



Cytokinetics, Incorporated Reports Second Quarter 2012 Financial Results

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Jul 31, 2012 (Marketwire via COMTEX) --Cytokinetics, Incorporated (NASDAQ: CYTK) reported total research and development revenues of \$1.8 million for the second quarter of 2012. The net loss allocable to common stockholders for the second quarter was \$10.3 million, or \$0.13 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 is compared with a net loss allocable to common stockholders of \$16.5 million, or \$0.23 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. As of June 30, 2012, cash, cash equivalents and investments totaled \$90.5 million.

"In the second quarter, we announced the results from two Phase II clinical trials of *tirasemtiv*, formerly known as CK-2017357, in ALS patients. We believe these data inform its progression into a Phase IIb clinical trial that may support potential registration," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We also announced that the ATOMIC-AHF clinical trial evaluating the intravenous form of *omecamtiv mecarbil* in hospitalized patients with heart failure has progressed to its second cohort. This trial continues to enroll patients internationally under our collaboration with Amgen and alongside the progress the companies are making in connection with the clinical development of oral formulations of our novel cardiac myosin activator."

Company Highlights

Skeletal Muscle Contractility

tirasemtiv (formerly CK-2017357)

- Cytokinetics has received notification from the United States Adopted Names (USAN) Council and the World Health Organization's International Nonproprietary Names for Pharmaceutical Substances (INN) Programme indicating the adoption of *tirasemtiv* as the generic name for CK-2017357.
- In April, Cytokinetics presented data from both Parts A and B of CY 4024, a Phase II, two-part, randomized, double-blind, placebo-controlled, multiple-dose, safety, tolerability, pharmacokinetic and pharmacodynamic clinical trial of *tirasemtiv* in patients with amyotrophic lateral sclerosis (ALS). Patients in Part A of this trial were not taking *riluzole*; patients in Part B received *riluzole* at the reduced dose of 50 mg daily. In this trial, *tirasemtiv* appeared to be generally safe and well-tolerated when dosed daily at 125 mg, 250 mg, and 375 mg for two weeks. Encouraging dose-related trends were observed in ALSFRS-R (a clinically validated instrument designed to measure disease progression and changes in functional status) and MVV (a clinical assessment of pulmonary function and endurance). As expected, plasma concentrations of *tirasemtiv* were unaffected by co-administration with *riluzole*, while *riluzole* levels increased during co-administration with *tirasemtiv*. Adverse events and clinical assessments during treatment with *tirasemtiv* 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.
- In April, Cytokinetics announced data from CY 4025, a Phase II, randomized, double-blind, placebo-controlled, multiple-dose titration clinical trial of *tirasemtiv* in patients with ALS receiving *riluzole* at the reduced dose of 50 mg daily. In this trial, the twice-daily dose-titration regimen of *tirasemtiv* appeared to be generally safe and well-tolerated. The dose escalation regimen we studied in CY 4025 enabled a majority of patients to achieve titration to 250 mg twice daily, a higher total daily dose of *tirasemtiv* than in prior studies of *tirasemtiv* in ALS patients with comparable tolerability. In this trial, *tirasemtiv* treatment was associated with increases in the ALSFRS-R that were similar in direction and in MVV that were similar in both direction and magnitude to those observed in CY 4024.
- During the quarter, Cytokinetics submitted a clinical trial protocol to the U.S. Food and Drug Administration (FDA) for a Phase IIb trial designed to evaluate the longer-term safety, tolerability and efficacy of *tirasemtiv* in patients with ALS. The trial, called CY 4026, is intended to be an international, randomized, double-blind, placebo-controlled, dose-titration clinical trial

of *tirasemtiv* dosed twice-daily in patients with ALS receiving *riluzole* at the reduced dose of 50 mg daily. The trial is designed to enroll approximately 400 patients who are expected to receive *tirasemtiv* or placebo for three months. The proposed primary endpoint is ALSFRS-R. The proposed secondary endpoints will include MVV. In April, Cytokinetics announced that *tirasemtiv* was granted Fast Track designation by FDA for the potential treatment of ALS.

- During the quarter, Cytokinetics met with the European Medicines' Agency (EMA) Scientific Advice Working Party (SAWP) to seek advice and protocol assistance in connection with its interest to further expand the clinical development program for *tirasemtiv* to include countries in Europe.
- In June, Cytokinetics announced the publication of the Phase II Evidence of Effect Study of *tirasemtiv* in the online edition of the journal *Amyotrophic Lateral Sclerosis*.
- Cytokinetics continues to enroll and dose 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 found at www.clinicaltrials.gov.

