Cytokinetics Reports Fourth Quarter 2023 Financial Results

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Topline Results from SEQUOIA-HCM Announced in December
Showed Statistically Significant and Clinically Meaningful Increase
in Primary Efficacy Endpoint and Improvements in All Secondary Endpoints

Company Plans to Submit New Drug Application for Aficamten to FDA in Q3 2024
and Marketing Authorization Application to EMA in Q4 2024

Primary Results from SEQUOIA-HCM Are Expected
to be Presented at an Upcoming Medical Conference in Q2 2024

Company Provides 2024 Financial Guidance; Approximately 2 Years of Cash Runway

SOUTH SAN FRANCISCO, Calif., Feb. 27, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the fourth quarter and full year 2023. Net loss for the fourth quarter was $136.9 million or $1.38 per share and the net loss for the year 2023 was $526.2 million or $5.45 per share. Net loss for the fourth quarter of 2022 was $137.4 million or $1.45 per share and net loss for the year 2022 was $389.0 million or $4.33 per share. Cash, cash equivalents and investments totaled $655.4 million on December 31, 2023. This cash balance does not include approximately $83 million in net proceeds generated in early 2024 from the sale of common stock through an at-the-market equity vehicle.

"We ended 2023 strong with positive results from SEQUOIA-HCM which now propel our company forward to the next stages of planning towards our specialty cardiology business model," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "As we prepare regulatory submissions for *aficamten,* we are executing on commercial readiness activities while also conducting Phase 3 clinical trials in patients with oHCM and nHCM which we believe may further generate evidence in support of our next-in-class objectives to reach a broader array of patients struggling with hypertrophic cardiomyopathy. With a strong balance sheet enabling ample cash runway and multiple levers to access capital, we are pleased to be turning the page onto the next chapter for Cytokinetics and all stakeholders."

Q4 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Announced positive results from SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A**ficamten* in **HCM**) in December demonstrating that treatment with *aficamten* significantly improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO_2) measured by cardiopulmonary exercise testing (CPET) by a least square mean difference (95% CI) of 1.74 (1.04 - 2.44) mL/kg/min (p=0.000002). Statistically significant (p<0.0001) and clinically meaningful improvements were also observed in all 10 prespecified secondary endpoints. *Aficamten* was well-tolerated with an adverse event profile comparable to placebo. There were no instances of worsening heart failure or treatment interruptions due to low left ventricular ejection fraction (LVEF).

- Presented new long-term data from FOREST-HCM (**F**ollow-up, **O**pen-Label, **R**esearch **E**valuation of **S**ustained **T**reatment with *Aficamten* in **HCM**) in January at CMR 2024 demonstrating that treatment with *aficamten* for 48 weeks resulted in favorable structural remodeling, improvements in cardiac function and stabilization of myocardial fibrosis.

- Convened meetings in February with the U.S. Food & Drug Administration (FDA) to discuss the topline results of SEQUOIA-HCM and prepare for the New Drug Application (NDA) submission.

- Engaged in commercial readiness activities for *aficamten* including market research with hypertrophic cardiomyopathy (HCM) patients and customer account profiling, and held initial conversations with specialty pharmacies and patient hub providers.

- Advanced profiling of HCM treatment programs, began development of payor clinical value proposition and continued support of medical education activities at medical conferences.

- Continued enrolling patients in MAPLE-HCM (**M**etoprolol vs ***A**ficamten* in **P**atients with **L**VOT Obstruction on **E**xercise Capacity in **HCM)**, the Phase 3 clinical trial comparing *aficamten* as monotherapy to *metoprolol* as monotherapy in patients with symptomatic obstructive HCM.

- Continued enrolling patients in ACACIA-HCM (**A**ssessment **C**omparing ***A**ficamten* to Placebo on **C**ardiac Endpoints **I**n **A**dults with Non-Obstructive **HCM**), the pivotal Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM.

- Published manuscript entitled "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*.

omecamtiv mecarbil (cardiac myosin activator)

- Received the Day 180 List of Outstanding Issues from the European Medicines Agency (EMA) regarding the Marketing Authorization Application (MAA) for *omecamtiv mecarbil* during Q4 2023, and submitted responses during Q1 2024.

- Received denial of our Formal Dispute Resolution Request (FDRR) to the Office of New Drugs of the FDA in connection to the Complete Response Letter (CRL) received in response to our NDA for *omecamtiv mecarbil*. FDA reaffirmed its decision in the CRL for *omecamtiv mecarbil* that GALACTIC-HF is not sufficiently persuasive to establish substantial evidence of effectiveness for reducing the risk of heart failure events and cardiovascular death in adults with chronic heart failure with reduced ejection fraction (HFrEF), in lieu of evidence from at least two adequate and well-controlled clinical investigations.

- Published manuscript entitled “Sex Differences in Heart Failure with Reduced Ejection Fraction in the GALACTIC-HF Trial” in the *Journal of the American College of Cardiology: Heart Failure*.

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

- Proceeded to multiple ascending dose (MAD) cohorts of the Phase 1 study of CK-586 in healthy participants.

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

- Proceeded to MAD cohorts of the Phase 1 study of CK-136 in healthy participants.

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Presented results from COURAGE-ALS (**C**linical **O**utcomes **U**sing ***R****eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS**) at the 34th International Symposium on ALS/MND showing that treatment with *reldesemtiv* for 24 weeks had no effect on the primary efficacy endpoint measure of change from baseline up to Week 24 in the ALS Functional Rating Scale Revised (ALSFRS-R) (joint rank test p=0.11).

