



Cytokinetics, Incorporated Reports Fourth Quarter 2013 Financial Results

February 6, 2014 9:00 PM EST

Company Summarizes Recent Progress in Development Programs and Provides Expected Milestones and Financial Guidance for 2014

SOUTH SAN FRANCISCO, CA, February 6, 2014 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported total revenues of \$24.3 million for the fourth quarter of 2013, compared to \$2.2 million during the same period in 2012. Net income for the fourth quarter was \$6.5 million, or \$0.22 per basic share and \$0.21 per diluted share. This is compared to a net loss for the same period in 2012, of \$(11.5) million, or \$(0.48) per basic and diluted share. As of December 31, 2013, cash, cash equivalents and investments totaled \$80.2 million.

"During the fourth quarter, Cytokinetics announced significant progress in both our clinical development programs. The recent completion of enrollment in BENEFIT-ALS shifts focus to finalizing patient treatment and the collection and analyses of data," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We anticipate announcing results from BENEFIT-ALS in the next few months and are now busily preparing for potential next steps in our development program for *tirasemtiv*. In parallel, we are pleased with the planned advancement of *omecamtiv mecarbil* into the final expansion phase of COSMIC-HF and with the continued progression of CK-2127107 in Phase I studies and Phase II readiness activities. Cytokinetics executed on operational and financial objectives in 2013 setting the stage for another productive year ahead."

Company Highlights

Skeletal Muscle Contractility

tirasemtiv

- During the quarter, Cytokinetics completed enrollment in BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional Improvement with *Tirasemtiv* in **ALS**). 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). Enrollment closed with 711 patients and, to date, over 400 patients have completed 12 weeks of treatment.
- Recently, the Data Safety Monitoring Board (DSMB) for BENEFIT-ALS reviewed data relating to safety, tolerability and potential efficacy of *tirasemtiv* from the ongoing trial. The DSMB recommended that the trial proceed to completion without any changes to the protocol.
- During the quarter, Cytokinetics continued to make preparations for the potential further development and the commercialization of *tirasemtiv*. These activities included interactions with regulatory authorities and other manufacturing, corporate development and commercial planning activities to support planning scenarios.
- During the quarter, a platform presentation providing an update on BENEFIT-ALS was made at the International Symposium on ALS/MND. In the presentation, the clinical trial design was explained and interim, double-blind, aggregate data on patient enrollment, baseline demographics, dose escalation, and tolerability were presented.

CK-2127107

- During the quarter, Cytokinetics presented data from CY 5011, a first-time-in-humans, Phase I clinical trial of CK-2127107 in healthy male volunteers. CY 5011 was a double-blind, randomized, placebo-controlled study designed to assess the safety, tolerability, and pharmacokinetics of single ascending oral doses of CK-2127107 administered in a three-period crossover design. Planned single doses of CK-2127107 up to 4000 mg, the highest dose administered in this trial were well-tolerated. A maximum tolerated dose was not defined. The pharmacokinetic profile of CK-2127107 was linear and dose-proportional across the dose range studied, with a mean terminal half-life compatible with once or twice daily dosing.
- During the quarter, Cytokinetics completed 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 designed to assess the relative oral bioavailability, pharmacokinetics, safety and tolerability of two oral formulations of CK-2127107.

The clinical trials of CK-2127107 described above are being conducted by Cytokinetics in collaboration with Astellas Pharma Inc.

Cardiac Muscle Contractility

omecamtiv mecarbil

- Recently, Cytokinetics and Amgen agreed to amend the protocol to evaluate a plasma concentration-guided dose titration strategy in the expansion phase of COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**ysin **A**ctivation to **I**ncrease **C**ontractility in **H**eart **F**ailure). The size of the expansion phase also has been increased with the objective to provide greater statistical power for the planned evaluation of several pharmacodynamic parameters during oral dosing with *omecamtiv mecarbil*. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- Recently, Cytokinetics and Amgen began making preparations for CY 1211, a Phase I single center, placebo-controlled, double-blind study comparing the pharmacokinetics of *omecamtiv mecarbil* between healthy Japanese and Caucasian volunteers. This trial is being conducted by Cytokinetics in collaboration with Amgen.
- Cytokinetics is collaborating with Amgen to respond to information requests received from regulatory authorities relating to their ongoing review of protocols submitted for COSMIC-HF and CY 1211.

