

Cytokinetics, Incorporated Reports First Quarter 2011 Financial Results

April 27, 2011 8:02 PM EDT

Company Reviews Advancements in the Cardiac Muscle Contractility Program and Outlines Plans Relating to the Skeletal Muscle Contractility Program

SOUTH SAN FRANCISCO, CA, Apr 27, 2011 (MARKETWIRE via COMTEX) — Cytokinetics, Incorporated (NASDAQ: CYTK) reported total research and development revenues of \$0.8 million for the first quarter of 2011. The net loss for the first quarter was \$11.7 million, or \$0.18 per basic and diluted share. This is compared to a net loss of \$12.2 million, or \$0.20 per basic and diluted share, for the same period in 2010. As of March 31, 2011, cash, cash equivalents and investments, excluding restricted cash, totaled \$59.9 million. In April 2011, the company completed a financing and received gross proceeds of approximately \$20.1 million before deducting estimated expenses.

"This past quarter marked the advancement of our cardiac muscle contractility program and our lead drug candidate, omecamtiv mecarbil. This progress is evidenced in the recent opening to enrollment of a Phase IIb clinical trial of this drug candidate in patients hospitalized with acute heart failure," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We are also pleased with the progress of our skeletal muscle contractility program which was highlighted as part of a clinical trials session at the recent American Academy of Neurology annual meeting. Encouraging results from our Phase IIa clinical trial results of CK-2017357 in patients with ALS underscore opportunities to move this important program forward. Progress in both programs reflects enthusiasm that the scientific and medical communities have demonstrated in connection with our expected plans."

Company Highlights

Cardiac Muscle Contractility

Omecamtiv Mecarbil

- -- Last week, Cytokinetics announced that its partner Amgen opened to enrollment 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. Additional information about this trial can be found at www.clinicaltrials.gov. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- -- Earlier this month, Cytokinetics announced the publication of preclinical research in the March 18, 2011 issue of the journal Science regarding the activation of cardiac myosin by omecamtiv mecarbil and the potential therapeutic role that this novel mechanism may play for patients with systolic heart failure.

Skeletal Muscle Contractility

CK-2017357

-- During the quarter, Cytokinetics initiated a Phase I drug-drug interaction study of CK-2017357 administered orally to healthy volunteers. The 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.

- -- In April, Cytokinetics presented data from its Phase IIa Evidence of Effect (EoE) clinical trial of CK-2017357 in amyotrophic lateral sclerosis (ALS) patients at the 63rd Annual Meeting of the American Academy of Neurology.
- -- Cytokinetics has completed enrollment and dosing of patients in its 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 its 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 (NINDS). 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

-- On April 18, 2011, Cytokinetics announced that it had entered into a definitive agreement to sell 5.3 million shares of its Common Stock at a price of \$1.50 per share, 8,070 shares of its Series A Convertible Preferred Stock at a price of \$1,500.00 per share and warrants to purchase an aggregate of 6,685,000 shares of its Common Stock at an exercise price of \$1.65 per share to entities affiliated with Deerfield Management Company, a healthcare investment manager. Cytokinetics received gross proceeds of approximately \$20.1 million from the offering, before deducting estimated expenses.

Financials

Revenues for the first quarter of 2011 were \$0.8 million, compared to \$0.6 million during the same period in 2010. Revenues for the first quarter of 2011 included \$0.4 million of reimbursements in program expenses under the Amgen collaboration and \$0.4 million in grant revenue from the NINDS. Revenues for the first quarter of 2010 of \$0.6 million were derived from our collaboration with Amgen.

Total Research and development (R&D) expenses in the first quarter of 2011 were \$9.2 million, compared to \$9.1 million for the same period in 2010. The \$0.1 million increase in R&D expenses for the first quarter of 2011, compared to the same period in 2010, was primarily due to increased spending related to the company's laboratory expenses and clinical and pre-clinical programs, partially offset by decreased spending in depreciation and personnel-related costs.

Total General and administrative (G&A) expenses in the first quarter of 2011 were \$3.3 million, compared to \$3.8 million during the same period in 2010. The \$0.5 million decrease in G&A expenses in the first quarter of 2011, compared to the same period in 2010, was primarily due to decreased spending for personnel-related and legal costs.

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

-- Cytokinetics and its partner Amgen are discussing the development strategy for oral formulations of omecamtiv mecarbil, including plans regarding the initiation of a Phase I study designed to investigate the safety, tolerability and pharmacokinetics of multiple oral formulations of omecamtiv mecarbil in healthy volunteers which may occur in the second half of 2011.

Skeletal Muscle Contractility

CK-2017357

- -- Cytokinetics plans to present two abstracts from the Phase IIa EoE clinical trial of CK-2017357 in patients with symptoms of claudication associated with peripheral artery disease in June at the 22nd Annual Sessions of the Society of Vascular Medicine in Boston, Massachusetts.
- -- Cytokinetics anticipates that data will be available from a Phase I drug-drug interaction study of CK-2017357 administered orally to healthy volunteers 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 in the second half of 2011.
- -- Cytokinetics anticipates initiating a Phase II multi-dose, safety, tolerability, pharmacokinetic and pharmacodynamic clinical trial of CK-2017357 in patients with ALS by mid-year 2011.
- -- Cytokinetics anticipates that data will be available from the ongoing Phase IIa EoE clinical trial of CK-2017357 in patients with generalized myasthenia gravis by the end of 2011.

- -- 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 each of its ongoing clinical trials following trial initiation and assessment of patient enrollment.

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 94564873.

An archived replay of the webcast will be available via Cytokinetics' website until May 11, 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 94564873 from April 27, 2011 at 5:30 PM Eastern Time until May 11, 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 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, 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. Addit

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 Statements relating to Cytokinetics' and its partners' research and development activities, including the initiation, enrollment, conduct, design, scope and results of clinical trials of omecamtiv mecarbil, CK-2017357 and CK-206626, the anticipated timing for the filing of an IND for CK-2066260, the anticipated timing for the availability of clinical trial results and the anticipated provision of guidance regarding such timing and other information relating to our clinical trials, and planned presentations of clinical data; and the properties and potential benefits of Cytokinetics' drug candidates and potential drug candidates. 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 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)

		March 31, 2011			
Revenues: Research and development	Ś	763	Ś	621	
Research and development					
Total revenues Operating expenses:		763		621	
Research and development General and administrative		3,336		9,068 3,836	
Total operating expenses		12,515		12,904	
Operating loss Interest and other, net)	(12,283)	
Net loss		 (11,712) =====		(12,189)	
Net loss per common share - basic and diluted Weighted average shares used in computing net los	\$			(0.20)	
per common share - basic and diluted Cytokinetics, Incorporated Condensed Balance Sheet (in thousands) (unaudited)		5,911,328	6	1,995,376	
(anadar cea)	March 31, 2011		2010		
Assets Cash and cash equivalents				17,514	
Short-term investments Related party receivables	٧	44,449			
Other current assets				1,813	
Total current assets Long-term investments		62 , 954 -		73,498 1,206	
Property and equipment, net Restricted cash		2,041 439		2,321 788	
Other assets		228		179	
Total assets				77 , 992	
Liabilities and stockholders' equity Current liabilities	\$	6 , 042	\$	7,324	
Long-term obligations Stockholders' equity		34		152 70,516	
Total liabilities and stockholders' equity				77 , 992	

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SOURCE: Cytokinetics, Inc.