



Cytokinetics, Incorporated Reports Third Quarter 2013 Financial Results

October 30, 2013 8:03 PM EDT

Company Provides Updates on Key Progress in Development Programs for Heart Failure and ALS

SOUTH SAN FRANCISCO, CA, October 30, 2013 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported total revenues for the third quarter of 2013 were \$4.5 million, compared to \$1.7 million during the same period in 2012. The net loss for the third quarter was \$12.6 million, or \$0.43 per basic and diluted share. This is compared to a net loss allocated to common stockholders for the same period in 2012, of \$10.0 million, or \$0.45 per basic and diluted share. As of September 30, 2013, cash, cash equivalents and investments totaled \$85.4 million.

"During the third quarter, Cytokinetics announced presentations of the results from ATOMIC-AHF relating to *omecamtiv mecarbil* at two leading scientific meetings, one in Europe and one in the United States," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We are pleased these data from ATOMIC-AHF were supported by the international cardiology community and inform decisions regarding potential progression of this drug candidate in continued development. In addition, the completion of the dose escalation phase of COSMIC-HF relating to *omecamtiv mecarbil*, alongside today's update on enrollment of BENEFIT-ALS relating to *tirasemtiv*, underscore significant positives in both of our lead clinical trials programs. We look forward to continued progress through the remainder of 2013 and are making preparations for results from both trials in 2014."

Company Highlights

Cardiac Muscle Contractility

omecamtiv mecarbil

- During the quarter, the results from ATOMIC-AHF (**A**cute **T**reatment with **O**me**ca**mtiv **M**ecarbil to Increase **C**ontractility in **A**cute **H**eart **F**ailure) were presented at the ESC Congress 2013, organized by the European Society of Cardiology in Amsterdam. Additional data were presented at the HFSA Annual Scientific Meeting, organized by the Heart Failure Society of America in Orlando, Florida. ATOMIC-AHF was conducted by Amgen in collaboration with Cytokinetics.
- During the quarter, the second cohort of the dose escalation phase of COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yo**s**in **A**ctivation to Increase **C**ontractility in **H**eart **F**ailure) completed enrollment. Recently, Cytokinetics and Amgen reviewed results from COSMIC-HF and selected an oral formulation of *omecamtiv mecarbil* for evaluation in the planned expansion phase of the trial. Cytokinetics and Amgen are discussing an amendment to the protocol of COSMIC-HF prior to initiating enrollment in the expansion phase. COSMIC-HF is a Phase II, double-blind, randomized, placebo-controlled, multicenter study designed to assess the pharmacokinetics, safety, tolerability and pharmacodynamic effects of oral modified-release 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.
- Recently, Cytokinetics and Amgen agreed on the protocol and budget for a planned Phase I pharmacokinetic study of *omecamtiv mecarbil* in healthy volunteers of both Japanese and non-Japanese ethnicity. The trial, CY 1211, will be conducted by Cytokinetics in collaboration with Amgen. The costs of the trial will be reimbursed by Amgen.

Additional information on these and other clinical trials of *omecamtiv mecarbil* can be found at www.clinicaltrials.gov.

Skeletal Muscle Contractility

tirasemtiv

- During the quarter, Cytokinetics continued enrollment in BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional **I**mprovement with **T**irasemtiv in **A**LS) trial. BENEFIT-ALS is a Phase IIb, multinational, double-blind, randomized, placebo-controlled clinical trial designed to evaluate the safety, tolerability and potential efficacy of *tirasemtiv* in patients with amyotrophic lateral sclerosis (ALS). BENEFIT-ALS is designed to enroll approximately 680 patients with ALS. To date, over 600 patients have been enrolled in BENEFIT-ALS and over 300 patients have completed 12 weeks of treatment. 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. Recently, the Data Safety Monitoring Board completed a pre-scheduled meeting to review the data and recommended that the trial continue without any changes to the protocol. Cytokinetics anticipates completion of enrollment in BENEFIT-ALS in the fourth quarter of 2013.
- During the quarter, Cytokinetics 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*.

CK-2127107

- During the quarter, Cytokinetics completed enrollment in CY 5011, a first-time-in-humans, Phase I clinical trial of CK-2127107 in healthy male volunteers. 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.
- Recently, Cytokinetics initiated dosing in CY 5014, a Phase I clinical trial of CK-2127107 in healthy male volunteers. CY 5014 is a randomized, open-label, 2-period crossover study to assess the relative oral bioavailability, pharmacokinetics, safety and tolerability of two oral formulations of CK-2127107.

