

CYTOKINETICS INC
Form 10-Q
November 05, 2015
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

or

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

For the transition period from _____ to _____

Commission file number: 000-50633

CYTOKINETICS, INCORPORATED
(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Number of shares of common stock, \$0.001 par value, outstanding as of October 30, 2015: 38,847,270

Table of Contents

CYTOKINETICS, INCORPORATED

TABLE OF CONTENTS FOR FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2015

	Page
<u>PART I. FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014 (Unaudited)</u>	3
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2015 and 2014 (Unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014 (Unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
Item 4. <u>Controls and Procedures</u>	31
<u>PART II. OTHER INFORMATION</u>	31
Item 1. <u>Legal Proceedings</u>	31
Item 1A. <u>Risk Factors</u>	32
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	52
Item 3. <u>Defaults Upon Senior Securities</u>	52
Item 4. <u>Mine Safety Disclosures</u>	52
Item 5. <u>Other Information</u>	52
Item 6. <u>Exhibits</u>	52
<u>SIGNATURES</u>	53
<u>EXHIBIT INDEX</u>	54

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CYTOKINETICS, INCORPORATED**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share data)

	September 30, 2015 (Unaudited)	December 31, 2014 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 25,962	\$ 20,215
Short-term investments	72,023	63,013
Related party accounts receivable	47	46,646
Prepaid and other current assets	2,483	1,257
Total current assets	100,515	131,131
Property and equipment, net	1,481	1,637
Other assets	200	200
Total assets	\$ 102,196	\$ 132,968
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 1,907	\$ 1,361
Accrued liabilities	6,759	5,400
Deferred revenue, current	21,367	17,042
Short-term portion of deferred rent	110	52
Total current liabilities	30,143	23,855
Deferred revenue, non-current	4,346	16,558
Long-term portion of deferred rent	407	491
Total liabilities	34,896	40,904
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value:		
Authorized: 10,000,000 shares;		
Issued and outstanding: Series A Convertible Preferred Stock zero shares at September 30, 2015 and December 31, 2014		
Common stock, \$0.001 par value:		

Edgar Filing: CYTOKINETICS INC - Form 10-Q

Authorized: 81,500,000 shares;		
Issued and outstanding: 38,756,313 shares at September 30, 2015 and 38,659,738 shares at December 31, 2014	39	39
Additional paid-in capital	592,760	589,272
Accumulated other comprehensive income (loss)	16	(4)
Accumulated deficit	(525,515)	(497,243)
Total stockholders' equity	67,300	92,064
Total liabilities and stockholders' equity	\$ 102,196	\$ 132,968

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

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

(In thousands, except per share data)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, September 30,		September 30, September 30,	
	2015	2014	2015	2014
Revenues:				
Research and development revenues from related parties	\$ 3,786	\$ 1,920	\$ 10,087	\$ 3,428
Research and development, grant and other revenues	27	4,761	27	14,189
License revenues from related parties	4,132		8,787	
License revenues		2,734		7,565
Total revenues	7,945	9,415	18,901	25,182
Operating expenses:				
Research and development	11,557	11,420	33,149	35,647
General and administrative	5,276	3,993	14,138	12,710
Total operating expenses	16,833	15,413	47,287	48,357
Operating loss	(8,888)	(5,998)	(28,386)	(23,175)
Interest and other, net	39	27	114	86
Loss before income taxes	(8,849)	(5,971)	(28,272)	(23,089)
Income tax benefit				
Net loss	\$ (8,849)	\$ (5,971)	\$ (28,272)	\$ (23,089)
Net loss per share basic and diluted	\$ (0.23)	\$ (0.16)	\$ (0.73)	\$ (0.65)
Weighted-average number of shares used in computing net loss per share basic and diluted	38,752	36,609	38,718	35,359
Other comprehensive gain:				
Unrealized gains on available-for-sale securities, net	2	11	19	17
Comprehensive loss	\$ (8,847)	\$ (5,960)	\$ (28,253)	\$ (23,072)

