



## Cytokinetics, Incorporated Reports Fourth Quarter 2012 Financial Results

February 5, 2013 9:00 PM EST

### **Company Recaps Significant Milestones in Ongoing Phase IIb Clinical Trials Expected to Generate Results in 2013**

**SOUTH SAN FRANCISCO, CA, February 5, 2013** - Cytokinetics, Incorporated (Nasdaq: CYTK) reported total research and development revenues of \$2.2 million for the fourth quarter of 2012. The net loss for the fourth quarter was \$10.1 million, or \$0.07 per basic and diluted share, compared to a net loss of \$11.9 million, or \$0.16 per basic and diluted share, for the same period in 2011. As of December 31, 2012, cash, cash equivalents and investments totaled \$74.0 million.

"During the fourth quarter, we continued to make substantial progress in both of our ongoing Phase IIb clinical development programs," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In the last quarter, we opened BENEFIT-ALS, our Phase IIb clinical trial evaluating *tirasemtiv* in patients with amyotrophic lateral sclerosis, to enrollment and also announced the progression to the third and final cohort of ATOMIC-AHF, our Phase IIb trial evaluating *omecamtiv mecarbil* in patients hospitalized with acute heart failure. We expect to announce results from each of these important trials in 2013, a year that holds significant promise for Cytokinetics and our first-in-class compounds directed to muscle biology."

### **Company Highlights**

#### **Skeletal Muscle Contractility**

*tirasemtiv* (formerly CK-2017357)

- In October, Cytokinetics announced the opening to enrollment of BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional Improvement with *Tirasemtiv* in **ALS**), a Phase IIb, multi-national, 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). This trial is designed to randomize approximately 400 patients to 12 weeks of double-blind treatment with *tirasemtiv* or placebo. The primary analysis of BENEFIT-ALS will compare the mean change from baseline in the ALS Functional Rating Scale in its revised form (ALSFERS-R) on *tirasemtiv* versus placebo. Secondary endpoints will include Maximum Voluntary Ventilation (MVV) and measures of skeletal muscle function. Cytokinetics plans to conduct BENEFIT-ALS at over 70 sites across the United States, Canada, and several European countries. Additional information about this trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).
- In November, Cytokinetics announced positive data from CY 4023, a Phase IIa Evidence of Effect, double-blind, randomized, three-period crossover, placebo-controlled, pharmacokinetic and pharmacodynamic clinical trial of *tirasemtiv* in patients with generalized myasthenia gravis (MG). In CY 4023, at six hours after dosing, improvements (i.e., decreases) in the Quantitative MG score (QMG) were related to the dose of *tirasemtiv* in a statistically significant manner (-0.49 QMG points per 250 mg;  $p = 0.02$ ). Also at six hours after dosing in CY 4023, increases in the percent predicted forced vital capacity were statistically significantly related to the dose level of *tirasemtiv* (2.2% per 250 mg;  $p = 0.04$ ), as were the individual comparisons of each dose level of *tirasemtiv* versus placebo. Both the 250 mg and 500 mg single oral doses of *tirasemtiv* studied in this Phase IIa clinical trial were well-tolerated by the 32 patients enrolled in CY 4023; there were no premature terminations and no serious adverse events were reported. This clinical trial and preclinical research on MG were funded by a grant from the National Institute of Neurological Disorders and Stroke (NINDS).
- In December, Cytokinetics announced pharmacokinetic data and pharmacokinetic/pharmacodynamic analyses from three previously-reported clinical trials of *tirasemtiv* in patients with ALS during a platform presentation at the 23<sup>rd</sup> International Symposium on ALS and Motor Neurone Diseases (ALS/MND) in Chicago, IL.

CK-2127107

- During the quarter, Cytokinetics filed an Investigational New Drug (IND) application for CK-2127107, which has recently cleared review by the U.S. Food and Drug Administration (FDA). CK-2127107, a selective, fast skeletal muscle troponin activator, is a drug candidate that was discovered during Cytokinetics' optimization of a different chemical series than that which produced *tirasemtiv*.

