CYTOKINETICS INC Form 10-Q November 06, 2013 Table of Contents

## **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, 2013

or

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

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

Commission file number: 000-50633

CYTOKINETICS, INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

94-3291317 (I.R.S. Employer

incorporation or organization)

**Identification No.)** 

280 East Grand Avenue

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

94080 (Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 25, 2013: 29,503,123.

# CYTOKINETICS, INCORPORATED

# TABLE OF CONTENTS FOR FORM 10-Q

# FOR THE QUARTER ENDED SEPTEMBER 30, 2013

		Page
PART I.	FINANCIAL INFORMATION	3
Item 1.	Financial Statements	3
	Unaudited Condensed Balance Sheets as of September 30, 2013 and December 31, 2012	3
	Unaudited Condensed Statements of Comprehensive Loss for the three and nine months ended	4
	September 30, 2013 and 2012, and the period from August 5, 1997 (date of inception) to	
	<u>September 30, 2013</u>	
	Unaudited Condensed Statements of Cash Flows for the nine months ended September 30, 2013	5
	and 2012, and the period from August 5, 1997 (date of inception) to September 30, 2013	
	Notes to Unaudited Condensed Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	26
Item 4.	Controls and Procedures	26
PART II.	OTHER INFORMATION	26
Item 1.	<u>Legal Proceedings</u>	26
Item 1A.	Risk Factors	26
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	43
Item 3.	<u>Defaults Upon Senior Securities</u>	43
Item 4.	Mine Safety Disclosures	43
Item 5.	Other Information	43
Item 6.	<u>Exhibits</u>	44
SIGNATU	<u>URES</u>	45
<b>EXHIBIT</b>	INDEX	46

# PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

# CYTOKINETICS, INCORPORATED

(A Development Stage Enterprise)

# **CONDENSED BALANCE SHEETS**

(In thousands, except share and per share data)

(Unaudited)

	Sept	tember 30, 2013	Dec	ember 31, 2012
ASSETS				
Current assets:				
Cash and cash equivalents	\$	19,258	\$	14,907
Short-term investments		62,384		59,093
Related party accounts receivable				4
Prepaid and other current assets		1,679		2,423
Total current assets		83,321		76,427
Property and equipment, net		804		997
Long-term investments		3,754		
Other assets		127		127
Total assets	\$	88,006	\$	77,551
LIABILITIES AND STOCKHOLDERS EQUITY				
Current liabilities:				
Accounts payable	\$	1,789	\$	2,002
Accrued liabilities		9,886		4,877
Deferred revenue, current		33,322		
Related party payables and accrued liabilities				150
Short-term portion of deferred rent		14		76
Total current liabilities		45,011		7,105
Deferred revenue, non-current		2,696		
Long-term portion of deferred rent		548		361
Total liabilities		48,255		7,466
Commitments and contingencies				

Stockholders equity:		
Preferred stock, \$0.001 par value:		
Authorized: 10,000,000 shares;		
Issued and outstanding: Series B convertible preferred stock 0 shares at		
September 30, 2013 and 23,026 shares at December 31, 2012		
Common stock, \$0.001 par value:		
Authorized: 81,500,000 shares;		
Issued and outstanding: 29,503,123 shares at September 30, 2013 and		
23,742,911 shares at December 31, 2012	29	24
Additional paid-in capital	528,831	518,923
Accumulated other comprehensive income	19	18
Deficit accumulated during the development stage	(489,128)	(448,880)
Total stockholders equity	39,751	70,085
Total liabilities and stockholders equity	\$ 88.006	\$ 77.551

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

# CYTOKINETICS, INCORPORATED

(A Development Stage Enterprise)

# CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except per share data)

(Unaudited)

	<b>Three Months Ended</b>		Nine Mor	Period from August 5, 1997 (Date of Inception) to	
	September 30 2013	September 30, 2012	September 30, 2013	September 30, 2012	
Revenues:					
Research and development revenues from related parties	\$ 564	\$ 963	\$ 1,455	\$ 3,234	\$ 56,783
Research and development, grant and other revenues	2,495	751	3,434	2,141	12,806
License revenues from related	2,493	731	3,434	2,141	12,000
parties					112,935
License revenues	1,410		1,410		1,410
Electise revenues	1,110		1,110		1,110
Total revenues	4,469	1,714	6,299	5,375	183,934
Operating expenses:					
Research and development	13,445	8,798	35,626	25,785	523,741
General and administrative	3,635	2,991	10,999	8,614	167,380
Restructuring charges (reversals)		(2)		(56)	3,586
Total operating expenses	17,080	11,787	46,625	34,343	694,707
Operating loss	(12,611)	(10,073)	(40,326)	(28,968)	(510,773)
Interest and other, net	23	29	78	54	21,619
Loss before income taxes	(12,588)	(10,044)	(40,248)	(28,914)	(489,154)
Income tax benefit					(26)
Net loss	(12,588)	(10,044)	(40,248)	(28,914)	(489,128)
Deemed dividend related to beneficial conversion feature of					
convertible preferred stock				(1,307)	(4,164)
	\$ (12,588)	\$ (10,044)	\$ (40,248)	\$ (30,221)	\$ (493,292)

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Net loss allocable to common stockholders

Net loss per share allocable to common stockholders basic and diluted	\$ (0.43)	\$ (0.45)	\$ (1.52)	\$ (1.86)	
Weighted-average number of shares used in computing net loss per share allocable to common stockholders basic and diluted	29,395	22,360	26,413	16,215	
Comprehensive loss	\$ (12,569)	\$ (10,030)	\$ (40,247)	\$ (28,904)	\$ (489,109)

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

# CYTOKINETICS, INCORPORATED

(A Development Stage Enterprise)

# CONDENSED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Mon	nths Ended	Period from August 5, 1997 (Date of Inception) to September		
	September 30, 2013	September 30, 2012	30, 2013		
Cash flows from operating activities:					
Net loss	\$ (40,248)	\$ (28,914)	\$ (489,128)		
Adjustments to reconcile net loss to net cash used in					
operating activities:					
Depreciation and amortization of property and equipment	345	462	29,599		
Loss on disposal of equipment	(2)	(2)	297		
Non-cash impairment charges		(= c)	103		
Non-cash restructuring expenses, net of reversals		(56)	636		
Non-cash interest expense			504		
Non-cash forgiveness of loans to officers			434		
Stock-based compensation	2,941	2,876	39,069		
Non-cash warrant expense			1,626		
Other non-cash expenses			141		
Changes in operating assets and liabilities:					
Related party accounts receivable	4	14	(351)		
Prepaid and other assets	744	(1,056)	(1,834)		
Accounts payable	(103)	334	1,935		
Accrued and other liabilities	5,162	(89)	10,166		
Related party payables and accrued liabilities	(150)	(12)			
Deferred revenue	36,018	129	36,018		
Net cash provided by (used in) operating activities	4,711	(26,314)	(370,785)		
Cash flows from investing activities:					
Purchases of investments	(68,286)	(81,513)	(1,120,529)		
Proceeds from sales and maturities of investments	61,241	45,950	1,034,468		
Proceeds from sales of auction rate securities			20,025		
Purchases of property and equipment	(290)	(66)	(31,451)		
Proceeds from sales of property and equipment	3	2	146		
Decrease in restricted cash		196			

