

Cytokinetics, Incorporated Reports Fourth Quarter 2014 Financial Results

2015-02-12

Ongoing Regulatory Interactions in US and Europe Inform Progression of Tirasemtiv to Phase III

COSMIC-HF Nears Completion of Enrollment with Results Expected Later This Year

Company Exceeded Financial Guidance in 2014 and Provides Milestones and Financial Guidance for 2015

SOUTH SAN FRANCISCO, CA, February 12, 2015 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported total research and development revenues for the fourth quarter of 2014 were \$21.8 million, compared to \$24.3 million during the same period in 2013. The net income for the fourth quarter was \$8.4 million, or \$0.23 per basic and diluted share. This is compared to a net income for the same period in 2013, of \$6.5 million, or \$0.22 per basic share and \$0.21 per diluted share. As of December 31, 2014, cash, cash equivalents and investments totaled \$83.2 million, which includes the receipt of \$10 million for the sale of common stock to Astellas Pharma Inc., but does not include \$45.0 million received from Astellas in January 2015. With the recognition of a milestone payment under its collaboration agreement with Astellas, the company exceeded its 2014 financial guidance.

"The recent expansion of our collaboration agreement with Astellas enables Cytokinetics to advance CK-2127107 into a Phase II trial in 2015 as well as the financial leverage to capitalize on other pipeline progress," stated Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Regulatory interactions over the last few months in both the United States and Europe inform a path forward for *tirasemtiv* to Phase III in patients with ALS. In addition, we are nearing completion of enrollment in COSMIC-HF, enabling the reporting of key data relating to *omecamtiv mecarbil* in chronic heart failure patients later this year. Taken all together, we have entered 2015 well positioned to achieve on program milestones relating to our first-in-class drug candidates directed to augmenting muscle function across multiple therapeutic categories."

Company Highlights

Skeletal Muscle Contractility

tirasemtiv

- Cytokinetics recently attended meetings with regulatory authorities in both the United States and Europe to discuss the results of BENEFIT-ALS and potential plans to advance *tirasemtiv* to Phase III. While regulatory interactions are ongoing, the company believes that current feedback enables advancement of *tirasemtiv* to a Phase III clinical development program that is designed to potentially confirm and extend results from BENEFIT-ALS. Objectives of the Phase III program will include measures of respiratory function after longer duration treatment in patients with amyotrophic lateral sclerosis (ALS), including effects on Slow Vital Capacity (SVC).
- Cytokinetics has initiated non-clinical and clinical development planning activities for the Phase III program.

CK-2127107

- During the quarter, Cytokinetics conducted development activities for CK-2127107 in accordance with an agreed plan under the joint oversight of the company and Astellas. These development activities included manufacturing of CK-2127107, review of results from pre-clinical and Phase I clinical studies with CK-2127107 and other planning for the progression of CK-2127107 to Phase II clinical development.

Cardiac Muscle Contractility

omecamtiv mecarbil

- During the quarter, enrollment continued in the expansion phase of 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. The expansion phase of COSMIC-HF has enrolled over 400 patients towards the total of 450 patients planned for this phase of the trial. Over 150 patients have completed dosing in the expansion phase of COSMIC-HF. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- Recently, a manuscript titled, "Safety and Tolerability of *Omeamtiv Mecarbil* During Exercise in Patients With Ischemic Cardiomyopathy and Angina" was published in the journal *JACC Heart Failure*. This manuscript highlights the results from a previously reported Phase IIa clinical trial designed to evaluate the safety and tolerability of treatment of *omecamtiv mecarbil* during symptom-limited exercise in patients with ischemic cardiomyopathy and angina. The publication concluded that doses of *omecamtiv mecarbil*, which produce plasma concentrations previously shown to increase systolic function, were well tolerated during exercise in patients with ischemic cardiomyopathy and angina who were evaluated in this trial and that there was no indication that *omecamtiv mecarbil* increased the likelihood of myocardial ischemia in this high-risk population.

