



Cytokinetics, Incorporated Reports First Quarter 2010 Financial Results

April 29, 2010 8:01 PM EDT

Advancement of CK-2017357 Into Phase IIa Evidence of Effect Studies; Planning Underway for a Phase IIb Clinical Trial of Intravenous Formulation of Omecamtiv Mecarbil With Initiation Anticipated in 2010

SOUTH SAN FRANCISCO, CA, Apr 29, 2010 (MARKETWIRE via COMTEX) --Cytokinetics, Incorporated (NASDAQ: CYTK) reported revenues from research and development collaborations of \$0.6 million for the first quarter of 2010. The net loss for the first quarter was \$12.2 million, or \$0.20 per basic and diluted share. This compared to a net loss of \$10.7 million, or \$0.21 per basic and diluted share, for the same period in 2009. As of March 31, 2010, cash, cash equivalents and investments, excluding restricted cash and the put option on the company's auction rate securities, totaled \$103.1 million.

"Cytokinetics has made significant strides in the last quarter in the development of CK-2017357, the lead drug candidate from our skeletal muscle activator program. In recent months, the speed with which we opened a hypothesis-generating Phase IIa Evidence of Effect clinical trial in amyotrophic lateral sclerosis, or ALS, reflects the strong enthusiasm our clinical investigators maintain for this innovative compound as a potential treatment for patients suffering from this severely debilitating and uniformly fatal disease," stated Robert I. Blum, President and Chief Executive Officer. "In addition, we are pleased to announce that we have been discussing an expanded clinical development plan with Amgen that may allow for the initiation of a Phase IIb clinical trial of the intravenous formulation of omecamtiv mecarbil, alongside our previously announced plans for the oral formulations, by year-end 2010. This accelerated development activity is further testament to the commitment both companies have to develop this drug candidate for the potential treatment of heart failure."

Company Highlights

Muscle Contractility

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.

- During the quarter, Cytokinetics announced that CK-2017357 was granted an orphan drug designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of ALS.

- During the quarter, Cytokinetics completed enrollment and treatment of healthy volunteers Part A, of a two-part, Phase I, first-time-in-humans, ascending, single-dose, double-blind, placebo-controlled clinical trial of CK-2017357. In Part A of this trial, the maximum-tolerated single dose was determined to be 2000 mg. [

- In January, Cytokinetics announced positive data from Part B of the first-time-in-humans, Phase I clinical trial of CK-2017357. Part B evaluated in healthy volunteers the pharmacodynamic effect of single doses of CK-2017357 that had been tolerated in Part A. Results from Part B of the trial showed that CK-2017357 produced concentration-dependent, statistically significant increases, versus placebo, in the force developed by the tibialis anterior muscle, and that the doses administered were well-tolerated.

- Also in January, Cytokinetics announced data from a second Phase I clinical trial designed to investigate the safety, tolerability and pharmacokinetic profile of CK-2017357 after multiple oral doses to steady state in healthy male volunteers. Results from this trial showed that both the maximum CK-2017357 plasma concentration and the area under the CK-2017357 plasma concentration versus time curve from dosing until 24 hours after dosing were generally dose-proportional and exhibited only modest accumulation compared to the values measured after the first dose. In general, systemic exposure to CK-2017357 in this trial was high and inter-subject variability was low. In addition, these multiple dose regimens of CK-2017357 were well-tolerated, and no serious adverse events were observed.

Non-Clinical Research

- Yesterday, at the Society of Vascular Medicine's 21st Annual Scientific Sessions, Cytokinetics presented non-clinical data on CK-2017357 in a femoral artery ligation model.
- In February, at the Biophysical Society 54th Annual Meeting, Cytokinetics presented four posters of non-clinical findings arising from Cytokinetics' skeletal and smooth muscle contractility programs and non-clinical research in oncology.

Corporate

- During the quarter, the company announced the appointment of L. Patrick Gage, Ph.D., as the company's Chairman of the Board of Directors. Dr. Gage replaced James H. Sabry, M.D., Ph.D., co-founder and former Chief Executive Officer of Cytokinetics, who resigned during the quarter in order to assume an operational role at another company. [

Financials

Revenues for the first quarter of 2010 were \$0.6 million compared to \$3.1 million during the same period in 2009. Revenues from research and development collaborations for the first quarter of 2010 and 2009 were primarily derived from the company's collaboration and option agreement with Amgen Inc. Research and development revenues for the first quarter of 2010 consisted of reimbursements of \$0.6 million in program expenses under the parties' collaboration and option agreement. License revenues from Amgen of \$3.1 million for the first quarter of 2009 were associated with the December 2006 non-exclusive license and technology fee to omecamtiv mecarbil.

Total research and development (R&D) expenses in the first quarter of 2010 were \$9.1 million, compared to \$10.0 million for the same period in 2009. The \$0.9 million decrease in R&D expenses in the first quarter of 2010, compared to the same period in 2009, was primarily due to decreased spending related to the company's clinical and pre-clinical programs and lower personnel expenses, which were offset in part by higher laboratory expenses.

