



Cytokinetics, Inc. Reports First Quarter 2018 Financial Results

April 26, 2018 8:00 PM EDT

*Completed Enrollment in Phase 2 Study of Reldesemtiv in Patients with SMA;
Data Expected in Q2 2018*

Preparing to Initiate Second Phase 3 Clinical Trial of Omecamtiv Mecarbil

SOUTH SAN FRANCISCO, Calif., April 26, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) reported financial results for the first quarter of 2018. Net loss for the first quarter was \$30.3 million, or \$0.56 per share, compared to a net loss for the first quarter of 2017 of \$25.9 million, or \$0.62 per share. Cash, cash equivalents and investments totaled \$255.5 million at March 31, 2018.

"In the first quarter of 2018 we made progress advancing our muscle biology directed drug candidates in mid- and late-stage clinical trials across diseases and conditions of impaired muscle function," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We completed enrollment of our Phase 2 clinical study of *reldesemtiv* in patients with spinal muscular atrophy and look forward to data from that study in the second quarter which may inform future development of *reldesemtiv* under our collaboration with Astellas. In addition, we made further preparations to initiate the second Phase 3 clinical trial of *omecamtiv mecarbil* in patients with heart failure under our collaboration with Amgen. We also continued preclinical development activities with the objective of advancing two drug candidates into Phase 1 trials."

Recent Highlights and Upcoming Milestones

Cardiac Muscle Program

omecamtiv mecarbil (cardiac myosin activator)

- Continued patient enrollment 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*. Enrollment is proceeding towards 50 percent completion with patients randomized to date having a risk profile consistent with the trial design. The Data Monitoring Committee for GALACTIC-HF has been meeting regularly and reviewing data arising from the trial; there have been no major changes to the trial following these reviews. We expect to complete enrolling patients with chronic heart failure in GALACTIC-HF in approximately one year.
- Continued protocol development, feasibility assessments, regulatory interactions and other readiness activities for a second Phase 3 clinical trial of *omecamtiv mecarbil*. This trial is intended to evaluate the potential effect of *omecamtiv mecarbil* on exercise performance in patients with heart failure and is planned to be conducted by Cytokinetics in collaboration with Amgen. We are finalizing preparations to ensure readiness to begin this trial on a timeframe to be agreed soon.

Skeletal Muscle Program

tirasemtiv (fast skeletal muscle troponin activator (FSTA))

- Convened an advisory board of ethicists, patient advocates, trial investigators and experts in pre-approval access to assess whether and how best to continue providing *tirasemtiv* to those people living with ALS currently in VIGOR-ALS, the open-label extension clinical trial following VITALITY-ALS. Informed by our advisory board, we decided to close VIGOR-ALS and transition patients who wish to remain on *tirasemtiv* to a Managed Access Program (MAP).
- The manuscript, "Respiratory Measures in Amyotrophic Lateral Sclerosis," published online in *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration*.
- The manuscript, "VITALITY-ALS, a Phase III Trial of *Tirasemtiv*, a Selective Fast Skeletal Muscle Troponin Activator, as a Potential Treatment for Patients with Amyotrophic Lateral

Sclerosis: Study Design and Baseline Characteristics,” published online in *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration*.

reldesemtiv (CK-2127107, next-generation FSTA)

- Completed enrollment of 70 patients in 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 is being conducted by Cytokinetics in collaboration with Astellas. We expect results to be presented on June 16 at the 2018 Annual Cure SMA Conference.
- Continued site activation and patient enrollment in 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**), the Phase 2 clinical trial of *reldesemtiv* which is designed to assess the change from baseline in percent predicted slow vital capacity and other measures of skeletal muscle function after 12 weeks of treatment with *reldesemtiv* in patients with ALS. This trial has enrolled over 150 patients toward the objective of 445 patients and is being conducted by Cytokinetics in collaboration with Astellas. We expect results from this clinical trial in Q4 2018.
- Continued 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, designed to enroll 40 patients, is nearing completion and is being conducted by Astellas in collaboration with Cytokinetics. We expect results from this clinical trial in 2H 2018.
- 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 is being conducted by Astellas in collaboration with Cytokinetics. We expect Astellas will conduct an interim analysis of data arising from this trial in Q4 2018.

