



Cytokinetics, Incorporated Reports Fourth Quarter and Year End 2008 Financial Results

February 10, 2009 9:03 PM EST

Company Updates Progress on Programs and Provides Milestones and Financial Guidance for 2009; Recent Highlights Include Presentation of Clinical Trials Data for CK-1827452 and Expansion of Muscle Contractility Pipeline

SOUTH SAN FRANCISCO, CA, Feb 10, 2009 (MARKET WIRE via COMTEX) -- Cytokinetics, Incorporated (NASDAQ: CYTK) reported revenues from research and development collaborations of \$3.2 million for the fourth quarter of 2008. The net loss for the three months ended December 31, 2008 was \$10.9 million, or \$0.22 per share compared to a net loss of \$13.3 million, or \$0.27 per share for the same period in 2007. As of December 31, 2008, cash, cash equivalents, restricted cash and investments totaled \$76.3 million.

"In the fourth quarter we were encouraged by data arising from our Phase IIa clinical trials in heart failure for our lead drug candidate CK-1827452. In particular, we believe the top-line results from our Phase IIa trial evaluating CK-1827452 in heart failure patients with ischemic cardiomyopathy and angina support the safety of this novel cardiac myosin activator in a high-risk heart failure patient population," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "More recently, we announced the extension and expansion of our development pipeline focused on the modulation of muscle contractility, with the progression of CK-2017357, our novel skeletal muscle activator, in IND-enabling studies and the designation of two additional potential drug candidates arising from our ongoing research activities."

Company Highlights

Cardiovascular

-- In December, Cytokinetics announced top-line results from a Phase IIa clinical trial evaluating the safety of CK-1827452 in patients with ischemic cardiomyopathy and angina. The primary safety endpoint was defined as stopping an exercise test during double-blind treatment with CK-1827452 or placebo due to unacceptable angina at an earlier exercise stage than at baseline. This endpoint was observed in one patient receiving placebo and did not occur in any patient receiving CK-1827452. The company believes that the results from this safety trial support the progression of CK- 1827452 into Phase IIb development.

-- In November, at the 2008 Scientific Sessions of the American Heart Association, Cytokinetics reported interim results from an ongoing Phase IIa clinical trial evaluating CK-1827452 administered intravenously to patients with stable heart failure. The interim results showed that CK- 1827452 demonstrated statistically significant increases in systolic ejection time and fractional shortening at plasma concentrations greater than 100 ng/mL, statistically significant increases in stroke volume at plasma concentrations greater than 200 ng/mL, and statistically significant increases in ejection fraction at plasma concentrations greater than 300 ng/mL. In addition, these data demonstrated statistically significant correlations between increasing CK-1827452 plasma concentration and increases in systolic ejection time, stroke volume, and fractional shortening, ejection fraction and cardiac output. The results also showed statistically significant correlations between increasing CK-1827452 concentrations and decreases in supine and standing heart rate and left ventricular end-systolic volume. Cytokinetics recently completed dosing in the fifth cohort of this trial.

-- Cytokinetics continues to enroll and dose patients 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.

-- In December, Cytokinetics provided an update on a recently completed Phase I clinical trial of CK-1827452 designed to evaluate the potential for certain drug-drug interactions mediated by two cytochrome P450 drug- metabolizing enzymes, 2D6 and 3A4. Results showed that there were no clinically important differences observed between extensive or poor metabolizers via 2D6 in the pharmacokinetics of CK-1827452. Furthermore no clinically meaningful drug-drug interactions were identified with either ketoconazole or diltiazem (a potent and a moderate inhibitor of 3A4, respectively) in either extensive or poor metabolizers via 2D6.

Oncology

-- In December, at the 31st Annual San Antonio Breast Cancer Symposium, Cytokinetics presented a clinical poster summarizing interim data from the Phase I portion of a Phase I/II clinical trial evaluating ispinesib 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 this trial.

-- In December, at the 2008 Annual Meeting of the American Society of Hematology, interim data from the Phase I portion of a Phase I/II clinical trial evaluating SB-743921 in patients with Hodgkin or non-Hodgkin lymphoma were presented. Cytokinetics continues to enroll and dose-escalate patients in the Phase I portion of this trial.

-- GlaxoSmithKline (GSK) continues to enroll and dose-escalate patients in a Phase I first-in-humans clinical trial evaluating GSK-923295, an inhibitor of centromere-associated protein E (CENP-E), in patients with advanced solid tumors.

