



Cytokinetics, Inc. Reports First Quarter 2017 Financial Results

April 27, 2017 8:00 PM EDT

*Data Monitoring Committee for VITALITY-ALS
Recommended Continuation of Phase 3 Trial; Results Expected in Q4*

*Sale of Royalty on Omecamtiv Mecarbil to Royalty Pharma
Contributed to Increased Cash Balance*

Expansion of Clinical Trials Program for CK-2127107 in Collaboration with Astellas

SOUTH SAN FRANCISCO, Calif., April 27, 2017 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total revenues for the first quarter of 2017 were \$4.2 million, compared to \$8.4 million, during the same period in 2016. Net loss for the first quarter was \$25.9 million, or \$0.62 per basic and diluted share, respectively. This is compared to a net loss for the same period in 2016 of \$12.5 million, or \$0.31 per basic and diluted share. As of March 31, 2017, cash, cash equivalents and investments totaled \$257.2 million.

"In the first quarter of 2017, we advanced our novel muscle biology-directed programs through important late-stage clinical trial milestones. In particular, the last patients enrolled in VITALITY-ALS moved through their primary efficacy endpoint visits towards the conclusion of the Phase 3 trial and we look forward to results expected later this year," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We also made key progress with Astellas in the expansion of our clinical trials programs for CK-2127107, opening enrollment for Cohort 2 in our ongoing Phase 2 trial in adolescent and adult patients living with spinal muscular atrophy, and preparing to start additional trials in patients with ALS and elderly subjects with limited mobility."

Recent Highlights and Upcoming Milestones

Skeletal Muscle Program

tirasemtiv

- Convened the third Data Monitoring Committee Meeting for VITALITY-ALS (**V**entilatory **I**nvestigation of *Tirasemtiv* and **A**ssessment of **L**ongitudinal **I**ndices after **T**reatment for a **Y**ear in **ALS**); the Committee recommended the continuation of VITALITY-ALS without modification.
- Continued conduct of VITALITY-ALS and enrollment in VIGOR-ALS (**V**entilatory **I**nvestigations in **G**lobal **O**pen-**L**abel **R**esearch in **ALS**), an open-label extension clinical trial designed to assess the long-term safety and tolerability of *tirasemtiv*, in patients with ALS who have completed participation in VITALITY-ALS.
- Announced the advancement of our research collaboration with Origent Data Sciences to prospectively validate Origent's computer model designed to predict the course of disease progression using baseline data from VITALITY-ALS. The model is expected to be completed prior to analyzing results of VITALITY-ALS.
- Conducted clinical, regulatory, non-clinical and other planning activities intended to support potential regulatory filings and registration of *tirasemtiv* in North America and Europe.
- Engaged Health Technology Assessment organizations to understand payor interests and to inform market access activities in ALS.
- Expect to continue to enroll patients who complete VITALITY-ALS into VIGOR-ALS throughout 2017.
- Expect results from VITALITY-ALS in Q4 2017.

CK-2127107

- Announced pre-clinical data for CK-2127107 showing that this next-generation fast skeletal troponin activator (FSTA) improves muscle function in mouse models of spinal muscular atrophy (SMA). The results were presented at the MDA Scientific Conference in Arlington, VA.
- Completed enrollment of Cohort 1 in the Phase 2 clinical trial of CK-2127107 in patients with SMA, conducted by Cytokinetics in collaboration with Astellas; announced that Cohort 2 opened enrollment.
- Expect data from the Phase 2 clinical trial of CK-2127107 in patients with SMA in 2H 2017.
- Expect Astellas to continue enrollment in a Phase 2 clinical trial of CK-2127107 in patients with COPD in 2017.
- Expect Astellas to begin a Phase 1b clinical trial of CK-2127107 in elderly patients with limited mobility in Q2 2017.
- Expect to begin a Phase 2 clinical trial of CK-2127107 in patients with ALS in mid-2017.

Cardiac Muscle Program

omecamtiv mecarbil

- Announced additional results from COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yo**s**in Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure), a Phase 2 trial evaluating *omecamtiv mecarbil* in patients with chronic heart failure, showing that *omecamtiv mecarbil* improved measures of left ventricular myocardial deformation, a marker of myocardial function that has been related to outcomes. These results further support the direct effect of *omecamtiv mecarbil* to improve myocardial contractile function. The results were presented in a Poster Session at the American College of Cardiology's 66th Annual Scientific Session (ACC.17) in Washington, D.C.
- Continued to activate sites and enroll patients in GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac **O**utcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure), the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil* which is being conducted by Amgen, in collaboration with Cytokinetics.
- Expect data from a Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese patients with chronic heart failure in Q3 2017.
- Expect continued enrollment of patients with chronic heart failure in GALACTIC-HF throughout 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.

Corporate

- Agreed to sell to Royalty Pharma a 4.5% royalty on potential worldwide sales of *omecamtiv mecarbil* for \$90 million and \$10 million of Cytokinetics common stock.
- Agreed to exercise an option under our collaboration agreement with Amgen to co-invest \$40 million in the Phase 3 development program of *omecamtiv mecarbil*. As a result, Cytokinetics is eligible to receive an incremental royalty of up to 4% on increasing worldwide sales of *omecamtiv mecarbil* outside of Japan. Exercising our option and co-funding affords Cytokinetics the right to co-promote *omecamtiv mecarbil* in institutional care settings in North America, with reimbursement by Amgen for certain sales force activities.
- Joined the global initiative with 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.

