



## Cytokinetics, Incorporated Reports Third Quarter 2009 Financial Results

October 28, 2009 8:02 PM EDT

### Quarterly Highlights Include Company's Research and Development Day Elaborating on Expansion of Development Pipeline; Company Provides Update on Next Steps in Development of Omecamtiv Mecarbil

SOUTH SAN FRANCISCO, CA, Oct 28, 2009 (MARKETWIRE via COMTEX) -- Cytokinetics, Incorporated (NASDAQ: CYTK) reported revenues from research and development collaborations of \$5.5 million for the third quarter of 2009. The net loss for the third quarter was \$8.2 million, or \$0.14 per basic and diluted share. This compared to a net loss of \$16.3 million, or \$0.33 per basic and diluted share, for the same period in 2008. As of September 30, 2009, cash, cash equivalents and investments, excluding restricted cash and the put option on the company's auction rate securities, totaled \$119.2 million.

"The highlight of the most recent quarter was Cytokinetics' first Research and Development Day which gave our management team an opportunity to elaborate on our expanded portfolio of drug candidates directed to the biology of muscle function," stated Robert I. Blum, President and Chief Executive Officer of Cytokinetics. "In particular, we believe that the advancement of CK-2017357 towards Phase II trials positions us to benefit from knowledge arising from our cardiac muscle program that is progressing towards late-stage development. I believe we are realizing important technical synergies and capital allocation efficiencies as a function of our increased focus in our R&D activities."

#### Company Highlights

##### Muscle Contractility

-- In September, Cytokinetics' hosted a Research and Development (R&D) Day at which the company detailed R&D strategies, data and plans relating to the company's expanded development pipeline focused on the biology of muscle function. Among the highlights was a review of the Phase IIa clinical trials data in heart failure patients from the ongoing clinical development program for omecamtiv mecarbil (formerly CK-1827452), a novel cardiac myosin activator, as well as non-clinical data supporting the advancement of CK-2017357, a fast skeletal muscle troponin activator and its potential applications in an array of neuromuscular diseases and medical conditions associated with muscle fatigue and wasting. In addition, the company highlighted its smooth muscle myosin inhibitor program and its potential application in diseases of vascular constriction and bronchoconstriction. The discussion which was led by Cytokinetics' senior management was supplemented by commentary by key opinion leaders who offered their perspectives on the clinical prospects for the drug candidates in Cytokinetics' development pipeline.

##### Omecamtiv Mecarbil

-- In August, at the Annual Meeting of the European Society of Cardiology (ESC), and in September at the 2009 Heart Failure Society of America (HFSA) Annual Meeting, Cytokinetics presented final data from the Phase IIa clinical trial of omecamtiv mecarbil in stable heart failure patients. The authors concluded that patients with reduced stroke volumes ( 50 mL) at baseline had generally greater pharmacodynamic responses to omecamtiv mecarbil than those in patients with greater stroke volumes at baseline, demonstrating robust pharmacodynamic activity in this more severely affected sub-population of patients from the study. Statistically significant increases in systolic ejection time, and in stroke volume, cardiac output, fractional shortening, and ejection fraction (all measures of cardiac function), occurred across the patient population in a concentration-dependent manner. In addition, the data demonstrated statistically significant correlations between increasing omecamtiv mecarbil plasma concentration and decreases in left ventricular end-systolic volume, left ventricular end-diastolic volume and heart rate.

-- In August, at the Annual Meeting of the ESC, and in September at the 2009 HFSA Annual Meeting, Cytokinetics presented final data from the Phase IIa clinical trial of omecamtiv mecarbil in patients with ischemic cardiomyopathy and angina. The authors concluded that in these patients, who theoretically could be most vulnerable to the possible deleterious consequences of systolic ejection time prolongation, treatment with omecamtiv mecarbil, at plasma concentrations previously demonstrated in other Phase IIa trials to increase cardiac function, did not adversely affect a broad range of safety assessments in the setting of exercise.

-- During the third quarter, the Phase IIa clinical trial designed to evaluate the pharmacokinetics of both modified and immediate release oral formulations of omecamtiv mecarbil in patients with stable heart failure continued to enroll patients.

