Cytokinetics, Incorporated Reports First Quarter 2014 Financial Results

May 6, 2014 8:01 PM EDT

Company Considers Potential Next Steps for First-in-Class Skeletal Muscle Activator Focused to ALS

Partnered and Funded Programs Advancing Through Clinical Trials in Parallel

SOUTH SAN FRANCISCO, CA, May 6, 2014 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported total revenues of $8.0 million for the first quarter of 2014, compared to $0.8 million during the same period in 2013. Net loss for the first quarter of 2014 was $8.7 million or $0.27 per basic share and diluted share. This is compared to a net loss for the same period in 2013, of $12.6 million, or $0.53 per basic and diluted share. As of March 31, 2014, cash, cash equivalents and investments totaled $101.9 million.

"Cytokinetics recently announced the results from BENEFIT-ALS. We believe that the initial data from BENEFIT-ALS demonstrate potentially important biological activity of *tirasemtiv* in patients with ALS that is consistent with its mechanism of action," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "While BENEFIT-ALS did not meet its primary efficacy endpoint, this large, international trial did show unprecedented effects on certain pre-specified endpoints that have been demonstrated in earlier trials of patients with ALS to be clinically meaningful to disease progression. It is incumbent on us to delve deeply into these data internally and with experts in the ALS community in order to inform a potential path forward for our first-in-class skeletal muscle activator. In parallel, in the first quarter, we made excellent progress in our other development programs that we believe are positioned well for advancement to key clinical stage milestones as funded by our partners. We maintain a portfolio of novel mechanism muscle activators at Cytokinetics that inform multiple paths toward innovative medicines."

Company Highlights

Skeletal Muscle Contractility

tirasemtiv

- Last week, Cytokinetics announced results from BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional **I**mprovement with ***T****irasemtiv* in **ALS**). BENEFIT-ALS was a Phase IIb, multinational, double-blind, randomized, placebo-controlled clinical trial designed to evaluate the safety, tolerability and potential efficacy of *tirasemtiv* in patients with amyotrophic lateral sclerosis (ALS). BENEFIT-ALS did not achieve its primary efficacy endpoint, the mean change from baseline in the ALS Functional Rating Scale in its revised form (ALSFRS-R). Treatment with *tirasemtiv* resulted in a statistically significant and potentially clinically meaningful reduction in the decline of Slow Vital Capacity (SVC), a measure of the strength of the skeletal muscles responsible for breathing that has been shown to be an important predictor of disease progression and survival in prior trials of patients with ALS. The analyses of other pre-specified secondary efficacy endpoints produced mixed results.

Serious adverse events (SAEs) during double-blind treatment were more frequent on *tirasemtiv* than on placebo. The most common SAE was respiratory failure, which occurred in 1 patient on *tirasemtiv* and 3 patients on placebo, while confusional state and delirium occurred in 2 patients on *tirasemtiv* and no patients on placebo. More patients on *tirasemtiv* withdrew from the trial following randomization than on placebo. Adverse events more common on *tirasemtiv* than on placebo (>10% difference) were dizziness, fatigue, and nausea.

- During the quarter, Cytokinetics made preparations for the potential further development and the commercialization of *tirasemtiv*. These activities included interactions with regulatory authorities and other manufacturing, corporate development and commercial planning activities to support planning scenarios.

CK-2127107

- During the quarter, Cytokinetics initiated enrollment in CY 5012, a double-blind, randomized, placebo-controlled, parallel group study in which the primary objective is to assess the safety, tolerability, and pharmacokinetics of CK-2127107 following multiple ascending doses in healthy volunteers. The initiation of this clinical trial triggered a $2.0 million milestone payment from Astellas Pharma Inc. to Cytokinetics under the terms of the collaboration between the companies established in June 2013. This trial is being conducted by Cytokinetics in

collaboration with Astellas.

Cardiac Muscle Contractility

omecamtiv mecarbil

- During the quarter, Cytokinetics announced that the expansion phase of COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure) opened to enrollment. COSMIC-HF is a Phase II, double-blind, randomized, placebo-controlled, multicenter clinical trial designed to assess the pharmacokinetics and tolerability of *omecamtiv mecarbil* dosed orally in patients with heart failure and left ventricular systolic dysfunction. The secondary objectives are to assess the changes from baseline in systolic ejection time, stroke volume, left ventricular end-systolic diameter, left ventricular end-diastolic diameter, heart rate and N-terminal pro-brain natriuretic peptide (a biomarker associated with the severity of heart failure) during 20 weeks of treatment. The expansion phase of COSMIC-HF is expected to enroll heart failure patients from approximately 100 clinical sites internationally. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- During the quarter, Cytokinetics began preparations for the initiation of CY 1211 following a review of the protocol for the trial with the FDA. CY 1211 is a Phase I, single center, placebo-controlled, double-blind study comparing the pharmacokinetics of *omecamtiv mecarbil* between healthy Japanese and Caucasian volunteers. CY 1211 will be conducted by Cytokinetics in collaboration with Amgen.

Additional information on COSMIC-HF and other clinical trials of *omecamtiv mecarbil* can be found at www.clinicaltrials.gov.

Pre-Clinical Research

- During the quarter, Cytokinetics continued to conduct research under our joint research program with Amgen, directed to the discovery of next-generation cardiac sarcomere activators, and our joint research program with Astellas, directed to the discovery of next-generation skeletal muscle activators. In addition, the company continued research activities directed to other muscle biology programs.

