CYTOKINETICS INC
Form 10-Q
November 06, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

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	**94-3291317**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
280 East Grand Avenue	
South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x
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 x

Number of shares of common stock, $0.001 par value, outstanding as of October 31, 2014: 36,608,781

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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)

	September 30, 2014 (Unaudited)	December 31, 2013 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,907	$ 20,158
Short-term investments	65,589	57,570
Accounts receivable and related party receivable	1,191	5
Prepaid and other current assets	1,804	1,605
Total current assets	81,491	79,338
Property and equipment, net	1,491	1,221
Long-term investments	4,003	2,502
Other assets	200	127
Total assets	$ 87,185	$ 83,188
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,646	$ 3,709
Accrued liabilities	6,012	8,272
Deferred revenue, current	5,284	14,701
Short-term portion of deferred rent	44	22
Total current liabilities	12,986	26,704
Deferred revenue, non-current	52	1,500
Long-term portion of deferred rent	517	542
Total liabilities	13,555	28,746
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock, $0.001 par value:		
Authorized: 10,000,000 shares; Issued and outstanding, none		
Common stock, $0.001 par value:		
Authorized: 81,500,000 shares;		
Issued and outstanding: 36,608,781 shares at September 30, 2014 and 30,681,624 shares at December 31, 2013	37	31
Additional paid-in capital	579,255	537,001
Accumulated other comprehensive income	24	7
Accumulated deficit	(505,686)	(482,597)

Total stockholders equity	73,630	54,442
Total liabilities and stockholders equity	$ 87,185	$ 83,188

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		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Revenues:				
Research and development revenues from related parties	$ 1,920	$ 564	$ 3,428	$ 1,455
Research and development, grant and other revenues	4,761	2,495	14,189	3,434
License revenues	2,734	1,410	7,565	1,410
Total revenues	9,415	4,469	25,182	6,299
Operating expenses:				
Research and development	11,420	13,445	35,647	35,626
General and administrative	3,993	3,635	12,710	10,999
Total operating expenses	15,413	17,080	48,357	46,625
Operating loss	(5,998)	(12,611)	(23,175)	(40,326)
Interest and other, net	27	23	86	78
Loss before income taxes	(5,971)	(12,588)	(23,089)	(40,248)
Income tax benefit				
Net loss	$ (5,971)	$ (12,588)	$ (23,089)	$ (40,248)
Net loss per share basic and diluted	$ (0.16)	$ (0.43)	$ (0.65)	$ (1.52)
Weighted-average number of shares used in computing net loss per share basic and diluted	36,609	29,395	35,359	26,413
Other comprehensive income:				
Unrealized gains on available-for-sale securities, net	11	19	17	1
Comprehensive loss	$ (5,960)	$ (12,569)	$ (23,072)	$ (40,247)

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)

	Nine Months Ended	
	September 30, 2014	**September 30, 2013**
Cash flows from operating activities:		
Net loss	$ (23,089)	$ (40,248)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	353	345
Stock-based compensation	2,444	2,941
Gain on sale of investments	(6)	
Gain (loss) on disposal of equipment		(2)
Changes in operating assets and liabilities:		
Accounts receivable and related party accounts receivable	(1,185)	4
Prepaid and other assets	(273)	744
Accounts payable	(1,863)	(103)
Accrued and other liabilities	(2,229)	5,162
Related party payables and accrued liabilities		(150)
Deferred revenue	(10,865)	36,018
Net cash provided by (used in) operating activities	(36,713)	4,711
Cash flows from investing activities:		
Purchases of investments	(93,244)	(68,286)
Proceeds from sales and maturities of investments	83,748	61,241
Purchases of property and equipment	(857)	(290)
Proceeds from sales of property and equipment		3
Net cash used in investing activities	(10,353)	(7,332)
Cash flows from financing activities:		
Proceeds from public offerings of common stock, net of issuance costs	39,869	7,450
Payments from stock based award activities and warrants, net	(54)	(478)
Net cash provided by financing activities	39,815	6,972
Net increase (decrease) in cash and cash equivalents	(7,251)	4,351
Cash and cash equivalents, beginning of period	20,158	14,907
Cash and cash equivalents, end of period	$ 12,907	$ 19,258

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 and Summary of Significant Accounting Policies

Overview

Cytokinetics, Incorporated (the Company , we or our) was incorporated under the laws of the state of Delaware on August 5, 1997. The Company is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions.

The Company s financial statements contemplate the conduct of the Company s operations in the normal course of business. The Company has incurred an accumulated deficit of $505.7 million since inception and there can be no assurance that the Company will attain profitability. The Company had a net loss of $23.1 million and net cash used in operations of $36.7 million for the nine months ended September 30, 2014. Cash, cash equivalents and investments increased from $80.2 million at December 31, 2013 to $82.5 million at September 30, 2014, principally due to net proceeds received of $37.5 million from the underwritten secondary offering which closed on February 25, 2014, partially offset by cash used by operations. The Company anticipates that it will continue to have operating losses and net cash outflows in future periods.

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

Based on the current status of its research and development plans, the Company believes that its existing cash, cash equivalents and investments at September 30, 2014 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 September 30, 2014, and the results of operations for the three and nine months ended September 30, 2014 and the cash flows for the nine months ended September 30, 2014. 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, 2013 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, 2013, as filed with the SEC on March 7, 2014.

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Comprehensive Loss

Comprehensive loss for the three and nine months ended September 30, 2014 was equal to net loss adjusted for unrealized gains on investments.

Reverse Stock Split

On June 24, 2013, the Company effected a one-for-six reverse stock split of its common stock through an amendment to its amended and restated certificate of incorporation (the COI Amendment). As of the effective time of the reverse stock split, every six shares of the Company s issued and outstanding common stock were converted into one issued and outstanding share of common stock, without any change in par value per share. The reverse stock split affected all shares of the Company s common stock outstanding immediately prior to the effective time of the reverse stock split, as well as the number of shares of common stock available for issuance under the Company s equity incentive plans. In addition, the reverse stock split effected a reduction in the number of shares of common stock issuable upon the conversion of shares of preferred stock or upon the exercise of stock options or warrants outstanding immediately prior to the effectiveness of the reverse stock split. No fractional shares were issued as a result of the reverse stock split. Stockholders who would otherwise have been entitled to receive a fractional share received cash payments in lieu thereof. In addition, the COI Amendment reduced the number of authorized shares of common stock to 81.5 million.

As the par value per share of the Company s common stock remained unchanged at $0.001 per share, a total of $139,000 was reclassified from common stock to additional paid-in capital. All references to shares of common stock and per share data for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

Recently Adopted Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (FASB) issued Accounting Statement Update (ASU) 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*. ASU 2013-11 amends accounting guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or tax credit carryforward exists. This new guidance requires entities, if certain criteria are met, to present an unrecognized tax benefit, or portion of an unrecognized tax benefit, in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward when such items exist in the same taxing jurisdiction. The Company adopted ASU 2013-11 effective January 1, 2014 and the adoption of ASU 2013-11 did not have a material effect on its financial statements.

Accounting Pronouncements Not Yet Adopted

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 upon its financial statements.

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

In April 2014, the FASB issued ASU 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*. ASU 2014-08 changes the criteria for determining which disposals can be presented as discontinued operations and modifies related disclosure requirements. This new guidance is effective for the Company beginning January 1, 2015. The Company does not expect the adoption of ASU 2014-08 to have a material effect upon its financial statements.

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Note 2. Net Loss Per Share

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

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Net loss	$ (5,971)	$ (12,588)	$ (23,089)	$ (40,248)
Weighted-average common shares outstanding (weighted average number of shares used in computing net loss per share) basic and diluted	36,609	29,395	35,359	26,413
Net loss per share basic and diluted	$ (0.16)	$ (0.43)	$ (0.65)	$ (1.52)

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 and Nine Months Ended	
	September 30, 2014	September 30, 2013
Options to purchase common stock	3,301	2,452
Warrants to purchase common stock	6,691	7,692
Restricted stock units	64	42
Shares issuable related to the ESPP	31	31
Total shares	10,087	10,217

All references to shares of common stock and per share data for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis. Refer to Reverse Stock Split in Note 1 for further detail.

Note 3. Supplemental Cash Flow Data

There was no cash paid for interest and no cash paid for taxes, for the periods presented. Supplemental cash flow data was as follows (in thousands):

	Nine Months Ended	
	September 30, 2014	September 30, 2013
Significant non-cash investing and financing activities:		
Purchases of property and equipment through accounts payable	$ 200	$ 110
Purchases of property and equipment through accrued liabilities	33	29
Conversion of convertible preferred stock to common stock		13,626

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.

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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 million in June 2013. Under the Amgen Agreement Amendment, the Company conducted a Phase I pharmacokinetic study intended to support inclusion of Japan in a potential Phase III clinical development program and potential global registration dossier for omecamtiv mecarbil. Amgen will reimburse 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 is recognized as revenue as revenue criteria is satisfied, or as services are 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.

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 the nine months ended September 30, 2014, the Company recognized $0.2 million of the previously deferred consideration attributable to the Amgen Agreement Amendment as research and development revenues from related parties. At September 30, 2014, the Company had $0.1 million of deferred revenue related to consideration allocated to research and development services pursuant to the Amgen Agreement Amendment.

Under the Amgen Agreement, as amended, the Company is eligible for potential pre-commercialization and commercialization milestone payments exceeding $650 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. None of the future contingent milestone payments pursuant to this arrangement are considered substantive as they are dependent upon Amgen s performance. Therefore, they are not considered milestones under ASC 605-28. The Amgen Agreement also provides for the Company to receive increased royalties by co-funding Phase III 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.