-- Cytokinetics and Amgen have agreed on next steps relating to the further development of omecamtiv mecarbil. The companies are planning a clinical trial designed to further assess the pharmacokinetics of both modified and immediate release oral formulations of omecamtiv mecarbil in patients with stable heart failure, using active pharmaceutical ingredient and drug product manufactured by Amgen. In addition, the companies are planning to conduct another pharmacokinetic trial to evaluate omecamtiv mecarbil in patients with renal dysfunction, along with additional pre-clinical activities. Cytokinetics and Amgen anticipate the initiation of the Phase IIb clinical trials program to occur in 2011, but the companies are discussing how the timeline could be accelerated into 2010.

##### CK-2071357

-- CK-2017357 is the lead drug candidate from Cytokinetics' skeletal sarcomere activator program. Cytokinetics continues to dose healthy volunteers in a Phase I, first-time-in-humans, ascending, single-dose, double-blind, placebo-controlled clinical trial of CK-2017357 designed to assess the safety, tolerability, and pharmacokinetic profile of this drug candidate and to determine its maximum tolerated dose and plasma concentration. Although the trial is still ongoing and thus remains blinded, to date, no adverse events have been observed in trial participants to indicate that an intolerable dose has been administered. Consequently, the maximum tolerated dose has not yet been determined; however, doses that produced CK-2017357 blood levels associated with increased skeletal muscle function in preclinical models have been tolerated by the healthy volunteers in this study.

## Financials

Revenues from research and development (R&D) collaborations for the third quarter of 2009 were \$5.5 million, compared to \$3.1 million for the same period in 2008. Revenues for the third quarter of 2009 and 2008 were primarily derived from the company's collaboration and option agreement with Amgen. Research and development revenues from Amgen for the third quarter of 2009 consisted of reimbursements of \$5.5 million in program expenses under the parties' collaboration and option agreement. License revenues of \$3.1 million for the third quarter of 2008 were associated with the December 2006 non-exclusive license and technology fee to omecamtiv mecarbil.

Total R&D expenses in the third quarter of 2009 were \$9.9 million, compared to \$13.5 million for the same period in 2008. The decrease in R&D expenses in the third quarter of 2009, compared to the same period in 2008, was primarily due to decreased spending related to the company's clinical and pre-clinical programs, and lower personnel expenses.

Total general and administrative (G&A) expenses for the third quarter of 2009 were \$3.9 million, compared to \$3.8 million for the same period in 2008. The increase in G&A expenses in the third quarter of 2009, compared to the same period in 2008, was primarily due to higher spending for outside services, offset in part by lower spending for legal services.

Total Interest and other, net income for the third quarter of 2009 was \$6,000, compared to income of \$0.5 million for 2008. The decrease in Interest and other, net in 2009, compared to the same period in 2008 was primarily due lower market interest rates earned on our investments.

The net loss for the three months ended September 30, 2009, was \$8.2 million, or \$0.14 per basic and diluted share, compared to a net loss for the same period in 2008 of \$16.3 million, or \$0.33 per share.

Cytokinetics also reported results of its operations for the nine months ended September 30, 2009. Revenues from R&D collaborations for the nine months ended September 30, 2009 were \$80.5 million, compared to revenues of \$9.3 million for the same period in 2008. Revenues for the first nine months of 2009 and 2008 were primarily derived from the company's collaboration and option agreement with Amgen. The revenue for the first nine months of 2009 included a \$50.0 million payment from Amgen relating to its exercise of its option for an exclusive worldwide license (excluding Japan) to the company's cardiac muscle contractility program, including omecamtiv mecarbil, the recognition of deferred revenue of \$24.5 million associated with Amgen's December 2006 non-exclusive license and technology access fee, and the reimbursement of \$6.1 million in program expenses under the parties' collaboration and option agreement.

Total R&D expenses for the nine months ended September 30, 2009 were \$30.0 million, compared to \$42.5 million for the same period in 2008. The decrease in R&D expenses in the first nine months of 2009, over the same period in 2008, was primarily due to decreased spending related to the company's clinical and pre-clinical programs, and lower personnel and laboratory expenses.

Total G&A expenses for the nine months ended September 30, 2009 were \$12.0 million, compared to \$12.2 million for the same period in 2008. The decreased spending in the first nine months of 2009, over the same period in 2008, was primarily due to lower spending for legal and outside services, which were offset in part by higher personnel-related costs.

