

CYTOKINETICS INC
Form 10-Q
May 05, 2016
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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, 2016

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)

Delaware
(State or other jurisdiction of
incorporation or organization)
280 East Grand Avenue
South San Francisco, California
(Address of principal executive offices)
Registrant's telephone number, including area code: (650) 624-3000

94-3291317
(I.R.S. Employer
Identification No.)
94080
(Zip Code)

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, 2016: 39,621,058

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CYTOKINETICS, INCORPORATED

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CYTOKINETICS, INCORPORATED**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share data) (Unaudited)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 42,269	\$ 65,076
Short-term investments	61,153	46,366
Related party accounts receivable		12
Prepaid and other current assets	2,696	1,653
Total current assets	106,118	113,107
Property and equipment, net	1,760	1,751
Long-term investments	5,140	179
Other assets	200	200
Total assets	\$ 113,218	\$ 115,237
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 547	\$ 2,238
Accrued liabilities	7,877	8,421
Deferred revenue, current	15,911	20,858
Short-term portion of deferred rent and interest payable	348	132
Total current liabilities	24,683	31,649
Long-term debt	29,466	14,639
Deferred revenue, non-current	851	
Long-term portion of deferred rent	312	359
Total liabilities	55,312	46,647
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock, \$0.001 par value:		
Authorized: 10,000,000 shares;		

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Issued and outstanding: Series A Convertible Preferred Stock	zero shares at		
March 31, 2016 and December 31, 2015			
Common stock, \$0.001 par value:			
Authorized: 81,500,000 shares;			
Issued and outstanding:	39,607,437 shares at March 31, 2016 and 39,581,692		
shares at December 31, 2015		40	40
Additional paid-in capital		604,909	603,145
Accumulated other comprehensive income		156	149
Accumulated deficit		(547,199)	(534,744)
Total stockholders' equity		57,906	68,590
Total liabilities and stockholders' equity		\$ 113,218	\$ 115,237

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

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CYTOKINETICS, INCORPORATED
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except per share data) (Unaudited)

	Three Months Ended	
	March 31,	March 31,
	2016	2015
Revenues:		
Research and development revenues from related parties	\$ 4,296	\$ 2,791
Research and development, grant and other revenues	151	
License revenues from related parties	3,974	1,623
Total revenues	8,421	4,414
Operating expenses:		
Research and development	13,534	8,956
General and administrative	6,841	4,367
Total operating expenses	20,375	13,323
Operating loss	(11,954)	(8,909)
Interest and other income (expense), net	(501)	37
Loss before income taxes	(12,455)	(8,872)
Income tax benefit		
Net loss	\$ (12,455)	\$ (8,872)
Net loss per share basic and diluted	\$ (0.31)	\$ (0.23)
Weighted-average number of shares used in computing net loss per share basic and diluted	39,592	38,675
Other comprehensive gain (loss):		
Unrealized gains (losses) on available-for-sale securities, net	7	(1)
Comprehensive loss	\$ (12,448)	\$ (8,873)

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

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CYTOKINETICS, INCORPORATED
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

	Three Months Ended	
	March 31,	March 31,
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (12,455)	\$ (8,872)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	170	145
Non-cash interest expense	119	
Stock-based compensation	1,611	896
Changes in operating assets and liabilities:		
Related party accounts receivable	12	45,676
Prepaid and other assets	(1,042)	(716)
Accounts payable	(1,462)	95
Accrued and other liabilities	(365)	(1,418)
Deferred revenue	(4,095)	(1,447)
Net cash provided by (used in) operating activities	(17,507)	34,359
Cash flows from investing activities:		
Purchases of investments	(50,146)	(49,840)
Proceeds from sales and maturities of investments	30,405	17,877
Purchases of property and equipment	(420)	(130)
Net cash used in investing activities	(20,161)	(32,093)
Cash flows from financing activities:		
Proceeds from long term debt, net of debt discount and issuance costs	14,996	
Proceeds (payments) from stock based award activities and warrants, net	(135)	65
Net cash provided by financing activities	14,861	65
Net increase (decrease) in cash and cash equivalents	(22,807)	2,331
Cash and cash equivalents, beginning of period	65,076	20,215
Cash and cash equivalents, end of period	\$ 42,269	\$ 22,546

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

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CYTOKINETICS, INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 Organization, Basis of Presentation and Recently Issued Accounting Standards

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 late 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 \$547.2 million since inception and there can be no assurance that the Company will attain profitability. The Company had a net loss of \$12.5 million and net cash used in operations of \$17.5 million for the three months ended March 31, 2016. Cash, cash equivalents and investments decreased from \$111.6 million at December 31, 2015 to \$108.6 million at March 31, 2016. 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, 2016 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, 2016, and the results of operations for the three months ended March 31, 2016 and the cash flows for the three months ended March 31, 2016. 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, 2015 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, 2015, as filed with the SEC on March 3, 2016.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Table of Contents***Recent Accounting Pronouncements***

In March 2016, the FASB issued ASU 2016-09, *Stock compensation (Topic 718)*. ASU 2016-09 simplifies various aspects of accounting for share-based payments and presentation in the financial statements. ASU 2016-09 is effective for annual and interim reporting periods beginning after December 15, 2016 and early adoption is permitted. The Company is in the process of evaluating the impact the adoption of ASU 2016-09 would have on its financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 requires management to record right-to-use asset and lease liability on the statement of financial position for operating leases. ASU 2016-02 is effective for annual and interim reporting periods beginning on or after December 15, 2018 and modified retrospective approach is required. The Company is in the process of evaluating the impact the adoption of ASU 2016-02 would have on its financial statements and disclosures.

In January 2016, the FASB issued ASU 2016-01, *Financial instruments (Subtopic 825-10)*. ASU 2016-01 requires management to measure equity investments at fair value with changes in fair value recognized in net income. ASU 2016-01 is effective for annual and interim reporting periods beginning on or after December 15, 2017 and early adoption is not permitted. The Company does not expect the adoption of ASU 2016-01 to have a material effect on its financial statements or disclosures.

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 214-15 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 on its financial statements or disclosures.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (reporting revenue gross versus net)*. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements of ASU 2014-09. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations.

Note 2 Net Loss Per Share

The following is the calculation of basic and diluted net loss per share (in thousands, except per share data):

Three Months Ended	
March 31,	March 31,
2016	2015

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Net loss	\$ (12,455)	\$ (8,872)
Weighted-average shares used in computing net loss per share basic and diluted	39,592	38,675
Net loss per share basic and diluted	\$ (0.31)	\$ (0.23)

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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, if they have a dilutive effect. 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,	March 31,
	2016	2015
Options to purchase common stock	5,869	4,556
Warrants to purchase common stock	5,710	6,691
Restricted and Performance stock units	758	73
Shares issuable related to the ESPP	40	36
Total shares	12,377	11,356

Note 3 Supplemental Cash Flow Data

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

	Three Months Ended	
	March 31,	March 31,
	2016	2015
Cash paid for interest	\$ 382	\$
Cash paid for income taxes	1	1
Significant non-cash investing and financing activities:		
Debt discount netted against proceeds from long term debt, recorded in equity	288	
Interest paid on the long-term debt, at inception	63	
Purchases of property and equipment through accounts payable	229	63
Purchases of property and equipment through accrued liabilities	11	8

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 1 pharmacokinetic study intended to support inclusion of Japan in a potential Phase 3 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.

