be accepted in the marketplace or that any future products can be developed or manufactured at an acceptable cost. These factors could have a material adverse effect on our future financial results, financial position and cash flows.

Based on the current status of our development plans, 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 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.

---

## **Table of Contents**

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

We are not party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **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, 2014.

### **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**

On December 1, 2014, we filed a lawsuit in the U.S. District Court for the Northern District of California, captioned Cytokinetics, Inc. v. Pharm-Olam International, Ltd., Case No. 3:14-cv-05256 (the California Lawsuit). This lawsuit alleges fraudulent inducement, breach of contract and negligence by Pharm-Olam International, Ltd. (Pharm-Olam) in connection with its performance as the data management vendor for the BENEFIT-ALS clinical trial. Under the agreement between Pharm-Olam and us, Pharm-Olam was obligated to provide a variety of services, including building and maintaining the electronic system for BENEFIT-ALS that combined the electronic data capture (EDC) for clinical data and the interactive web response system (IWRS) used for patient randomization and treatment assignments to either tirasemtiv or placebo. Pharm-Olam's failure to conduct these services in accordance with the agreement, regulatory requirements and industry standards resulted in programming errors in the IWRS which caused delay of the trial and additional expenses. We are seeking monetary damages from Pharm-Olam. On January 23, 2015, Pharm-Olam filed a motion to dismiss the complaint, or in the alternative, to transfer the California Lawsuit to U.S. District Court for the Middle District of North Carolina. The motion to dismiss was denied in part and granted in part and the motion to transfer was denied on March 10, 2015. Pharm-Olam answered the complaint on March 24, 2015.

On November 28, 2014, Pharm-Olam filed a lawsuit in the U.S. District Court for the Middle District of North Carolina, captioned Pharm-Olam International, Ltd. v. Cytokinetics, Inc. and Datatrak International, Inc., Civil Action No. 1:14-cv-01000 (the North Carolina Lawsuit). In this

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

lawsuit, Pharm-Olam is seeking declaratory judgments that (1) the limitation of liability provisions in the agreement between Pharm-Olam and us are enforceable and limit Pharm-Olam's liability for the claims asserted by us to the direct services fees, and (2) Pharm-Olam's subcontractor, Datatrak International, Inc. ( Datatrak ), the provider of the core EDC and IWRS system for BENEFIT-ALS, must indemnify, defend and hold harmless Pharm-Olam for the claims asserted against it by Cytokinetics, pursuant to the indemnification provision in the agreement between Pharm-Olam and Datatrak. On December 17, 2014, we filed a motion to dismiss or transfer the North Carolina Lawsuit to the U.S. District Court for the Northern District of California based on lack of jurisdiction and improper venue.

Page 28

---

**Table of Contents**

**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. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also adversely affect our business.*

**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.*

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, Astellas 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. For example, we will require significant additional funding to enable us to conduct further development of tirasemtiv for the potential treatment of ALS, including any additional Phase III clinical trials that may be required by regulatory authorities to receive marketing approval for tirasemtiv. 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 reimbursements, milestone and royalty payments that we may receive under our collaboration agreements with Amgen and Astellas. We may not receive any further funds under those agreements. Our ability to raise funds may be adversely impacted by current economic conditions. 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 and our share price may decline. 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 cannot raise the funds we need to operate our business, we will need to delay or discontinue certain research and development activities. For example, if we cannot raise the funds necessary to enable the conduct of further development for tirasemtiv for the potential treatment of ALS, our ability to continue the development of tirasemtiv will be delayed or suspended. If we delay or discontinue research and development activities, our stock price may be negatively affected.