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Issuance of related party notes receivable			(1,146)
Proceeds from repayments of notes receivable			859
Net cash used in investing activities	(7,332)	(35,431)	(97,628)
	, ,	, , ,	, , ,
Cash flows from financing activities:			
Proceeds from initial public offering, sale of common stock			
to related party, and public offerings, net of issuance costs	7,450	43,678	257,998
Proceeds from draw down of committed equity financing			
facilities and at-the-market facility, net of commission and			
issuance costs		2,819	58,095
Proceeds from other issuances of common stock and			
warrants, net	(478)	(361)	17,301
Proceeds from issuance of preferred stock, net of issuance			
costs		12,318	154,819
Repurchase of common stock			(68)
Proceeds from loan with UBS			12,441
Repayment of loan with UBS			(12,441)
Proceeds from equipment financing lines			23,696
Repayment of equipment financing lines		(152)	(24,170)
Net cash provided by financing activities	6,972	58,302	487,671
Net increase (decrease) in cash and cash equivalents	4,351	(3,443)	19,258
Cash and cash equivalents, beginning of period	14,907	18,833	.,
	,	-,	
Cash and cash equivalents, end of period	\$ 19,258	\$ 15,390	\$ 19,258

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

## CYTOKINETICS, INCORPORATED

(A Development Stage Enterprise)

#### NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

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

#### **Overview**

Cytokinetics, Incorporated (the Company, we or our) was incorporated under the laws of the state of Delaware on August 5, 1997. The Company is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. The Company is a development stage enterprise and has been primarily engaged in conducting research, developing drug candidates and technologies, and raising capital.

The Company 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 \$489.1 million since inception and there can be no assurance that the Company will attain profitability. The Company had a net loss of \$40.2 million for the nine months ended September 30, 2013. Cash, cash equivalents and investments increased to \$85.4 million at September 30, 2013 from \$74.0 million at December 31, 2012 due principally to cash receipts from licensing transactions and sales of common stock. 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 development 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 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, licensing of its patents and know-how, contract payments under its collaboration agreements, debt financing arrangements, government grants and interest income. Until it achieves profitable operations, the Company intends to continue to fund operations through payments from strategic collaborations, additional sales of equity securities, government grants and debt financings. 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, 2013 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 accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim financial information and the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The financial statements include all adjustments (consisting only of normal recurring adjustments) that management believes are necessary for the fair statement of the balances and results for the periods presented. These interim financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future interim period.

The balance sheet at December 31, 2012 has been derived from the audited financial statements at that date. The financial statements and related disclosures have been prepared with the presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto contained in the Company s Form 10-K for the year ended December 31, 2012, as filed with the SEC on March 15, 2013.

## **Significant Accounting Policies**

The Company s significant accounting policies are disclosed in its annual report on Form 10-K for the year ended December 31, 2012, as filed with the SEC on March 15, 2013, and have not changed as of September 30, 2013, except as noted below.

6

## 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 financial statements and notes thereto have been adjusted to reflect the reverse stock split on a retroactive basis.

## Recently Adopted Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Statement Update (ASU) 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. This update requires entities to disclose items reclassified out of accumulated other comprehensive income and into net income in a single location within the financial statements. On January 1, 2013, the Company adopted this new accounting guidance and discloses reclassifications out of accumulated other comprehensive income and into net income in the footnotes to the financial statements.

## Accounting Pronouncements Not Yet Adopted

In July 2013, the FASB issued 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 provisions of ASU 2013-11 are effective for fiscal years and interim periods beginning after December 15, 2013, which corresponds to the Company s first quarter of fiscal year 2014. This update can be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. The Company is evaluating when to adopt ASU 2013-11 and the effect the adoption will have on its financial statements.

#### Note 2. Net Loss Per Share

Basic net loss per share allocable to common stockholders is computed by dividing net loss allocable to common stockholders by the weighted average number of vested common shares outstanding during the period. Diluted net loss per share allocable to common stockholders 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 allocable to common stockholders (in thousands, except per share data):

	Three Mo	onths Ended	<b>Nine Months Ended</b>		
	September 30, 2013	September 30 2012	, September 30, 2013	September 30, 2012	
Net loss	\$ (12,588)	\$ (10,044)	\$ (40,248)	\$ (28.914)	
Deemed dividend related to beneficial conversion feature of convertible					
preferred stock				(1,307)	
Net loss allocable to common					
stockholders	\$ (12,588)	\$ (10,044)	\$ (40,248)	\$ (30,221)	
Weighted-average common shares outstanding (weighted average number of shares used in computing net loss per share allocable to common stockholders) basic and diluted	29,395	22,360	26,413	16,215	
Net loss per share allocable to common stockholders basic and diluted	\$ (0.43)	\$ (0.45)	\$ (1.52)	\$ (1.86)	

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, 2013	September 30, 2012	
Options to purchase common stock	2,452	1,819	
Warrants to purchase common stock	7,692	9,009	
Series A convertible preferred stock (as converted			
to common stock)			
Series B convertible preferred stock (as converted			
to common stock)		3,838	
Restricted stock units	42	226	
Shares issuable related to the ESPP	31	20	
Total shares	10,217	14,912	

Note 3. Supplemental Cash Flow Data

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

	Nine Mor	Period from August 5, 1997 (date of inception		
	September 30, 2013	September 30, 2012	to Septe	mber 30,
Significant non-cash investing and				
financing activities:  Deferred stock-based compensation	\$	\$	\$	6,940
Purchases of property and equipment	110			110
through accounts payable Purchases of property and equipment	110			110
through accrued liabilities	29	5		29
Purchases of property and equipment through trade in value of disposed				
property and equipment				258
Penalty on restructuring of equipment				475
financing lines Conversion of convertible preferred				475
stock to common stock	13,626			146,798
Warrants issued in equity financing				1,585

Note 4. Related Party Research and Development Arrangements

Amgen Inc. ( Amgen )

In 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 2009, Amgen exercised its option.

