Cytokinetics, Incorporated Reports Second Quarter 2014 Financial Results

July 30, 2014 8:00 PM EDT

Company Provides Updates to Development Programs Focused to Muscle Biology

SOUTH SAN FRANCISCO, CA, July 30, 2014 **-** Cytokinetics, Incorporated (Nasdaq: CYTK) reported total research and development revenues for the second quarter of 2014 were $7.8 million, compared to $1.0 million during the same period in 2013. The net loss for the second quarter was $8.4 million, or $0.23 per basic and diluted share. This is compared to a net loss for the same period in 2013, of $15.0 million, or $0.58 per basic and diluted share. As of June 30, 2014, cash, cash equivalents and investments totaled $92.1 million.

"In the second quarter, we conducted additional pre-specified analyses of data arising from BENEFIT-ALS and consulted with expert neuromuscular and pulmonary specialists with the objective to better understand the significance of the effects of *tirasemtiv* on respiratory function and its implications for the potential further development of our novel mechanism skeletal muscle activator," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Potential next steps in the development of *tirasemtiv* will be defined by our continuing analysis of results from this Phase IIb clinical trial as well as our expected interactions with regulatory authorities and possible corporate partners. In the meantime, we continue to advance our heart failure program with Amgen and our skeletal muscle program with Astellas and look forward to important milestones from both of these programs."

Company Highlights

Skeletal Muscle Contractility

tirasemtiv

- During the quarter, Cytokinetics announced further results from BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional **I**mprovement with ***T****irasemtiv* in **ALS**) at the Joint Congress of European Neurology. BENEFIT-ALS was 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). The differences in the decline in Slow Vital Capacity (SVC, a measure of the strength of the skeletal muscles responsible for breathing) on *tirasemtiv* versus placebo observed after 12 weeks of double-blind treatment were maintained for up to 4 weeks after discontinuation of treatment.
- Recently, Cytokinetics announced the results relating to *tirasemtiv* from pre-specified subgroup analyses of BENEFIT-ALS at the 13th International Congress on Neuromuscular Diseases. The results indicate that reduced declines in SVC on *tirasemtiv* versus placebo were observed consistently across all subgroups of patients in BENEFIT-ALS that were examined.
- During the quarter, Cytokinetics announced that data from preclinical research relating to *tirasemtiv* in mouse models of spinal muscular atrophy (SMA) were presented at the 2014 Annual Spinal Muscular Atrophy Conference. In these models, *tirasemtiv* increased muscle force and improved grip strength, grid hang time, and resistance to fatigue. These studies were supported in part by a grant from the Families of Spinal Muscular Atrophy.
- During the quarter, Cytokinetics announced the publication of three peer-reviewed manuscripts relating to *tirasemtiv* and fast skeletal muscle troponin activation in the journals *PLOS ONE***,** *Muscle & Nerve*, and the *American Journal of Respiratory and Critical Care Medicine*. These papers elaborated on the mechanistic effects of *tirasemtiv* and related compounds in humans as well as in a mouse model of ALS.

CK-2127107

- During the quarter, Cytokinetics continued to enroll patients in CY 5012, a double-blind, randomized, placebo-controlled, multiple ascending dose, parallel group study intended to assess the safety, tolerability, and pharmacokinetics of CK-2127107 following multiple ascending doses in healthy volunteers.

- During the quarter, Cytokinetics initiated and completed enrollment in CY 5013, a Phase I randomized, placebo-controlled, single dose, 4-period crossover study of CK-2127107 in healthy male volunteers. CY 5013 is designed to evaluate the change in the force-frequency profile and its relationship to dose and plasma concentrations of CK-2127107.

These trials are being conducted by Cytokinetics in collaboration with Astellas.

Cardiac Muscle Contractility

omecamtiv mecarbil

- During the quarter, enrollment continued in the expansion phase of COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure). COSMIC-HF is a Phase II, double-blind, randomized, placebo-controlled, multicenter clinical trial designed to assess the pharmacokinetics and tolerability of ***omecamtiv mecarbil*** dosed orally in patients with heart failure and left ventricular systolic dysfunction as well as its effects on echocardiographic measures of cardiac function. The expansion phase of COSMIC-HF has enrolled over 150 of the 450 planned heart failure patients from 95 clinical sites in 13 countries. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- During the quarter, Cytokinetics initiated dosing in 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.

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 second quarter of 2014 were $7.8 million, compared to $1.0 million during the same period in 2013. Revenues for the second quarter of 2014 included $4.2 million of research and development revenues and $2.7 million of license revenues from Cytokinetics' collaboration with Astellas, and $0.8 million of research and development revenues from Cytokinetics' collaboration with Amgen. Revenues for the same period in 2013 included $0.4 million of revenue from Cytokinetics' collaboration with MyoKardia, Inc., $0.6 million of revenue from Cytokinetics' collaboration with Amgen, and $36,000 of grant revenue.

Total research and development (R&D) expenses in the second quarter of 2014 were $11.7 million, compared with $12.3 million for the same period in 2013. The $0.6 million decrease in R&D expenses for the second quarter of 2014, compared with the same period in 2013, was primarily due to a decrease of $2.5 million in outsourced clinical costs partially offset by an increase of $1.0 million in outsourced pre-clinical costs and an increase of $0.7 million in personnel expenses.

