

# Cytokinetics, Inc. Reports Fourth Quarter 2015 Financial Results

2016-02-16

## Company Provides 2016 Financial Guidance and Expected Milestones

SOUTH SAN FRANCISCO, Calif., Feb. 16, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total research and development revenues for the fourth quarter of 2015 were \$9.8 million, compared to \$21.8 million, which included a \$15 million milestone payment from Astellas, during the same period in 2014. The net loss for the fourth quarter was \$9.2 million, or \$0.24 per basic and diluted share. This is compared to net income for the same period in 2014 of \$8.4 million, or \$0.23 per basic share and diluted share. As of December 31, 2015, cash, cash equivalents and investments totaled \$111.6 million.

"2015 was a transformational year for Cytokinetics and we start 2016 strong with momentum across our three muscle biology-directed development programs. As we recently outlined in our Vision 2020 strategic initiative, over the next five years our goal is to expand our portfolio of novel muscle activators and mature operations to enable commercialization of our multiple, first-in-class compounds for the potential treatment of people living with diseases of impaired muscle function," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In 2016, we look forward to the potential advancement of the clinical development program for *omecamtiv mecarbil* in patients with heart failure under our collaboration with Amgen, and the enrollment of patients in our Phase 2 trial of CK-2127107 in patients with Spinal Muscular Atrophy under our collaboration with Astellas. At the same time, we are also focused on completing enrollment in VITALITY-ALS, our Phase 3 trial of *tirasemtiv* in patients with ALS. This is a truly exciting year for our company and our key stakeholders."

## Recent Highlights

### Cardiac Muscle Program

#### *omecamtiv mecarbil*

- Announced presentation of data from the expansion phase of COSMIC-HF (Chronic Oral Study of Mynosin Activation to Increase Contractility in Heart Failure), a Phase 2 trial of *omecamtiv mecarbil* in patients with heart failure, in a Late-Breaking Clinical Trial session at the American Heart Association (AHA) Scientific Sessions 2015 in Orlando, Fla. The clinical trial met its primary pharmacokinetic objective and demonstrated statistically significant improvements in all pre-

specified secondary measures of cardiac function in the treatment group employing pharmacokinetic-based dose titration. Adverse events, including serious adverse events, in patients on *omecamtiv mecarbil* were similar to those on placebo. COSMIC-HF was conducted by Amgen in collaboration with Cytokinetics.

- Conducted planning activities in collaboration with Amgen to support the potential advancement of *omecamtiv mecarbil* into a Phase 3 program.

### **Skeletal Muscle Program**

#### *tirasemtiv*

- Continued enrollment in VITALITY-ALS (Ventilatory Investigation of *Tirasemtiv* and Assessment of Longitudinal Indices after Treatment for a Year in ALS), a Phase 3 clinical trial designed to assess the effects of *tirasemtiv* versus placebo on slow vital capacity (SVC) and other measures of skeletal muscle strength in patients with ALS.
- Amended the protocol of VITALITY-ALS to increase the number of patients to be enrolled from approximately 445 to approximately 600 patients. Increasing the number of patients in VITALITY-ALS may enable increased statistical power to detect a difference in the primary endpoint (change from baseline in SVC at 24 weeks) between *tirasemtiv* and placebo.
- Announced the presentation of exploratory analyses of data from EMPOWER, a Phase 3 clinical trial of dexpramipexole in patients with ALS, which demonstrated the rate of decline of SVC predicts the risk of meaningful clinical events, including a decline in the three respiratory questions of the ALSFRS-R, as well as the time to the first occurrence of respiratory insufficiency, tracheostomy or death.

#### CK-2127107

- Recently announced the start of a Phase 2 clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA), in collaboration with Astellas.

### **Pre-Clinical Research**

- Continued research activities under our joint research program with Amgen directed to the discovery of next-generation cardiac muscle activators and under our joint research program with Astellas directed to the discovery of next-generation skeletal muscle activators. In addition, company scientists continued independent research activities directed to our other muscle biology programs.

