Cytokinetics, Incorporated Reports First Quarter 2013 Financial Results

April 30, 2013 8:00 PM EDT

Company Elaborates on Key Progress in Cardiac and Skeletal Muscle Programs

SOUTH SAN FRANCISCO, CA, April 30, 2013 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported total research and development revenues of $0.8 million for the first quarter of 2013. The net loss for the first quarter was $12.6 million, or $0.09 per basic and diluted share, compared to a net loss of $9.9 million, or $0.13 per basic and diluted share, for the same period in 2012. As of March 31, 2013, cash, cash equivalents and investments totaled $61.6 million.

"In the first quarter, we progressed through important milestones in both of our later-stage clinical development programs," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We recently announced the completion of enrollment in ATOMIC-AHF, our Phase IIb trial evaluating an intravenous form of *omecamtiv mecarbil* in acute heart failure patients, and the initiation of dosing in COSMIC-HF, our Phase II trial evaluating oral forms of *omecamtiv mecarbil* in outpatients with heart failure. In addition, during the last quarter, BENEFIT-ALS, our Phase IIb clinical trial evaluating *tirasemtiv* in patients with ALS, exceeded 200 patients enrolled, and we initiated Phase I dosing of CK-2127107, our second fast skeletal muscle troponin activator. We believe Cytokinetics is executing well on our key milestones for 2013 and we are looking forward to Phase IIb clinical trial results from each of ATOMIC-AHF and BENEFIT-ALS."

Company Highlights

Cardiac Muscle Contractility

omecamtiv mecarbil

- In March, Cytokinetics announced that ATOMIC-AHF completed patient enrollment in its third and final cohort. ATOMIC-AHF (**A**cute **T**reatment with ***O****mecamtiv* ***M****ecarbil* to **I**ncrease **C**ontractility in **A**cute **H**eart **F**ailure) is a Phase IIb international, randomized, double-blind placebo-controlled clinical trial designed to evaluate the safety, tolerability and efficacy of an intravenous formulation of *omecamtiv mecarbil* in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure.
- In March, Cytokinetics announced that patient dosing initiated in COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure). This Phase II, double-blind, randomized, placebo-controlled, multicenter, dose escalation study is designed to evaluate three modified-release oral formulations of *omecamtiv mecarbil* in patients with heart failure and left ventricular systolic dysfunction. COSMIC-HF is expected to inform the selection of an oral formulation for potential advancement into the Phase III clinical development program.
- During the quarter, dosing completed in Part A of a Phase I open-label, single-dose clinical trial designed to evaluate the pharmacokinetics, safety and tolerability of *omecamtiv mecarbil* in patients with various degrees of renal insufficiency and in patients undergoing hemodialysis.

The trials described above are being conducted by Amgen in collaboration with Cytokinetics. Additional information on these and other clinical trials relating to *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 **ALS**). This Phase IIb, multi-national, double-blind, randomized, placebo-controlled clinical trial is designed to evaluate the safety, tolerability and potential efficacy of *tirasemtiv* in patients with amyotrophic lateral sclerosis (ALS). To date, Cytokinetics has enrolled over 200 patients in this clinical trial. A recent review of the double-blind, aggregate data from BENEFIT-ALS indicated that the actual standard deviation about the primary endpoint (i.e., the change from baseline in the ALS Functional Rating Scale in its revised form) is slightly higher than the estimate used to initially calculate the sample size for the trial. Consequently, in order to preserve the intended statistical power for the trial, the company is amending the protocol to allow approximately 500 patients to be enrolled. Additional information about BENEFIT-ALS can be found at www.clinicaltrials.gov.
- In March, Cytokinetics announced the presentation of data from CY 4023, a Phase IIa Evidence of Effect clinical trial of *tirasemtiv* in patients with generalized myasthenia gravis (MG), during the Emerging Science Program at the American Academy of Neurology Annual Meeting. CY 4023 was a double-blind, randomized, three-period crossover, placebo-controlled, pharmacokinetic and pharmacodynamic trial evaluating single doses of *tirasemtiv. Tirasemtiv* treatment was associated with statistically significant, dose-related increases in skeletal muscle endurance in the patients with MG studied, as determined by the Quantitative MG score (QMG). This clinical trial and preclinical research related to *tirasemtiv* in MG were funded by a grant from the National Institute of Neurological Disorders and Stroke (NINDS).

