Cytokinetics, Inc. Reports Fourth Quarter 2016 Financial Results

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Company Provides 2017 Financial Guidance and Expected Milestones

Phase 3 Results Expected from VITALITY-ALS in Q4 2017

SOUTH SAN FRANCISCO, Calif., Feb. 16, 2017 (GLOBE NEWSWIRE) -- Cytokinetics, Inc. (Nasdaq:CYTK) reported total revenues for the fourth quarter of 2016 were $33.1 million, compared to $9.8 million, during the same period in 2015. Net income for the fourth quarter was $7.2 million, or $0.18 and $0.16 per basic and diluted share, respectively. This is compared to a net loss for the same period in 2015 of $9.2 million, or $0.24 per basic and diluted share. As of December 31, 2016, cash, cash equivalents and investments totaled $163.9 million. The 2016 year-end cash and cash equivalents does not include $100 million received from a royalty monetization deal with Royalty Pharma that closed in February 2017.

“2016 culminated with another productive quarter marked by progress and momentum across our pipeline of late-stage muscle biology-directed drug candidates,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “With two drug candidates in Phase 3 clinical trials and a third advancing in multiple Phase 2 clinical trials, we are executing well against our Vision 2020 strategic initiative, alone and in collaboration with our partners. We expect 2017 to be a pivotal year highlighted by the expected results from VITALITY-ALS, our Phase 3 trial of *tirasemtiv*, as well as key data from our Phase 2 trial of CK-2127107 in patients with spinal muscular atrophy.”

Recent Highlights

Cardiac Muscle Program

omecamtiv mecarbil

- Announced the start of GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **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.

- Announced additional results from COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin 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 left atrial (LA) structure and function in patients with chronic heart failure with reduced systolic function. The results were presented in a Clinical Poster Session at the American Heart Association’s Scientific Sessions 2016 in New Orleans.

- Completed enrollment of a Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese patients with chronic heart failure.

Skeletal Muscle Program

tirasemtiv

- Announced the first patient has been enrolled in VIGOR-ALS (**V**entilatory **I**nvestigations in **G**lobal **O**pen-Label **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 their participation in VITALITY-ALS.

- Announced new data at the 27th International Symposium on ALS/MND in Dublin, Ireland including:

  - Baseline characteristics from VITALITY-ALS showed patients enrolled in VITALITY-ALS are similar to those from BENEFIT-ALS and other recently conducted clinical trials in patients with ALS.

- Results from the first part of a research collaboration to refine and prospectively validate a computer model developed by Origent Data Sciences to predict the course of ALS disease progression analyzing data from the placebo groups of earlier clinical trials in patients with ALS (including BENEFIT-ALS, Cytokinetics' Phase 2b clinical trial of *tirasemtiv*) and the open-access Pro-Act database. The analyses showed that the Gradient Boosting Machine (GBM) algorithm was the optimal model to predict slow vital capacity (SVC) at times subsequent to baseline and that forced vital capacity (FVC) records could be used to predict slow vital capacity (SVC) scores of ALS patients using this machine learning technique.

- Results of an international physician survey on the use of non-invasive ventilation (NIV) in the treatment of ALS presented by Terry Heiman-Patterson, M.D., Director of the Center for Neurodegenerative Disorders, and Professor of the Department of Neurology at the Lewis Katz School of Medicine at Temple University, revealed similarities in best practices for initiating NIV in North America and Europe, and differences in the time to initiation.

CK-2127107

- Continued enrollment of Cohort 1 in the Phase 2 clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA), conducted by Cytokinetics in collaboration with Astellas.

- Continued enrollment in a Phase 2 clinical trial of CK-2127107 in patients with COPD, conducted by Astellas in collaboration with Cytokinetics.

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.

- Announced the publication of preclinical data characterizing a smooth muscle myosin inhibitor that induces smooth muscle relaxation. The manuscript titled, "Highly Selective Inhibition of Myosin Motors Provides the Basis of Potential Therapeutic Application," published in PNAS, Proceedings of the National Academy of Sciences, illustrates a mechanism of action with potential relevance for diseases of smooth muscle hypercontractility such as asthma and chronic obstructive pulmonary disease.

Corporate

- Received a $26.7 million milestone payment from Amgen coincident to the start of GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **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.

