Cytokinetics, Inc. Reports Third Quarter 2015 Financial Results

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Recently Announced Positive Top-line Results From COSMIC-HF; Data Demonstrated Statistically Significant Improvements in Several Pre-Specified Measures of Cardiac Function

Company Lowers 2015 R&D Expense Guidance

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2015 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total research and development revenues for the third quarter of 2015 were $7.9 million, compared to $9.4 million during the same period in 2014. The net loss for the third quarter was $8.8 million, or $0.23 per basic and diluted share. This is compared to a net loss for the same period in 2014 of $6.0 million, or $0.16 per basic share and diluted share. As of September 30, 2015, cash, cash equivalents and investments totaled $98.0 million.

"With the recently announced positive results from COSMIC-HF, Cytokinetics has entered a transformative time in the maturation of our company. We look forward to working with our partners at Amgen to prepare for potential progression of *omecamtiv mecarbil* to Phase 3," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "During the quarter, we achieved another key milestone for the company with the start of our first Phase 3 clinical trial of *tirasemtiv* in patients with ALS and prepared to advance CK-2127107 into a Phase 2 clinical trial in patients with SMA, in collaboration with Astellas. This is truly an exciting time for our company and our key stakeholders."

Recent Highlights and Upcoming Milestones

Skeletal Muscle Program

tirasemtiv

- Initiated enrollment in VITALITY-ALS (**V**entilatory **I**nvestigation of ***T****irasemtiv* and **A**ssessment of **L**ongitudinal **I**ndices after **T**reatment for a **Y**ear 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.
- Achieved first milestone in accordance with a $1.5M grant from The ALS Association to support VITALITY-ALS and the collection of plasma samples to advance the discovery of biomarkers for ALS.

CK-2127107

- Continued planning for the initiation of a Phase 2 clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA), in collaboration with Astellas, to occur in the fourth quarter of 2015.
- Anticipate Astellas will initiate a Phase 2 clinical trial of CK-2127107 in patients with COPD in the first half of 2016.

Cardiac Muscle Program

omecamtiv mecarbil

- Recently announced positive results from COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) which demonstrated statistically significant improvements in several pre-specified echocardiographic measures of cardiac function, including systolic ejection time, stroke volume and N-terminal-pro-brain natriuretic peptide, at 20 weeks following randomization. These pharmacodynamic effects of *omecamtiv mecarbil* were generally dose dependent. Data from the expansion phase of COSMIC-HF showed that pharmacokinetic-guided dose titration adequately controlled patient exposure to *omecamtiv mecarbil* and resulted in statistically significant decreases in cardiac dimensions and heart rate in the dose-titration group. Adverse events, including serious adverse events, in patients on *omecamtiv mecarbil,* appeared comparable to those on placebo. COSMIC-HF was conducted by Amgen in collaboration with Cytokinetics.
- Conducted planning in collaboration with Amgen, for the potential advancement of *omecamtiv*

mecarbil into a Phase 3 program.

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

- Established a $40 million Controlled Equity Offering line with Cantor Fitzgerald.
- Entered into a $40 million tranched growth capital loan with Oxford Financial LLC and Silicon Valley Bank, with the first tranche of $15 million funded in October 2015.
- Participated in several events associated with Gold Level Sponsorship of the National Walks to Defeat ALS and Platinum Level Sponsorship of the ALS Association Golden West Chapter.

Financials

Revenues for the third quarter of 2015 were $7.9 million, compared to $9.4 million during the same period in 2014. Revenues for the third quarter of 2015 included $4.1 million of license revenues and $3.2 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 $2.7 million of license revenues and $4.8 million of research and development revenues from our collaboration with Astellas, and $1.9 million of research and development revenues from our collaboration with Amgen.

Total research and development (R&D) expenses for the third quarter of 2015 were $11.6 million, compared to $11.4 million for the same period in 2014. The $0.2 million increase in R&D expenses for the third quarter of 2015, compared with the same period in 2014, was primarily due to an increase of $0.6 million in outsourced preclinical costs and lab expenses and an increase of $0.6 million in personnel related expenses, partially offset by a decrease of $1.0 million in outsourced clinical costs associated with the completion of BENEFIT-ALS in the second quarter of 2014.