Total Interest and other, net expense for the nine months ended September 30, 2009 was \$1.4 million, compared to income of \$2.4 million for 2008. The increase in Interest and other, net expense in 2009, compared to the same period in 2008, was primarily due to the recognition of \$1.6 million in the non-cash fair value expense for the warrants associated with our May 2009 registered direct financing, along with a decline of \$2.3 million in interest income as a result of a lower portfolio balance and lower market interest rates earned on our investments.

The net income for the nine months ended September 30, 2009, was \$37.1 million, or \$0.66 and \$0.65 per basic and diluted share, respectively, compared to a net loss of \$45.5 million, or \$0.92 per share, for the same period in 2008.

## Company Milestones

### Skeletal Muscle

#### CK-2071357

-- In December, Cytokinetics is scheduled to present non-clinical data from CK-2071357 at the Society on Cachexia and Wasting Disorders' 5th Annual Cachexia Conference in Barcelona, Spain.

-- In 2009, Cytokinetics anticipates initiating the second portion of its two-part Phase I study of CK-2071357 designed to assess the safety, pharmacokinetics and pharmacodynamic effects of the drug candidate in healthy volunteers.

-- In 2009, Cytokinetics anticipates initiating a Phase I multi-dose study of CK-2071357 in healthy volunteers.

### Smooth Muscle

-- In November, Cytokinetics is scheduled to present non-clinical data from its smooth muscle myosin inhibitor at the 2009 Scientific Sessions of the American Heart Association in Orlando, Florida.

-- In 2009, Cytokinetics anticipates continuing to progress its smooth muscle myosin inhibitors in non-clinical development activities.

### Oncology

#### SB-743921

-- In December, Cytokinetics is scheduled to present data from the Phase I portion of a Phase I/II clinical trial evaluating SB-743921 in patients with Hodgkin or non-Hodgkin lymphoma at the Annual Meeting of the American Society of Hematology in New Orleans, Louisiana.

#### GSK-923295

-- In November, GSK is scheduled to present pharmacogenomic and drug combination data evaluating GSK-923295 with a MEK inhibitor in preclinical models at the AACR-NCI-EORTC International Conference: Molecular Targets and Cancer Therapeutics in Boston, Massachusetts.

## Use of Non-GAAP Financial Measures

To supplement our financial results presented on a U.S. generally accepted accounting principles (GAAP) basis, we have included a schedule of non-GAAP financial measures. These measures are not in accordance with GAAP, are not an alternative for GAAP, and may be different from non-GAAP financial measures used by other companies. Among the items included in our GAAP earnings but excluded for purposes of determining

non-GAAP net income that we present are: the recognition of the deferred revenue associated with Amgen's 2006 non-exclusive license and technology access fee under the parties' collaboration and option agreement, the non-cash fair value expense related to the warrants associated with our May 2009 registered direct financing, employee stock-based compensation, and depreciation, amortization, and other. We believe the presentation of non-GAAP financial measures provides useful information to management and investors regarding various financial and business trends relating to our financial condition and results of operations, and that when GAAP financial measures are viewed in conjunction with non-GAAP financial measures, investors are provided with a more meaningful understanding of our ongoing operating performance. In addition, these non-GAAP financial measures are among the primary indicators we use as a basis for evaluating performance, allocating resources, and planning and forecasting future periods.

#### 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](http://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 81445416.

An archived replay of the webcast will be available via Cytokinetics' website until November 11, 2009. The replay will also be available via telephone by dialing (800) 642-1687 (United States and Canada) or (706) 645-9291 (international) and typing in the passcode 81445416 from October 28, 2009 at 5:30 PM Eastern Time until November 11, 2009.

