Cytokinetics, Incorporated Reports Third Quarter 2014 Financial Results

October 30, 2014 8:00 PM EDT

Company Provides Updates on the Advancement of Development Programs Focused to Muscle Biology

SOUTH SAN FRANCISCO, CA, October 30, 2014 **-** Cytokinetics, Incorporated (Nasdaq: CYTK) reported total research and development revenues for the third quarter of 2014 were $9.4 million, compared to $4.5 million during the same period in 2013. The net loss for the third quarter was $6.0 million, or $0.16 per basic and diluted share. This is compared to a net loss for the same period in 2013, of $12.6 million, or $0.43 per basic and diluted share. As of September 30, 2014, cash, cash equivalents and investments totaled $82.5 million.

"In the third quarter, Cytokinetics made considerable progress across our development stage programs as we elaborated in our public announcements containing program updates. In particular, I am pleased that we have completed our review of the results from BENEFIT-ALS and that we may have identified a potential path forward for *tirasemtiv* to Phase III development. In recent months, we have witnessed increases in the levels of awareness, education, fundraising and advocacy for ALS and Cytokinetics is proud to stand tall with patients with ALS and their caregivers and lead the fight against this grievous illness," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In the most recent quarter, we also concluded the conduct of the clinical trials for which we are responsible under our collaborations with each of Astellas and Amgen. We look forward to the advancement of CK-2127107 towards Phase II and *omecamtiv mecarbil* towards Phase III under our strategic alliances."

Company Highlights

Skeletal Muscle Contractility

tirasemtiv

- During the quarter, Cytokinetics completed its review of results from BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional **I**mprovement with ***T****irasemtiv* in **ALS**) and has concluded that effects observed on Slow Vital Capacity (SVC) in patients treated with *tirasemtiv* are robust and potentially clinically meaningful. In addition, following consultation with clinical and statistical advisors, the company believes that data from BENEFIT-ALS support progression of *tirasemtiv* to a Phase III clinical trial in patients with amyotrophic lateral sclerosis (ALS).
- Recently, Cytokinetics announced that it has begun regulatory interactions with the U.S. Food and Drug Administration (FDA) regarding results from BENEFIT-ALS and has received initial feedback from the FDA. The company believes that effects on SVC could be a Phase III clinical trial endpoint and could support registration of *tirasemtiv* as a potential treatment for patients with ALS. As a result, Cytokinetics has initiated planning for a potential Phase III clinical trial of *tirasemtiv* that could begin in 2015.
- During the quarter, a manuscript was published in the August edition of the journal *Vascular Medicine* highlighting the results from a previously reported Phase IIa "Evidence of Effect" clinical trial designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of a single doses of *tirasemtiv* in patients with claudication due to peripheral artery disease (PAD). The published results from this trial suggest that *tirasemtiv* was associated with a positive effect on calf muscle performance at the highest dose and plasma concentrations in individuals with PAD and claudication.

CK-2127107

- Recently, Cytokinetics announced the completion of five Phase I clinical trials evaluating CK-2127107 in healthy volunteers. These studies were conducted pursuant to an agreed development plan under the collaboration between the company and Astellas Pharma Inc. Results are summarized below:

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 to healthy adult males. Planned single doses of CK-2127107 up to 4000 mg, the highest dose administered in this trial, were well-tolerated without an emerging pattern of adverse events observed; therefore, a maximum tolerated dose could not be 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.

CY 5012 was a double-blind, randomized, placebo-controlled, multiple ascending dose, parallel group study designed to assess the safety, tolerability, and pharmacokinetics of CK-2127107 in healthy young and elderly volunteers. This Phase I clinical trial demonstrated that a 10-day course of CK-2127107, either 300 mg or 500 mg twice daily, was well-tolerated by both younger (18-55 years) and older (65-85 years) subjects. Plasma concentrations of CK-2127107 achieved steady state and no differences in pharmacokinetics between younger and older subjects were observed.

CY 5013 was a randomized, placebo-controlled, single dose, 4-period crossover study of CK-2127107 in healthy male volunteers designed to evaluate the change in the force-frequency profile of the tibialis anterior muscle during transcutaneous stimulation of the deep fibular nerve and its relationship to dose and plasma concentrations of CK-2127107. This clinical trial demonstrated that CK-2127107 amplified the response of muscle to nerve activation following a single dose of CK-2127107 in these subjects and that the results observed in preclinical models can be translated into humans.