Pre-Clinical Development and Ongoing Research

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

Corporate

- Raised $162.9 million, net, from the sale of common stock through an at-the-market (ATM) equity vehicle in Q4 2023, and approximately $83 million, net, in Q1 2024 as of February 26, 2024.

2024 Corporate Milestones

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Expect to present primary results from SEQUOIA-HCM at a medical conference in Q2 2024.

- Expect to submit a New Drug Application (NDA) to the FDA in Q3 2024 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in Q4 2024.

- Complete enrollment of MAPLE-HCM in Q3 2024.

- Continue enrollment of ACACIA-HCM in 2024.

- Continue advancing go-to-market strategies for *aficamten.*

omecamtiv mecarbil (cardiac myosin activator)

- Expect the Committee for Medicinal Products for Human Use (CHMP) to issue an opinion regarding the MAA for *omecamtiv mecarbil* in Q2 2024.

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

- Expect to share data from the Phase 1 study of CK-586 in Q2 2024.

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

- Expect to complete Phase 1 study of CK-136 in Q2 2024.

Financials

Revenues for the three months and year ended December 31, 2023 were $1.7 million and $7.5 million, respectively, compared to $2.0 million and $94.6 million in the corresponding periods of 2022. The decrease in revenues was primarily due to the recognition in 2022 of $87.0 million of deferred revenue for royalties on the net sales of products containing *mavacamten* as a result of the extinguishment of royalty obligations.

Research and development expenses for the three months and year ended December 31, 2023 increased to $85.0 million and $330.1 million, respectively, compared to $75.0 million and $240.8 million for the same periods in 2022, respectively, due primarily to spending on our cardiac myosin inhibitor programs.

General and administrative expenses for the three and twelve months ended December 31, 2023 decreased to $44.1 million and $173.6 million, respectively, from $54.0 million and $178.0 million for the same period in 2022 due to lower outside spending on commercial readiness activities offset by higher personnel related costs including stock-based compensation.

2024 Financial Guidance

The company today announced financial guidance for 2024. The company anticipates revenue will be in the range of $3 to $5 million, operating expenses will be in the range of $420 to 450 million, and net cash utilization will be approximately $390 to $420 million. Inclusive of approximately $83 million, net, raised in early 2024 through our ATM equity vehicle, our year end cash balance of $655.4 million, plus available long-term debt from Royalty Pharma, represents approximately two years of forward cash based on our projected 2024 operating expenses and net cash utilization.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth quarter 2023 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 Q4 2023 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 two ongoing Phase 3 clinical trials: MAPLE-HCM, evaluating *aficamten* as monotherapy compared to metoprolol as monotherapy in patients with obstructive HCM and ACACIA-HCM, evaluating *aficamten* in patients with non-obstructive 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 HFrEF 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 or a marketing authorisation application for *aficamten* in the European Union, our ability to obtain approval of our marketing authorisation application for *omecamtiv mecarbil* in the E.U., 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*, *aficamten*, 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.

Contact:
Cytokinetics
Diane Weiser
Senior Vice President, Corporate Communications, Investor Relations
(415) 290-7757

Cytokinetics, Incorporated

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and short-term investments	$ 614,824	$ 782,577
Other current assets	13,227	12,609
Total current assets	628,051	795,186
Long-term investments	40,534	46,708
Property and equipment, net	68,748	80,453
Operating lease right-of-use assets	78,987	82,737
Other assets	7,996	9,691
Total assets	$ 824,316	$ 1,014,775
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 64,148	$ 69,707
Short-term lease liability	17,891	12,829
Current portion of long-term debt	10,080	958
Other current liabilities	10,559	1,123
Total current liabilities	102,678	84,617
Term loan, net	58,384	63,810
Convertible notes, net	548,989	545,808
Liabilities related to revenue participation right purchase agreements, net	379,975	300,501
Long-term operating lease liabilities	120,427	126,895
Other non-current liabilities	186	1,044
Total liabilities	1,210,639	1,122,675
Commitments and contingencies		
Stockholders' deficit:		
Common stock	102	94
Additional paid-in capital	1,725,823	1,481,590
Accumulated other comprehensive loss	(10)	(3,590)
Accumulated deficit	(2,112,238)	(1,585,994)
Total stockholders' deficit	(386,323)	(107,900)
Total liabilities and stockholders' deficit	$ 824,316	$ 1,014,775

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenues:				
Research and development revenues	$ 672	$ 1,957	$ 4,030	$ 6,588
Milestone revenues	1,000	—	3,500	1,000
Realization of revenue participation right purchase agreement	—	—	—	87,000
Total revenues	1,672	1,957	7,530	94,588
Operating expenses:				
Research and development	84,976	75,018	330,123	240,813
General and administrative	44,114	53,969	173,612	177,977
Total operating expenses	129,090	128,987	503,735	418,790
Operating loss	(127,418)	(127,030)	(496,205)	(324,202)
Interest expense	(7,164)	(7,057)	(28,306)	(19,414)
Loss on settlement of debt	—	—	—	(24,939)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(9,900)	(9,212)	(29,362)	(31,742)
Interest and other income, net	7,586	5,919	27,629	11,342
Net loss before income taxes	(136,896)	(137,380)	(526,244)	(388,955)
Income tax benefit	—	—	—	—
Net loss	$ (136,896)	$ (137,380)	$ (526,244)	$ (388,955)
Net loss per share — basic and diluted	$ (1.38)	$ (1.45)	$ (5.45)	$ (4.33)

Weighted-average shares in net loss per share — basic and diluted	99,067	94,681	96,524	89,825

Source: Cytokinetics, Incorporated