



Cytokinetics, Inc. Reports Third Quarter 2017 Financial Results

October 26, 2017 8:00 PM EDT

VITALITY-ALS Proceeding towards Planned Database Lock and Read-out in Q4;

Commercial Planning and Preparations for Potential Regulatory Submissions Underway

CK-2127107 Advancing in Four Mid-Stage Clinical Trials Under Collaboration with Astellas

First Patient Recently Dosed in Japan in GALACTIC-HF Under Collaboration with Amgen

SOUTH SAN FRANCISCO, Calif., Oct. 26, 2017 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported total revenues for the third quarter of 2017 were \$6.2 million, compared to \$59.0 million, during the same period in 2016. Net loss for the third quarter was \$32.4 million, or \$0.60 per basic and diluted share, respectively, compared to net income for the same period in 2016 of \$33.4 million, or \$0.84 and \$0.77 per basic and diluted share, respectively. As of September 30, 2017, cash, cash equivalents and investments totaled \$308.2 million.

"We are proud of the key milestones we recently achieved in preparation for the planned release of results from VITALITY-ALS, and potential regulatory filings and commercialization of *tirasemtiv* in North America and Europe," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In the third quarter, we also advanced CK-2127107 into two additional mid-stage clinical trials, one in patients with ALS and another in elderly subjects with limited mobility; we look forward to data from four clinical trials in this program in 2018. Finally, we are pleased that patient enrollment in GALACTIC-HF continues on target and commenced in Japan triggering a \$10 million milestone payment to Cytokinetics."

Recent Highlights and Upcoming Milestones

Skeletal Muscle Program

tirasemtiv (fast skeletal muscle troponin activator)

- Completed dosing of patients in VITALITY-ALS (**V**entilatory **I**nterest of *T*irasemtiv and **A**ssessment of **L**ongitudinal **I**ndices after **T**reatment for a **Y**ear in **ALS**), our Phase 3 clinical trial of *tirasemtiv* in patients with ALS.
- Continued enrollment in VIGOR-ALS (**V**entilatory **I**nterestations in **G**lobal **O**pen-Label **R**esearch in **ALS**), an open-label clinical trial designed to assess the long-term safety and tolerability of *tirasemtiv* in patients with ALS who have completed participation in VITALITY-ALS.
- Conducted clinical, regulatory, non-clinical and other activities intended to support potential regulatory filings and registration of *tirasemtiv* in North America and Europe.
- Conducted manufacturing, logistical planning, market research, market access and other commercial readiness activities intended to support potential registration and commercialization of *tirasemtiv* in North America and Europe.
- Proceeding to collection of final data from VITALITY-ALS and clinical trial database lock in Q4 2017. We plan to conduct analyses of data from VITALITY-ALS and present results from this clinical trial on December 8, 2017 at the 28th International Symposium on ALS/MND in Boston.
- Expect to continue to enroll patients who complete VITALITY-ALS into VIGOR-ALS throughout 2017.

CK-2127107 (next-generation fast skeletal muscle troponin activator)

- Announced the start of a Phase 1b, double-blind, randomized, placebo-controlled, multiple dose, two-period crossover study to assess the effect of CK-2127107 on measures of physical function in elderly adults with limited mobility. This study is being conducted by Astellas, in

collaboration with Cytokinetics.

- Announced the start of FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of Investigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**). This Phase 2 clinical trial is designed to assess the change from baseline in the percent predicted slow vital capacity (SVC) and other measures of skeletal muscle function after 12 weeks of treatment with CK-2127107 in patients with ALS. This trial is being conducted by Cytokinetics, in collaboration with Astellas.
- “Reasons for Screen Failures and Baseline Characteristics of Randomized Patients from the First Cohort of the Phase 2 Clinical Trial of CK-2127107 in Patients with SMA,” presented by Stacy Rudnicki, M.D., Director, Clinical Research, Cytokinetics, at the Cure SMA 2017 Annual SMA Conference in Orlando, FL.
- Expect to complete enrollment of Cohort 2 of the Phase 2 clinical trial of CK-2127107 in patients with SMA in 2017.
- Expect data from the Phase 2 clinical trial of CK-2127107 in patients with SMA in Q1 2018.
- Expect Astellas to continue enrollment in a Phase 2 clinical trial of CK-2127107 in patients with COPD in 2017.
- Expect Astellas to continue enrollment in a Phase 1b clinical trial of CK-2127107 in adults with limited mobility in 2017.
- Expect to continue enrollment in FORTITUDE-ALS, a Phase 2 clinical trial of CK-2127107 in patients with ALS in 2017.

Cardiac Muscle Program

omecamtiv mecarbil (cardiac muscle myosin activator)

- Announced that the Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese patients with heart failure met its pharmacokinetic primary endpoint and demonstrated statistically significant improvements in systolic ejection time (SET), a secondary endpoint.
- Announced that the first patient has been dosed in Japan 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. Coincident with patient dosing in Japan, Cytokinetics earned a \$10 million milestone payment from Amgen.
- Announced that additional results from COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**ynosin **A**ctivation to **I**ncrease **C**ontractility in **H**eart **F**ailure), a Phase 2 trial evaluating *omecamtiv mecarbil* in patients with chronic heart failure, were presented by John Teerlink, M.D., Professor of Clinical Medicine at the University of California San Francisco and Director of Heart Failure at the San Francisco Veterans Affairs Medical Centers in a Rapid Fire Abstracts Presentation at the 21st Annual Heart Failure Society of America Scientific Meeting in Dallas, TX. The results suggest that *omecamtiv mecarbil* may produce similar results with regard to cardiac function, heart rate, biomarkers and adverse events in patients with ischemic and non-ischemic heart failure due to left ventricular systolic dysfunction.

