Cytokinetics Reports Third Quarter 2024 Financial Results

November 6, 2024 9:00 PM EST

Rolling Submission of NDA for Aficamten Completed and Submitted to FDA in Q3

COMET-HF, Confirmatory Phase 3 Clinical Trial of Omecamtiv Mecarbil, and AMBER-HFpEF, Phase 2 Clinical Trial of CK-586, Expected to Begin in Q4

Plan to Advance CK-089, Fast Skeletal Muscle Troponin Activator, into First-In-Human Study in Q4 2024

~$1.3 Billion in Cash, Cash Equivalents and Investments as of September 30, 2024

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported a management update and financial results for the third quarter of 2024.

"The progress we made in the third quarter reflects disciplined planning and prudent capital deployment throughout 2024 that has laid the foundation for our specialty cardiology business. The submission of the NDA for *aficamten* is an important regulatory milestone that brings us one step closer to the potential approval and commercial launch of *aficamten* in the United States alongside the scale-up of global workstreams," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "While *aficamten* remains our top priority, our development pipeline is advancing and expanding with later-stage cardiovascular drug candidates as well as an earlier potential medicine focused to neuromuscular indications. With more than $1 billion on the balance sheet and access to additional long-term capital, we are well-funded and well-prepared to sustain momentum into 2025 with objective to deliver on the promise of our science for patients and to deliver meaningfully increased value to shareholders."

Q3 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Completed the rolling submission of the New Drug Application (NDA) for *aficamten* and submitted the NDA for the treatment of obstructive hypertrophic cardiomyopathy (HCM).
- Presented additional results from SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A**ficamten* in **H**CM) at the European Society of Cardiology 2024 Congress, Heart Failure Society of America (HFSA) Annual Scientific Meeting and Hypertrophic Cardiomyopathy Medical Society Scientific Sessions. Collectively, the data showed that treatment with *aficamten* in SEQUOIA-HCM was associated with improvements in cardiac structure and function, heart failure symptoms, cardiac biomarkers, and multiple assessments of clinical significance to cardiologists.
- Presented additional data related to the longer-term use of *aficamten* at the European Society of Cardiology 2024 Congress from an integrated safety analysis of three clinical studies of *aficamten* that reinforced the robust safety profile of *aficamten*. Additionally, an analysis from FOREST-HCM (**F**ollow-up, **O**pen-Label, **R**esearch **E**valuation of **S**ustained **T**reatment with *Aficamten* in **HCM**,) the open label extension clinical study of *aficamten* in patients with HCM, demonstrated that patients who attempted withdrawal of standard of care medications did not experience negative impacts on the efficacy or safety of *aficamten*.
- Continued U.S. commercial readiness activities for *aficamten* including selecting third-party external partners for our bespoke patient support programs and distribution strategy, refining our sales force strategy, engaging with payers through pre-approval information exchange and developing our U.S. value dossier. Launched "HCM Beyond the Heart," an unbranded disease awareness campaign for healthcare professionals highlighting the holistic burden of HCM.
- Continued preparing a Marketing Authorization Application (MAA) for *aficamten*, expected to be submitted to the European Medicines Agency (EMA) and National Agencies in the EU in Q4 2024.
- Continued European commercial readiness activities including designing the distribution model, refining regulatory and labeling strategies, establishing country launch sequencing, and engaging with European key opinion leaders. Established initial go-to-market plans for Germany, the first potential European market launch.
- Corxel (formerly Ji Xing Pharmaceuticals) completed submission of the NDA for *aficamten* to treat obstructive HCM, which was accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China.
- Completed enrollment 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. We expect to report topline results from MAPLE-HCM in 1H 2025.
- 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. We expect to complete enrollment in ACACIA-HCM in 2025.

- Continued patient enrollment in CEDAR-HCM (**C**linical **E**valuation of **D**osing with ***A**ficamten* to **R**educe Obstruction in a Pediatric Population in **HCM**), a clinical trial of *aficamten* in a pediatric population with symptomatic obstructive HCM. We expect to continue enrollment in CEDAR-HCM throughout 2024.

- Published the following manuscripts:

