Cytokinetics, Inc. Reports Fourth Quarter 2017 Financial Results

February 15, 2018 9:00 PM EST

Company Provides 2018 Financial Guidance and Expected Milestones;
Reduced Operating Expenses vs. 2017; Over Two Years of Cash Based on Current Burn Rate

CK-2127107 Advancing in Four Clinical Trials Under Collaboration with Astellas;
Results Expected in 2018 with Data from Phase 2 Clinical Trial in Patients with SMA Anticipated in Q2

Enrollment in GALACTIC-HF on Track Under Collaboration with Amgen;
Finalizing Plans for Second Phase 3 Clinical Trial in 2018

SOUTH SAN FRANCISCO, Calif., Feb. 15, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported financial results for the fourth quarter of 2017. Net loss for the fourth quarter was $40.5 million, or $0.75 per basic share and diluted share, respectively, compared to net income for the same period in 2016 of $7.2 million, or $0.18 and $0.16 per basic and diluted share, respectively. Cash, cash equivalents and investments totaled $285.4 million at December 31, 2017.

"We had a productive fourth quarter and begin the year with optimism for our growing pipeline of muscle biology directed drug candidates," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In 2018, we are looking forward to results from four mid-stage clinical trials of CK-2127107 in our skeletal muscle activator program which may inform plans to advance to a Phase 3 clinical program under our collaboration with Astellas. Additionally, enrollment in GALACTIC-HF remains on track with planning under our collaboration with Amgen. Our research continues to power innovation with two potential drug candidates expected to move through IND-enabling studies and into Phase 1 trials in 2018."

Recent Highlights and Upcoming Milestones

Cardiac Muscle Program

omecamtiv mecarbil (cardiac myosin activator)

- Continued site activation and patient enrollment in GALACTIC-HF, the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil.* Enrollment is proceeding according to plan with patients that have the intended risk profile consistent with the trial design.

- Continued protocol development, feasibility assessments, regulatory interactions and other readiness activities for a second Phase 3 clinical trial of *omecamtiv mecarbil*. This trial which is intended to evaluate the potential of *omecamtiv mecarbil* to increase exercise performance in patients with heart failure is planned to be conducted by Cytokinetics in collaboration with Amgen.

- Announced that a post-hoc responder analysis 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 clinical trial evaluating *omecamtiv mecarbil* in patients with chronic heart failure and left ventricular systolic dysfunction, was presented by John Teerlink, M.D. in an Abstract Rapid Fire Oral presentation at the American Heart Association Scientific Sessions. The proportion of patients achieving various thresholds in the percent reduction of NT-proBNP was larger in patients who received *omecamtiv mecarbil* than in patients who received placebo.

Skeletal Muscle Program

tirasemtiv (fast skeletal muscle troponin activator (FSTA))

- Announced the presentation of results from 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**), the international Phase 3 clinical trial of *tirasemtiv* in patients with amyotrophic lateral sclerosis (ALS), at the 28th International Symposium on ALS and Motor Neurone Disease (MND) in Boston. The presentation, by Jeremy Shefner, M.D., Ph.D., Lead Investigator of VITALITY-ALS, Professor and Chair of Neurology at Barrow Neurological Institute, and Professor and Executive Chair of Neurology at University of Arizona, Phoenix, followed our

prior announcement that the trial did not meet the primary endpoint of change from baseline in slow vital capacity which was evaluated at 24 weeks following randomization or any of the secondary endpoints in the trial which were evaluated at 48 weeks.

- Continued treatment of patients in VIGOR-ALS (**V**entilatory **I**nvestigations 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. Currently, there are still over 100 patients who are receiving *tirasemtiv* in VIGOR-ALS.

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

- Received final approval from the World Health Organization and the United States Adopted Name Council for *reldesemtiv* to be used as the International Nonproprietary Name for CK-2127107.

- Continued conduct of our Phase 2 clinical trial of *reldesemtiv* which is designed to assess its effect on multiple measures of muscle function in both ambulatory and non-ambulatory patients with SMA. This trial has enrolled over 60 patients toward the objective of 72 patients and is being conducted by Cytokinetics in collaboration with Astellas.