In June 2013, the Company and Amgen amended the Amgen Agreement to expand Amgen's exclusive license to include Japan, resulting in a worldwide collaboration (the Amgen Agreement Amendment). Under the Amgen Agreement Amendment, the Company received a non-refundable upfront license fee of \$15 million. As of September 30, 2013, the Company determined that all conditions necessary for revenue recognition under Accounting Standards Codification (ASC) 605-10 had not been met and accordingly, deferred the revenue attributable to the Amgen Agreement Amendment until the criteria of ASC 605-10 have been satisfied. In October 2013, the Company determined that all conditions necessary for revenue recognition under ASC 605-10 had been satisfied and accordingly, will begin recognizing revenue attributable to the Amgen Agreement Amendment in the fourth quarter of 2013.

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

At September 30, 2013, the Company had \$17.5 million of deferred revenue under the Amgen Agreement Amendment.

8

Under the Amgen Agreement Amendment, the Company plans to conduct 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 in Japan of up to \$50 million, and royalties on net sales of omecamtiv mecarbil in Japan. Such royalty rates will range from the high single digits to the low teens. The Company has determined that the additional milestones are not substantive, as they are primarily the result of Amgen s performance and therefore revenue will be recognized as the Company completes any performance obligations, or if all performance obligations have been delivered at the point the milestone is reached, the revenue from the milestone would be recognized at that time.

Pursuant to the Amgen Agreement, the Company has recognized research and development revenue from Amgen for reimbursements of its costs of certain full-time employee equivalents (FTEs) 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. Revenue from Amgen was as follows (in thousands):

	<b>Three Months Ended</b>			Nine Months Ended		
	September 30,	Sept	tember 30,	September 30,	Sept	ember 30,
	2013		2012	2013		2012
FTE reimbursements	\$ 564	\$	963	\$ 1,455	\$	3,231
Reimbursements of other costs						3
Total revenue from Amgen	\$ 564	\$	963	\$ 1,455	\$	3,234

At both December 31, 2012 and September 30, 2013, there were no related party receivables under the Amgen Agreement.

## Note 5. Other Research and Development Revenue Arrangements

#### Grants

In 2010, the National Institute of Neurological Disorders and Stroke (NINDS) awarded the Company a \$2.8 million grant to support research and development of tirasemtiv, a fast skeletal troponin activator currently in Phase II clinical trials, directed to the potential treatment of myasthenia gravis for a period of up to three years. In September 2012, the NINDS awarded the Company an additional \$0.5 million for this program under a separate grant. Management determined that the Company was the principal participant in the grant arrangement, and, accordingly, the Company recorded amounts earned under the arrangement as revenue. The project period for both of these grants ended June 30, 2013 and no further funds are available to us under these grants.

The Company recognized grant revenue under this grant arrangement as follows (in thousands):

Three Months Ended
September 30, September 30, September 30, September 30, September 30, September 30, 2013

2013

2012

2013

2012

NINDS myasthenia gravis \$ \$ 264 \$ 69 \$ 896

## Other Research and Development 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 to be conducted under the Astellas Agreement 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, will be developed jointly by the Company and Astellas. The Company will be 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 parties will jointly conduct 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 co-development and co-promotion rights of the Company under the Astellas Agreement. Astellas will be 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.

9

In July 2013, the Company received an upfront payment of \$16 million in connection with the execution of the Astellas Agreement, and is eligible to potentially receive over \$24 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 tirasemtiv for the potential treatment of amyotrophic lateral sclerosis and other neuromuscular disorders independently from the Astellas Agreement.

As of June 30, 2013, 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 recognition 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. As of September 30, 2013, the Company has recognized \$1.4 million of the \$16 million upfront license fee as license revenue and deferred the remaining \$14.6 million.

The Company recognizes milestone payments utilizing the milestone method of revenue recognition. The Company believes the milestones related to research and early development are substantive as there is uncertainty that the milestones will be met, the milestone can only be achieved with the Company s past and current performance and the achievement of the milestone will result in additional payment to the Company. The Company believes that the milestones related to later development and commercialization are not substantive as they are primarily the result of the collaborative partner s performance and therefore will be recognized as the Company completes its performance obligations under the agreement, if any. To date, the Company has not recognized any milestone revenue from its collaboration with Astellas.

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

	Three Mo	nths Ended	Nine Months Ende		
	September 30,	September 30,	September 30,	September 30,	
	2013	2012	2013	2012	
License revenues	\$ 1,410	\$	\$ 1,410	\$	
FTE reimbursements	1,191		1,191		
Reimbursements of other costs	1,118		1,118		

Total revenue from Astellas

\$ 3,719

\$3,719

At September 30, 2013, the Company had \$18.4 million of deferred revenue under the Astellas Agreement as the Company has received prepayment on expenses expected to be incurred in the fourth quarter of 2013.

As part of an initiative to seek certain more focused collaborations intended to offset certain research costs, the Company entered into agreements with two early-stage biopharmaceutical companies during 2011 and 2012.

## Global Blood Therapeutics, Inc. (Global Blood)

In October 2011, the Company entered into a collaboration agreement with Global Blood. Under an agreed research plan, scientists from Global Blood and our FTEs conducted research focused on small molecule therapeutics that target the blood. The Company provided Global Blood access to certain research facilities, FTEs and other resources at agreed reimbursement rates that approximated our costs. In April 2012, the Company extended this agreement through December 2012. The Company was the primary obligor in the collaboration arrangement, and accordingly, the Company recorded expense reimbursements from Global Blood as research and development revenue.

10

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

	Three N	Ended	Nine Months Ended					
	September 30, September 30, September							
	2013	2	2012	2013		2012		
Expense reimbursements from Global Blood								
Therapeutics	\$ 7	\$	358	\$7	\$	1,116		

## 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 FTEs conducted research focused on small molecule therapeutics that inhibit cardiac sarcomere proteins. The Company provided to MyoKardia access to certain research facilities, and continues to provide FTEs and other resources at agreed reimbursement rates that approximate our costs. The Company was the primary obligor in the collaboration arrangement, and accordingly, the Company recorded expense reimbursements from MyoKardia as research and development revenue.

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

	<b>Three Months Ended</b>			Nine Mo	nded	
	September 30,	ember 30,	September 30,	, September 30,		
	2013	2012		2013	2	012
Expense reimbursements from MyoKardia	\$ 179	\$	129	\$ 1,024	\$	129

## Note 6. Cash Equivalents and Investments

The amortized cost and fair value of cash equivalents and available for sale investments at September 30, 2013 and December 31, 2012 were as follows (in thousands):

	<b>September 30, 2013</b>							
	11111011111111		Unrealized Unrealized Gains Losses		Unrealized Losses	l Fair Value		Maturity Dates
Cash equivalents money market funds	\$	17,201	\$		\$	\$	17,201	
Short-term investments U.S. Treasury securities	\$	62,367	\$	17	\$	\$	62,384	10/2013-9/2014
Long-term investments U.S. Treasury securities	\$	3,752	\$	2	\$	\$	3,754	11/2014

	December 31, 2012							
	Amortized Cost		Unrealized Gains		Unrealized Losses		Fair Value	Maturity Dates
Cash equivalents money market funds	\$	10,655	\$		\$	\$	10,655	
Short-term investments U.S. Treasury securities	\$	59,075	\$	18	\$	\$	59,093	1/2013-11/2013

As of both September 30, 2013 and December 31, 2012, the Company s U.S. Treasury securities classified as short-term investments had unrealized losses of zero. The Company collected the contractual cash flows on its U.S. Treasury securities that matured from January 1, 2013 through October 25, 2013, and expects to be able to collect all contractual cash flows on the remaining maturities of its U.S. Treasury securities.