The trials described above are being conducted by Cytokinetics pursuant to our collaboration with Astellas Pharma Inc.

Pre-Clinical Research

- During the quarter, Cytokinetics continued to conduct research under our joint research program with Amgen, directed to the discovery of next-generation cardiac sarcomere activators, and our joint research program with Astellas, directed to the discovery of next-generation skeletal muscle activators. In addition, the company continued research activities directed to other muscle biology programs.

Financials

Revenues for the third quarter of 2013 were \$4.5 million, compared to \$1.7 million during the same period in 2012. Revenues for the third quarter of 2013 included \$1.4 million of license revenues and \$2.3 million of research and development revenues from our collaboration with Astellas. Revenues for the third quarter of 2013 also included \$0.2 million of research and development revenue from our collaboration with MyoKardia, Inc., and \$0.6 million of revenue from our collaboration with Amgen. Revenues for the same period in 2012 included \$1.0 million of revenue from our collaboration with Amgen, \$0.3 million in grant revenue, \$0.3 million of revenue from our collaboration with Global Blood Therapeutics, Inc., and \$0.1 million of revenue from our collaboration with MyoKardia.

Total research and development (R&D) expenses in the third quarter of 2013 were \$13.4 million, compared with \$8.8 million for the same period in 2012. The \$4.6 million increase in R&D expenses for the third quarter of 2013, compared with the same period in 2012, was primarily due to increased spending for outsourced clinical costs.

Total general and administrative (G&A) expenses for the third quarter of 2013 were \$3.6 million, compared with \$3.0 million for the same period in 2012. The \$0.6 million increase in G&A expenses in the third quarter of 2013, compared with the same period in 2012, was primarily due to increased spending for personnel-related costs and outsourced costs.

Revenues for the nine months ended September 30, 2013 were \$6.3 million, compared to \$5.4 million for the same period in 2012. Revenues for the nine months ended September 30, 2013 included \$1.4 million of license revenues and \$2.3 million of research and development revenues from our collaboration with Astellas. Revenues for the first nine months of 2013 also included \$1.5 million of revenue from our collaboration with Amgen, \$1.0 million revenue from our collaboration with MyoKardia and \$0.1 million of grant revenue. Revenues for the same period in 2012 included \$3.2 million of revenue from our collaboration with Amgen, \$0.9 million in grant revenue, and \$1.1 million of revenue from our collaboration with Global Blood Therapeutics and \$0.1 million of revenue from our collaboration with MyoKardia.

Total R&D expenses for the nine months ended September 30, 2013 were \$35.6 million, compared to \$25.8 million for the same period in 2012. The \$9.8 million increase in R&D expenses in the first nine months of 2013, over the same period in 2012, was primarily due to increased spending for outsourced clinical and personnel-related costs, partially offset by decreased spending for outsourced preclinical expenses.

Total G&A expenses for the nine months ended September 30, 2013 were \$11.0 million, compared to \$8.6 million for the same period in 2012. The \$2.4 million increase in G&A spending in the first nine months of 2013 compared to the same period in 2012 was primarily due to increased spending for personnel-related costs, legal expenses and outside services.

The net loss allocable to common stockholders for the nine months ended September 30, 2013 was \$40.2 million, or \$1.52 per basic and diluted share. The net loss allocable to common stockholders for the same period in 2012 was \$30.2 million, or \$1.86 per basic and diluted share, which included a one-time, non-cash dividend of \$1.3 million related to the beneficial conversion feature of the Series B convertible preferred stock.

Financial Guidance 2013

Cytokinetics affirmed its previous financial guidance for 2013: cash revenue are expected to be approximately \$40 to \$42 million, cash R&D expenses are expected to be in the range of \$52 to \$55 million, and cash G&A expenses are expected to be in the range of \$15 to \$16 million. This financial guidance is on a cash basis and does not include the deferral of approximately \$10 million in revenue to future calendar years and an estimated \$5.6 million in non-cash related operating expenses primarily related to stock compensation expense. The company anticipates recognizing the license fee of \$15 million associated with the June 2013 amendment to our collaboration agreement with Amgen in the fourth quarter of 2013.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's second quarter results via a webcast and conference call today at 4:30 PM Eastern Time. The webcast can be accessed through the Homepage and Investor Relations section of the Cytokinetics website at www.cytokinetics.com. The live audio of the conference call can also be accessed by telephone by dialing either (866) 999-CYTK (2985) (United States and Canada) or (706) 679-3078 (international) and typing in the passcode 92574472.

An archived replay of the webcast will be available via Cytokinetics' website until November 7, 2013. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (international) and typing in the passcode 92574472 from October 30, 2013 at 5:30 PM Eastern Time until November 7, 2013.