Research and development revenues from Amgen were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Reimbursement of internal costs	$ 1,747	$ 564	$ 3,210	$ 1,455
Allocated consideration	173		218	
Total research and development revenues from related parties	$ 1,920	$ 564	$ 3,428	$ 1,455

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

	September 30, 2014	December 31, 2013
Related party accounts receivable Amgen	$ 1,169	$

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Note 5. Other Research and Development Revenue Arrangements

Astellas Pharma Inc. (Astellas)

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

Under the 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. CK-2127107, which is currently in Phase I clinical development, is being developed jointly by the Company and Astellas. The Company is primarily responsible for the conduct of Phase I clinical trials and certain Phase II readiness activities for CK-2127107 and Astellas will be primarily responsible for the conduct of subsequent development and commercialization activities for CK-2127107.

The companies are jointly conducting research to identify next-generation skeletal muscle activators to be nominated as potential drug candidates, at Astellas expense, over a two-year term, which may be extended by the companies mutual consent. Astellas has the exclusive rights to develop and commercialize fast skeletal troponin activators from this research program in non-neuromuscular indications and to develop and commercialize other novel mechanism skeletal muscle activators from this research program in all indications, subject to certain co-development and co-promotion rights of the Company under the Astellas Agreement. Astellas is responsible for the costs associated with the development of all collaboration products, including CK-2127107.

The Company retains an option to conduct early-stage development for certain agreed upon indications at its initial expense, subject to reimbursement if development continues under the collaboration. The Company also retains an option to co-promote collaboration products in the United States and Canada. Astellas will reimburse the Company for certain expenses associated with its co-promotion activities.

In July 2013, the Company received an upfront, non-refundable license fee of $16 million in connection with the execution of the Astellas Agreement, and is eligible to potentially receive approximately $25.5 million in reimbursement of sponsored research and development activities during the initial two years of the collaboration. Based on the achievement of pre-specified criteria, the Company may receive over $250 million in milestone payments relating to the development and commercial launch of collaboration products, including up to $112 million in development and commercial launch milestones for CK-2127107. The Company may also receive up to $200 million in payments for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Astellas Agreement. In the event Astellas commercializes any collaboration products, the Company 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. In addition to the foregoing development, commercial launch and sales milestones, the Company may also receive payments for the achievement of pre-specified milestones relating to the joint research program. The Company retains the exclusive right to develop and commercialize another skeletal muscle activator, tirasemtiv, for the potential treatment of amyotrophic lateral sclerosis and other neuromuscular disorders independently from the Astellas Agreement.

At the inception of the Astellas Agreement, the Company deferred revenue related to the 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 is deferred with revenue for the license fee being 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. During the three and nine months ended September 30, 2014, the Company recorded $2.7 and $7.6 million in license revenue, respectively, based on the proportional performance model. As of September 30, 2014, the Company has recognized $11.4 million of the $16 million upfront license fee as license revenue, and has $4.6 million of deferred license revenue under the Astellas Agreement.

Pursuant to the Astellas Agreement, the Company has recognized research and development revenue from Astellas for reimbursements of internal costs of certain full-time employee equivalents, supporting collaborative research and development programs, and of other costs related to those programs. During the three and nine months ended September 30, 2014, the Company recorded research and development revenue from Astellas of $2.9 million and $7.1 million, respectively, related to the reimbursement of internal costs and $1.9 million and $5.0 million, respectively, related to the reimbursement of other costs.

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The Company recognizes substantive milestone payments utilizing the milestone method of revenue recognition. The Company concluded that the milestones related to research and early development under the Astellas Agreement are substantive, since there is uncertainty that the milestones will be met, the milestones can only be achieved with the Company s past and current performance, and the achievement of the milestones will result in additional payment to the Company. For the nine months ended September 30, 2014, the Company earned $2.0 million in a milestone payment from Astellas related to CK-2127107. Milestone payments earned under this agreement are classified as research and development revenue.

The Company believes that the future milestones, if any, related to subsequent development and commercialization are not substantive as they are primarily the result of Astellas performance and therefore will be recognized as the Company completes its performance obligations under the agreement.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Reimbursement of internal cost	$ 2,895	$ 1,191	$ 7,092	$ 1,191
Reimbursements of other costs	1,866	1,118	5,023	1,118
Research and development milestone fees			2,000	
Total research and development revenue from Astellas	$ 4,761	$ 2,309	$ 14,115	$ 2,309

At September 30, 2014, the Company had $5.3 million of deferred revenue under the Astellas Agreement, reflecting the unrecognized portion of the license revenue and unearned revenue relating to reimbursements of internal and other costs.

MyoKardia, Inc.

In August 2012, the Company entered into a collaboration agreement with MyoKardia, Inc. Under an agreed research plan, scientists from MyoKardia and our employees conducted research focused on small molecule therapeutics that inhibit cardiac sarcomere proteins. The Company provided MyoKardia access to certain research facilities, and employees and other resources at agreed reimbursement rates that approximated our costs. The Company was the primary obligor in the collaboration arrangement, and accordingly, recorded expense reimbursements from MyoKardia as research and development revenue. The research plan terminated as planned in August 2013.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Expense reimbursements from MyoKardia	$	$ 179	$	$ 1,024

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Note 6. Marketable Securities

Marketable securities consisted of the following (in thousands):

		September 30, 2014				
		Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Maturity Dates
Cash equivalents	money market funds	$ 10,629	$	$	$ 10,629	
Short-term investments	U.S. Treasury securities	$ 65,567	$ 22	$	$ 65,589	10/2014-9/2015
Long-term investments	U.S. Treasury securities	$ 4,001	$ 2	$	$ 4,003	10/2015-11/2015

		December 31, 2013				
		Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Maturity Dates
Cash equivalents	money market funds	$ 15,858	$	$	$ 15,858	
Short-term investments	U.S. Treasury securities	$ 57,564	$ 7	$ (1)	$ 57,570	1/2014-12/2014
Long-term investments	U.S. Treasury securities	$ 2,502	$	$	$ 2,502	1/2015

Marketable securities consist primarily of debt securities of United States government agencies and money market funds and are classified as available for sale. Available for sale securities are reported at fair value based on quoted market prices, with unrealized gains and losses reported in accumulated other comprehensive income (loss) within stockholders equity. The cost of a security sold or the amount reclassified out of accumulated other comprehensive income (loss) into earnings is determined using specific identification. The Company may pay a premium or receive a discount upon the purchase of marketable securities. Interest earned and gains/losses realized on marketable securities and amortization of discounts received and accretion of premiums paid on the purchase of marketable securities are included in investment income/expense. Refer to Note 7, Fair Value Measurements, for further details.

Interest income was as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Interest income from marketable securities	$ 26	$ 23	$ 78	$ 74

Note 7. Fair Value Measurements

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

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

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

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

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

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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 September 30, 2014 and December 31, 2013 were classified in one of the three categories described above as follows (in thousands):

	September 30, 2014			
	Fair Value Measurements Using			Assets
	Level 1	Level 2	Level 3	At Fair Value
Money market funds	$ 10,629	$	$	$ 10,629
U.S. Treasury securities	69,592			69,592
Total	$ 80,221	$	$	$ 80,221
Amounts included in:				
Cash and cash equivalents	$ 10,629	$	$	$ 10,929
Short-term investments	65,589			65,589
Long-term investments	4,003			4,003
Total	$ 80,221	$	$	$ 80,221

	December 31, 2013			
	Fair Value Measurements Using			Assets
	Level 1	Level 2	Level 3	At Fair Value
Money market funds	$ 15,858	$	$	$ 15,858
U.S. Treasury securities	60,072			60,072
Total	$ 75,930	$	$	$ 75,930
Amounts included in:				
Cash and cash equivalents	$ 15,858	$	$	$ 15,858
Short-term investments	57,570			57,570
Long-term investments	2,502			2,502
Total	$ 75,930	$	$	$ 75,930

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 September 30, 2014 and December 31, 2013, the Company had no financial assets measured at fair value on a recurring basis using significant Level 2 or Level 3 inputs.

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

Note 8. Stockholders Equity (Deficit)

Accumulated Other Comprehensive Income

In the first nine months of 2014, the Company reclassified insignificant amounts of unrealized gains on investments from accumulated other comprehensive income into net loss.

Common Stock Outstanding

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

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Warrants

As of September 30, 2014, the Company had warrants outstanding to purchase 6.7 million shares of the Company s common stock. These warrants were issued pursuant to an April 2011 securities purchase agreement (the Deerfield Agreement) with Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited (collectively, Deerfield); and pursuant to the June 2012 underwriting agreements the Company entered into in connection with two separate, concurrent offerings for our securities (the June 2012 Public Offerings).

In February 2014, warrants to purchase 1,000 shares of the Company s common stock, which were issued pursuant to the June 2012 Public Offerings, at an exercise price of $5.28 per share, were cash exercised. In April 2014, the Company issued 509,125 shares of common stock related to cashless exercises of warrants that were issued pursuant to the June 2012 Public Offerings.

Outstanding warrants as of September 30, 2014 were as follows:

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

MLV

In June 2011, the Company entered into an At-The-Market Issuance Sales Agreement (the MLV Agreement) with McNicoll, Lewis & Vlak LLC (MLV.) In January 2014, the Company sold 364,103 shares of common stock through MLV for net proceeds of approximately $2.4 million. As of January 8, 2014, the Company had sold 2,397,278 shares of common stock, the maximum allowable under the MLV Agreement and therefore, no shares remain available to the Company for sale through MLV.

