

Cytokinetics, Incorporated Reports First Quarter 2012 Financial Results

April 26, 2012 8:02 PM EDT Company Reviews Recent Advancements in Its Skeletal and Cardiac Muscle Contractility Programs

SOUTH SAN FRANCISCO, CA, Apr 26, 2012 (MARKETWIRE via COMTEX) --Cytokinetics, Incorporated (NASDAQ: CYTK) reported total research and development revenues of \$1.8 million for the first quarter of 2012. The net loss for the first quarter was \$9.9 million, or \$0.13 per basic and diluted share. This compared to a net loss of \$11.7 million, or \$0.18 per basic and diluted share, for the same period in 2011. As of March 31, 2012, cash, cash equivalents and investments, excluding restricted cash, totaled \$43.1 million.

"I am pleased to update our recent progress relating to the first quarter of 2012 by first highlighting yesterday's important announcements at the American Academy of Neurology 64th Annual Meeting in New Orleans regarding additional Phase II safety and tolerability data for CK-2017357 in ALS patients," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We believe that the results we announced can importantly inform our plans to proceed to a potential registration program for CK-2017357 and we look forward to further interactions with regulatory authorities to discuss those plans. In addition, we are pleased that the Phase IIb clinical trial of omecamtiv mecarbil in patients hospitalized with acute heart failure has recently achieved a key enrollment milestone. We look forward to a decision from the data monitoring committee that may enable dose-escalation and enrollment into the second cohort of this trial."

Company Highlights

Skeletal Muscle Contractility

CK-2017357

- At the American Academy of Neurology (AAN) 64th Annual meeting, ___ investigators presented data from the second cohort, or Part B, of CY 4024, a Phase II, two-part, randomized, double-blind, placebo-controlled, multiple dose, safety, tolerability, pharmacokinetic and pharmacodynamic clinical trial of CK-2017357 in patients with ALS who received riluzole at the reduced dose of 50 mg daily. In Part B, CK-2017357 appeared to be safe and well-tolerated dosed daily for two weeks at 125 mg, 250 mg, or 375 mg. Adverse events and clinical assessments during treatment with CK-2017357 appeared similar, with or without co-administration of riluzole. Dizziness, the most commonly reported adverse event, was mostly mild and generally began and resolved early after initiating treatment. While the trial was not designed or powered to evaluate statistically the effects of CK-2017357 on the various outcome measures that were assessed during the study, a combined analysis of patients from Part A (without riluzole) and Part B (with riluzole) suggests encouraging trends that appear dose-related and potentially clinically meaningful in magnitude. Such trends were observed in the ALS Functional Rating Scale in its revised form (ALSFRS-R) and in Maximum Voluntary Ventilation (MVV). There were no statistically significant differences in outcomes measures between patients in Part A and those in Part B.
- -- Also at the AAN Annual meeting, investigators presented data from CY 4025, a Phase II, randomized, double-blind, placebo-controlled, multiple dose clinical trial of CK-2017357 in patients with ALS receiving riluzole at the reduced dose of 50 mg daily. The primary objective of CY 4025 was to assess the safety and tolerability of CK-2017357 when administered using a twice-daily dose titration regimen to patients with ALS, and to determine if the total daily dose

of CK-2017357 could be increased from the 375 mg once daily dose that had been evaluated in earlier trials of CK-2017357 in patients with ALS to a target of 250 mg dosed twice daily. The authors concluded that the twice-daily dose titration regimen evaluated in the trial was generally safe and well-tolerated, that the majority of patients could be titrated successfully to a CK-2017357 dose level of 250 mg twice daily, and that encouraging trends toward functional improvements were observed on CK-2017357 versus placebo. CY 4025 was not designed or powered to evaluate statistically the effects of CK-2017357 on the various outcome measures that were assessed during the study; nevertheless, increases in ALSFRS-R and MVV were observed on CK-2017357 relative to placebo that were similar in direction and magnitude to those observed in CY 4024.

