



Cytokinetics, Inc. Reports Second Quarter 2016 Financial Results

July 28, 2016 8:00 PM EDT

***Company Recently Announced Option Right for Tirasemtiv
and Expansion of Global Collaboration for CK-2127107 in ALS with Astellas***

Nearing Completion of Patient Enrollment in VITALITY-ALS

SOUTH SAN FRANCISCO, Calif., July 28, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total revenues for the second quarter of 2016 were \$5.8 million, compared to \$6.5 million, during the same period in 2015. The net loss for the second quarter was \$11.6 million, or \$0.29 per basic and diluted share. This is compared to the net loss for the same period in 2015 of \$10.6 million, or \$0.27 per basic and diluted share. As of June 30, 2016, cash, cash equivalents and investments totaled \$98.0 million.

"We had a productive quarter advancing key clinical, regulatory and commercial planning initiatives across our portfolio of muscle-biology directed drug candidates," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Our recently expanded collaboration with Astellas aligns our interests with regard to *tirasemtiv* and ALS and provides a path forward for our two skeletal muscle activators as potential treatments for ALS. Toward that objective, we expect that VITALITY-ALS will soon conclude patient enrollment, a major milestone for our Phase 3 clinical trial of *tirasemtiv* in patients with ALS. We also continue to prepare for the start of a potential Phase 3 development program for *omecamtiv mecarbil* in collaboration with Amgen. These are especially promising and hopeful times at Cytokinetics as our programs advance towards late-stage milestones."

Recent Highlights and Upcoming Milestones

Cardiac Muscle Program

omecamtiv mecarbil

- Announced the start of a double-blind, randomized, placebo-controlled, multi-center Phase 2 clinical trial to evaluate the safety, pharmacokinetics and efficacy of *omecamtiv mecarbil* in Japanese subjects with heart failure and reduced ejection fraction.
- Presented a poster titled "COSMIC-HF: Improved Contractility and Evolution of Ventricular Remodeling through Time" at Heart Failure 2016, the annual congress of the Heart Failure Association of the European Society of Cardiology. The results indicated that *omecamtiv mecarbil* improved left ventricular (LV) systolic function, LV end-diastolic volume and NT-proBNP over time, suggesting potentially favorable ventricular remodeling and progressive reduction in myocardial wall stress.
- Participated with Amgen in additional regulatory interactions with the FDA, EMA and Health Canada to inform the design and conduct of a potential Phase 3 development program for *omecamtiv mecarbil*.
- Conducted clinical, regulatory, non-clinical and commercial planning activities in collaboration with Amgen to support the potential advancement of *omecamtiv mecarbil* to a Phase 3 development program.
- Expect to make a decision regarding the advancement of *omecamtiv mecarbil* to Phase 3 in the third quarter of 2016.

Skeletal Muscle Program

tirasemtiv

- Recently announced that we have granted Astellas an option right for the development and commercialization of *tirasemtiv* outside of North America, Europe and other select countries.*
- Completing screening of patients in VITALITY-ALS (**V**entilatory Investigation of **T**irasemtiv and **A**ssessment of **L**ongitudinal Indices after **T**reatment for a **Y**ear in **ALS**), an ongoing,

international 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.

- Expect to complete enrollment of VITALITY-ALS in August 2016. Expect data from VITALITY-ALS in the second half of 2017.
- Conducted regulatory interactions with each of FDA and EMA to inform the design and conduct of an open-label extension clinical trial for patients who complete VITALITY-ALS.
- Expect to begin an open-label extension trial for patients who complete VITALITY-ALS in the fourth quarter of 2016.

CK-2127107

- Recently announced that we have amended our collaboration agreement with Astellas to enable the development of CK-2127107 for the potential treatment of ALS.*
- Continued enrollment of the ongoing Phase 2 clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA) in collaboration with Astellas.
- Expect to complete enrollment of Cohort 1 in the Phase 2 clinical trial of CK-2127107 in patients with SMA in the second half of 2016. Expect data from this clinical trial in first half of 2017.
- Announced the start of a Phase 2 clinical trial of CK-2127017 in patients with COPD. Expect to complete enrollment and to analyze data from this clinical trial in 2017.