Stock Option Plans

Stock option activity for the nine months ended September 30, 2014 under the Company s 2004 Equity Incentive Plan, as amended, and the Company s 1997 Stock Option/Stock Issuance Plan was as follows:

	Shares Available for Grant of Options or Awards	Stock Options Outstanding	Weighted Average Exercise Price per Share of Stock Options
Balance at December 31, 2013	2,161,829	2,449,365	$15.15
Options granted	(920,881)	920,881	8.91
Options exercised		(390)	6.00
Options forfeited	12,928	(12,928)	7.31
Options expired	56,205	(56,205)	44.55
Restricted stock units granted	(43,500)		
Balance at September 30, 2014	1,266,581	3,300,723	$12.94

Restricted stock unit activity for the nine months ended September 30, 2014 was as follows:

	Number of Shares	Weighted Average Award Date Fair Value per Share

Restricted stock units outstanding at December 31, 2013	41,663	$6.00
Restricted stock units granted	43,500	9.65
Restricted stock units released	(20,833)	6.00
Unvested restricted stock units outstanding at September 30, 2014	64,330	$8.47

The Company measures compensation expense for restricted stock units at fair value on the grant date and recognizes the expenses over the expected vesting period. The fair value for restricted stock units is based on the closing price of the Company s common stock on the grant date. Unvested restricted stock awards are subject to repurchase at no cost to the Company. Restricted stock activities were limited to non-executive employees for the nine months ended September 30, 2014.

All references to shares of common stock and per share data for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis. Refer to Reverse Stock Split in Note 1 for further detail.

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Note 9. Interest and Other, Net

Interest income and other income 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. The Company recognizes rent expense on a straight-line basis over the lease period. Rent expense for the three months ended September 30, 2014 and 2013 was $0.8 million, respectively. Rent expense for the nine months ended September 30, 2014 and 2013 was $2.5 million, respectively.

Contingencies

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

Note 11. Income Taxes

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 2014;

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

our capital requirements and needs for additional financing;

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

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

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

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

our and our partners plans or ability to conduct the continued research and development of our drug candidates and other compounds;

our expected roles in research, development or commercialization under our strategic alliances with Amgen and Astellas;

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

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

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

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

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

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

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

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

expected future sources of revenue and capital;

losses, costs, expenses and expenditures;

future payments under loan and lease obligations;

potential competitors and competitive products;

retaining key personnel and recruiting additional key personnel;

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

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

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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 Slow Vital Capacity as an appropriate clinical trial endpoint to support the registration of tirasemtiv for the treatment of ALS;
- Amgen s decisions with respect to the timing, design and conduct of research and development activities for omecamtiv mecarbil and related compounds, including decisions to postpone or discontinue research or development activities relating to omecamtiv mecarbil and related compounds;
- Astellas decisions with respect to the timing, design and conduct of research and development activities for CK-2127107 and other skeletal muscle activators, including decisions to postpone or discontinue research or development activities relating to CK-2127107 and other skeletal muscle activators;
- our ability to enter into strategic partnership agreements for any of our programs on acceptable terms and conditions or in accordance with our planned timelines;
- our ability to obtain additional financing on acceptable terms, if at all;
- our receipt of funds and access to other resources under our current or future strategic alliances;
- difficulties or delays in the development, testing, manufacturing or commercialization of our drug candidates;
- difficulties or delays, or slower than anticipated patient enrollment, in our or partners clinical trials;
- difficulties or delays in the manufacture and supply of clinical trial materials;
- failure by our contract research organizations, contract manufacturing organizations and other vendors to properly fulfill their obligations or otherwise perform as expected;
- results from non-clinical studies that may adversely impact the timing or the further development of our drug candidates and other compounds;
- the possibility that the U.S. Food and Drug Administration (FDA) or foreign regulatory agencies may delay or limit our or our partners ability to conduct clinical trials or may delay or withhold approvals for the manufacture and sale of our products;

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

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

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

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

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

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

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

potential ownership changes under Internal Revenue Code Section 382; and

the timeliness and accuracy of information filed with the U.S. Securities and Exchange Commission (the SEC) by third parties.

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

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

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

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Overview

We were incorporated in Delaware in August 1997 as Cytokinetics, Incorporated. We are a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Our research and development activities relating to the biology of muscle function have evolved from our knowledge and expertise regarding the cytoskeleton, a complex biological infrastructure that plays a fundamental role within every human cell. Our most advanced research and development programs relate to the biology of muscle function and are directed to small molecule modulators of the contractility of skeletal or cardiac muscle. Our earlier-stage research is directed to other compounds with the potential to modulate muscle contractility and other muscle functions, such as growth, energetics and metabolism.

Our drug candidates currently in clinical development are our skeletal muscle activators tirasemtiv and CK-2127107, and our cardiac muscle activator omecamtiv mecarbil. Tirasemtiv is being evaluated for the potential treatment of ALS and other neuromuscular disorders. CK-2127107 is being evaluated for the potential treatment of non-neuromuscular indications associated with skeletal muscle weakness. Omecamtiv mecarbil is being evaluated for the potential treatment of heart failure.

Muscle Contractility Programs

Skeletal Muscle Contractility Program

Tirasemtiv is the lead drug candidate from this program, and is the subject of a Phase II clinical trials program. Cytokinetics holds the exclusive rights to tirasemtiv. We are also developing another drug candidate from this program, CK-2127107, in collaboration with Astellas Pharma Inc. (Astellas) for potential non-neuromuscular indications associated with muscle weakness. 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 potential indications for which tirasemtiv and CK-2127107 may be useful.

Tirasemtiv

BENEFIT-ALS (Blinded Evaluation of Neuromuscular Effects and Functional Improvement with Tirasemtiv in ALS): In October 2012, we initiated BENEFIT-ALS, a Phase IIb, multi-national, double-blind, randomized, placebo-controlled, clinical trial designed to evaluate the safety, tolerability and efficacy of tirasemtiv in patients with ALS. BENEFIT-ALS enrolled patients in 73 centers in 8 countries. Patients enrolled in BENEFIT-ALS began treatment with open-label tirasemtiv at 125 mg twice daily. Patients who tolerated this open-label treatment for one week were randomized to receive 12 weeks of double-blind treatment with twice-daily oral ascending doses of tirasemtiv or placebo, beginning at 125 mg twice daily and increasing weekly up to 250 mg twice daily (or a dummy dose titration with placebo). Clinical assessments occurred every four weeks during double-blind treatment; patients also returned for follow-up evaluations at one and four weeks after their final dose of double-blind study medication. The primary efficacy analysis of BENEFIT-ALS compared the mean change from baseline in the ALS Functional Rating Scale in its revised form (ALSFRS-R) to the average of the scores obtained after 8 and 12 weeks of double-blind treatment on tirasemtiv versus placebo.

In April 2014, BENEFIT-ALS results were presented at the American Academy of Neurology (AAN) in Philadelphia, PA. In this trial, 711 patients with amyotrophic lateral sclerosis (ALS) were enrolled into the open-label phase of the trial; subsequently 605 patients were randomized 1:1 to double-blind treatment with either tirasemtiv or placebo for 12 weeks. BENEFIT-ALS did not achieve its primary efficacy endpoint, the mean change from baseline in the ALSFRS-R (-2.98 points in the tirasemtiv group versus -2.40 points in the placebo group; $p = 0.11$).

Treatment with tirasemtiv resulted in a statistically significant and potentially clinically meaningful reduction in the decline of Slow Vital Capacity (SVC), a measure of the strength of the skeletal muscles responsible for breathing. SVC has been shown to be an important predictor of disease progression and survival in prior trials of patients with ALS. At week 12, the decline in SVC from baseline was -3.12 for patients receiving tirasemtiv versus -8.66 for those receiving placebo ($p < 0.0001$). From week 0 to week 12, the slope of decline in SVC measured as percentage points per day was -0.0394 for patients receiving tirasemtiv versus -0.0905 for those receiving placebo ($p = 0.0006$).

The analyses of other pre-specified secondary efficacy endpoints in BENEFIT-ALS produced mixed results. The Muscle Strength Mega-Score, a measure of strength combining the data from several muscle groups in each patient, declined more slowly on tirasemtiv versus placebo. The difference in the rate of decline for Sniff Nasal Inspiratory Pressure (SNIP) was not statistically significant); however, SNIP decreased more on tirasemtiv compared with placebo in a statistically significant manner at 4 and 12 weeks. No differences in Maximum Voluntary Ventilation and

Hand Grip Fatigue were observed on tirasemtiv versus placebo.

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Serious adverse events (SAEs) during double-blind treatment were more frequent on tirasemtiv than on placebo (9.0% vs. 5.4%). The most common SAE was respiratory failure which occurred in 1 patient on tirasemtiv and 3 patients on placebo. Confusional state and delirium occurred in 2 patients on tirasemtiv and no patients on placebo. More patients on tirasemtiv withdrew from the trial following randomization than on placebo (99 vs. 33 patients, respectively). Adverse events more common on tirasemtiv than on placebo (>10% difference) were dizziness, fatigue, and nausea.

In May 2014, we announced the presentation of further results from BENEFIT-ALS at the Joint Congress of European Neurology. These results indicated that differences in the decline in SVC on tirasemtiv versus placebo observed after 12 weeks of double-blind treatment were maintained for up to 4 weeks after discontinuation of treatment.

In July 2014, we announced the presentation of results from pre-specified subgroup analyses of BENEFIT-ALS at the 13th International Congress on Neuromuscular Diseases. The results indicate that the reduced decline in SVC on tirasemtiv versus placebo was observed consistently across all subgroups of patients in BENEFIT-ALS that were examined.