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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.

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.

Amgen and the Company agreed to extend the term of the research program in 2016. Under the amended Amgen Agreement, the Company is entitled to receive reimbursements of internal costs of certain full-time employee equivalents during 2016, 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, 2016 and 2015, the Company recognized no revenues for milestones achieved under the Amgen Agreement.

The Amgen Agreement also provides for the Company to receive increased royalties by co-funding Phase 3 development costs of omecamtiv 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 were recorded as research and development revenues from related parties. During the three months ended March 31, 2016 and 2015, the Company recorded research and development revenue from Amgen of \$0.6 million and \$0.7 million, respectively, under the Amgen Agreement.

Revenue from Amgen was as follows (in thousands):

	Three Months Ended	
	March 31,	March 31,
	2016	2015
Research and development revenues from related parties		
Reimbursement of internal costs	\$ 617	\$ 667
Allocated consideration		21

Total revenues from Amgen \$ 617 \$ 688

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

		March 31, 2016	December 31, 2015
Related party accounts receivable	Amgen	\$	\$

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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.

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 1 clinical trials and certain Phase 2 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 over \$24.0 million in reimbursement of sponsored research and development activities during the initial two years of the collaboration. The agreement 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. No license revenue was recorded in 2016 under the Original Astellas Agreement, and as of March 31, 2016, no license revenue remains deferred under the Original Astellas Agreement.

Pursuant to the Original Astellas Agreement, the Company 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 \$1.8 million under the Original Astellas Agreement. No research and development revenue from Astellas was recorded in 2016 under the Original Astellas Agreement.

Amended Astellas Agreement (Expansion to include neuromuscular indications)

In December 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 with CK-2127107 and other fast skeletal troponin activators, in addition to the non-neuromuscular indications provided for in the Original Astellas Agreement.

Under 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 2 clinical development. The Company is also eligible to potentially receive over \$20.0 million in reimbursement of sponsored research and development activities during the two years of the collaboration following the execution of the Amended Astellas Agreement. Under the Amended Astellas Agreement, the Company is conducting the initial Phase 2 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 research term of the Amended Astellas Agreement using the proportional performance model.

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During the three months ended March 31, 2016 and 2015, the Company recorded \$4.0 million and \$0.4 million, respectively, in license revenue based on the proportional performance model under the Amended Astellas Agreement. As of March 31, 2016, \$16.3 million license revenue remains deferred under the Amended Astellas Agreement.

Pursuant to the Amended Astellas Agreement, the Company 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, 2016 and 2015, the Company recorded research and development revenue from Astellas of \$3.7 million and \$0.3 million, respectively, under the Amended Astellas Agreement.

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, 2016 and 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 under the collaboration for each future potential drug 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 stage 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.

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 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 is classified as related party revenue.

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

	Three Months Ended March 31, 2016	Three Months Ended March 31, 2015
License Revenues from Related Parties	\$ 3,974	\$ 1,624
Research and development revenues with related parties:		
Reimbursement of internal costs	2,239	909
Reimbursement of other costs	1,440	1,193
Total research and development revenue with related parties from Astellas	3,679	2,102
Total Revenue from Astellas	\$ 7,653	\$ 3,726

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

	March 31, 2016	December 31, 2015
Related party accounts receivable - Astellas	\$	\$

At March 31, 2016 and December 31, 2015, the Company had \$16.3 million and \$20.4 million, respectively, of deferred revenue under the Amended Astellas Agreement, reflecting the unrecognized portion of the license revenue, allocation of consideration and payment of expenses.

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, 2016 and December 31, 2015 were as follows (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Maturity Dates
Cash equivalents - money market funds and U.S. Treasury securities	\$ 37,765	\$	\$	\$ 37,765	
Short-term investments - U.S. Treasury securities	\$ 61,137	\$ 16	\$	\$ 61,153	4/2016-3/2017

Long-term investments	Equity and U.S.					
Treasury securities		\$ 5,179	\$ 3	\$ (42)	\$ 5,140	4/2017-8/2017

		December 31, 2015				
		Amortized	Unrealized	Unrealized	Fair	Maturity
		Cost	Gains	Losses	Value	Dates
Cash equivalents	money market funds	\$ 63,136	\$	\$	\$ 63,136	
Short-term investments	U.S. Treasury securities	\$ 46,395	\$ 1	\$ (30)	\$ 46,366	2/2016-8/2016
Long-term investments	Equity securities	\$	\$ 179	\$	\$ 179	

At March 31, 2016 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, 2016 through April 28, 2016 and expects to be able to collect all contractual cash flows on the remaining maturities of its U.S. Treasury securities.

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Interest income was as follows (in thousands):

	Three Months Ended	
	March 31, 2016	March 31, 2015
Interest income	\$ 62	\$ 37

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.

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

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

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

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

Financial assets measured at fair value on a recurring basis as of March 31, 2016 and December 31, 2015 are classified in the table below in one of the three categories described above (in thousands):

	March 31, 2016			Assets At Fair Value
	Fair Value Measurements Using Level 1	Level 2	Level 3	
Assets:				
Money market funds	\$ 35,265	\$	\$	\$ 35,265
U.S. Treasury securities	68,656			68,656

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Equity securities	137			137
Total	\$ 104,058	\$	\$	\$ 104,058
Amounts included in:				
Cash and cash equivalents	\$ 37,765	\$	\$	37,765
Short-term investments	61,153			61,153
Long-term investments	5,140			5,140
Total	\$ 104,058	\$	\$	\$ 104,058

	December 31, 2015			Assets
	Fair Value Measurements Using			At Fair Value
	Level 1	Level 2	Level 3	
Assets:				
Money market funds	\$ 63,136	\$	\$	\$ 63,136
U.S. Treasury securities	46,366			46,366
Equity securities	179			179
Total	\$ 109,681	\$	\$	\$ 109,681

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	December 31, 2015			Assets At Fair Value
	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	
Amounts included in:				
Cash and cash equivalents	\$ 63,136	\$	\$	\$ 63,136
Short-term investments	46,366			46,366
Long-term investments	179			179
Total	\$ 109,681	\$	\$	\$ 109,681

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, 2016 and December 31, 2015, 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.

Long Term Debt:

As of March 31, 2016 and December 31, 2015, the fair value of the long-term debt, payable in installments through year ended 2020, approximated its carrying value of \$29.5 million and \$14.6 million, respectively, because it is carried at a market observable interest rate, which are considered Level 2.