*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.*

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

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

Page 29

## **Table of Contents**

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 in clinical development are omecamtiv mecarbil for the potential treatment of heart failure, tirasemtiv for the potential treatment of ALS, and CK-2127107 for the potential treatment of SMA and potentially other neuromuscular and non-neuromuscular indications associated with muscle weakness. 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, that they will ultimately be accepted by prescribers or reimbursed by insurers 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 satisfaction of FDA and foreign regulatory authorities that the drug candidate is sufficiently safe and effective with substantial evidence from well-controlled clinical trials. We or our partners will need to demonstrate efficacy in clinical trials for the treatment of specific indications and monitor safety throughout the clinical development process and following approval. None of our drug candidates have yet met the safety and efficacy standards required for regulatory approval for commercialization and they may never do so. In addition, for each of our preclinical compounds, we or our partners must adequately demonstrate satisfactory chemistry, formulation, stability and toxicity in order to submit an investigational new drug application ( 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.

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 later and larger 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, and results from early Phase II clinical trials may not be indicative of the results from later clinical trials. For example, early Phase II clinical trials of tirasemtiv in patients with ALS showed encouraging dose-related trends in measurements of the ALS Functional Rating Scale in its revised form (ALSFRS-R), a clinically validated instrument designed to measure disease progression and changes in functional status, for patients receiving tirasemtiv compared to those receiving placebo. However, BENEFIT-ALS, a Phase IIb clinical trial of tirasemtiv in patients with ALS, did not achieve its primary efficacy endpoint, the mean change from baseline in the ALSFRS-R for patients receiving tirasemtiv compared to those receiving placebo.

In addition, while the clinical trials of our drug candidates are designed based on the available relevant information, such information may not accurately predict what actually occurs during the course of the trial itself, which may have consequences for the conduct of an ongoing clinical trial or for the eventual results of that trial. For example, the number of patients planned to be enrolled in a placebo-controlled clinical trial is determined in part by estimates relating to expected treatment effect and variability about the primary endpoint. These estimates are based upon earlier nonclinical and clinical studies of the drug candidate itself and clinical trials of other drugs thought to have similar effects in a similar patient population. If information gained during the conduct of the trial shows these estimates to be inaccurate, we may elect to adjust the enrollment accordingly, which may cause delays in completing the trial, additional expense or a statistical penalty to apply to the evaluation of the trial results.

Furthermore, in view of the uncertainties inherent in drug development, such clinical trials may not be designed with focus on indications, patient populations, dosing regimens, endpoints, safety, efficacy or pharmacokinetic parameters or other variables that will provide the necessary safety or efficacy data to support regulatory approval to commercialize the resulting drugs. For example, we believe that effects measures of clinical benefit related to respiratory function, including slow vital capacity (SVC), may be appropriate as a clinical endpoint for tirasemtiv;

however, regulatory authorities may not accept these effects as a clinical endpoint to

**Table of Contents**

support registration of tirasemtiv for the treatment of ALS. Clinical trials of our drug candidates are designed based on guidance or advice from regulatory agencies, which is subject to change during the development of the drug candidate at any time. Such a change in a regulatory agency's guidance or advice may cause that agency to deem results from trials to be insufficient to support approval of the drug candidate and require further clinical trials of that drug candidate to be conducted. 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, efficacy or pharmacokinetic parameters may not yield the same statistical precision in estimating our drug candidates' effects as may other 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. Non-clinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, 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 events. Toxicities and adverse events 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 events 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, our partners or the FDA or foreign regulatory authorities to modify, suspend or terminate clinical trials with respect to any drug candidate at any time during the development program. Further, the administration of two or more drugs contemporaneously can lead to interactions between them, and our drug candidates may interact with other drugs that trial subjects are taking. For example, co-administration of tirasemtiv and riluzole (an approved treatment for ALS) approximately doubles the average maximum riluzole plasma level. If the adverse events 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 events when used in large populations may cause the FDA or foreign regulatory authorities to impose restrictions on, or stop, the further marketing of those drugs. Indications of potential adverse events or toxicities which do not seem significant during the course of clinical trials may later turn out to actually constitute serious adverse events or toxicities when a drug is used in large populations or for extended periods of time.