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 under 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 amended its strategic collaboration with Astellas focused on the research, development and commercialization of skeletal muscle activators. The expansion of

the collaboration enables the development of CK-2127107 in spinal muscular atrophy (SMA) and potentially other neuromuscular indications. Cytokinetics and Astellas will jointly develop and may jointly commercialize CK-2127107 and other fast skeletal troponin activators in neuromuscular indications in designated countries. Cytokinetics and Astellas extended their joint research program focused on the discovery of additional skeletal sarcomere activators through 2016. Cytokinetics has recently received \$55 million from Astellas comprised of \$30 million as an upfront license fee in connection with the execution of the amended collaboration agreement, \$10 million paid for Astellas' purchase of Cytokinetics' common stock and \$15 million in a milestone payment in connection with the decision made by Astellas to advance CK-2127107 into Phase II clinical development. Cytokinetics expects to receive potentially over \$20 million payable by Astellas to reimburse Cytokinetics for planned research and development expenses over the next 2 years. Under the amended agreement, Cytokinetics is eligible to receive over \$600 million in pre-commercialization and commercialization milestone payments, of which over \$100 million is payable for CK-2127107 in each of SMA and other neuromuscular indications. The agreed terms also provide for escalating royalties to Cytokinetics with increased sales. Cytokinetics retains the option to co-fund the development of CK-2127107 in SMA and other neuromuscular indications in exchange for increased milestone payments and royalties and, if Cytokinetics exercises its co-promotion option, Astellas will reimburse Cytokinetics for certain expenses associated with its promotion activities.

Financials

Revenues for the fourth quarter of 2014 were \$21.8 million, compared to \$24.3 million during the same period in 2013. Revenues for the fourth quarter of 2014 included \$2.3 million of license revenues, \$3.3 million of research and development revenues, and \$15.0 million in milestone revenues from our collaboration with Astellas, \$1.1 million in research and development revenues from our collaboration with Amgen, and \$0.1 million in milestone revenues from our collaboration with MyoKardia. Revenues for the same period in 2013 included \$2.4 million of license revenues and \$4.1 million of research and development revenues from our collaboration with Astellas, and \$17.2 million of license revenues and \$0.6 million of research and development revenues from our collaboration with Amgen.

Total research and development (R&D) expenses for the fourth quarter of 2014 were \$8.8 million, compared with \$13.8 million for the same period in 2013. The \$5.0 million decrease in R&D expenses for the fourth quarter of 2014, compared with the same period in 2013, was primarily due to a decrease of \$5.9 million in outsourced clinical and preclinical costs partially offset by an increase of \$0.6 million in personnel expenses and an increase of \$0.2 million in laboratory expenses.

Total general and administrative (G&A) expenses for the fourth quarter of 2014 were \$4.6 million, compared with \$4.1 million for the same period in 2013. The \$0.5 million increase in G&A expenses in the fourth quarter of 2014, compared with the same period in 2013, was primarily due to an increase of \$0.6 million in legal expenses and \$0.5 million in personnel expenses, partially offset by a decrease of \$0.6 million in outsourced expenses.

Revenues for the twelve months ended December 31, 2014 were \$46.9 million, compared to \$30.6 million for the same period in 2013. Revenues for the twelve months of 2014 were primarily comprised of \$15.4 million of research and development revenues, \$9.8 million of license revenues and \$17.0 million in milestone revenues from our collaboration with Astellas, \$4.5 million of research and development revenues from our collaboration with Amgen and \$0.1 million in milestone revenue from our collaboration with MyoKardia. Revenues for the same period in 2013 primarily comprised of \$3.9 million of license revenues and \$6.4 million of research and development revenues from our collaboration with Astellas and \$17.2 million of license revenue and \$2.0 million of research and development revenues from our collaboration with Amgen, and \$1.0 million in revenue from our collaboration with MyoKardia.

Total R&D expenses for the twelve months ended December 31, 2014 were \$44.4 million, compared to \$49.5 million for the same period in 2013. The \$5.1 million decrease in R&D expenses for the twelve months of 2014, compared the same period in 2013, was primarily due to decreased spending of \$8.2 million for outsourced clinical and preclinical costs, partially offset by increased spending of \$2.6 million in personnel-related costs.

Total G&A expenses for the twelve months ended December 31, 2014 were \$17.3 million, compared to \$15.1 million for the same period in 2013. The \$2.2 million increase in G&A spending for the twelve months of 2014, compared to the same period in 2013, was primarily due to increased spending for personnel-related costs and outside services.

The net loss for the twelve months ended December 31, 2014 was \$(14.6) million, or \$(0.41) per basic and diluted share, compared to a net loss of \$(33.7) million or \$(1.24) per basic and diluted share, for the same period in 2013.

