Cytokinetics, Inc. Reports First Quarter 2016 Financial Results

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VITALITY-ALS on Track to Complete Patient Enrollment in 1H 2016

SOUTH SAN FRANCISCO, Calif., April 28, 2016 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total research and development revenues for the first quarter of 2016 were $8.4 million, compared to $4.4 million, during the same period in 2015. The net loss for the first quarter was $12.5 million, or $0.31 per basic and diluted share. This is compared to the net loss for the same period in 2015 of $8.9 million, or $0.23 per basic and diluted share. As of March 31, 2016, cash, cash equivalents and investments totaled $108.6 million.

"We made meaningful progress this quarter advancing our portfolio of muscle-biology directed programs," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Notably, in partnership with Amgen we participated in several productive meetings with regulatory authorities which inform the potential Phase 3 development program for *omecamtiv mecarbil*. We also made strides in our ongoing skeletal muscle activator clinical development programs for *tirasemtiv* and CK-2127107 and decided with Astellas to move a next-generation skeletal muscle activator into IND enabling studies, further expanding our development pipeline."

Recent Highlights and Upcoming Milestones

Cardiac Muscle Program

omecamtiv mecarbil

- Announced the start of a Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese subjects with heart failure due to reduced ejection fraction. The primary objectives of the trial are to assess the pharmacokinetics, safety and tolerability of *omecamtiv mecarbil*. The secondary objective of the trial is to measure changes from baseline in systolic ejection time.

- The manuscript, "Acute Treatment with *Omecamtiv Mecarbil* to Increase Contractility in Acute Heart Failure, The ATOMIC-AHF Study," published in the Journal of the American College of Cardiology. Results from this trial were first presented at the European Society of Cardiology Meeting in 2013.

- Participated with Amgen in regulatory meetings with the FDA, EMA and Health Canada intended to inform the design of a potential Phase 3 development program for *omecamtiv mecarbil*.

- Conducted various clinical, non-clinical and planning activities in collaboration with Amgen to support the potential advancement of *omecamtiv mecarbil* into a Phase 3 development program.

- Expect to make a decision regarding the advancement of *omecamtiv mecarbil* to Phase 3 in the coming months.

Skeletal Muscle Program

tirasemtiv

- Enrolled more than 50% of targeted patients 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**), 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.

- Convened the first Data Monitoring Committee Meeting for VITALITY-ALS to review unblinded safety and efficacy data; Committee recommended continuing the trial without modifications or

changes to the protocol.

- Presented “Decline in Slow Vital Capacity Predicts Respiratory Insufficiency in Patients with ALS,” at the Muscular Dystrophy Association’s 2016 National Clinical Conference.

- The manuscript, “A Randomized, Placebo-controlled, Double-blind Phase IIb Trial Evaluating the Safety and Efficacy of *Tirasemtiv* in Patients with Amyotrophic Lateral Sclerosis,” published in *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration*. Results from this trial were first presented at the Annual Meeting of the American Academy of Neurology in 2014.

- Participated in the ALS Guidance Development Project and the Clinical Trial Guidelines Workshop Meeting in collaboration with ALS community stakeholders.

- Announced a collaboration with Origent Data Sciences to refine and prospectively validate an Origent computer model to predict ALS disease progression leveraging data from our clinical trials of *tirasemtiv*.

- Expect to complete target enrollment of 600 patients in VITALITY-ALS in the first half of 2016.

CK-2127107

- Continued enrollment of Phase 2 clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA), in collaboration with Astellas.

- 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-2127107 in patients with COPD in the first half of 2016.

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.

- Anticipate potential advancement of one next-generation compound from each joint research program into pre-clinical development in 2016.

Corporate

- Announced Cytokinetics’ Vision 2020: Empowering Our Future, a strategic initiative designed to deepen and expand our pipeline over the next five years as well as advance a portfolio of muscle-biology directed drug candidates toward late-stage development and commercialization to address unmet needs of people living with conditions characterized by impaired muscle function.