CY 5014 was 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 in healthy volunteers. This clinical trial demonstrated that single doses of CK-2127107 in suspension, dosed at 300 mg and 1000 mg, were well-tolerated by all 25 healthy men enrolled and provided pharmacokinetic data on two different physical forms of CK-2127107 to inform ongoing development of tablet formulations for use in potential future trials.

CY 5015 was an open-label, randomized, single dose study designed to evaluate the pharmacokinetics, in a fed and fasted state, of an oral tablet form of CK-2127107 in healthy male volunteers. This clinical trial demonstrated that single doses of CK-2127107, administered at doses of 250 mg, 500 mg and 1000 mg, were well-tolerated and appeared appropriate for use in potential future clinical trials.

These trials were conducted by Cytokinetics under Astellas' sponsorship.

- During the quarter, Cytokinetics conducted other Phase II readiness activities for CK-2127107 in accordance with an agreed development plan under the joint oversight of the company and Astellas. These activities included process improvement and optimization activities for the manufacturing of CK-2127107, pre-clinical and toxicology studies, and Phase II indication prioritization analyses.

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 275 towards the objective of 450 patients. Over 70 patients in the expansion phase of COSMIC-HF have completed dosing. Recently, The Data Monitoring Committee reviewed data from COSMIC-HF and recommended that the trial continue without any changes to the protocol. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- During the quarter, Cytokinetics completed the trial known as CY 1211, a Phase I single center, placebo-controlled, double-blind study comparing the pharmacokinetics of *omecamtiv mecarbil* between healthy Japanese and Caucasian volunteers. Data from CY 1211 indicate no clinically meaningful differences between the two groups studied. This trial was 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 under 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 third quarter of 2014 were $9.4 million, compared to $4.5 million during the same period in 2013. Revenues for the third quarter of 2014 included $4.8 million of research and development revenues and $2.7 million of license revenues from Cytokinetics' collaboration with Astellas,

and $1.9 million of research and development revenues from Cytokinetics' collaboration with Amgen. Revenues for the same period in 2013 included $2.3 million of research and development revenues and $1.4 million of license revenues from Cytokinetics' collaboration with Astellas, and $0.6 million of research and development revenues from Cytokinetics' collaboration with Amgen.

Total research and development (R&D) expenses in the third quarter of 2014 were $11.4 million, compared with $13.4 million for the same period in 2013. The $2.0 million decrease in R&D expenses for the third quarter of 2014, compared with the same period in 2013, was primarily due to a decrease of $2.7 million in outsourced clinical costs partially offset by an increase of $0.6 million in personnel expenses.

Total general and administrative (G&A) expenses for the third quarter of 2014 were $4.0 million, compared with $3.6 million for the same period in 2013. The $0.4 million increase in G&A expenses in the third quarter of 2014, compared with the same period in 2013, was primarily due to an increase of $0.2 million in personnel expenses.

Revenues for the nine months ended September 30, 2014 were $25.2 million, compared to $6.3 million for the same period in 2013. Revenues for the first nine months of 2014 were primarily comprised of $14.1 million of research and development revenues and $7.6 million of license revenues from Cytokinetics' collaboration with Astellas, and $3.4 million of research and development revenues from Cytokinetics' collaboration with Amgen. Revenues for the same period in 2013 included $2.3 million of research and development revenues and $1.4 million of license revenues from Cytokinetics' collaboration with Astellas, $1.5 million of research and development revenues from Cytokinetics' collaboration with Amgen, and $1.0 million revenue from Cytokinetics' collaboration with MyoKardia.

Total R&D expenses for the nine months ended September 30, 2014 and September 30, 2013 were $35.6 million, in both periods. The R&D expenses for 2014 compared to the same period in 2013 reflected a decrease of $5.2 million in outsourced clinical costs were mainly offset by an increase of $2.4 million in outsourced pre-clinical costs and an increase of $2.1 million in personnel expense.

Total G&A expenses for the nine months ended September 30, 2014 were $12.7 million, compared to $11.0 million for the same period in 2013. The $1.7 million increase in G&A spending in the first nine 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, and $0.4 million in personnel expenses, partially offset by a decrease of $0.2 million in legal expenses.

The net loss for the nine months ended September 30, 2014 was $23.1 million, or $0.65 per basic and diluted share, compared to a net loss of $40.2 million, or $1.52 per basic and diluted share, for the same period in 2013.

