NEWS RELEASE

Cytokinetics Reports First Quarter 2025 Financial Results and Provides Business Update

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PDUFA Date for Aficamten in Obstructive HCM Extended by FDA to December 26, 2025

Topline Results from MAPLE-HCM Expected in May

Enrollment Completed in ACACIA-HCM; Topline Results Expected in 1H 2026

~$1.1 Billion in Cash, Cash Equivalents and Investments as of March 31, 2025

SOUTH SAN FRANCISCO, Calif., May 06, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported a management update and financial results for the first quarter of 2025.

“In the first quarter, we made progress towards commercial readiness and advanced our specialty cardiology pipeline,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “Recently, our PDUFA date for *aficamten* in obstructive HCM was extended by FDA to provide time to review a REMS submission made at the Agency’s request subsequent to the initial NDA filing acceptance. We remain confident in the distinct benefit-risk and pharmaceutic profile of *aficamten*, and our top priority is bringing this potential therapy to patients. This month, we also expect to report topline results from MAPLE-HCM, and we continue conduct of ACACIA-HCM, for which we have now completed enrollment of patients. With a strong balance sheet and prudent attention to capital deployment, we are well positioned to deliver across regulatory, clinical and commercial milestones.”

Q1 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- The U.S. Food & Drug Administration (FDA) extended the Prescription Drug User Fee Act (PDUFA) target action date for the New Drug Application (NDA) for *aficamten* for the treatment of patients with obstructive hypertrophic cardiomyopathy (HCM) to December 26, 2025. Following pre-NDA discussions with FDA in which safety and risk mitigation were discussed, Cytokinetics submitted

the NDA for *aficamten* in obstructive HCM without an accompanying REMS and the FDA accepted the NDA for filing. During the NDA review, the FDA requested that Cytokinetics submit a REMS consistent with the inherent characteristics of *aficamten*, which the company provided. The submission of a REMS has now been determined by FDA to be a Major Amendment to the NDA resulting in a standard three-month extension to the original PDUFA action date. No additional clinical data or studies have been requested of Cytokinetics by FDA.

- Completed a mid-cycle review meeting with FDA for the NDA for *aficamten*. The FDA indicated that it does not plan to convene an Advisory Committee meeting to review the NDA for *aficamten*. We expect to participate in a late-cycle meeting with the FDA in June.
- Received Day 120 List of Questions from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) regarding the Marketing Authorization Application (MAA) for *aficamten* for the treatment of obstructive HCM and have begun to prepare responses.
- Continued to support the review of the NDA for *aficamten* for obstructive HCM by the Center for Drug Evaluation (CDE) in China.
- Advanced the ongoing clinical trials program for *aficamten:*
    - Continued conduct of MAPLE-HCM (***M****etoprolol* vs ***A****ficamten* in **P**atients with **L**VOT Obstruction on **E**xercise Capacity in **HCM**), a Phase 3 clinical trial comparing *aficamten* as monotherapy to *metoprolol* as monotherapy in patients with symptomatic obstructive HCM. We expect to share topline results in May 2025.
    - Completed enrollment in the primary cohort (excluding Japan) of ACACIA-HCM (**A**ssessment **C**omparing ***A****ficamten* to Placebo on **C**ardiac Endpoints **I**n **A**dults with Non-Obstructive **HCM**), a pivotal Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, in Q1 2025, ahead of schedule and with over 500 patients enrolled, surpassing the original enrollment target. We expect to share topline results in 1H 2026.
    - Updated the primary endpoint for ACACIA-HCM from a single primary endpoint of change in Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score to a dual primary endpoint of change in KCCQ Clinical Summary Score and change in maximal exercise performance (peak VO_2) from baseline to Week 36. This change in the primary endpoint is intended to unify the protocol and statistical analysis plans across regions in response to feedback from global regulators. The update to the primary endpoint does not change conduct of the clinical trial.
    - Conducted start-up activities for the Japan cohort of ACACIA-HCM with enrollment expected to begin in Q2 2025 to support regulatory activities in Japan.
    - Continued enrolling patients 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 complete patient enrollment of the adolescent cohort in 2H 2025.
    - Completed conduct of the Phase 1 study of *aficamten* in healthy Japanese and Caucasian participants.
- Presented new analyses at the American College of Cardiology Annual Scientific Session and Expo related to *aficamten* expanding on its metabolic pathways, combination therapy with *disopyramide* and longer-term effects on cardiac structure and function.
- Expanded U.S. commercial readiness activities for *aficamten* including initiating sales force recruiting. Continued building our bespoke patient support programs by contracting with strategic partners and finalizing the design of our customer-facing teams. Confirmed channel distribution partners and continued market research on our promotional launch campaign.
- Advanced European commercial readiness activities including hiring key leadership positions in

Europe, establishing new regional entities in France and the U.K., validating our reimbursement strategy and began developing our Health Technology Assessment (HTA) dossiers.