### **Corporate**

- Announced an expanded partnership with Cure SMA to increase education, awareness and fundraising for SMA. As a National Gold Partner, Cytokinetics will lend support to key national and local initiatives to advance understanding of, and research toward potential treatments for SMA.
- Recently drew down the second, \$15.0 million tranche from our existing growth capital loan with Oxford Finance LLC and Silicon Valley Bank, with the tranche being funded in February 2016.

### **Financials**

Revenues for the fourth quarter of 2015 were \$9.8 million, compared to \$21.8 million during the same period in 2014. Revenues for the fourth quarter of 2015 included \$5.1 million of license revenues and

\$4.0 million of research and development revenues from our collaboration with Astellas, and \$0.6 million in research and development revenues from our collaboration with Amgen. Revenues for the same period in 2014 were comprised of \$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 of research and development revenues from our collaboration with Amgen, and \$0.1 million in milestone revenues from our collaboration with MyoKardia.

Total research and development (R&D) expenses for the fourth quarter of 2015 were \$13.2 million, compared to \$8.8 million for the same period in 2014. The \$4.4 million increase in R&D expenses for the fourth quarter of 2015, compared with the same period in 2014, was primarily due to an increase of \$3.9 million in outsourced clinical and preclinical costs and an increase of \$0.7 million in personnel related expenses.

Total general and administrative (G&A) expenses for the fourth quarter of 2015 were \$5.5 million compared to \$4.6 million for the same period in 2014. The \$0.9 million increase in G&A expenses for the fourth quarter of 2015, compared to the same period in 2014, was primarily due to an increase of \$0.8 million in outsourced expenses and \$0.6 million in personnel related expenses due to an increase in headcount, partially offset by a decrease of \$0.5 million in legal fees.

Revenues for the twelve months ended December 31, 2015 were \$28.7 million, compared to \$46.9 million for the same period in 2014. Revenues for the twelve months of 2015 included \$13.9 million of license revenues and \$12.2 million of research and development revenues from our collaboration with Astellas, and \$2.5 million of research and development revenues from our collaboration with Amgen. Revenues for the same period in 2014 were comprised of \$9.8 million of license revenues, \$17.0 million of milestone revenues and \$15.4 million of research and development 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.

Total R&D expenses for the twelve months ended December 31, 2015 were \$46.4 million, compared to \$44.4 million for the same period in 2014. The \$2.0 million increase in R&D expenses in the twelve months of 2015, over the same period in 2014, was primarily due to an increase of \$2.0 million in outsourced preclinical costs, an increase of \$1.8 million in personnel related expenses due to increased headcount, and an increase of \$0.4 million in lab expenses, partially offset by a decrease of \$2.1 million in outsourced clinical costs associated with the completion of BENEFIT-ALS in the second quarter of 2014.

Total G&A expenses for the twelve months ended December 31, 2015 were \$19.7 million, compared to \$17.3 million for the same period in 2014. The \$2.4 million increase in G&A spending in the twelve months of 2015 compared to the same period in 2014, was primarily due to an increase of \$1.4 million in personnel related costs due to an increase in headcount and an increase of \$0.8 million in outsourced costs.

The net loss for the twelve months ended December 31, 2015, was \$37.5 million, or \$0.97 per basic and diluted share, compared to a net loss of \$14.6 million, or \$0.41 per basic and diluted share, for the same period in 2014.

## **2016 Financial Guidance**

Cytokinetics also announced financial guidance for 2016. The company anticipates cash revenue will be in the range of \$13 to \$16 million, cash R&D expenses will be in the range of \$67 to \$70 million, and cash G&A expenses will be in the range of \$21 to \$24 million. This guidance excludes approximately \$20.5 million in deferred revenue from the expansion of our collaboration with Astellas in 2015, which

will be recognized in 2016 under generally accepted accounting principles, as well as any potential milestones that may be achieved in accordance with our collaboration agreements with our partners Amgen and Astellas. This guidance excludes an estimated \$4.5 million in non-cash related operating expenses primarily related to stock compensation expense.

## **2016 Corporate Milestones**

### **Cardiac Muscle Program**

*omecamtiv mecarbil*

- Expect to make a decision regarding the potential advancement to Phase 3 in the coming months.