Total general and administrative (G&A) expenses for the second quarter of 2014 were $4.5 million, compared with $3.7 million for the same period in 2013. The $0.8 million increase in G&A expenses in the second quarter of 2014, compared with the same period in 2013, was primarily due to an increase of $0.8 million in outside services costs related to commercial development and medical affairs, partially offset by a decrease of $0.2 million in legal expenses.

Revenues for the six months ended June 30, 2014 were $15.8 million, compared to $1.8 million for the same period in 2013. Revenues for the first six months of 2014 included $9.4 million of research and development revenues and $4.8 million of license revenues from Cytokinetics' collaboration with Astellas, and $1.5 million of research and development revenues from Cytokinetics' collaboration with Amgen. Revenues for the same period in 2013 included $0.9 million of research and development expenses from Cytokinetics' collaboration with Amgen collaboration, $0.8 million revenue from Cytokinetics' collaboration with MyoKardia and $0.1 million of grant revenue.

Total R&D expenses for the six months ended June 30, 2014 were $24.2 million, compared to $22.2 million for the same period in 2013. The $2.0 million increase in R&D expenses in the first six months of 2014, over the same period in 2013, was primarily due to an increase of $2.5 million in outsourced pre-clinical costs and an increase of $1.5 million in personnel expenses, partially offset by a decrease of $2.5 million in outsourced clinical costs.

Total G&A expenses for the six months ended June 30, 2014 were $8.7 million, compared to $7.4 million for the same period in 2013. The $1.3 million increase in G&A spending in the first six months of 2014 compared to the same period in 2013, was primarily due to an increase of $1.4 million in outside services costs related to commercial development, partially offset by a decrease of $0.3 million in legal expenses.

The net loss for the six months ended June 30, 2014, was $17.1 million, or $0.49 per basic and diluted share, compared to a net of $27.7 million, or $1.11 per basic and diluted share, for the same period in 2013.

Company Milestones

Skeletal Muscle Contractility

tirasemtiv

- Cytokinetics expects to interact with regulatory authorities regarding a potential development path for *tirasemtiv* in the second half of 2014.

CK-2127107

- Cytokinetics expects to conduct additional Phase I studies and certain Phase II readiness activities for CK-2127107 in 2014 pursuant to our collaboration agreement with Astellas.

Cardiac Muscle Contractility

omecamtiv mecarbil

- Cytokinetics expects both the enrollment of patients in the expansion phase of COSMIC-HF and 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 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 **34950990**.

An archived replay of the webcast will be available via Cytokinetics' website until August 6, 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 **34950990** from July 30, 2014 at 5:30 PM Eastern Time until August 6, 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 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' and its partners' research and development activities, including the initiation, conduct, design, enrollment, progress, continuation, completion and results of clinical trials and preclinical research, the potential significance and utility of the results from such trials and research, planned further analyses of the results from BENEFIT-ALS and the potential outcomes of such analyses, potential further development of tirasemtiv, conduct of additional Phase I clinical trials and Phase II readiness activities for CK-2127107 and the anticipated timing for the occurrence of events; expected interactions with regulatory authorities and possible corporate partners; and the properties and potential benefits of tirasemtiv and Cytokinetics' other 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: further clinical development of tirasemtiv in ALS patients will require significant additional funding, and Cytokinetics 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 Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Revenues:				
Research and development revenues from related parties	$ 843	$ 563	$ 1,508	$ 891
Research and development, grant and other revenues	4,196	446	9,428	939
License revenues	2,749	-	4,831	-
Total revenues	7,788	1,009	15,767	1,830
Operating Expenses:				
Research and development	11,737	12,347	24,227	22,181
General and administrative	4,458	3,730	8,717	7,364
Total operating expenses	16,195	16,077	32,944	29,545
Operating loss	(8,407)	(15,068)	(17,177)	(27,715)
Interest and other, net	33	27	59	55
Net loss	$ (8,374)	$ (15,041)	$ (17,118)	$ (27,660)
Net loss per share - basic and diluted	$ (0.23)	$ (0.58)	$ (0.49)	$ (1.11)
Weighted average shares used in computing net loss per share - basic and diluted	36,443	25,773	34,724	24,896

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2014 (unaudited)	December 31, 2013[1]
Assets		
Cash and cash equivalents	$ 12,355	$ 20,158
Short term investments	65,395	57,570
Accounts receivable and related party receivable	319	5
Other current assets	2,009	1,605
Total current assets	80,078	79,338
Property and equipment, net	1,513	1,221
Long-term investments	14,352	2,502
Other assets	200	127
Total assets	$ 96,143	$ 83,188
Liabilities and stockholders' equity		
Deferred revenue, current	$ 8,984	$ 14,701
Other current liabilities	7,933	12,003
Total current liabilities	16,917	26,704
Deferred revenue, non-current	-	1,500
Other non-current liabilities	529	542
Stockholders' equity	78,697	54,442
Total liabilities and stockholders' equity	$ 96,143	$ 83,188

[1] Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.