- -- Last week, Cytokinetics announced that CK-2017357 has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of ALS.
- -- In March, Cytokinetics announced that CK-2017357 was granted orphan medicinal product designation by the European Medicines Agency (EMA) for the potential treatment of ALS.
- -- Cytokinetics continues to enroll and dose patients in its Phase IIa Evidence of Effect clinical trial of CK-2017357, CY 4023, in patients with generalized myasthenia gravis (MG). This clinical trial and preclinical research on MG are funded by a grant from the National Institute of Neurological Disorders and Stroke (NINDS). Additional information about this trial can be found at www.clinicaltrials.gov.

Cardiac Muscle Contractility

Omecamtiv Mecarbil

- -- Enrollment in the first cohort of the international, randomized, double-blind, placebo-controlled, Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil, known as ATOMIC-AHF (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure), was completed with over 200 patients enrolled. This trial, sponsored by Amgen in collaboration with Cytokinetics, 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.
- -- In February, Cytokinetics announced that Amgen initiated a randomized, open-label, 4-way cross-over Phase I study designed to assess the

safety, tolerability and pharmacokinetics of multiple oral formulations of omecamtiv mecarbil in healthy volunteers.

Other Non-Clinical Development and Pre-Clinical Research

- -- During the quarter, Cytokinetics announced the publication of preclinical research regarding the activation of the troponin complex of fast skeletal muscle by CK-2017357, and the potential role that this novel mechanism may play for improving muscle function in patients with neuromuscular disorders, in the March 2012 issue of the journal Nature Medicine.
- -- In addition, at the AAN Annual Meeting, Cytokinetics presented results from a preclinical study designed to examine the effects of CK-2017357 in SOD1 mutant transgenic mice, a model of ALS in humans. Company scientists concluded that mice treated with CK-2017357 maintained hindlimb grip strength during disease progression and that CK-2017357 increased muscle strength of a nerve-muscle pair in situ. There appeared to be a delay in the time to a pre-specified humane endpoint in the CK-2017357-treated mice compared to the age-matched control SOD1 mice. The authors concluded that the preclinical findings support the hypothesis that CK-2017357 may benefit patients with ALS by increasing force generation in fast skeletal muscle fibers.
- -- Yesterday, at the 2012 Experimental Biology Annual Conference, Cytokinetics presented results from a preclinical study designed to assess the effects of CK-2017357 in two models of running fatigue, one of aerobic exercise and the other of anaerobic exercise. The authors concluded that troponin activators, such as CK-2017357 are capable of substantially improving performance in an endurance-type fatigue assay and in an assay that tests motor coordination under moderately fatiguing and increasingly difficult conditions. These data suggest a role for CK-2017357 and other troponin activators in reducing muscle-related fatigue that may have utility in disease conditions in which muscle-related fatigue may lead to disability.
- -- Cytokinetics continued investigational new drug application (IND)-enabling studies of CK-2127107, a selective, fast skeletal muscle troponin activator. CK-2127107 is a potential drug candidate that was discovered during Cytokinetics' optimization of a different chemical series than that which produced CK-2017357.
- -- Cytokinetics continues to conduct research in its smooth muscle myosin inhibitor program.

Corporate

-- During the quarter, the company announced changes to its Board of Directors with the appointment of Sandford D. Smith and the resignation of James A. Spudich, Ph.D.

Financials

Revenues for the first quarter of 2012 were \$1.8 million, compared to \$0.8 million during the same period in 2011. Revenues for the first quarter of 2012 included \$1.2 million of revenue from our collaboration agreement with Amgen, \$0.3 million from our collaboration agreement with Global Blood Therapeutics, Inc., and \$0.3 million of grant revenue from the NINDS. Revenues for the first quarter of 2011 included \$0.4 million of revenue under the Amgen collaboration and \$0.4 million in grant revenue from the NINDS.

Total research and development (R&D) expenses in the first quarter of 2012 were \$8.7 million, compared to \$9.2 million for the same period in 2011. The \$0.5 million decrease in R&D expenses for the first quarter of 2012, compared to the same period in 2011, was primarily due to decreases in laboratory expense and personnel-related costs, partially offset by increases in preclinical and clinical outsourced expenses and facility-related costs.

Total general and administrative (G&A) expenses for the first quarter of 2012 were \$3.1 million, compared to \$3.3 million for the same period in 2011. The \$0.2 million decrease in G&A expenses in the first quarter of 2012, compared to the same period in 2011, was primarily due to decreased personnel-related costs and facility-related costs, partially offset by an increase in 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 10:00 AM on Tuesday, May 22, 2012.

