

# Cytokinetics, Incorporated Reports First Quarter 2015 Financial Results

2015-04-30

*Company is Ready to Initiate a Phase III Clinical Trial of Tirasemtiv in Patients With ALS following Recent Meetings With FDA and EMA*

*Completion of Patient Enrollment in COSMIC-HF Enable Results Expected Later This Year*

SOUTH SAN FRANCISCO, Calif., April 30, 2015 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported total research and development revenues for the first quarter of 2015 were \$4.4 million, compared to \$8.0 million during the same period in 2014. The net loss for the first quarter was \$8.9 million, or \$0.23 per basic and diluted share. This is compared to a net loss for the same period in 2014, of \$8.7 million, or \$0.27 per basic share and diluted share. As of March 31, 2015, cash, cash equivalents and investments totaled \$117.5 million.

"During the first quarter, Cytokinetics convened meetings with each of FDA and EMA to review results from BENEFIT-ALS and to discuss plans to advance *tirasemtiv* to the next stage of clinical development. Based on feedback from those meetings, Cytokinetics is preparing to initiate a large, international Phase III clinical trial of *tirasemtiv* in patients with ALS." stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In addition, we are pleased that COSMIC-HF recently completed patient enrollment. We are readying for the availability of results from this clinical trial which are expected later this year and are preparing for the potential progression of *omecamtiv mecarbil* to Phase III in collaboration with Amgen."

## Company Highlights

### Skeletal Muscle Contractility

#### *tirasemtiv*

- During the quarter, Cytokinetics convened meetings with regulatory authorities in both the United States and Europe to discuss the results of BENEFIT-ALS and plans to advance *tirasemtiv* to Phase III. While regulatory interactions are on-going, the company believes that the current feedback from the FDA and EMA inform the advancement of *tirasemtiv* to a Phase III program.

- During the quarter, Cytokinetics conducted readiness activities to support the initiation of a Phase III clinical trial of *tirasemtiv* in patients with amyotrophic lateral sclerosis (ALS). Objectives of the Phase III program are to confirm and extend results observed in BENEFIT-ALS and will include assessments of measures of respiratory function after longer duration treatment with *tirasemtiv* in patients with ALS, including effects on slow vital capacity (SVC).
- During the quarter, a manuscript titled "A Double-Blinded, Randomized, Placebo-Controlled Trial to Evaluate Efficacy, Safety, and Tolerability of Single Doses of *Tirasemtiv* in Patients with Acetylcholine Receptor-Binding Antibody-Positive Myasthenia Gravis" was published in the journal *Neurotherapeutics*. This publication summarized results from a Phase IIa clinical trial which evaluated two doses of *tirasemtiv* in patients with generalized myasthenia gravis (MG). The authors concluded that *tirasemtiv* may improve muscle function in patients with MG and that the results support further development of *tirasemtiv* in neuromuscular diseases.

#### CK-2127107

- During the quarter, Cytokinetics and Astellas Pharma Inc. engaged neuromuscular experts to inform the planning of a Phase II clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA) which is expected to be conducted by Cytokinetics in accordance with an agreed plan with Astellas. Cytokinetics and Astellas also engaged in additional preclinical activities, including manufacturing and formulation development for CK-2127107.

#### Cardiac Muscle Contractility

##### *omecamtiv mecarbil*

- During the quarter, patient enrollment completed in COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure). 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 as well as its effects on echocardiographic measures of cardiac function. Over 275 patients have completed the 20-week duration of dosing in the expansion phase of COSMIC-HF. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- During the quarter, Cytokinetics collaborated with Amgen on activities directed to the potential advancement of *omecamtiv mecarbil* to a Phase III program.

#### Pre-Clinical Research

- During the quarter, Cytokinetics and Amgen agreed to extend the joint research program directed to next-generation cardiac sarcomere activator compounds. Terms of the amendment to the companies' collaboration agreement provide for Amgen's continued support of Cytokinetics scientists through 2015 and potential additional milestone payments from Amgen to Cytokinetics for compounds that may arise out of the collaborative research.
- During the quarter, a manuscript titled "The Small Molecule Fast Skeletal Troponin Activator, CK-2127107, Improves Exercise Tolerance in a Rat Model of Heart Failure" was published in *The Journal of Pharmacology and Experimental Therapeutics*. In this preclinical study, CK-2127107 was associated with increased exercise performance in this heart failure model. The authors concluded that CK-2127107 substantially increased exercise performance in this model, suggesting that modulation of skeletal muscle function by a fast skeletal troponin activator may be a useful therapeutic approach in heart failure associated exercise intolerance.

## Corporate

- During the quarter, Cytokinetics supported the global efforts of patient and disease advocacy groups to raise awareness of rare diseases, like ALS and SMA, through participation in Rare Disease Day on February 28, 2015.

## Financials

Revenues for the first quarter of 2015 were \$4.4 million, compared to \$8.0 million during the same period in 2014. Revenues for the first quarter of 2015 included \$1.6 million of license revenues and \$2.1 million of research and development revenues from our collaboration with Astellas, and \$0.7 million in research and development revenues from our collaboration with Amgen. Revenues for the same period in 2014 were comprised of \$2.1 million of license revenues and \$5.2 million of research and development revenues from our collaboration with Astellas, which included a \$2.0 million milestone payment related to research activities; and \$0.7 million of research and development revenues from our collaboration with Amgen.

