NEWS RELEASE

Cytokinetics Reports Fourth Quarter 2024 Financial Results and Provides Business Update

2025-02-27

Commercial Launch Preparations Advancing Prior to September 26 PDUFA Date;
Regulatory Filings Under Review in U.S., Europe and China

Topline Results from MAPLE-HCM Expected in Q2 2025

Company Provides 2025 Financial Guidance;
~$1.2 Billion in Cash, Cash Equivalents and Investments as of December 31, 2024

SOUTH SAN FRANCISCO, Calif., Feb. 27, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported a management update and financial results for the fourth quarter and full year of 2024. The company also provided full year 2025 financial guidance.

"The fourth quarter of 2024 capped off a momentous year for Cytokinetics with progress and achievements across our business. With regulatory submissions on file in the U.S., Europe and China for *aficamten* and regulatory review activities underway, we are approaching a key inflection point, and our commercial readiness activities are on track to support planned launch activities," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "During recent months, we also started important clinical trials advancing later-stage development programs, setting us up to potentially deliver multiple new medicines to patients over the next several years. With a strong balance sheet and additional access to investment capital, we are well-funded to execute the potential commercial launch of *aficamten* in 2025, while we advance our pipeline and continue investing in research for the benefit of all stakeholders."

Q4 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- The U.S. Food & Drug Administration (FDA) accepted our New Drug Application (NDA) for *aficamten*, a next-in-class cardiac myosin inhibitor, for the treatment of obstructive hypertrophic cardiomyopathy (HCM). The NDA was assigned standard review with a Prescription Drug User Fee

Act (PDUFA) target action date of September 26, 2025. We are responding to information requests from FDA and preparing for clinical site and other inspections. We expect to participate in a mid-cycle meeting with FDA in March.
- Submitted the 120-Day Safety Update to FDA for the NDA for *aficamten* with an additional ten months of safety data arising 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, consistent with previously presented data from FOREST-HCM.
- The European Medicines Agency (EMA) validated our Marketing Authorization Application (MAA) for *aficamten* for the treatment of obstructive HCM. The MAA will now be reviewed by the Committee for Medicinal Products for Human Use (CHMP). We expect to receive the Day 120 List of Questions from EMA in April.
- The Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) accepted the NDA for *aficamten* for the treatment of obstructive HCM with Priority Review. We are responding to information requests from the NMPA and preparing for clinical site inspections.
- Entered into a collaboration and license agreement with Bayer for the exclusive development and commercialization of *aficamten* in Japan for the treatment of patients with obstructive and non-obstructive HCM, subject to certain reserved development rights of Cytokinetics.
- Announced that Sanofi acquired from Corxel Pharmaceuticals (CORXEL) the exclusive rights to develop and commercialize *aficamten* for the treatment of patients with obstructive and non-obstructive HCM in Greater China.
- Presented new data related to *aficamten* at the American Heart Association Scientific Sessions 2024 showing that in SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A**ficamten* in **HCM**) treatment with *aficamten* was associated with improvements in post-exercise oxygen uptake recovery and quality of life. Additionally, an analysis from FOREST-HCM demonstrated that treatment with *aficamten* for 12 weeks reduced the proportion of patients who were guideline-eligible for septal reduction therapy by 97%.
- Expanded U.S. commercial readiness activities for *aficamten* including launching HCM Beyond the Heart, an unbranded disease awareness campaign for healthcare professionals and patients highlighting the holistic burden of HCM. Continued building our bespoke patient support programs, advanced sales force preparations including finalizing territory deployment, sales representative recruiting timeline and sales training curriculum, and initiating market research on our promotional launch campaign.
- Advanced European commercial readiness activities including hiring key leadership positions in Europe and Heads of France and the U.K., validating our reimbursement strategy and developing our Health Technology Assessment (HTA) dossier submissions.
- Advanced the following clinical trials:

    - 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. Patient enrollment completed in Q3 2024, and the trial is proceeding through final data collection towards database lock.
    - 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. We have completed site activations in North America, South America, Europe, and Israel and observed robust enrollment over the last few months.
    - 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.