Non-Clinical Research and Development

-- In January 2009, Cytokinetics announced updates relating to its internal programs directed to muscle biology. The company announced that it plans to submit an investigational new drug application (IND) in 2009 for CK-2017357, a skeletal muscle activator, which had been selected for development in April 2008. This compound is the lead potential drug candidate arising from the company's skeletal muscle activator research program. The company also announced that it has recently designated a second skeletal muscle activator from this research program for development. In addition, Cytokinetics announced the selection of a small molecule inhibitor of smooth muscle myosin for development. This potential drug candidate is expected to enter IND-enabling studies in 2009.

Corporate

-- In December, GSK informed Cytokinetics that it would not exercise its option to license ispinesib or SB-743921 as provided under the companies' collaboration and license agreement. As a result, all rights to ispinesib and SB-743921, each novel inhibitors of kinesin spindle protein, remain with Cytokinetics, on agreed terms. The collaboration between Cytokinetics and GSK is continuing with a focus on GSK-923295 and translational research related to CENP-E.

-- In October, Cytokinetics accepted an offer of settlement with UBS AG relating to certain auction rate securities (ARS). Pursuant to the settlement, UBS AG has issued to Cytokinetics Series C-2 Auction Rate Securities Rights, which provide the company the right to cause UBS to purchase these ARS at par value at any time between June 30, 2010 and July 2, 2012. In addition, UBS may elect to purchase some or all of the ARS at par value at anytime prior to June 30, 2010. In connection with the settlement, Cytokinetics entered into a no net cost loan agreement with UBS Bank USA and UBS Financial Services Inc., and on January 5, 2009 borrowed approximately \$12.4 million under the loan agreement, with the company's ARS held in accounts with UBS and its affiliates as collateral.

Financials

Revenues from research and development collaborations for the fourth quarter of 2008 were \$3.2 million, compared to \$3.1 million for the same period in 2007. Revenues for the fourth quarter of 2008 and 2007 were primarily derived from the company's collaboration and option agreement with Amgen, Inc.

Total research and development (R&D) expenses in the fourth quarter of 2008 were \$11.5 million, compared to \$14.0 million for the same period in 2007. The decrease in R&D expenses in the fourth quarter of 2008, compared to the same period in 2007, was primarily due to decreased laboratory and personnel expenses, which were partially offset by increased spending related to the company's clinical trial programs.

Total general and administrative (G&A) expenses for the fourth quarter of 2008 were \$2.8 million, compared to \$4.1 million for the same period in 2007. The decrease in G&A expenses in the fourth quarter of 2008, compared to the same period in 2007, was primarily due to decreased legal fees and personnel expenses.

Cytokinetics also reported results of its operations for the twelve months ended December 31, 2008. Revenues from research and development collaborations for the twelve months ended December 31, 2008 were \$12.4 million, compared to revenues of \$13.6 million for the same period in 2007. The decrease in collaborative research revenues in 2008, as compared to the same period in 2007, was primarily the result of lower revenue from the company's collaboration with GSK.

Total R&D expenses for the twelve months ended December 31, 2008 were \$54.0 million, compared to \$53.4 million for the same period in 2007. The increase in R&D expenses in 2008, compared to the same period in 2007, was primarily due to higher clinical trial related costs, which were offset in part by decreased laboratory and personnel expenses.

Total G&A expenses for the twelve months ended December 31, 2008 were \$15.1 million, compared to \$16.7 million for the same period in 2007. The decreased G&A expenses in 2008, compared to the same period in 2007, was primarily due to decreased legal and personnel expenses.

The net loss for the twelve months ended December 31, 2008, which included \$2.5 million in restructuring charges, was \$56.4 million, or \$1.14 per share, compared to a net loss of \$48.9 million, or \$1.03 per share, for the same period in 2007.

Company Milestones for 2009

Cardiovascular

CK-1827452

-- In March, Cytokinetics plans to present final data from its ongoing Phase IIa clinical trial of CK-1827452 in patients with stable heart failure at the Annual Meeting of the American College of Cardiology in Orlando, Florida.

-- In 2009, Cytokinetics plans to present final data from its Phase IIa clinical trial of CK-1827452 in patients with ischemic cardiomyopathy and angina.

-- In mid-2009, Cytokinetics anticipates the initiation of a Phase IIb clinical trial of CK-1827452 in chronic heart failure outpatients at increased risk for death and hospitalization.

Oncology

GSK-923295

-- In 2009, Cytokinetics anticipates that GSK will initiate a Phase II clinical trial of GSK-923295.