Total research and development (R&D) expenses for the first quarter of 2015 were \$9.0 million, compared with \$12.5 million for the same period in 2014. The \$3.5 million decrease in R&D expenses for the first quarter of 2015, compared with the same period in 2014, was primarily due to a decrease of \$3.9 million in outsourced clinical and preclinical costs partially offset by an increase of \$0.2 million in personnel related expenses.

Total general and administrative (G&A) expenses for the first quarter of 2015 were \$4.4 million, compared with \$4.3 million for the same period in 2014.

## R&D Day Meeting

Cytokinetics is hosting a R&D Day on Tuesday, May 12, 2015. The meeting is scheduled to occur from 8:00 AM – 11:00 AM Eastern Time at the New York Grand Hyatt Hotel in New York, New York and will be simultaneously webcast. Representatives of Cytokinetics' senior management team will be joined by expert clinicians to provide updates regarding the company's discovery and development programs including recent progress, milestones and other commentary.

## Annual Stockholders' Meeting

Cytokinetics' Annual Stockholders' Meeting will be held on Wednesday, May 20, 2015. The meeting is scheduled to occur at 10:30 AM Pacific Time at the Embassy Suites Hotel in South San Francisco, CA and will be simultaneously webcast.

## Company Milestones

### Skeletal Muscle Contractility

#### *tirasemtiv*

- Cytokinetics expects to initiate a Phase III clinical development program for *tirasemtiv* in patients with ALS in the second quarter of 2015.

CK-2127107

- Cytokinetics expects to initiate a Phase II trial of CK-2127107 in patients with SMA in the second half of 2015.

### Cardiac Muscle Contractility

#### *omecamtiv mecarbil*

- Cytokinetics expects results from COSMIC-HF to be available in the second half of 2015.
- Cytokinetics expects to continue joint development activities in collaboration with Amgen directed to the potential advancement of *omecamtiv mecarbil* to Phase III clinical development.

### 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](http://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 34463154.

An archived replay of the webcast will be available via Cytokinetics' website until May 7, 2015. 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 34463154 from April 30, 2015 at 5:30 PM Eastern Time until May 7, 2015.

### 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 is developing *tirasemtiv*, a fast skeletal muscle activator, as a potential treatment for amyotrophic lateral sclerosis (ALS). *Tirasemtiv* 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 ALS. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a cardiac muscle activator, for the potential treatment of heart failure. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy. Amgen holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and Astellas holds an exclusive license worldwide to develop and commercialize CK-2127107. Both licenses are subject to Cytokinetics' specified development and commercialization participation rights. 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 <http://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 expected revenue and R&D and G&A expenses, the initiation, conduct, design, enrollment, progress, continuation, completion and results of*

clinical trials, the significance and utility of preclinical study and clinical trial results, the expected availability of clinical trial results, planned interactions with regulatory authorities and the outcomes of such interactions, the potential conduct of a Phase III trial of tirasemtiv and the timing for initiation of such a trial; the potential progression of CK-2127107 to Phase II development, the potential progression of omecamtiv mecarbil to Phase III development; potential milestone payments; the expected timing of events; and the properties and potential benefits of Cytokinetics' 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 further clinical development of tirasemtiv in ALS patients which will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding on acceptable terms, if at all; the FDA and/or other regulatory authorities may not accept effects on slow vital capacity as a clinical endpoint to support registration of tirasemtiv for the treatment of ALS; additional Phase I clinical trials for CK-2127107 may be required; 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.

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

	Three Months Ended	
	March 31, 2015	March 31, 2014
Revenues:		
Research and development revenues from related parties	\$ 2,791	\$ 665
Research and development, grant and other revenues	—	5,232
License revenues from related parties	1,623	—
License revenues	—	2,082
Total revenues	4,414	7,979
Operating Expenses:		
Research and development	8,956	12,490
General and administrative	4,367	4,259

Total operating expenses	13,323	16,749
Operating loss	(8,909)	(8,770)
Interest and other, net	37	26
Net loss	\$ (8,872)	\$ (8,744)
Net loss per share – basic and diluted	\$ (0.23)	\$ (0.27)
Weighted average shares used in computing net loss per share - basic and diluted	38,675	32,985

**Cytokinetics, Incorporated**  
**Condensed Consolidated Balance Sheets**  
(in thousands)

	March 31, 2015 (unaudited)	December 31, 2014 <sup>(1)</sup>
<b>Assets</b>		
Cash and cash equivalents	\$ 22,546	\$ 20,215
Short-term investments	85,322	63,013
Related party accounts receivable	970	46,646
Prepaid and other current assets	1,972	1,257
Total current assets	110,810	131,131
Property and equipment, net	1,551	1,637
Long-term investments	9,653	—
Other assets	200	200
<b>Total assets</b>	<b>\$ 122,214</b>	<b>\$ 132,968</b>
<b>Liabilities and stockholders' equity</b>		
Deferred revenue, current	\$ 19,942	\$ 17,042
Other current liabilities	5,443	6,813
Total current liabilities	25,385	23,855
Deferred revenue, non-current	12,211	16,558
Other non-current liabilities	466	491
Stockholders' equity	84,152	92,064
<b>Total liabilities and stockholders' equity</b>	<b>\$ 122,214</b>	<b>\$ 132,968</b>

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

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Cytokinetics