CK-2127107

- In April, Cytokinetics announced the initiation of CY 5011, a first-time-in-humans, Phase I clinical trial of CK-2127107, a novel small molecule activator of the fast skeletal muscle troponin complex, 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.

Pre-Clinical Research

- During the quarter, Cytokinetics scientists continued to conduct research in our muscle biology programs.
- During the quarter, Cytokinetics and Amgen agreed to extend a collaborative research program directed to the discovery of next-generation cardiac sarcomere activator compounds. Amgen will reimburse Cytokinetics for certain research expenses incurred in connection with agreed activities performed under the collaboration.
- In March, Cytokinetics and Families of Spinal Muscular Atrophy (FSMA) announced the award of a grant from FSMA to support Cytokinetics' preclinical research with *tirasemtiv* related to muscle function in a mouse model of SMA.

Corporate

- In February, Cytokinetics announced that B. Lynne Parshall had been appointed to the company's Board of Directors. The company also announced that Steve Dow provided notification that he will not stand for re-election to the Board of Directors at the Annual Meeting of Shareholders.

Financials

Revenues for the first quarter of 2013 were $0.8 million, compared to $1.8 million during the same period in 2012. Revenues for the first quarter of 2013 included $0.4 million of revenue from our collaboration with MyoKardia, Inc., $0.3 million of revenue from our collaboration with Amgen, and $0.1 million of grant revenue from the NINDS. Revenues for the first quarter of 2012 included $1.2 million of revenue from our collaboration with Amgen, $0.3 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 first quarter of 2013 were $9.8 million, compared with $8.7 million for the same period in 2012. The $1.1 million increase in R&D expenses for the first quarter of 2013, compared with 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 general and administrative (G&A) expenses for the first quarter of 2013 were $3.6 million, compared with $3.1 million for the same period in 2012. The $0.5 million increase in G&A expenses in the first quarter of 2013, compared with the same period in 2012, was primarily due to increased spending for personnel-related costs, outside services and legal expenses.

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

Cardiac Muscle Contractility

omecamtiv mecarbil

- In mid-2013, Cytokinetics expects to report results from ATOMIC-AHF.

Skeletal Muscle Contractility

tirasemtiv

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

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first 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. 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 92569832.
An archived replay of the webcast will be available via Cytokinetics' website until May 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 92569832 from April 30, 2013 at 5:30 PM Eastern Time until May 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 (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* and CK-2127107, both fast skeletal muscle activators, as potential treatments for diseases and medical 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.

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' and Amgen's research and development activities, including the conduct, design, enrollment, progress and results of clinical trials, the anticipated timing for the availability of clinical trial results, and the significance and utility of clinical trial results; Amgen's reimbursement of certain Cytokinetics research expenses; 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 decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil; 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 share and per share data)
(unaudited)

	Three Months Ended	
	March 31, 2013	March 31, 2012
Revenues:		
Research and development	$ 821	$ 1,820
Total revenues	821	1,820
Operating Expenses:		
Research and development	9,834	8,745
General and administrative	3,634	3,056
Restructuring	-	(41)
Total operating expenses	13,468	11,760
Operating loss	(12,647)	(9,940)
Interest and other, net	28	12
Net loss	(12,619)	(9,928)
Net loss per share allocable to common stockholders - basic and diluted	$ (0.09)	$ (0.13)
Weighted average shares used in computing net loss per share allocable to common stockholders - basic and diluted	144,061,001	76,081,592

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

	March 31, 2013	December 31, 2012
Assets		
Cash and cash equivalents	$ 13,160	$ 14,907
Short-term investments	48,438	59,093
Related party receivables	328	4
Other current assets	1,739	2,423
Total current assets	63,665	76,427
Property and equipment, net	898	997
Other assets	127	127
Total assets	$ 64,690	$ 77,551
Liabilities and stockholders' equity		
Current liabilities	$ 5,819	$ 7,105
Long-term liabilities	441	361
Stockholders' equity	58,430	70,085
Total liabilities and stockholders' equity	$ 64,690	$ 77,551