

Cytokinetics, Incorporated Reports Third Quarter 2010 Financial Results

October 28, 2010 8:01 PM EDT Company Reports Encouraging Results From Interim Reviews of Two Ongoing Phase IIa Evidence of Effect Trials of CK-2017357

SOUTH SAN FRANCISCO, CA, Oct 28, 2010 (MARKETWIRE via COMTEX) --

Cytokinetics, Incorporated (NASDAQ: CYTK) reported revenues from research and development collaborations of \$0.4 million for the third quarter of 2010. The net loss for the third quarter was \$12.3 million, or \$0.19 per basic and diluted share. This compared to a net loss of \$8.2 million, or \$0.14 per basic and diluted share, for the same period in 2009. As of September 30, 2010, cash, cash equivalents and investments, excluding restricted cash, totaled \$77.2 million.

"We are encouraged by the interim results from both of our ongoing Evidence of Effect trials of CK-2017357, one in patients with amyotrophic lateral sclerosis and one in patients with claudication associated with peripheral artery disease, and are pleased to be proceeding with the further development of this novel drug candidate. Moving forward, we are readying for the initiation of a third Evidence of Effect trial in patients with myasthenia gravis," stated Robert I. Blum, President and Chief Executive Officer of Cytokinetics. "Data from these trials appear consistent with our therapeutic hypotheses and are planned to be the subject of presentations at upcoming medical conferences starting in December."

Company Highlights

Muscle Contractility

Omecamtiv Mecarbil

- -- In September, Cytokinetics and its partner, Amgen, Inc., announced plans to initiate a Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil in hospitalized patients with acutely decompensated heart failure prior to initiating further clinical trials of oral formulations of omecamtiv mecarbil.
- -- In September, additional data from a Phase I clinical trial of omecamtiv mecarbil were presented in a poster at the 2010 Heart Failure Society of America Annual Meeting.

CK-2017357

- In September, Cytokinetics conducted a second interim review of data from the ongoing Phase IIa Evidence of Effect (EoE) clinical trial of CK-2017357 in patients with amyotrophic lateral sclerosis (ALS), also commonly known as Lou Gehrig's disease. These data suggested potential pharmacodynamic activity across multiple assessments of patient function and skeletal muscle performance. In addition, this review indicated that single oral doses of CK-2017357, at each of 250 mg and 500 mg, continue to be well-tolerated. Two serious adverse events, one of pancreatic cancer and another of pulmonary embolism, were reported; each was judged by the respective investigator to be unrelated to treatment with CK-2017357. Enrollment in this trial was recently completed. Additional information about this trial can be found at www.clinicaltrials.gov.
- -- Recently, Cytokinetics conducted an interim review of data from the

ongoing Phase IIa EoE clinical trial of CK-2017357 in patients with symptoms of claudication associated with peripheral artery disease. The review suggested potential pharmacodynamic activity of CK-2017357 to increase skeletal muscle performance in these patients. In addition, this review suggested that single oral doses of CK-2017357 were generally well-tolerated by most patients in this trial. Serious adverse events were reported by two patients: dizziness and mental confusion in one patient and dizziness and dyskinesia (or abnormal movements) in the other. All these events were judged by the respective investigators to be related to treatment with CK-2017357. Both patients required inpatient observation until their symptoms resolved. The investigators judged these events not to have been life-threatening and to have resolved spontaneously and completely without any additional treatment. Following these observations, the protocol has been amended to lower the 750 mg dose to 500 mg. Additional information about this trial can be found at www.clinicaltrials.gov.

-- In September, two abstracts relating to CK-2017357 were presented at the 2010 Annual Aging Muscle Symposium.

Non-Clinical Research and Development

- -- During the quarter, Cytokinetics continued non-clinical development of the backup potential drug candidate in its skeletal muscle troponin activation program.
- -- During the quarter, Cytokinetics continued non-clinical development of its smooth muscle myosin inhibitors.

Financials

Revenues for the third quarter of 2010 were \$0.4 million, compared to \$5.5 million during the same period in 2009. Revenues from research and development (R&D) collaborations for the third quarter of 2010 and 2009 were primarily derived from the company's collaboration and option agreement with Amgen, Inc. Revenues for the third quarter of 2010 consisted of reimbursements of \$0.3 million in program expenses under the collaboration and option agreement and \$0.1 million in program expenses for the myasthenia gravis development program being conducted under a grant from the National Institute of Neurological Disorders and Stroke (NINDS), a division of the National Institutes of Health, awarded to the company in July 2010.