- Published the following manuscripts:
    - "*Aficamten* and *Disopyramide* in Symptomatic Obstructive Hypertrophic Cardiomyopathy" in the *Journal of the American College of Cardiology: Heart Failure*
    - "*Aficamten* vs *Metoprolol* for Obstructive Hypertrophic Cardiomyopathy: MAPLE-HCM Rationale, Study Design, and Baseline Characteristics" in the *Journal of the American College of Cardiology: Heart Failure*
    - "Effect of Hepatic Impairment or Renal Impairment on the Pharmacokinetics of *Aficamten*" in *Clinical Pharmacokinetics*
    - "Clinical Evaluation of the Effect of *Aficamten* on QT/QTc Interval in Healthy Participants" in *Clinical and Translational Science*
    - "A Characterization of the Nonclinical Pharmacology and Toxicology of *Aficamten*, a Reversible Allosteric Inhibitor of Cardiac Myosin" in the *International Journal of Toxicology*

omecamtiv mecarbil (cardiac myosin activator)

- Continued conduct of COMET-HF (**C**onfirmation of ***O****mecamtiv* ***M****ecarbil* **E**fficacy **T**rial in **H**eart **F**ailure), a confirmatory Phase 3 clinical trial of *omecamtiv mecarbil* in patients with symptomatic heart failure with severely reduced ejection fraction. We expect to continue enrollment through 2025 to enable completion of enrollment in 2026.

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

- Continued conduct of 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 clinical trial of CK-586 in patients with symptomatic heart failure with preserved ejection fraction (HFpEF) with left ventricular ejection fraction (LVEF) ≥ 60%. We expect to complete patient enrollment of the first two cohorts in 2H 2025.

CK-4015089 (CK-089, fast skeletal muscle troponin activator)

- Conducted the initial single ascending dose cohorts of the Phase 1 randomized, double-blind, placebo-controlled clinical study of CK-4015089 (CK-089) in healthy human participants.

Pre-Clinical Development and Ongoing Research

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

Corporate

- Participated in Series B financing of Imbria Pharmaceuticals to support advancement of *ninerafaxstat* for the treatment of non-obstructive HCM.
- Released the 2024 Corporate Responsibility Report outlining the Company's commitment and activities related to social and environmental responsibility, ethics and governance and patient and community engagement.
- Launched EARTH-HCM (**E**pidemiology, **A**wareness, **R**eal-world **T**reatment and **H**ealth Outcomes in **HCM**), an online, open access, interactive public health education tool developed by Cytokinetics in collaboration with leading academic institutions, that leverages real-world, de-identified claims data to visualize and analyze population differences in patient characteristics, treatments, clinical

outcomes, healthcare resource utilization and costs in HCM in the U.S.

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

First Quarter 2025 Financial Results

Cash, Cash Equivalents and Investments

- As of March 31, 2025, the company had approximately $1.1 billion in cash, cash equivalents and investments compared to $1.2 billion at December 31, 2024. Cash, cash equivalents and investments declined by approximately $132.2 million during the first quarter of 2025.

Revenue

- Total revenues for the first quarter of 2025 were $1.6 million compared to $0.8 million for the same period in 2024.

Research and Development (R&D) Expenses

- R&D expenses for the first quarter of 2025 were $99.8 million, which included $11.7 million of non-cash stock-based compensation expense, compared to $81.6 million for the same period in 2024, which included $8.6 million of non-cash stock-based compensation expense. The increase was primarily due to advancing our clinical trials and higher personnel-related costs.

General and Administrative (G&A) Expenses

- G&A expenses for the first quarter of 2025 were $57.4 million, which included $11.9 million of non-cash stock-based compensation expense, compared to $45.5 million for the same period in 2024, which included $13.0 million of non-cash stock-based compensation expense. The increase was primarily due to investments in commercial readiness and higher personnel-related costs.