Total general and administrative (G&A) expenses for the first quarter of 2010 were \$3.8 million, compared to \$4.0 million for the same period in 2009. The \$0.2 million decrease in G&A expenses in the first quarter of 2010, compared to the same period in 2009, was primarily due to decreased spending for legal and personnel-related costs.

Total interest and other, net income for the first quarter of 2010 was \$0.1 million, compared to \$0.2 million for 2009. The \$0.1 million decrease in Interest and other, net in 2010, compared to the same period in 2009 was primarily due to decreased interest income offset in part by lower interest expense.

Company Milestones

Cardiac Muscle

Omecamtiv mecarbil

- The company anticipates that in mid-2010, Amgen will initiate a Phase IIa multi-center, open-label, dose-escalating, sequential-cohort pharmacokinetic clinical trial of a modified-release and an immediate-release oral formulation of omecamtiv mecarbil in stable heart failure patients. The trial is anticipated to enroll up to 84 patients with the primary objective to evaluate the pharmacokinetics of the two formulations of omecamtiv mecarbil following dosing twice or three times a day for eight days. The secondary endpoint will be to evaluate the safety and tolerability of the two formulations of omecamtiv mecarbil at steady state.

- The company anticipates that by mid-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. The trial is anticipated to examine clinical, echocardiographic, and pharmacokinetic endpoints at three dose levels of omecamtiv mecarbil and placebo. The primary and secondary endpoints to be assessed in this trial are still under discussion. This clinical trial is expected to proceed alongside the previously announced plans to conduct additional pharmacokinetic studies of the oral formulations of omecamtiv mecarbil.

Skeletal Muscle

CK-2017357

- Cytokinetics anticipates the initiation of a Phase IIa EoE clinical trial of CK-2017357 in patients with claudication associated with peripheral artery disease in the second quarter of 2010.

- Cytokinetics anticipates that data from the Phase IIa EoE clinical trial of CK-2017357 in patients with ALS will be available in the second half of 2010.

- Cytokinetics anticipates continuing non-clinical development of the backup potential drug candidate in its skeletal muscle troponin activation program throughout 2010.

Smooth Muscle

-- Cytokinetics anticipates continuing non-clinical development of its smooth muscle myosin inhibitors throughout 2010.

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 20, 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, 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 first 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 53715893.

An archived replay of the webcast will be available via Cytokinetics' website until May 13, 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 53715893 from April 29, 2010 at 5:30 PM Eastern Time until May 13, 2010.

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 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 United States Food and Drug Administration (FDA) 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 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 anticipated availability of clinical trial results, 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; 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 Statement of Operations
(in thousands, except share and per share data)

(unaudited) [

	Three Months Ended	
	March 31, 2010	March 31, 2009
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Revenues: [
Research and development	\$ 621	\$ 20
License revenues	-	3,058
	-----	-----
Total revenues	621	3,078
Operating expenses:		
Research and development	9,068	9,959
General and administrative	3,836	4,020
Restructuring charges	-	(58)
	-----	-----
Total operating expenses	12,904	13,921
Operating loss	(12,283)	(10,843)
Interest and other, net	94	158
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Net loss	\$ (12,189)	\$ (10,685)
	=====	=====
Net loss per common share - basic and diluted	\$ (0.20)	\$ (0.21)
Weighted average shares used in computing net loss per common share - basic and diluted	61,995,376	51,581,921
Cytokinetics, Incorporated		
Condensed Balance Sheet		
(in thousands)		
(unaudited) [
	March 31, 2010	December 31, 2009
	-----	-----
Assets [
Cash and cash equivalents	\$ 20,715	\$ 25,561
Short-term investments	67,091	71,266
Investment in auction rate securities	15,311	15,542
Investment put option	2,339	2,358
Related party receivables	20	189
Other current assets	1,613	2,005
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Total current assets	107,089	116,921
Property and equipment, net	3,282	3,713
Restricted investments	1,233	1,674
Other assets	289	291
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Total assets	\$ 111,893	\$ 122,599
	=====	=====
Liabilities and stockholders' equity		
Current liabilities	\$ 17,534	\$ 20,186
Long-term obligations	724	985
Stockholders' equity	93,635	101,428

Total liabilities and stockholders' equity	-----	-----
	\$ 111,893	\$ 122,599
	=====	=====

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

	Three Months Ended	
	March 31,	
	----- [
	2010	2009

GAAP net loss	\$ (12,189)	\$ (10,685)
Non-cash deferred revenue related to Amgen collaboration	-	(3,074)
Non-cash stock-based compensation	994	1,249
Non-cash depreciation, amortization, and other	489	447

Non-GAAP net loss	\$ (10,706)	\$ (12,063)
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SOURCE: Cytokinetics, Inc.