



Cytokinetics, Incorporated Reports First Quarter 2009 Financial Results

April 30, 2009 8:03 PM EDT

Quarterly Highlights Include Delivery of Clinical Data Package to Amgen Required to Inform Option Exercise and Presentation of Final Data for CK-1827452 in Stable Heart Failure Patients

SOUTH SAN FRANCISCO, CA, Apr 30, 2009 (MARKET WIRE via COMTEX) -- Cytokinetics, Incorporated (NASDAQ: CYTK) reported revenues from research and development collaborations of \$3.1 million for the first quarter of 2009. The net loss for the three months ended March 31, 2009 was \$10.7 million, or \$0.21 per share, compared to a net loss of \$13.9 million, or \$0.28 per share for the same period in 2008. As of March 31, 2009, cash, cash equivalents and investments, excluding restricted cash and the put option on its auction rate securities, totaled \$81.4 million.

"Cytokinetics began 2009 on solid footing with our delivery to Amgen of the clinical trials data package intended to inform its option decision relating to CK-1827452 and the presentation of promising and clinically meaningful data from our Phase IIa clinical trial of this novel cardiac muscle myosin activator in stable heart failure patients," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We believe the totality of data generated from our Phase IIa clinical trials program of CK-1827452 support progression to the next stages of clinical development. We also plan to initiate a Phase I, first-in-humans clinical trial of our fast skeletal muscle troponin activator, CK-2017357, in the United States in mid-2009, thereby expanding our clinical pipeline focused on the biology of muscle function."

Company Highlights

Cardiovascular

-- In March, at the 2009 Annual American College of Cardiology Meeting, final data were presented from Cytokinetics' Phase IIa clinical trial evaluating CK-1827452 administered intravenously to patients with stable heart failure. The final results demonstrated that CK-1827452 increased systolic ejection time, stroke volume, cardiac output, fractional shortening and ejection fraction (by either the hybrid or 2D method) in a concentration-dependent manner. In addition, these results showed that CK-1827452 decreased left ventricular end-systolic volume and left ventricular end-diastolic volume in a concentration dependent manner. Decreases in ventricular volumes observed in response to treatment with other therapies have been associated with improved outcomes in heart failure. Increases in indices of ventricular systolic function and decreases in ventricular volumes observed with CK-1827452 in this trial were associated with decreases in heart rate. CK-1827452 appeared to be generally well tolerated in stable heart failure patients over a range of plasma concentrations during continuous intravenous administration.

-- Cytokinetics recently initiated an additional Phase IIa clinical trial of CK-1827452. This clinical trial is an open label, multi-center, multiple-dose trial designed to evaluate and compare the oral pharmacokinetics of both a modified release as well as an immediate release formulation of CK-1827452 in patients with stable heart failure. The clinical trial is currently planned to enroll three cohorts, each of between 6 and 12 patients.

-- Cytokinetics continues to screen patients for potential enrollment in an ongoing Phase IIa trial to evaluate an intravenous formulation of CK-1827452 in patients with stable heart failure undergoing clinically indicated coronary angiography in the cardiac catheterization laboratory.

Oncology

-- Cytokinetics continues to dose patients in the Phase I portion of a Phase I/II clinical trial evaluating ispinosib in the treatment of women with locally advanced or metastatic breast cancer.

-- Cytokinetics continues to enroll and dose-escalate patients in the Phase I portion of a Phase I/II clinical trial evaluating SB-743921 in patients with Hodgkin or non-Hodgkin lymphoma.

-- At the 2009 American Association of Cancer Research Annual Meeting, GlaxoSmithKline (GSK) presented two abstracts containing non-clinical data relating to GSK-923295, an inhibitor of centromere-associated protein E (CENP-E).

-- GSK continues to enroll and dose-escalate patients in a Phase I, first-in-humans clinical trial evaluating GSK-923295 in patients with advanced, refractory solid tumors.

Non-Clinical Research and Development

-- In March, at the 53rd Annual Meeting of the Biophysical Society, Cytokinetics presented three abstracts summarizing non-clinical data regarding its skeletal muscle contractility program.

-- In April, at the 2009 Experimental Biology Conference, Cytokinetics presented data relating to CK-2017357, a fast skeletal muscle troponin activator.

Corporate

-- In February, Cytokinetics delivered to Amgen Inc. the data from the Phase I and IIa clinical trials conducted with CK-1827452 that we believe were required to inform Amgen's exercise of its option to acquire an exclusive license to CK-1827452 worldwide, excluding Japan.

-- During the quarter, Cytokinetics appointed Dr. John Henderson to the company's Board of Directors and named current director, Stephen Dow as the company's Lead Outside Director.

Financials

Revenues from research and development collaborations for the first quarter of each of 2009 and 2008 were \$3.1 million. Revenues from research and development collaborations for the first quarter of 2009 and 2008 were primarily derived from the company's collaboration and option agreement with Amgen Inc.