Interest income was as follows (in thousands):

	Three M	Ionths H	Ended	Nine M	onths E	anded	August	iod from 5, 1997(date aception)
	September 30	, Septer	nber 30,S	eptember 30	),Septer	nber 30,		to
	2013	2	012	2013	20	012	Septem	ber 30,2013
Interest income	\$ 23	\$	30	\$74	\$	52	\$	28,683

## **Note 7. Fair Value Measurements**

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

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

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

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

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

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

Financial assets measured at fair value on a recurring basis as of September 30, 2013 and December 31, 2012 were classified in one of the three categories described above as follows (in thousands):

	<b>September 30, 2013</b>							
	Fair Value I	Measuremo	ents Using	A	Assets			
	Level 1	Level 2	Level 3	At F	air Value			
Money market funds	\$ 17,201	\$	\$	\$	17,201			
U.S. Treasury securities	66,138				66,138			
Total	\$83,339	\$	\$	\$	83,339			
Amounts included in:								
Cash and cash equivalents	\$ 17,201	\$	\$	\$	17,201			
Short-term investments	62,384				62,384			
Long-term investments	3,754				3,754			
Total	\$83,339	\$	\$	\$	83,339			

		<b>December 31, 2012</b>							
	Fair Value	Fair Value Measurements Using							
	Level 1	Level 2	Level 3	At F	air Value				
Money market funds	\$ 10,655	\$	\$	\$	10,655				
U.S. Treasury securities	59,093				59,093				
Total	\$ 69,748	\$	\$	\$	69,748				
Amounts included in:									
Cash and cash equivalents	\$ 10,655	\$	\$	\$	10,655				
Short-term investments	59,093				59,093				
Total	\$ 69,748	\$	\$	\$	69,748				

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, 2013 and December 31, 2012, 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.

12

## Note 8. Stockholders Equity (Deficit)

## Accumulated Other Comprehensive Income

In the first nine months of 2013, the Company reclassified insignificant amounts of unrealized gains (losses) on investments out of accumulated other comprehensive income into net loss.

## Common stock

In conjunction with the Amgen Agreement Amendment (see Note 4), in June 2013, Amgen purchased 1,404,100 shares of the Company s common stock at a price per share of \$7.12. 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 deferred and will be recognized as revenue as services are performed over approximately 12 months.

## Convertible Preferred Stock

Each share of Series B convertible preferred stock is convertible into common stock at any time at the holder s option. As a result of the one-for-six reverse stock split effected in June 2013, the conversion ratio for Series B convertible preferred stock changed from 1,000 shares of common stock per share of Series B convertible preferred stock to 166.67 shares of common stock per share of Series B convertible preferred stock.

In the first quarter of 2013, 4,000 shares of Series B convertible preferred stock were converted into 666,667 shares of common stock. In the second quarter of 2013, 15,026 shares of Series B convertible preferred stock were converted into 2,504,334 shares of common stock. On July 2, 2013, 4,000 shares of Series B convertible preferred stock, which represented all remaining shares of Series B convertible preferred stock, were converted into 666,667 shares of common stock. The conversions were in accordance with the terms of the original agreement under which the Series B convertible preferred stock was issued in 2012.

#### Warrants

In February 2013, warrants to purchase 1,000 shares of the Company s common stock at an exercise price of \$5.28 per share were cash exercised in accordance with the June 20, 2012 underwriting agreements the Company entered into in connection with two separate, concurrent offerings for our securities (the June 2012 Public Offerings).

In the second quarter of 2013, the Company issued 358,460 shares of common stock related to cashless exercise of warrants in accordance with the June 2012 Public Offerings. There were no exercises of warrants in the third quarter of 2013.

#### MLV

On June 10, 2011, the Company entered into an At-The-Market Issuance Sales Agreement (the MLV Agreement ) with McNicoll, Lewis & Vlak LLC (MLV), pursuant to which the Company may issue and sell shares of common stock having an aggregate offering price of up to \$20.0 million or 2,397,279 shares, whichever occurs first, from time to time through MLV as the sales agent. The issuance and sale of shares by the Company under the MLV Agreement, if any, are subject to the continued effectiveness of the Company s registration statement on Form S-3, which was declared effective by the SEC on June 23, 2011 (File No. 333-174869) and the terms and conditions of the MLV Agreement. As of December 31, 2012, the Company had issued a total of 862,592 shares through MLV for total net proceeds of approximately \$5.3 million. As of October 25, 2013, there have been no further issuances of shares

# through MLV.

# Stock Option Plans

Stock option activity for the nine months ended September 30, 2013 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	Avera Price p	eighted ge Exercise per Share of Stock Options
Balance at December 31, 2012	878,711	1,790,527	\$	18.96
Options granted	(769,979)	769,979		5.93
Options exercised		(21,397)		5.32
Options forfeited	19,382	(19,382)		4.88
Options expired	68,205	(68,205)		16.17
Restricted stock units granted	(41,661)			
Restricted stock units forfeited	5,014			
Balance at September 30, 2013	159,672	2,451,522	\$	15.18

13

Restricted stock unit activity for the nine months ended September 30, 2013 was as follows:

	Number of	Avera	eighted ge Award in Value non
	Shares		ir Value per Share
Restricted stock units outstanding at			
December 31, 2012	216,913	\$	6.78
Restricted stock units granted	41,661		6.00
Restricted stock units vested	(211,897)		6.78
Restricted stock units forfeited	(5,014)		6.78
Unvested restricted stock units outstanding at			
September 30, 2013	41,663	\$	6.00

# Note 9. Interest and Other, Net

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

	Three Months Ended September 30,September 30,Sep				Ionths E 0\$epten		Period from August 5, 1997 (date of inception)		
	2013	20	012	2013	20	)12	to Septe	mber 30, 2013	
Interest income and other income	\$ 24	\$	30	\$76	\$	56	\$	29,176	
Interest expense and other expense	(1)		(1)	2		(2)		(5,972)	
Warrant expense								(1,585)	
-									
Interest and other, net	\$ 23	\$	29	\$78	\$	54	\$	21,619	

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

Warrant expense for the period from inception to September 30, 2013 was related to the change in the fair value of the warrant liability that was recorded in connection with the Company s registered direct equity offering in May 2009.

