



Cytokinetics®

Cytokinetics Reports First Quarter 2024 Financial Results

May 8, 2024 8:00 PM EDT

Primary Results and Two Additional Analyses from SEQUOIA-HCM to be Presented in a Late-Breaking Clinical Trial Session at the European Society of Cardiology Heart Failure 2024 Congress

Opened Enrollment to CEDAR-HCM, a Clinical Trial of Aficamten in a Pediatric Population with Obstructive HCM

Announced Topline Data from the Phase 1 Study of CK-586; Phase 2 Clinical Trial to Begin in Q4 2024

SOUTH SAN FRANCISCO, Calif., May 08, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the first quarter of 2024. Net loss for the first quarter was \$135.6 million, or \$1.33 per share, compared to net loss for the first quarter of 2023 of \$131.3 million, or \$1.38 per share. Cash, cash equivalents and investments totaled \$634.3 million at March 31, 2024.

"In the first quarter, we advanced our muscle-biology portfolio anchored by the broad development program of *aficamten*. In parallel with our preparation of regulatory submissions in multiple geographies alongside executing on our go-to-market strategies, we also furthered ongoing clinical trials, FOREST-HCM, MAPLE-HCM and ACACIA-HCM, and opened enrollment to a fourth clinical trial of *aficamten*, CEDAR-HCM, a clinical trial in pediatric patients with obstructive HCM, another underserved cohort of patients with HCM," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "At the same time, we progressed CK-586 towards a Phase 2 clinical trial expected to begin later this year. We believe that our cohesive biology anchored in cardiac myosin positions the company well to fulfill our mission to deliver important medicines and increase shareholder value as will be further enabled by solid financials, access to diversified capital and executing on capital efficient Business and Corporate Development plans."

Q1 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Announced three late-breaking clinical trial presentations relating to SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction Impact of **A**ficamten in **H**CM), at the European Society of Cardiology Heart Failure 2024 Congress on May 13, 2024 in Lisbon, Portugal.
- Participated in two meetings with the U.S. Food and Drug Administration (FDA) related to our New Drug Application (NDA) for *aficamten*, and continued activities supportive of our plan to submit the NDA in Q3 2024. Readied for a Type B meeting with FDA scheduled to occur in Q2 2024 to discuss key data that inform safety monitoring and risk minimization strategies for *aficamten*.
- Continued preparing our Marketing Authorization Application (MAA) for *aficamten*, which we expect to submit to the European Medicines Agency (EMA) in Q4 2024.
- Continued commercial readiness activities for *aficamten* including refining our market development campaign and product positioning as well as initiating the design and build of our patient support services program. Completed profiling HCM treatment programs, finalized our Payor Clinical Value Proposition and began development of our Payer Clinical Value Deck.
- Presented additional data from FOREST-HCM (**F**ollow-up, **O**pen-Label, **R**esearch **E**valuation of **S**ustained **T**reatment with **A**ficamten in **H**CM) in April at the American College of Cardiology 73rd Annual Scientific Session demonstrating that treatment with *aficamten* for 48 weeks was associated with improvements in clinical efficacy endpoints, New York Heart Association (NYHA) Functional Class and cardiac biomarkers, structure and function, and was well-tolerated.
- Opened enrollment to CEDAR-HCM (**C**linical **E**valuation of **D**osing with **A**ficamten to **R**educe **O**bstruction in a Pediatric Population in **H**CM), a clinical trial of *aficamten* in a pediatric population with symptomatic obstructive HCM.
- Continued enrolling patients in MAPLE-HCM (**M**etoprolol vs **A**ficamten in **P**atients with **L**VOT Obstruction on **E**xercise Capacity in **H**CM), the Phase 3 clinical trial comparing *aficamten* as monotherapy to *metoprolol* as monotherapy in patients with symptomatic obstructive HCM. Enrollment is expected to be completed in Q3 2024.
- Continued enrolling patients in ACACIA-HCM (**A**ssessment **C**omparing **A**ficamten to **P**lacebo on **C**ardiac **E**ndpoints **I**n **A**dults with **N**on-**O**bstructive **H**CM), the pivotal Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM. We expect to continue enrollment throughout 2024.
- Published the following manuscripts:
 - "Exercise Capacity in Patients with Obstructive Hypertrophic Cardiomyopathy: SEQUOIA-HCM Baseline Characteristics and Study Design" in the *Journal of the American College of Cardiology: Heart Failure*.