Corporate

- During the quarter, Cytokinetics completed an underwritten public offering for the sale of 5.0 million shares of common stock for net proceeds of $37.5 million, after deducting the underwriting discount and offering expenses.

Financials

Revenues for the first quarter of 2014 were $8.0 million, compared to $0.8 million during the same period in 2013. Revenues for the first quarter of 2014 included $2.1 million of license revenues and $5.2 million of research and development revenues from our collaboration with Astellas, and $0.7 million of research and development revenues from our collaboration with Amgen. Revenues for the same period in 2013 included $0.4 million of research and development revenues from our collaboration with MyoKardia, Inc., and $0.3 million of research and development revenues from our collaboration with Amgen.

Total research and development (R&D) expenses in the first quarter of 2014 were $12.5 million, compared with $9.8 million for the same period in 2013. The $2.7 million increase in R&D expenses for the first quarter of 2014, compared with the same period in 2013, was primarily due to increased spending for outsourced clinical costs and personnel expenses.

Total general and administrative (G&A) expenses for the first quarter of 2014 were $4.3 million, compared with $3.6 million for the same period in 2013. The $0.7 million increase in G&A expenses in the first quarter of 2014, compared with the same period in 2013, was primarily due to increased spending for personnel expenses and corporate development planning.

Cash, cash equivalents and investments totaled $101.9 million as of March 31, 2014, compared to $80.2 million as of December 31, 2014. The increase was primarily due to net proceeds of approximately $37.5 million received from a public offering of 5.0 million shares of common stock, completed in February 2014, offset primarily by net operating expenses.

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 3:00 PM on Wednesday, May 21, 2014.

Company Milestones

Skeletal Muscle Contractility

tirasemtiv

- Cytokinetics expects to analyze further the data from BENEFIT-ALS to inform potential further development in ALS.

CK-2127107

- Cytokinetics expects to conduct additional Phase I studies and certain Phase II readiness activities in 2014 pursuant to our collaboration agreement with Astellas.

Cardiac Muscle Contractility

omecamtiv mecarbil

- Cytokinetics anticipates commencement of patient enrollment in CY 1211 to occur by mid-year 2014.
- Cytokinetics expects both the enrollment of patients in the expansion phase of COSMIC-HF and the conduct of CY 1211 to be completed in 2014.

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 Homepage and 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 34949399.

An archived replay of the webcast will be available via Cytokinetics' website until May 20, 2014. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (international) and typing in the passcode 34949399 from May 6, 2014 at 5:30 PM Eastern Time until May 13, 2014.

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*, is in Phase II clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing *tirasemtiv*, a fast skeletal muscle activator, as a potential treatment for diseases and medical conditions associated with neuromuscular dysfunction. *Tirasemtiv* is the subject of a Phase II clinical trials program and has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency for the potential treatment of amyotrophic lateral sclerosis (ALS). Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a skeletal muscle activator structurally distinct from *tirasemtiv*, for non-neuromuscular indications. All of these drug candidates have arisen from Cytokinetics' muscle biology focused 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.

Forward-Looking Statements

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, conduct, design, enrollment, progress, continuation, completion and results of clinical trials, the potential significance and utility of the results from BENEFIT-ALS, planned further analyses of the results from BENEFIT-ALS and the potential outcomes of such analyses, potential further development of tirasemtiv; the anticipated timing for the occurrence of events; and the properties and potential benefits of tirasemtiv and Cytokinetics' other 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, the results of BENEFIT-ALS may not support further clinical development of tirasemtiv; further clinical development of tirasemtiv in ALS patients, if supported by the BENEFIT-ALS data, will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding on acceptable terms, if at all; 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 and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil and CK-2127107, 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; 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.

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Cytokinetics, Incorporated
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended	
	March 31, 2014	**March 31, 2013**
Revenues:		
Research and development revenues from related parties	$ 665	$ 328
Research and development, grant and other revenues	5,232	493
License revenues	2,082	-
Total revenues	7,979	821
Operating Expenses:		
Research and development	12,490	9,834
General and administrative	4,259	3,634
Total operating expenses	16,749	13,468
Operating loss	(8,770)	(12,647)
Interest and other, net	26	28
Net loss	$ (8,744)	$ (12,619)
Net loss per share - basic and diluted	$ (0.27)	$ (0.53)
Weighted average shares used in computing net loss per share - basic and diluted	32,985	24,010

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2014	**December 31, 2013 (1)**
Assets	**(unaudited)**	
Cash and cash equivalents	$ 13,256	$ 20,158
Short term investments	69,090	57,570
Accounts receivable and related party receivable	2,116	5
Other current assets	1,592	1,605
Total current assets	86,054	79,338
Property and equipment, net	1,508	1,221
Long-term investments	19,515	2,502
Other assets	200	127
Total assets	$ 107,277	$ 83,188
Liabilities and stockholders' equity		
Deferred revenue, current	$ 10,396	$ 14,701
Other current liabilities	9,396	12,003
Total current liabilities	19,792	26,704
Deferred revenue, non-current	772	1,500
Other non-current liabilities	535	542
Stockholders' equity	86,178	54,442
Total liabilities and stockholders' equity	$ 107,277	$ 83,188

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.