#### **Note 10. Income Taxes**

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

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

14

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

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

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

guidance concerning revenues, research and development expenses and general and administrative expenses for 2013;

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 anticipated timing of revenue recognition events;

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 dates 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 ability of our amendment to the protocol of our BENEFIT-ALS clinical trial to maintain the originally intended statistical power of the trial;

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 and sponsored research arrangements, 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;

the expected recognition of revenue under our collaboration agreements;

potential competitors and competitive products;

retaining key personnel and recruiting additional key personnel;

expected future amortization of employee stock-based compensation; and

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

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

our ability to acquire the funding necessary to conduct the one or more confirmatory Phase III clinical trials for tirasemtiv in patients with amyotrophic lateral sclerosis (also known as ALS or Lou Gehrig s disease) that we expect will be required to obtain marketing approval for 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 other related molecules, including decisions to postpone or discontinue research or development activities relating to omecamtiv mecarbil and other related molecules;

15

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 or sponsored research arrangements;

difficulties or delays in the development, testing, production 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 make our drug candidates commercially unviable;

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;

our ability to issue and sell shares of our common stock under our At-The-Market Issuance Sales Agreement with McNicoll, Lewis & Vlak LLC;

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. Operating results reported are not necessarily indicative of results that may occur in future periods.

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

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

## Overview

We 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. We are also conducting or may conduct earlier-stage research directed to other compounds with the potential to modulate muscle contractility and other muscle functions, such as growth, energetics and metabolism.

Our drug candidates currently in clinical development are our skeletal muscle activators tirasemtiv and CK-2127107, and our cardiac muscle activator omecamtiv mecarbil. 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.

## Skeletal Muscle Contractility

Tirasemtiv is the lead drug candidate from this program, and is in Phase II clinical development. Cytokinetics holds the rights to tirasemtiv. We are also developing another drug candidate from this program, CK-2127107, which is being evaluated in Phase I clinical trials in collaboration with Astellas for potential 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. We are evaluating potential indications for which tirasemtiv and CK-2127107 may be useful.

Each of tirasemtiv and CK-2127107 has demonstrated encouraging pharmacological activity in preclinical models. In our Phase I clinical trials of tirasemtiv in healthy volunteers, tirasemtiv appeared well-tolerated and no serious adverse events were reported. We have conducted three evidence of effect Phase IIa clinical trials of tirasemtiv: one in patients with ALS, one in patients with myasthenia gravis and one in patients with claudication associated with peripheral artery disease. Evidence of potentially clinically relevant pharmacodynamic effects was observed in each of these trials for their respective indications. In two further Phase II clinical trials of tirasemtiv in patients with ALS, encouraging trends toward functional improvements were observed in patients receiving tirasemtiv versus those receiving placebo. We are now conducting BENEFIT-ALS (Blinded Evaluation of Neuromuscular Effects and Functional Improvement with Tirasemtiv in ALS), a Phase IIb clinical trial of tirasemtiv in patients with ALS. We anticipate that we will need to conduct at least one confirmatory Phase III clinical trial of tirasemtiv in patients with ALS to gain marketing approval.

#### **Tirasemtiv**

#### ALS

In October 2012, we initiated BENEFIT-ALS, a multi-national, double-blind, randomized, placebo-controlled trial originally planned to enroll at least 400 patients and subsequently increased to enroll up to 500 patients. All patients begin treatment with open-label tirasemtiv at 125 mg twice daily. Patients who complete a week of open-label tirasemtiv at this starting dose are randomized 1-to-1 to receive 12 weeks of double-blind treatment with tirasemtiv or placebo. Clinical assessments take place monthly during double-blinded treatment. Randomized patients also participate in follow-up evaluations at both 7 and 28 days after their final dose of double-blind study drug. The primary analysis of BENEFIT-ALS will compare the mean change from baseline in the ALS Functional Rating Scale in its revised form, or ALSFRS-R (a clinically validated instrument designed to measure disease progression and changes in functional status), in patients receiving tirasemtiv versus those receiving placebo. We are conducting BENEFIT-ALS at over 70 sites across the United States, Canada and several European countries.

In July 2013, we were informed by our data management vendor 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 study visit and for the remainder of the study. No patients randomized to placebo were dispensed incorrect treatment. Cytokinetics and all clinical trial site personnel remain blinded to the specific patients affected by the error. Following detection of the error, we took steps to ensure that no further incorrect study drug assignments occurred and to correct the programming error in the electronic data capture system controlling study drug assignment. In addition, we convened an ad hoc meeting of the Data Safety Monitoring Board (DSMB) for BENEFIT-ALS to assess whether the error in dispensing study drug had impacted the safety of the 58 affected patients. After review of the then-available safety data from BENEFIT-ALS, the DSMB reported no concerns regarding patient safety.

Following interactions with regulatory authorities, we amended the protocol for BENEFIT-ALS to enable increased enrollment to approximately 680 patients and to update the statistical methods section, in both cases with the objective to maintain the originally intended statistical power of the trial. These changes to BENEFIT-ALS are expected to increase the direct clinical trial costs by approximately \$6 million in 2013 and 2014.

To date, we have enrolled over 600 patients in BENEFIT-ALS and over 300 patients have completed 12 weeks of treatment. Recently, the DSMB completed a scheduled meeting to review the data and recommended that the trial continue without any changes to the protocol. We expect to complete patient enrollment in BENEFIT-ALS during the fourth quarter of 2013, with results expected to be available in the first half of 2014.

In August 2013, we announced the publication of results from two Phase II trials of tirasemtiv in patients with ALS (CY 4024 and CY 4025) in the online edition of the journal Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration.

#### Myasthenia Gravis

In 2010, the National Institute of Neurological Disorders and Stroke (NINDS) awarded us a grant of \$2.8 million under the American Recovery and Reinvestment Act of 2009, which was intended to support three years of research and development of tirasemtiv for the potential treatment of myasthenia gravis. In September 2012, the NINDS awarded us an additional \$0.5 million for this program under a separate grant. We recognized revenue under this grant in the first nine months of 2013 and 2012 of \$0.1 and \$0.9 million, respectively, which we recorded as research and development grant and other revenues. The project period for both of these grants ended June 30, 2013, and no additional funds are available to us under these grants.

17

## CK-2127107

<u>Phase I Clinical Trials</u>. In April 2013, we announced the initiation of a first-time-in-humans Phase I clinical trial of CK-2127107 in healthy male volunteers, known as CY 5011. CY 5011 is a double-blind, randomized, placebo-controlled study designed to assess the safety, tolerability, and pharmacokinetics of single ascending oral doses of CK-2127107 administered in a three-period crossover design. During the third quarter of 2013, we completed enrollment in this clinical trial.

We recently initiated dosing in CY 5014, a Phase I clinical trial of CK-2127107 in healthy male volunteers. CY 5014 is a randomized, open-label, two-period crossover study to assess the relative oral bioavailability, pharmacokinetics, safety and tolerability of two oral formulations of CK-2127107.