We have observed certain adverse events in the clinical trials conducted with our drug candidates. For example, in BENEFIT-ALS, adverse events of dizziness, fatigue, nausea, confusional state, muscle spasms, somnolence (sleepiness), decreased appetite, headache, insomnia, dyspnea (difficulty breathing) and dysarthria (difficulty speaking) occurred more frequently during treatment with tirasemtiv than with placebo. In addition, weight loss was significantly greater in patients with gastrointestinal adverse events (e.g., nausea and decreased appetite), which occurred more frequently on tirasemtiv than on placebo. In clinical trials of omecamtiv mecarbil, adverse events 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 were observed during treatment with omecamtiv mecarbil.

In addition, clinical trials of tirasemtiv and omecamtiv mecarbil 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.

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.

***The failure of a number of Phase III clinical trials evaluating other compounds as potential treatments for patients with ALS may suggest an increased risk that our planned Phase III clinical development program of tirasemtiv in patients with ALS will also fail.***

The FDA has not approved any drug for the treatment of ALS since its approval of riluzole in 1995. In recent years, a number of Phase III clinical trials of potential treatments for ALS have failed to demonstrate the requisite efficacy for approval or for their continued development. These include Biogen Idec's trial of dexamipexole, known as EMPOWER, the National Institute of Neurological Disorders and Stroke's trial of ceftriaxone, and Trophos SA's trial of olesoxime. Tirasemtiv, like these compounds, may fail in Phase III clinical development if it does not show a statistically significant level of clinical efficacy or if the adverse event profile is too great compared to its benefits. Further, even if we believe the data collected from our planned Phase III clinical development program of tirasemtiv are promising and should support approval, the FDA or other regulatory authorities may not deem these data to be sufficient to support approval.





**Table of Contents**

*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 our drug candidates may take significantly longer to complete. The commencement and completion of our or our partners' 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 or our partners' 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;

unforeseen safety issues;

inadequate supply, or delays in the manufacture or 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;

failure by our clinical research organizations, clinical manufacturing organizations and other third parties supporting our or our partners' clinical trials to fulfill their obligations;

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.

***We depend on Amgen for the conduct and funding of the development and commercialization of omecamtiv mecarbil.***

Under our strategic alliance, Amgen holds an exclusive license to our drug candidate omecamtiv mecarbil worldwide. As a result, Amgen is responsible for the development and obtaining and maintaining regulatory approval of omecamtiv mecarbil for the potential treatment of heart failure worldwide.

We do not control the 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

**Table of Contents**

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

If the results of one or more clinical trials with omecamtiv mecarbil do not meet Amgen's expectations at any time, Amgen may elect to terminate further development of omecamtiv mecarbil or certain of the potential clinical trials for omecamtiv mecarbil, even if the actual number of patients treated at that time is relatively small. In addition, Amgen generally has discretion to elect whether to pursue or abandon the development of omecamtiv mecarbil and may terminate our strategic alliance for any reason upon six months prior notice. If Amgen abandons omecamtiv mecarbil, it would result in a delay in or could prevent us from commercializing omecamtiv 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 omecamtiv 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 omecamtiv 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 omecamtiv mecarbil. If Amgen abandons development of omecamtiv 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 development or commercialization, curtail or abandon that development or commercialization, or undertake and fund the development of omecamtiv 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 omecamtiv mecarbil ourselves, we would have to curtail or abandon that development or commercialization, which could harm our business.

***We depend on Astellas for the conduct and funding of the development and commercialization of CK-2127107.***

In December 2014, we expanded our strategic alliance with Astellas focused on the research, development and commercialization of skeletal muscle activators, other than tirasemtiv and certain related compounds. The primary objective of the strategic alliance is to advance novel therapies for indications associated with muscle weakness.

