Cytokinetics, Incorporated Reports Fourth Quarter and Year End Highlights and 2010 Financial Results

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Company Outlines Next Steps in Phase II Clinical Development Programs of Omecamtiv Mecarbil in Heart Failure and CK-2017357 in ALS

SOUTH SAN FRANCISCO, CA, Feb 14, 2011 (MARKETWIRE via COMTEX) --

Cytokinetics, Incorporated (NASDAQ: CYTK) reported total research and development revenues of $1.1 million for the fourth quarter of 2010. The net loss for the fourth quarter was $11.6 million, or $0.17 per basic and diluted share. This compared to a net loss of $12.5 million, or $0.21 per basic and diluted share, for the same period in 2009. As of December 31, 2010, cash, cash equivalents and investments, excluding restricted cash, totaled $72.8 million.

"In 2010, Cytokinetics took significant steps forward in connection with a strategic commitment to advance our portfolio of muscle biology programs. In particular, we demonstrated evidence of potentially clinically relevant effects of CK-2017357 in patients suffering from ALS. This occurred alongside preparations for the initiation of a Phase IIb trial of omecamtiv mecarbil, and progress with other compounds in both research and development," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Looking forward, we are enthusiastic about the opportunity to now translate pharmacodynamic effects observed in patients with ALS and patients with heart failure into potentially meaningful clinical benefits as may be demonstrated with our first-in-class drug candidates. 2011 promises to be an important year for Cytokinetics as we push forward towards key milestones that may inform future registration programs."

Company Highlights

Cardiac Muscle Contractility

Omecamtiv Mecarbil

-- During the quarter, Cytokinetics and its partner Amgen collaborated on the development of a protocol and related regulatory submissions pertaining to a randomized, double-blind, placebo-controlled multi-center Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil in patients with left ventricular systolic dysfunction who have been hospitalized for acute heart failure.

Ongoing Research

-- During the quarter, Cytokinetics and Amgen agreed upon a research plan focused on joint research activities in 2011 that will be directed to potential next-generation compounds in our cardiac muscle contractility program.

Skeletal Muscle Contractility

CK-2017357

-- In December, Cytokinetics announced the successful completion of a Phase IIa Evidence of Effect (EoE) clinical trial of CK-2017357 in patients with amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. Increases in multiple clinically relevant pharmacodynamic assessments were observed; in addition, the single oral doses of CK-2017357 administered (250 mg and 500 mg) appeared safe and generally well-tolerated. Finally, these two doses of CK-2017357 exhibited dose-proportional pharmacokinetics.

-- Recently, Cytokinetics initiated enrollment of patients in a Phase IIa EoE clinical trial of CK-2017357 in patients with generalized myasthenia gravis (MG). This clinical trial and preclinical research on MG is being funded by a $2.8 million grant from the National Institute of Neurological Disorders and Stroke. Additional information about this trial can be found at www.clinicaltrials.gov.

-- Cytokinetics continues to enroll and dose patients in a Phase IIa EoE clinical trial of CK-2017357 in patients with symptoms of claudication associated with peripheral artery disease. Additional information about this trial can be found at www.clinicaltrials.gov.

CK-2066260

-- During the quarter, Cytokinetics continued non-clinical development of CK-2066260, a potential drug candidate arising from our skeletal muscle contractility program.

Other Non-Clinical Research and Development

-- During the quarter, Cytokinetics continued non-clinical development of its smooth muscle myosin inhibitors and ongoing research relating to programs directed to muscle contractility, growth, energetics and metabolism.

Corporate

-- The company announced changes to its Board of Directors with the appointments of Santo J. Costa and Dr. Wendell Wierenga and the resignations of Michael Schmertzler and Grant Heidrich.

Financials

Revenues for the fourth quarter of 2010 were $1.1 million, compared to $1.0 million during the same period in 2009. Revenues for the fourth quarter of 2010 were primarily derived from the U.S. Department of Treasury's (DOT) Section 48D grants. Revenues for the fourth quarter of 2009 were primarily derived from the company's collaboration and option agreement with Amgen, Inc. Revenues for the fourth quarter of 2010 included $0.7 million in U.S. DOT Section 48D grant revenue, $0.3 million from the National Institute of Neurological Disorders and Stroke (NINDS) grant revenue, and $0.1 million of reimbursements in program expenses under the Amgen collaboration and option agreement.