- Announced Cytokinetics has been selected for addition to the Nasdaq Biotechnology Index (NBI) as part of the annual re-ranking of the NBI.

- Announced that Cytokinetics has 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.

- Announced that Cytokinetics agreed to exercise its option under its 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 its option and co-funding will afford Cytokinetics the right to co-promote *omecamtiv mecarbil* in institutional care settings in North America, with reimbursement by Amgen for certain sales force activities.

Financials

Revenues for the fourth quarter of 2016 were $33.1 million, compared to $9.8 million during the same period in 2015. Revenues for the fourth quarter of 2016 included $26.0 million from our collaboration with Amgen, and $3.6 million of research and development revenues and $3.2 million of license revenues from our collaboration with Astellas, and $0.3 million in research and development revenues from our collaboration with The ALS Association (ALSA). Revenues from our collaboration with Amgen included $26.7 million in a milestone payment, and $0.6 million in research and development revenue, partially offset by a payment of $1.3 million related to the option to co-fund a Phase 3 clinical trial for an increased royalty percentage. Revenues for the same period in 2015 were comprised of $5.1 million of license revenues and $4.0 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 fourth quarter of 2016 were $18.8 million, compared to $13.2 million for the same period in 2015. The $5.6 million increase in R&D expenses for the fourth quarter of 2016, compared with the same period in 2015, was primarily due to an increase of $4.0 million in outsourced clinical costs mainly associated with VITALITY-ALS, our ongoing Phase 3 trial of *tirasemtiv*, an increase of $1.2 million in personnel related expenses due to increased headcount costs and increased non-cash stock compensation expense, and an increase of $0.3 million in laboratory expenses, partially offset by a decrease of $0.3 million in outsourced pre-clinical costs.

Total general and administrative (G&A) expenses for the fourth quarter of 2016 were $6.7 million compared to $5.5 million for the same period in 2015. The $1.2 million increase in G&A expenses for the fourth quarter of 2016, compared to the same period in 2015, was primarily due to an increase of $0.8 million in personnel related expenses due to increased headcount and non-cash stock compensation expense and an increase of $0.2 million in outsourced costs related to commercial development, recruitment, consulting, and patent legal fees.

Revenues for the twelve months ended December 31, 2016 were $106.4 million, compared to $28.7 million for the same period in 2015. Revenues for the twelve months of 2016 included $62.2 million of license revenues, $13.1 million of research and development revenue, and $2.0 million of milestone payments from our collaboration with Astellas, and $27.9 million from our collaboration Amgen, and $1.1 million in research and development revenues from our collaboration with ALSA. Revenues from our collaboration with Amgen included $26.7 million in a milestone payment, and $2.5 million in research and development revenue, partially offset by a payment of $1.3 million related to the option to co-fund a Phase 3 clinical trial for an increased royalty percentage. Revenues for the same period in 2015 included $13.9 million of license revenues and $12.2 million of research and development revenues from our collaboration with Astellas, and $2.5 million of research and development revenues from our collaboration with Amgen.

Total R&D expenses for the twelve months ended December 31, 2016 were $59.9 million, compared to $46.4 million for the same period in 2015. The $13.5 million increase in R&D expenses for the twelve months of 2016, over the same period in 2015, was primarily due to an increase of $12.1 million in outsourced clinical costs, $4.5 million in personnel related expenses and non-cash stock compensation expense, and $0.8 million in outsourced research costs, partially offset by a decrease of $4.2 million in outsourced preclinical costs mainly associated with clinical manufacturing activities. The increase in outsourced clinical costs was comprised of an increase of $16.6 million in outsourced clinical costs mainly associated with VITALITY-ALS offset by a $4.5 million litigation settlement in June 2016 from a contract research organization for BENEFIT-ALS, our Phase 2 clinical trial of *tirasemtiv* which was concluded in 2014.

Total G&A expenses for the twelve months ended December 31, 2016 were $27.8 million, compared to $19.7 million for the same period in 2015. The $8.1 million increase in G&A spending in the twelve months of 2016 compared to the same period in 2015, was primarily due to $4.2 million in personnel related expenses due to increased headcount and non-cash stock compensation expense, an increase of $1.7 million in corporate and patent legal fees, and an increase of $1.7 million in outsourced costs related to commercial development, grants and sponsorships, and accounting and finance and recruitment related costs.

