Cytokinetics, Incorporated Reports Third Quarter 2012 Financial Results

October 30, 2012 8:00 PM EDT

Company Provides Updates Regarding Continued Progress in Phase IIb Clinical Development Programs in ALS and Heart Failure

SOUTH SAN FRANCISCO, CA, October 30, 2012 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported total research and development revenues of $1.7 million for the third quarter of 2012. The net loss for the third quarter was $10.0 million, or $0.07 per basic and diluted share, compared to a net loss of $10.6 million, or $0.15 per basic and diluted share, for the same period in 2011. As of September 30, 2012, cash, cash equivalents and investments totaled $81.2 million.

"During the third quarter, we continued to make substantial progress in both of our clinical stage development programs," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We recently opened our Phase IIb clinical trial evaluating *tirasemtiv* in patients with amyotrophic lateral sclerosis, known as BENEFIT-ALS, and enrollment is now complete in the second cohort of ATOMIC-AHF, our Phase IIb clinical trial of *omecamtiv mecarbil* in patients hospitalized with acute heart failure. We are grateful for the enthusiastic commitment of clinical trial investigators as well as participating patients and are looking forward to the projected availability of important results in 2013 relating to these novel drug candidates."

Company Highlights

Skeletal Muscle Contractility

tirasemtiv (formerly CK-2017357)

- During the quarter, Cytokinetics interacted with both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) Scientific Advice Working Party to seek advice on the design of a Phase IIb clinical trial in patients with amyotrophic lateral sclerosis (ALS). Based on feedback from these interactions, we finalized the protocol of our Phase IIb trial BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional **I**mprovement with ***T****irasemtiv* in **ALS**), formerly referred to as CY 4026.
- Yesterday, Cytokinetics announced that it has opened enrollment of BENEFIT-ALS. BENEFIT-ALS is 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 ALS. This trial is designed to enroll approximately 400 patients who will be randomized to receive 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 (ALSFRS-R) on *tirasemtiv* versus placebo. Secondary endpoints will include Maximum Voluntary Ventilation (MVV) and other measures of respiratory and skeletal muscle function. Patients will receive *tirasemtiv* or placebo dosed twice daily. 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.
- Cytokinetics closed enrollment and completed treatment of patients in its Phase IIa Evidence of Effect clinical trial of *tirasemtiv*, 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 fo*und at* www.clinicaltrials.gov.

Cardiac Muscle Contractility

omecamtiv mecarbil

- During the quarter, enrollment was completed in the second cohort of the international, randomized, double-blind, placebo-controlled, Phase IIb clinical trial of an intravenous formulation of *omecamtiv mecarbil*, known as *ATO*MIC-AHF (**A**cute **T**reatment with ***O****mecamtiv* ***M****ecarbil* to **I**ncrease **C**ontractility in **A**cute **H**eart **F**ailure). To date, over 400 patients have been enrolled in this trial. 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.
- During the quarter, Cytokinetics and Amgen collaborated to plan the manufacturing of drug product and to draft regulatory submissions to enable the potential initiation in early 2013 of a Phase II double-blind, randomized, placebo-controlled, multicenter, dose escalation study designed to evaluate several modified-release oral formulations of *omecamtiv mecarbil* in patients with heart failure and left ventricular systolic dysfunction. This trial is expected to inform the potential selection of one of these oral formulations for advancement into later-phase clinical trials.

Other Non-Clinical Development and Pre-Clinical Research

- 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 *tirasemtiv*.
- Cytokinetics continues to conduct research in its muscle biology-related research programs.

Corporate

- In September, Cytokinetics announced its participation in the launch of MyoKardia, Inc., a start-up company that is focused to genetic heart disease and which is being funded by Third Rock Ventures, LLC. Contemporaneous with the launch of MyoKardia, Cytokinetics entered into a research collaboration with the company.

