

Cytokinetics, Incorporated Reports Second Quarter 2010 Financial Results

July 28, 2010 8:01 PM EDT

Company Reports on Progress of Drug Candidates in Clinical Trials; Interim Review of Data From Phase IIa Evidence of Effect Trial in ALS Patients Supports Continuation

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

Cytokinetics, Incorporated (NASDAQ: CYTK) reported revenues from research and development collaborations of \$0.5 million for the second quarter of 2010. The net loss for the second quarter was \$13.1 million, or \$0.21 per basic and diluted share. This compared to a net income of \$56.0 million, or \$0.99 and \$0.98 per basic and diluted share, respectively, for the same period in 2009. As of June 30, 2010, cash, cash equivalents and investments, excluding restricted cash, totaled \$87.6 million.

"In the second quarter, Cytokinetics initiated patient dosing in two Phase IIa clinical trials of our fast skeletal muscle troponin activator, CK-2017357, one in patients with amyotrophic lateral sclerosis and the other in patients with claudication. In addition, results from a recent interim review of the data from the Phase IIa trial in patients with amyotrophic lateral sclerosis demonstrated that CK-2017357 appeared to be well tolerated in these patients and exhibited predictable pharmacokinetics. Based on this review, we intend to proceed without changes to the protocol. In fact, both trials are enrolling according to plan. We look forward to results that may provide evidence of pharmacodynamic effect in patients with impaired neuromuscular function by the end of the year," stated Robert I. Blum, President and Chief Executive Officer. "These activities further underscore our commitment to advance our pipeline of novel drug candidates and occurred in parallel with our continued collaboration with Amgen to ready for the initiation of additional clinical trials relating to omecamtiv mecarbil, our cardiac myosin activator. We are pleased with the significant progress that our company continues to achieve in furthering the development of first-in-class compounds that have the potential to transform the treatment of patients suffering from grievous illnesses."

Company Highlights

Muscle Contractility

Omecamtiv Mecarbil

-- Omecamtiv mecarbil was the subject of a manuscript entitled "Improvement of Cardiac Function by a Cardiac Myosin Activator in Conscious Dogs with Systolic Heart Failure," which appeared in Circulation: Heart Failure, a journal of the American Heart Association. The authors concluded that chronic infusion of omecamtiv mecarbil improves left ventricular function in a preclinical model of systolic heart failure without the limitations of progressive desensitization and increased oxygen consumption.

CK-2017357

- -- In April, Cytokinetics initiated dosing in a 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.
- -- In July, Cytokinetics conducted an interim analysis of the ongoing Phase IIa EoE clinical trial of CK-2017357 in patients with ALS. Results from this analysis demonstrated that CK-2017357 appears to be well tolerated in these patients. No serious adverse events have been reported. CK-2017357 exhibited dose proportional and predictable pharmacokinetics. Based on the review of these data, the company has decided to proceed with this trial under the current protocol. Cytokinetics continues to enroll and dose patients in this trial at fifteen clinical trial sites in accordance with the company's plans. This and additional information about this trial can be found at www.clinicaltrials.gov.
- -- In June, Cytokinetics initiated dosing in a Phase IIa EoE clinical

trial of CK-2017357 in patients with symptoms of claudication associated with peripheral artery disease. Cytokinetics continues to enroll and dose patients in this trial at eight clinical trial sites in accordance with the company's plans. This and additional information about this trial can be found at www.clinicaltrials.gov.

- -- In July, Cytokinetics announced the company has been awarded a grant in the amount of \$2.9 million by the National Institute of Neurological Disorders and Stroke which is intended to support research and development of CK-2017357 for the potential treatment of myasthenia gravis. The grant was awarded to Cytokinetics under the American Recovery and Reinvestment Act of 2009.
- -- In July, Cytokinetics presented a late-breaking abstract summarizing data from the second part of a two-part Phase I clinical trial of CK-2017357 in healthy volunteers at the XII International Congress on Neuromuscular Diseases.

Non-Clinical Research and Development

- -- In May, a poster summarizing non-clinical data regarding the company's smooth muscle contractility program was presented at the American Thoracic Society's 2010 International Conference.
- -- 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.

Corporate

-- In July, as part of a settlement agreement with UBS AG relating to the failed auctions of the auction rate securities held by Cytokinetics, the remaining auction rate securities of \$7.5 million were purchased at par by UBS AG.

Financials

Revenues for the second quarter of 2010 were \$0.5 million, compared to \$71.9 million during the same period in 2009. Revenues from research and development collaborations for the second quarter of 2010 and 2009 were primarily derived from the company's collaboration and option agreement with Amgen, Inc. Revenues for the second quarter of 2010 consisted of reimbursements of \$0.5 million in program expenses under the collaboration and option agreement. Revenues in the second quarter of 2009 included Amgen's payment of \$50.0 million related to the exercise of its option to an exclusive worldwide license (excluding Japan) to omecamtiv mecarbil and related compounds, and the recognition of the remaining deferred revenue of \$21.3 million associated with Amgen's December 2006 non-exclusive license and technology access fee to omecamtiv mecarbil.

Total research and development (R&D) expenses in the second quarter of both 2010 and 2009 were \$10.2 million. The R&D expenses for the second quarter of 2010, compared to the same period in 2009, reflected increased spending related to the company's clinical and preclinical programs and laboratory expenses, which were offset by lower personnel-related expenses.

Total general and administrative (G&A) expenses for the second quarter of 2010 were \$3.4 million, compared to \$4.1 million for the same period in 2009. The \$0.7 million decrease in G&A expenses in the second quarter of 2010, compared to the same period in 2009, was primarily due to lower personnel-related costs.