Under this strategic alliance, we have granted Astellas an exclusive license to co-develop and commercialize CK-2127107 for potential application in spinal muscular atrophy (SMA) and potentially other indications worldwide. We expect to conduct the early stage development of CK-2127107 including a Phase II clinical trial of patients with SMA. Unless otherwise agreed by the parties, Astellas will be primarily responsible for the conduct of subsequent development and commercialization activities for CK-2127107.

We do not control the development activities that may be conducted by Astellas, 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 Astellas' results. Astellas may conduct these activities more slowly or in a different manner than we would. In general, Astellas is responsible for filing future applications with the FDA or other regulatory authorities for approval of CK-2127107 and will be the owner of any marketing approvals issued by the FDA or other regulatory authorities for CK-2127107. If the FDA or other regulatory authorities approve CK-2127107, Astellas will also be responsible for the marketing and sale of the resulting drug, subject to our right to co-promote the drug in the United States, Canada and, for neuromuscular indications, Europe. However, we cannot control whether Astellas will devote sufficient attention and resources to the development of CK-2127107 or will proceed in an expeditious manner. Even if the FDA or other regulatory agencies approve CK-2127107, Astellas may elect not to proceed with the commercialization of the resulting drug in one or more countries.

If the results of one or more clinical trials with CK-2127107 do not meet Astellas' expectations at any time, Astellas may elect to terminate further development of CK-2127107 or certain of the potential clinical trials for CK-2127107, even if the actual number of patients treated at that time is relatively small. In addition, Astellas generally has discretion to elect whether to pursue or abandon the development of CK-2127107. Astellas may terminate our strategic alliance in whole or in part for any reason upon six months prior notice at any time following expiration of the strategic alliance's research term, which will expire December 31, 2016. If Astellas abandons CK-2127107, it would result in a delay in or could prevent us from further developing or commercializing CK-2127107, and would delay and could prevent us from obtaining revenues for this drug candidate. Disputes may arise between us and Astellas, which may delay or cause the termination of any CK-2127107 clinical trials, result in significant litigation or cause Astellas to act in a manner that is not in our best interest. If development of CK-2127107 does not progress for these or any other reasons, we would not receive further milestone payments or royalties on product sales from Astellas with respect to CK-2127107. If Astellas abandons development of CK-2127107 prior to regulatory approval or if it elects not to proceed with

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

commercialization of the resulting drug following regulatory approval, we would have to seek a new partner for development or commercialization, curtail or abandon that development or commercialization, or undertake and fund the development of CK-2127107 or commercialization of the resulting drug

Page 33

---

**Table of Contents**

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 CK-2127107 ourselves, we would have to curtail or abandon that development or commercialization, which could harm our business.

***If we do not enter into strategic alliances for our unpartnered drug candidates or research and development programs or fail to successfully maintain our current or future strategic alliances, we may have to reduce, delay or discontinue our advancement of our 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 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 exclusive rights to develop and commercialize tirasemtiv. We currently do not have a strategic partner for this drug candidate. We may seek one or more strategic partners or other arrangements with third parties to support further clinical development and commercialization of tirasemtiv. 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. If we are unable to enter into a strategic alliance for tirasemtiv, we will be unable to conduct further clinical development of tirasemtiv for the potential treatment of ALS unless we are able to acquire the funding to do so from another source.

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 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.

***To the extent we elect to fund the development of a drug candidate, such as omecamtiv mecarbil, tirasemtiv or CK-2127107, 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, such as omecamtiv mecarbil, tirasemtiv or CK-2127107, or the commercialization of a drug, we will need to raise additional capital to:

fund clinical trials and seek regulatory approvals;

expand our development capabilities;

engage third party manufacturers for such drug candidate or drug;

build or access 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 or our partners' 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;

---

**Table of Contents**

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.

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.