Non-Clinical Research and Development

-- In 2009, Cytokinetics plans to submit an IND application relating to CK-2017357 and to initiate a Phase I study of CK-2017357 in healthy volunteers.

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

Corporate

-- In the first quarter of 2009, Cytokinetics anticipates providing the required clinical data from its CK-1827452 Phase IIa clinical trials program to Amgen in order to inform the potential exercise of Amgen's option under the companies' strategic alliance.

Financial Guidance for 2009

Cytokinetics also announced its financial 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. On this basis, the company believes that it has over 12 months of cash resources to fund operations.

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 will provide an update to its 2009 financial guidance, taking into account the \$50 million option exercise fee that Amgen would pay to the company, as well as 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. Cytokinetics expects that if Amgen exercises its option related to CK-1827452, the company's cash resources would be then sufficient for approximately 24 months of operations. This financial guidance is on a cash basis and does not include an estimated \$12.0 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.

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.

Conference Call and Webcast Information

Members of Cytokinetics' management team will review fourth quarter and year end results via a webcast and conference call today at 4:30 PM Eastern Time. The webcast can be accessed in the Investor Relations section of 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 81393620.

An archived replay of the webcast will be available via Cytokinetics' website until February 24, 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 81393620 from February 10, 2009 at 5:30 PM Eastern Time until February 24, 2009.

About Cytokinetics

Cytokinetics is a biopharmaceutical company with a focus on muscle contractility that engages in the discovery, development and commercialization of novel small molecule drugs that may address areas of significant unmet clinical needs. Cytokinetics' cardiovascular disease program is focused on cardiac myosin, a motor protein essential to cardiac muscle contraction. Cytokinetics' lead compound from this program, CK-1827452, a novel small molecule cardiac 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 commercial participation rights. In April 2008, Cytokinetics announced the selection of a potential drug candidate, CK-2017357, directed towards skeletal muscle contractility which may be developed as a potential treatment for skeletal muscle weakness associated with neuromuscular diseases or other conditions. 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 bronchoconstriction and vasoconstriction.

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, a mitotic kinesin. 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 utility of clinical trial results, the anticipated availability and presentation of clinical trial results, the initiation and progression of IND-enabling studies and the timing and occurrence of IND filings; the potential receipt of payments under Cytokinetics' strategic alliance with Amgen; potential future collaborations; and the properties and potential benefits of Cytokinetics' compounds. 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; 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		Twelve Months Ended	
December	December	December	December
31,	31,	31,	31,
2008	2007	2008	2007

Revenues: [

Research and development	\$ 93	\$ 51	\$ 186	\$ 1,388
License revenues	3,058	3,058	12,234	12,234
	-----	-----	-----	-----
Total revenues	3,151	3,109	12,420	13,622
	-----	-----	-----	-----
Operating Expenses:				
Research and development	11,470	13,958	53,950	53,388
General and administrative	2,841	4,110	15,076	16,721
Restructuring charges	(19)	-	2,473	-
	-----	-----	-----	-----
Total operating expenses	14,292	18,068	71,499	70,109
	-----	-----	-----	-----
Operating loss:	(11,141)	(14,959)	(59,079)	(56,487)
Interest and other income, net	285	1,706	2,705	7,593
	-----	-----	-----	-----
Net loss	\$ (10,856)	\$ (13,253)	\$ (56,374)	\$ (48,894)
	=====	=====	=====	=====
Net loss per common share				
- basic and diluted	\$ (0.22)	\$ (0.27)	\$ (1.14)	\$ (1.03)
Weighted average shares used in computing net loss per common share				
- basic and diluted	49,490,917	49,224,043	49,391,939	47,590,205

Condensed Balance Sheet
(in thousands)
(unaudited) [

	December 31, 2008	December 31, 2007
	-----	-----
Assets [
Cash and cash equivalents	\$ 41,819	\$ 116,564
Short term investments	15,048	3,175
Other current assets	2,043	2,277
	-----	-----
Total current assets	58,910	122,016
	-----	-----
Investments in auction rate securities	16,636	20,025
Investment put option	3,389	-
Property and equipment, net	5,087	7,728
Restricted investments	2,750	5,167
Other assets	682	434
	-----	-----
Total assets	\$ 87,454	\$ 155,370
	=====	=====
Liabilities and stockholders' equity		
Current liabilities	\$ 22,877	\$ 26,448
Long-term obligations	14,811	29,006

Stockholders' equity	49,766	99,916
	-----	-----
Total liabilities and stockholders' equity	\$ 87,454	\$ 155,370
	=====	=====

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

SOURCE: Cytokinetics, Inc.