- Continued site activation and patient enrollment in FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**nvestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**), the Phase 2 clinical trial of *reldesemtiv* which 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 *reldesemtiv* in patients with ALS. This trial has screened over 100 patients and enrolled nearly 90 patients toward the objective of 445 patients and is being conducted by Cytokinetics in collaboration with Astellas.

- Continued site activation and patient enrollment in the Phase 2 clinical trial of *reldesemtiv* in patients with chronic obstructive pulmonary disease (COPD) which is designed to assess its effect on physical function. This trial has enrolled over 30 patients towards the objective of 40 patients and is being conducted by Astellas in collaboration with Cytokinetics.

- Continued site activation and patient enrollment in the Phase 1b clinical trial of *reldesemtiv* in elderly subjects with limited mobility which is designed to assess its effect on measures of physical function. This trial has enrolled over 20 subjects towards the objective of 60 subjects and is being conducted by Astellas in collaboration with Cytokinetics.

- Announced the publication of “CK-2127107 Amplifies Skeletal Muscle Response to Nerve Activation in Humans,” in *Muscle & Nerve*, which showed that *reldesemtiv* increased the force generated by the tibialis anterior muscle versus placebo in response to nerve stimulation in a dose, plasma concentration, and frequency-dependent manner. Single doses of *reldesemtiv* were well-tolerated in healthy volunteers up to 4000 mg. No serious adverse events were reported and adverse events were all mild or moderate.

Pre-Clinical Research and Development

- Advanced a next-generation cardiac muscle activator into development under our collaboration with Amgen. This milestone triggered a $1 million payment from Amgen to Cytokinetics.

- Advanced a next-generation skeletal muscle activator into development under our collaboration with Astellas.

- Announced that Cytokinetics is advancing an unpartnered cardiac sarcomere directed compound from research into IND-enabling studies in 2018.

- Continued collaboration 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. Cytokinetics and Astellas recently agreed to extend the joint research program through 2019.

- Company scientists continued independent research activities directed to our other muscle biology programs.

Financials

Revenues for the year ended December 31, 2017 included $11.0 million in milestone revenues from Amgen as well as $1.3 million of research and development revenues from our collaboration with Amgen, and $11.9 million of research and development revenues plus $8.8 million of license revenues from our collaboration with Astellas. Revenues for the year ended December 31, 2017 were offset by $20.0 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 and a $26.7 million milestone payment from Amgen.

Research and development expenses for the three months and year ended December 31, 2017 increased to $26.3 million and $90.3 million, respectively, from $18.8 million and $59.9 million for the same periods in 2016, primarily due to increased clinical activity, including activity for VITALITY-ALS, increased clinical trials activity for *reldesemtiv*, as well as increased personnel.

General and administrative expenses for the three months and year ended December 31, 2017 increased to $10.3 million and $36.5 million, respectively, from $6.7 million and $27.8 million for the same periods in 2016, primarily due to increased personnel, non-cash stock compensation expense and commercial readiness activities.

2018 Financial Guidance

The Company also announced financial guidance for 2018. The company anticipates cash revenue will be in the range of $17 to $23 million, operating expenses will be in the range of $105 to $115 million, and net cash utilization will be approximately $100 million.

2018 Corporate Milestones

Cardiac Muscle Program

omecamtiv mecarbil (cardiac myosin activator)

- Expect to complete enrolling patients with chronic heart failure in GALACTIC-HF in approximately one year.

- Expect to finalize plans and prepare to start the second Phase 3 trial of *omecamtiv mecarbil*.

Skeletal Muscle Program

CK-2127107 (*reldesemtiv*), (next-generation fast skeletal muscle troponin activator (FSTA))

- Expect results from a Phase 2 clinical trial of *reldesemtiv* in patients with SMA in Q2 2018.

- Expect results from a Phase 2 clinical trial of *reldesemtiv* in patients with ALS in 2H 2018.