***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 tirasemtiv, CK-2127107 and omecamtiv mecarbil, and related activities. 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 as agreed and in accordance with our and the FDA's or other regulatory agencies' requirements and 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. For example, in June 2013, we learned from our data management vendor for our BENEFIT-ALS clinical trial that a programming error in the electronic data capture system controlling study drug assignment caused 58 patients initially randomized to and treated with tirasemtiv to receive placebo instead at a certain trial visit and for the remainder of the trial. In order to maintain the originally intended statistical power of the trial, we amended the protocol to permit enrollment of approximately 680 patients, or 180 patients in addition to the 500 patients allowed under the existing protocol. This protocol amendment resulted in additional costs and delays in conducting BENEFIT-ALS. 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 materials, including our 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. We have limited experience in drug formulation and manufacturing, and we lack the resources and the capabilities to manufacture any of our drug candidates on a clinical or commercial scale. Amgen has assumed responsibility to conduct these activities for the ongoing development of omecamtiv mecarbil worldwide. Following our conduct of the early development of CK-2127107, including the planned Phase II clinical trial in patients with SMA, Astellas will assume primary responsibility to conduct the manufacturing for the ongoing development of CK-2127107 worldwide. For tirasemtiv, we rely 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, as well as other materials required to conduct our clinical trials. We expect to rely on contract manufacturers to supply all future drug candidates for which we conduct development, as well as other materials required to conduct our clinical trials. If any of our existing or future contract manufacturers fail to perform satisfactorily, it could delay 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 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



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

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

Page 35

---

**Table of Contents**

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, 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 and mid-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 regulatory authorities 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. In addition, data demonstrating the stability of both drug substance and drug product using the commercial manufacturing process and at commercial scale are required for marketing applications. Failure to produce drug substance and drug products in a timely manner and obtain stability data could result in delay of submission of marketing applications.

***The mechanisms of action of our 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 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 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 it will be accepted by prescribers or be reimbursed by insurers or 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, compounds and research technologies.***

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

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

Page 36

**Table of Contents**

States and in other countries for our drug candidates, their methods of manufacture and use, and our technologies. Our ability to protect our drug candidates, compounds 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, including omecamtiv mecarbil, tirasemtiv and CK-2127107, we or our 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

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

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 America Invents Act of 2011 may affect the scope, strength and enforceability of our patent rights in the United States or the nature of proceedings which may be brought by us related to our patent rights in the United States.

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

---

**Table of Contents**

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 could 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.

Other future products of ours may be impacted by patents of companies engaged in competitive programs with significantly greater resources. 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 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.***

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

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.

Page 38

**Table of Contents**

***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.***

We compete with companies that have developed drugs or are developing drug candidates for cardiovascular diseases, diseases and conditions associated with muscle weakness or wasting and other diseases for which our drug candidates may be useful treatments. For example, if tirasemtiv is approved for marketing by the FDA or other regulatory authorities for the treatment of ALS, it may then compete with other potential new therapies for ALS that are currently being developed by companies such as Neuraltus Pharmaceuticals, Inc., Isis Pharmaceuticals, Inc., Genervon Biopharmaceuticals, LLC, MediciNova, Inc., Viropharm, Pharnext, Newron, and GlaxoSmithKline plc. In addition, BrainStorm Cell Therapeutics and Neuralstem, Inc. are each conducting clinical development of stem cell therapies for the potential treatment of ALS.

If CK-2127107 is approved by the FDA or other regulatory authorities for the potential treatment of SMA, potential competitors include Roche (in collaboration with PTC Therapeutics), AveXis, Inc., Pfizer Inc., Isis Pharmaceuticals, Inc., Trophos SA, and Bioblast Pharma, Ltd. Drugs that could compete with CK-2127107 could also compete against tirasemtiv in ALS or other neuromuscular diseases, should the appropriate clinical trials be conducted. If CK-2127107 is approved by the FDA for the potential treatment of non-neuromuscular indications associated with muscle weakness, 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 and potentially other indications; Regeneron Pharmaceuticals, Inc. (in collaboration with Sanofi), which is developing SAR391786, a monoclonal antibody targeted to GDF8, for sarcopenia; Eli Lilly & Company, which is developing LY2495655, a monoclonal antibody targeted to myostatin, for muscular atrophy after hip arthroplasty; Acceleron Pharma, which is developing ACE-083 for diseases such as inclusion body myositis and certain forms of muscular dystrophy; and Pfizer Inc., which is developing PF-06252616, a monoclonal antibody targeted to myostatin, in Duchenne muscular dystrophy. Novartis (in collaboration with Morphosys AG), is conducting clinical development with an activin type-IIb receptor antagonist, bimagrumab, to evaluate its ability to treat diseases involving the loss of muscle mass, strength and function.