Note 7 Long-Term Debt

Long-term debt and unamortized debt discount balances are as follows (in thousands):

	March 31, 2016	December 31 2015
Notes payable, gross	\$ 30,000	\$ 15,000
Less: Unamortized debt discount	(620)	(389)
Accretion of final payment fee	86	28
Carrying value of notes payable	\$ 29,466	\$ 14,639

In October 2015, the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford,") as the collateral agent and a lender, and Silicon Valley Bank ("SVB,") as a lender (Oxford and SVB collectively the "Lenders") to fund its working capital and other general corporate needs. The Loan Agreement provided for (1) term loans of up to \$40.0 million in aggregate, (2) warrants to purchase 65,189 shares of the Company's common stock at an exercise price of \$6.90 per share under the first term loan, and (3) additional warrants to purchase shares of the Company's common stock to be based on the amount of the additional term loans and a price per share determined on the day of funding in accordance with the Grant Agreement, which is also the exercise price per share for the warrants.

The Company drew down \$15.0 million in funds under the Loan Agreement in October 2015 at the time of the first draw down, and at that time, could at its sole discretion draw down an additional \$25.0 million under the Loan Agreement in two term loans, provided certain specified conditions stipulated in the Loan Agreement are met

preceding those draws. During February 2016, the Company drew down an additional \$15.0 million in funds under the Loan Agreement and issued warrants to purchase 68,285 shares of the Company's common stock at an exercise price of \$6.59 per share under the second term loan. As of April 28, 2016, there were 133,474 warrants outstanding and exercisable. As of April 28, 2016 the Company has received \$29.8 million from this loan and security agreement, net of issuance cost. The Company can at its sole discretion draw down an additional \$10.0 million under the Loan Agreement from the Lenders, at any time prior to March 31, 2017, subject to the Company's satisfaction of specified conditions precedent related to the earlier of (i) the occurrence of an equity event as described in the Loan Agreement, or (ii) specified results from the Company's VITALITY-ALS Phase 3 trial of tirasemtiv, each as specified in the Loan Agreement.

The Company is required to repay the outstanding principal in 36 equal installments beginning October 2017 and is due in full in October 2020. The first and second term loans bear interest at a rate of 7.5% per annum, respectively. The remaining term loans, if drawn, will bear interest at a rate fixed at the time of draw, equal to the greater of (i) 7.50% and (ii) the sum of the three month U.S. LIBOR rate plus 7.31%. The Company is required to make a final payment fee of 4.00% of the amounts of the Term Loans drawn payable on the earlier of (i) the prepayment of the Term Loans or (ii) the Maturity Date. The loan carries prepayment penalties of 3% and 2% for prepayment within one and two years, respectively, of the loan origination and 1% thereafter. The warrants issued in the Loan Agreement became exercisable upon issuance and will remain exercisable for five years from issuance or the closing of a merger consolidation transaction in which the Company is not the surviving entity.

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The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to the Company and its subsidiaries, including, among other things, restrictions on dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. The Agreement also includes customary events of default, including but not limited to the nonpayment of principal or interest, violations of covenants, material adverse changes, attachment, levy, restraint on business, cross-defaults on material indebtedness, bankruptcy, material judgments, misrepresentations, subordinated debt, governmental approvals, lien priority and delisting. Upon an event of default, the Lenders may, among other things, accelerate the loans and foreclose on the collateral. The Company's obligations under the Agreement are secured by substantially all of the Company's current and future assets, other than its intellectual property.

The Company recorded interest expense related to the long term debt of \$0.6 million for the three months ended March 31, 2016. Included in interest expense for this period was interest on principal, amortization of the debt discount and debt issuance costs, and the accretion of the final payment fee. For the three months ended March 31, 2016, the effective interest rate on the amounts borrowed under the Agreement, including the amortization of the debt discount and issuance cost, and the accretion of the final payment, was 9.3%. No interest expense was recorded during the three months ended March 31, 2015.

Future minimum payments under the Loan, as of March 31, 2016 are as follows (in thousands):

Remainder of 2016	\$ 1,721
2017	4,768
2018	11,743
2019	10,981
2020	8,938
Total minimum payments	38,151
Less: Interest and final payment	(8,151)
Notes payable, gross	\$ 30,000

Note 8 Stockholders Equity***Accumulated Other Comprehensive Loss***

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) is comprised of unrealized holding gains and losses on the Company's available-for-sale securities that are excluded from net loss and reported separately in stockholders' equity.

In the first three months of 2016 and 2015, the Company recorded insignificant amounts of unrealized gains (losses) in available-for-sale securities in accumulated other comprehensive loss, and did not reclassify any unrealized gains on investments from accumulated other comprehensive income into net loss.

Warrants

As of March 31, 2016, the Company had warrants outstanding to purchase 5.7 million shares of the Company's common stock.

In June 2012, warrants were issued pursuant to the June 2012 underwriting agreements the Company entered into in connection with two separate, concurrent offerings for our securities (the June 2012 Public Offerings). In accordance with the accounting guidance for valuing stock and warrants when stock is issued in conjunction with other securities, and the stock and other securities are to be accounted for as equity, the Company allocated the gross purchase proceeds using the relative fair value method. For accounting purposes, the June 2012 Public Offerings were considered to be one transaction. The fair value of the common stock issued in the June 2012 Public Offerings was calculated based on the closing price of the stock on the commitment date as quoted on The NASDAQ Global Market.

In October 2015, warrants to purchase 65,189 shares of the Company's common stock at an exercise price of \$6.90 per share were issued in accordance with the Loan Agreement. Refer to Note 7 Long Term Debt, for further details regarding the Loan Agreement.

In February 2016, warrants to purchase 68,285 shares of the Company's common stock at an exercise price of \$6.59 per share were issued in accordance with the Loan Agreement. The Company valued the warrants as of the date of issuance at \$288,000 using the Black-Scholes option pricing model and the following assumptions: a contractual term of five years, a risk-free interest rate of 1.7%, volatility of 75%, and the fair value of the Company's common stock of \$7.00.

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Outstanding warrants as of March 31, 2016 were as follows:

	Number of Shares	Exercise Price	Expiration Date
Issued 6/25/2012	5,576,048	\$ 5.28	06/25/17
Issued 10/19/2015	65,189	\$ 6.90	10/19/20
Issued 02/10/2016	68,285	\$ 6.59	02/10/21

Committed Equity Offering

On September 4, 2015, the Company entered into an Committed Equity Offering (an "CE Offering") that is an at-the-market issuance sales agreement (the "Cantor Fitzgerald Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), pursuant to which the Company may issue and sell shares of common stock having an aggregate offering price of up to \$40.0 million, from time to time through Cantor Fitzgerald as its sales agent. The issuance and sale of these shares by the Company under the Cantor Fitzgerald Agreement, if any, are subject to the continued effectiveness of its registration statement on Form S-3, which was declared effective by the SEC on September 17, 2015 (File No. 333-206795).

