Cytokinetics Reports Second Quarter 2024 Financial Results

August 8, 2024 8:00 PM EDT

Type B Meeting Held with FDA Related to Potential Risk Mitigation Strategies for Aficamten; Company Has Initiated Rolling NDA Submission

FDA Cleared Protocol Amendment for FOREST-HCM Reducing Frequency of Echocardiographic Monitoring Required During Maintenance Treatment

~$1.4 Billion in Cash, Cash Equivalents and Investments as of June 30, 2024

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2024 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported a management update and financial results for the second quarter of 2024.

"Cytokinetics made substantial progress during the second quarter across our pipeline and aligned to near-term goals as well as our longer-term vision to build a sustainable specialty cardiology business. In May, we secured contingent access to more than $1 billion in funding to support the potential global launch of *aficamten* as well as to continue conduct of label-expanding clinical trials of *aficamten* worldwide and to advance our later-stage pipeline including *omecamtiv mecarbil* and CK-586," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "These three programs, anchored in our pioneering science of myosin modulation, provide synergistic opportunities in adjacent specialty cardiology indications that we believe will unlock shareholder value while making good on our promise to patients."

Q2 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Presented primary results from SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A**ficamten* in **HCM)** at the European Society of Cardiology Heart Failure 2024 Congress, demonstrating statistically significant and clinically meaningful improvements in the primary efficacy endpoint of peak oxygen uptake (pVO_2) and all secondary endpoints with results consistent across all prespecified subgroups. Additional results presented from SEQUOIA-HCM showed that treatment with *aficamten* resulted in predictable dosing with no dose interruptions or associated heart failure due to left ventricular ejection fraction (LVEF) <50% and improved a novel integrated exercise performance metric. Improvements in pVO_2 were shown to be highly correlated with improvements in cardiac structure and function.

- Participated in a Type B meeting with the U.S. Food and Drug Administration (FDA) to discuss potential strategies related to safety monitoring and risk mitigation for *aficamten* and included a review of how results from SEQUOIA-HCM and intrinsic properties of *aficamten* may inform risk mitigation. The Company expects to propose a distinct risk mitigation approach specific to *aficamten* with the New Drug Application (NDA) for which the rolling submission is underway. The Company is on track to complete the rolling NDA submission for *aficamten* in Q3 2024.

- The FDA recently cleared a protocol amendment for FOREST-HCM (**F**ollow-up, **O**pen-Label, **R**esearch **E**valuation of **S**ustained **T**reatment with *Aficamten* in **HCM**) reducing the frequency of echocardiographic monitoring for patients with obstructive HCM to every 6 months during maintenance treatment for patients with LVEF >55%.

- Participated in meetings with the European Medicines Agency (EMA) and National Agencies in the EU during which the company confirmed plans to submit a Marketing Authorization Application (MAA) for *aficamten* in Q4 2024 and discussed the content of the expected filing.

- Coordinated with Ji Xing Pharmaceuticals to support the planned submission of an NDA for *aficamten* to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China in 2H 2024.

- Continued commercial readiness activities for *aficamten* including refining our market development campaign, designing the treatment experience inclusive of distribution and patient support programs, advancing key market research, and finalizing the structure for the field-based sales team. Began pre-approval information exchange activities to proactively share health care economic and scientific information with payers and initiated development of U.S. and global value dossiers.

- Initiated a Phase 1 study evaluating the pharmacokinetics, safety and tolerability of *aficamten* in healthy Japanese and Caucasian participants. We expect to continue enrollment throughout 2024.

- Opened enrollment to 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.

- 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. We expect to complete enrollment in MAPLE-HCM in Q3 2024.

- 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 continue enrollment in ACACIA-HCM throughout 2024 and complete enrollment in 2025.

- Published the following manuscripts:
  - "*Aficamten* for Symptomatic Obstructive Hypertrophic Cardiomyopathy" in the *New England Journal of Medicine.*
  - "The Prognostic Value of Peak Oxygen Uptake in Obstructive Hypertrophic Cardiomyopathy: A Literature Review to Inform Economic Model Development" in the *Journal of Medical Economics*.
  - "Safety and Efficacy of *Aficamten* in Patients with Non-Obstructive Hypertrophic Cardiomyopathy: A 36-Week Analysis from FOREST-HCM" in the *European Journal of Heart Failure.*
  - "*Aficamten* is a Small-Molecule Cardiac Myosin Inhibitor Designed to Treat Hypertrophic Cardiomyopathy" in *Nature Cardiovascular Research.*
  - "Dosing and Safety Profile of *Aficamten* in Symptomatic Obstructive Hypertrophic Cardiomyopathy: Results From SEQUOIA-HCM" in the *Journal of the American Heart Association.*

omecamtiv mecarbil (cardiac myosin activator)

- Participated in a Type C meeting with the FDA that addressed design features of a confirmatory Phase 3 clinical trial of *omecamtiv mecarbil* with discussion of patient population, endpoints, as well as several additional pragmatic elements related to clinical trial conduct.
- Advanced preparations to conduct a confirmatory Phase 3 clinical trial of *omecamtiv mecarbil* in patients with heart failure with reduced ejection fraction (HFrEF) expected to start in Q4 2024.

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

- Announced topline data from the Phase 1 study of CK-586 and expect to present primary data in Q3 2024. Data from the Phase 1 study support progression to a Phase 2a 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 analyses of the Phase 1 study of CK-136, which met its primary objective to assess the safety, tolerability and pharmacokinetics of single and multiple doses of CK-136 in healthy participants. Due to the Company's strategic prioritization of its other clinical trial programs, further development of CK-136 has been discontinued.