If omecamtiv mecarbil is approved for marketing by the FDA or other regulatory authorities for the treatment of heart failure, it would compete against other drugs used for the treatment of acute and chronic heart failure. These include generic drugs, such as milrinone, dobutamine or digoxin and branded drugs such as Natrecor (nesiritide) and Corlanor (ivabradine). Omecamtiv mecarbil could also potentially compete against other novel drug candidates and therapies in development, such as bucindolol, which is being developed by ARCA Biopharma, Inc.; Reasanz (serelaxin), Tekuma and LCZ-696, which are being developed by Novartis; cenderitide (CD-NP), which is being developed by Carpicor Therapeutics, Inc.; ularitide, which is being developed by Cardiorentis Ltd.; aladorian, which is being developed by ARMGO Pharma, Inc.; TRV027, which is being developed by Trevena, Inc. in partnership with Forest Laboratories, Inc.; certain cardioprotectants which are being developed by Cardioxyl Pharmaceuticals, Inc.; glial growth factor (GGF-2) which is being developed by Acorda Therapeutics, Inc.; Neurocardin, which is being developed by Zensun Sci & Tech, Ltd; Mydicar, a genetically-targeted enzyme replacement therapy for advanced heart failure which is being developed by Celladon Corporation; and levosimendan, which was acquired for development by Oxygen Biotherapeutics, Inc. In addition, there are a number of medical devices being developed for the potential treatment of heart failure.





**Table of Contents**

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. Many of these competitors have larger research and development programs or 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;

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.

***We have been granted orphan designations in the U.S. and in the E.U. for tirasemtiv; however, there can be no guarantee that we will receive orphan approval for tirasemtiv nor that we will be able to prevent third parties from developing and commercializing products that are competitive to tirasemtiv.***

We have been granted orphan drug designation in the U.S. by the FDA and orphan medicinal product designation by the European Medicines Agency, in each case for tirasemtiv for the potential treatment of ALS. In the U.S., upon approval from the FDA of an NDA, products granted orphan drug approval are generally provided with seven years of marketing exclusivity in the U.S., meaning the FDA will generally not approve applications for other product candidates for the same orphan indication that contain the same active ingredient. Even if we are the first to obtain approval of an orphan product and are granted exclusivity in the U.S., there are limited circumstances under which a later competitor product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to our product or due to an inability to assure a sufficient quantity of the orphan drug.

Orphan medicinal product status in Europe Union can provide up to 10 years of marketing exclusivity, meaning that another application for marketing authorization of a later similar medicinal product for the same therapeutic indication will generally not be approved in the European Union. Although we may have drug candidates that may obtain orphan drug exclusivity in Europe, the orphan approval and associated exclusivity period may be modified for several reasons, including a significant change to the orphan medicinal product designations or approval criteria after market authorization of the orphan product (*e.g.*, product profitability exceeds the criteria for orphan drug designation), problems with the production or supply of the orphan drug or a competitor drug, although similar, is safer, more effective or otherwise clinically superior than the initial orphan drug.