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

Table of Contents

CYTOKINETICS, INCORPORATED
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended	
	September 30,	September 30,
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (28,272)	\$ (23,089)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	438	353
Stock-based compensation	3,219	2,444
Gain on sale of investments	(1)	(6)
Changes in operating assets and liabilities:		
Related party accounts receivable	46,598	(1,185)
Prepaid and other assets	(1,226)	(273)
Accounts payable	616	(1,863)
Accrued and other liabilities	1,341	(2,229)
Deferred revenue	(7,888)	(10,865)
Net cash provided by (used in) operating activities	14,825	(36,713)
Cash flows from investing activities:		
Purchases of investments	(94,658)	(93,244)
Proceeds from sales and maturities of investments	85,668	83,748
Purchases of property and equipment	(358)	(857)
Net cash used in investing activities	(9,348)	(10,353)
Cash flows from financing activities:		
Proceeds from public offerings of common stock, net of issuance costs		39,869
Proceeds (payments) from stock based award activities and warrants, net	270	(54)
Net cash provided by financing activities	270	39,815
Net increase (decrease) in cash and cash equivalents	5,747	(7,251)
Cash and cash equivalents, beginning of period	20,215	20,158
Cash and cash equivalents, end of period	\$ 25,962	\$ 12,907

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

Table of Contents

CYTOKINETICS, INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 Organization and Summary of Significant Accounting Policies

Overview

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

The Company's financial statements contemplate the conduct of the Company's operations in the normal course of business. The Company has incurred an accumulated deficit of \$525.5 million since inception and there can be no assurance that the Company will attain profitability. The Company had a net loss of \$28.3 million and net cash provided by operations of \$14.8 million for the nine months ended September 30, 2015. Cash, cash equivalents and investments increased from \$83.2 million at December 31, 2014 to \$98.0 million at September 30, 2015, principally due to the receipt of \$45.0 million from Astellas in January 2015, partially offset by the use of cash to fund operations. The Company anticipates that it will continue to have operating losses and net cash outflows in future periods.

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

Based on the current status of its research and development plans, the Company believes that its existing cash, cash equivalents and investments at September 30, 2015 will be sufficient to fund its cash requirements for at least the next 12 months. If, at any time, the Company's prospects for financing its research and development programs decline, the Company may decide to reduce research and development expenses by delaying, discontinuing or reducing its funding of one or more of its research or development programs. Alternatively, the Company might raise funds through strategic collaborations, public or private financings or other arrangements. Such funding, if needed, may not be available on favorable terms, or at all. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis of Presentation

The consolidated financial statements include the accounts of Cytokinetics and its wholly owned subsidiary. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim financial information and the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The financial statements include all adjustments (consisting only of normal recurring adjustments) that management believes are necessary for the fair statement of the Company s position at September 30, 2015, and the results of operations for the three and nine months ended September 30, 2015 and the cash flows for the nine months ended September 30, 2015. These interim financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future interim period. The balance sheet at December 31, 2014 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements. The financial statements and related disclosures have been prepared with the presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto contained in the Company s Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 6, 2015.

Comprehensive Loss

Comprehensive loss for the three and nine months ended September 30, 2015 was equal to net loss adjusted for unrealized gains and losses on investments.

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

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

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

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

Note 2 Net Loss Per Share

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

	Three Months Ended		Nine Months Ended	
	September 30,	September 30,	September 30,	September 30,
	2015	2014	2015	2014
Net loss	\$ (8,849)	\$ (5,971)	\$ (28,272)	\$ (23,089)
Weighted-average common shares outstanding (weighted average number of shares used in computing net loss per share) basic and diluted	38,752	36,609	38,718	35,359
Net loss per share basic and diluted	\$ (0.23)	\$ (0.16)	\$ (0.73)	\$ (0.65)

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,	September 30,
	2015	2014
Options to purchase common stock	3,513	3,301
Warrants to purchase common stock	5,576	6,691
Restricted stock units	757	64
Shares issuable related to the ESPP	26	31
Total shares	9,872	10,087

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

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

	Nine Months Ended	
	September 30, 2015	September 30, 2014
Significant non-cash investing and financing activities:		
Purchases of property and equipment through accounts payable	\$ 68	\$ 200
Purchases of property and equipment through accrued liabilities	8	33

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

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

In June 2013, Cytokinetics and Amgen executed an amendment to the Amgen Agreement to include Japan, resulting in a worldwide collaboration (the Amgen Agreement Amendment). Under the terms of the Amgen Agreement Amendment, the Company received a non-refundable upfront license fee of \$15.0 million in June 2013. Under the Amgen Agreement Amendment, the Company conducted a Phase 1 pharmacokinetic study intended to support inclusion of Japan in a potential Phase 3 clinical development program and potential global registration dossier for omecamtiv mecarbil. Amgen reimbursed the Company for the costs of this study. In addition, the Company is eligible to receive additional pre-commercialization milestone payments relating to the development of omecamtiv mecarbil and royalties on sales of omecamtiv mecarbil in Japan.