Sales of the Company's common stock through Cantor Fitzgerald, if any, will be made on The NASDAQ Global Market by means of ordinary brokers' transactions at market prices or as otherwise agreed to by the Company and Cantor Fitzgerald. Subject to the terms and conditions of the Cantor Fitzgerald Agreement, Cantor Fitzgerald will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). The Company is not obligated to make any sales of common stock under the Cantor Fitzgerald Agreement. The offering of shares of common stock pursuant to the Cantor Fitzgerald Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the Cantor Fitzgerald Agreement or (2) termination of the Cantor Fitzgerald Agreement. The Cantor Fitzgerald Agreement may be terminated by Cantor Fitzgerald at any time upon ten days notice to the Company or may be terminated by the Company at any time upon five days notice to Cantor Fitzgerald, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material adverse change in the Company's business. The Company will pay Cantor Fitzgerald a commission rate equal to 3.0% of the gross proceeds of the sales price per share of any common stock sold through Cantor Fitzgerald under the Cantor Fitzgerald Agreement. The Company has also provided Cantor Fitzgerald with customary indemnification and contribution rights. As of March 31, 2016, 808,193 shares have been issued through Cantor Fitzgerald under the Cantor Fitzgerald Agreement for total net proceeds of approximately \$8.7 million.

Equity Incentive Plan

Total employee stock-based compensation expenses were \$1.6 million and \$0.9 million for the three months ended March 31, 2016 and 2015, respectively.

Stock Options

Activity under the 2004 Equity Incentive Plan, for the three months ended March 31, 2016, 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, 2015	2,816,010	4,078,159	\$ 10.94
Options granted	(1,174,200)	1,174,200	6.82
Options exercised			
Options forfeited/expired	140,968	(140,968)	34.52
Restricted stock units granted	(47,000)		
Balance at March 31, 2016	1,735,778	5,111,391	\$ 9.35

Table of Contents***Restricted Stock Units***

Restricted stock unit activity for the three months ended March 31, 2016 was as follows:

	Number of Shares	Weighted Average Award Date Fair Value per Share
Restricted stock units outstanding at December 31, 2015	71,752	\$ 8.49
Restricted stock units granted	47,000	6.67
Restricted stock units released	(45,750)	8.69
Restricted stock units forfeited		
Unvested restricted stock units outstanding at March 31, 2016	73,002	\$ 7.19

Restricted stock activities were limited to non-executive employees for the three months ended March 31, 2016.

Restricted Stock Units that Contain Performance Conditions

Performance stock unit activity was as follows:

	Number of Shares	Weighted Average Award Date Fair Value per Share
Performance stock units outstanding at December 31, 2015	685,000	\$ 7.00
Restricted stock units granted		
Restricted stock units vested		
Restricted stock units forfeited		
Unvested restricted stock units outstanding at March 31, 2016	685,000	\$ 7.00

As of March 31, 2016, all these performance stock units remain unvested.

Note 9 Interest and Other Income (Expense), Net

Interest and other income (expense) for the three months ended March 31, 2016 primarily consisted of interest expense on long term debt, amortization of the debt discount and debt issuance costs, and the accretion of the final payment fee related to long term debt. Interest and other income (expense) for the three months ended March 31, 2015 primarily consisted of interest income generated from the Company's cash, cash equivalents and investments.

Note 10 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. During March 2016, the Company amended the lease agreement to include certain additional operating expenses, related to the replacement of two boilers. The Company recognizes rent expense on a straight-line basis over the lease period. Rent expense was \$0.8 million and \$0.8 million, respectively, for the three months ended March 31, 2016 and 2015.

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 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.

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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 11 Income Taxes

During the three months ended March 31, 2016 and 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, 2016 and 2015, respectively.

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.

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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 2016;

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;

anticipated interactions with regulatory authorities;

the 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 Phase 3 clinical trial endpoints 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;

the potential advancement of omecamtiv mecarbil into Phase 3 clinical development;

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 and other obligations under loan and lease agreements

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.

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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 effects on respiratory function, including slow vital capacity, as an appropriate clinical trial endpoints 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.

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When used in this report, unless otherwise indicated, Cytokinetics, the Company, we, our and us refers to Cytokinetics, Incorporated. CYTOKINETICS, and our logo used alone and with the mark CYTOKINETICS, are registered service marks and trademarks of Cytokinetics. Other service marks, trademarks and trade names referred to in this report are the property of their respective owners.

Overview

We were incorporated in Delaware in August 1997 as Cytokinetics, Incorporated. We are a late-stage biopharmaceutical company focused on the discovery and development of first-in-class muscle activators as potential treatments for debilitating diseases in which muscle performance is compromised and or declining. 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. We are also conducting earlier-stage research 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 conducted a Phase 2 clinical development program for tirasemtiv, and we started a Phase 3 clinical development program for this drug candidate in patients with ALS in July 2015. In collaboration with Astellas, we are also developing another drug candidate from this program, CK-2127107, for potential indications associated with muscle weakness. We are started a Phase 2 clinical trial for CK-2127107 in patients with SMA in December 2015. 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.

Our lead drug candidate from our skeletal muscle contractility program, tirasemtiv (formerly known as CK-2017357), is a fast skeletal muscle troponin activator. Cytokinetics retains exclusive rights to tirasemtiv and is independently developing this drug candidate for the potential treatment of ALS. We conducted a Phase 2 clinical trials program for tirasemtiv, including a Phase 2b clinical trial in patients with ALS, known as BENEFIT-ALS (Blinded Evaluation of Neuromuscular Effects and Functional Improvement with Tirasemtiv in ALS). Based on the results of BENEFIT-ALS, we started a Phase 3 clinical development program for tirasemtiv in patients with ALS in July 2015 known as VITALITY-ALS (Ventilatory Investigation of Tirasemtiv and Assessment of Longitudinal Indices after

Treatment for a Year in ALS). Tirasemtiv has been granted orphan drug designation and fast track status by the FDA and orphan medicinal product designation by the European Medicines Agency, in each case for the potential treatment of ALS.

VITALITY-ALS is a multi-national, randomized, double-blind, placebo-controlled trial that was originally designed to enroll 445 patients with possible, probable or definite ALS diagnosed within 24 months, and with a baseline vital capacity > 70 % of predicted, based on age, sex, and height. Patients may be enrolled whether or not they are on riluzole therapy. The primary endpoint of the trial will assess change from baseline in SVC, to be assessed after 24 weeks of double-blind, placebo-controlled treatment. Secondary endpoints include time to decline from baseline in percent predicted SVC by ≥ 20 percentage points or the onset of respiratory insufficiency or death; time to decline from baseline in percent predicted SVC to ≤ 50 percent predicted or the onset of respiratory insufficiency or death; time to first occurrence of any use of assisted ventilation or death; time to decline in any of the three respiratory domains of the ALSFRS-R or death; and change in the Mega-Score of muscle strength.

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Patients enrolled in VITALITY-ALS will receive two-weeks of open-label treatment with tirasemtiv administered at 250 mg/day and will then be randomized to double-blind treatment with placebo or one of three target tirasemtiv dose levels (250 mg/day, 375 mg/day, 500 mg/day) in a 3:2:2:2 ratio for a total of 48 weeks of randomized, double-blind, placebo-controlled treatment. Then in a four-week double-blind, tirasemtiv withdrawal phase, patients on tirasemtiv will be randomized either to continue the double-blind tirasemtiv dose they were receiving or to be withdrawn to placebo in a 1:1 ratio. Patients who had been receiving placebo during the 48 weeks of double-blind, placebo-controlled treatment will continue to receive placebo.