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

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 fourth quarter of 2013 were \$24.3 million, compared to \$2.2 million during the same period in 2012. Revenues for the fourth quarter of 2013 included \$2.4 million of license revenues and \$4.1 million of research and development revenues from our collaboration with Astellas and \$17.2 million of license revenues and \$0.6 million of research and development revenues from our collaboration with Amgen. Revenues for the same period in 2012 included \$0.9 million of revenue from our collaboration with Amgen, \$0.4 million in grant revenue, \$0.5 million of revenue from our collaboration with MyoKardia and \$0.4 million in revenue from our collaboration with Global Blood Therapeutics, Inc.

Total research and development (R&D) expenses in the fourth quarter of 2013 were \$13.8 million, compared with \$9.9 million for the same period in 2012. The \$3.9 million increase in R&D expenses for the fourth quarter of 2013, compared with the same period in 2012, was primarily due to increased spending for outsourced clinical and preclinical costs.

Total general and administrative (G&A) expenses for the fourth quarter of 2013 were \$4.1 million, compared with \$3.8 million for the same period in 2012. The \$0.3 million increase in G&A expenses in the fourth quarter of 2013, compared with the same period in 2012, was primarily due to increased spending for corporate development planning.

Revenues for the twelve months ended December 31, 2013 were \$30.6 million, compared to \$7.6 million for the same period in 2012. Revenues for the twelve months ended December 31, 2013 primarily consisted of \$3.9 million of license revenues and \$6.4 million of research and development revenues from our collaboration with Astellas, \$17.2 million of license revenue and \$2.0 million of research and development revenues from our collaboration with Amgen and \$1.0 million in revenue from our collaboration with MyoKardia. Revenues for the same period in 2012 included \$4.2 million of revenue from our collaboration with Amgen, \$1.3 million in grant revenue, and \$1.5 million of revenue from our collaboration with Global Blood Therapeutics and \$0.6 million of revenue from our collaboration with MyoKardia.

Total R&D expenses for the twelve months ended December 31, 2013 were \$49.5 million, compared to \$35.6 million for the same period in 2012. The \$13.9 million increase in R&D expenses in the twelve months of 2013, over the same period in 2012, was primarily due to increased spending for outsourced clinical and laboratory costs, partially offset by decreased spending for outsourced preclinical expenses.

Total G&A expenses for the twelve months ended December 31, 2013 were \$15.1 million, compared to \$12.4 million for the same period in 2012. The \$2.7 million increase in G&A spending in the twelve months of 2013 compared to the same period in 2012 was primarily due to increased spending for personnel-related costs, outside services and legal expenses.

The net loss allocable to common stockholders for the twelve months ended December 31, 2013 was \$(33.7) million, or \$(1.24) per basic and diluted share. The net loss allocable to common stockholders for the same period in 2012 was \$(41.7) million, or \$(2.30) 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 2014

Cytokinetics also announced its financial guidance for 2014. The company anticipates cash revenue will be in the range of \$19 to \$21 million, cash R&D expenses will be in the range of \$50 to \$53 million, and cash G&A expenses will be in the range of \$15 to \$17 million. This guidance is on a cash basis and does not include approximately \$10 million in revenue deferred from 2013 to 2014 under generally accepted accounting principles and an estimated \$3 million in non-cash related operating expenses primarily related to stock compensation expense. In addition, this guidance does not reflect potential revenues from milestone payments that may be achieved in partnered programs.

Company Milestones

Skeletal Muscle Contractility

tirasemtiv

- Cytokinetics expects to report data from BENEFIT-ALS at the American Academy of Neurology Annual Meeting in Philadelphia in April 2014.