Total general and administrative (G&A) expenses for the third quarter of 2015 were $5.3 million compared to $4.0 million for the same period in 2014. The $1.3 million increase in G&A expenses for the third quarter of 2015, compared to the same period in 2014, was primarily due to an increase of $0.7 million in outsourced costs, $0.4 million in legal fees, and $0.2 million in personnel related expenses due to an increase in headcount.

Revenues for the nine months ended September 30, 2015 were $18.9 million, compared to $25.2 million for the same period in 2014. Revenues for the first nine months of 2015 included $8.8 million of license revenues and $8.2 million of research and development revenues from our collaboration with Astellas, and $1.9 million of research and development revenues from our collaboration with Amgen. Revenues for the same period in 2014 were comprised of $7.6 million of license revenues and $14.1 million of research and development revenues from our collaboration with Astellas, and $3.4 million of research and development revenues from our collaboration with Amgen.

Total R&D expenses for the nine months ended September 30, 2015 were $33.1 million, compared to $35.6 million for the same period in 2014. The $2.5 million decrease in R&D expenses in the first nine months of 2015, over the same period in 2014, was primarily due to a decrease of $5.0 million in outsourced clinical costs associated with the completion of BENEFIT-ALS in the second quarter of 2014, partially offset by an increase of $0.8 million in outsourced preclinical costs, an increase of $0.6 million in lab expenses, and an increase of $1.0 million in personnel related expenses due to increased headcount.

Total G&A expenses for the nine months ended September 30, 2015 were $14.1 million, compared to $12.7 million for the same period in 2014. The $1.4 million increase in G&A spending in the first nine months of 2015 compared to the same period in 2014, was primarily due to an increase of $0.8 million in personnel related costs due to an increase in headcount, an increase of $0.6 in legal fees, and an increase of $0.1 million in outsourced costs.

The net loss for the nine months ended September 30, 2015, was $28.3 million, or $0.73 per basic and diluted share, compared to a net loss of $23.1 million, or $0.65 per basic and diluted share, for the same period in 2014.

Financial Guidance

Cytokinetics also announced updated financial guidance for 2015. The company anticipates cash revenue will be in the range of $44 to $47 million, cash R&D expenses will be in the range of $51 to $54 million, and cash G&A expenses will be in the range of $18 to $21 million. This guidance includes approximately $30.0 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 an estimated $4.6 million in non-cash related operating expenses primarily related to stock compensation expense.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third 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 34469080.

An archived replay of the webcast will be available via Cytokinetics' website until November 5, 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 34469080 from October 29, 2015 at 5:30 PM Eastern Time until November 5, 2015.

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.

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; 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. 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		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Revenues:				
Research and development revenues from related parties	$ 3,786	$ 1,920	$ 10,087	$ 3,428
Research and development, grant and other revenues	27	4,761	27	14,189
License revenues from related parties	4,132	—	8,787	—
License revenues	—	2,734	—	7,565
Total revenues	7,945	9,415	18,901	25,182
Operating Expenses:				
Research and development	11,557	11,420	33,149	35,647
General and administrative	5,276	3,993	14,138	12,710

Total operating expenses	16,833	15,413	47,287	48,357
Operating loss	(8,888)	(5,998)	(28,386)	(23,175)
Interest and other, net	39	27	114	86
Net loss	$ (8,849)	$ (5,971)	$ (28,272)	$ (23,089)
Net loss per share – basic and diluted	$ (0.23)	$ (0.16)	$ (0.73)	$ (0.65)
Weighted average shares used in computing net loss per share – basic and diluted	38,752	36,609	38,718	35,359

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2015 (unaudited)	December 31, 2014[(1)]
Assets		
Cash and cash equivalents	$ 25,962	$ 20,215
Short term investments	72,023	63,013
Accounts receivable and related party receivable	47	46,646
Other current assets	2,483	1,257
Total current assets	100,515	131,131
Property and equipment, net	1,481	1,637
Other assets	200	200
Total assets	$ 102,196	$ 132,968
Liabilities and stockholders' equity		
Deferred revenue, current	$ 21,367	$ 17,042
Other current liabilities	8,776	6,813
Total current liabilities	30,143	23,855
Deferred revenue, non-current	4,346	16,558
Other non-current liabilities	407	491
Stockholders’ equity	67,300	92,064
Total liabilities and stockholders' equity	$ 102,196	$ 132,968

(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