- Published a manuscript entitled “Standard-of-Care Medication Withdrawal in Patients With Obstructive Hypertrophic Cardiomyopathy Receiving *Aficamten* in FOREST-HCM” in the *Journal of*

the American College of Cardiology.

omecamtiv mecarbil (cardiac myosin activator)

- Started 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.
- Presented additional data from GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure) at the American Heart Association Scientific Sessions 2024 demonstrating that treatment with *omecamtiv mecarbil* reduced the risk of the primary composite endpoint in patients with severe heart failure, independent of age and reduced the risk of ventricular arrythmias in patients with severely reduced left ventricular ejection fraction.
- Published the following manuscripts:
    - "Optimizing the Posthospital Period After Admission for Worsening Heart Failure" in the *Journal of the American College of Cardiology – Heart Failure.*
    - "Clinicoeconomic Burden Among Heart Failure Patients With Severely Reduced Ejection Fraction After Hospital Admission: HF-RESTORE" in the *European Heart Journal – Quality of Care and Clinical Outcomes.*

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

- Started 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%.

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

- Started a Phase 1 randomized, double-blind, placebo-controlled, multi-part, single and multiple ascending dose 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

- Announced Vision 2030, our five-year strategic objectives designed to propel Cytokinetics' aspiration to become the leading muscle-focused specialty biopharmaceutical company intent on meaningfully improving the lives of patients through global access to innovative medicines.
- Named Robert E. Landry to the company's Board of Directors. Mr. Landry is an accomplished pharmaceutical industry leader with over three decades of financial and operational expertise.

2025 Corporate Milestones

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Advance NDA review activities with U.S. FDA to support the potential U.S. approval of *aficamten* in

2H 2025.
- Advance go-to-market strategies and prepare to commercially launch *aficamten* in the U.S. in 2H 2025, subject to approval by FDA.
- Continue go-to-market plans in Germany and expand commercial readiness activities in Europe in 2025, in preparation for potential approval by the EMA in 1H 2026.
- Coordinate with Sanofi to support the potential approval of *aficamten* in China in 2H 2025, pending approval by the NMPA.
- Report topline results from MAPLE-HCM in Q2 2025.
- Complete patient enrollment of ACACIA-HCM in 2H 2025.
- Complete patient enrollment of the adolescent cohort in CEDAR-HCM in 2H 2025.

omecamtiv mecarbil (cardiac myosin activator)

- Continue patient enrollment in COMET-HF through 2025 to enable completion of enrollment in 2026.

CK-586 (cardiac myosin inhibitor)

- Complete patient enrollment of the first two cohorts in AMBER-HFpEF in 2H 2025.

Skeletal Muscle Program

CK-089 (fast skeletal muscle troponin activator)

- Complete the Phase 1 study of CK-089 in healthy human participants in 2025.

Ongoing Research

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

Fourth Quarter and Full Year 2024 Financial Results

Cash, Cash Equivalents and Investments

- As of December 31, 2024, the company had approximately $1.2 billion in cash, cash equivalents and investments compared to $1.3 billion at September 30, 2024. Cash, cash equivalents and investments declined by approximately $60 million during the fourth quarter of 2024 and benefitted from the receipt of the $52.4 million (€50 million) payment from Bayer for the exclusive license to develop and commercialize *aficamten* in Japan.

Revenues

- Total revenues for the fourth quarter of 2024 were $16.9 million compared to $1.7 million for the same period in 2023. Total revenues for the full year of 2024 were $18.5 million compared to $7.5 million in 2023. Total revenues in the fourth quarter and full year 2024 benefitted from a $15.0 million upfront payment from Corxel in connection with the assignment to Sanofi of Corxel's rights to develop and commercialize *aficamten* in Greater China.

Research and Development (R&D) Expenses

- R&D expenses for the fourth quarter of 2024 were $93.6 million, which included $12.5 million of non-cash stock-based compensation expense, compared to $85.0 million for the same period in 2023, which included $9.3 million of non-cash stock-based compensation expense. R&D expenses

for the full year of 2024 were $339.4 million, which included $44.0 million of non-cash stock-based compensation expense, compared to $330.1 million in 2023, which included $32.1 million of non-cash stock-based compensation expense. The increase for both the fourth quarter and full year was primarily due to our advancing clinical trials and higher personnel-related costs.