- Continued to enroll patients in GALACTIC-HF, the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil*, conducted by Amgen, in collaboration with Cytokinetics.
- 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.
- Expect to nominate at least 2 compounds from ongoing Research programs (partnered and unpartnered) as potential drug candidates by the end of 2017.

Financials

Revenues for the three and nine months ended September 30, 2017 were \$6.2 million and \$13.4 million, respectively, compared to \$59.0 million and \$73.3 million for the corresponding periods in 2016. Revenues for the first nine months of 2017 included the \$10 million milestone payment from Amgen as well as \$8.8 million of research and development revenues and \$6.7 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 first nine months of 2017 were offset by \$13.8 million (out of the total of \$40 million) for payments to Amgen related to our option to co-fund the Phase 3 development program of *omecamtiv mecarbil* in exchange for an increased royalty upon potential commercialization. Revenues in 2016 were primarily due to license revenue from the September 2016 expansion of our collaboration with Astellas. Astellas paid us \$65 million in connection with the expanded collaboration.

Total research and development expenses for the three and nine months ended September 30, 2017 increased to \$24.9 million and \$64.0 million, respectively, from \$17.9 million and \$41.1 million for the same periods in 2016, primarily due to increased clinical activity, including activity for VITALITY-ALS and other activities intended to support potential regulatory filings and registration of *tirasemtiv* in North America and Europe, increased CK-2127107 clinical trials activity, as well as increased personnel.

General and administrative expenses for the three and nine months ended September 30, 2017 increased to \$9.7 million and \$26.2 million from \$7.2 million and \$21.1 million for the same periods in 2016, primarily due to increased personnel, non-cash stock compensation expense and commercial readiness activities.

Financial Guidance

The Company also announced updated financial guidance for 2017. The Company anticipates cash research and development expenses will be in the range of \$103 to \$107 million, cash revenue will be in the range of \$16 to \$18 million, and cash general and administrative expenses will remain in the range of \$30 million to \$32 million.

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 46689063.

An archived replay of the webcast will be available via Cytokinetics' website until November 2, 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 46689063 from October 26, 2017 at 7:30 PM Eastern Time until November 2, 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 muscle 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 (FDA) and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS. Cytokinetics is preparing for the potential commercialization of *tirasemtiv* in North America and Europe and has granted an option to Astellas Pharma Inc. ("Astellas") for development and commercialization in other countries. Cytokinetics is collaborating with Astellas to develop CK-2127107, a next-generation FSTA. CK-2127107 has been granted orphan drug designation by the FDA for the potential treatment of SMA. CK-2127107 is the subject of three ongoing Phase 2 clinical trials enrolling patients with spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Astellas is also conducting a Phase 1b clinical trial of CK-2127107 in elderly adults with limited mobility. Cytokinetics is collaborating with Amgen Inc. ("Amgen") 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 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; 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; 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; the timing and receipt of milestone payments; 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 Cytokinetics need for additional funding and such additional funding may not be available 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; 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.

Contact:

Diane Weiser
Vice President, Corporate Communications, Investor Relations
(650) 624-3000

Cytokinetics, Incorporated
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Revenues:				
Research and development, grant and other revenues, net	\$ 5,862	\$ 6,014	\$ 6,680	\$ 14,313
License revenues	318	53,033	6,706	58,956
Total revenues	6,180	59,047	13,386	73,269
Operating Expenses:				
Research and development	24,947	17,865	64,045	41,121
General and administrative	9,657	7,217	26,210	21,149
Total operating expenses	34,604	25,082	90,255	62,270
Operating (loss) income	(28,424)	33,965	(76,869)	10,999
Interest and other income (expense), net	(3,933)	(603)	(10,436)	(1,703)
Net (loss) income	<u>\$ (32,357)</u>	<u>\$ 33,362</u>	<u>\$ (87,305)</u>	<u>\$ 9,296</u>
Net (loss) income per share – basic	\$ (0.60)	\$ 0.84	\$ (1.82)	\$ 0.23
Net (loss) income per share – diluted	\$ (0.60)	\$ 0.77	\$ (1.82)	\$ 0.22

Weighted average shares used in computing net (loss) income				
per share – basic	53,719	39,926	47,879	39,729
Weighted average shares used in computing net (loss) income				
per share – diluted	53,719	43,217	47,879	42,247

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2017	December 31, 2016⁽¹⁾
	<u>(unaudited)</u>	
Assets		
Cash and cash equivalents	\$ 116,320	\$ 66,874
Short term investments	191,247	89,375
Accounts receivable	10,000	24
Other current assets	<u>4,420</u>	<u>2,360</u>
Total current assets	321,987	158,633
Property and equipment, net	3,294	3,637
Long-term investments	583	7,672
Other assets	<u>449</u>	<u>200</u>
Total assets	\$ <u>326,313</u>	\$ <u>170,142</u>
Liabilities and stockholders' equity		
Deferred revenue, current	\$ 9,570	\$ 8,060
Other current liabilities	<u>32,787</u>	<u>25,198</u>
Total current liabilities	42,357	33,258
Long-term debt	20,471	27,381
Deferred revenue, non-current	15,872	15,000
Liability related to sale of future royalties	100,575	-
Other non-current liabilities	-	142
Stockholders' equity	<u>147,038</u>	<u>94,361</u>
Total liabilities and stockholders' equity	\$ <u>326,313</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.



Source: Cytokinetics, Incorporated