Company Milestones

Skeletal Muscle Contractility

CK-2017357

- In the second half of 2012, Cytokinetics anticipates that data will be available from its ongoing Phase IIa Evidence of Effect clinical trial of CK-2017357 in patients with generalized myasthenia gravis (CY 4023).
- -- In 2012, Cytokinetics anticipates additional interactions with regulatory authorities to discuss the development of CK-2017357 as a potential treatment for patients with ALS, including potential registration strategies.

CK-2127107

-- By the end of 2012, Cytokinetics anticipates filing an IND for CK-2127107.

Cardiac Muscle Contractility

Omecamtiv Mecarbil

In the second quarter of 2012, Cytokinetics anticipates a decision regarding the potential progression to the second cohort of the ATOMIC-AHF clinical trial, following a review of data from the first cohort by an independent data monitoring committee. -- In the second half of 2012, Cytokinetics anticipates that safety, tolerability, and pharmacokinetic data from the ongoing Phase I clinical trial of oral formulations of omecamtiv mecarbil in healthy volunteers will be evaluated in order to enable selection of one or more of these oral formulations for potential use in future clinical studies in stable heart failure patients.

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 21514127.

An archived replay of the webcast will be available via Cytokinetics' website until May 3, 2012. 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 21514127 from April 26, 2012 at 5:30 PM Eastern Time until May 3, 2012.

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 CK-2017357, a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or neuromuscular dysfunction. CK-2017357 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 CK-2017357 demonstrated potentially clinically relevant pharmacodynamic effects in Phase II a trials. Cytokinetics is also conducting research of compounds that inhibit smooth muscle contractility and which may be useful as potential treatments for diseases and conditions associated with excessive smooth muscle contractil drug candidates have arisen from Cytokinetics' 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 its partners' research and development activities, including the initiation, enrollment, conduct, design, size, scope, progress and results of clinical trials of CK-2017357 and omecamtiv mecarbil, the significance and utility of clinical trial results and the anticipated timing for the availability of clinical trial results, anticipated meetings with regulatory authorities, plans with respect to a potential registration program for CK-2017357; 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, 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 (FDA) or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, regulatory authorities may not grant CK-2017357 orphan drug/medicinal product exclusivity in ALS even if it is approved for marketing, 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 will require significant additional funding to conduct the registration program for CK-2017357 for the potential treatment of ALS and may be unable to obtain such additional funding on acceptable terms, if at all; funding from the National Institute of Neurological Disorders and Stroke may not be available in future periods; 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; 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.

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

	N 	March 31, 2012		
Revenues: Research and development	\$	1,820	\$	763
Total revenues		1,820		763
Operating expenses: Research and development General and administrative Restructuring				9,179 3,336 _
Total operating expenses		11,760		12,515
Operating loss		(9,940)		(11,752)
Interest and other, net		12		40
Net loss		(9,928)		
Net loss per common share - basic and diluted	\$	(0.13)	\$	(0.18)
Weighted average shares used in computing net loss per common share - basic and diluted		76,081,592		66,911,328
Cytokinetics, Incorpo Condensed Balance Sh (in thousands) (unaudited)				
		March 31, 2012		ecember 31, 2011
Assets	-			
Cash and cash equivalents		\$ 17,81	5\$	18,833
Short-term investments		25,26	5	30,190
Related party receivables		8	3	14
Other current assets	-	2,05	8 	2,103

Total current assets		45 , 221		51,140
Property and equipment, net		1,132		1,310
Restricted cash		51		196
Other assets	=====	127		127
Total assets	\$ =====	46,531 ======	\$ =====	52,773
Liabilities and stockholders' equity				
Current liabilities	Ş	4,467	\$	4,592
Long-term liabilities		57		3
Stockholders' equity		42,007		48,178
Total liabilities and stockholders' equity	\$ =====	46,531 ======	\$ =====	52 , 773

Cytokinetics, Incorporated: Jodi L. Goldstein Manager, Investor Relations, Corporate Communications & Marketing (650) 624-3000

SOURCE: Cytokinetics, Inc.