Cytokinetics, Inc. Reports Second Quarter 2015 Financial Results

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Company Recently Started VITALITY-ALS; Results from COSMIC-HF Expected in Q4

Company Updates Financial Guidance for 2015

SOUTH SAN FRANCISCO, Calif., July 29, 2015 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total research and development revenues for the second quarter of 2015 were $6.5 million, compared to $7.8 million during the same period in 2014. The net loss for the second quarter was $10.6 million, or $0.27 per basic and diluted share. This is compared to a net loss for the same period in 2014, of $8.4 million or $0.23 per basic share and diluted share. As of June 30, 2015, cash, cash equivalents and investments totaled $108.2 million.

"Our company marked a key milestone recently with the start of VITALITY-ALS, our Phase 3 clinical trial of *tirasemtiv* in patients with ALS, which is designed to confirm and extend results observed in prior clinical trials. We are grateful for the continued commitment of patients and caregivers as we advance our novel skeletal muscle activator to the final stages of clinical testing," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Leveraging partnerships remains a core component of our corporate strategy as we mature our late-stage development pipeline. In the last quarter, we also made substantial progress with Amgen towards completing COSMIC-HF and with Astellas beginning the Phase 2 clinical trials program of CK-2127107."

Recent Highlights and Upcoming Milestones

Skeletal Muscle Contractility

tirasemtiv

- Started 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 effects of *tirasemtiv* versus placebo on slow vital capacity (SVC) and other measures of respiratory function in patients with ALS.
- Awarded a $1.5M grant from The ALS Association from proceeds raised during the Ice Bucket Challenge to support VITALITY-ALS and the collection of plasma samples to advance the discovery of biomarkers.

CK-2127107

- Presented results from three double-blind, randomized, placebo-controlled Phase 1 studies of CK-2127107 in healthy volunteers in poster and oral presentations at the 19th International SMA (Spinal Muscular Atrophy) Researcher Meeting held during the 2015 Annual SMA Conference.
- Continued planning activities in anticipation of initiating a Phase 2 clinical trial of CK-2127107 in patients with SMA in collaboration with Astellas in the fourth quarter of 2015.

Cardiac Muscle Contractility

omecamtiv mecarbil

- More than 400 patients have concluded dosing in the expansion phase of COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure). COSMIC-HF is a Phase 2, 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. This trial is being conducted by Amgen in collaboration with Cytokinetics.
- A paper titled, "Population Pharmacokinetic-Pharmacodynamic Modeling of *Omecamtiv Mecarbil*, a Cardiac Myosin Activator, in Healthy Volunteers and Patients with Stable Heart Failure," was published in the Journal of Clinical Pharmacology. Data from three clinical trials

of *omecamtiv mecarbil* in healthy volunteers and patients with stable heart failure were analyzed using a nonlinear mixed-effects model to investigate the pharmacokinetics of *omecamtiv mecarbil* and the relationship of systolic ejection time and Doppler-derived left ventricular outflow tract stroke volume to the plasma concentration of *omecamtiv mecarbil*.
- Conducted collaboration activities directed to the potential advancement of *omecamtiv mecarbil* into a Phase 3 program.
- Anticipate announcing data from COSMIC-HF in the fourth quarter of 2015.

Pre-Clinical Research

- Continued research activities 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 other independent research activities directed to other muscle biology programs.

Corporate

- Hosted an R&D Day featuring senior management and an expert clinician panel to provide discovery and development program updates, milestones and perspectives.
- Held our Annual Stockholder's Meeting.
- Announced an expanded partnership with The ALS Association in which the company will provide Gold Level Sponsorship of the National Walks to Defeat ALS as well as Platinum Level Sponsorship for ALS Association Golden West Chapter initiatives. Cytokinetics also committed to a challenge grant to fund care services in the Bay Area.

Financials

Revenues for the second quarter of 2015 were $6.5 million, compared to $7.8 million during the same period in 2014. Revenues for the second quarter of 2015 included $3.0 million of license revenues and $2.9 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 $4.2 million of research and development revenues from our collaboration with Astellas, and $0.8 million of research and development revenues from our collaboration with Amgen.