In January 2016, we amended the protocol of VITALITY-ALS to provide for an increase in the number of patients to be enrolled in the clinical trial from approximately 445 patients to approximately 600 patients. Increasing the number of patients enrolled in VITALITY-ALS will increase the statistical power to detect a difference in the primary efficacy endpoint (change from baseline in SVC at 24 weeks) between *tirasemtiv* and placebo.

At the end of the first quarter of 2016, there were approximately 300 patients enrolled in VITALITY-ALS. VITALITY-ALS is expected to complete enrollment of 600 patients in the first half of 2016. In the first quarter, a meeting of the Data Monitoring Committee (DMC) for VITALITY-ALS was held. The accumulated safety and efficacy data were reviewed by the committee and the committee recommended continuing the trial without any changes or modifications to the trial.

On March 31, we announced a research collaboration with Origent Data Sciences, Inc. (Origent) to refine and prospectively validate an Origent computer model to predict the course of ALS disease progression leveraging data from Cytokinetics' clinical trials of *tirasemtiv*. Funded by Origent's receipt of a grant from The ALS Association, this joint research program will enable the first prospective validation of the predictive model in a clinical trial setting. Previously, the Origent models predicting both function and survival of ALS patients have been validated using their internal and retrospective external datasets.

Also during the quarter, the manuscript, "A randomized, placebo-controlled, double-blind phase IIb trial evaluating the safety and efficacy of tirasemtiv in patients with amyotrophic lateral sclerosis," was published in the *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration* journal.

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 are expected to increase as we continue to progress tirasemtiv towards potential registration.

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 for CK-2127107 and other fast skeletal troponin activators, 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 2 clinical development. Cytokinetics started a Phase 2 clinical trial of CK-2127107 in patients with SMA in December 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 companies 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.

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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 2 clinical development. Cytokinetics is also eligible to potentially receive over \$20.0 million in reimbursement of sponsored research and development activities during the two years of the collaboration following the execution of 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 \$95.0 million relating to 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.

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, 2016 and 2015, we recorded \$4.0 million and \$1.6 million, respectively, of license revenue and \$3.7 million and \$2.1 million, respectively, 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.

CK-2127107 Clinical Development

Phase 2 Clinical Development: Cytokinetics, in partnership with Astellas, started a Phase 2 clinical trial of CK-2127107 in patients with SMA in December 2015. The clinical trial is designed to assess effects of CK-2127107 on multiple measures of muscle function in both ambulatory and non-ambulatory patients with SMA, a severe, genetic neuromuscular disease that leads to debilitating muscle wasting and progressive, often fatal, muscle weakness. The primary objective of this double-blind, randomized, placebo-controlled clinical trial is to determine the potential pharmacodynamic effects of a suspension formulation of CK-2127107 following multiple oral doses in patients with

Type II, Type III, or Type IV SMA. Secondary objectives are to evaluate the safety, tolerability and pharmacokinetics of CK-2127107. The trial will enroll seventy-two patients in two sequential, ascending dose cohorts (two cohorts of 36 patients each, stratified half ambulatory and half non- ambulatory).

The first cohort of patients is receiving 150 mg of CK-2127107 dosed twice daily for eight weeks; the second cohort of patients will receive 450 mg of CK-2127107 dosed twice daily or a lower dose, depending on the data from the first cohort. At the conclusion of the trial, approximately 24 patients will have been randomized to placebo, approximately 24 patients to 150 mg of CK-2127107 twice daily and approximately 24 patients to 450 mg of CK-2127107 twice daily (or a lower dose, pending the review of data from the first cohort). In each of these three treatment groups of approximately 24 patients each, roughly half will be ambulatory and half will be non-ambulatory. Multiple assessments of skeletal muscle function and fatigability will be performed including respiratory assessments, upper limb strength and functionality for non-ambulatory patients, as well as six-minute walk and timed-up-and-go for ambulatory patients.

During the quarter, we continued enrollment of the Phase 2 clinical trial of CK-2127107 in patients with SMA, in collaboration with Astellas. We expect to complete enrollment of our Phase 2 trial of CK-2127107 in patients with SMA in the second half of 2016.

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We expect Astellas, in collaboration with Cytokinetics, will initiate a Phase 2 clinical trial of CK-2127107 in patients with chronic obstructive pulmonary disease in the first half of 2016.

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 in 2016 and Astellas will reimburse us for certain research activities. We expect that a next-generation skeletal muscle activator will advance into IND-enabling studies in 2016.

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 for use in the hospital setting and for use in the outpatient setting. During the quarter, we participated with Amgen in regulatory meetings with the FDA, EMA and Health Canada intended to inform the design of a potential Phase 3 development program for omecamtiv mecarbil. We also conducted various clinical, non-clinical and planning activities in collaboration with Amgen to support the potential advancement of omecamtiv mecarbil into a Phase 3 development program. We expect to make a decision regarding the advancement to Phase 3 in the coming months. We expect to continue our joint research with Amgen directed to next-generation compounds in our cardiac muscle contractility program in 2016.

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 1 pharmacokinetic study intended to support inclusion of Japan in a potential Phase 3 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.

Under the Amgen Agreement as amended, we are eligible for potential pre-commercialization and commercialization milestone payments of over \$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 3 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.

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.

We recorded reimbursement of sponsored research and development activities in connection with our strategic alliance with Amgen of \$0.6 million and \$0.7 million, respectively in the three months ended March 31, 2016 and 2015. 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

Omecamtiv mecarbil has been the subject of an extensive Phase 1 and Phase 2 clinical trials program. In November 2015, we announced the results of COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure), the last planned Phase 2 trial of omecamtiv mecarbil to be conducted prior to a decision regarding the potential advancement of this drug candidate to Phase 3. COSMIC-HF was designed to assess the pharmacokinetics and tolerability of omecamtiv mecarbil dosed orally.

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in patients with heart failure and left ventricular systolic dysfunction and its effects on echocardiographic measures of cardiac function. An intravenous formulation of omecamtiv mecarbil was studied in a Phase 2b clinical trial known as ATOMIC-AHF (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure), which was designed to evaluate the safety and efficacy of omecamtiv mecarbil in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure.

Phase 2 Clinical Development Program

COSMIC-HF. COSMIC-HF is a Phase 2, 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 was conducted by Amgen in collaboration with Cytokinetics. The trial began with two dose escalation cohorts of 40 patients each, randomized 1:1:1:1 to placebo or one of three different modified release oral formulations of *omecamtiv mecarbil* for seven days. The *omecamtiv mecarbil* dose in the first of these two dose escalation cohorts was 25 mg twice daily; in the second, it was 50 mg twice daily. The purpose of the dose escalation cohorts was to select one of the three modified release oral formulations of *omecamtiv mecarbil* for further evaluation in a larger group of patients treated for a longer period of time.