### **Skeletal Muscle Program**

*tirasemtiv*

- Expect to complete enrollment of VITALITY-ALS in the first half of 2016.

CK-2127107

- Expect to complete enrollment of our Phase 2 clinical trial of CK-2127107 in patients with SMA in the second half of 2016.
- Expect Astellas will initiate a Phase 2 clinical trial of CK-107 in patients with COPD in the first half of 2016.

### **Pre-Clinical Research**

- Expect to continue research activities under our joint research program with Amgen directed to the discovery of next-generation cardiac muscle activators and under our joint research program with Astellas directed to the discovery of next-generation skeletal muscle activators.
- Anticipate potential advancement of one next-generation compound from each joint research program into pre-clinical development in 2016.

### **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 Investors & Media 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 29637209.

An archived replay of the webcast will be available via Cytokinetics' website until February 23, 2016. 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 29637209 from February 16, 2016 at 5:30 PM Eastern Time until February 23, 2016.

### **About Cytokinetics**

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and

commercializing first-in-class muscle activators as potential treatments for debilitating diseases in which muscle performance is compromised and/or declining. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to increase muscle function and contractility. Cytokinetics' lead drug candidate is *tirasemtiv*, a fast skeletal muscle activator, for the potential treatment of 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 holds the exclusive right to develop and commercialize *tirasemtiv* throughout the world. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel 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. For additional information about Cytokinetics, visit [www.cytokinetics.com](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; enrollment in VITALITY-ALS; enrollment and progress of the Phase 2 clinical trial of CK-2127107 in patients with SMA; the significance and utility of preclinical study and clinical trial results; and the properties and potential efficacy and safety profile of CK-2127107, 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;; 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. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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

	Three Months Ended December 31, 2015		Year Ended December 31, 2014 <sup>(1)</sup>	
	December 31, 2015	December 31, 2014 <sup>(1)</sup>	December 31, 2015	December 31, 2014 <sup>(1)</sup>
Revenues:				
Research and development revenues from related parties	\$ 4,578	\$ 16,110	\$ 14,665	\$ 19,538
Research and development, grant and other revenues	48	3,377	75	17,566
License revenues from related parties	5,131	—	13,918	—
License revenues	—	2,271	—	9,836
Total revenues	9,757	21,758	28,658	46,940
Operating Expenses:				
Research and development	13,249	8,779	46,398	44,426
General and administrative	5,529	4,558	19,667	17,268
Total operating expenses	18,778	13,337	66,065	61,694
Operating income (loss)	(9,021 )	8,421	(37,407 )	(14,754 )
Interest and other income (expense), net	(208 )	22	(94 )	108
Net income (loss)	\$(9,229 )	\$ 8,443	\$(37,501 )	\$(14,646 )
Net income (loss) per share – basic and	\$(0.24 )	\$ 0.23	\$(0.97 )	\$(0.41 )
Weighted average shares used in computing net income (loss) per share – basic	39,098	36,748	38,814	35,709
Weighted average shares used in computing net income (loss) per share - diluted	39,098	36,786	38,814	35,709

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

	December 31, 2015 (unaudited)	December 31, 2014 <sup>(1)</sup>
<b>Assets</b>		
Cash and cash equivalents	\$ 65,076	\$ 20,215
Short term investments	46,366	63,013
Related party accounts receivable	12	46,646
Other current assets	1,653	1,257
Total current assets	113,107	131,131
Property and equipment, net	1,751	1,637
Long-term investments	179	—
Other assets	200	200
<b>Total assets</b>	<b>\$ 115,237</b>	<b>\$ 132,968</b>
<b>Liabilities and stockholders' equity</b>		
Deferred revenue, current	\$ 20,858	\$ 17,042
Other current liabilities	10,791	6,813
Total current liabilities	31,649	23,855
Long-term debt	14,639	—
	—	16,558
Deferred revenue, non-current		
Other non-current liabilities	359	491
Stockholders' equity	68,590	92,064
<b>Total liabilities and stockholders' equity</b>	<b>\$ 115,237</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, Inc