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.
- Recently announced that we have extended our joint research program with Astellas focused on the discovery of next-generation skeletal muscle activators through 2017.*
- Anticipate potential advancement of one next-generation compound from a joint research program into pre-clinical development during 2016.

Corporate

- Expect to receive \$65 million in committed capital from Astellas which includes upfront payments for Astellas' option right exercisable for *tirasemtiv* and amended terms of the companies' collaboration agreement to include ALS for CK-2127107. In addition, Cytokinetics expects to receive approximately \$30 million in additional sponsored research and development funding through 2017 from Astellas.*
- Received 2016 Essey Commitment to a Cure Award from the ALS Association Golden West Chapter.

- Announced appointment of Edward M. Kaye, M.D. to Cytokinetics Board of Directors.
- Appointed Caryn McDowell, Cytokinetics' General Counsel as Chief Compliance Officer.
- Rang the closing bell at NASDAQ accompanied by leaders of the ALS Association in recognition of ALS Awareness month and the company's commitment to education, awareness, research and development activities focused to amyotrophic lateral sclerosis (ALS).

* The effectiveness of the amended agreement with Astellas is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

Financials

Revenues for the second quarter of 2016 were \$5.8 million, compared to \$6.5 million during the same period in 2015. Revenues for the second quarter of 2016 included \$2.9 million of research and development revenues and \$1.9 million of license revenues from our collaboration with Astellas, \$0.6 million in research and development revenues from our collaboration with Amgen and \$0.3 million in research and development revenues from our collaboration with ALSA. Revenues for the same period in 2015 were comprised of \$3.0 million of license revenues and \$2.9 million of research and development revenues from our collaboration with Astellas, and \$0.6 million of research and development revenues from our collaboration with Amgen. The decrease in revenues for the second quarter of 2016, compared with the same period in 2015, was mainly due to timing of license revenue recorded under the Astellas collaboration agreement, due to the extension of the timeframe of development services.

Total research and development (R&D) expenses for the second quarter of 2016 were \$9.7 million, compared to \$12.6 million for the same period in 2015. The \$2.9 million decrease in R&D expenses for the second quarter of 2016, compared with the same period in 2015, was primarily due to a decrease of \$2.3 million in outsourced preclinical costs associated with clinical manufacturing activities, and a decrease of \$1.7 million in outsourced clinical costs, partially offset by an increase of \$1.3 million in personnel related expenses due to increased headcount costs. The decrease in outsourced clinical costs was comprised of an increase of \$2.8 million in outsourced clinical costs mainly associated with the ongoing VITALITY-ALS trial, offset by a \$4.5 million litigation settlement in June 2016 from a contract research organization for our Phase 2 BENEFIT-ALS clinical trial which was concluded in 2014.

Total general and administrative (G&A) expenses for the second quarter of 2016 were \$7.1 million compared to \$4.5 million for the same period in 2015. The \$2.6 million increase in G&A expenses for the second quarter of 2016, compared to the same period in 2015, was primarily due to an increase of \$1.1 million in personnel related expenses due to increased non-cash stock compensation expense and increased headcount, an increase of \$0.7 million in outsourced costs related to accounting and finance and commercial development, and an increase of \$0.8 million in corporate and patent legal fees.

Revenues for the six months ended June 30, 2016 were \$14.2 million, compared to \$11.0 million for the same period in 2015. Revenues for the first six months of 2016 included \$6.6 million of research and development revenues and \$5.9 million of license revenues from our collaboration with Astellas, \$1.2 million of research and development revenues from our collaboration with Amgen, and \$0.5 million in research and development revenues from our collaboration with ALSA. Revenues for the same period in 2015 included \$5.0 million of research and development revenues and \$4.7 million of license revenues from our collaboration with Astellas, and \$1.3 million of research and development revenues from our collaboration with Amgen.

