



Cytokinetix Reports First Quarter 2019 Financial Results

May 9, 2019 8:00 PM EDT

*GALACTIC-HF Continues Following Interim Analysis for Futility;
METEORIC-HF Opened to Enrollment*

*Phase 1 Data for CK-274 Expected in Q3 2019;
Planning Underway for Potential Progression to Phase 2*

FORTITUDE-ALS Demonstrates Patients on All Doses of Reldesemtiv Declined Less Than Patients on Placebo for SVC and ALSFRS-R, With Clinically Meaningful Differences Emerging Over Time

SOUTH SAN FRANCISCO, Calif., May 09, 2019 (GLOBE NEWSWIRE) -- Cytokinetix, Incorporated (Nasdaq: CYTK) reported financial results for the first quarter of 2019. Net loss for the first quarter was \$29.4 million, or \$0.54 per share, compared to net loss for the first quarter of 2018 of \$30.3 million, or \$0.56 per share. Cash, cash equivalents and investments totaled \$176.6 million at March 31, 2019.

"We are pleased with the progress made across our pipeline of muscle-directed investigational medicines during the first quarter of 2019," said Robert I. Blum, Cytokinetix' President and Chief Executive Officer. "Recently, we shared encouraging data from FORTITUDE-ALS demonstrating consistency of effect for doses, endpoints and timepoints in patients treated with *rel-des-em-tiv* and we believe the results may support progression to further clinical trials toward potential registration. We also passed through the first planned interim analysis of GALACTIC-HF and opened enrollment in METEORIC-HF while we also independently continued the conduct of the Phase 1 study of CK-274 and prepared for potential progression to Phase 2. Our strategy to advance multiple drug candidates, under our collaborations and independently, continues to generate upside potential for patients and shareholders."

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbii (cardiac myosin activator)

- Continued conduct of 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 mecarbii*, following first planned interim analysis for futility. We expect screening in this event-driven trial to complete in the second quarter of 2019.
- Opened METEORIC-HF, (**M**ulticenter **E**xercise **T**olerance **E**valuation of *Omecamtiv Mecarbii*/**R**elated to **I**ncreased **C**ontractility in **H**eart **F**ailure), the second Phase 3 trial of *omecamtiv mecarbii*, to enrollment. METEORIC-HF is a randomized, placebo-controlled, double-blind, parallel group, multicenter clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbii* compared to placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET) following 20 weeks of treatment. We expect to continue enrollment of METEORIC-HF throughout 2019.
- John Teerlink, M.D., Professor of Clinical Medicine, University of California San Francisco and Director of Heart Failure, San Francisco Veterans Affairs Medical Center, presented additional results from COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yo-sin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure) at the American College of Cardiology's 68th Annual Scientific Session. The results of a post hoc subgroup analysis of the COSMIC-HF data showed that, between 32 patients with atrial fibrillation (AF) and 117 patients without AF, there were no statistically significant differences in the effects of treatment with *omecamtiv mecarbii* on cardiac function, including systolic ejection time and stroke volume, as well as ventricular volumes, heart rate, and NT-proBNP.

AMG 594 (cardiac troponin activator)

- Continued conduct of the Phase 1 study of AMG 594 to assess its safety, tolerability, pharmacokinetics and potential to increase cardiac function in healthy volunteers. AMG 594 is

a novel, selective, oral, small molecule cardiac troponin activator, discovered under a joint research program with Amgen. This Phase 1 study is being conducted by Amgen in collaboration with Cytokinetics. We expect the conduct of this study to continue throughout 2019.

CK-3773274 (CK-274, cardiac myosin inhibitor)

- Continued conduct of the Phase 1 double-blind, randomized, placebo-controlled, multi-part, single and multiple ascending dose clinical study of CK-274 in healthy adult subjects. CK-274 is a wholly-owned, novel cardiac myosin inhibitor, discovered by company scientists, in development for the potential treatment of hypertrophic cardiomyopathy (HCM). We expect results from this study in the third quarter of 2019 and are preparing for potential progression of CK-274 to Phase 2 in the second half of 2019.