- On September 26, 2012, 8,070 shares of Series A Convertible Preferred Stock were converted into 8,070,000 shares of our common stock in accordance with the terms of Cytokinetics' April 2011 financing.

Financials

Revenues for the third quarter of 2012 were $1.7 million, compared to $1.4 million during the same period in 2011. Revenues for the third quarter of 2012 included $1.0 million of revenue from our collaboration agreement with Amgen, $0.3 million from our collaboration agreement with Global Blood Therapeutics, Inc., $0.3 million of grant revenue from the NINDS, and $0.1 million from our collaboration agreement with MyoKardia. Revenues for the third quarter of 2011 included $1.0 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 third quarter of 2012 were $8.8 million, compared with $8.9 million for the same period in 2011. The $0.1 million decrease in R&D expenses for the third quarter of 2012, compared with the same period in 2011, was primarily due to decreased spending for personnel-related costs, laboratory and facilities expenses, partially offset by increased outsourced clinical and preclinical expenses.

Total general and administrative (G&A) expenses for the third quarter of 2012 were $3.0 million, compared with $3.2 million for the same period in 2011. The $0.2 million decrease in G&A expenses in the third quarter of 2012, compared with the same period in 2011, was primarily due to decreased spending for personnel-related costs and facility expenses, partially offset by increased outside services and legal expenses.

Revenues for the nine months ended September 30, 2012 were $5.4 million, compared to $3.2 million for the same period in 2011. Revenues for the first nine months of 2012 included $3.2 million of reimbursements in program expenses under our Amgen collaboration, $1.1 million from our collaboration with Global Blood Therapeutics, $0.9 million of grant revenue from the NINDS, and $0.1 million from our collaboration with MyoKardia. Revenues for the first nine months of 2011 included $2.0 million from our collaboration with Amgen and $1.2 million from our NINDS grant.

Total R&D expenses for the nine months ended September 30, 2012 were $25.8 million, compared to $28.6 million for the same period in 2011. The $2.8 million decrease in R&D expenses in the first nine months of 2012, over the same period in 2011, was primarily due to decreased spending for laboratory expenses, personnel-related costs and facility expenses, partially offset by increased outsourced preclinical expenses.

Total G&A expenses for the nine months ended September 30, 2012 were $8.6 million, compared to $10.7 million for the same period in 2011. The $2.1 million decrease in G&A spending in the first nine months of 2012 compared to the same period in 2011, was primarily due to decreased spending for personnel-related costs, financial services, legal, facility expenses.

The net loss allocable to common stockholders for the nine months ended September 30, 2012, was $30.2 million, or $0.31 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 $38.8 million, or $0.55 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.

Company Milestones

Skeletal Muscle Contractility

tirasemtiv (formerly CK-2017357)

- In the fourth quarter of 2012, Cytokinetics anticipates that data will be available from its recently completed Phase IIa Evidence of Effect clinical trial of *tirasemtiv* in patients with generalized myasthenia gravis (CY 4023).

CK-2127107

- In the fourth quarter of 2012, Cytokinetics anticipates filing an IND for CK-2127107.

Cardiac Muscle Contractility

omecamtiv mecarbil

- In the fourth quarter of 2012, Cytokinetics anticipates a decision regarding the potential progression to the third cohort of the ATOMIC-AHF clinical trial of *omecamtiv mecarbil* in patients hospitalized with acute heart failure, following a review of data from the second cohort by an independent data monitoring committee.

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 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 21519721.

An archived replay of the webcast will be available via Cytokinetics' website until November 6, 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 21519721 from October 30, 2012 at 5:30 PM Eastern Time until November 6, 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 *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.

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 initiation, enrollment, conduct, design, endpoints, size, scope, progress and results of clinical trials of tirasemtiv and omecamtiv mecarbil, 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, 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 tirasemtiv 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 tirasemtiv for the potential treatment of ALS and may be unable to obtain such additional funding on acceptable terms, if at all; 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, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

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