Total R&D expenses for the six months ended June 30, 2016 were \$23.3 million, compared to \$21.6 million for the same period in 2015. The \$1.7 million increase in R&D expenses in the first six months of 2016, over the same period in 2015, was primarily due to an increase of \$2.4 million in outsourced clinical costs and an increase of \$2.3 million in personnel related expenses due to increased headcount, partially offset by a decrease of \$2.9 million in outsourced preclinical costs associated with clinical manufacturing activities. The increase in outsourced clinical costs was comprised of an increase of \$6.9 million in outsourced clinical costs mainly associated with the ongoing VITALITY-ALS trial, offset by a \$4.5 million settlement in June 2016 with a contract research organization for our Phase 2 BENEFIT-ALS clinical trial which was concluded in 2014.

Total G&A expenses for the six months ended June 30, 2016 were \$13.9 million, compared to \$8.9 million for the same period in 2015. The \$5.0 million increase in G&A spending in the first six months of 2016 compared to the same period in 2015, was primarily due to an increase of \$2.1 million in personnel related expenses due to increased non-cash stock compensation expense and increased headcount, an increase of \$1.3 million in outsourced costs related to accounting and finance and commercial development, and an increase of \$1.4 million in corporate and patent legal fees.

The net loss for the six months ended June 30, 2016, was \$24.1 million, or \$0.61 per basic and diluted share, compared to a net loss of \$19.4 million, or \$0.50 per basic and diluted share, for the same period in 2015.

Financial Guidance

We will not update our financial guidance until our Q3 Earnings due to the recent expansion of our collaboration with Astellas; at that time we expect to provide updated 2016 financial guidance on both a cash and GAAP basis.

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 Investors & Media 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 29639098.

An archived replay of the webcast will be available via Cytokinetics' website until August 4. 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 29639098 from July 28, 2016 at 5:30 PM Eastern Time until August 4, 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 retains the right to develop and commercialize *tirasemtiv*, subject to Astellas Pharma Inc.'s option. 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 to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. 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.

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 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; initiation, design and conduct of the potential Phase 3 clinical trial of omeamtiv mecarbil; the significance and utility of preclinical study and clinical trial results; the potential benefits of Cytokinetics' expanded collaboration with Astellas, 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; the U.S. Food and Drug Administration or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omeamtiv 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; and competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target. 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		Six Months Ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Revenues:				
Research and development revenues from related parties	\$ 3,515	\$ 3,510	\$ 7,811	\$ 6,301
Research and development, grant and other revenues	337	—	488	—
License revenues from related parties	1,950	3,032	5,923	4,655
Total revenues	5,802	6,542	14,222	10,956
Operating Expenses:				
Research and development	9,723	12,636	23,256	21,592
General and administrative	7,090	4,495	13,931	8,862
Total operating expenses	16,813	17,131	37,187	30,454
Operating loss	(11,011)	(10,589)	(22,965)	(19,498)

Interest and other income(expense), net	<u>(600)</u>	<u>38</u>	<u>(1,101)</u>	<u>75</u>
Net loss	<u>\$ (11,611)</u>	<u>\$ (10,551)</u>	<u>\$ (24,066)</u>	<u>\$ (19,423)</u>
Net loss per share – basic and diluted	\$ (0.29)	\$ (0.27)	\$ (0.61)	\$ (0.50)
Weighted average shares used in computing net loss per share – basic and diluted	39,666	38,725	39,629	38,700

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

	<u>June 30, 2016</u>	<u>December 31, 2015⁽¹⁾</u>
Assets		
Cash and cash equivalents	\$ 27,724	\$ 65,076
Short term investments	62,614	46,366
Related party accounts receivable	26	12
Prepaid and other current assets	<u>6,254</u>	<u>1,653</u>
Total current assets	96,618	113,107
Property and equipment, net	1,659	1,751
Long-term investments	7,684	179
Other assets	<u>200</u>	<u>200</u>
Total assets	<u>\$ 106,161</u>	<u>\$ 115,237</u>
Liabilities and stockholders' equity		
Deferred revenue, current	\$ 13,559	\$ 20,858
Other current liabilities	12,713	10,791
Total current liabilities	<u>26,272</u>	<u>31,649</u>
Long-term debt	29,604	14,639
Deferred revenue, non-current	1,275	—
Other non-current liabilities	264	359
Stockholders' equity	<u>48,746</u>	<u>68,590</u>
Total liabilities and stockholders' equity	<u>\$ 106,161</u>	<u>\$ 115,237</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, 2015.

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Cytokinetics

Cytokinetics, Inc