Astellas Agreement. 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 will be developed jointly by Cytokinetics and Astellas. Cytokinetics will be 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 parties will jointly conduct 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 Agreement, and we are eligible to potentially receive over \$24 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, 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 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.

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 recorded research and development expenses for our skeletal muscle contractility program of approximately \$28.6 million and \$17.8 million in the first nine months of 2013 and 2012, respectively. We anticipate that our expenditures on research and development in our skeletal muscle contractility program will increase significantly as we may continue the clinical development of tirasemtiv, CK-2127107 or other compounds from the skeletal muscle contractility program.

# Cardiac Muscle Contractility

Our lead drug candidate from this program is omecamtiv mecarbil, a novel cardiac muscle myosin activator, which is being developed in collaboration with Amgen.

<u>Amgen Agreement.</u> In December 2006, we entered into a collaboration and option agreement with Amgen to discover, develop and commercialize novel small molecule therapeutics, including omecamtiv mecarbil, that activate cardiac muscle contractility for potential applications in the treatment of heart failure (the Amgen Agreement ). The agreement granted Amgen an option to obtain an exclusive license worldwide, except Japan, to develop and commercialize omecamtiv mecarbil and other drug candidates arising from the collaboration.

In May 2009, Amgen exercised its option. As a result, Amgen became responsible for the development and commercialization of omecamtiv mecarbil and related compounds at its expense worldwide (excluding Japan), subject to our development and commercialization participation rights. Amgen will reimburse us for agreed research and development activities we perform under the collaboration. We are eligible for potential pre-commercialization and commercialization milestone payments of up to \$600 million in the aggregate on omecamtiv mecarbil and other potential products arising from research under the collaboration, and royalties that

18

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.

In June 2013, Cytokinetics and Amgen announced an amendment to the Amgen Agreement to include Japan, resulting in a worldwide collaboration (the Amgen Agreement Amendment ). (See Note 4 to unaudited condensed financial statements.) 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 plan to conduct 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 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. As of September 30, 2013, we determined that all conditions necessary for revenue recognition of the upfront license fee under Accounting Standards Codification (ASC) 605-10 had not been met and accordingly, deferred the revenue attributable to the Amgen Agreement Amendment until the criteria of ASC 605-10 have been satisfied, which we anticipate will be in the fourth quarter of 2013.

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. 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.

<u>Omecamtiv Mecarbil.</u> 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.

ATOMIC-AHF. In September 2013, results from ATOMIC-AHF (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure) were presented at the European Society of Cardiology Congress and the Heart Failure Society of America Annual Scientific Meeting. ATOMIC-AHF was an international, randomized, double-blind, placebo-controlled, Phase IIb clinical trial of intravenous omecamtiv mecarbil in patients with left ventricular systolic dysfunction hospitalized with acutely decompensated heart failure. ATOMIC-AHF was conducted by Amgen in collaboration with Cytokinetics. This clinical trial enrolled over 600 patients in three sequential, ascending-dose cohorts. In each cohort, patients were randomized to receive omecamtiv mecarbil or placebo. The primary efficacy objective of this trial was to evaluate the effect of 48 hours of intravenous omecamtiv mecarbil compared to placebo on dyspnea (shortness of breath). The secondary objectives were to assess the safety and tolerability of three dose levels of intravenous omecamtiv mecarbil compared with placebo and to evaluate the effects of 48 hours of treatment with intravenous omecamtiv mecarbil on additional measures of dyspnea, patients global assessments, change in N-terminal pro brain-type natriuretic peptide (a biomarker associated with the severity of heart failure) and short-term clinical outcomes in these patients. In addition, the trial evaluated the relationship between plasma concentrations of omecamtiv mecarbil and echocardiographic parameters in patients with acute heart failure.

The omecamtiv mecarbil treatment groups were not statistically different in their 7-point Likert scale dyspnea symptom response rates compared to the pooled placebo group (p=0.33); therefore, the primary endpoint was not met.

Omecamtiv mecarbil demonstrated favorable dose- and concentration-related trends (nominal p=0.025 and nominal p=0.007, respectively) on dyspnea response. Improvement in dyspnea was observed in the highest omecamtiv mecarbil dose group when compared against its paired placebo group in the third cohort (dyspnea symptom response in 51 percent of subjects on omecamtiv mecarbil versus 37 percent on placebo, nominal p=0.03). The incidence of worsening heart failure within seven days of initiating treatment was 17 percent in the pooled placebo group and was 13 percent, 8 percent and 9 percent on omecamtiv mecarbil in the first, second and third cohorts, respectively. Systolic ejection time, the echocardiographic signature of omecamtiv mecarbil, increased in a concentration-dependent manner similar to that previously reported in healthy volunteers and stable heart failure patients.

Rates of adverse events (AEs), serious AEs, adjudicated deaths and hospitalizations were similar between omecamtiv mecarbil and placebo groups. There were seven post-randomization myocardial infarctions in the treatment groups receiving omecamtiv mecarbil compared with three in the placebo groups (2.3 percent vs. 1.0 percent, respectively). However, there was no relationship between the maximum increase from the baseline troponin (a biomarker specific for cardiac muscle damage) and increasing plasma concentrations of omecamtiv mecarbil. Four of the myocardial infarctions were observed to be temporally remote from study drug administration. The estimated plasma concentrations near the time of these events were zero. Three of these events occurred in patients who received omecamtiv mecarbil and one occurred in a patient who received placebo. One myocardial infarction occurred subsequent to a percutaneous coronary intervention in a patient who received omecamtiv mecarbil. One myocardial infarction occurred in a patient with sepsis who received placebo. Omecamtiv mecarbil was not associated with an increased incidence of tachyarrhythmias nor were heart rate or blood pressure adversely affected.

<u>COSMIC-HF.</u> 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,

19

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. The primary objectives of this trial are to select an oral modified release formulation and doses of omecamtiv mecarbil for chronic twice-daily dosing in patients with heart failure and left ventricular systolic dysfunction and to characterize its pharmacokinetics after 12 weeks of treatment. The secondary objective is to evaluate the safety and tolerability of oral omecamtiv mecarbil. In addition, we will have an opportunity to evaluate the potential for sustained pharmacodynamic effects and their relationship to the pharmacokinetics of this drug candidate. During the third quarter of 2013, the second cohort of the dose escalation phase of COSMIC-HF completed enrollment. We and Amgen recently reviewed results from COSMIC-HF and selected an oral formulation of omecamtiv mecarbil for evaluation in the planned expansion phase of the trial. We and Amgen are discussing an amendment to the COSMIC-HF protocol prior to initiating enrollment in the expansion phase.