The expansion phase of COSMIC-HF was designed to evaluate the pharmacokinetics, pharmacodynamics, safety and tolerability of the modified release oral formulation *omecamtiv mecarbil* selected based on the results of the two dose escalation cohorts in 448 patients with chronic heart failure and left ventricular systolic dysfunction. Patients were randomized 1:1:1 to receive either placebo or treatment with *omecamtiv mecarbil* 25 mg twice daily or a dose titration group where 25 mg twice daily dosing could be increased to 50 mg twice daily depending on plasma concentrations of *omecamtiv mecarbil* after two weeks of treatment with the 25 mg dose.

In November 2015, the results from the expansion phase of COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) were presented in a Late-Breaking Clinical Trial session at the American Heart Association Scientific Sessions 2015 in Orlando, Florida. Data from the expansion phase showed that dose titration controlled patient exposure to omecamtiv mecarbil. Approximately 60 percent of patients in the dose titration group escalated dosing to 50 mg twice daily. The study met its primary pharmacokinetics objective.

Following 20 weeks of treatment, statistically significant improvements were observed in pre-specified secondary endpoint measures of cardiac function in the dose titration group, compared to placebo. Systolic ejection time increased by 25.0 msec ($p<0.001$), stroke volume increased by 3.63 mL ($p=0.022$) and heart rate decreased by 2.97 beats per min ($p=0.007$). Left ventricular end-systolic and end-diastolic dimensions decreased by 1.79 mm ($p=0.003$) and 1.29 mm ($p=0.013$), respectively, and were associated with statistically significant reductions in left ventricular end-systolic and end-diastolic volumes. N-terminal pro-brain natriuretic peptide (NT-proBNP) decreased by 970 pg/mL ($p=0.007$). Additionally, in the 25 mg twice daily group, there were statistically significant increases in systolic ejection time and stroke volume and a decrease in NT-proBNP. All changes are from baseline compared to placebo. The pharmacodynamic effects of *omecamtiv mecarbil* were generally dose dependent and larger in patients that received oral dosing with 50 mg twice daily.

Adverse events (AEs), including serious AEs, in patients on *omecamtiv mecarbil* were comparable to placebo. The incidence of adjudicated deaths (2.7 percent died on placebo, 1.4 percent died on *omecamtiv mecarbil*), myocardial infarction (1.34 percent on placebo, 0.34 percent on *omecamtiv mecarbil*) and unstable angina (0 percent on placebo, 0.34 percent on *omecamtiv mecarbil*) was similar. Other cardiac AEs were generally balanced between placebo and active treatment groups. In the *omecamtiv mecarbil* groups, compared to placebo, cardiac troponin increased by 0.001 ng/mL and 0.006 ng/mL (median change from baseline at week 20) in the 25 mg twice daily group and dose titration

group, respectively. Events of increased troponin (n=278 across all treatment groups) were independently adjudicated and none were determined to be myocardial ischemia or infarction.

On April 4, 2016, we announced the start of a Phase 2 clinical trial of omecamtiv mecarbil in Japanese subjects with heart failure and reduced ejection fraction.

Also during the quarter, the manuscript, Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure, The ATOMIC-AHF Study, was published in the Journal of the American College of Cardiology. Results from this trial were first presented at the European Society of Cardiology Meeting in 2013.

During the quarter, we participated with Amgen in regulatory meetings with the FDA, EMA and Health Canada intended to inform design of a potential Phase 3 development program for omecamtiv mecarbil. We also conducted various clinical, non-clinical and planning activities in collaboration with Amgen to support the potential advancement of omecamtiv mecarbil into a Phase 3 development program. We expect to make a decision regarding the advancement of omecamtiv mecarbil into Phase 3 in the coming months.

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Ongoing Research in Cardiac Muscle Contractility.

We expect to continue our joint research program with Amgen directed to next-generation compounds in our cardiac muscle contractility program in 2016. Under the Amgen Agreement, Amgen reimburses us for certain research activities we perform.

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.

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 on respiratory function, including SVC, as an appropriate clinical trial endpoints to support the registration of tirasemtiv for the treatment of ALS;

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

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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, manufacture, packaging, labeling and distribution 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.

Results of Operations**Revenues**

We recorded total revenues of \$8.4 million and \$4.4 million for the first quarter of 2016 and 2015, respectively.

Total revenues were as follows (in thousands):

	Three Months Ended		
	March 31,	March 31,	Increase
	2016	2015	(Decrease)
Research and development revenues from related parties	\$ 4,296	\$ 2,791	\$ 1,505
Research and development, grant and other revenues	151		151
License revenues from related parties	3,974	1,623	2,351
Total revenues	\$ 8,421	\$ 4,414	\$ 4,007

Research and development revenues from related parties refers to research and development revenues from our strategic alliances with Astellas and Amgen. Research and development revenues from Astellas were \$3.7 million and \$2.1 million in the first quarter of 2016 and 2015, respectively, and consisted of reimbursements of internal costs of certain full-time employee equivalents, and other research and development expenses. Research and development revenues from Amgen were \$0.6 million and \$0.7 million for the first quarter of 2016 and 2015, respectively, and consisted of reimbursements of internal costs of certain full-time employee equivalents. The increase in research and development revenues from related parties of \$4.0 million was primarily due to the timing of research and development activities under the Astellas collaboration as noted above.

Research and development, grant and other revenues in the first quarter of 2016 consisted of \$0.2 million of research and development revenues from our collaboration with The ALS Association (ALSA). In July 2015, we were awarded

a \$1.5 million grant from ALSA (the ALSA Grant) to support the conduct of VITALITY-ALS as well as the collection of clinical data and plasma samples from patients in VITALITY-ALS in order to help advance the discovery of potentially useful biomarkers in ALS.

License revenues from related parties refers to license revenues from our strategic alliance with Astellas. License revenues from Astellas were \$4.0 million and \$1.6 million in the first quarter of 2016 and 2015, respectively, and consisted of the recognition of a portion of the \$30.0 million upfront license fee received from Astellas in January 2015, using the proportional performance model. The increase in license revenues from related parties of \$2.4 million was primarily due to the timing of research and development activities under the Astellas collaboration, as noted above.

Research and Development Expenses

Research and development expenses were \$13.5 million and \$9.0 million in the first quarter of 2016 and 2015, respectively.

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

	Three Months Ended		
	March 31,	March 31,	Increase
	2016	2015	(Decrease)
Research and development expenses	\$ 13,534	\$ 8,956	\$ 4,578

The increase in research and development expenses in 2016, compared to the same period in 2015, was primarily due to an increase of \$4.2 million for outsourced clinical costs mainly associated with the ongoing VITALITY-ALS trial and an increase of \$1.0 million in personnel related expenses due to increased headcount, partially offset by a decrease of \$0.6 million in outsourced preclinical costs associated with research activities conducted in 2015.

The following presents our research and development expenses by program (in thousands):

	Three Months Ended		
	March 31,	March 31,	Increase
	2016	2015	(Decrease)
Cardiac muscle contractility	\$ 1,743	\$ 1,435	308
Skeletal muscle contractility	11,038	6,376	4,662
All other research programs	753	1,145	(392)
Total research and development expenses	\$ 13,534	\$ 8,956	\$ 4,578

From a program perspective, the increase in research and development spending in the first quarter of 2016, compared to the same period in 2015, was primarily due to increased spending of \$4.6 million for our skeletal muscle contractility program, which included the clinical program for tirasemtiv for the treatment of ALS, and the clinical program for CK-2127107 under our collaboration with Astellas, and an increase of \$0.3 million for our cardiac muscle contractility program, partially offset by a decrease of \$0.4 million for the rest of our other research programs.