About Cytokinetics

Cytokinetics 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. Cytokinetics' lead drug candidate from its cardiac muscle contractility program, *omecamtiv mecarbil*, is in Phase II clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing *tirasemtiv*, a fast skeletal muscle activator, as a potential treatment for diseases and medical conditions associated with neuromuscular dysfunction. *Tirasemtiv* is currently the subject of a Phase II clinical trials program and has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency for the potential treatment of amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a skeletal muscle activator structurally distinct from *tirasemtiv*, for non-neuromuscular indications. All of these drug candidates have arisen from Cytokinetics' muscle biology focused research activities and are directed towards the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Additional information about Cytokinetics can be obtained at www.cytokinetics.com.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Cytokinetics disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the Act's Safe Harbor for forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Cytokinetics' financial guidance, including expected revenue and R&D and G&A expenses for 2013 and the expected timing of revenue recognition events; Cytokinetics' and its partners' research and development activities, including the initiation, conduct, design, enrollment, progress, continuation, completion and results of clinical trials, and the significance and utility of clinical trial results; and the properties and potential benefits of Cytokinetics' drug candidates. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to, Cytokinetics anticipates that it will be required to conduct at least one confirmatory Phase III clinical trial of tirasemtiv in ALS patients which will require significant additional funding, and it may be unable to obtain such additional funding on acceptable terms, if at all; potential difficulties or delays in the development, testing, regulatory approvals for trial commencement, progression or product sale or manufacturing, or production of Cytokinetics' drug candidates that could slow or prevent clinical development or product approval, including risks that current and past results of clinical trials or preclinical studies may not be indicative of future clinical trials results, patient enrollment for or conduct of clinical trials may be difficult or delayed, Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy, the U.S. Food and Drug Administration or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, and Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil and CK-2127107, respectively; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; Cytokinetics may be unable to enter into future collaboration agreements for its drug candidates and programs on acceptable terms, if at all; standards of care may change, rendering Cytokinetics' drug candidates obsolete; competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including milestones and royalties on future potential product sales under Cytokinetics' collaboration agreements with such partners. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

Contact:

Joanna L. Goldstein
Manager, Investor Relations & Corporate Communications
(650) 624-3000

Cytokinetics, Incorporated
Condensed Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Revenues:				
Research and development	\$ 3,059	\$ 1,714	\$ 4,889	\$ 5,375
License and technology fees	1,410	-	1,410	-
Total revenues	<u>4,469</u>	<u>1,714</u>	<u>6,299</u>	<u>5,375</u>
Operating Expenses:				
Research and development	13,445	8,798	35,626	25,785
General and administrative	3,635	2,991	10,999	8,614
Restructuring	-	(2)	-	(56)
Total operating expenses	<u>17,080</u>	<u>11,787</u>	<u>46,625</u>	<u>34,343</u>
Operating loss	<u>(12,611)</u>	<u>(10,073)</u>	<u>(40,326)</u>	<u>(28,968)</u>
Interest and other, net	<u>23</u>	<u>29</u>	<u>78</u>	<u>54</u>
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	<u>(12,588)</u>	<u>(10,044)</u>	<u>(40,248)</u>	<u>(30,221)</u>
Net loss per share allocable to common stockholders - basic and diluted	\$ (0.43)	\$ (0.45)	\$ (1.52)	\$ (1.86)
Weighted average shares used in computing net loss per share allocable to common stockholders - basic and diluted	29,395	22,360	26,413	16,215

Cytokinetics, Incorporated
Condensed Balance Sheets
(in thousands)
(unaudited)

	September 30, 2013	December 31, 2012
Assets		
Cash and cash equivalents	\$ 19,258	\$ 14,907
Short term investments	62,384	59,093
Related party receivables	-	4
Other current assets	<u>1,679</u>	<u>2,423</u>
Total current assets	83,321	76,427
Property and equipment, net	804	997
Long-term investments	3,754	-
Other assets	<u>127</u>	<u>127</u>
Total assets	<u>\$ 88,006</u>	<u>\$ 77,551</u>
Liabilities and stockholders' equity		
Deferred revenue, current	\$ 33,322	-

Other current liabilities	<u>11,689</u>	<u>7,105</u>
Total current liabilities	45,011	7,105
Deferred revenue, non-current	2,696	-
Other non-current liabilities	548	361
Stockholders' equity	<u>39,751</u>	<u>70,085</u>
Total liabilities and stockholders' equity	<u>\$ 88,006</u>	<u>\$ 77,551</u>

HUG#1739381