- Drew down the second, $15.0 million tranche from our growth capital loan with Oxford Finance LLC and Silicon Valley Bank.

- Announced support of the European Organisation for Rare Diseases (EURORDIS) and the National Organization for Rare Disorders (NORD) to raise awareness of Rare Disease Day®, an international campaign dedicated to elevating the public understanding of rare diseases.

- In observance of ALS Awareness Month, Cytokinetics will ring the Nasdaq closing bell on Monday, May 2, 2016.

Financials

Revenues for the first quarter of 2016 were $8.4 million, compared to $4.4 million during the same period in 2015. Revenues for the first quarter of 2016 included $4.0 million of license revenues and $3.7 million of research and development revenues from our collaboration with Astellas, $0.6 million in research and development revenues from our collaboration with Amgen and $0.2 million in research and development revenues from our collaboration with ALSA. Revenues for the same period in 2015 were comprised of $1.6 million of license revenues and $2.1 million of research and development revenues from our collaboration with Astellas, and $0.7 million of research and development revenues from our collaboration with Amgen.

Total research and development (R&D) expenses for the first quarter of 2016 were $13.5 million, compared to $9.0 million for the same period in 2015. The $4.5 million increase in R&D expenses for the first quarter of 2016, compared with the same period in 2015, was primarily due to an increase of $4.2 million in outsourced clinical costs mainly associated with the ongoing VITALITY-ALS trial, and an increase of $1.0 million in personnel related expenses due to increased headcount, partially offset by a decrease of $0.6 million in outsourced preclinical costs associated with research activities conducted in 2015.

Total general and administrative (G&A) expenses for the first quarter of 2016 were $6.8 million compared to $4.4 million for the same period in 2015. The $2.4 million increase in G&A expenses for the first 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 $0.6 million in outsourced costs related to medical affairs and commercial development, and an increase of $0.6 million in corporate and patent legal fees.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first 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 29638364.

An archived replay of the webcast will be available via Cytokinetics' website until May 5, 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 29638364 from April 28, 2016 at 5:30 PM Eastern Time until May 5, 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 and chronic obstructive pulmonary disease. 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 omecamtiv mecarbil; the significance and utility of preclinical study and clinical trial results; 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 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; 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	
	March 31, 2016	**March 31, 2015**
Revenues:		
Research and development revenues from related parties	$ 4,296	$ 2,791
Research and development, grant and other revenues	151	—
License revenues from related parties	3,974	1,623
License revenues	—	—
Total revenues	8,421	4,414
Operating Expenses:		
Research and development	13,534	8,956
General and administrative	6,841	4,367
Total operating expenses	20,375	13,323
Operating loss	(11,954)	(8,909)
Interest and other income (expense), net	(501)	37
Net loss	$ (12,455)	$ (8,872)
Net loss per share – basic and diluted	$ (0.31)	$ (0.23)
Weighted average shares used in computing net loss per share – basic and diluted	39,592	38,675

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2016 (unaudited)	**December 31, 2015**[(1)]
Assets		
Cash and cash equivalents	$ 42,269	$ 65,076
Short term investments	61,153	46,366

Related party accounts receivable	----	12
Prepaid and other current assets	2,696	1,653
Total current assets	106,118	113,107
Property and equipment, net	1,760	1,751
Long-term investments	5,140	179
Other assets	200	200
Total assets	$ 113,218	$ 115,237
Liabilities and stockholders' equity		
Deferred revenue, current	$ 15,911	$ 20,858
Other current liabilities	8,772	10,791
Total current liabilities	24,683	31,649
Long-term debt	29,466	14,639
Deferred revenue, non-current	851	----
Other non-current liabilities	312	359
Stockholders’ equity	57,906	68,590
Total liabilities and stockholders' equity	$ 113,218	$ 115,237

(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, Inc