Cardiac Muscle Contractility

omecamtiv mecarbil

- In May, Cytokinetics announced the opening to enrollment of the second 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), which is designed to evaluate the safety, tolerability, and efficacy of successive ascending-dose cohorts of *omecamtiv mecarbil* in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure. Following a review of the data from the first cohort in this ongoing Phase IIb clinical trial, the independent data monitoring committee concluded that the data supported progression to the second cohort of this trial. ATOMIC-AHF is sponsored by Amgen in collaboration with Cytokinetics. Additional information about the trial can be found at www.clinicaltrials.gov.
- Recently, Cytokinetics and Amgen reviewed data from the completed randomized, open-label, 4-period cross-over, Phase I clinical trial designed to assess the safety, tolerability and pharmacokinetics of multiple oral formulations of *omecamtiv mecarbil* in healthy volunteers. The companies have selected oral formulations that warrant further evaluation in patients with heart failure.

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 smooth muscle myosin inhibitor program.

Corporate

- In June, Cytokinetics announced two separate concurrent, underwritten offerings of shares of its common stock and accompanying warrants and shares of its Series B Convertible Preferred Stock ("Series B") and accompanying warrants. In aggregate for the concurrent

offerings, the company issued 55.9 million shares of common stock, 23,026 shares of Series B Convertible Preferred Stock and warrants to purchase 47.4 million shares of its common stock at an exercise price of \$0.88 per share. Cytokinetics received gross proceeds of \$60.0 million from these offerings before deducting the issuance costs.

Financials

Revenues for the second quarter of 2012 were \$1.8 million, compared to \$1.1 million during the same period in 2011. Revenues for the second quarter of 2012 included \$1.1 million of revenue from our collaboration agreement with Amgen, \$0.4 million from our collaboration agreement with Global Blood Therapeutics, Inc., and \$0.3 million of grant revenue from the NINDS. Revenues for the second quarter of 2011 included \$0.7 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 second quarter of 2012 were \$8.2 million, compared with \$10.5 million for the same period in 2011. The \$2.3 million decrease in R&D expenses for the second quarter of 2012, compared with the same period in 2011, was primarily due to decreases in outsourced clinical expenses, laboratory expense, personnel-related costs, and facility costs.

Total general and administrative (G&A) expenses for the second quarter of 2012 were \$2.6 million, compared with \$4.2 million for the same period in 2011. The \$1.6 million decrease in G&A expenses in the second quarter of 2012, compared with the same period in 2011, was primarily due to decreased financial services, legal, personnel-related and facility costs.

Revenues for the six months ended June 30, 2012 were \$3.7 million, compared to \$1.8 million for the same period in 2011. Revenues for the first six months of 2012 included \$2.3 million of reimbursements in program expenses under the Amgen collaboration, \$0.8 million from our collaboration agreement with Global Blood Therapeutics, Inc., and \$0.6 million of grant revenue from the NINDS. Revenues for the first six months of 2011 of \$1.0 million were derived from our collaboration with Amgen and \$0.8 million from our NINDS grant.

Total R&D expenses for the six months ended June 30, 2012 were \$17.0 million, compared to \$19.7 million for the same period in 2011. The \$2.7 million decrease in R&D expenses in the first six months of 2012, over the same period in 2011, was primarily due to decreased spending for laboratory expenses, personnel-related costs, outsourced clinical expenses, and facility costs, partially offset by increased outsourced pre-clinical costs.

Total G&A expenses for the six months ended June 30, 2012 were \$5.6 million, compared to \$7.5 million for the same period in 2011. The \$1.9 million decrease in G&A spending in the first six months of 2012 compared to the same period in 2011, was primarily due to lower financial services, legal, personnel-related and facility costs.

The net loss allocable to common stockholders for the six months ended June 30, 2012, was \$20.2 million, or \$0.26 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, compared to a net loss allocable to common stockholders of \$28.2 million, or \$0.41 per basic and diluted share, for the same period in 2011, which includes a one-time, non-cash dividend of \$2.9 million related to the beneficial conversion feature of the Series A Convertible Preferred Stock.