- “Efficacy and Safety of *Aficamten* in Symptomatic Non-Obstructive Hypertrophic Cardiomyopathy: Results From the REDWOOD-HCM Trial, Cohort 4” in the *Journal of Cardiac Failure*.

omecamtiv mecarbil (cardiac myosin activator)

- Withdrew the Marketing Authorization Application (MAA) from the European Medicines Agency (EMA) for *omecamtiv mecarbil* based on feedback from the Committee for Medicinal Products for Human Use (CHMP) indicating that the Committee will not be able to conclude that the benefits outweigh the risks on the basis of the results from GALACTIC-HF alone.

CK-4021586 (CK-586, cardiac myosin inhibitor)

- Announced topline data from the Phase 1 study of CK-586. The data support progression to a Phase 2 clinical trial in patients with heart failure with preserved ejection fraction (HFpEF) which we expect to start in Q4 2024.

CK-3828136 (CK-136, cardiac troponin activator)

- Completed the Phase 1 study of CK-136 and began data analyses.

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development and research activities directed to additional muscle biology focused programs. We expect to initiate clinical development with another muscle directed compound later this year.

Corporate

- Announced the appointment of Sung Lee to serve as the Company's Executive Vice President, Chief Financial Officer effective as of May 8, 2024.
- Released 2023 Corporate Responsibility Report outlining the Company's commitment and activities related to social and environmental responsibility, ethics and governance and patient and community engagement.
- Awarded Cytokinetics Communications Fellowship Grants to patient advocacy organizations serving the HCM, heart failure and amyotrophic lateral sclerosis (ALS) communities to support increased capacity in communications, awareness building and community engagement.
- Announced the launch of ENACT: Empower, Navigate, Activate for Clinical Trials, a joint initiative with The Mended Hearts, Inc. and WomenHeart: The National Coalition for Women with Heart Disease, to champion greater awareness and engagement in cardiovascular clinical trials by reducing barriers, increasing support and empowering patients in groups historically underrepresented in clinical research.

Financials

Revenues for the first quarter 2024 were \$0.8 million compared to \$4.6 million for the corresponding period in 2023. The decrease in revenues was primarily due to milestone revenue of \$2.5 million received from Ji Xing Pharmaceuticals for the start of ACACIA-HCM and higher collaboration revenues in 2023.

Research and development expenses for the first quarter 2024 increased to \$81.6 million compared to \$79.4 million for the same period in 2023, due to spending for our clinical development activities for our cardiac myosin inhibitor programs.

General and administrative expenses for the first quarter 2024 decreased to \$45.5 million from \$49.7 million for the same period in 2023 due to lower outside spending for pre-commercial launch activities.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first quarter 2024 results on a conference call today at 4:30 PM Eastern Time. The conference call will be simultaneously webcast and can be accessed from the Investors & Media section of Cytokinetics' website at www.cytokinetics.com. The live audio of the conference call can also be accessed by telephone by registering in advance at the following link: [Cytokinetics Q1 2024 Earnings Conference Call](#). Upon registration, participants will receive a dial-in number and a unique passcode to access the call. An archived replay of the webcast will be available via Cytokinetics' website for twelve months.

About Cytokinetics

Cytokinetics is a late-stage, specialty cardiovascular 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 cardiac muscle performance is compromised. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to impact myocardial muscle function and contractility. Cytokinetics is preparing for regulatory submissions for *aficamten*, its next-in-class cardiac myosin inhibitor, following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial in obstructive hypertrophic cardiomyopathy. *Aficamten* is also currently being evaluated in MAPLE-HCM, a Phase 3 clinical trial of *aficamten* as monotherapy compared to metoprolol as monotherapy in patients with obstructive HCM, ACACIA-HCM, a Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, CEDAR-HCM, a clinical trial of *aficamten* in a pediatric population with obstructive HCM, and FOREST-HCM, an open-label extension clinical study of *aficamten* in patients with HCM. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac muscle activator, in patients with heart failure. Additionally, Cytokinetics is developing CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten* for the potential treatment of HFpEF, and CK-136, a cardiac troponin activator for the potential treatment HFpEF and other types of heart failure, such as right