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 significantly in 2016 compared to 2015. We expect to continue the Phase 3 clinical development of our drug candidate tirasemtiv for the potential treatment of ALS. Under 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. Under our strategic alliance with Amgen, we expect to continue development of our drug candidate omecamtiv mecarbil for the potential treatment of heart failure.

General and Administrative Expenses

General and administrative expenses were \$6.8 million and \$4.4 million in the first quarter of 2016 and 2015, respectively.

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

	Three Months Ended		
	March 31,	March 31,	Increase
	2016	2015	(Decrease)
General and Administrative expenses	\$ 6,841	\$ 4,367	\$ 2,474

The increase in general and administrative expenses in the first quarter of 2016, compared to the same period in 2015, was primarily due to an increase of \$1.1 million in personnel related expenses due to increased non-cash stock compensation expense and an increase in headcount, an increase of \$0.6 million in outsourced costs mainly related to medical affairs and commercial development, and an increase of \$0.6 million in corporate and patent legal fees.

We anticipate that general and administrative expenses in 2016 will increase significantly compared to 2015, mainly due to increased headcount.

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Interest and Other Income (Expense), Net

Interest expense increased in the first quarter of 2016 compared to the same period in 2015, primarily due to interest expense related to the long-term debt obligations which commenced in fourth quarter 2015.

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, 2015. There has been no material change to our critical accounting policies since then.

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, 2016, we funded our operations through the sale of equity securities, non-equity payments from collaborators, long term debt, capital equipment financings, grants and interest income. Due to our substantial research and development expenditures, we have generated significant operating losses since our inception. Our expenditures are primarily related to research and development activities. As of March 31, 2016, we had available cash, cash equivalents and investments of \$108.6 million.

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 over \$24.0 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. During the three months ended March 31, 2016 and 2015, the Company recognized no revenues for milestones achieved under the Original Astellas Agreement. The \$15.0 million milestone payment which was paid in January 2015 was recognized in 2014.

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. We 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 and will be recognized as revenue as services are performed over approximately 24 months.

We are eligible to potentially receive over \$20.0 million in reimbursement of sponsored research and development activities during the two years of the collaboration following the execution of the Amended Astellas Agreement. 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 \$95.0 million relating to 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.

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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 launch and sales milestones, Cytokinetics may also receive payments for the achievement of pre-specified milestones relating to the joint research program.

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. We 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 deferred and was recognized as revenue as services were performed over approximately 12 months.

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

Amgen and the Company agreed to further extend the term of the research program in 2016. Under the amended Amgen Agreement, we are entitled to receive reimbursements of internal costs for certain full-time employee equivalents during 2016, as well as potential additional milestone payments related to the research activities.

Cantor Fitzgerald

On September 4, 2015, we entered into a \$40.0 million Controlled Equity Offering Sales Agreement (*CE Offering*) with Cantor Fitzgerald & Co., pursuant to which we issue and sold, through March 31, 2016, 808,193 shares for total net proceeds of approximately \$8.7 million. As of April 28, 2016, \$31.3 million remains available to us under the September 2015 Registration Statement.

October 2015 Loan Agreement

On October 19, 2015 and February 10, 2016, we entered into a loan and security agreement (the *Loan Agreement*) with Oxford Finance LLC (*Oxford*,) as the collateral agent and a lender, and Silicon Valley Bank (*SVB*,) as a lender (Oxford and SVB collectively the *Lenders*) to fund our working capital and other general corporate needs, for Term A and term B, respectively. As of March 31, 2016 we received \$29.8 million from these loan and security agreements for Term A and Term B, net of issuance cost. See Note 7, *Long-Term Debt* of the Notes to Consolidated Financial Statements for further details.

Sources and Uses of Cash

Our cash, cash equivalents and investments totaled \$108.6 million at March 31, 2016, compared to \$111.6 million at December 31, 2015. The decrease of \$3.0 million was primarily due to the use of cash to fund operations, partially offset by net proceeds of \$15.0 million received from long-term debt.

Net cash used in operating activities was \$17.5 million in the three months ended March 31, 2016 and was largely due to the ongoing research and development activities. The net loss for the three months ended March 31, 2016 included non-cash stock based compensation of \$1.6 million. At March 31, 2016, deferred revenue of \$16.7 million related largely to the deferral of revenue for Astellas based on the proportional performance model.

Net cash used in investing activities was \$20.2 million in the first three months of 2016 was primarily due to purchases of investments, exceeding proceeds from the maturity of investments, by \$19.7 million.

Net cash provided by financing activities was \$14.9 million in the first three months of 2016 and primarily consisted of net proceeds received of \$15.0 million from long-term debt.

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, 2016, \$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.

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As of March 31, 2016, our contractual obligations are as follows (in thousands):

	Payments Due by Period				Total
	Remainder of 2016	2017-2018	2019-2020	Beyond	
Long-term debt (1)	\$	\$ 12,500	\$ 17,500	\$	\$ 30,000
Interest obligation on long-term debt (2)	\$ 1,721	\$ 4,011	\$ 2,419	\$	\$ 8,151
Operating lease obligations (3)	\$ 2,635	\$ 5,486	\$	\$	\$ 8,121
Total obligations	\$ 4,356	\$ 21,997	\$ 19,919	\$	\$ 46,272

- (1) For further discussion regarding long-term debt, see Note 7, Long-Term Debt of the Notes to Consolidated Financial Statements.
- (2) Interest obligation on long-term debt has been calculated based on the interest rate applicable as of March 31, 2016.
- (3) 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.

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;

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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 \$547.2 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.

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.

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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, 2015.

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 November 28, 2014, Pharm-Olam International, Ltd. (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 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. Pharm-Olam entered into an agreement with Datatrak International Inc. (Datatrak) by which Datatrak provided the core EDC and IWRS system for BENEFIT-ALS. In the North Carolina lawsuit, Pharm-Olam sought

declaratory judgment 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, 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. On September 16, 2015, the U.S. District Court for the Middle District of North Carolina dismissed the North Carolina lawsuit.

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 in connection with its performance as the data management vendor for the BENEFIT-ALS clinical trial. 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. Datatrak filed a motion to intervene on June 5, 2015, which the court granted on July 1, 2015. Datatrak seeks a declaratory judgment that the indemnification provision of the agreement between Pharm-Olam and Datatrak does not require Datatrak to indemnify Pharm-Olam for the claims asserted against Pharm-Olam by Cytokinetics. This is the only pending matter among the parties because the U.S. District Court for the Middle District of North Carolina dismissed the North Carolina lawsuit on September 16, 2015.

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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 through late-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, long term debt, equipment financings, interest on investments, government grants and other 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 3 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.

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Covenants in our loan and security agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient revenue to meet the condition required in order to access the final loan available under the agreement and may also not provide sufficient cash to meet the repayment obligations of our debt incurred under the loan and security agreement.