Total R&D expenses in the third quarter of 2010 were \$9.5 million, compared to \$9.9 million for the same period in 2009. The \$0.4 million decrease in R&D expenses for the third quarter of 2010, compared to the same period in 2009, was primarily due to lower personnel-related and laboratory expenses, which were offset in part by higher outsourced spending related to the company's preclinical and clinical development programs.

Total general and administrative (G&A) expenses for the third quarter of 2010 were \$3.4 million, compared to \$3.9 million for the same period in 2009. The \$0.5 million decrease in G&A expenses in the third quarter of 2010, compared to the same period in 2009, was primarily due to lower personnel-related and outside services expenses.

Revenues for the nine months ended September 30, 2010 were \$1.5 million, compared to \$80.5 million for the same period in 2009. Revenues from R&D collaborations for the first nine months of 2010 and 2009 were primarily derived from the company's collaboration and option agreement with Amgen. R&D revenues for the first nine months of 2010 consisted of reimbursements of \$1.4 million in program expenses from Amgen under the collaboration and option agreement and \$0.1 million in program expenses for the myasthenia gravis development program being conducted under the NINDS grant awarded to the company in July 2010. The revenues 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 omecamtiv mecarbil and related compounds, the recognition of deferred revenue of \$24.4 million in program expenses under the parties' collaboration and option agreement.

Total R&D expenses for the nine months ended September 30, 2010 were \$28.9 million, compared to \$30.0 million for the same period in 2009. The \$1.1 million decrease in R&D expenses in the first nine months of 2010, compared to the same period in 2009, was primarily due to lower personnel-related costs, which were offset in part by higher outsourced spending related to the company's preclinical and clinical development programs and

laboratory expenses.

Total G&A expenses for the nine months ended September 30, 2010 were \$10.6 million, compared to \$12.0 million for the same period in 2009. The \$1.4 million decrease in G&A spending in the first nine months of 2010, compared to the same period in 2009, was primarily due to lower personnel-related costs and outside services expenses.

Total interest and other, net, for the nine months ended September 30, 2010 was \$0.2 million of income, compared to \$1.4 million of expense for the same period in 2009. The change in interest and other, net, in 2010, compared to the same period in 2009, was largely due to the recognition of \$1.6 million in non-cash fair value expense in 2009 for the warrants associated with the company's May 2009 registered direct financing.

The net loss for the nine months ended September 30, 2010, was \$37.7 million, or \$0.59 per basic and diluted share, compared to net income of \$37.1 million, or \$0.66 and \$0.65 per basic and diluted share, respectively, for the same period in 2009.

Updated Financial Guidance for 2010

Cytokinetics announced updated financial guidance for 2010 which reflects lower spending than previously anticipated. The company anticipates cash R&D expenses to be in the range of \$37.0 to \$40.0 million, and cash G&A expenses to be in the range of \$12.0 to \$13.0 million. This financial guidance is on a cash basis and does not include an estimated \$6.0 million in non-cash operating expenses primarily related to stock compensation expense. This guidance does not reflect potential revenue from Amgen, NINDS or potential collaborations with other partners.

Company Milestones

Cardiac Muscle

Omecamtiv Mecarbil

- -- The company anticipates that, in the first half of 2011, Amgen will initiate a randomized, double-blind, placebo-controlled Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil in hospitalized acute heart failure patients with left ventricular systolic dysfunction.
- -- The company anticipates that, in 2011, Amgen will initiate an open-label, multiple-dose Phase IIa clinical trial designed to investigate the pharmacokinetics of two formulations of omecamtiv mecarbil administered orally to patients with stable heart failure.
- -- The company anticipates that, following discussions with regulatory authorities, Amgen will initiate a Phase Ib multi-center, open-label, single-dose, safety and pharmacokinetic clinical study of a modified-release oral formulation of omecamtiv mecarbil in patients with renal dysfunction.

Skeletal Muscle

CK-2017357

- -- In December, Cytokinetics plans to present data from the Phase IIa EoE clinical trial of CK-2017357 in patients with ALS at the 21st Annual International Symposium on ALS/Motor Neurone Disease in Orlando, Florida.
- -- Cytokinetics anticipates that, in the first half of 2011, data will be available from the Phase IIa EoE clinical trial of CK-2017357 in patients with symptoms of claudication associated with peripheral artery disease.

-- Cytokinetics anticipates initiating a Phase IIa EoE clinical trial of CK-2017357 in patients with myasthenia gravis by the end of 2010.