Updated Financial Guidance for 2012

Cytokinetics also announced its updated financial guidance for 2012 which incorporates the estimated costs associated with CY 4026. The company anticipates revenue will be in the range of \$5.0 to \$7.0 million, cash R&D expenses will be in the range of \$40.0 to \$44.0 million, and cash G&A expenses will be in the range of \$10.0 to \$12.0 million. This financial guidance is on a cash basis and does not include an estimated \$4.0 million in non-cash related operating expenses primarily related to stock compensation expense. In addition, this guidance does not reflect potential revenue from potential collaborations with other partners.

Company Milestones

Skeletal Muscle Contractility

tirasemtiv (formerly known as 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 *tirasemtiv* in patients with generalized myasthenia gravis (CY 4023).
- In the fourth quarter of 2012, Cytokinetics plans to initiate CY 4026, a Phase IIb, multi-national, double-blind, randomized, placebo-controlled trial designed to evaluate the safety, tolerability and efficacy of *tirasemtiv* in patients with ALS.
- In 2012, Cytokinetics anticipates additional interactions with regulatory authorities to discuss the development of *tirasemtiv* 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 fourth quarter of 2012, Cytokinetics anticipates a decision regarding the potential progression to the third cohort of the ATOMIC-AHF clinical trial, following a review of data from the second cohort by an independent data monitoring committee.
- In the second half of 2012, Cytokinetics expects to collaborate with Amgen in the finalization of a protocol for a Phase II clinical trial of oral formulations of *omecamtiv mecarbil* in patients with heart failure. In addition, the companies anticipate making other preparations for the potential initiation of this Phase II clinical trial.

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 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 21517396.

An archived replay of the webcast will be available via Cytokinetics' website until August 7, 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 21517396 from July 31, 2012 at 5:30 PM Eastern Time until August 7, 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* (formerly CK-2017357), 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 *tirasemtiv* demonstrated potentially clinically relevant pharmacodynamic effects in Phase II 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 contraction, such as bronchoconstriction associated with asthma and chronic obstructive pulmonary disease (COPD). All of these drug candidates and potential 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' financial guidance, including expected R&D and G&A expenses for 2012; Cytokinetics' and its partners' research and development activities, including the initiation, enrollment, conduct, design, endpoints, 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, the ability of CY 4026 to support potential registration, and anticipated interactions with regulatory authorities; 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)

Three Months Ended		Six Months Ended	
June 30,	June 30,	June 30,	June 30,
2012	2011	2012	2011

Revenues:				
Research and development	\$ 1,841	\$ 1,053	\$ 3,661	\$ 1,817
Total revenues	<u>1,841</u>	<u>1,053</u>	<u>3,661</u>	<u>1,817</u>
Operating Expenses:				
Research and development	8,242	10,513	16,987	19,692
General and administrative	2,568	4,187	5,624	7,524
Restructuring	<u>(13)</u>	<u>-</u>	<u>(54)</u>	<u>-</u>
Total operating expenses	<u>10,797</u>	<u>14,700</u>	<u>22,557</u>	<u>27,216</u>
Operating loss	(8,956)	(13,647)	(18,896)	(25,399)
Interest and other, net	<u>13</u>	<u>15</u>	<u>26</u>	<u>55</u>
Net loss	(8,943)	(13,632)	(18,870)	(25,344)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	<u>(1,307)</u>	<u>(2,857)</u>	<u>(1,307)</u>	<u>(2,857)</u>
Net loss allocable to common stockholders	<u>\$ (10,250)</u>	<u>\$ (16,489)</u>	<u>\$ (20,177)</u>	<u>\$ (28,201)</u>
Net loss per share allocable to common stockholders - basic and diluted	\$ (0.13)	\$ (0.23)	\$ (0.26)	\$ (0.41)
Weighted average shares used in computing net loss per share allocable to common stockholders - basic and diluted	81,230,292	71,151,486	78,655,935	69,043,119

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

	<u>June 30, 2012</u>	<u>December 31, 2011</u>
Assets		
Cash and cash equivalents	\$ 63,654	\$ 18,833
Short term investments	26,821	30,190
Related party receivables	3	14
Other current assets	<u>2,482</u>	<u>2,103</u>
Total current assets	92,960	51,140
Property and equipment, net	994	1,310
Restricted cash	-	196
Other assets	<u>127</u>	<u>127</u>

Total assets	\$ <u>94,081</u>	\$ <u>52,773</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 3,989	\$ 4,592
Long-term liabilities	111	3
Stockholders' equity	<u>89,981</u>	<u>48,178</u>
Total liabilities and stockholders' equity	\$ <u>94,081</u>	\$ <u>52,773</u>

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