---

**Table of Contents**

We are not guaranteed to maintain orphan status for tirasemtiv or to receive orphan status for tirasemtiv for any other indication or for any of our other drug candidates for any indication. If our drug candidates that are granted orphan status were to lose their status as orphan drugs or the marketing exclusivity provided for them in the U.S. or the European Union, our business and results of operations could be materially adversely affected. While orphan status for any of our products, if granted or maintained, would provide market exclusivity in the U.S. and the European Union for the time periods specified above, we would not be able to exclude other companies from manufacturing and/or selling products using the same active ingredient for the same indication beyond the exclusivity period applicable to our product on the basis of orphan drug status. Moreover, we cannot guarantee that another company will not receive approval before we do of an orphan drug application in the U.S. or the European Union for a product candidate that has a similar medicinal product for the same indication as any of our drug candidates for which we plan to file for orphan designation and status. If that were to happen, our orphan drug applications for our drug candidate for that indication may not be approved until the competing company's period of exclusivity has expired in the U.S. or the European Union, as applicable. Further, application of the orphan drug regulations in the U.S. and Europe is uncertain, and we cannot predict how the respective regulatory bodies will interpret and apply the regulations to our or our competitors' products.

***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 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.***

Our future success will depend in large part upon our ability to attract and retain highly 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 could further limit our research and development activities. For example, in October 2011, we reduced our workforce by approximately 18% in order to reduce expenses and to focus resources primarily on our later-stage development programs for tirasemtiv and omecamtiv mecarbil and certain other research and development programs also directed to muscle biology. These headcount reductions and the cost control measures we have implemented may negatively affect our productivity and limit our research and development activities. 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 any additional 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 capabilities 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.***

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 and

---

## **Table of Contents**

Astellas, 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.

*Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.*

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

### **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 NDA or other marketing approval for any of our 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, and the guidance and advice issued by such agencies is subject to change at any time. Despite the time and efforts exerted, failure can occur at any stage, and we may 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 nonclinical 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.

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

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

---

**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 events 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 events;

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.



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

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 events. We cannot predict all the possible harms or adverse events that may result from our clinical trials. We currently maintain limited product liability insurance. We may not have sufficient 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

---

**Table of Contents**

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.

***Our relationships with customers, healthcare providers, clinical trial sites and professionals and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we may obtain marketing approval. Our arrangements with customers, healthcare providers and professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, and may market, sell and distribute, our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others. Several other countries, including the United Kingdom, have enacted similar anti-kickback, fraud and abuse, and healthcare laws and regulations.

The federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The government and qui tam relators have brought False Claims Act actions against pharmaceutical companies on the theory that their practices have caused false claims to be submitted to the government. There is also a separate false claims provision imposing criminal penalties.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also imposes criminal liability for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal Physician Sunshine Act requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, referred to together as the Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law.

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

Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare

---

## **Table of Contents**

programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Exclusion, suspension and debarment from government funded healthcare programs would significantly impact our ability to commercialize, sell or distribute any drug. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

In addition, health care providers in the United States, including research institutions from which we or our partners obtain patient information, are subject to privacy rules under HIPAA and state and local privacy laws. In the European Union, these entities are subject to the Directive 95/46-EC of the European Parliament on the protection of individuals with regard to the processing of personal data and individual European Union member states implementing additional legislation. Other countries have similar privacy legislation. We could face substantial penalties if we knowingly receive individually identifiable health information from a health care provider that has not satisfied the applicable privacy laws. In addition, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our partners and may impose restrictions on the use and dissemination of individuals' health information and use of biological samples.

***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 drug candidates, such as tirasemtiv for the potential treatment of ALS, CK-2127107 for the potential treatment of SMA or other indications associated with muscle weakness and omecamtiv mecarbil for the potential treatment of heart failure (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 Astellas or future strategic alliances;

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

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;

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

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

Page 45

**Table of Contents**

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 stockholders, whether or not related to our performance;

automated trading activity by algorithmic and high-frequency trading programs; 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 28, 2015, our executive officers, directors and their affiliates beneficially owned or controlled approximately 6.5% of the outstanding shares of our common stock (after giving effect to the exercise of all outstanding vested and unvested options, restricted stock units 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 stock exchanges 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 clinical 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.***

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.