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 expense related to the fair value of 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 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. 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 53716324.

An archived replay of the webcast will be available via Cytokinetics' website until November 11, 2010. 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 53716324 from October 28, 2010 at 5:30 PM Eastern Time until November 11, 2010.

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 (formerly CK-1827452), is in 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 currently the subject of a Phase IIa clinical trials program and has been granted orphan-drug designation by the U.S. Food and Drug Administration for the potential treatment of amyotrophic lateral sclerosis. 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 associated with excessive smooth muscle contraction, such as systemic hypertension or bronchoconstriction. In addition, prior Cytokinetics' research generated three anti-cancer 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 2010; Cytokinetics' and its partners' research and development activities, including the initiation, enrollment, conduct, design and results of clinical trials of omecamtiv mecarbil and CK-2017357, the significance and utility of clinical trial results for CK-2017357, the timing for the anticipated availability of clinical trial results for CK-2017357, planned presentations relating to CK-2017357, the availability of grant funds to support the research and development of CK-2017357 in future periods, and the conduct of non-clinical studies for Cytokinetics' skeletal muscle activators and smooth muscle myosin inhibitors; the properties and potential benefits of Cytokinetics' drug candidates and potential drug candidates, such as omecamtiv mecarbil and CK-2017357; and the utility of non-GAAP financial measures. 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, the FDA may not grant CK-2017357 orphan drug market exclusivity 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; the availability of funds under the National Institute of Neurological Disorders and Stroke grant is not assured; 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.

> Cytokinetics, Incorporated Condensed Statements of Operations (in thousands, except share and per share data) (unaudited) Three Months Ended Nine Months Ended

	September 30 2010	, S	=		=	September 30, 2009				
Revenues: Research and development License revenues	\$ 394 	\$	5,506 	\$	1,478 	Ş	6,148 74,367			
Total revenues	394	_	5,506	_	1,478		80,515			
Operating expenses: Research and development General and administrative Restructuring	9,547 3,412		9,857 3,878	_	28,852 10,629		30,018 12,025			
charges		_	(21)	_		(23)				
Total operating expenses	12,959	_	13,714	_	39,481		42,020			
Operating income (loss) Interest and other, net)	(8,208) 6		(38,003) 153		38,495 (1,422)			
Income (loss) before income taxes Income tax benefit	(12,517) (176)		(8,202)	_	(37,850) (176)		37,073			
Net income (loss)	\$ (12,341		(8,202)		(37,674)		37,073			
Basic net income (loss) per common share Diluted net income (loss) per common share Shares used in calculating: Basic net income (loss) per common share Diluted net income (loss) per common	\$ (0.19)	Ş	(0.14)	\$	(0.59)	\$	0.66			
	\$ (0.19)	\$	(0.14)	\$	(0.59)	\$	0.65			
	64,433,999		60,501,962		63,423,633		56,212,160			
share	64,433,999 60,501,962 63,423,633 56,696,84 Cytokinetics, Incorporated Condensed Balance Sheets (in thousands)									

(unaudited)										
					September 30, 2010			December 31, 2009		
Assets	G			-			30 439			 25 , 561
Cash and cash equivalents Short-term investments Investment in auction rate securities					Ŷ		46,780			71,266 15,542
Investment put option Related party receivables Other current assets							262			2,358 189 2,005
Total current assets Property and equipment,	net			-						116,921 3,713
Restricted cash Other assets							788 298			1,674 291
Total assets								\$		122,599
Liabilities and stockholders' equity Current liabilities Long-term obligations							6,487 309	\$		20,186 985
Stockholders' equity Total liabilities and stockholders' equity					 \$					101,428
										=======
Reconcilia		(Unau	amou dite	unts to d)			AAP amou	ints	5	
		(In thousands) Three Months Ended September 30,					Nine Mont Septem			
		2010	2009				2010		2009	
GAAP net income (loss) Non-cash deferred revenu related to Amgen		(12,341)	\$	(8,20	2)	\$	(37,674	1)	\$	37,073
collaboration Non-cash warrant expense Non-cash stock-based compensation Non-cash depreciation,		 1,158		 :	 51					(24,493) 1,585
				1,263			3,165	ō		3,734
amortization, and other		459		48	9		1,433			1,512
Non-GAAP net income (loss)	\$ ==	(10,724)		(6,45			(33,076 ======			19,411

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SOURCE: Cytokinetics, Inc.