Pre-Clinical Development and Ongoing Research

- Continued pre-clinical development and research activities directed to additional muscle biology focused programs. In 2024, we expect to initiate Phase 1 clinical development of a fast skeletal troponin activator with potential therapeutic application to a specific type of muscular dystrophy.

Corporate

- Hosted the inaugural CLIMB Research Symposium: **C**ontemporary **L**andscapes **I**n **M**uscle **B**iology, a one-day research symposium that brought scientists, researchers and emerging professionals together to share innovative research in the field of muscle biology.

Second Quarter 2024 Financial Results

Cash, Cash Equivalents and Investments

As of June 30, 2024, the company had approximately $1.4 billion in cash, cash equivalents and investments compared to $634.3 million at March 31, 2024. In the second quarter, the company completed a public offering of 11,274,510 shares of its common stock which included the underwriters' exercise in full of their option to purchase additional shares, raising approximately $563.2 million in net proceeds, after deducting underwriting discounts and commissions. On May 22, 2024, the company entered into a strategic funding collaboration with Royalty Pharma totaling up to $575 million to support the commercialization of *aficamten* and to advance the company's expanding cardiovascular pipeline as the company advances its muscle biology-directed specialty cardiology business. The company received $250 million upon execution, including $100 million to fund a confirmatory Phase 3 trial of *omecamtiv mecarbil*, $50 million to fund a proof-of-concept Phase 2a clinical trial for CK-586, $50 million term loan to support the potential commercial launch of *aficamten* in obstructive HCM, and $50 million from the purchase of Cytokinetics' common stock in a private placement. Under the terms of the collaboration, the company, at its option, can borrow up to $175 million upon satisfaction of certain conditions and receive up to $150 million investment in a Phase 3 clinical trial of CK-586 subject to Royalty Pharma exercising its option to participate in the funding of such a trial in exchange for an additional revenue interest in the net sales of CK-586.

Revenues

- Total revenues for the second quarter of 2024 were $0.2 million compared to $0.9 million for the same period in 2023.

Research and Development (R&D) Expenses

- R&D expenses for the second quarter of 2024 were $79.6 million which included $11.5 million of non-cash stock-based compensation expense, compared to $83.2 million for the same period in 2023 which included $8.2 million of non-cash stock-based compensation expense. The decrease was primarily driven by the timing of clinical trial activities and wind down activities for COURAGE-ALS which ended in the first

quarter of 2023.

General and Administrative (G&A) Expenses

- G&A expenses for the second quarter of 2024 were $50.8 million which included $13.1 million of non-cash stock-based compensation expense, compared to $39.7 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 second quarter of 2024 was $143.3 million, or $(1.31) per share, basic and diluted, compared to a net loss of $128.6 million, or $(1.34) per share, basic and diluted, for the same period in 2023.

2024 Financial Guidance

The company is updating its full year 2024 financial guidance:

	Current Guidance	Previous Guidance
GAAP Operating Expense[1]	$555m to $575m	$535m to $555m
Non-cash Expense[2] Included in GAAP Operating Expense	$110m to $105m	$115m to $105m
Non-GAAP Operating Expense[3]	$445m to $470m	$420m to $450m
Net Cash Utilization[4]	$400m to $420m	$390m to $420m

The financial guidance does not include the effect of GAAP adjustments caused by events that may occur subsequent to the 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 second 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 Q2 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. 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 which were published in the *New England Journal of Medicine*. *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.

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, our ability to complete enrollment of ACACIA-HCM in 2025, our ability to start a new Phase 3 confirmatory trial of *omecamtiv mecarbil* in the fourth quarter of 2024, and to commence a Phase 2a 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.

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Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and short term investments	$ 1,056,775	$ 614,824
Other current assets	11,035	13,227
Total current assets	1,067,810	628,051
Long-term investments	305,361	40,534
Property and equipment, net	65,689	68,748
Operating lease right-of-use assets	77,249	78,987
Other assets	7,679	7,996
Total assets	$ 1,523,788	$ 824,316
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 49,283	$ 64,148
Short-term operating lease liabilities	18,507	17,891
Current portion of long-term debt	11,520	10,080
Derivative liabilities measured at fair value	13,200	—
Other current liabilities	10,267	10,559
Total current liabilities	102,777	102,678
Term loan, net	92,831	58,384
Convertible notes, net	550,600	548,989
Liabilities related to revenue participation right purchase agreements, net	435,112	379,975
Long-term operating lease liabilities	116,718	120,427
Liabilities related to RPI Transactions measured at fair value	117,200	—
Other non-current liabilities	—	186
Total liabilities	1,415,238	1,210,639
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	117	102
Additional paid-in capital	2,500,654	1,725,823
Accumulated other comprehensive loss	(1,022)	(10)
Accumulated deficit	(2,391,199)	(2,112,238)
Total stockholders' equity (deficit)	108,550	(386,323)
Total liabilities and stockholders' equity (deficit)	$ 1,523,788	$ 824,316

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

	Three Months Ended	
	June 30, 2024	June 30, 2023

Revenues:		
Research and development revenues	$ 249	$ 867
Milestone revenues	—	—
Total revenues	249	867
Operating expenses:		
Research and development	79,597	83,194
General and administrative	50,824	39,722
Total operating expenses	130,421	122,916
Operating loss	(130,172)	(122,049)
Interest expense	(12,732)	(7,045)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(11,567)	(6,322)
Interest and other income, net	11,553	6,779
Change in fair value of derivative liabilities	(600)	—
Change in fair value of liabilities related to RPI Transactions	200	—
Net loss	$ (143,318)	$ (128,637)
Net loss per share — basic and diluted	$ (1.31)	$ (1.34)
Weighted-average number of shares used in computing net loss per share — basic and diluted	109,240	95,755

Source: Cytokinetics, Incorporated