Cytokinetics, Incorporated Reports Second Quarter 2009 Financial Results

July 29, 2009 8:18 PM EDT

Quarterly Highlights Include Amgen's Exercise of Option to Company's Cardiac Contractility Program and Initiation of a Phase I Clinical Trial With CK-2017357; Omecamtiv Mecarbil Adopted as Generic Name for CK-1827452

SOUTH SAN FRANCISCO, CA, Jul 29, 2009 (MARKETWIRE via COMTEX) -- Cytokinetics, Incorporated (NASDAQ: CYTK) reported revenues from research and development collaborations of $71.9 million for the second quarter of 2009. Of this revenue, $50.0 million was related to Amgen's payment for the exercise of its option to an exclusive worldwide license (excluding Japan) to the company's cardiac contractility program, including omecamtiv mecarbil (formerly CK-1827452), and $21.4 million was related to the recognition of the remaining deferred revenue associated with Amgen's December 2006 non-exclusive license and technology access fee under the parties' collaboration and option agreement. The net income for the second quarter was $56.0 million, or $0.99 and $0.98 per basic and diluted shares, respectively. This compared to a net loss of $15.4 million, or $0.31 per basic and diluted share, for the same period in 2008. As of June 30, 2009, cash, cash equivalents and investments, excluding restricted cash and the put option on the company's auction rate securities, totaled $132.0 million

"Cytokinetics executed effectively on key activities in the second quarter, which we believe positions the company well both financially and operationally, to advance our pipeline with emphasis to our drug candidates that leverage our muscle contractility expertise," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We are pleased that Amgen recently exercised its option to our cardiac contractility program and look forward to our continuing collaboration. We now proceed with over two years of cash at our current burn rate and a portfolio of five novel compounds in development highlighted by our recent advancement of CK-2017357 into a first-time-in-humans Phase I clinical trial."

Company Highlights

Muscle Contractility

Omecamtiv Mecarbil (formerly CK-1827452)

-- In May, Cytokinetics announced that Amgen exercised its option to obtain an exclusive worldwide license (excluding Japan) to the company's cardiac contractility program. The license includes omecamtiv mecarbil (formerly CK-1827452), a novel cardiac muscle myosin activator being developed for the potential treatment of heart failure.

-- During the second quarter, Cytokinetics received notification from the United States Adopted Names (USAN) Council indicating the adoption of omecamtiv mecarbil as the USAN or generic name for CK-1827452. This information has been posted on the USAN website (www.ama-assn.org/go /usan). Information on omecamtiv mecarbil is planned to be submitted to the United States Pharmacopeial Convention, Inc. for publication in the USP Dictionary of USAN and International Drug Names.

-- In June, investigators presented final data from a Phase IIa clinical trial of omecamtiv mecarbil in patients with stable heart failure as part of the Late Breaking Trials Session of the 2009 Heart Failure Congress of the European Society of Cardiology in Nice, France. This presentation included the first public disclosure of analyses showing that patients with reduced stroke volumes (50ml) at baseline had generally greater pharmacodynamic responses to omecamtiv mecarbil than those in patients with greater stroke volumes at baseline, demonstrating robust pharmacodynamic activity in this more severely affected sub-population of patients from the trial. The authors concluded that these findings support further study and translation of this novel mechanism into patients with heart failure. In addition, a poster presentation containing data from the same trial compared the standard, image-based method for calculating left ventricular ejection fraction with "hybrid" methods that use a combination of image-based measurements of ventricular volumes and Doppler-derived measurements of stroke volume. The authors concluded that hybrid ejection fraction calculations relating Doppler-derived stroke volume to an image-derived ventricular volume may be more sensitive to increases in systolic function than assessments of ejection fraction based entirely on imaging.

-- Also at the 2009 Heart Failure Congress of the European Society of Cardiology, investigators presented a poster containing final data from a Phase IIa clinical trial evaluating omecamtiv mecarbil in patients with ischemic cardiomyopathy and angina. The authors concluded that in these patients, who theoretically could be most vulnerable to the possible deleterious consequences of systolic ejection time prolongation, treatment with omecamtiv mecarbil at concentrations that increase cardiac function did not deleteriously affect a broad range of safety assessments in the setting of exercise.

-- The Phase IIa clinical trial of omecamtiv mecarbil designed to evaluate and compare the oral pharmacokinetics of both a modified-release and an immediate-release formulation in patients with stable heart failure continues to enroll patients. Based on results from this open-label trial, Cytokinetics and Amgen have agreed to proceed with a modified-release oral formulation in the planned Phase IIb clinical trials.