    - "Dosing and Safety Profile of *Aficamten* in Symptomatic Obstructive Hypertrophic Cardiomyopathy: Results From SEQUOIA-HCM" in the *Journal of the American Heart Association*
    - "Effect of *Aficamten* on Cardiac Structure and Function in Obstructive Hypertrophic Cardiomyopathy: SEQUOIA-HCM CMR Substudy" in the *Journal of the American College of Cardiology*
    - "Impact of *Aficamten* on Echocardiographic Cardiac Structure and Function in Symptomatic Obstructive Hypertrophic Cardiomyopathy" in the *Journal of the American College of Cardiology*
    - "Effect of *Aficamten* on Health Status Outcomes in Obstructive Hypertrophic Cardiomyopathy: Results from SEQUOIA-HCM" in the *Journal of the American College of Cardiology*
    - "Cardiac Biomarkers and Effects of *Aficamten* in Obstructive Hypertrophic Cardiomyopathy: the SEQUOIA-HCM Trial" in the *European Heart Journal*
    - *"Aficamten* and Cardiopulmonary Exercise Test Performance A Substudy of the SEQUOIA-HCM Randomized Clinical Trial" in the *Journal of the American Medical Association Cardiology*
    - "Impact of *Aficamten* on Disease and Symptom Burden in Obstructive Hypertrophic Cardiomyopathy: Results from SEQUOIA-HCM" in the *Journal of the American College of Cardiology*
    - *"Aficamten* , a Novel and Selective Small-molecule Cardiac Myosin Inhibitor for the Treatment of Hypertrophic Cardiomyopathy" in *Nature Cardiovascular Research*
    - "Pharmacokinetics, Excretion, and Metabolism of [^{14}C] *Aficamten* Following Single Oral Dose Administration to Rats" in *Xenobiotica*
    - *"In Vitro* and *In Vivo* Pharmacokinetic Preclinical Characterization of *Aficamten*, a Small Molecule Cardiac Myosin Inhibitor" in *Xenobiotica*
    - "Pharmacokinetics, Disposition and Biotransformation of the Cardiac Myosin Inhibitor *Aficamten* in Humans" in *Pharmacology Research and Perspectives*
    - "Qualitative Interview Study of Patient-reported Symptoms, Impacts and Treatment Goals of Patients With Obstructive Hypertrophic Cardiomyopathy" in *British Medical Journal: Open Heart*
    - "An Evidence Review and Gap Analysis for Obstructive Hypertrophic Cardiomyopathy" in *BMC Cardiovascular Disorders*
    - "Differences in Healthcare Resource Use and Cost by Pharmacotherapy Among Patients with Symptomatic Obstructive Hypertrophic Cardiomyopathy: Real-World Analysis of Claims Data" in the *American Journal of Cardiovascular Drugs*

omecamtiv mecarbil (cardiac myosin activator)

- Conducted start-up activities for COMET-HF (**C**onfirmation of ***O**mecamtiv **M**ecarbil* **E**fficacy **T**rial in **H**eart **F**ailure), a confirmatory Phase 3 multi-center, double-blind, randomized, placebo-controlled trial to assess the efficacy and safety of *omecamtiv mecarbil* in patients with symptomatic heart failure with severely reduced ejection fraction, expected to start in Q4 2024.

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

- Presented data from the Phase 1 study of CK-586 at the American College of Clinical Pharmacology (ACCP) Annual Meeting. The study met its primary and secondary objectives to assess the safety, tolerability and pharmacokinetics of single and multiple oral doses of CK-586.

- Conducted start-up activities for AMBER-HFpEF (**A**ssessment of CK-586 in a **M**ulti-Center, **B**linded **E**valuation of Safety and Tolerability **R**esults in **HFpEF**), a Phase 2 randomized, placebo-controlled, double-blind, multi-center, dose-finding clinical trial in patients with symptomatic heart failure with preserved ejection fraction (HFpEF) with left ventricular ejection fraction (LVEF) ≥ 60%, expected to start in Q4 2024.

Pre-Clinical Development and Ongoing Research

- Expect to advance CK-4015089 (CK-089), a fast skeletal muscle troponin activator (FSTA) with potential therapeutic application to a specific type of muscular dystrophy, into a first-in-human Phase 1 study in Q4 2024.

- Continued pre-clinical development and research activities directed to additional muscle biology focused programs.

Corporate

- Announced a call for proposals for the Cytokinetics Corporate Giving Program. The program provides charitable donations to eligible non-profit organizations in the United States to support diversity in science education, equitable healthcare initiatives for cardiovascular disease and certain essential services for local and at-risk communities.

- Announced a call for proposals for the seventh annual Cytokinetics Communications Grant Program. The program awards five grants to patient advocacy organizations serving the HCM or heart failure communities and is intended to support increased capacity in communications and outreach.

Third Quarter 2024 Financial Results

Cash, Cash Equivalents and Investments

- As of September 30, 2024, the company had approximately $1.3 billion in cash, cash equivalents and investments compared to $1.4 billion at June 30, 2024. Cash, cash equivalents and investments declined by approximately $81 million during the third quarter of 2024.

Revenues

- Total revenues for the third quarter of 2024 were $0.5 million compared to $0.4 million for the same period in 2023.

Research and Development (R&D) Expenses

- R&D expenses for the third quarter of 2024 were $84.6 million which included $11.4 million of non-cash stock-based compensation expense, compared to $82.5 million for the same period in 2023 which included $8.2 million of non-cash stock-based compensation expense. The increase was primarily driven by higher personnel related expenses to progress our pipeline partially offset by the completion of clinical trials.

General and Administrative (G&A) Expenses

- G&A expenses for the third quarter of 2024 were $56.7 million which included $13.9 million of non-cash stock-based compensation expense, compared to $40.1 million for the same period in 2023 which included $10.5 million in non-cash stock-based compensation expense. The increase was primarily driven by investments toward commercial readiness and personnel related expenses.