Total research and development (R&D) expenses in the first quarter of 2009 were \$10.0 million, compared to \$14.1 million for the same period in 2008. The \$4.1 million decrease in R&D expenses in the first quarter of 2009, compared to the same period in 2008, was primarily due to decreased spending related to the company's clinical and preclinical programs, along with decreased personnel and laboratory expenses.

Total general and administrative (G&A) expenses for the first quarter of 2009 were \$4.0 million, compared to \$4.2 million for the same period in 2008. The \$0.2 million decrease in G&A expenses in the first quarter of 2009, compared to the same period in 2008, was primarily due to a decrease in legal expenses.

The net loss for the three months ended March 31, 2009 was \$10.7 million, or \$0.21 per share, compared to a net loss of \$13.9 million, or \$0.28 per share, for the same period in 2008.

As of March 31, 2009, cash, cash equivalents and investments, excluding restricted cash and the put option on the company's auction rate securities totaled \$81.4 million, compared to \$73.5 million at December 31, 2008. The increase in cash and investments was primarily due to the receipt of loan proceeds of \$12.4 million from UBS and \$6.8 million, net, from the company's committed equity financing facility with Kingsbridge Capital Limited, offset by cash used to fund operations.

Reiterating Financial Guidance for 2009

Cytokinetics is reiterating its previously announced guidance for 2009. The company anticipates its 2009 net cash utilization to be in the range of \$52.0 to \$57.0 million, with cash R&D expenses expected to be in the range of \$38.0 to \$42.0 million and cash G&A expenses to be in the range of \$14.0 to \$15.0 million.

While Amgen may choose to exercise its option for an exclusive license to develop and commercialize CK-1827452, there is no certainty this will occur. Accordingly, this financial guidance excludes any revenues associated with such an option exercise by Amgen, including any projections regarding potential reimbursement of R&D expenses related to CK-1827452. This guidance also does not take into account revenues from other potential collaborations that Cytokinetics may enter into in 2009 relating to CK-1827452 or other programs.

If Amgen does exercise its option, Cytokinetics intends to provide an update to its 2009 financial guidance, taking into account the \$50 million option exercise fee that Amgen would pay to the company and any other payments that Cytokinetics may receive from Amgen for R&D activities related to CK-1827452 that it may conduct under Amgen's sponsorship. This financial guidance is on a cash basis and does not include an estimated \$12.2 million in GAAP revenues related to Amgen's initial payment for its option for a license of CK-1827452 and \$7.5 million in non-cash related operating expenses primarily related to FAS 123R stock compensation expense.

Company Milestones

Cardiovascular

CK-1827452

-- Cytokinetics plans to present data from its Phase IIa clinical trial of CK-1827452 in patients with stable heart failure as a Late Breaking Trial at the 2009 Heart Failure Congress of the European Society of Cardiology to be held from May 30 - June 2 in Nice, France. Additional echocardiographic data from the trial also will be presented in a separate poster session at that meeting.

-- Cytokinetics also plans to present data from its Phase IIa clinical trial of CK-1827452 in patients with ischemic cardiomyopathy and angina at the 2009 Heart Failure Congress of the European Society of Cardiology. Cytokinetics presented top-line data from this trial by press release in December 2008.

-- In mid-2009, Cytokinetics plans to initiate a Phase IIb clinical trial of CK-1827452 in chronic heart failure outpatients at increased risk for death and rehospitalization for heart failure. Should Amgen exercise its option to acquire an exclusive license to CK-1827452, thereafter, Amgen would control the timing and design of development activities for this program.

Oncology

Ispinesib (SB-715992)

-- Cytokinetics plans to present data from the Phase I portion of the ongoing Phase I/II clinical trial of ispinesib administered as monotherapy as a first-line treatment in chemotherapy-naïve patients with locally advanced or metastatic breast cancer at the annual meeting of the American Society of Clinical Oncology (ASCO) to be held from May 29 - June 2 in Orlando, Florida.

SB-743921

-- Cytokinetics plans to present data from the Phase I portion of the ongoing Phase I/II clinical trial in patients with Hodgkin or non-Hodgkin lymphoma at ASCO.

GSK-923295

-- GSK has informed Cytokinetics that it anticipates presenting data from the Phase I clinical trial evaluating GSK-923295 in patients with advanced, refractory solid tumors at ASCO.

-- GSK has informed Cytokinetics that it anticipates initiating a Phase II clinical trial of GSK-923295 in 2010.

Other Research and Development

-- In mid-2009, Cytokinetics plans to initiate a Phase I, first-in-humans clinical trial of CK-2017357 in healthy volunteers in the United States.

-- In 2009, Cytokinetics anticipates progressing its smooth muscle myosin inhibitor in IND-enabling studies.

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 21, 2009. Copies of the company's Annual Report and Proxy Statement and electronic voting information can be found at www.cytokinetics.com/proxy.