#### **Cardiac Muscle Contractility**

*omecamtiv mecarbil*

- In November, Cytokinetics announced the opening to enrollment of the third and final cohort of the ongoing, international, randomized, double-blind, placebo-controlled, Phase IIb clinical trial of an intravenous formulation of *omecamtiv mecarbil*, known as ATOMIC-AHF (**A**cute **T**reatment with *O**me**camtiv Mecarbil* to Increase **C**ontractility in **A**cute **H**eart **F**ailure). This trial is sponsored by Amgen in collaboration with Cytokinetics and is designed to evaluate the safety, tolerability, and efficacy of *omecamtiv mecarbil* in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure. Additional information about ATOMIC-AHF can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).
- During the quarter, Cytokinetics and Amgen collaborated to enable the initiation of a Phase II double-blind, randomized, placebo-controlled, multicenter, dose escalation study designed to evaluate several modified-release oral formulations of *omecamtiv mecarbil*, known as COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yo**s**in **A**ctivation to Increase **C**ontractility in **H**eart **F**ailure) in patients with heart failure and left ventricular systolic dysfunction. This trial is expected to inform the selection of an oral formulation for potential advancement into the Phase III clinical program.
- During the quarter, dosing initiated in a Phase I open-label, single-dose clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of *omecamtiv mecarbil* in patients with various degrees of renal insufficiency and in patients undergoing hemodialysis. This trial is sponsored by Amgen in collaboration with Cytokinetics. Additional information about this trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## **Pre-Clinical Research**

- During the quarter, Cytokinetics continued to conduct research in its muscle biology-related research programs.

## **Corporate**

- In December, Cytokinetics hosted an R&D Day to update the investment community on the company's research and development pipeline and to highlight the potential opportunities, specifically in ALS and heart failure, for novel drug candidates directed to the biology of muscle contractility. Following the company update, Cytokinetics hosted a panel discussion with experts convened to discuss the integrated care of patients with ALS.
- Recently, Cytokinetics received a notice from The Nasdaq Stock Market ("Nasdaq") confirming that it has regained compliance with the minimum \$1.00 bid price per share requirement for its common stock.

## **Financials**

Revenues for the fourth quarter of 2012 were \$2.2 million, compared to \$0.8 million during the same period in 2011. Revenues for the fourth quarter of 2012 included \$0.9 million of revenue from our collaboration with Amgen, \$0.5 million from our collaboration with MyoKardia, Inc., \$0.4 million from our collaboration with Global Blood Therapeutics, Inc., and \$0.4 million of grant revenue from the NINDS. Revenues for the fourth quarter of 2011 included \$0.5 million in grant revenue from the NINDS, and \$0.3 million of revenue from our collaboration with Global Blood Therapeutics, Inc.

Total research and development (R&D) expenses in the fourth quarter of 2012 were \$9.2 million, compared with \$8.6 million for the same period in 2011. The \$0.6 million increase in R&D expenses for the fourth quarter of 2012, compared with the same period in 2011, was primarily due to increased spending for outsourced clinical and preclinical expenses and facility expenses, partially offset by decreased spending for personnel-related costs and laboratory expenses.

Total general and administrative (G&A) expenses for the fourth quarter of 2012 were \$3.1 million, compared with \$2.9 million for the same period in 2011. The \$0.2 million increase in G&A expenses in the fourth quarter of 2012, compared with the same period in 2011, was primarily due to increased spending for outside services and legal expenses, partially offset by decreased spending for personnel-related costs and facility expenses.

Revenues for the twelve months ended December 31, 2012 were \$7.6 million, compared to \$4.0 million for the same period in 2011. Revenues for the twelve months of 2012 included \$4.2 million from our collaboration with Amgen, \$1.5 million from our collaboration with Global Blood Therapeutics, Inc., \$1.3 million of grant revenue from the NINDS, and \$0.6 million from our collaboration with MyoKardia, Inc. Revenues for the twelve months of 2011 included \$2.0 million from our collaboration with Amgen, \$1.7 million from our NINDS grant, and \$0.3 million from our collaboration with Global Blood Therapeutics, Inc.

Total R&D expenses for the twelve months ended December 31, 2012 were \$35.0 million, compared to \$37.2 million for the same period in 2011. The \$2.2 million decrease in R&D expenses in the twelve months of 2012, over the same period in 2011, was primarily due to decreased spending for laboratory expenses, and personnel-related costs, partially offset by increased outsourced preclinical and clinical expenses, and facility expenses.

Total G&A expenses for the twelve months ended December 31, 2012 were \$11.7 million, compared to \$13.6 million for the same period in 2011. The \$1.9 million decrease in G&A spending in the twelve months of 2012 compared to the same period in 2011, was primarily due to decreased spending for personnel-related costs, outside services, and facility expenses.

The net loss allocable to common stockholders for the twelve months ended December 31, 2012, was \$40.3 million, or \$0.37 per basic and diluted share, which includes a one-time, non-cash dividend of \$1.3 million related to the beneficial conversion feature of the Series B Convertible Preferred Stock. This compares to a net loss allocable to common stockholders of \$50.7 million, or \$0.72 per basic and diluted share, for the same period in 2011, which included a one-time, non-cash dividend of \$2.9 million related to the beneficial conversion feature of the Series A Convertible Preferred Stock.