Net Income (Loss)

- Net loss for the third quarter of 2024 was $160.5 million, or $(1.36) per share, basic and diluted, compared to a net loss of $129.4 million, or $(1.35) per share, basic and diluted, for the same period in 2023.

2024 Financial Guidance

The company is reiterating its full year 2024 financial guidance:

	2024 Guidance
GAAP Operating Expense[1]	$555m to $575m
Non-cash Expense[2] Included in GAAP Operating Expense	$110m to $105m
Non-GAAP Operating Expense[3]	$445m to $470m
Net Cash Utilization[4]	$400m to $420m

The financial guidance does not include the effect of GAAP adjustments as may be caused by events that occur subsequent to publication of this guidance including but not limited to Business Development activities.

[1]GAAP operating expense comprised of R&D and G&A expenses.

[2]Non-cash operating expense comprised of stock-based compensation and depreciation.

[3]Non-GAAP operating expense comprised of R&D and G&A expenses but excludes non-cash operating expense.

[4]Net cash utilization is a non-GAAP financial measure that we define as our ending 2023 cash, cash equivalents, and investments balance of $655 million plus the net proceeds of $707 million received from the sale of common stock (through the at-the-market facility, public offerings, and stock purchase agreement with Royalty Pharma) plus proceeds of $200 million received from the structured financing agreement with Royalty Pharma announced on May 22, 2024 minus our projected ending 2024 cash, cash equivalents, and investments balance of between $1,142 million and $1,162 million.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third 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 Q3 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 muscle biology-directed drug candidates 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. Following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial evaluating *aficamten,* a next-in-class cardiac myosin inhibitor, in obstructive hypertrophic cardiomyopathy (HCM), Cytokinetics submitted an NDA for *aficamten* to the U.S. Food & Drug Administration and is progressing regulatory submissions for *aficamten* for the treatment of obstructive HCM in Europe. *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 with severely reduced ejection fraction (HFrEF), CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten* for the potential treatment of heart failure with preserved ejection fraction (HFpEF), and CK-089, a fast skeletal muscle troponin activator (FSTA) for the potential treatment of a specific type of muscular dystrophy.

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 submit a marketing authorisation application for *aficamten* in the European Union in the fourth quarter of 2024, our ability to complete enrollment of ACACIA-HCM in 2025, our ability to start COMET-HF or AMBER-HFpEF in the fourth quarter of 2024, and to commence a Phase 1 study of CK-089 in

the fourth quarter of 2024, 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-089 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 Corxel (f/k/a 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 Affairs
(415) 290-7757

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and short term investments	$ 1,011,692	$ 614,824
Other current assets	6,909	13,227
Total current assets	1,018,601	628,051
Long-term investments	269,168	40,534
Property and equipment, net	64,222	68,748
Operating lease right-of-use assets	76,344	78,987
Other assets	7,725	7,996
Total assets	$ 1,436,060	$ 824,316
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 61,407	$ 64,148
Short-term operating lease liabilities	18,856	17,891
Current portion of long-term debt	11,520	10,080
Derivative liabilities measured at fair value	12,500	—
Other current liabilities	5,529	10,559
Total current liabilities	109,812	102,678
Term loan, net	93,017	58,384
Convertible notes, net	551,481	548,989
Liabilities related to revenue participation right purchase agreements, net	448,509	379,975
Long-term operating lease liabilities	114,752	120,427
Liabilities related to RPI Transactions measured at fair value	132,400	—
Other non-current liabilities	—	186
Total liabilities	1,449,971	1,210,639
Commitments and contingencies		
Stockholders' deficit		
Common stock	118	102
Additional paid-in capital	2,532,328	1,725,823
Accumulated other comprehensive income (loss)	5,387	(10)
Accumulated deficit	(2,551,744)	(2,112,238)
Total stockholders' deficit	(13,911)	(386,323)
Total liabilities and stockholders' deficit	$ 1,436,060	$ 824,316

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

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Revenues:				
Research and development revenues	$ 463	$ 378	$ 1,547	$ 3,358
Milestone revenues	—	—	—	2,500
Total revenues	463	378	1,547	5,858
Operating expenses:				
Research and development	84,612	82,532	245,779	245,147
General and administrative	56,652	40,111	152,976	129,498
Total operating expenses	141,264	122,643	398,755	374,645
Operating loss	(140,801)	(122,265)	(397,208)	(368,787)
Interest expense	(8,928)	(7,136)	(28,763)	(21,142)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(13,370)	(6,860)	(35,155)	(19,462)
Interest and other income, net	17,054	6,839	36,520	20,043
Change in fair value of derivative liabilities	700	—	100	—
Change in fair value of liabilities related to RPI Transactions	(15,200)	—	(15,000)	—
Net loss	$ (160,545)	$ (129,422)	$ (439,506)	$ (389,348)
Net loss per share — basic and diluted	$ (1.36)	$ (1.35)	$ (4.00)	$ (4.07)
Weighted-average number of shares used in computing net loss per share — basic and diluted	117,685	96,071	109,932	95,666

Source: Cytokinetics, Incorporated