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

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

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

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

Table of Contents

Under the Amgen Agreement, as amended, the Company is eligible to receive over \$350.0 million in development milestone payments which are based on various clinical milestones, including the initiation of certain clinical studies, the submission of a drug candidate to certain regulatory authorities for marketing approval and the receipt of such approvals. Additionally, the Company is eligible to receive up to \$300.0 million in commercial milestone payments provided certain sales targets are met. Due to the nature of drug development, including the inherent risk of development and approval of drug candidates by regulatory authorities, it is not possible to estimate if and when these milestone payments would become due. The achievement of each of these milestones is dependent solely upon the results of Amgen's development and commercialization activities and therefore none of these milestones was deemed to be substantive. During the three and nine months ended September 30, 2015, no revenues were recognized for milestones achieved under the Amgen Agreement.

The Amgen Agreement also provides for the Company to receive increased royalties by co-funding Phase 3 development costs of omecamtiv mecarbil and other drug candidates under the collaboration. If the Company elects to co-fund such costs, it would be entitled to co-promote the co-funded drug in North America and participate in agreed commercialization activities in institutional care settings, at Amgen's expense.

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

Revenue from Amgen was as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Research and development revenues from related parties				
Reimbursement of internal costs	\$ 598	\$ 1,747	\$ 1,862	\$ 3,210
Allocated consideration		173	21	218
Total revenues from Amgen	\$ 598	\$ 1,920	\$ 1,883	\$ 3,428

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

	September 30, 2015	December 31, 2014
Related party accounts receivable Amgen	\$ 1,642	\$ 1,642

Astellas Pharma Inc. (Astellas)

Original Astellas Agreement (Non-neuromuscular license)

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

Under the Original Astellas Agreement, the Company granted Astellas an exclusive license to co-develop and jointly commercialize CK-2127107, a fast skeletal troponin activator, for potential application in non-neuromuscular indications worldwide. The Company was primarily responsible for the conduct of Phase 1 clinical trials and certain Phase 2 readiness activities for CK-2127107 and Astellas was primarily responsible for the conduct of subsequent development and commercialization activities for CK-2127107.

In July 2013, the Company received an upfront, non-refundable license fee of \$16.0 million in connection with the execution of the Original Astellas Agreement. Under the agreement, the Company was eligible to potentially receive approximately \$25.4 million in reimbursement of sponsored research and development activities during the initial two years of the collaboration. The agreement also provided for research and early and late stage development milestone payments based on various research and clinical milestones, including the initiation of certain clinical studies, the submission for approval of a drug candidate to certain regulatory authorities for marketing approval and the commercial launch of collaboration products, and royalties on sales of commercialized products.

Table of Contents

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

The Company determined that the license and the research and development services are a single unit of accounting as the license was determined to not have stand-alone value. Accordingly, the Company is recognizing this revenue using the proportional performance model over the initial research term of the Original Astellas Agreement. During the three and nine months ended September 30, 2015, the Company recorded \$4.1 million and \$8.8 million, respectively, in license revenue based on the proportional performance model. As of September 30, 2015, the Company has recognized \$15.9 million of the \$16.0 million upfront license fee as license revenue, and has \$0.1 million of deferred license revenue under the Original Astellas Agreement.

Pursuant to the Original Astellas Agreement, the Company has recognized research and development revenue from Astellas for reimbursements of internal costs of certain full-time employee equivalents, supporting collaborative research and development programs, and of other costs related to those programs. During the three months ended September 30, 2015, the Company recorded research and development revenue from Astellas of \$1.6 million related to the reimbursement of internal costs and \$1.6 million related to the reimbursement of other costs. During the nine months ended September 30, 2015, the Company recorded research and development revenue from Astellas of \$4.1 million related to the reimbursement of internal costs and \$4.1 million related to the reimbursement of other costs.