CK-2127107

- Cytokinetics expects to conduct additional Phase I studies and certain Phase II readiness activities in 2014 pursuant to our collaboration agreement with Astellas.

Cardiac Muscle Contractility

omecamtiv mecarbil

- Cytokinetics expects commencement of patient enrollment in both the expansion phase of COSMIC-HF and in CY 1211 to occur in the first half of 2014 following regulatory authorities' review of responses relating to information requests provided in connection with the protocols submitted for the two trials.
- Cytokinetics expects both the enrollment of patients in the expansion phase of COSMIC-HF as well as the conduct of CY 1211 to be completed in 2014.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth 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 34948581.

An archived replay of the webcast will be available via Cytokinetics' website until February 13, 2014. 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 34948581 from February 6, 2014 at 5:30 PM Eastern Time until February 13, 2014.

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 (ALS). 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 2014; Cytokinetics' and its partners' research and development activities, including the initiation, conduct, design, enrollment, progress, continuation, completion and results of clinical trials, the anticipated timing for the availability of clinical trial results and planned presentations of such results, and the significance and utility of clinical trial results; the further development and commercialization of *tirasemtiv*; 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.*

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

	Three Months Ended		Year Ended	
	December 31, 2013	December 31, 2012	December 31, 2013	December 31, 2012
Revenues:				
Research and development	\$ 4,677	\$ 2,184	\$ 9,566	\$ 7,559
License and technology fees	19,672	-	21,082	-
Total revenues	<u>24,349</u>	<u>2,184</u>	<u>30,648</u>	<u>7,559</u>
Operating Expenses:				
Research and development	13,824	9,857	49,450	35,643
General and administrative	4,093	3,815	15,092	12,429
Restructuring	-	-	-	(56)
Total operating expenses	<u>17,917</u>	<u>13,672</u>	<u>64,542</u>	<u>48,016</u>
Operating income (loss)	<u>6,432</u>	<u>(11,488)</u>	<u>(33,894)</u>	<u>(40,457)</u>
Interest and other, net	<u>99</u>	<u>33</u>	<u>177</u>	<u>87</u>
Net income (loss)	6,531	(11,455)	(33,717)	(40,370)

Deemed dividend related to beneficial conversion feature of convertible preferred stock
Net income (loss) allocable to common stockholders
Net income (loss) per share allocable to common stockholders - basic
Net income (loss) per share allocable to common stockholders - diluted
Weighted average shares used in computing net income (loss) per share allocable to common stockholders - basic
Weighted average shares used in computing net income (loss) per share allocable to common stockholders - diluted

	-	-	-	(1,307)
	<u>6,531</u>	<u>(11,455)</u>	<u>(33,717)</u>	<u>(41,677)</u>
\$	0.22\$	(0.48)	(1.24)\$	(2.30)
\$	0.21\$	(0.48)	(1.24)\$	(2.30)
	29,836	23,740	27,275	18,107
	31,190	23,740	27,275	18,107

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

	December 31, 2013	December 31, 2012
Assets		
Cash and cash equivalents	\$ 20,158\$	14,907
Short term investments	57,570	59,093
Related party receivables	5	4
Other current assets	<u>1,605</u>	<u>2,423</u>
Total current assets	79,338	76,427
Property and equipment, net	1,221	997
Long-term investments	2,502	-
Other assets	<u>127</u>	<u>127</u>
Total assets	<u>\$ 83,188\$</u>	<u>77,551</u>
Liabilities and stockholders' equity		
Deferred revenue, current	\$ 14,701\$	-
Other current liabilities	<u>12,003</u>	<u>7,105</u>
Total current liabilities	26,704	7,105
Deferred revenue, non-current	1,500	-
Other non-current liabilities	542	361
Stockholders' equity	<u>54,442</u>	<u>70,085</u>
Total liabilities and stockholders' equity	<u>\$ 83,188\$</u>	<u>77,551</u>