Total Research and development (R&D) expenses in the fourth quarter of 2010 were $9.2 million, compared to $9.8 million for the same period in 2009. The $0.6 million decrease in R&D expenses for the fourth quarter of 2010, compared to the same period in 2009, was primarily due to decreases of $0.4 million in clinical and preclinical outsourcing costs related to our skeletal muscle contractility clinical trial programs and $0.4 million in personnel expenses, partially offset by an increase of $0.2 million in laboratory expenses.

Total General and administrative (G&A) expenses were $3.6 million for the fourth quarters of both 2010 and 2009.

Revenues for the twelve months ended December 31, 2010 were $2.6 million, compared to $81.5 million for the same period in 2009. Revenues for 2010 were derived from $1.5 million of reimbursements in program expenses from Amgen under the collaboration and option agreement, $0.7 million in U.S. DOT Section 48D grant revenue and $0.4 million in NINDS grant revenue. Revenues for 2009 were primarily derived from our collaboration and option agreement with Amgen. License revenues for 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 associated with Amgen's December 2006 non-exclusive license and technology access fee to omecamtiv mecarbil, and R&D revenues included the reimbursement of $7.1 million in program expenses under the parties' collaboration and option agreement.

Total R&D expenses for the twelve months ended December 31, 2010 were $38.0 million, compared to $39.8 million for the same period in 2009. The $1.8 million decrease in R&D expenses in 2010, compared to the same period in 2009, was primarily due to a decrease of $2.3 million in personnel expenses, partially offset by increases of $0.3 million in outsourcing costs related to our skeletal muscle contractility clinical trial programs and $0.3 million in laboratory expenses.

Total G&A expenses for the twelve months ended December 31, 2010 were $14.2 million, compared to $15.6 million for the same period in 2009. The $1.4 million decrease in G&A spending in 2010, compared to the same period in 2009, was primarily due to lower personnel expenses.

Total Interest and other, net, for the twelve months ended December 31, 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 twelve months ended December 31, 2010, was $49.3 million, or $0.77 per basic and diluted share, compared to net income $24.5 million, or $0.43 and $0.42 per basic and diluted share, respectively, for the same period in 2009.

Financial Guidance for 2011

Cytokinetics also announced its financial guidance for 2011. The company anticipates cash revenue will be in the range of $2.0 to $4.0 million, R&D expenses are anticipated to be in the range of $40.0 to $45.0 million, and cash G&A expenses to be in the range of $13.0 to $15.0 million. This financial guidance is on a cash basis and does not include an estimated $4.8 million in non-cash related operating expenses primarily related to stock compensation expense and depreciation. This guidance does not reflect revenue from any new potential collaborations or partnerships.

Annual Stockholders' Meeting

Cytokinetics' Annual Stockholders' Meeting will be held at the Embassy Suites Hotel located at 250 Gateway Boulevard in South San Francisco, CA at 10:00 AM on May 18, 2011.

Company Milestones

Cardiac Muscle Contractility

Omecamtiv Mecarbil

-- The company anticipates that, in the first half of 2011, Amgen will initiate an international, randomized, double-blind, placebo-controlled Phase IIb clinical trial of an intravenous formulation of omecamtiv mecarbil in patients with left ventricular systolic dysfunction hospitalized with acute heart failure.

-- Cytokinetics and its partner Amgen are in active discussions regarding the development strategy for oral formulations of omecamtiv mecarbil. The company anticipates that these plans may include studies designed to investigate the safety, tolerability and pharmacokinetics of multiple oral formulations of omecamtiv mecarbil. Additional information will be provided following the finalization of these plans.

Skeletal Muscle Contractility

CK-2017357

-- Cytokinetics plans to present data from the Phase IIa EoE clinical trial of CK-2017357 in ALS patients during a Plenary Session at the 63rd Annual Meeting of the American Academy of Neurology in April in Honolulu, Hawaii.

-- Cytokinetics anticipates that, in the first half of 2011, data will be available from the ongoing Phase IIa EoE clinical trial of CK-2017357 in patients with symptoms of claudication associated with peripheral artery disease.

-- Cytokinetics anticipates initiating, in the first half of 2011, a Phase I drug-drug interaction study of CK-2017357 administered orally to healthy volunteers. This study is intended to evaluate the effects

of CK-2017357 on the pharmacokinetics of riluzole and other drugs and the pharmacokinetics of CK-2017357 when administered after a meal and when fasting.

-- Cytokinetics anticipates initiating a Phase II multi-dose, safety, tolerability, pharmacokinetic and pharmacodynamic clinical trial of CK-2017357 in patients with ALS. This trial, which may begin in mid-year 2011 following the availability of data from the riluzole arm of the Phase I drug-drug interaction study, is expected to evaluate patients receiving daily oral doses of CK-2017357 for 10 to 14 days.