Amended Astellas Agreement (Expansion to include neuromuscular indications)

On December 22, 2014, the Company entered into an amended and restated license and collaboration agreement with Astellas (the Amended Astellas Agreement). This agreement superseded the Original Astellas Agreement. The Amended Astellas Agreement expanded the objective of the collaboration of advancing novel therapies for diseases and medical conditions associated with muscle weakness to include spinal muscular atrophy (SMA) and potentially other neuromuscular indications with CK-2127107 and other fast skeletal troponin activators, in addition to the non-neuromuscular indications provided for in the Original Astellas Agreement. Under the terms of the Amended Astellas Agreement, we received a non-refundable upfront license fee of \$30.0 million in January 2015. Concurrently, the Company received \$15.0 million as a milestone payment relating to Astellas' decision to advance CK-2127107 into Phase 2 clinical development. The Company is also eligible to potentially receive over \$20.0 million in reimbursement of sponsored research and development activities through December 2016. Under the Amended Astellas Agreement, the Company plans to conduct the initial Phase 2 clinical trial of CK-2127107 in patients with SMA. In addition, the Company is entitled to receive additional pre-commercialization milestone payments related to the development of CK-2127107 in neuromuscular indications, and royalties on sales of CK-2127107 in neuromuscular indications.

The Company determined that the license and the research and development services relating to the Amended Astellas Agreement are a single unit of accounting as the license was determined to not have stand-alone value. Accordingly, the Company is recognizing this revenue over the initial research term of the Amended Astellas Agreement using the proportional performance model. As of September 30, 2015, the Company has recognized \$6.5 million of the \$30.0 million upfront license fee as license revenue and deferred the remaining amount.

The Company believes that each of the milestones related to research and early development under the Amended Astellas Agreement is substantive and can only be achieved with the Company's past and current performance and each milestone will result in additional payments to the Company. During the three and nine months ended September 30, 2015, no milestone revenue for early development was recognized under this agreement. The Company is eligible to receive up to \$2.0 million in research milestone payments for each future collaboration product candidate.

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

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

Table of Contents

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

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

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

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

	Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Research and development revenues with related parties:				
Reimbursement of internal costs	\$ 1,552	\$	\$ 4,082	\$
Reimbursement of other costs	1,636		4,121	
Research and development revenues:				
Reimbursement of internal costs		2,895		7,092
Reimbursement of other costs		1,866		5,023
Research and development milestone fees				2,000
Total research and development revenue from Astellas	\$ 3,188	\$ 4,761	\$ 8,203	\$ 14,115

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

		September 30, 2015	December 31, 2014
Related party accounts receivable	Astellas	\$	\$ 45,000

At September 30, 2015, the Company had \$25.2 million of deferred revenue under the Amended Astellas Agreement, reflecting the unrecognized portion of the license revenue, allocation of consideration and payment of expenses.

Table of Contents**Note 5 Cash Equivalents and Investments*****Cash Equivalents and Available for Sale Investments***

The amortized cost and fair value of cash equivalents and available for sale investments at September 30, 2015 and December 31, 2014 were as follows (in thousands):

		September 30, 2015				Maturity
		Amortized	Unrealized	Unrealized	Fair	Dates
		Cost	Gains	Losses	Value	
Cash equivalents	money market funds	\$ 22,336	\$	\$	\$ 22,336	
Short-term investments	U.S. Treasury securities	\$ 72,009	\$ 16	\$ (1)	\$ 72,024	10/2015-8/2016

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

At September 30, 2015 there were no investments that had been in a continuous unrealized loss position for 12 months or longer. The Company collected the contractual cash flows on its U.S. Treasury securities that matured from October 1, 2015 through October 30, 2015 and expects to be able to collect all contractual cash flows on the remaining maturities of its U.S. Treasury securities.