Our loan and security agreement with Oxford Finance LLC and Silicon Valley Bank provides for up to \$40.0 million in term loans due on October 1, 2020, of which \$30.0 million in term loans has been borrowed to date. All of our current and future assets, except for intellectual property, are secured for our borrowings under the loan and security agreement. The loan and security agreement requires that we comply with certain covenants applicable to us, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the loan and security agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the loan and security agreement. If we are unable to repay those amounts, the lenders under the loan and security agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5.0% penalty and restrict access to additional borrowings under the loan and security agreement. Moreover, our ability to access the final \$10.0 million under the loan and security agreement is subject to our ability to achieve a certain conditions, including certain clinical development milestones or an equity financing milestone, which conditions we may not be able to meet and which could adversely affect our liquidity. In addition, although we expect to borrow additional funds under the loan and security agreement, before we do so, we must first satisfy ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

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

We currently have no drugs for sale and we cannot guarantee that we will ever develop or obtain approval to market any drugs. To receive marketing approval for any drug candidate, we must demonstrate that the drug candidate satisfies rigorous standards of safety and efficacy to the FDA in the United States and other regulatory authorities abroad. We and our partners will need to conduct significant additional research and preclinical and clinical testing before we or our partners can file applications with the FDA or other regulatory authorities for approval of any of our drug candidates. In addition, to compete effectively, our drugs must be easy to use, cost-effective and economical to manufacture on a commercial scale, compared to other therapies available for the treatment of the same conditions. We may not achieve any of these objectives. Currently, our only drug candidates in clinical development are omecantiv 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.

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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 1 clinical trials in healthy volunteers and clinical results from Phase 1 and 2 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 2 clinical trials may not be indicative of the results from later clinical trials. For example, early Phase 2 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 2b 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 on 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 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.

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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 dysathria (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 3 clinical trials evaluating other compounds as potential treatments for patients with ALS may suggest an increased risk that our planned Phase 3 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 3 clinical trials of potential treatments for ALS have failed to demonstrate the requisite efficacy for approval or for their continued development. These include Biogen'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 3 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 3 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.

We have never before conducted a Phase 3 clinical trial nor submitted an application for marketing authorization to regulatory authorities, and may be unable to do so for tirasemtiv or any other drug candidates we are developing.

We are conducting VITALITY-ALS, a Phase 3 clinical trial, designed to assess the effects of tirasemtiv versus placebo on slow vital capacity (SVC) and other measure of respiratory function in patients with ALS. Conducting Phase 3 clinical trials and submitting a successful application for marketing authorization is complex, time consuming and expensive. We have not previously conducted a Phase 3 clinical trial and have limited experience in preparing, submitting and prosecuting a marketing authorization. Consequently, we may be unable to effectively and efficiently execute and complete the trial in a manner that leads to the submission to and approval by regulatory authorities of a marketing application for tirasemtiv. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of products that we develop. Failure to commence or complete, or delays in, our planned clinical trials, would prevent us from or delay us in commercializing tirasemtiv, and other product candidates we are developing.

Neither the FDA nor European regulatory authorities has accepted the primary endpoint in our Phase 3 clinical trial in patients with ALS (a statistically significant reduction in the decline in SVC) as a sufficient measure of clinical significance alone to support regulatory approval of tirasemtiv for the treatment of ALS.

To commercialize tirasemtiv, we must first demonstrate to the satisfaction of the FDA or foreign regulatory authorities that tirasemtiv is sufficiently safe and effective. To date, neither the FDA nor European regulatory authorities has indicated that the primary end point that we have specified in our Phase 3 clinical trial in patients with ALS (change from baseline to 24 weeks in SVC) is, in and of itself, a sufficient measure of clinical significance to establish the efficacy of tirasemtiv. Our Phase 3 clinical trial will also be measuring secondary endpoints of respiratory function and patient condition to provide further evidence of the potential clinical significance of a treatment effect. However, there is no assurance as to which of these secondary endpoints (if any) will be affected even if treatment with tirasemtiv achieves the primary efficacy objective of the trial. Further, there is no assurance as to whether regulatory authorities would accept the outcome of the trial as being a sufficient demonstration of clinical efficacy even if the primary endpoint and all secondary endpoints are achieved. We will continue interactions with regulatory authorities regarding the appropriate assessment(s) of the clinical meaningfulness and potential efficacy of therapy in the ALS population. If the results of our

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Phase 3 clinical trial in ALS are not sufficient to persuade regulatory authorities of the safety and efficacy of tirasemtiv, either because of a failure to achieve pre-specified endpoints or because the authorities do not accept such endpoints as being sufficient, then we would be required to conduct successfully one or more additional Phase 3 clinical trials, prior to receiving marketing authorization, which would be expensive, time consuming and uncertain.

It is not known whether the FDA or other regulatory authorities would accept a single Phase 3 clinical trial as being adequate to support marketing approval of tirasemtiv, even if the results of such trial are positive.

The conventional standard for granting marketing authorization of a new investigational medicine is the demonstration of safety and efficacy in two large, well-controlled Phase 3 clinical trials. The Phase 3 trial of tirasemtiv in ALS that we are currently conducting will be the first Phase 3 trial of this drug candidate. In the case of diseases with high unmet medical need, such as ALS, regulatory authorities may exercise their discretion to approve a new pharmaceutical on the basis of a single outcomes trial (sometimes subject to the conduct of subsequent confirmatory trial(s)). However, this is always within the judgment of the regulatory authorities and is dependent on their assessment of the degree of success achieved in the clinical trial as balanced by the potential risks associated with treatment. Even if our first Phase 3 trial of tirasemtiv shows positive results, regulatory authorities may require us to successfully conduct one or more additional Phase 3 clinical trials prior to receiving marketing authorization, which would be expensive, time consuming and uncertain.

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;

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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 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 3 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 have initiated a Phase 2 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.

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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 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 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

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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;

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

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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 ongoing Phase 2 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 candidates and following approval will be subject to ongoing periodic unannounced inspections by the FDA, the U.S. Drug Enforcement Agency and other regulatory agencies, to ensure strict compliance with current good manufacturing practices and other applicable government regulations and corresponding foreign laws and standards. We seek to ensure that our contract manufacturers comply fully with all applicable regulations, laws and standards. However, we do not have control over our contract manufacturers' compliance with these regulations, laws and standards. If one of our contract manufacturers fails to pass its pre-approval inspection or maintain ongoing compliance at any time, the production of our drug candidates could be interrupted, resulting in delays or discontinuance of our clinical trials, additional costs and potentially lost revenues. In addition, failure of any third party manufacturers or us to comply with applicable regulations, including pre- or post-approval inspections and the current good manufacturing practice requirements of the FDA or other comparable regulatory agencies, could result in sanctions being imposed on us. These sanctions could include fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, 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 through late-stage clinical trials. In order to conduct larger scale 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,

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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.

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 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;

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

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

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

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

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

Changes in either the patent laws or their interpretation in the United States or other countries may diminish the value of our intellectual property or our ability to obtain patents. For example, the 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 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.

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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