- Expect results from a Phase 2 clinical trial of *reldesemtiv* in patients with COPD in 2H 2018.

- Expect results from a Phase 1b clinical trial of *reldesemtiv* in adults with limited mobility in 2H 2018.

Pre-Clinical Research

- Expect to advance one development compound, under each of our collaborations with Amgen and Astellas, into IND-enabling studies in 2018, one of which may proceed to Phase 1 this year.

- Expect to advance an unpartnered cardiac sarcomere directed compound through IND-enabling studies in 2018 to enable initiation of Phase 1 in 2018.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth 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 3665278.

An archived replay of the webcast will be available via Cytokinetics' website until February 22, 2018. 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 3665278 from February 15, 2018 at 7:30 PM Eastern Time until February 22, 2018.

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 is collaborating with Amgen Inc. ("Amgen") 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. Cytokinetics is collaborating with Astellas Pharma Inc. ("Astellas") to develop *reldesemtiv* (CK-2127107), a next-generation FSTA. *Reldesemtiv* has been granted orphan drug designation by the FDA for the potential treatment of SMA. *Reldesemtiv* 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 *reldesemtiv* in elderly adults with limited mobility. Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization rights. Cytokinetics continues its 20-year history of innovation with three new muscle biology directed compounds advancing from research to development in 2018. 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 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, timing and results of clinical trials; the significance and utility of pre-clinical study and clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions; the expected timing of events and milestones, including the 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; 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; 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 *reldesemtiv*, respectively; Cytokinetics may incur unanticipated research and development and other costs; 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.

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

	Three Months Ended		Year Ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016

Revenues:				
License and research and development revenues from Astellas	$ 5,216	$ 6,792	$ 20,733	$ 77,281
Milestone revenues from Amgen	1,000	26,667	11,000	26,667
Research and development revenues from Amgen	-	616	1,279	2,466
Co-investment payments to Amgen	(6,250)	(1,250)	(20,000)	(1,250)
Grant and other revenues	16	313	356	1,243
Total revenues, net	(18)	33,138	13,368	106,407
Operating Expenses:				
Research and development	26,250	18,775	90,296	59,897
General and administrative	10,259	6,675	36,468	27,823
Total operating expenses	36,509	25,450	126,764	87,720
Operating (loss) income	(36,527)	7,688	(113,396)	18,687
Interest expense	(670)	(714)	(3,016)	(2,698)
Non-cash interest expense on liability related to sale of royalties	(4,061)	-	(13,980)	-
Interest and other income (expense), net	774	183	2,602	464
Net (loss) income	$ (40,484)	$ 7,157	$ (127,790)	$ 16,453
Net (loss) income per share – basic	$ (0.75)	$ 0.18	$ (2.59)	$ 0.41
Net (loss) income per share – diluted	$ (0.75)	$ 0.16	$ (2.59)	$ 0.39
Weighted average shares used in computing net (loss) income per share – basic	53,929	40,581	49,404	39,943
Weighted average shares used in computing net (loss) income per share – diluted	53,929	43,696	49,404	42,561

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2017 (unaudited)	December 31, 2016[1]
Assets		
Cash and cash equivalents	$ 125,206	$ 66,874
Short term investments	143,685	89,375
Accounts receivable	1,112	24
Other current assets	4,292	2,360
Total current assets	274,295	158,633
Long-term investments	16,518	7,672
Property and equipment, net	3,568	3,637

Other assets	429	200
Total assets	$ 294,810	$ 170,142
Liabilities and stockholders' equity		
Deferred revenue, current	$ 9,572	$ 8,060
Other current liabilities	22,872	25,198
Total current liabilities	32,444	33,258
Long-term debt	31,777	27,381
Deferred revenue, non-current	15,000	15,000
Liability related to sale of future royalties	104,650	-
Other non-current liabilities	1,097	142
Stockholders' equity	109,842	94,361
Total liabilities and stockholders' equity	$ 294,810	$ 170,142

(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.

Cytokinetics

Source: Cytokinetics, Incorporated