Financial Guidance

Cytokinetics provided updated financial guidance for 2014: cash revenues are expected to be approximately $19 to $21 million, cash R&D expenses are expected to be in the range of $45 to $48 million, and cash G&A expenses are expected to be in the range of $15 to $17 million. This financial guidance is on a cash basis and does not include the deferral of approximately $11 million in revenue associated with the Astellas and Amgen collaborations and an estimated $3.6 million in non-cash related operating expenses primarily related to stock compensation expense.

Company Milestones

Skeletal Muscle Contractility

tirasemtiv

- Cytokinetics expects to have further interactions with regulatory authorities regarding the potential path forward for *tirasemtiv.*
- Cytokinetics expects to continue planning for a potential Phase III clinical trial of *tirasemtiv* that could begin in 2015.

CK-2127107

- Cytokinetics expects to conclude certain Phase II readiness activities in 2014 pursuant to our collaboration agreement with Astellas in order to inform the potential progression of CK-2127107 to Phase II development.

Cardiac Muscle Contractility

omecamtiv mecarbil

- Cytokinetics expects the enrollment of patients in the expansion phase of COSMIC-HF to conclude by the end of 2014.
- Cytokinetics expects the data from CY 1211 to inform plans for the development of *omecamtiv mecarbil* in Japan and the inclusion of Japan in potential global Phase III program activities.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third 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 34950991.

An archived replay of the webcast will be available via Cytokinetics' website until November 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 34950991 from October 30, 2014 at 5:30 PM Eastern Time until November 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 expected revenue and R&D and G&A expenses; Cytokinetics' and its partners' research and development activities, including the initiation, conduct, design, enrollment, progress, continuation, completion and results of clinical trials, the significance and utility of clinical trial results, planned interactions with regulatory authorities and the outcomes of such interactions, the potential conduct of a Phase III clinical trial of tirasemtiv and the timing for the initiation of such a trial; the use of effects on slow vital capacity as a Phase III clinical trial endpoint for tirasemtiv; the potential progression of CK-2127107 to Phase II development and omecamtiv mecarbil to Phase III development; the expected timing of events; 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 further clinical development of tirasemtiv in ALS patients which will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding on acceptable terms, if at all; the FDA and/or other regulatory authorities may not accept effects on slow vital capacity as a clinical endpoint to support registration of tirasemtiv for the treatment of ALS; additional Phase I clinical trials for CK-2127107 may be required; 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.

Contact:
Joanna L. Goldstein
Manager, Investor Relations & Corporate Communications
(650) 624-3000

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

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Revenues:				
Research and development revenues from related parties	$ 1,920	$ 564	$ 3,428	$ 1,455
Research and development, grant and other revenues	4,761	2,495	14,189	3,434
License revenues	2,734	1,410	7,565	1,410
Total revenues	9,415	4,469	25,182	6,299
Operating Expenses:				
Research and development	11,420	13,445	35,647	35,626
General and administrative	3,993	3,635	12,710	10,999
Total operating expenses	15,413	17,080	48,357	46,625

Operating loss	(5,998)	(12,611)	(23,175)	(40,326)
Interest and other, net	27	23	86	78
Net loss	$ (5,971)	$ (12,588)	$ (23,089)	$ (40,248)
Net loss per share - basic and diluted	$ (0.16)	$ (0.43)	$ (0.65)	$ (1.52)
Weighted average shares used in computing net loss per share - basic and diluted	36,609	29,395	35,359	26,413

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2014 (unaudited)	December 31, 2013[1]
Assets		
Cash and cash equivalents	$ 12,907	$ 20,158
Short term investments	65,589	57,570
Accounts receivable and related party receivable	1,191	5
Other current assets	1,804	1,605
Total current assets	81,491	79,338
Property and equipment, net	1,491	1,221
Long-term investments	4,003	2,502
Other assets	200	127
Total assets	$ 87,185	$ 83,188
Liabilities and stockholders' equity		
Deferred revenue, current	$ 5,284	$ 14,701
Other current liabilities	7,702	12,003
Total current liabilities	12,986	26,704
Deferred revenue, non-current	52	1,500
Other non-current liabilities	517	542
Stockholders' equity	73,630	54,442
Total liabilities and stockholders' equity	$ 87,185	$ 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.