Conference Call and Webcast Information

Members of Cytokinetics' 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 is also accessible via telephone to investors, members of the news media and the general public by dialing either (866) 999-CYTK (2985) (United States and Canada) or (706) 679-3078 (international) and typing in the passcode 81444878.

An archived replay of the webcast will be available via Cytokinetics' website until May 14, 2009. 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 81444878 from April 30, 2009 at 5:30 PM Eastern Time until May 14, 2009.

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' cardiac muscle contractility program is focused on cardiac muscle myosin, a motor protein essential to cardiac muscle contraction. Cytokinetics' lead compound from this program, CK-1827452, a novel small molecule cardiac muscle myosin activator, is in Phase II clinical trials for the treatment of heart failure. Amgen Inc. has obtained an option for an exclusive license to develop and commercialize CK-1827452, subject to Cytokinetics' development and commercialization participation rights. In mid-2009, Cytokinetics plans to initiate a Phase I clinical trial of CK-2017357, a fast skeletal muscle troponin activator, in healthy volunteers in the United States. CK-2017357 is being developed as a potential treatment for diseases and medical conditions associated with aging, muscle wasting, and neuromuscular dysfunction. In January 2009, Cytokinetics announced the selection of a potential drug candidate directed towards smooth muscle contractility which may be developed as a potential treatment for diseases associated with pulmonary arterial hypertension and bronchoconstriction.

Cytokinetics' cancer program is focused on mitotic kinesins, a family of motor proteins essential to cell division. Cytokinetics is developing two drug candidates that have arisen from this program, ispinesib and SB-743921, each an inhibitor of kinesin spindle protein. In addition, Cytokinetics and GlaxoSmithKline are conducting research and development activities focused on GSK-923295, an inhibitor of centromere-associated protein E (CENP-E).

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 Amgen's potential exercise of its option to CK-1827452; Cytokinetics' financial guidance, including expected cash operating expenditures, revenues and R&D and G&A expenses for 2009; Cytokinetics' and its partners' research and development activities, including the initiation, conduct, focus, scope and completion of clinical trials, the significance of clinical trial results, the anticipated presentation of clinical trial results, and the progression of IND-enabling studies; the potential receipt of payments under Cytokinetics' strategic alliance with Amgen; potential future collaborations; and the properties and potential benefits of Cytokinetics' compounds, including the potential for CK-1827452 for reverse remodeling or improvement in ventricular mechanics and function with chronic dosing. 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 production of Cytokinetics' compounds 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' compounds 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 may elect not to exercise its option with respect to CK-1827452; if Amgen exercises its option with respect to CK-1827452, then it will control the design, conduct and timing of development activities for CK-1827452; GSK may alter or terminate its development activities for GSK-923295; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain the additional funding necessary to conduct development of some or all of its compounds; standards of care may change rendering Cytokinetics' compounds obsolete; others may introduce products or alternative therapies for the treatment of indications Cytokinetics' compounds may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including option fees, 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.

Condensed Statement of Operations
(in thousands, except share and per share data)
(unaudited) [

	Three Months Ended	
	March 31, 2009	March 31, 2008
	-----	-----
Revenues: [
Research and development	\$ 20	\$ 11
License revenues	3,058	3,058
	-----	-----
Total revenues	3,078	3,069
	-----	-----
Operating Expenses:		

Research and development	9,959	14,102
General and administrative	4,020	4,157
Restructuring charges	(58)	-
	-----	-----
Total operating expenses	13,921	18,259
	-----	-----
Operating loss	(10,843)	(15,190)
Interest and other, net	158	1,295
	-----	-----
Net loss	\$ (10,685)	\$ (13,895)
	=====	=====
Net loss per common share - basic and diluted	\$ (0.21)	\$ (0.28)
Weighted average shares used in computing net loss per common share - basic and diluted	51,581,921	49,293,865

Condensed Balance Sheet
(in thousands)
(unaudited) [

	March 31, 2009	December 31, 2008
	-----	-----
Assets [
Cash and cash equivalents	\$ 48,489	\$ 41,819
Short term investments	15,607	15,048
Other current assets	1,236	2,043
	-----	-----
Total current assets	65,332	58,910
	-----	-----
Investments in auction rate securities	17,306	16,636
Investment put option	2,719	3,389
Property and equipment, net	4,714	5,087
Restricted investments	2,232	2,750
Other assets	619	682
	-----	-----
Total assets	\$ 92,922	\$ 87,454
	=====	=====
Liabilities and stockholders' equity		
Current liabilities	\$ 22,062	\$ 22,877
Long-term obligations	23,664	14,811
Stockholders' equity	47,196	49,766
	-----	-----
Total liabilities and stockholders' equity	\$ 92,922	\$ 87,454
	=====	=====

Cytokinetics, Incorporated:

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

SOURCE: Cytokinetics, Inc.