Cytokinetics Reports First Quarter 2020 Financial Results

May 6, 2020 8:00 PM EDT

Top-line Results for GALACTIC-HF Expected in Q4 2020

Ended Q1 with More Than Two Years of Going Forward Cash Based on 2020 Guidance

SOUTH SAN FRANCISCO, Calif., May 06, 2020 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the first quarter of 2020. Net loss for the first quarter was $39.4 million, or $0.66 per share, compared to net loss for the first quarter of 2019 of $29.4 million, or $0.54 per share. Cash, cash equivalents and investments totaled $237.2 million at March 31, 2020.

"While we face challenges due to the COVID-19 pandemic, we believe we are on track to achieve our key strategic objectives in 2020, in particular, the sharing of top-line results from GALACTIC-HF, expected in the fourth quarter of this year," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We are fortunate to have ended the first quarter with more than two years of forward cash runway based on our expected net cash spending of $105-115 million in 2020. We will continue to assess the impact of the pandemic to our business, with an eye toward prudently managing our cash and other resources and to prioritizing our strategic programs in our pipeline."

Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Continued conduct 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*, following the second and final planned interim analysis, which considered pre-specified criteria for futility and superiority. We expect top-line results in Q4 2020. GALACTIC-HF is being conducted by Amgen in collaboration with Cytokinetics.

- Published patient baseline characteristics and demographics from GALACTIC-HF during the Virtual American College of Cardiology 69th Annual Scientific Session together with the World Congress of Cardiology (ACC.20/WCC Virtual). Patients enrolled in the trial represent a population at risk for heart failure events despite being well-treated in accordance with international guidelines.

- Announced the publication of a manuscript relating to the design of GALACTIC-HF in the *Journal of American College of Cardiology: Heart Failure (JACC: HF).*

- Continued conduct of METEORIC-HF (**M**ulticenter **E**xercise **T**olerance **E**valuation of ***O****mecamtiv Mecarbil* **R**elated to **I**ncreased **C**ontractility in **H**eart **F**ailure), the second Phase 3 trial of *omecamtiv mecarbil,* in Q1. In response to the COVID-19 pandemic, Cytokinetics and Amgen recently agreed to temporarily suspend enrollment in METEORIC-HF to protect the safety and health of clinical trial participants and healthcare professionals. Clinical site start-up activities are continuing to be prioritized with an objective to activate new sites throughout North America and Europe. We believe enrollment may be completed by the end of Q4 2020 if enrollment can be reactivated by the end of Q2 2020. METEORIC-HF is being conducted by Cytokinetics in collaboration with Amgen.

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 in Q1. In response to the COVID-19 pandemic, Amgen and Cytokinetics recently agreed to temporarily suspend enrollment in the Phase 1 study of AMG 594 to protect the safety and health of

clinical study participants and healthcare professionals. This Phase 1 study is being conducted by Amgen in collaboration with Cytokinetics.

- Presented preclinical data at the Keystone Symposium “Charting a New Course for Heart Failure: From Discovery to Data,” showing that AMG 594 selectively increases calcium sensitivity of cardiac muscle fibers and increased cardiac contractility.

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

- Prepared for and started REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM)**, the Phase 2 clinical trial designed to determine the safety and tolerability of CK-274 in patients with obstructive hypertrophic cardiomyopathy (HCM). REDWOOD-HCM started in Q1 2020 and will continue through 2020. In response to the COVID-19 pandemic, Cytokinetics recently temporarily suspended enrollment in REDWOOD-HCM, to protect the safety and health of clinical study participants and healthcare professionals. Clinical site start-up activities are continuing to be prioritized with an objective to activate new sites throughout North America and Europe. We believe data from the first cohort of patients enrolled in REDWOOD-HCM can be available in 2H 2020 if enrollment in the first cohort can be completed by mid-year.

- Presented preclinical data at the Biophysical Society 64th Annual Meeting demonstrating that CK-274 has a distinct binding site on cardiac myosin, and selectively reduces cardiac myosin activity *in vitro*.

CK-271 (CK-271, second cardiac myosin inhibitor)

- Submitted IND and plan to start Phase 1 study of CK-271 in Q2 2020.

Skeletal Muscle Program

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

- Convened a Type C meeting with FDA and continued regulatory interactions with FDA and EMA in Q1. In addition, we conducted additional feasibility and other planning activities in preparation for the potential advancement of *reldesemtiv* to a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS). We do not expect that the COVID-19 pandemic will affect 2020 objectives relating to this program.

- Received European Orphan Designation for *reldesemtiv* for the potential treatment of ALS from the European Medicines Agency (EMA).

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development of CK-3762601 (CK-601), a next-generation FSTA. We expect to continue the conduct of IND-enabling studies of CK-601 in 2020.

- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators.

- Continued independent research activities directed to our other muscle biology research programs.

Corporate

- Unveiled Cytokinetics' Vision 2025, "Leading with Science, Delivering for Patients," articulating the company's five-year key imperatives enabling Cytokinetics to be the leading muscle biology biopharmaceutical company that meaningfully improves the lives of patients with diseases of impaired muscle function through access to novel medicines arising from our research.

- Joined with 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.