Interest income was as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,	September 30,	September 30,	September 30,
	2015	2014	2015	2014
Interest income	\$ 38	\$ 26	\$ 114	\$ 78

Note 6 Fair Value Measurements

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

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

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

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

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

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

Table of Contents

Financial assets measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 are classified in the table below in one of the three categories described above (in thousands):

	September 30, 2015			
	Fair Value Measurements Using			Assets
	Level 1	Level 2	Level 3	At Fair Value
Money market funds	\$ 22,336	\$	\$	\$ 22,336
U.S. Treasury securities	72,024			72,024
Total	\$ 94,360	\$	\$	\$ 94,360
Amounts included in:				
Cash and cash equivalents	\$ 22,336	\$	\$	\$ 22,336
Short-term investments	72,024			72,024
Total	\$ 94,360	\$	\$	\$ 94,360

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

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

Note 7 Stockholders' Equity*Accumulated Other Comprehensive Income*

In the first nine months of 2015 and 2014, the Company did not reclassify any unrealized gains on investments from accumulated other comprehensive income into net loss.

Warrants

As of September 30, 2015, the Company had warrants outstanding to purchase 5.6 million shares of the Company's common stock. These warrants were issued pursuant to the June 2012 underwriting agreements the Company entered into in connection with two separate, concurrent offerings for our securities (the June 2012 Public Offerings).

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

Table of Contents

Outstanding warrants as of September 30, 2015 were as follows:

	Number of Shares	Exercise Price	Expiration Date
Issued pursuant to the June 2012 Public Offerings	5,576,048	\$ 5.28	06/25/17

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

Committed Equity Offering

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

Sales of the Company's common stock through Cantor Fitzgerald, if any, will be made on The NASDAQ Global Market by means of ordinary brokers' transactions at market prices or as otherwise agreed to by the Company and Cantor Fitzgerald. Subject to the terms and conditions of the Cantor Fitzgerald Agreement, Cantor Fitzgerald will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). The Company is not obligated to make any sales of common stock under the Cantor Fitzgerald Agreement. The offering of shares of common stock pursuant to the Cantor Fitzgerald Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the Cantor Fitzgerald Agreement or (2) termination of the Cantor Fitzgerald Agreement. The Cantor Fitzgerald Agreement may be terminated by Cantor Fitzgerald at any time upon ten days notice to the Company or may be terminated by the Company at any time upon five days notice to Cantor Fitzgerald, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material adverse change in the Company's business. The Company will pay Cantor Fitzgerald a commission rate equal to 3.0% of the gross proceeds of the sales price per share of any common stock sold through Cantor Fitzgerald under the Cantor Fitzgerald Agreement. The Company has also provided Cantor Fitzgerald with customary indemnification and contribution rights. As of September 30, 2015, no shares have been issued to Cantor Fitzgerald under the Cantor Fitzgerald Agreement.

Equity Incentive Plans

Stock option activity for the nine months ended September 30, 2015 under the Company's 2004 Equity Incentive Plan, as amended, and the Company's 1997 Stock Option/Stock Issuance Plan was as follows:

Shares Available for Grant of Options or Awards	Stock Options Outstanding	Weighted Average Exercise Price per Share of Stock Options
--	--------------------------------------	---

Edgar Filing: CYTOKINETICS INC - Form 10-Q

Balance at December 31, 2014	1,270,478	3,297,826	\$	12.62
Increase in authorized shares	3,130,000			
Options granted	(1,154,130)	1,154,130		7.56
Options exercised		(62,325)		6.12
Options forfeited	170,665	(170,665)		7.58
Options expired	146,465	(146,465)		27.90
Restricted stock units granted	(54,000)			
Balance at September 30, 2015	3,509,478	4,072,501	\$	10.94

Table of Contents

Restricted stock unit activity for the nine months ended September 30, 2015 was as follows:

	Number of Shares	Weighted Average Award Date Fair Value per Share
Restricted stock units outstanding at December 31, 2014	63,330	\$ 8.51
Restricted stock units granted	54,000	7.96
Restricted stock units released	(42,078)	7.82
Restricted stock units forfeited	(3,500)	8.68
Unvested restricted stock units outstanding at September 30, 2015	71,752	\$ 8.49

Restricted stock activities were limited to non-executive employees for the nine months ended September 30, 2015.

During the three months ended September 30, 2015, the Company granted 685,000 performance stock unit awards with a grant date fair value of \$7.00 per share that contain performance conditions. As of September 30, 2015, all these performance stock units remain unvested.

Total employee stock-based compensation expenses were \$1.1 million and \$0.9 million for the three months ended September 30, 2015 and 2014, respectively and \$3.2 million and \$2.4 million for the nine months ended September 30, 2015 and 2014, respectively.