In October 2014, we announced that we had completed our review of results from BENEFIT-ALS and concluded that effects observed on SVC in patients treated with *tirasemtiv* were robust and potentially clinically meaningful. In addition, following consultation with clinical and statistical experts, we believe that data from BENEFIT-ALS support progression of *tirasemtiv* to a potential Phase III clinical trial in patients with ALS. We have begun regulatory interactions with the FDA regarding results from BENEFIT-ALS and have received initial feedback from the FDA. We believe that effects on SVC could be a Phase III clinical trial endpoint and could support registration of *tirasemtiv* as a potential treatment for patients with ALS. As a result, we have initiated planning for a potential Phase III clinical trial of *tirasemtiv* that could begin in 2015.

Other Activities. During the first nine months of 2014, we made preparations for the potential further development and commercialization of tirasemtiv. These activities included interactions with regulatory authorities and other manufacturing, corporate development and commercial planning activities to support planning scenarios.

We intend to seek damages from our data management vendor for the study drug assignment error caused by a programming error in the electronic data capture system that occurred during the BENEFIT-ALS trial in 2013.

CK-2127107 and Other Skeletal Muscle Activators

Astellas Strategic Alliance. In June 2013, we entered into a collaboration and license agreement with Astellas (the Astellas Agreement). Under the Astellas Agreement, we granted Astellas an exclusive license to co-develop and jointly commercialize CK-2127107 for potential application in non-neuromuscular indications associated with skeletal muscle weakness worldwide. CK-2127107 is being developed jointly by Cytokinetics and Astellas. Cytokinetics is primarily responsible for the conduct of Phase I clinical trials and certain Phase II readiness activities for CK-2127107. Astellas will be primarily responsible for the conduct of subsequent development and commercialization activities for CK-2127107.

The companies are jointly conducting research to identify next-generation skeletal muscle activators to be nominated as potential drug candidates, at Astellas expense. Astellas has the exclusive rights to develop and commercialize fast skeletal troponin activators from this research program in non-neuromuscular indications and to develop and commercialize other novel mechanism skeletal muscle activators from this research program in all indications, subject to certain Cytokinetics co-development and co-promotion rights. Astellas will be responsible for the costs associated with the development of all collaboration products, including CK-2127107.

Under the Astellas Agreement, we retain an option to conduct early-stage development for certain agreed indications at our initial expense, subject to reimbursement if development continues under the collaboration. We also retain an option to co-promote collaboration products in the United States and Canada. Astellas will reimburse us for certain expenses associated with our co-promotion activities.

In July 2013, we received an upfront payment of $16 million in connection with the execution of the Astellas Agreement. We are eligible to potentially receive approximately $25.5 million in reimbursement of sponsored research and development activities during the initial two years of the collaboration. During the three and nine months ended September 30, 2014, we recorded $2.7 million and $7.6 million, respectively, of license revenue and $4.8 million and $14.1 million, respectively, in reimbursement of sponsored research and development activities. Based on the achievement of pre-specified criteria, we may receive over $250 million in milestone payments relating to the development and commercial launch of collaboration products, including up to $112 million in development and commercial launch milestones for CK-2127107. We may also receive up to $200 million in payments for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Astellas Agreement. If Astellas commercializes any collaboration products, we 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. In addition to these development, commercial launch and sales milestones, we may also receive payments for the achievement of pre-specified milestones relating to the joint research program.

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In the first nine months of 2014, we recognized $2.0 million in milestone revenue relating to CK-2127107 development activities. Research and development milestone payments are classified as research and development revenue in the statement of operations.

CK-2127107: Current Clinical Development

In October 2014, we announced the completion of five Phase I clinical trials evaluating CK-2127107 in healthy volunteers, and certain other Phase II readiness activities, all in connection with the agreed development plan under our collaboration with Astellas. The Phase I clinical trials demonstrated that CK-2127107 appeared well-tolerated in healthy volunteers and that exposures generally increased across dose ranges studied. CK-2127107 increased the response of muscle to neuromuscular input in a dose and plasma concentration related fashion in healthy volunteers consistent with preclinical observations. In addition, an oral tablet formulation of CK-2127107 appears appropriate for use in Phase II clinical trials.

CY 5011 was a double-blind, randomized, placebo-controlled study designed to assess the safety, tolerability, and pharmacokinetics of single ascending oral doses of CK-2127107 administered to healthy adult males. Planned single doses of CK-2127107 up to 4000 mg, the highest dose administered in this trial, were well-tolerated without an emerging pattern of adverse events observed; therefore, a maximum tolerated dose could not be defined. The pharmacokinetic profile of CK-2127107 was linear and dose-proportional across the dose range studied with a mean terminal half-life compatible with once or twice daily dosing.

CY 5012 was a double-blind, randomized, placebo-controlled, parallel group study. The primary objective of CY 5012 was to assess the safety, tolerability, and pharmacokinetics of CK-2127107 following multiple ascending doses in healthy volunteers. This clinical trial consisted of three ascending dose cohorts of 12 young volunteers (ages 18-55), and two ascending dose cohorts of 12 elderly volunteers (ages 65-85), split evenly between men and women. In each cohort, volunteers received CK-2127107 or placebo in accordance with 2:1 randomization over a 10-day period. This clinical trial demonstrated that a 10-day course of CK-2127107, either 300 mg or 500 mg twice daily, was well-tolerated by both younger (18-55 years) and older (65-85 years) subjects. Plasma concentrations of CK-2127107 achieved steady state and no differences in pharmacokinetics between younger and older subjects were observed.

CY 5013 was a Phase I randomized, placebo-controlled, single dose, 4-period crossover study of CK-2127107 in healthy male volunteers. CY 5013 was designed to evaluate the change in the force-frequency profile and its relationship to dose and plasma concentrations of CK-2127107. This clinical trial demonstrated that the response of skeletal muscle to nerve input increased with both the dose and plasma concentration of CK-2127107 and were most evident in the middle of the range of stimulation frequencies tested, consistent with preclinical observations. Compared to pre-dose measurements, statistically significant, placebo-corrected increases in skeletal muscle function were demonstrated at every time point tested after dosing. This clinical trial demonstrated that CK-2127107 amplified the response of muscle to nerve activation following a single dose of CK-2127107 in these subjects and that the results observed in preclinical models were translated into humans.

CY 5014 was a Phase I clinical trial of CK-2127107 in healthy male volunteers. CY 5014 was a randomized, open-label, two-period crossover study designed to assess the relative oral bioavailability, pharmacokinetics, safety and tolerability of two oral formulations of CK-2127107. This clinical trial demonstrated that single doses of CK-2127107 in suspension, dosed at 300 mg and 1000 mg, were well-tolerated by all 25 healthy men enrolled and provided pharmacokinetic data on two different physical forms of CK-2127107 to inform ongoing development of tablet formulations for use in potential future trials.

CY 5015 was an open-label, randomized, single dose study designed to evaluate the pharmacokinetics, in a fed and fasted state, of an oral tablet form of CK-2127107 in healthy male volunteers. This clinical trial demonstrated that single doses of CK-2127107, administered at doses of 250 mg, 500 mg and 1000 mg, were well-tolerated and appeared appropriate for use in potential future clinical trials.

Other Development. We expect to conduct additional activities for CK-2127107 pursuant to our collaboration agreement with Astellas.

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 Astellas Agreement, Astellas will reimburse us for certain research activities we perform.

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The clinical trials programs for each of tirasemtiv and 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.

Tirasemtiv and CK-2127107 are each at too early a stage of development for us to predict if or when this may occur. Our expenditures will increase if and as we move tirasemtiv into later development. Our expenditures will also 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. We anticipate that our expenditures relating to the research and development of compounds in our skeletal muscle contractility program will increase significantly if and as we advance tirasemtiv, CK-2127107 or other compounds from this program into and through development.

Cardiac Muscle Contractility Program

Our lead drug candidate from this program is omecamtiv mecarbil, a novel cardiac muscle myosin activator. We expect omecamtiv mecarbil to be developed as a potential treatment across the continuum of care in heart failure both as an intravenous formulation for use in the hospital setting and as an oral formulation for use in the outpatient setting.

Amgen Strategic Alliance. In December 2006, we entered into a collaboration and option agreement with Amgen Inc. 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 million in June 2013. Under the Amgen Agreement Amendment, we conducted a Phase I pharmacokinetic study (CY 1211) intended to support inclusion of Japan in a potential Phase III clinical development program and potential global registration dossier for omecamtiv mecarbil. Amgen will reimburse 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 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 has agreed to certain trading and other restrictions with respect to our common stock. During the three and nine months ended September 30, 2014, we recorded $1.9 million and $3.4 million, respectively, in reimbursement of sponsored research and development activities relating to the Amgen Agreement.

Under the Amgen Agreement, as amended, we are eligible for potential pre-commercialization and commercialization milestone payments exceeding $650 million in the aggregate on omecamtiv mecarbil and other potential products arising from research under the collaboration, and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. The Amgen Agreement also provides for us to receive increased royalties by co-funding Phase III development costs of omecamtiv mecarbil and other drug candidates under the collaboration. If we elect to co-fund such costs, we would be entitled to co-promote the co-funded drug in North America and participate in agreed commercialization activities in institutional care settings, at Amgen s expense.

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.

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Omecamtiv Mecarbil: Current Clinical Development

In March 2013, we announced the initiation of dosing of patients in COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure). COSMIC-HF is a Phase II, double-blind, randomized, placebo-controlled, multicenter, dose escalation study designed to evaluate several modified-release oral formulations of omecamtiv mecarbil in patients with heart failure and left ventricular systolic dysfunction. COSMIC-HF is being conducted by Amgen in collaboration with Cytokinetics. Cytokinetics and Amgen reviewed results from the dose escalation phase of COSMIC-HF and selected an oral formulation of omecamtiv mecarbil for evaluation in the expansion phase of the trial.