Total research and development (R&D) expenses for the second quarter of 2015 were $12.6 million, compared with $11.7 million for the same period in 2014. The $0.9 million increase in R&D expenses for the second quarter of 2015, compared with the same period in 2014, was primarily due to an increase of $1.4 million in outsourced preclinical costs, 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 second quarter of 2015 remained unchanged at $4.5 million, compared to the same period in 2014.

Revenues for the six months ended June 30, 2015 were $11.0 million, compared to $15.8 million for the same period in 2014. Revenues for the first six months of 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. Revenues for the same period in 2014 included $9.4 million of research and development revenues and $4.8 million of license revenues from our collaboration with Astellas, and $1.5 million of research and development revenues from our collaboration with Amgen.

Total R&D expenses for the six months ended June 30, 2015 were $21.6 million, compared to $24.2 million for the same period in 2014. The $2.6 million decrease in R&D expenses in the first six months of 2015, over the same period in 2014, was primarily due to a decrease of $4.1 million in outsourced clinical costs associated with the completion of BENEFIT-ALS in the second quarter of 2014 partially offset by an increase of $0.5 million in outsourced preclinical costs and an increase of $0.2 million in personnel expenses due to increased headcount.

Total G&A expenses for the six months ended June 30, 2015 were $8.9 million, compared to $8.7 million for the same period in 2014. The $0.2 million increase in G&A spending in the first six months of 2015 compared to the same period in 2014, was primarily due to an increase of $0.8 million in personnel cost, due to an increase in headcount, partially offset by a decrease of $0.6 million in outside services costs related to commercial development.

The net loss for the six months ended June 30, 2015, was $19.4 million, or $0.50 per basic and diluted share, compared to a net loss of $17.1 million, or $0.49 per basic and diluted share, for the same period in 2014.

Company Updates Financial Guidance

The company anticipates cash revenue to be in the range of $44 to $47 million, cash R&D expenses in the range of $58 to $61 million, and cash G&A expenses to be in the range of $18 to $21 million. This guidance includes the $30 million upfront payment from Astellas that 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.

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 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 34466161.

An archived replay of the webcast will be available via Cytokinetics' website until August 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 34466161 from July 29, 2015 at 5:30 PM Eastern Time until August 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. With an unmatched understanding of 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, the potential conduct of a Phase 3 trial of tirasemtiv and the timing for initiation of such a trial; the potential progression of CK-2127107 to Phase 2 development, the potential progression of omecamtiv mecarbil to Phase 3 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 1 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		Six Months Ended	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Revenues:				
Research and development revenues from related parties	$ 3,510	$ 843	$ 6,301	$ 1,508
Research and development, grant and other revenues	—	4,196	—	9,428
License revenues from related parties	3,032	—	4,655	—
License revenues	—	2,749	—	4,831

Total revenues	6,542	7,788	10,956	15,767
Operating Expenses:				
Research and development	12,636	11,737	21,592	24,227
General and administrative	4,495	4,458	8,862	8,717
Total operating expenses	17,131	16,195	30,454	32,944
Operating loss	(10,589)	(8,407)	(19,498)	(17,177)
Interest and other, net	38	33	75	59
Net loss	$ (10,551)	$ (8,374)	$ (19,423)	$ (17,118)
Net loss per share – basic and diluted	$ (0.27)	$ (0.23)	$ (0.50)	$ (0.49)
Weighted average shares used in computing net loss per share – basic and diluted	38,725	36,443	38,700	34,724

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2015 (unaudited)	December 31, 2014[(1)]
Assets		
Cash and cash equivalents	$ 24,839	$ 20,215
Short term investments	80,344	63,013
Accounts receivable and related party receivable	4	46,646
Other current assets	2,713	1,257
Total current assets	107,900	131,131
Property and equipment, net	1,571	1,637
Long-term investments	3,035	—
Other assets	200	200
Total assets	$ 112,706	$ 132,968
Liabilities and stockholders' equity		
Deferred revenue, current	$ 20,993	$ 17,042
Other current liabilities	8,119	6,813

Total current liabilities	29,112	23,855
Deferred revenue, non-current	8,293	16,558
Other non-current liabilities	440	491
Stockholders' equity	74,861	92,064
Total liabilities and stockholders' equity	$ 112,706	$ 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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Primary Logo

Cytokinetics, Inc