## **Financial Guidance for 2013**

Cytokinetics also announced its financial guidance for 2013. The company anticipates revenue will be in the range of \$1 to \$3 million, cash R&D expenses will be in the range of \$40 to \$44 million, and cash G&A expenses will be in the range of \$12 to \$13 million. This financial guidance is on a cash basis and does not include an estimated \$4.8 million in non-cash related operating expenses primarily related to stock compensation expense. In addition, this guidance does not reflect potential revenue from any new collaborations.

## **Annual Stockholders' Meeting**

Cytokinetics' Annual Stockholders' Meeting will be held at the Embassy Suites Hotel located at 250 Gateway Boulevard in South San Francisco, CA at 1:30 PM on Wednesday, May 22, 2013.

## **Company Milestones**

### **Skeletal Muscle Contractility**

#### *tirasemtiv*

- By mid-year 2013, Cytokinetics anticipates completion of enrollment in BENEFIT-ALS.
- By the end of 2013, Cytokinetics expects to report data from BENEFIT-ALS.

CK-2127107

- In the first half of 2013, Cytokinetics anticipates initiating a Phase I clinical trial evaluating CK-2127107 in healthy volunteers.

### **Cardiac Muscle Contractility**

#### *omecamtiv mecarbil*

- In the first quarter of 2013, Cytokinetics anticipates the opening to enrollment of COSMIC-HF.
- In the first half of 2013, Cytokinetics anticipates the completion of enrollment in ATOMIC-AHF.
- In mid-year 2013, Cytokinetics expects to report results from ATOMIC-AHF.

### 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 Investor Relations section of the Cytokinetics' website at [www.cytokinetics.com](http://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 92558691.

An archived replay of the webcast will be available via Cytokinetics' website until February 12, 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 92558691 from February 5, 2013 at 5:30 PM Eastern Time until February 12, 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 (excluding Japan) to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing *tirasemtiv*, a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or 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 in which treatment with *tirasemtiv* produced potentially clinically relevant pharmacodynamic effects in Phase II trials. 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](http://www.cytokinetics.com).

*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; statements relating to Cytokinetics' and Amgen's research and development activities, including the initiation, enrollment, conduct, design, endpoints, size, scope, progress and results of clinical trials of tirasemtiv, omeclamtiv mecarbil and CK-2127107; the significance and utility of clinical trial results and the anticipated timing for the availability of clinical trial results; and the properties and potential benefits of Cytokinetics' drug candidates and potential 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, and the U.S. Food and Drug Administration (FDA) or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omeclamtiv mecarbil; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Cytokinetics may incur unanticipated research and development and other costs; 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; regulatory authorities may not grant tirasemtiv orphan drug exclusivity in ALS even if it is approved for marketing; 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:

Jodi L. Goldstein  
Manager, Corporate Communications & Marketing  
(650) 624-3000

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

	Three Months Ended		Twelve Months Ended	
	December	December	December	December 31,
	31,	31,	31,	2011
	2012	2011	2012	2011
Revenues:				
Research and development	\$ 2,184	\$ 757	\$ 7,559	\$ 4,000
Total revenues	2,184	757	7,559	4,000
Operating Expenses:				
Research and development	9,214	8,599	35,000	37,182
General and administrative	3,103	2,863	11,717	13,590
Restructuring	-	1,192	(56)	1,192

Total operating expenses	12,317	12,654	46,661	51,964
Operating loss	(10,133)	(11,897)	(39,102)	(47,964)
Interest and other, net	33	20	87	104
Net loss	(10,100)	(11,877)	(39,015)	(47,860)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	-	-	(1,307)	(2,857)
Net loss allocable to common stockholders	<u>\$ (10,100)</u>	<u>\$ (11,877)</u>	<u>\$ (40,322)</u>	<u>\$ (50,717)</u>
Net loss per share allocable to common stockholders - basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.16)</u>	<u>\$ (0.37)</u>	<u>\$ (0.72)</u>
Weighted average shares used in computing net loss per share allocable to common stockholders - basic and diluted	142,442,508	72,775,298	108,641,962	70,799,637

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

	<b>December 31, 2012</b>	<b>December 31, 2011</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 14,907	\$ 18,833
Short-term investments	59,093	30,190
Related party receivables	4	14
Other current assets	<u>2,423</u>	<u>2,103</u>
Total current assets	76,427	51,140
Property and equipment, net	997	1,310
Restricted cash	-	196
Other assets	<u>127</u>	<u>127</u>
<b>Total assets</b>	<u><u>\$ 77,551</u></u>	<u><u>\$ 52,773</u></u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities	\$ 5,750	\$ 4,592
Long-term liabilities	361	3
Stockholders' equity	<u>71,440</u>	<u>48,178</u>
<b>Total liabilities and stockholders' equity</b>	<u><u>\$ 77,551</u></u>	<u><u>\$ 52,773</u></u>

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