Skeletal Muscle Program

reldesemtiv (next-generation fast skeletal muscle troponin activator (FSTA))

- Results from 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* in patients with amyotrophic lateral sclerosis (ALS), were presented during a platform presentation at the American Academy of Neurology 71st Annual Meeting in Philadelphia on Sunday, May 5, 2019.
- FORTITUDE-ALS did not achieve statistical significance for a pre-specified dose-response relationship in its primary endpoint of change from baseline in slow vital capacity (SVC) after 12 weeks of dosing ($p=0.11$). Similar analyses of ALSFRS-R and slope of the Muscle Strength Mega-Score yielded p values of 0.09 and 0.31, respectively. While the dose-response analyses for the primary and secondary endpoints did not achieve statistical significance at the level of 0.05, in a post-hoc analysis pooling the doses together, patients who received *reldesemtiv* in FORTITUDE-ALS declined less than patients who received placebo. The trial showed effects favoring *reldesemtiv* across dose levels and timepoints with clinically meaningful magnitudes of effect observed at 12 weeks for the primary and secondary endpoints. The differences between *reldesemtiv* and placebo in SVC and ALSFRS-R total score observed after 12 weeks of treatment were still evident at follow-up, four weeks after the last dose of study drug.

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation fast skeletal muscle troponin activator (FSTA), under our collaboration with Astellas.
- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators; Astellas is sponsoring Cytokinetics' activities through 2019.
- Continued independent research activities directed to our other muscle biology research programs.

Corporate

- Joined the European Organisation for Rare Diseases (EURORDIS) and the National Organization for Rare Disorders (NORD) to recognize Rare Disease Day®, an international campaign elevating the public understanding of rare diseases.

Financials

Revenues for the first quarter of 2019 increased to \$8.5 million from \$5.3 million for the first quarter of 2018, primarily due to increased research and development revenues from our collaborations with Astellas and Amgen. License revenues in the first quarter of 2018 were related to the Phase 2 study of *reldesemtiv* in spinal muscle atrophy completed in 2018.

Research and development expenses for the first quarter of 2019 increased to \$23.5 million from \$22.1 million for the first quarter of 2018, primarily due to increased spending related to the opening of METEORIC-HF and development of CK-274, offset in part by reduced spending for *reldesemtiv* as well as for *tirasemtiv*, following suspension of development of *tirasemtiv* in late 2017. General and administrative expenses increased slightly to \$9.4 million for the first quarter of 2019 from \$9.3 million for the first quarter of 2018.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first quarter 2019 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 4486595.

An archived replay of the webcast will be available via Cytokinetics' website until May 16, 2019. 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 4486595 from May 9, 2019 at 7:30 PM Eastern Time until May 16, 2019.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and best-in-class muscle inhibitors 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 impact 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 an international Phase 3 clinical trials program in patients with heart failure including GALACTIC-HF and METEORIC-HF. 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*, a fast skeletal muscle troponin activator (FSTA). Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies. Cytokinetics continues its over 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on [Twitter](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

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	
	March 31, 2019	March 31, 2018
Revenues:		
Research and development revenues	\$ 8,464	\$ 3,585
License revenues	—	1,683

Total revenues	8,464	5,268
Operating expenses:		
Research and development	23,545	22,135
General and administrative	9,437	9,264
Total operating expenses	32,982	31,399
Operating loss	(24,518)	(26,131)
Interest expense	(1,170)	(863)
Non-cash interest expense on liability related to sale of future royalties	(4,819)	(4,129)
Interest and other income, net	1,141	842
Net loss	<u>\$ (29,366)</u>	<u>\$ (30,281)</u>
Net loss per share — basic and diluted	<u>\$ (0.54)</u>	<u>\$ (0.56)</u>
Weighted-average shares in net loss per share — basic and diluted	<u>54,821</u>	<u>54,062</u>

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2019	December 31,
	(unaudited)	2018⁽¹⁾
ASSETS		
Current assets:		
Cash and short term investments	\$ 176,622	\$ 198,731
Other current assets	9,778	8,943
Total current assets	186,400	207,674
Property and equipment, net	3,175	3,204
Other assets	9,036	300
Total assets	<u>\$ 198,611</u>	<u>\$ 211,178</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 15,491	\$ 19,521
Current portion of long-term debt	6,212	2,607
Short-term lease liability	4,499	—
Other current liabilities	75	66
Total current liabilities	26,277	22,194
Long-term debt, net	36,382	39,806
Liability related to the sale of future royalties, net	127,308	122,473
Long-term lease liability	5,272	—
Other long-term liabilities	—	771
Total liabilities	195,239	185,244
Stockholders' equity:		
Common stock	55	55
Additional paid-in capital	775,401	768,703
Accumulated other comprehensive income	606	500
Accumulated deficit	(772,690)	(743,324)
Total stockholders' equity	3,372	25,934
Total liabilities and stockholders' equity	<u>\$ 198,611</u>	<u>\$ 211,178</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, 2018.



Source: Cytokinetics, Incorporated