Net Income (Loss)

- Net loss for the first quarter of 2025 was $161.4 million, or $(1.36) per share, basic and diluted, compared to a net loss of $135.6 million, or $(1.33) per share, basic and diluted, for the same period in 2024.

2025 Financial Guidance

The company is maintaining its full year 2025 financial guidance:

GAAP operating expense*	$670 million to $710 million
Non-cash stock-based compensation expense included in GAAP operating expense	$120 million to $110 million

*GAAP operating expense comprised of R&D and SG&A expenses.

Anticipated year-over-year increase in GAAP operating expense includes investments toward

commercial readiness for the potential approval and launch of *aficamten* for patients with obstructive HCM.

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.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first quarter 2025 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 2025 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 specialty cardiovascular biopharmaceutical company, building on its over 25 years of pioneering scientific innovations in muscle biology to advance a pipeline of potential new medicines for patients suffering from diseases of cardiac muscle dysfunction. Cytokinetics is readying for potential regulatory approvals and commercialization of *aficamten,* a cardiac myosin inhibitor following positive results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial in patients with obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in additional clinical trials enrolling patients with obstructive and non-obstructive HCM. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac myosin 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 with potential therapeutic application to a specific type of muscular dystrophy and other conditions of impaired skeletal muscle function.

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 receipt of regulatory approval by FDA or any other regulatory authority to enable our commercialization of *aficamten* in the United States or any other jurisdiction by the target PDUFA date or any other date, if ever, our ability to complete enrollment of CEDAR-HCM and AMBER-HFpEF in the second half of 2025, our ability to complete patient enrollment of COMET-HF in 2026, our ability to commence enrollment of ACACIA-HCM in Japan in the second quarter of 2025, our ability to announce the results of any of our clinical trials by any particular date, 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 Sanofi or Bayer in connection with our collaborations for *aficamten* in China or Japan respectively; statements relating to our operating expenses or cash utilization for the remainder of 2025 or any other period, statements relating to our cash balance at any particular date or the amount of cash runway such cash balances represent at any particular time and statements related to the potential benefits of our participation in the Series B financing of Imbria Pharmaceuticals to support the advancement of *ninerafaxstat* for the treatment of nHCM. 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 ended December 31, 2024. 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)

	March 31, 2025 (unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash and short term investments	$ 938,218	$ 1,076,014
Other current assets	17,835	31,926
Total current assets	956,053	1,107,940

Long-term investments	150,687	145,055
Property and equipment, net	67,175	65,815
Operating lease right-of-use assets	77,439	75,158
Other assets	12,697	7,705
Total assets	$ 1,264,051	$ 1,401,673
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 57,300	$ 75,692
Short-term operating lease liabilities	19,574	18,978
Current portion of long-term debt	12,960	11,520
Derivative liabilities measured at fair value	11,700	11,300
Deferred revenue	52,370	52,370
Other current liabilities	5,822	9,814
Total current liabilities	159,726	179,674
Term loan, net	92,025	93,227
Convertible notes, net	553,143	552,370
Liabilities related to revenue participation right purchase agreements, net	476,296	462,192
Long-term operating lease liabilities	113,353	112,582
Liabilities related to RPI Transactions measured at fair value	133,100	137,000
Other non-current liabilities	2,821	—
Total liabilities	1,530,464	1,537,045
Commitments and contingencies		
Stockholders' deficit		
Common stock	119	118
Additional paid-in capital	2,595,063	2,563,876
Accumulated other comprehensive income	1,545	2,398
Accumulated deficit	(2,863,140)	(2,701,764)
Total stockholders' deficit	(266,413)	(135,372)
Total liabilities and stockholders' deficit	$ 1,264,051	$ 1,401,673

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

	Three Months Ended	
	March 31, 2025	March 31, 2024
Revenues:		
Collaboration revenues	$ 1,579	$ 835
Operating expenses:		
Research and development	99,841	81,570
General and administrative	57,369	45,500
Total operating expenses	157,210	127,070
Operating loss	(155,631)	(126,235)
Interest and other expense, net	(8,868)	(7,103)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(14,078)	(10,218)
Interest and other income, net	13,701	7,913
Change in fair value of derivative liabilities	(400)	—
Change in fair value of liabilities related to RPI Transactions	3,900	—
Net loss	$ (161,376)	$ (135,643)
Net loss per share — basic and diluted	$ (1.36)	$ (1.33)
Weighted-average number of shares used in computing net loss per share		

— basic and diluted	118,496	101,924

Source: Cytokinetics, Incorporated