-- Cytokinetics and Amgen have agreed to discontinue the Phase IIa clinical trial evaluating an intravenous formulation of omecamtiv mecarbil in patients with stable heart failure undergoing clinically indicated coronary angiography in the cardiac catheterization laboratory. This decision, made jointly by the companies, was due to the challenges of the current trial design and the constraints on enrolling eligible and consenting patients. The companies may revisit the objectives of this trial in the context of the ongoing development program.

CK-2017357

-- In June, Cytokinetics initiated a first-time-in-humans, Phase I clinical trial of CK-2017357 in healthy male volunteers. CK-2017357 is a fast skeletal muscle troponin activator and is the lead drug candidate that has emerged from the company's skeletal sarcomere activator program. Cytokinetics continues to enroll and dose-escalate subjects in this trial.

Smooth Muscle Program

-- In May, at the American Society of Hypertension 24th Annual Scientific Meeting and Exposition, Cytokinetics presented non-clinical data suggesting that direct inhibition of smooth muscle myosin may offer a novel therapeutic approach for the treatment of hypertension.

Oncology

-- In June, at the Annual Meeting of the American Society of Clinical Oncology (ASCO), Cytokinetics presented interim data from the Phase I portion of a Phase I/II clinical trial evaluating ispinesib administered as monotherapy as a first-line treatment in chemotherapy-naive patients with locally advanced or metastatic breast cancer. Cytokinetics continues the Phase I portion of this trial.

-- At ASCO, Cytokinetics presented 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. Cytokinetics continues the Phase I portion of this trial.

-- Also at ASCO, GlaxoSmithKline (GSK) presented interim data from the Phase I, first-time-in-humans clinical trial evaluating GSK-923295 in patients with advanced, refractory solid tumors. GSK continues to enroll and dose-escalate patients in this trial.

Corporate

-- In May, Cytokinetics announced a registered direct offering to certain of its existing institutional shareholders to sell an aggregate of 7,106,600 units. Each unit consisted of one share of Cytokinetics' common stock and one warrant to purchase 0.5 shares of Cytokinetics' common stock. Gross proceeds were approximately $14.0 million before deducting placement agents' fees and estimated offering expenses.

Financials

Revenues from research and development (R&D) collaborations for the second quarter of 2009 were $71.9 million, compared to $3.1 million for the same period in 2008. Revenues for the second quarter of 2009 and 2008 were primarily derived from the company's collaboration and option agreement with Amgen. The revenue in the second quarter of 2009 included Amgen's payment of $50.0 million related to the exercise of its option to an exclusive worldwide license (excluding Japan) to the company's cardiac contractility program, including omecamtiv mecarbil, and the recognition of the remaining deferred revenue of $21.4 million associated with Amgen's December 2006 non-exclusive license and technology access fee to omecamtiv mecarbil.

Total R&D expenses in the second quarter of 2009 were $10.2 million, compared to $14.9 million for the same period in 2008. The decrease in R&D expenses in the second quarter of 2009, compared to the same period in 2008, was primarily due to decreased spending related to the company's clinical and pre-clinical programs, and lower personnel and laboratory expenses.

Total General and administrative (G&A) expenses for the second quarter of 2009 were $4.1 million, compared to $4.3 million for the same period in 2008. The decrease in G&A expenses in the second quarter of 2009, compared to the same period in 2008, was primarily due to lower spending for legal and outside services, which were offset in part by higher personnel-related costs.

Total Interest and other, net expense for the second quarter of 2009 was $1.6 million, compared to income of $0.7 million for 2008. The increase in Interest and other, net in 2009, compared to the same period in 2008 was primarily due to the recognition of $1.6 million in the non-cash fair value expense for the warrants associated with our May 2009 registered direct financing, along with a decline of $0.7 million in interest income as a result of lower market interest rates earned on our investments and lower average balances of cash, cash equivalents and investments.

The net income for the three months ended June 30, 2009, was $56.0 million, or $0.99 and $0.98 per basic and diluted share, compared to a net loss for the same period in 2008 of $15.4 million, or $0.31 per share.

Cytokinetics also reported results of its operations for the six months ended June 30, 2009. Revenues from R&D collaborations for the six months ended June 30, 2009 were $75.0 million, compared to revenues of $6.1 million for the same period in 2008. The increase in collaborative research revenues for the first six months of 2009, as compared to the same period in 2008, was primarily the result of a $50.0 million payment from Amgen relating to its exercise of its option for an exclusive worldwide license (excluding Japan) to the company's cardiac contractility program, including omecamtiv mecarbil, and the recognition of deferred revenue of $24.5 million associated with Amgen's December 2006 non-exclusive license and technology access fee under the parties' collaboration and option agreement.