***Our stockholders will experience substantial additional dilution if outstanding options or warrants are exercised for common stock.***

As of April 28, 2015, there were 5,576,048 shares of common stock issuable upon the exercise of warrants, having a weighted average exercise price of \$5.28 per share, and 3,962,792 shares of common stock issuable upon the exercise of stock options outstanding, having a weighted average exercise price of \$11.24 per share. The exercise of outstanding options or warrants for common stock would be substantially dilutive to the outstanding shares of common stock. Any dilution or potential dilution may cause our stockholders to sell their shares, which would contribute to a downward movement in the stock price of our common stock.

***Ownership changes may limit our ability to use our net operating losses and tax credits in the future.***

In general, under Section 382 of the Internal Revenue Code ( Section 382 ), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses and tax credits to offset future taxable

---

**Table of Contents**

income. We have performed a Section 382 analysis and do not believe that we have experienced an ownership change since 2006. A portion of our existing net operating losses and tax credits are subject to limitations arising from previous ownership changes. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 and result in additional limitations. We intend to continue to monitor public filings made by third parties with the SEC to assess whether an ownership change under Section 382 has occurred. Our ability to accurately assess any such ownership change is limited by the timeliness and accuracy of these public filings.

***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 SEC regulations and NASDAQ Stock Market LLC rules create uncertainty for public companies. We regularly evaluate and monitor developments with respect to new and proposed laws, regulations and standards. We cannot accurately predict or estimate the amount of the additional costs we may incur in connection with complying with such laws, regulations and standards 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 us to commit 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 require us to file corporate financial statement information in an interactive data format known as XBRL. We may incur significant costs and need to invest considerable resources to remain in compliance with these regulations.

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. MINE SAFETY DISCLOSURES**

None.



ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

A list of exhibits filed with this Quarterly Report on Form 10-Q or incorporated herein by reference is found in the Index to Exhibits immediately following the signature page of this report and is incorporated into this Item 6 by reference.

**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 4, 2015

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)

Page 48

**Table of Contents****EXHIBIT INDEX**

Exhibit No.	Exhibit	Incorporated by Reference			Exh. No.	Filed Herewith
		Form	File No.	Filing Date		
3.1	Amended and Restated Certificate of Incorporation.	S-3	333-174869	June 13, 2011	3.1	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation.	10-Q	000-50633	August 4, 2011	3.2	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation.	8-K	000-50633	June 25, 2013	5.1	
3.4	Amended and Restated Bylaws.	S-1	333-112261	April 29, 2004	3.2	
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	000-50633	April 18, 2011	4.5	
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.	8-K	000-50633	June 20, 2012	4.1	
4.1	Specimen Common Stock Certificate.	10-Q	000-50633	May 9, 2007	4.1	
4.2	Registration Rights Agreement, dated as of December 29, 2006, by and between the Company and Amgen Inc.	8-K	000-50633	January 3, 2007	10.7	
4.3	Form of Warrant to Purchase Common Stock of Cytokinetics, Inc.	8-K	000-50633	April 18, 2011	10.68	
4.4	Form of Common Stock Warrant Agreement	S-3	333-178189	November 25, 2011	4.4	
4.5	Form of Preferred Stock Warrant Agreement	S-3	333-178189	November 25, 2011	4.5	
4.6	Form of Warrant	10-Q	000-50633	August 6, 2012	4.6	
4.7	Form of Common Stock Warrant and Warrant Certificate	S-3	333-192125	November 6, 2013	4.4	
4.8	Form of Preferred Stock Warrant and Warrant Certificate	S-3	333-192125	November 6, 2013	4.5	
10.41*	Amendment No. 7, dated March 19, 2015, to the Collaboration and Option Agreement by and between the Company and Amgen Inc.					X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
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).					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

\* Pursuant to a request for confidential treatment, portions of this Exhibit have been redacted from the publicly filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 406 under the Securities Act or Rule 24b-2 under the Exchange Act, as applicable.