Note 8 Interest and Other, Net

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

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

The Company leases office space and equipment under a non-cancelable operating lease that expires in 2018, with an option to extend the lease for an additional three-year period. The lease terms provide for rental payments on a graduated scale and the Company's payment of certain operating expenses. The Company recognizes rent expense on a straight-line basis over the lease period. Rent expense was \$0.8 million and \$0.8 million, respectively, for the three months ended September 30, 2015 and 2014, and \$2.5 and \$2.5 million, respectively, for the nine months ended September 30, 2015 and 2014.

Contingencies

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

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

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

Table of Contents

Note 10 Income Taxes

During the three and nine months ended September 30, 2015 and 2014, the Company did not record a provision for income taxes because it expected to generate a net operating loss for the year ending December 31, 2015 and 2014, respectively.

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

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

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

Note 11 Subsequent Events

As of October 30, 2015, 90,957 shares have been issued to Cantor Fitzgerald under the Cantor Fitzgerald Agreement entered into in September 2015 and as described in Note 7, for net proceeds of \$0.6 million. Refer to Note 7 for further details.

In October 2015, the Company entered into a loan and security agreement (the *Loan Agreement*) with Oxford Finance LLC (*Oxford*,) as the collateral agent and a lender, and Silicon Valley Bank (*SVB*,) as a lender (Oxford and SVB collectively the *Lenders*) to fund its working capital and other general corporate needs. The Loan Agreement provided for (1) term loans of up to \$40.0 million in aggregate, (2) warrants to purchase 65,189 shares of the Company's common stock at an exercise price of \$6.90 per share under the first term loan, and (3) additional warrants to purchase shares of the Company's common stock to be based on the amount of the additional term loans and a price per share determined on the day of funding in accordance with the Grant Agreement, which is also the exercise price per share for the warrants. The Company drew down \$15.0 million in funds under the Loan Agreement in October 2015, and may at its sole discretion draw down the additional \$25 million under the Loan Agreement in two term loans, provided certain specified conditions stipulated in the Loan Agreement are met preceding those draws. The expiration date of the remaining term loans of \$15.0 million and \$10 million are June 2016 and March 2017, respectively. The Company is required to repay the outstanding principal in 36 equal installments beginning October 2017 and is due in full in October 2020. The first term loan bears interest at a rate of 7.5% per annum. The remaining term loans, if drawn, will bear interest at a rate fixed at the time of draw, equal to the greater of (i) 7.50% and (ii) the sum of the three month U.S. LIBOR rate plus 7.31%. The loan carries prepayment penalties of 3% and 2% for prepayment within one and two years, respectively, of the loan origination and 1% thereafter. The warrants issued in the Loan Agreement

became exercisable upon issuance and will remain exercisable for five years until the earlier of October 19, 2020 or the closing of a merger consolidation transaction in which the Company is not the surviving entity.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to the Company and its subsidiaries, including, among other things, restrictions on dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. The Agreement also includes customary events of default, including but not limited to the nonpayment of principal or interest, violations of covenants, material adverse changes, attachment, levy, restraint on business, cross-defaults on material indebtedness, bankruptcy, material judgments, misrepresentations, subordinated debt, governmental approvals, lien priority and delisting. Upon an event of default, the Lenders may, among other things, accelerate the loans and foreclose on the collateral. The Loan Agreement and Warrant Agreements will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

As of October 30, 2015, all of the warrants were outstanding and exercisable. As of October 30, 2015, we have received \$15.0 million from this loan and security agreement, net of issuance cost.

Table of Contents

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

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

This report contains forward-looking statements indicating expectations about future performance and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. We intend that such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to, statements about or relating to:

guidance concerning revenues, research and development expenses and general and administrative expenses for 2015;

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

our capital requirements and needs for additional financing;

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

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

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

the expected acceptability by regulatory authorities of the effects of tirasemtiv on Slow Vital Capacity or other measures of clinical benefit related to respiratory function in patients with ALS as a Phase 3 clinical trial endpoint to support the registration of tirasemtiv as a treatment for ALS;

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

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

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

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

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

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

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

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

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

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

expected future sources of revenue and capital;

losses, costs, expenses and expenditures;

future payments and other obligations under loan and lease agreements

potential competitors and competitive products;

retaining key personnel and recruiting additional key personnel;

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

difficulties or delays in