In the first quarter of 2014, the expansion phase of COSMIC-HF opened to enrollment. The expansion phase of COSMIC-HF will enroll approximately 450 patients from approximately 95 clinical sites internationally. Patients will be randomized 1:1:1 to receive placebo, 25 mg, or 50 mg twice daily of omecamtiv mecarbil. Escalation to the 50 mg dose will depend on the plasma concentration of omecamtiv mecarbil following 2 weeks of oral dosing at 25 mg twice daily. The primary objective of the expansion phase of this trial is to characterize the safety, tolerability, and pharmacokinetics of omecamtiv mecarbil dosed orally during 20 weeks of treatment. The secondary objectives are to assess the changes from baseline in systolic ejection time, stroke volume, left ventricular end-systolic diameter, left ventricular end-diastolic diameter, heart rate and N-terminal pro-brain natriuretic peptide (a biomarker associated with the severity of heart failure) during 20 weeks of treatment. Over 275 patients have been enrolled towards the objective of 450 patients in the ongoing expansion phase of the trial. In addition, over 70 patients have completed dosing in the expansion phase of COSMIC-HF. Recently, the Data Monitoring Committee reviewed data from COSMIC-HF and recommended that the trial continue without any changes to the protocol. Patient enrollment in COSMIC-HF is expected to conclude by the end of 2014.

During the fourth quarter of 2014, we announced that CY 1211, a Phase I study comparing the tolerability and pharmacokinetics of *omecamtiv mecarbil* between Japanese and Caucasian healthy volunteers, is complete and indicates no clinically meaningful differences between the two groups studied. Data from CY 1211 are expected to inform plans for the development of *omecamtiv mecarbil* in Japan and the inclusion of Japan in potential global Phase III program activities. This trial was conducted by Cytokinetics in collaboration with Amgen. The costs of the trial will be reimbursed by Amgen.

Ongoing Research in Cardiac Muscle Contractility. In 2013, we agreed with Amgen to additional research activities intended to be conducted through 2014 under the research plan directed to next-generation compounds in our cardiac muscle contractility program. Under the Amgen Agreement, Amgen will reimburse us for certain activities we perform.

The clinical trials program for omecamtiv mecarbil may proceed for several years, and we will not be in a position to generate any revenues or material net cash flows from sales of this drug candidate until the program is successfully completed, regulatory approval is achieved, and the drug is commercialized. Omecamtiv mecarbil is at too early a stage of development for us to predict if or when this may occur. We funded all research and development costs associated with this program prior to Amgen s option exercise in May 2009. We anticipate that our expenditures relating to the research and development of compounds in our cardiac muscle contractility program will increase if we participate in the future advancement of omecamtiv mecarbil through clinical development. Our expenditures will also increase if Amgen terminates development of omecamtiv mecarbil or related compounds and we elect to develop them independently, or if we elect to co-fund later-stage development of omecamtiv mecarbil or other compounds in our cardiac muscle contractility program under our collaboration and option agreement with Amgen.

Beyond Muscle Contractility

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

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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 Slow Vital Capacity as an appropriate clinical trial endpoint to support the registration of tirasemtiv for the treatment of ALS;
- decisions made by Amgen with respect to the development of 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;

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

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

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

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Results of Operations

Revenues

Total revenues were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2014	September 30, 2014	September 30, 2013
Research and development revenues from related parties	$ 1,920	$ 564	$ 3,428	$ 1,455
Research and development, grants and other revenues	4,761	2,495	14,189	3,434
License revenues	2,734	1,410	7,565	1,410
Total revenues	$ 9,415	$ 4,469	$ 25,182	$ 6,299

We recorded total revenues of $9.4 million and $4.5 million for the third quarter of 2014 and 2013, respectively and $25.2 million and $6.3 million for the first nine months of 2014 and 2013, respectively.

Research and development revenues from related parties for the third quarter and first nine months of 2014 and 2013 consisted of research and development revenues from our strategic collaboration with Amgen. Research and development revenues from Amgen were $1.9 million and $0.6 million for the third quarter of 2014 and 2013, respectively, and in both periods consisted of reimbursements of internal costs and other research and development expenses. Research and development revenues from Amgen were $3.4 million and $1.5 million for the first nine months of 2014 and 2013, respectively, and in both periods consisted of reimbursements of internal costs and other research and development expenses. The research activities under our collaboration with Amgen are anticipated to continue through December 2014.

Research and development, grant and other revenues were $4.8 million and $2.5 million for the third quarter of 2014 and 2013, respectively. Research and development, grant and other revenues in the third quarter of 2014 included reimbursement of internal costs from Astellas of $2.9 million and reimbursement of third party costs from Astellas of $1.9 million. Research and development, grant and other revenues in the third quarter of 2013 included research and development revenues from Astellas of $2.3 million and from MyoKardia, Inc. of $0.2 million. Our contract with MyoKardia ended in August 2013.

Research and development, grant and other revenues were $14.2 million and $3.4 million for the first nine months of 2014 and 2013, respectively. Research and development, grant and other revenues in the first nine months of 2014 included reimbursement of internal costs from Astellas of $7.1 million, reimbursement of third party costs from Astellas of $5.0 million, milestone revenues from Astellas of $2.0 million and grant revenue of $0.1 million. Research and development, grant and other revenues in the first nine months of 2013 included research and development revenues from Astellas of $2.3 million, grant revenue of $0.1 million and research and development revenues from MyoKardia of $1.0 million.

License revenues were $2.7 million and $7.6 million for the third quarter and the first nine months of 2014, respectively, and consisted of recognition of a portion of the $16.0 million upfront license fee received from Astellas in July 2013, using the proportional performance model. The Astellas collaboration began in July 2013; license revenues relating to this collaboration in the third quarter and the first nine months of 2013 were $1.4 million. The research activities with Astellas are anticipated to continue through June 2015 under the current agreement.

We anticipate that revenue for the full year 2014 will be in the range of $29 million to $31 million.

Research and Development Expenses

Research and development expenses were $11.4 million and $13.4 million in the third quarter of 2014 and 2013, respectively. The $2.0 million decrease in research and development expenses in the third quarter of 2014, compared to the same period in 2013, was primarily due to a decrease of $2.7 million in outsourced clinical costs partially offset by an increase of $0.6 million in personnel expenses.

From a program perspective, the $2.0 million decrease in spending in the third quarter of 2014, compared to the same period in 2013, was primarily due to decreased spending of $4.0 million for our skeletal muscle contractility program partially offset by increases of $1.9 million for

our cardiac muscle contractility program.

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Research and development expenses were $35.6 million in the first nine months of 2014 and 2013, respectively. Increases of $2.4 million in outsourced pre-clinical costs, $0.4 million in outsourced research costs, $2.1 million in personnel expenses and $0.2 million in lab expenses were offset by a decrease of $5.2 million in outsourced clinical costs.

From a program perspective, spending in the first nine months of 2014 was approximately equal to the same period in 2013, due to increased spending of $3.1 million for our cardiac muscle contractility program offset by decreases of $1.4 million for our skeletal muscle contractility program and $1.6 million for our other research and preclinical programs.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Cardiac muscle contractility	$ 2.8	$ 0.9	$ 5.5	$ 2.5
Skeletal muscle contractility	7.6	11.6	27.2	28.6
All other research programs	1.0	0.9	2.9	4.5
Total research and development expenses	$ 11.4	$ 13.4	$ 35.6	$ 35.6

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 to continue development of our drug candidate tirasemtiv for the potential treatment of ALS. As part of our strategic alliance with Astellas, we expect to continue development of our drug candidate CK-2127107 for the potential treatment of non-neuromuscular indications associated with muscle weakness or wasting. As part of our strategic alliance with Amgen, we expect to continue development of our drug candidate omecamtiv mecarbil for the potential treatment of heart failure. We anticipate that research and development expenses in 2014 will increase compared to 2013 and will be in the range of $47 million to $50 million. Non-cash expenses such as stock-based compensation and depreciation of approximately $1.5 million are included in our estimate of 2014 research and development expenses.

General and Administrative Expenses

General and administrative expenses were $4.0 million and $3.6 million in the third quarter of 2014 and 2013, respectively. The increase in the third quarter of 2014, compared to the same period in 2013, was primarily due to increases of $0.2 million in personnel expenses.

General and administrative expenses were $12.7 million and $11.0 million in the first nine months of 2014 and 2013, respectively. The increase in the first nine months of 2014, compared to the same period in 2013, was primarily due to increases of $1.4 million in outside services costs related to commercial development and $0.4 million in personnel expenses, partially offset by a decrease of $0.2 million in legal expenses.

We anticipate that general and administrative expenses in 2014 will increase compared to 2013 and will be in the range of $18 million to $21 million. Non-cash expenses such as stock-based compensation and depreciation of approximately $2.1 million are included in our estimate of 2014 general and administrative expenses.

Interest and Other, Net

Interest income and other income increased in the third quarter and first nine months of 2014 compared to the same periods in 2013, due principally to higher average invested balances and higher interest rates in the current year periods.

Income Taxes

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

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The significant jurisdictions in which we file income tax returns are the United States and the state of California. For jurisdictions in which tax filings are made, we are subject to income tax examination for all fiscal years since inception. 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. We believe that we maintain adequate reserves for uncertain tax positions.

In general, under Internal Revenue Code Section 382 (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. We have performed a Section 382 analysis and do not believe that we have experienced an ownership change since 2006. A portion of our existing NOLs and tax credits are subject to limitations arising from previous ownership changes. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 and result in additional limitations.

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, 2013. 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 September 30, 2014, we funded our operations through the sale of equity securities, equipment financings, non-equity payments from collaborators, grants and interest income.