Pre-Clinical Research and Development

- Continued collaboration activities under our joint research program with Astellas directed to the discovery of next-generation skeletal muscle activators.
- Continued independent research activities directed to our other muscle biology programs.
- Continued to advance development compounds under our collaborations with Amgen and Astellas. We expect to advance one of these potential drug candidates to Phase 1 in 2018.
- Continued IND-enabling studies for our unpartnered cardiac sarcomere directed compound. We expect to advance this potential drug candidate to Phase 1 in 2018.

Corporate

- Announced progress against our Vision 2020 initiatives designed to advance and expand our pipeline of muscle biology directed drug candidates in late-stage development to address urgent needs of people living with conditions characterized by impaired muscle function and weakness.
- Announced that Robert Califf, M.D., has been appointed to the company’s Board of Directors.

Dr. Califf is the Vice Chancellor for Health Data Science at Duke Health and Director of the Duke University Center for Health Data Science. He is also serving as an advisor to the senior management team at Verily Life Sciences, a subsidiary of Alphabet, Inc. (parent company to Google) and was appointed an adjunct professor of medicine at Stanford University.

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

Annual Stockholders' Meeting

Cytokinetics' Annual Stockholders' Meeting will be held on Wednesday, May 16, 2018 at 10:30 AM Pacific Time at the Embassy Suites Hotel in South San Francisco, CA and simultaneously webcast.

Financials

Revenues for the first quarter of 2018 consisted of revenues from our collaboration with Astellas, including research and development revenues of \$3.6 million and license revenues of \$1.7 million.

Research and development expenses fell to \$22.1 million for the first quarter of 2018 from \$26.2 million for the fourth quarter of 2017. General and administrative expenses fell to \$9.3 million for the first quarter of 2018 from \$10.3 million for the fourth quarter of 2017.

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 3488889.

An archived replay of the webcast will be available via Cytokinetics' website until May 3, 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 3488889 from April 26, 2018 at 7:30 PM Eastern Time until May 3, 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. *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 *omeclamtiv 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; 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, 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 *omeclamtiv 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	
	March 31, 2018	March 31, 2017
Revenues:		
Research and development, grant and other revenues, net	\$ 3,585	\$ 2,707
License revenues	1,683	1,446
Total revenues	5,268	4,153
Operating expenses:		
Research and development	22,135	19,289
General and administrative	9,264	8,115
Total operating expenses	31,399	27,404
Operating loss	(26,131)	(23,251)
Interest expense	(863)	(745)
Non-cash interest expense on liability related to sale of future royalties	(4,129)	(2,307)
Interest and other income, net	842	436
Net loss	\$ (30,281)	\$ (25,867)
Net loss per share - basic and diluted	\$ (0.56)	\$ (0.62)
Weighted-average shares used to compute net loss per share — basic and diluted	54,062	41,578

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2018	December 31, 2017⁽¹⁾
	(unaudited)	
ASSETS		
Current assets:		
Cash and short term investments	\$ 251,454	\$ 268,891
Other current assets	20,885	5,404
Total current assets	272,339	274,295
Long-term investments	4,015	16,518
Property and equipment, net	3,156	3,568
Other assets	416	429
Total assets	\$ 279,926	\$ 294,810
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 30,469	\$ 22,645
Deferred revenue, current	7,842	9,572
Other current liabilities	235	227
Total current liabilities	38,546	32,444
Long-term debt, net	31,954	31,777
Liability related to the sale of future royalties, net	108,792	104,650
Deferred revenue, non-current	—	15,000
Other long-term liabilities	1,035	1,097
Total liabilities	180,327	184,968
Stockholders' equity:		
Common stock	54	54
Additional paid-in capital	757,405	755,526
Accumulated other comprehensive income	489	343
Accumulated deficit	(658,349)	(646,081)
Total stockholders' equity	99,599	109,842

Total liabilities and stockholders' equity

\$ 279,926

\$ 294,810

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.



Source: Cytokinetics, Incorporated