ventricular failure resulting from impaired cardiac contractility.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on [X](#), [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 not limited to, statements, express or implied, relating to our or our partners' research and development and commercial readiness activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of any of our clinical trials, or more specifically, our ability to file a new drug application for *aficamten* in the United States in the third quarter of 2024 or a marketing authorisation application for *aficamten* in the European Union in the fourth quarter of 2024, our ability to complete enrollment of MAPLE-HCM in the third quarter of 2024 and to commence a Phase 2 study of CK-586, if ever, the timing of interactions with FDA or any other regulatory authorities in connection to any of our drug candidates and the outcomes of such interactions; statements relating to the potential patient population who could benefit from *aficamten*, *omecamtiv mecarbil*, CK-586, CK-136 or any of our other drug candidates; statements relating to our ability to receive additional capital or other funding, including, but not limited to, our ability to meet any of the conditions relating to or to otherwise secure additional loan disbursements under any of our agreements with entities affiliated with Royalty Pharma or additional milestone payments from Ji Xing; statements relating to our operating expenses or cash utilization for the remainder of 2024, and statements relating to our cash balance at year-end 2024 or any other particular date or the amount of cash runway such cash balances represent at any particular time. 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; 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, particularly under the caption "Risk Factors" in Cytokinetics' Annual Report on Form 10-K for the year 2023. 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® and the CYTOKINETICS and C-shaped logo are registered trademarks of Cytokinetics in the U.S. and certain other countries.

Contact:

Cytokinetics
Diane Weiser
Senior Vice President, Corporate Affairs
(415) 290-7757

Cytokinetics, Incorporated Condensed Consolidated Balance Sheets (in thousands)

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and short term investments	\$ 618,961	\$ 614,824
Other current assets	19,743	13,227
Total current assets	<u>638,704</u>	<u>628,051</u>
Long-term investments	15,376	40,534
Property and equipment, net	68,018	68,748
Operating lease right-of-use assets	78,170	78,987
Other assets	7,814	7,996
Total assets	<u>\$ 808,082</u>	<u>\$ 824,316</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 53,090	\$ 64,148
Short-term operating lease liabilities	18,230	17,891
Current portion of long-term debt	11,520	10,080
Other current liabilities	6,015	10,559
Total current liabilities	<u>88,855</u>	<u>102,678</u>
Term loan, net	56,822	58,384
Convertible notes, net	549,790	548,989
Liabilities related to revenue participation right purchase agreements, net	390,219	379,975
Long-term operating lease liabilities	118,554	120,427
Other non-current liabilities	2	186
Total liabilities	<u>1,204,242</u>	<u>1,210,639</u>
Commitments and contingencies		
Stockholders' deficit:		

Common stock	105	102
Additional paid-in capital	1,852,155	1,725,823
Accumulated other comprehensive loss	(539)	(10)
Accumulated deficit	<u>(2,247,881)</u>	<u>(2,112,238)</u>
Total stockholders' deficit	<u>(396,160)</u>	<u>(386,323)</u>
Total liabilities and stockholders' deficit	\$ 808,082	\$ 824,316

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

	Three Months Ended	
	March 31, 2024	March 31, 2023
Revenues:		
Research and development revenues	\$ 835	\$ 2,113
Milestone revenues	—	2,500
Total revenues	<u>835</u>	<u>4,613</u>
Operating expenses:		
Research and development	81,570	79,421
General and administrative	45,500	49,665
Total operating expenses	<u>127,070</u>	<u>129,086</u>
Operating loss	(126,235)	(124,473)
Interest expense	(7,103)	(6,961)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(10,218)	(6,280)
Interest and other income, net	7,913	6,425
Net loss	\$ (135,643)	\$ (131,289)
Net loss per share — basic and diluted	\$ (1.33)	\$ (1.38)
Weighted-average number of shares used in computing net loss per share — basic and diluted	101,924	95,164



Source: Cytokinetics, Incorporated