Total R&D expenses for the six months ended June 30, 2009 were $20.2 million, compared to $29.0 million for the same period in 2008. The decrease in R&D expenses in the first six months of 2009, over the same period in 2008, was primarily due to decreased spending associated with the company's clinical and pre-clinical programs, along with lower personnel and laboratory expenses.

Total G&A expenses for the six months ended June 30, 2009 were $8.1 million, compared to $8.4 million for the same period in 2008. The decrease spending in the first six months of 2009, over the same period in 2008, was primarily due to lower spending for legal and outside services, offset in part by higher personnel-related costs.

Total Interest and other, net expense for the six months ended June 30, 2009 was $1.4 million, compared to income of $2.0 million for 2008. The increase in Interest and other, net in 2009, compared to the same period in 2008 was primarily due to the recognition of $1.6 million in the non-cash fair value expense for the warrants associated with our May 2009 registered direct financing, along with a decline of $1.9 million in interest income as a result of lower market interest rates earned on our investments and lower average balances of cash, cash equivalents and investments.

The net income for the six months ended June 30, 2009, was $45.3 million, or $0.84 and $0.83 per basic and diluted share, respectively, compared to a net loss of $29.3 million, or $0.59 per share, for the same period in 2008.

As of June 30, 2009, cash, cash equivalents and investments, excluding restricted cash and the put option on the company's auction rate securities, totaled $132.0 million. This represents over 24 months of going-forward cash burn at our current burn rate.

Updated Financial Guidance for 2009

Cytokinetics also announced updated financial guidance for 2009. The company anticipates its 2009 cash revenues to be in the range of $54.0 to $58.0 million, cash R&D expenses are anticipated to be in the range of $40.0 to $45.0 million and cash G&A expenses are anticipated to be in the range of $15.0 to $17.0 million. This financial revenue guidance includes the $50.0 million received during the second quarter associated with Amgen's exercise of its option for the company's cardiac contractility program and anticipated revenues associated with Amgen's reimbursement of certain R&D expenses related to the non-clinical and clinical development program for omecamtiv mecarbil (formerly CK-1827452).

Cytokinetics may further update its financial guidance based on ongoing discussions with Amgen and the possibility that the company may assume responsibility for additional R&D activities under the collaboration. These additional activities may be reimbursed by Amgen.

This financial guidance is on a cash basis and does not include an estimated $24.5 million in GAAP revenues related primarily to Amgen's initial up-front payment for its non-exclusive license and technology access fee under the parties' collaboration and option agreement and $7.3 million in non-cash related operating expenses primarily related to FAS 123R stock compensation expense.

Company Milestones

Cardiovascular

Omecamtiv Mecarbil (formerly CK-1827452)

-- In August, Cytokinetics plans to present final data from the Phase IIa clinical trial of omecamtiv mecarbil in stable heart failure patients at the Annual Meeting of the European Society of Cardiology (ESC) in Barcelona, Spain.

-- At the August ESC meeting, Cytokinetics also plans to present final data from the Phase IIa clinical trial of omecamtiv mecarbil in patients with ischemic cardiomyopathy and angina.

-- In September, Cytokinetics plans to present final data from the Phase IIa clinical trial of omecamtiv mecarbil in stable heart failure patients at the Annual Meeting of the Heart Failure Society of America (HFSA) in Boston, Massachusetts.

-- At the September HFSA meeting, Cytokinetics also plans to present final data from the Phase IIa clinical trial of omecamtiv mecarbil in patients with ischemic cardiomyopathy and angina.

-- Amgen and Cytokinetics are planning to move rapidly into larger and more definitive clinical trials of omecamtiv mecarbil as part of a robust development program that is anticipated to include Phase IIb clinical trials in subjects with heart failure, as well as non-clinical activities and additional clinical pharmacology studies that support these trials. Certain collaborative activities under this program are ongoing and will continue through the remainder of 2009, while others are anticipated to be initiated in 2010.

Other Research and Development

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

Corporate

-- On September 18, 2009, Cytokinetics plans to host a Research and Development Day for the investment community at the Grand Hyatt Hotel in New York, NY. The event is intended to highlight the company's pipeline and Cytokinetics' recent progress in advancing its muscle biology drug development programs. Members of the company's senior management team will make presentations with additional commentary to be provided by translational research and clinical development thought leaders.

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 fair value expense related to 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 second 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 81445235.