Total interest and other, net for the second quarter of 2010 was \$10,000 net income, compared to \$1.6 million net expense for the same period in 2009. The change in interest and other, net in 2010, compared to the same period in 2009, was primarily due to the recognition of \$1.6 million in non-cash fair value expense in the second quarter of 2009 for the warrants associated with the company's May 2009 registered direct financing.

Revenues for the six months ended June 30, 2010 were \$1.1 million, compared to \$75.0 million for the same period in 2009. Revenues from research and development collaborations for the first six months of 2010 and 2009 were primarily derived from the company's collaboration and option agreement with Amgen. Research and development revenues for the six months of 2010 consisted of reimbursements of \$1.1 million in program

expenses under the collaboration and option agreement. The revenues for the first six months of 2009 consisted of 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, and the recognition of deferred revenue of \$24.4 million associated with Amgen's December 2006 non-exclusive license and technology access to omecamtiv mecarbil.

Total R&D expenses for the six months ended June 30, 2010 were \$19.3 million, compared to \$20.2 million for the same period in 2009. The \$0.9 million decrease in R&D expenses in the first six months of 2010, over the same period in 2009, was primarily due to lower personnel-related costs, which were offset in part by higher spending related to the company's laboratory expenses and clinical and preclinical programs.

Total G&A expenses for the six months ended June 30, 2010 were \$7.2 million, compared to \$8.1 million for the same period in 2009. The \$0.9 million decrease in G&A spending in the first six months of 2010, over the same period in 2009, was primarily due to lower personnel-related costs and legal services.

Total interest and other, net for the six months ended June 30, 2010 was \$0.1 million of income, compared to an expense of \$1.4 million for 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 the second quarter of 2009 for the warrants associated with the company's May 2009 registered direct financing.

The net loss for the six months ended June 30, 2010, was \$25.3 million, or \$0.40 per basic and diluted share, compared to net income of \$45.3 million, or \$0.84 and \$0.83 per basic and diluted share, respectively, for the same period in 2009.

Company Milestones

Cardiac Muscle

Omecamtiv Mecarbil

- -- The company anticipates that in mid-2010, 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 both male and female patients with stable heart failure.
- -- The company anticipates that in the second half of 2010, 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.
- -- The company anticipates that by year-end 2010, 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.

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/MND in Orlando, Florida.

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, 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 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 53716226.

An archived replay of the webcast will be available via Cytokinetics' website until August 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 53716226 from July 28, 2010 at 5:30 PM Eastern Time until August 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 an 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 that have progressed into clinical development: ispinesib, SB-743921 and GSK-923295. 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' 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 interim clinical trial results for CK-2017357, the timing for the anticipated receipt and availability of clinical trial results for 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 mecambil: 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)

1				
			ths Ended June 30, 2009	
\$ 462 	\$ 622 71,308	\$ 1,084 	\$ 641 74,367	
462	71,930	1,084	75 , 008	
10,236	10,202	19,304	20,161	
3,380 	4,127 56	7,217 	8,147 (2)	
	June 30, 2010 \$ 462 10,236	2010 2009 \$ 462 \$ 622 71,308	June 30, June 30, June 30, 2010 \$ 462 \$ 622 \$ 1,084 71,308 462 71,930 1,084 10,236 10,202 19,304 3,380 4,127 7,217	

-						
Operating income (loss) Interest and other, net	(13,154) 10		57,545 (1,586)			46,702 (1,428)
interest and other, net			(1,300)	-		(1,420)
Net income (loss)	\$ (13,144) =======		55 , 959			\$ 45,274
Basic net income (loss) per						
common share	\$ (0.21)	Ś	0 99	\$ (O	40)	\$ 0.84
Diluted net income (loss)	· (0.21)	Τ	0.33	7 (0.	• 10)	7 0.01
per common share	\$ (0.21)	\$	0.98	\$ (0.	.40)	\$ 0.83
Shares used in calculating:	. ,	·			,	•
Basic net income (loss) per						
common share	63,814,731	56,	454,574	62,910,	077	54,031,708
Diluted net income (loss)						
per common share	63,814,731	56,	902,550	62,910,	077	54,449,630
-	okinetics, I		_			
Cor	ndensed Bala					
	(in thous)			
	(unaudit	ted)				
					Dec	ember 31,
			201	0		2009
7 + -						
Assets Cash and cash equivalents			\$	18,365	Ċ	25 , 561
Short-term investments			۲	61,739		
Investment in auction rate :	sacuritias			6,698		15,542
Investment put option	securrers			777		2,358
Related party receivables				211		189
Other current assets				2,349		
Total current assets				90,139		116,921
Property and equipment, net				2 , 953		3,713
Restricted investments				1,233		1,674
Other assets				291		291
Total assets			\$	94,616	\$	122,599
			======		====	
Liabilities and stockholder	s' equity					
Current liabilities			\$	6 , 875		20,186
Long-term obligations				489		985
Stockholders' equity				87 , 252		101,428
Total liabilities and stock	holders' equ	ity	\$	94,616	\$	122,599

13,616 14,385 26,521 28,306

Total operating

expenses

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	 2010		2009		2010		2009	
GAAP net income (loss) Non-cash deferred revenue related to	\$ (13,144)	\$	55 , 959	\$	(25,333)	\$	45 , 274	
Amgen collaboration			(21,418)				(24,492)	
Non-cash warrant expense			1,585				1,585	
Non-cash stock-based compensation Non-cash depreciation,	1,012		1,224		2,006		2,473	
amortization, and other	 485		576 		975		1,022	
Non-GAAP net income (loss)	\$ (11,647)		37 , 926	\$	(22 , 352)	\$	25 , 862	

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

SOURCE: Cytokinetics, Inc.