Additional Phase I Clinical Trials. Recently, Cytokinetics and Amgen agreed on the protocol and budget for the planned Phase I pharmacokinetic study, CY 1211, in healthy volunteers of both Japanese and non-Japanese ethnicity. The trial will be conducted by Cytokinetics in collaboration with Amgen. The costs of the trial will be reimbursed by Amgen.

Ongoing Research in Cardiac Muscle Contractility. In the first quarter of 2013, we and Amgen agreed to additional research activities intended to be conducted through 2014 under a collaborative research program directed to the discovery of next-generation cardiac sarcomere activator compounds. Under the Amgen Agreement, Amgen will reimburse us for certain agreed research activities we perform.

The clinical trials program for omecamtiv mecarbil may proceed for several years, and we will not be in a position to generate any revenues or material net cash flows from sales of this drug candidate until the program is successfully completed, regulatory approval is achieved, and the drug is commercialized. Omecamtiv mecarbil is at too early a stage of development for us to predict if or when this may occur. We recorded research and development expenses for our cardiac muscle contractility program of approximately \$2.5 million and \$3.3 million in the first nine months of 2013 and 2012, respectively. We recognized research and development revenue from Amgen of \$1.5 million and \$3.2 million in the first nine months of 2013 and 2012, respectively, consisting of reimbursements of full-time employee equivalent (FTE) and other expenses.

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

# **Other Research and Preclinical Programs**

We are leveraging our current understandings of muscle biology to investigate new ways to modulate muscle function beyond contractility (such as metabolism, growth and energetics) for other potential therapeutic applications. For example, we are conducting research with compounds that may 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. Similarly, we may perform research on compounds that may affect muscle metabolism and that

may have application in conditions such as diabetes or obesity as well as other conditions of metabolic dysfunction.

# **Development Risks**

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

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

our potential inability to obtain the additional funding necessary for us to conduct the one or more confirmatory Phase III clinical trials for tirasemtiv in patients with ALS that we anticipate will be required to obtain marketing approval for this indication;

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

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

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;

20

failure by our clinical trial sites, clinical research organizations, clinical manufacturing organizations and other third parties supporting our 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.

# Restructuring

In October 2011, we announced a restructuring plan to realign our workforce and operations in line with our continued commitment to focus primarily on the development of our key later-stage development programs for tirasemtiv and omecamtiv mecarbil and on our follow-on skeletal muscle troponin activator program and joint research with Amgen directed to next-generation cardiac sarcomere activator compounds. As a result, we reduced our workforce by 18 employees, or approximately 18%, to 83 employees. We provided severance, employee benefit continuation and career transition assistance to the employees directly affected by the restructuring. We incurred restructuring charges of \$1.2 million in the fourth quarter of 2011, primarily personnel-related termination costs. We completed all restructuring activities and recognized all anticipated restructuring charges by December 31, 2012. All payments relating to the restructuring were made prior to December 31, 2012; therefore there was no liability for restructuring at

December 31, 2012, or at September 30, 2013.

## **Results of Operations**

#### Revenues

We recorded total revenues of \$4.5 million and \$1.7 million for the third quarter of 2013 and 2012, respectively, and \$6.3 million and \$5.4 million for the first nine months of 2013 and 2012, respectively.

Research and development revenues from related parties for the third quarter and first nine months of 2013 and 2012 consisted of revenues from our strategic alliance with Amgen. Revenues from Amgen were \$0.6 million and \$1.0 million for the third quarter of 2013 and 2012, respectively, and in both periods consisted of reimbursements of FTE expenses and other research and development expenses. Revenues from Amgen were \$1.5 million and \$3.2 million for the first nine months of 2013 and 2012, respectively, and in both periods consisted of reimbursements of FTE expenses 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 \$2.5 million and \$0.7 million for the third quarter of 2013 and 2012, respectively. 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. Research and development, grant and other revenues in the third quarter of 2012 included grant revenue from the NINDS of \$0.3 million, research and development revenue from Global Blood Therapeutics, Inc. ( Global Blood ) of \$0.3 million and research and development revenue of \$0.1 million from MyoKardia, Inc.

Research and development, grant and other revenues were \$3.4 million and \$2.1 million for the first nine months of 2013 and 2012, respectively. 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. Research and development, grant and other revenues in the first nine months of 2012 included grant revenue of \$0.9 million, research and development revenue from Global Blood of \$1.1 million and research and development revenue from MyoKardia of \$0.1 million.

License and technology fee revenue was \$1.4 million for the third quarter and the first nine months of 2013 and consisted entirely of revenue relating to our strategic alliance with Astellas. We entered into this agreement in June 2013 and first recognized revenues relating to this agreement in the third quarter of 2013.

We anticipate that revenue for the full year 2013 will be in the range of \$30 million to \$32 million.

## Research and Development Expenses

Research and development expenses were \$13.4 million and \$8.8 million in the third quarter of 2013 and 2012, respectively. The \$4.6 million increase in research and development expenses in the third quarter of 2013, compared to the same period in 2012, was primarily due to increases of \$4.0 million in outsourced clinical costs, \$0.3 million in laboratory costs, \$0.3 million in facilities costs and \$0.2 million in outsourced pre-clinical costs, partially offset by a decrease of \$0.1 million in personnel related costs.

Research and development expenses were \$35.6 million and \$25.8 million in the first nine months of 2013 and 2012, respectively. The \$9.8 million increase in research and development expenses in the first nine months of 2013, compared to the same period in 2012, was primarily due to increases of \$10.5 million in outsourced clinical costs, \$0.8 million in facilities costs, \$0.3 million in laboratory costs and \$0.1 million in personnel related costs, partially offset by a decrease of \$1.7 million in outsourced pre-clinical costs.

From a program perspective, the \$9.8 million increase in spending in the first nine months of 2013, compared to the same period in 2012, was due to increased spending of \$10.8 million for our skeletal muscle contractility program and \$1.4 million for our other research and preclinical programs, partially offset by decreases of \$0.7 million for our cardiac muscle contractility program and \$1.7 million for our smooth muscle contractility program.

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

	<b>Three Months Ended</b>			<b>Nine Months Ended</b>		
	September 30,	Sept	ember 30,	September 30,	Sept	ember 30,
	2013		2012	2013		2012
Cardiac muscle contractility	\$ 0.9	\$	1.1	\$ 2.5	\$	3.3
Skeletal muscle contractility	11.6		6.4	28.6		17.8
Smooth muscle contractility			0.3	0.1		1.7
All other research programs	0.9		1.0	4.4		3.0
Total research and development						
expenses	\$ 13.4	\$	8.8	\$ 35.6	\$	25.8

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

We expect our research and development expenditures to continue to increase in 2013 compared to 2012. We expect to continue development of tirasemtiv for the potential treatment of ALS and other neuromuscular disorders. As part of our strategic alliance with Astellas, we expect to continue the development of CK-2127107 for the potential treatment of non-neuromuscular indications associated with skeletal muscle weakness. As part of our strategic alliance with Amgen, we expect to continue development of omecamtiv mecarbil for the potential treatment of heart failure. We anticipate that research and development expenses in 2013 will increase compared to 2012 and will be in the range of \$56 million to \$59 million. Non-cash expenses such as stock-based compensation and depreciation of approximately \$3.0 million are included in our estimate of 2013 research and development expenses.