An archived replay of the webcast will be available via Cytokinetics' website until August 13, 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 81445235 from July 30, 2009 at 5:30 PM Eastern Time until August 13, 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, omecamtiv mecarbil (formerly CK-1827452), a novel small molecule cardiac muscle myosin activator, is in Phase II clinical trials for the potential treatment of heart failure. Amgen Inc. has exercised an option for an exclusive license to develop and commercialize omecamtiv mecarbil worldwide (excluding Japan), subject to Cytokinetics' development and commercialization participation rights. In June 2009, Cytokinetics initiated 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. Cytokinetics' smooth muscle myosin inhibitors have arisen from research focused towards potential treatments for diseases and conditions, such as systemic hypertension, pulmonary arterial hypertension or bronchoconstriction.

Cytokinetics' cancer development programs are focused on mitotic kinesins, a family of motor proteins essential to cell division. Cytokinetics is developing two drug candidates from this program, ispinesib and SB-743921, each an inhibitor of kinesin spindle protein. In addition, Cytokinetics and GlaxoSmithKline are collaborating on 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 Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, statements relating to Cytokinetics' financial guidance, including expected cash operating expenditures, revenues and R&D and G&A expenses for 2009 and the ability of its cash reserves to suffice for over 24 months; Cytokinetics' and its partners' research and development activities, including the initiation, conduct, focus, scope and completion of development activities (including of clinical trials) for omecamtiv mecarbil (formerly CK-1827452) and Cytokinetics' other drug candidates and potential drug candidates, the significance of clinical trial results for omecamtiv mecarbil, the planned presentation of clinical trial results, the progression of IND-enabling studies, the advancement of Cytokinetics' pipeline, and the activities to be conducted by Cytokinetics under its collaboration with Amgen; the potential receipt of funds under Cytokinetics' collaboration with Amgen; the submission of the omecamtiv mecarbil name for publication; 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 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, including without limitation, due to political instability in countries where clinical trials of Cytokinetics' drug candidates are being conducted, 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 and GSK's decisions with respect to the design, conduct, timing and continuation of development activities for omecamtiv mecarbil and GSK-923295, respectively; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; standards of care may change rendering Cytokinetics' drug candidates obsolete; others may introduce products or alternative therapies 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		Six Months Ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
Revenues:				
Research and development	$ 622	$ 16	$ 641	$ 27
License revenues	71,308	3,058	74,367	6,117
Total revenues	71,930	3,074	75,008	6,144
Operating Expenses:				
Research and development	10,202	14,859	20,161	28,961
General and administrative	4,127	4,252	8,147	8,409
Restructuring charges	56	-	(2)	-
Total operating expenses	14,385	19,111	28,306	37,370
Operating income (loss):	57,545	(16,037)	46,702	(31,226)
Interest and other, net	(1,586)	673	(1,428)	1,968
Net income (loss)	$ 55,959	$ (15,364)	$ 45,274	$ (29,258)
Basic net income (loss) per common share	$ 0.99	$ (0.31)	$ 0.84	$ (0.59)
Diluted net income (loss) per common share	$ 0.98	$ (0.31)	$ 0.83	$ (0.59)

Shares used in calculating:				
Basic net income (loss) per common share	56,454,574	49,365,685	54,031,708	49,329,775
Diluted net income (loss) per common share	56,902,550	49,365,685	54,449,630	49,329,775

Cytokinetics, Incorporated
Condensed Balance Sheet
(in thousands)
(unaudited)

	June 30, 2009	December 31, 2008
Assets		
Cash and cash equivalents	$ 85,032	$ 41,819
Short term investments	29,691	15,048
Investment in auction rate securities	17,254	-
Investment put option	2,721	-
Other current assets	2,402	2,043
Total current assets	137,100	58,910
Investment in auction rate securities	-	16,636
Investment put option	-	3,389
Property and equipment, net	4,249	5,087
Restricted investments	2,232	2,750
Other assets	488	682
Total assets	$ 144,069	$ 87,454
Liabilities and stockholders' equity		
Current liabilities	$ 23,248	$ 22,877
Long-term obligations	1,757	14,811
Stockholders' equity	119,064	49,766
Total liabilities and stockholders' equity	$ 144,069	$ 87,454

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

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
GAAP net income (loss)	$ 55,959	$ (15,364)	$ 45,274	$ (29,258)
Non-cash deferred revenue related to Amgen collaboration	(21,418)	(3,058)	(24,493)	(6,117)
Non-cash warrant expense	1,585	-	1,585	-
Non-cash stock-based compensation	1,224	1,347	2,473	2,873

Non-cash depreciation, amortization, and other	576	668	1,023	1,331
Non-GAAP net income (loss)	$ 37,926	$ (16,407)	$ 25,862	$ (31,171)

Cytokinetics, Incorporated:

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

SOURCE: Cytokinetics, Inc.