February 2014 Public Offering

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

Amgen Agreement Amendment

In June 2013, we entered into the Amgen Agreement Amendment, which expanded our strategic alliance to include Japan (see Note 4, Related Party Research and Development Arrangements in the Notes to Unaudited Condensed Consolidated Financial Statements). Under the terms of the Amgen Agreement Amendment, we received a non-refundable upfront license fee of $15 million in June 2013. In conjunction with the Amgen Agreement Amendment, we also entered into a common stock purchase agreement pursuant to which we sold 1,404,100 shares common stock to Amgen at a price per share of $7.12. The aggregate purchase price of $10.0 million was received in June 2013. 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 will be recognized as revenue as services are performed over approximately 12 months.

Astellas Agreement

In June 2013, we entered into the Astellas Agreement (see Note 5, Other Research and Development Revenue Arrangements , in the Notes to Unaudited Condensed Consolidated Financial Statements). In July 2013, we received an upfront non-refundable license payment of $16 million in connection with the execution of the Astellas Agreement. We are eligible to potentially receive approximately $25.5 million in reimbursement of sponsored research and development activities during the initial two years of the collaboration. In addition, we may also receive payments for the achievement of pre-specified milestones relating to the joint research program. In the first nine months of 2014, we recognized revenue of $2.0 million relating to Astellas Agreement milestones.

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MLV

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

Sources and Uses of Cash

Our cash, cash equivalents and investments totaled $82.5 million at September 30, 2014, compared to $80.2 million at December 31, 2013. The increase of $2.3 million was primarily due to by net proceeds received of $37.5 million from the February 2014 public offering partially offset by the use of cash to fund operations.

Net cash used in operating activities was $36.7 million in the nine months of 2014 was largely due to the ongoing research and development activities and recognition of deferred revenue for which payment had been received in prior periods. The net loss for the nine months ended September 30, 2014 included non-cash stock based compensation of $2.4 million. At September 30, 2014, deferred revenue of $5.3 million related largely to the deferral of revenue for Astellas based on the proportional performance model. Net cash provided by operating activities was $4.7 million in the first nine months of 2013 and primarily resulted from cash received from licensing transactions partially offset by the net loss of $40.2 million.

Net cash used in investing activities was $10.4 million in the first nine months of 2014 was primarily due to purchases of investments, exceeding proceeds from the maturity of investments, by $9.5 million. Net cash used in investing activities was $7.3 million in the first nine months of 2013 and primarily consisted cash used to purchase investments, net of proceeds from the maturity of investments, of $7.0 million.

Net cash provided by financing activities was $39.8 million in the first nine months of 2014 and primarily consisted of net proceeds of $37.5 million from the February 2014 public offering and net proceeds of $2.4 million from sales of our common stock through MLV. Net cash provided by financing activities was $7.0 million in the first nine months of 2013 and primarily consisted of the purchase of stock by Amgen (see Note 4, Related Party Research and Development Arrangements , in the Notes to Unaudited Condensed Consolidated Financial Statements).

Shelf Registration Statements. In November 2011, we filed a shelf registration statement with the SEC, which was declared effective in December 2011 (the December 2011 Shelf). The December 2011 Shelf allowed us to issue securities from time to time for an aggregate offering price of up to $100.0 million. In June 2012, we filed a supplemental shelf registration statement with the SEC, which was declared effective in June 2012 (the Supplemental Shelf). The Supplemental Shelf allows us to issue additional securities from time to time for an aggregate offering price of up to $20.0 million, and for a total aggregate offering price under the December 2011 Shelf and the Supplemental Shelf of up to $120.0 million. As of October 31, 2014, $18.3 million remains available to us under these shelf registration statements. The specific terms of offerings, if any, under these shelf registration statements will be established at the time of such offerings.

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 October 31, 2014, $109.8 million remains available to us under the December 2013 Shelf. The specific terms of offerings, if any, under the December 2013 Shelf will be established at the time of such offerings.

As of September 30, 2014, future minimum payments under our lease obligations were as follows (in thousands):

	Within One Year	One to Three Years	Three to Five Years	After Five Years	Total
Operating leases (1)	$ 852	$ 7,057	$ 5,619	$	$ 13,528

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

In future periods, we expect to incur substantial costs as we continue to expand our research programs and related research and development activities. We plan to continue 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 non-neuromuscular 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

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muscle myosin activator omecamtiv mecarbil for the potential treatment of heart failure and research of potential next-generation compounds as part of our strategic alliance with Amgen. We 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 s decisions with regard to funding of development and commercialization of CK-2127107 or other skeletal muscle activators under our collaboration;
- our level of funding for the development of current or future drug candidates;
- the number of drug candidates we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our ability to establish and maintain selected strategic alliances required for the development of drug candidates and commercialization of our potential drugs;
- our plans or ability to expand our drug development capabilities, including our capabilities to conduct clinical trials for our drug candidates;
- our plans or ability to engage third party manufacturers for our drug candidates and potential drugs;
- our plans or ability to build or access sales and marketing capabilities and to achieve market acceptance for potential drugs;
- the expansion and advancement of our research programs;

the hiring of additional employees and consultants;

the expansion of our facilities;

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

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

We have incurred an accumulated deficit of $505.7 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

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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.

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, 2013.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

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

(b) Changes in internal control over financial reporting

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

(c) Limitations on the effectiveness of controls

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

In evaluating our business, you should carefully consider the following risks in addition to the other information in this report. Any of the following risks could materially and adversely affect our business, results of operations, financial condition or your investment in our securities, and many are beyond our control. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also adversely affect our business.

Risks Related To Our Business

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

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

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

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

For the foreseeable future, our operations will require significant additional funding, in large part due to our research and development expenses and the absence of any revenues from product sales. For example, we will require significant additional funding to enable us to conduct further development of tirasemtiv for the potential treatment of ALS. Until we can generate a sufficient amount of product revenue, we expect to raise future capital through strategic alliance and licensing arrangements, public or private equity offerings and debt financings. We do not currently have any commitments for future funding other than reimbursements, milestone and royalty payments that we may receive under our collaboration agreements with Amgen and Astellas. We may not receive any further funds under those agreements. Our ability to raise funds may be adversely impacted by current economic conditions. As a result of these and other factors, we do not know whether additional financing will be available when needed, or that, if available, such financing would be on terms favorable to our stockholders or us.

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

If we cannot raise the funds we need to operate our business, we will need to delay or discontinue certain research and development activities. For example, if we cannot raise the funds necessary to enable the conduct of further development for tirasemtiv for the potential treatment of ALS, our ability to continue the development of tirasemtiv will be delayed or suspended. If we delay or discontinue research and development activities, our stock price may be negatively affected.

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

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 omecamtiv mecarbil for the potential treatment of heart failure, tirasemtiv for the potential treatment of ALS and other neuromuscular disorders and CK-2127107 for the potential treatment of 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.

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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 been demonstrated to be safe and effective in clinical trials and they may never be. In addition, for each of our preclinical compounds, we or our partners must adequately demonstrate satisfactory chemistry, formulation, stability and toxicity in order to submit an investigational new drug application (IND) to the FDA, or an equivalent application in foreign jurisdictions, that would allow us to advance that compound into clinical trials. Furthermore, we or our partners may need to submit separate INDs (or foreign equivalent) to different divisions within the FDA (or foreign regulatory authorities) in order to pursue clinical trials in different therapeutic areas. Each new IND (or foreign equivalent) must be reviewed by the new division before the clinical trial under its jurisdiction can proceed, entailing all the risks of delay inherent to regulatory review. If our or our partners current or future preclinical studies or clinical trials are unsuccessful, our business will be significantly harmed and our stock price could be negatively affected.

All of our drug candidates are prone to the risks of failure inherent in drug development. Preclinical studies may not yield results that would adequately support the filing of an IND (or a foreign equivalent) with respect to our potential drug candidates. Even if the results of preclinical studies for a drug candidate are sufficient to support such a filing, the results of preclinical studies do not necessarily predict the results of clinical trials. As an example, because the physiology of animal species used in preclinical studies may vary substantially from other animal species and from humans, it may be difficult to assess with certainty whether a finding from a study in a particular animal species will result in similar findings in other animal species or in humans. For any of our drug candidates, the results from Phase I clinical trials in healthy volunteers and clinical results from Phase I and II trials in patients are not necessarily indicative of the results of later and larger clinical trials that are necessary to establish whether the drug candidate is safe and effective for the applicable indication. Likewise, interim results from a clinical trial may not be indicative of the final results from that trial, and results from early Phase II clinical trials may not be indicative of the results from later clinical trials. For example, early Phase II clinical trials of tirasemtiv in patients with ALS showed encouraging dose-related trends in measurements of the ALS Functional Rating Scale in its revised form (ALSFRS-R) for patients receiving tirasemtiv compared to those receiving placebo. However, BENEFIT-ALS, a Phase IIb clinical trial of tirasemtiv in patients with ALS, did not achieve its primary efficacy endpoint, the mean change from baseline in the ALSFRS-R for patients receiving tirasemtiv compared to those receiving placebo.

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

Furthermore, in view of the uncertainties inherent in drug development, such clinical trials may not be designed with focus on indications, patient populations, dosing regimens, 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. 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. Preclinical 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

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ingredient. These toxicities or adverse events could delay or prevent the filing of an IND (or a foreign equivalent) with respect to our drug candidates or potential drug candidates or cause us, our partners or the FDA or foreign regulatory authorities to modify, suspend or terminate clinical trials with respect to any drug candidate at any time during the development program. Further, the administration of two or more drugs contemporaneously can lead to interactions between them, and our drug candidates may interact with other drugs that trial subjects are taking. For example, co-administration of tirasemtiv and riluzole (an approved treatment for ALS) approximately doubles the average maximum riluzole plasma level. If the adverse events are severe or frequent enough to outweigh the potential efficacy of a drug candidate, the FDA or other regulatory authorities could deny approval of that drug candidate for any or all targeted indications. Even if one or more of our drug candidates were approved for sale as drugs, the occurrence of even a limited number of toxicities or adverse events when used in large populations may cause the FDA or foreign regulatory authorities to impose restrictions on, or stop, the further marketing of those drugs. Indications of potential adverse events or toxicities which do not seem significant during the course of clinical trials may later turn out to actually constitute serious adverse events or toxicities when a drug is used in large populations or for extended periods of time.