Financial Guidance

Cytokinetics also announced its financial guidance for 2015. The company anticipates cash revenue will be in the range of \$40 to \$43 million, cash R&D expenses will be in the range of \$55 to \$58 million, and cash G&A expenses will be in the range of \$15 to \$18 million. This guidance includes approximately \$30 million in revenue which will be deferred and recognized over a two year period ending in 2016 under generally accepted accounting principles. This guidance excludes the \$15 million milestone payment earned in 2014 from Astellas and an estimated \$3.6 million in non-cash related operating expenses primarily related to stock compensation expense.

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 enrollment of patients in the expansion phase of COSMIC-HF to conclude in the first quarter of 2015 and 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 fourth 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 34459599.

An archived replay of the webcast will be available via Cytokinetics' website until February 19, 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 34459599 from February 12, 2015 at 5:30 PM Eastern Time until February 19, 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 skeletal muscle activator, for 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; Cytokinetics' and its partners' research and development activities, including the initiation, conduct, design, enrollment, progress, continuation, completion and results of clinical trials, the significance and utility of 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 clinical trial of *tirasemtiv* and the timing for the initiation of such a trial; the use of effects on slow vital capacity as a Phase III clinical trial endpoint for *tirasemtiv*; the potential progression of CK-2127107 to Phase II development and *omecamtiv mecarbil* to Phase III development; potential milestone payments, royalties and other payments; the expected roles of Cytokinetics and Astellas under the collaboration and in developing or commercializing drug candidates or products subject to the collaboration; the indications to be pursued under the Astellas collaboration; 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.

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

	<u>Three Months Ended</u>		<u>Year Ended</u>	
	<u>December</u>	<u>December</u>	<u>December</u>	<u>December</u>
	<u>31,</u>	<u>31,</u>	<u>31,</u>	<u>31,</u>
	<u>2014</u>	<u>2013⁽¹⁾</u>	<u>2014</u>	<u>2013⁽¹⁾</u>
Revenues:				
Research and development revenues from related parties	\$ 16,110	\$ 564	\$ 19,538	\$ 2,019
Research and development, grant and other revenues	3,377	4,113	17,566	7,547
License revenues from related parties	-	17,230	-	17,230
License revenues	<u>2,271</u>	<u>2,442</u>	<u>9,836</u>	<u>3,852</u>
Total revenues	<u>21,758</u>	<u>24,349</u>	<u>46,940</u>	<u>30,648</u>
Operating Expenses:				
Research and development	8,779	13,824	44,426	49,450
General and administrative	<u>4,558</u>	<u>4,093</u>	<u>17,268</u>	<u>15,092</u>

Total operating expenses	<u>13,337</u>	<u>17,917</u>	<u>61,694</u>	<u>64,542</u>
Operating income (loss)	8,421	6,432	(14,754)	(33,894)
Interest and other, net	<u>22</u>	<u>99</u>	<u>108</u>	<u>177</u>
Net income (loss)	<u>\$ 8,443</u>	<u>\$ 6,531</u>	<u>\$ (14,646)</u>	<u>\$ (33,717)</u>
Net income (loss) per share - basic	\$ 0.23	\$ 0.22	\$ (0.41)	\$ (1.24)
	\$ 0.23	\$ 0.21	\$ (0.41)	\$ (1.24)
Net income (loss) per share - diluted				
Weighted average shares used in computing net income (loss) per share - basic	36,748	29,836	35,709	27,275
Weighted average shares used in computing net income (loss) per share - diluted	36,786	31,190	35,709	27,275

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	<u>December 31,</u> <u>2014</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2013⁽¹⁾</u>
Assets		
Cash and cash equivalents	\$ 20,215	\$ 20,158
Short term investments	63,013	57,570
Related party accounts receivable	46,646	5
Other current assets	<u>1,257</u>	<u>1,605</u>
Total current assets	131,131	79,338
Property and equipment, net	1,637	1,221
Long-term investments	-	2,502
Other assets	<u>200</u>	<u>127</u>
Total assets	<u>\$ 132,968</u>	<u>\$ 83,188</u>
Liabilities and stockholders' equity		
Deferred revenue, current	\$ 17,042	\$ 14,701

Other current liabilities	6,813	12,003
Total current liabilities	<u>23,855</u>	<u>26,704</u>
Deferred revenue, non-current	16,558	1,500
Other non-current liabilities	491	542
Stockholders' equity	<u>92,064</u>	<u>54,442</u>
Total liabilities and stockholders' equity	<u>\$ 132,968</u>	<u>\$ 83,188</u>

(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.

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