Financials

Revenues for the first quarter of 2017 were \$4.2 million, compared to \$8.4 million during the same period in 2016. Revenues for the first quarter of 2017 included \$2.7 million of research and development revenues and \$1.4 million of license revenues from our collaboration with Astellas, \$0.9 million in research and development revenues from our collaboration with Amgen, and \$0.3 million in research and development revenues from our collaboration with The ALS Association. Revenues from our collaboration with Amgen were offset by a payment of \$1.3 million to Amgen related to the option to co-fund the Phase 3 development program of *omecamtiv mecarbil* in exchange for an increased royalty upon potential commercialization. Revenues for the same period in 2016 were comprised of \$4.0 million of license revenues and \$3.7 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.

Total research and development (R&D) expenses for the first quarter of 2017 were \$19.3 million, compared to \$13.5 million for the same period in 2016. The \$5.8 million increase in R&D expenses for the first quarter of 2017, compared with the same period in 2016, was primarily due to an increase of \$2.5 million in outsourced clinical costs mainly associated with VITALITY-ALS, our ongoing Phase 3 trial of *tirasemtiv*, \$1.4 million in outsourced research and pre-clinical costs mainly associated with clinical manufacturing activities, \$1.3 million in personnel related expenses due to increased headcount costs, and \$0.2 million in laboratory expenses.

Total general and administrative (G&A) expenses for the first quarter of 2017 were \$8.1 million compared to \$6.8 million for the same period in 2016. The \$1.3 million increases in G&A expenses for the first quarter of 2017, compared to the same period in 2016, was primarily due to an increase of \$0.7 million in personnel-related expenses due to increased headcount and non-cash stock compensation expense and \$0.8 million in outsourced costs primarily related to commercial development, partially offset by a decrease in corporate legal fees of \$0.5 million.

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 46685336.

An archived replay of the webcast will be available via Cytokinetics' website until May 4, 2017. 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 46685336 from April 27, 2017 at 7:30 PM Eastern Time until May 4, 2017.

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 troponin activator (FSTA). *Tirasemtiv* is the subject of VITALITY-ALS, an international Phase 3 clinical trial in patients with 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. Cytokinetics is preparing for the potential commercialization of *tirasemtiv* in North America and Europe and has granted an option to Astellas for development and commercialization in other countries. Cytokinetics is collaborating with Astellas to develop CK-2127107, a next-generation fast skeletal muscle activator. CK-2127107 is the subject of two ongoing Phase 2 clinical trials enrolling patients with spinal muscular atrophy and chronic obstructive pulmonary disease. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omeclamtiv mecarbil* is the subject of GALACTIC-HF, an international Phase 3 clinical trial in patients with heart failure. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Astellas holds an exclusive worldwide license to develop and commercialize CK-2127107. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization participation rights. For additional information about Cytokinetics, visit <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 the initiation, conduct, design, enrollment, progress, continuation, completion and results of clinical trials, including VITALITY-ALS, the Phase 2 clinical trials of CK-2127107 in patients with SMA and in patients with COPD and the Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese patients with chronic heart failure; the significance and utility of pre-clinical study and clinical trial results, the expected

availability of clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions, including our discussions with the FDA regarding the key elements of GALACTIC-HF and the potential for a SPA; the significance and utility of pre-clinical study and clinical trial results; the potential benefits of Cytokinetics' expanded collaboration with Astellas; the expected timing of events and milestones; 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 pre-clinical studies may not be indicative of future clinical trials results; patient enrollment for or conduct of clinical trials may be difficult or delayed; the FDA 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)

	<u>Three Months Ended</u>	
	<u>March 31,</u>	<u>March 31,</u>
	<u>2017</u>	<u>2016</u>
Revenues:		
Research and development revenues from related parties, net	\$ 2,366	\$ 4,296
Research and development, grant and other Revenues	341	151
License revenues from related parties	<u>1,446</u>	<u>3,974</u>
Total revenues	<u>4,153</u>	<u>8,421</u>
Operating Expenses:		
Research and development	19,289	13,534
General and administrative	<u>8,115</u>	<u>6,841</u>
Total operating expenses	<u>27,404</u>	<u>20,375</u>
Operating loss	(23,251)	(11,954)
Interest and other income (expense), net	<u>(2,616)</u>	<u>(501)</u>
Net loss	\$ <u>(25,867)</u>	\$ <u>(12,455)</u>
Net loss per share – basic and diluted	\$ (0.62)	\$ (0.31)
Weighted average shares used in computing net loss per share – basic and diluted	41,578	39,592

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	<u>March 31,</u> <u>2017</u> (unaudited)	<u>December 31,</u> <u>2016⁽¹⁾</u>
Assets		
Cash and cash equivalents	\$ 49,364	\$ 66,874
Short term investments	157,192	89,375
Related party accounts receivable	910	24
Other current assets	<u>3,557</u>	<u>2,360</u>
Total current assets	211,023	158,633
Property and equipment, net	3,488	3,637
Long-term investments	50,622	7,672
Other assets	<u>241</u>	<u>200</u>
Total assets	\$ <u>265,374</u>	\$ <u>170,142</u>
Liabilities and stockholders' equity		
Deferred revenue, current	\$ 10,974	\$ 8,060
Other current liabilities	<u>25,822</u>	<u>25,198</u>
Total current liabilities	36,796	33,258
Long-term debt	25,195	27,381
Deferred revenue, non-current	15,000	15,000
Liability related to sale of future royalties	92,928	-
Other non-current liabilities	72	142
Stockholders' equity	<u>95,383</u>	<u>94,361</u>
Total liabilities and stockholders' equity	\$ <u>265,374</u>	\$ <u>170,142</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, 2016.

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Cytokinetics

Cytokinetics, Inc