Net income for the twelve months ended December 31, 2016, was $16.5 million, or $0.41 and $0.39 per basic and diluted share, respectively, compared to a net loss of $37.5 million, or $0.97 per basic and diluted share, for the same period in 2015.

2017 Financial Guidance

Cytokinetics also announced financial guidance for 2017. The company anticipates cash revenue will be in the range of $21 to $23 million, cash R&D expenses will be in the range of $108 to $112 million, and cash G&A expenses will be in the range of $30 to $32 million. This guidance excludes approximately $7.0 million in unearned revenue from the 2014 amendment of our collaboration with Astellas, which will be recognized in 2017 under generally accepted accounting principles, as well as any potential future milestones that may be achieved in accordance with our collaboration agreements with our partner Astellas. This guidance also excludes an estimated $8.9 million in non-cash related operating expenses primarily related to stock compensation expense.

2017 Corporate Milestones

Skeletal Muscle Program
Tirasemtiv

- Expect results from VITALITY-ALS in Q4 2017.
- Expect to continue to enroll patients who complete VITALITY-ALS into VIGOR-ALS, an open-label extension trial throughout 2017.

- Expect data from a 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 1H 2017.
- Expect to begin a Phase 2 clinical trial of CK-2127107 in patients with ALS in mid-2017.

Cardiac Muscle Program

omecamtiv mecarbil

- Expect to continue to enroll patients with chronic heart failure in GALACTIC-HF, our Phase 3 clinical trial of *omecamtiv mecarbil*, throughout 2017.
- Expect data from a Phase 2 clinical trial of *omecamtiv mecarbil* in Japanese patients with chronic heart failure in Q3 2017.

Pre-Clinical Research

- Expect to continue 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.

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 46421080.

An archived replay of the webcast will be available via Cytokinetics' website until February 23, 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 46421080 from February 16, 2017 at 7:30 PM Eastern Time until February 23, 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 Pharma Inc 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. *Omecamtiv 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 preclinical 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 preclinical study and clinical trial results; the potential benefits of Cytokinetics' expanded collaboration with Astellas; 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 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)

	Three Months Ended		Year Ended	
	December 31, 2016	December 31, 2015[1]	December 31, 2016	December 31, 2015[1]
Revenues:				
Research and development revenues from related parties, net	$ 29,610	$ 4,578	$ 42,994	$ 14,665
Research and development, grant and other revenues	313	48	1,242	75
License revenues from related parties	3,215	5,131	62,171	13,918
Total revenues	33,138	9,757	106,407	28,658
Operating Expenses:				
Research and development	18,775	13,249	59,897	46,398
General and administrative	6,675	5,529	27,823	19,667
Total operating expenses	25,450	18,778	87,720	66,065
Operating income (loss)	7,688	(9,021)	18,687	(37,407)
Interest and other income (expense), net	(531)	(208)	(2,234)	(94)
Net income (loss)	$ 7,157	$ (9,229)	$ 16,453	$ (37,501)
Net income (loss) per share – basic	$ 0.18	$ (0.24)	$ 0.41	$ (0.97)
Net income (loss) per share – diluted	$ 0.16	$ (0.24)	$ 0.39	$ (0.97)
Weighted average shares used in computing net income (loss) per share – basic	40,581	39,098	39,943	38,814
Weighted average shares used in computing net income (loss) per share – diluted	43,696	39,098	42,561	38,814

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2016 (unaudited)	December 31, 2015[1]
Assets		
Cash and cash equivalents	$ 66,874	$ 65,076
Short term investments	89,375	46,366
Related party accounts receivable	24	12
Other current assets	2,360	1,653
Total current assets	158,633	113,107
Property and equipment, net	3,637	1,751
Long-term investments	7,672	179
Other assets	200	200
Total assets	$ 170,142	$ 115,237
Liabilities and stockholders' equity		
Deferred revenue, current	$ 8,060	$ 20,858
Other current liabilities	25,198	10,791
Total current liabilities	33,258	31,649
Long-term debt	27,381	14,639
Deferred revenue, non-current	15,000	—
Other non-current liabilities	142	359
Stockholders' equity	94,361	68,590
Total liabilities and stockholders' equity	$ 170,142	$ 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.

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

Cytokinetics

Cytokinetics, Inc