## General and Administrative Expenses

General and administrative expenses were \$3.6 million and \$3.0 million in the third quarter of 2013 and 2012, respectively. The increase in the third quarter of 2013, compared to the same period in 2012, was primarily due to increases of \$0.7 million in personnel related expenses, and \$0.3 million in outsourced costs, partially offset by a \$0.3 million decrease in facilities costs and a \$0.1 million decrease in legal costs.

General and administrative expenses were \$11.0 million and \$8.6 million in the first nine months of 2013 and 2012, respectively. The increase in the first nine months of 2013, compared to the same period in 2012, was primarily due to increases of \$2.0 million in personnel related expenses, \$0.5 million in legal costs and \$0.5 million in outsourced costs, partially offset by a decrease of \$0.8 million in facilities costs.

22

We expect that general and administrative expenses in 2013 will increase compared to 2012. We anticipate that general and administrative expenses will be in the range of \$17.0 million to \$18.0 million. Non-cash expenses such as stock-based compensation and depreciation of approximately \$2.6 million are included in our estimate of 2013 general and administrative expenses.

# Interest and Other, Net

Interest income and other income decreased in the third quarter of 2013 and increased in the first nine months of 2013 compared to the same periods in 2012. In both periods, the changes in interest income and other income were primarily due to changes in average invested balances.

Interest and other expense was insignificant in the third quarter and first nine months of both 2013 and 2012.

### **Income Taxes**

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

We file income tax returns with the United States Internal Revenue Service (IRS) and the state of California. For jurisdictions in which tax filings are made, we are subject to income tax examination for all fiscal years since inception. 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, 2012. 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 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, 2013, we funded our operations through the sale of equity securities, equipment financings, non-equity payments from collaborators, government grants and interest income.

In June 2013, we and Amgen announced the Amgen Agreement Amendment, which expanded our collaboration to include Japan (see Note 4 to unaudited condensed 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 with Amgen 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.

In June 2013, we entered into the Astellas Agreement. (See Note 5 to unaudited condensed financial statements). In July 2013, we received an upfront license payment of \$16 million in connection with the execution of the Astellas Agreement. We are eligible to potentially receive over \$24 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, 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 the foregoing development, commercial launch and sales milestones, we may also receive payments for the achievement of pre-specified milestones relating to the joint research program.

## June 2012 Public Offerings

On June 20, 2012, we entered into underwriting agreements for two separate, concurrent offerings of our securities (the June 2012 Public Offerings). On June 25, 2012, pursuant to the underwriting agreements, in aggregate we issued to various investors (i) 9,320,176 shares of common stock for a purchase price of \$4.56 per share, (ii) 23,026 shares of Series B convertible preferred stock (the Series B Preferred Stock) for a purchase price of \$760.00 per share, and (iii) warrants to purchase 7,894,704 shares of our common stock at an exercise price of \$5.28 per share, for aggregate gross proceeds of approximately \$60.0 million. After issuance costs of approximately \$4.0 million, the net proceeds from the June 2012 Public Offerings were approximately \$56.0 million.

The warrants issued in the June 2012 Public Offerings became exercisable upon issuance and will remain exercisable for five years until June 25, 2017. The warrant holders are prohibited from exercising the warrants and obtaining shares of common stock if, as a result of such exercise, the holder and its affiliates would own more than 9.98% of the total number of shares of our common stock then issued and outstanding. We valued the warrants as of the date of issuance at \$16.2 million using the Black-Scholes option pricing model and the following assumptions: a contractual term of five years, a risk-free interest rate of 0.73%, volatility of 76%, and the fair value of our common stock on the issuance date of \$3.78. In February 2013, warrants to purchase 1,000 shares of our common stock at an exercise price of \$5.28 per share were exercised in accordance with the June 2012 Public Offerings underwriting agreements. In April 2013, we issued 358,460 shares of common stock related to cashless exercise of warrants. As of September 30, 2013, warrants to purchase 6,577,928 shares of our common stock were outstanding and exercisable.

In the first quarter of 2013, 4,000 shares of Series B convertible preferred stock were converted into 666,667 shares of our common stock. In the second quarter of 2013, 15,026 shares of Series B convertible preferred stock were converted into 2,504,333 shares of our common stock. In July, 2013, 4,000 shares of Series B convertible preferred stock, which represented all remaining shares of Series B convertible preferred stock, were converted into 666,667 shares of our common stock. The conversions were in accordance with the terms of the original agreement under which the Series B Preferred Stock was issued in 2012.

#### 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 may issue and sell shares of common stock having an aggregate offering price of up to \$20.0 million or 2,397,278 shares, whichever occurs first, from time to time through MLV as the sales agent. Our issuance and sale of shares under the MLV Agreement, if any, are subject to the continued effectiveness of our registration statement on Form S-3, which was declared effective by the SEC on June 23, 2011 (File No. 333-174869), and the terms and conditions of the MLV Agreement. As of December 31, 2012, we had issued a total of 862,592 shares through MLV for total net proceeds of approximately \$5.3 million. As of October 25, 2013, there have been no further issuances of shares through MLV.

### Sources and Uses of Cash

Our cash and cash equivalents, totaled \$19.3 million at September 30, 2013, up from \$14.9 million at December 31, 2012. The increase of \$4.4 million was primarily due to cash receipts from a licensing transaction partially offset by the use of cash to fund operations.

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 operating activities was \$26.3 million in the first nine months of 2012 and primarily resulted from the net loss of \$28.9 million.

Net cash used by investing activities was \$7.3 million in the first nine months of 2013 and primarily consisted of cash used to purchase investments, net of proceeds from the maturity of investments, of \$7.0 million. Net cash provided by investing activities was \$35.4 million in the first nine months of 2012 and primarily consisted of proceeds from the maturity of investments, net of cash used to purchase investments, of \$35.6 million.

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 to unaudited condensed financial statements). Net cash provided by financing activities was \$58.3 million in the first nine months of 2012 and primarily consisted of net proceeds of \$56.0 million from the sale of 9,320,176 shares of common stock and 23,026 shares of Series B Preferred Stock in the June 2012 Public Offerings and the net proceeds of \$2.8 million from our sale of 432,724 shares of common stock through MLV.

Shelf Registration Statement. 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 25, 2013, \$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.

24

As of September 30, 2013, future minimum payments under our lease obligations were as follows (in thousands):