- Awarded Cytokinetics Communications Fellowship Grants to patient advocacy organizations serving the heart failure, HCM, ALS and SMA communities to support increased capacity in communications, awareness building and community engagement.

- Entered into agreements with Astellas, which, taken together, amend and restate our research, development and commercialization collaboration agreement with Astellas in follow up to the previously disclosed agreement in principle which now provide, amongst other terms, that:

    - Cytokinetics has exclusive control and responsibility for the development and commercialization of *reldesemtiv*, CK-601 and other fast skeletal regulatory activator (FSRA) compounds. Astellas agreed to pay certain costs which may be incurred in connection with Cytokinetics' potential Phase 3 clinical trial of *reldesemtiv* in ALS. Astellas has agreed to non-cash contributions to Cytokinetics including the transfer of its inventories of active pharmaceutical ingredient of *reldesemtiv* and CK-601 and the continued conduct of ongoing stability studies at its cost. Cytokinetics will pay Astellas a low- to mid- single digit royalty on sales of *reldesemtiv* in certain countries.

    - Astellas extended the joint research program at Cytokinetics through 2020, with a minimum of fifteen (15) research FTE's being supported by Astellas, and has exclusive rights to co-develop and commercialize skeletal sarcomere activators (other than FSRA compounds) in all indications, subject to certain Cytokinetics' development and commercialization rights; Cytokinetics may co-promote and conduct certain commercial activities in the U.S., Canada and/or Europe.

Financials

Revenues for the first quarter of 2020 decreased to $3.8 million from $8.5 million for the first quarter of 2019, primarily due to decreased research and development revenue from our collaborations with Astellas and Amgen.

Research and development expenses for the first quarter 2020 decreased to $21.7 million from $23.5 million for the first quarter of 2019. The changes were primarily due to the completion of clinical studies for *reldesemtiv* in 2019 offset by an increase in clinical development activities for our cardiac muscle inhibitor programs.

General and administrative expenses for the first quarter of 2020 increased to $12.4 million from $9.4 million for the first quarter in 2019, due primarily to personnel related costs including stock-based compensation and outside services.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first quarter 2020 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 +1 (706) 679-3078 (international) and typing in the passcode 9063637.

An archived replay of the webcast will be available via Cytokinetics' website until May 20, 2020. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or +1 (404) 537-3406 (international) and typing in the passcode 9063637 from May 6, 2020 at 7:30 PM Eastern Time until May 20, 2020.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and next-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. *Omecamtiv mecarbil* is the subject of an international 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 developing *reldesemtiv,* a fast skeletal muscle troponin activator (FSTA) for the potential treatment of ALS and other neuromuscular indications following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is considering potential advancement of *reldesemtiv* to Phase 3 pending ongoing regulatory interactions. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to research, develop and commercialize other novel mechanism skeletal sarcomere activators (not including FSTAs). 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 (HCM). Cytokinetics is conducting REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. 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 related to the potential impact of the COVID-19 pandemic on our research and development activities and business operations, including our anticipated cash expenditures during the 2020 calendar year, statements relating to Cytokinetics' and its partners' research and development and commercial readiness activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of clinical trials, Cytokinetics' ability to ensure commercial readiness and develop co-promotion plans in collaboration with Amgen; the significance and utility of pre-clinical study and clinical trial results; planned interactions with regulatory authorities and the outcomes of such interactions, including discussions in preparation for a potential Phase 3 clinical trial and registration program for *reldesemtiv* in patients with ALS; the expected timing of events and milestones; 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 decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; 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, 2020	**March 31, 2019**
Revenues:		
Research and development revenues	$ 3,825	$ 8,464
Total revenues	3,825	8,464
Operating expenses:		
Research and development	21,738	23,545
General and administrative	12,449	9,437
Total operating expenses	34,187	32,982
Operating loss	(30,362)	(24,518)
Interest expense	(4,077)	(1,170)
Non-cash interest expense on liability related to the sale of future royalties	(5,689)	(4,819)
Interest and other income	723	1,141
Net loss	$ (39,405)	$ (29,366)

Net loss per share — basic and diluted	$ (0.66)	$ (0.54)
Weighted-average number of shares used in computing net loss per share — basic and diluted	59,270	54,821

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and short term investments	$ 220,706	$ 225,112
Other current assets	5,232	8,640
Total current assets	225,938	233,752
Long-term investments	16,510	42,650
Property and equipment, net	5,162	4,530
Operating lease right-of-use assets and other assets	8,972	8,882
Total assets	$ 256,582	$ 289,814
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 13,204	$ 20,283
Short-term lease liability	5,030	4,616
Other current liabilities	2,507	1,124
Total current liabilities	20,741	26,023
Term loan, net	45,340	45,052
Convertible notes, net	85,455	84,205
Liability related to the sale of future royalties, net	148,983	143,276
Long-term lease liability	1,774	2,195
Total liabilities	302,293	300,751
Commitments and contingencies		
Stockholders' deficit:		
Common stock	59	59
Additional paid-in capital	857,038	853,341
Accumulated other comprehensive income	1,613	679
Accumulated deficit	(904,421)	(865,016)
Total stockholders' deficit	(45,711)	(10,937)
Total liabilities and stockholders' deficit	$ 256,582	$ 289,814

Cytokinetics

Source: Cytokinetics, Incorporated