We have observed certain adverse events in the clinical trials conducted with our drug candidates. For example, in BENEFIT-ALS, adverse events of dizziness, fatigue, nausea, confusional state, muscle spasms, somnolence (sleepiness), decreased appetite, headache, insomnia, dyspnea (difficulty breathing) and 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.

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 clinical trials could be delayed or prevented by many factors, including, but not limited to:

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

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

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

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

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

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

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

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

lack of effectiveness of our drug candidates during clinical trials;

unforeseen safety issues;

inadequate supply, or delays in the manufacture or supply, of clinical trial materials;

uncertain dosing issues;

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

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

failure by our clinical research organizations, clinical manufacturing organizations and other third parties supporting our 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 III development costs of omecamtiv mecarbil under the collaboration. However, we

cannot control whether Amgen will devote sufficient attention and resources to the development of omecamtiv mecarbil or will proceed in an expeditious manner, even if we do exercise our option to co-fund the development of omecamtiv mecarbil. Even if the FDA or other regulatory agencies approve omecamtiv mecarbil, Amgen may elect not to proceed with the commercialization of the resulting drug in one or more countries.

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

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

In June 2013, we entered into a 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.

As part of the strategic alliance, we granted Astellas an exclusive license to co-develop and commercialize CK-2127107 for potential application in non-neuromuscular indications worldwide. Following Cytokinetics conduct of Phase I clinical trials and certain Phase II readiness activities for CK-2127107, Astellas will be primarily responsible for the conduct of subsequent development and commercialization activities for CK-2127107. Astellas may elect not to continue development of CK-2127107 following Cytokinetics completion of these activities. In such event, we would need significant additional funding to continue the development of CK-2127107 on our own, which may not be available on attractive or acceptable terms, if at all, and we would be limited in the indications that we could pursue with this drug candidate.

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. 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 and Canada. 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 two-year research term. 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 the 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.

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Our ability to commercialize drugs that we develop with our partners and that generate royalties from product sales depends on our partners abilities to assist us in establishing the safety and efficacy of our drug candidates, obtaining and maintaining regulatory approvals and achieving market acceptance of the drugs once commercialized. Our partners may elect to delay or terminate development of one or more drug candidates, independently develop drugs that could compete with ours or fail to commit sufficient resources to the marketing and distribution of drugs developed through their strategic alliances with us. Our partners may not proceed with the development and commercialization of our drug candidates with the same degree of urgency as we would because of other priorities they face. In addition, new business combinations or changes in a partner s business strategy may adversely affect its willingness or ability to carry out its obligations under a strategic alliance.

If we are not able to successfully maintain our existing strategic alliances or establish and successfully maintain additional strategic alliances, we will have to limit the size or scope of, or delay or discontinue, one or more of our drug development programs or research programs, or undertake and fund these programs ourselves. Alternatively, if we elect to continue to conduct any of these drug development programs or research programs on our own, we will need to expand our capability to conduct clinical development by bringing additional skills, technical expertise and resources into our organization. This would require significant additional funding, which may not be available to us on acceptable terms, or at all.

To the extent we elect to fund the development of a drug candidate, such as omecamtiv mecarbil, tirasemtiv or CK-2127107, or the commercialization of a drug at our expense, we will need substantial additional funding.

The discovery, development and commercialization of new drugs is costly. As a result, to the extent we elect to fund the development of a drug candidate, such as omecamtiv mecarbil, tirasemtiv or CK-2127107, or the commercialization of a drug, we will need to raise additional capital to:

- fund clinical trials and seek regulatory approvals;
- expand our development capabilities;
- engage third party manufacturers for such drug candidate or drug;
- build or access commercialization capabilities;
- implement additional internal systems and infrastructure;
- maintain, defend and expand the scope of our intellectual property; and
- hire and support additional management and scientific personnel.

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

- the rate of progress and costs of our 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

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they devote to our programs. CROs may not assign as high a priority to our programs or pursue them as diligently as we would if we were undertaking these programs ourselves. The activities conducted by our CROs therefore may not be completed on schedule or in a satisfactory manner. CROs may also give higher priority to relationships with our competitors and potential competitors than to their relationships with us. Outside of the United States, we are particularly dependent on our CROs expertise in communicating with clinical trial sites and regulatory authorities and ensuring that our clinical trials and related activities and regulatory filings comply with applicable laws.

Our CROs failure to carry out development activities on our behalf as agreed and in accordance with our and the FDA s or other regulatory agencies requirements and applicable U.S. and foreign laws, or our failure to properly coordinate and manage these activities, could increase the cost of our operations and delay or prevent the development, approval and commercialization of our drug candidates. For example, in June 2013, we learned from our data management vendor for our BENEFIT-ALS clinical trial that a programming error in the electronic data capture system controlling study drug assignment caused 58 patients initially randomized to and treated with tirasemtiv to receive placebo instead at a certain trial visit and for the remainder of the trial. In order to maintain the originally intended statistical power of the trial, we amended the protocol to permit enrollment of approximately 680 patients, or 180 patients in addition to the 500 patients allowed under the existing protocol. This protocol amendment resulted in additional costs and delays in conducting BENEFIT-ALS. In addition, if a CRO fails to perform as agreed, our ability to collect damages may be contractually limited. If we fail to effectively manage the CROs carrying out the development of our drug candidates or if our CROs fail to perform as agreed, the commercialization of our drug candidates will be delayed or prevented.

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

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates. We have limited experience in drug formulation and manufacturing, and we lack the resources and the capabilities to manufacture any of our drug candidates on a clinical or commercial scale. Amgen has assumed responsibility to conduct these activities for the ongoing development of omecamtiv mecarbil worldwide. Following our conduct of the Phase I clinical trials for CK-2127107, Astellas will assume responsibility to conduct these activities 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.

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

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

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

The mechanisms of action of our drug candidates 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

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applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. In particular:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we or our licensors might not have been the first to file patent applications for the inventions covered by our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- some or all of our or our licensors pending patent applications may not result in issued patents or the claims that issue may be narrow in scope and not provide us with competitive advantages;
- our and our licensors issued patents may not provide a basis for commercially viable drugs or therapies or may be challenged and invalidated by third parties;
- our or our licensors patent applications or patents may be subject to interference, opposition or similar administrative proceedings that may result in a reduction in their scope or their loss altogether;
- we may not develop additional proprietary technologies or drug candidates that are patentable; or
- the patents of others may prevent us or our partners from discovering, developing or commercializing our drug candidates.

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

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

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

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

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

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

Other future products of ours may be impacted by patents of companies engaged in competitive programs with significantly greater resources. Further development of these products could be impacted by these patents and result in significant legal fees.

If a third party claims that our actions infringe its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including, but not limited to:

- infringement and other intellectual property claims that, even if meritless, can be costly and time-consuming to litigate, delay the regulatory approval process and divert management s attention from our core business operations;
- substantial damages for past infringement which we may have to pay if a court determines that our drugs or technologies infringe a third party s patent or other proprietary rights;
- a court prohibiting us from selling or licensing our drugs or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do; and
- if a license is available from a holder, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

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

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

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

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

Inventions discovered under our current or future strategic alliance agreements may become jointly owned by our strategic partners and us in some cases, and the exclusive property of one of us in other cases. Under some circumstances, it may be difficult to determine who owns a

particular invention or whether it is jointly owned, and disputes could arise regarding ownership or use of those inventions. These disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions. In addition, our research collaborators and clinical investigators generally have contractual rights to publish data arising from their work. Publications by our research collaborators and clinical investigators relating to our research and development programs, either with or without our consent, could benefit our current or potential competitors and may impair our ability to obtain patent protection or protect our proprietary information, which could significantly harm our business.

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

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

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

We compete with companies that have developed drugs or are developing drug candidates for cardiovascular diseases, diseases and conditions associated with muscle weakness or wasting and other diseases for which our drug candidates may be useful treatments. For example, if tirasemtiv is approved for marketing by the FDA or other regulatory authorities for the treatment of ALS, it may then compete with other potential new therapies for ALS that are currently being developed by companies such as Mitsubishi Tanabe Pharma Corporation, Eisai Inc., Trophos SA, Neuraltus Pharmaceuticals, Inc., Isis Pharmaceuticals, Inc., Genervon Biopharmaceuticals, Inc., MediciNova, Inc., and GlaxoSmithKline plc. In addition, BrainStorm Cell Therapeutics and Neuralstem, Inc. are each conducting clinical development of stem cell therapies for the potential treatment of ALS. If CK-2127107 is approved by the FDA for the potential treatment of non-neuromuscular indications associated with muscle weakness, potential competitors include Ligand Pharmaceuticals, Inc., which is developing LGD-4033, a selective androgen receptor modulator, for muscle wasting; GTx, Inc., which is developing ostarine, a selective androgen receptor modulator, for cancer cachexia and potentially other indications; Regeneron Pharmaceuticals, Inc. (in collaboration with Sanofi), which is developing SAR391786, a monoclonal antibody targeted to GDF8, for sarcopenia; Eli Lilly & Company, which is developing LY2495655, a monoclonal antibody targeted to myostatin, for muscular atrophy after hip arthroplasty; Acceleron Pharma, which is developing ACE-083 for diseases such as inclusion body myositis and certain forms of muscular dystrophy; and Pfizer Inc., which is developing PF-06252616, a monoclonal antibody targeted to myostatin, in Duchenne muscular dystrophy. Novartis (in collaboration with Morphosys AG), is conducting clinical development with an activin type-IIB receptor antagonist, bimagrumab, to evaluate its ability to treat diseases involving the loss of muscle mass, strength and function. Depending on the indication(s) that may be selected for Phase II clinical development of CK-2127107, additional drugs with other mechanisms may compete with CK-2127107 for reimbursement and patient resources. Drugs that could compete with CK-2127107 could also compete against tirasemtiv in ALS or other neuromuscular diseases, should the appropriate clinical trials be conducted.