#### About Cytokinetics

Cytokinetics is a clinical-stage biopharmaceutical company focused on the discovery and development of 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 (formerly CK-1827452), 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 in Phase I clinical development. Cytokinetics is also conducting non-clinical development of compounds that inhibit smooth muscle contractility and which may be useful as potential treatments for diseases and conditions such as systemic hypertension, pulmonary arterial hypertension or bronchoconstriction. In addition, prior Cytokinetics' research generated three anti-cancer drug candidates in Phase I clinical development: ispinesib, SB-743921 and GSK-923295. Cytokinetics is seeking a partner for ispinesib and SB-743921 and GSK-923295 is being developed under Cytokinetics' collaboration with GlaxoSmithKline. 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](http://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 Safe Harbor for forward-looking statements contained in the Act. 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, focus, scope and results of development activities (including of clinical trials) for omecamtiv mecarbil (formerly CK-1827452), CK-2017357 and Cytokinetics' other drug candidates and potential drug candidates, including the significance of clinical trial results, the planned presentation of clinical trial results, the progression of IND-enabling studies, and the further clinical and pre-clinical development activities for omecamtiv mecarbil planned to be conducted under Cytokinetics' collaboration with Amgen; and the properties and potential benefits of Cytokinetics' compounds. 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 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 GSK's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil and GSK-923295, 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; others may introduce products or alternative therapies 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 Statement of Operations  
(in thousands, except share and per share data)  
(unaudited) [

	Three Months Ended		Nine Months Ended	
	September	September	September	September
	30,	30,	30,	30,
	2009	2008	2009	2008
	-----	-----	-----	-----
Revenues: [				
Research and development	\$ 5,506	\$ 67	\$ 6,148	\$ 93
License revenues	-	3,058	74,367	9,175
	-----	-----	-----	-----
Total revenues	5,506	3,125	80,515	9,268

Operating Expenses:				
Research and development	9,857	13,519	30,018	42,480
General and administrative	3,878	3,826	12,025	12,235
Restructuring charges	(21)	2,492	(23)	2,492
Total operating expenses	13,714	19,837	42,020	57,207
Operating income (loss):	(8,208)	(16,712)	38,495	(47,939)
Interest and other, net	6	453	(1,422)	2,421
Net income (loss)	\$ (8,202)	\$ (16,259)	\$ 37,073	\$ (45,518)

Basic net income (loss) per common share	\$ (0.14)	\$ (0.33)	\$ 0.66	\$ (0.92)
--	-----------	-----------	---------	-----------

Diluted net income (loss) per common share	\$ (0.14)	\$ (0.33)	\$ 0.65	\$ (0.92)
--	-----------	-----------	---------	-----------

Shares used in calculating:

Basic net income (loss) per common share	60,501,962	49,415,937	56,212,160	49,358,705
--	------------	------------	------------	------------

Diluted net income (loss) per common share	60,501,962	49,415,937	56,696,840	49,358,705
--	------------	------------	------------	------------

Cytokinetics, Incorporated  
Condensed Balance Sheet  
(in thousands)  
(unaudited) [

	September 30, 2009	December 31, 2008
Assets [		
Cash and cash equivalents	\$ 23,715	\$ 41,819
Short term investments	79,723	15,048
Investment in auction rate securities	15,782	-
Investment put option	2,368	-
Related party receivables	4,553	261
Other current assets	2,010	1,782
Total current assets	128,151	58,910
Investment in auction rate securities	-	16,636
Investment put option	-	3,389
Property and equipment, net	3,865	5,087
Restricted investments	1,674	2,750
Other assets	474	682
Total assets	\$ 134,164	\$ 87,454
Liabilities and stockholders' equity		
Current liabilities	\$ 20,469	\$ 22,877

Long-term obligations	1,338	14,811
Stockholders' equity	112,357	49,766
	-----	-----
Total liabilities and stockholders' equity	\$ 134,164	\$ 87,454
	=====	=====

Cytokinetics, Incorporated  
Reconciliation of GAAP amounts to non-GAAP amounts  
(Unaudited) [

(In thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
	-----	-----	-----	-----
GAAP net income (loss)	\$ (8,202)	\$ (16,259)	\$ 37,073	\$ (45,518)
Non-cash deferred revenue related to Amgen collaboration	-	(3,058)	(24,493)	(9,175)
Non-cash warrant expense	-	-	1,585	-
Non-cash stock-based compensation	1,261	1,435	3,734	4,309
Non-cash depreciation, amortization, and other	489	1,482	1,512	2,819
	-----	-----	-----	-----
Non-GAAP net income (loss)	\$ (6,452)	\$ (16,400)	\$ 19,411	\$ (47,565)
	=====	=====	=====	=====

Cytokinetics, Incorporated:  
Christopher S. Keenan  
Director, Investor & Media Relations  
(650) 624-3000

SOURCE: Cytokinetics, Inc.