-- Cytokinetics anticipates that, by the end of 2011, data will be available from the ongoing Phase IIa EoE clinical trial of CK-2017357 in patients with generalized myasthenia gravis.

CK-2066260

-- Cytokinetics anticipates filing an Investigational New Drug Application (IND) for CK-2066260, a potential drug candidate from its skeletal muscle contractility program, by mid-year 2011.

-- Cytokinetics anticipates initiating a first-in-humans Phase I clinical trial of CK-2066260 in healthy volunteers in the second half of 2011.

The company will provide further guidance on the expected availability of data from clinical trials relating to each of omecamtiv mecarbil, CK-2017357 and CK-2066260 following each trial's initiation and an assessment of patient enrollment.

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 fourth quarter and year-end 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 94564856.

An archived replay of the webcast will be available via Cytokinetics' website until February 28, 2011. 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 94564856 from February 14, 2011 at 5:30 PM Eastern Time until February 21, 2011.

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 II 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, a debilitating disease of neuromuscular impairment in which CK-2017357 demonstrated potentially clinically relevant pharmacodynamic effects in a Phase IIa trial. Cytokinetics is also conducting research and 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 bronchoconstriction associated with asthma and chronic obstructive pulmonary disorder (COPD). 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.

Cytokinetics, Incorporated
Condensed Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Twelve Months Ended	
	December 31, 2010	December 31, 2009	December 31, 2010	December 31, 2009
Revenues:				
Research and development	$ 1,099	$ 1,023	$ 2,577	$ 7,171
License revenues	--	--	--	74,367
Total revenues	1,099	1,023	2,577	81,538
Operating expenses:				
Research and development	9,161	9,822	38,013	39,840
General and administrative	3,570	3,601	14,199	15,626
Restructuring charges	--	--	--	(23)
Total operating expenses	12,731	13,423	52,212	55,443
Operating income (loss)	(11,632)	(12,400)	(49,635)	26,095
Interest and other, net	19	21	172	(1,401)
Income (loss) before income taxes	(11,613)	(12,379)	(49,463)	24,694
Provision for income taxes	--	150	(176)	150
Net income (loss)	$ (11,613)	$ (12,529)	$ (49,287)	$ 24,544
Basic net income (loss) per common share	$ (0.17)	$ (0.21)	$ (0.77)	$ 0.43
Diluted net income (loss) per common share	$ (0.17)	$ (0.21)	$ (0.77)	$ 0.42
Shares used in calculating:				
Basic net income (loss) per common share	66,365,271	60,886,179	64,165,085	57,390,269
Diluted net income (loss) per common share	66,365,271	60,886,179	64,165,085	57,961,106

Cytokinetics, Incorporated
Condensed Balance Sheets
(in thousands)

(unaudited)

	December 31, 2010	December 31, 2009
Assets		
Cash and cash equivalents	$ 17,514	$ 25,561
Short-term investments	54,125	71,266
Investment in auction rate securities	--	15,542
Investment put option	--	2,358
Related party receivables	46	189
Other current assets	1,813	2,005
Total current assets	73,498	116,921
Long-term investments	1,206	--
Property and equipment, net	2,321	3,713
Restricted cash	788	1,674
Other assets	179	291
Total assets	$ 77,992	$ 122,599
Liabilities and stockholders' equity		
Current liabilities	$ 7,324	$ 20,186
Long-term obligations	152	985
Stockholders' equity	70,516	101,428
Total liabilities and stockholders' equity	$ 77,992	$ 122,599

Cytokinetics, Incorporated
Reconciliation of GAAP amounts to non-GAAP amounts
(unaudited)
(in thousands)

	Three Months Ended		Twelve Months Ended	
	December 31, 2010	December 31, 2009	December 31, 2010	December 31, 2009
GAAP net income (loss)	$ (11,613)	$ (12,529)	$ (49,287)	$ 24,544
Non-cash deferred revenue related to Amgen collaboration	-	-	-	(24,493)
Non-cash warrant expense	-	-	-	1,585
Non-cash stock-based compensation	852	1,172	4,017	4,906
Non-cash depreciation, amortization, and other	462	605	1,896	2,117
Non-GAAP net income (loss)	$ (10,299)	$ (10,752)	$ (43,374)	$ 8,659

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SOURCE: Cytokinetics, Inc.