If omecamtiv mecarbil is approved for marketing by the FDA for heart failure, it would compete against other drugs used for the treatment of acute and chronic heart failure. These include generic drugs, such as milrinone, dobutamine or digoxin and branded drugs such as Natrecor (nesiritide). Omecamtiv mecarbil could also potentially compete against other novel drug candidates and therapies in development, such as bucindolol, which is being developed by ARCA biopharma, Inc.; Reasanz (serelaxin) and LCZ-696, which are being developed by Novartis; cenderitide (CD-NP), which is being developed by Capricor Therapeutics, Inc.; TRV-027, which is being developed by Trevena; ularitide, which is being developed by Cardiorentis Ltd.; aladorian, which is being developed by Armgo Pharma, Inc; TRV027, which is being developed by Trevena, Inc. in partnership with Forest Laboratories, Inc.; certain cardioprotectants which are being developed by Cardioxyl Pharmaceuticals, Inc.; glial growth factor (GGF-2) which is being developed by Acorda Therapeutics, Inc.; Neurocardin, which is being developed by Zensun Sci & Tech, Ltd; Mydicar, a genetically-targeted enzyme replacement therapy for advanced heart failure which is being developed by Celladon Corporation; and levosimendan, which was recently acquired for development by Oxygen Biotherapeutics, Inc. In addition, there are a number of medical devices being developed for the potential treatment of heart failure.

Our competitors may:

- develop drug candidates and market drugs that are less expensive or more effective than our future drugs;
- commercialize competing drugs before we or our partners can launch any drugs developed from our drug candidates;
- hold or obtain proprietary rights that could prevent us from commercializing our products;

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

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

more effectively negotiate third-party licenses and strategic alliances;

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

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

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

We will compete for market share against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their partners, may develop new drug candidates that will compete with ours. Many of these competitors have larger research and development programs or substantially greater financial resources than we do. Our competitors may also have significantly greater experience in:

developing drug candidates;

undertaking preclinical testing and clinical trials;

building relationships with key customers and opinion-leading physicians;

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

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

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

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

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

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

Our future success will depend in large part upon our ability to attract and retain highly skilled personnel. In light of our continued need for funding and cost control, we may be required to implement future workforce and expense reductions, which could further limit our research and development activities. For example, in October 2011, we reduced our workforce by approximately 18% in order to reduce expenses and to

focus resources primarily on our later-stage development programs for tirasemtiv and omecamtiv mecarbil and certain other research and development programs also directed to muscle biology. These headcount reductions and the cost control measures we have implemented may negatively affect our productivity and limit our research and development activities. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce reductions. In addition, the implementation of any additional workforce or expense reduction programs may divert the efforts of our management team and other key employees, which could adversely affect our business.

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

We may have growth in our expenditures, the number of our employees and the scope of our operations, in particular with respect to those drug candidates that we elect to develop or commercialize independently or together with a partner. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our

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facilities and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

Risks Related To Our Industry

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

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

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

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

- they might determine that a drug candidate is not safe or effective;
- they might not find the data from preclinical testing and clinical trials sufficient and could request that additional trials be performed;
- they might not approve our, our partner s or the contract manufacturer s processes or facilities; or
- they might change their approval policies or adopt new regulations.

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

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If we or our partners receive regulatory approval for our drug candidates, we or they will be subject to ongoing obligations to and continued regulatory review by the FDA and foreign regulatory agencies, and may be subject to additional post-marketing obligations, all of which may result in significant expense and limit commercialization of our potential drugs.

Any regulatory approvals that we or our partners receive for our drug candidates may be subject to limitations on the indicated uses for which the drug may be marketed or require potentially costly post-marketing follow-up studies or compliance with a REMS. In addition, if the FDA or foreign regulatory agencies approves any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, or the discovery that adverse events or toxicities observed in preclinical research or clinical trials that were believed to be minor actually constitute much more serious problems, may result in restrictions on the marketing of the drug or withdrawal of the drug from the market.

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

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

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

- introduction of competitive drugs to the market;
- clinical safety and efficacy of alternative drugs or treatments;
- cost-effectiveness;
- availability of coverage and reimbursement from health maintenance organizations and other third-party payors;
- convenience and ease of administration;
- prevalence and severity of adverse events;
- other potential disadvantages relative to alternative treatment methods; or
- insufficient marketing and distribution support.

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

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

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

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

The use of our drug candidates in clinical trials may result in adverse events. We cannot predict all the possible harms or adverse events that may result from our clinical trials. We currently maintain limited product liability insurance. We may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim excluded from, or beyond the limit of, our insurance coverage. Our insurance does not cover third parties negligence or malpractice, and our clinical investigators and sites may have inadequate insurance or none at all. In addition, in order to conduct clinical trials or otherwise carry out our business, we may have to contractually assume liabilities for which we may not be insured. If we are unable to look to our own or a third party s insurance to pay claims against us, we may have to pay any arising costs and damages ourselves, which may be substantial.

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

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

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

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

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

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

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

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

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

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Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Exclusion, suspension and debarment from government funded healthcare programs would significantly impact our ability to commercialize, sell or distribute any drug. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

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

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

Risks Related To an Investment in Our Securities

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

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

- announcements concerning any of the clinical trials for our drug candidates, such as tirasemtiv for the potential treatment of ALS, CK-2127107 for the potential treatment of non-neuromuscular indications associated with muscle weakness and omecamtiv mecarbil for the potential treatment of heart failure (including, but not limited to, the timing of initiation or completion of such trials and the results of such trials, and delays or discontinuations of such trials, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical end points);

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

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

failure or discontinuation of any of our research programs;

issuance of new or changed securities analysts reports or recommendations;

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

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

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

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

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

issues in manufacturing our drug candidates or drugs;

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market acceptance of our drugs;

third-party healthcare coverage and reimbursement policies;

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

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

additions or departures of key personnel;

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

automated trading activity by algorithmic and high-frequency trading programs; and

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

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

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

As of October 31, 2014, our executive officers, directors and their affiliates beneficially owned or controlled approximately 5.6% of the outstanding shares of our common stock (after giving effect to the exercise of all outstanding vested and unvested options, restricted stock units and warrants). Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors perception that conflicts of interest may exist or arise.

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

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

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

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

shares may have a disproportionate effect on the market price of our common stock.

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

As of October 31, 2014, there were 6,691,096 shares of common stock issuable upon the exercise of warrants, having a weighted average exercise price of $6.05 per share, and 3,300,723 shares of common stock issuable upon the exercise of stock options outstanding, having a weighted average exercise price of $12.94 per share. The exercise of outstanding options or warrants for common stock would be substantially dilutive to the outstanding shares of common stock. Any dilution or potential dilution may cause our stockholders to sell their shares, which would contribute to a downward movement in the stock price of our common stock.

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

In general, under Section 382 of the Internal Revenue Code (Section 382), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses and tax credits to offset future taxable income. We have performed a Section 382 analysis and do not believe that we have experienced an ownership change since 2006. A portion of our existing net operating losses and tax credits are subject to limitations arising from previous ownership changes. Future

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changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 and result in additional limitations. We intend to continue to monitor public filings made by third parties with the SEC to assess whether an ownership change under Section 382 has occurred. Our ability to accurately assess any such ownership change is limited by the timeliness and accuracy of these public filings.

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

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

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

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit No.	Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Filing Date	Exh. No.	
3.1	Amended and Restated Certificate of Incorporation.	S-3	333-174869	June 13, 2011	3.1	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation.	10-Q	000-50633	August 4, 2011	3.2	
3.3	Amended and Restated Bylaws.	S-1	333-112261	April 29, 2004	3.2	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	000-50633	April 18, 2011	4.5	
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.	8-K	000-50633	June 20, 2012	4.1	
4.1	Specimen Common Stock Certificate.	10-Q	000-50633	May 9, 2007	4.1	
4.2	Registration Rights Agreement, dated as of December 29, 2006, by and between the Company and Amgen Inc.	8-K	000-50633	January 3, 2007	10.7	
4.3	Form of Warrant to Purchase Common Stock of Cytokinetics, Inc.	8-K	000-50633	April 18, 2011	10.68	
4.4	Form of Common Stock Warrant Agreement	S-3	333-178189	November 25, 2011	4.4	
4.5	Form of Preferred Stock Warrant Agreement	S-3	333-178189	November 25, 2011	4.5	
4.6	Form of Warrant	10-Q	000-50633	August 6, 2012	4.6	
10.45	Compensation Information for the Company s Named Executive Officers.	8-K	000-50633	February 27, 2014	10.1	
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

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SIGNATURES

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

Dated: November 6, 2014

CYTOKINETICS, INCORPORATED
(Registrant)

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

/s/ Sharon A. Barbari
Sharon A. Barbari
Executive Vice President, Finance and

Chief Financial Officer
(Principal Financial Officer)

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