General and Administrative (G&A) Expenses

- G&A expenses for the fourth quarter of 2024 were $62.3 million, which included $13.8 million of non-cash stock-based compensation expense, compared to $44.1 million for the same period in 2023, which included $10.2 million of non-cash stock-based compensation expense. G&A expenses for the full year of 2024 were $215.3 million, which included $53.8 million of non-cash stock-based compensation expense, compared to $173.6 million in 2023, which included $39.9 million of non-cash stock-based compensation expense. The increase for both the fourth quarter and full year was primarily driven by investments toward commercial readiness and higher personnel-related costs.

Net Income (Loss)

- Net loss for the fourth quarter of 2024 was $150.0 million, or $(1.26) per share, basic and diluted, compared to a net loss of $136.9 million, or $(1.38) per share, basic and diluted, for the same period in 2023. Net loss for the year of 2024 was $589.5 million, or $(5.26) per share, basic and diluted, compared to a net loss of $526.2 million, or $(5.45) per share, basic and diluted, in 2023.

2025 Financial Guidance

The company today announced financial guidance for 2025:

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 oHCM.

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 fourth 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 Q4 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 leading muscle biology specialty biopharmaceutical company focused on discovering, developing and commercializing muscle biology-directed drug candidates as potential treatments for debilitating diseases in which muscle performance is compromised. As a pioneer in muscle and the mechanics of muscle performance, Cytokinetics is intent on meaningfully improving the lives of patients through global access to innovative medicines. Cytokinetics is readying for potential regulatory approvals and commercialization of *aficamten,* a potential next-in-class 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 ACACIA-HCM, CEDAR-HCM and AMBER-HFpEF in the second half of 2025, our ability to complete patient enrollment of COMET-HF in 2026, 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, and statements relating to our cash balance at any 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 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.

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

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and short-term investments	$ 1,076,014	$ 614,824
Other current assets	31,926	13,227
Total current assets	1,107,940	628,051
Long-term investments	145,055	40,534
Property and equipment, net	65,815	68,748
Operating lease right-of-use assets	75,158	78,987
Other assets	7,705	7,996
Total assets	$ 1,401,673	$ 824,316
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 75,692	$ 64,148
Short-term operating lease liabilities	18,978	17,891
Current portion of long-term debt	11,520	10,080
Derivative liabilities measured at fair value	11,300	—
Deferred revenue	52,370	—
Other current liabilities	9,814	10,559
Total current liabilities	179,674	102,678
Term loan, net	93,227	58,384
Convertible notes, net	552,370	548,989
Liabilities related to revenue participation right purchase agreements, net	462,192	379,975
Long-term operating lease liabilities	112,582	120,427
Liabilities related to RPI Transactions measured at fair value	137,000	—
Other non-current liabilities	—	186

Total liabilities	1,537,045	1,210,639
Commitments and contingencies		
Stockholders' deficit		
Common stock	118	102
Additional paid-in capital	2,563,876	1,725,823
Accumulated other comprehensive income (loss)	2,398	(10)
Accumulated deficit	(2,701,764)	(2,112,238)
Total stockholders' deficit	(135,372)	(386,323)
Total liabilities and stockholders' deficit	$ 1,401,673	$ 824,316

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

	Three Months Ended December 31,		Years Ended December 31,	
	2024	2023	2024	2023
Revenues:				
License and milestone revenues	$ 15,000	$ 1,000	$ 15,000	$ 3,500
Collaboration revenues	1,927	672	3,474	4,030
Realization of revenue participation right purchase agreement	—	—	—	—
Total revenues	16,927	1,672	18,474	7,530
Operating expenses:				
Research and development	93,629	84,976	339,408	330,123
General and administrative	62,338	44,114	215,314	173,612
Total operating expenses	155,967	129,090	554,722	503,735
Operating loss	(139,040)	(127,418)	(536,248)	(496,205)
Interest expense	(8,938)	(7,164)	(37,701)	(28,306)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(13,656)	(9,900)	(48,811)	(29,362)
Interest and other income, net	15,014	7,586	51,534	27,629
Change in fair value of derivative liabilities	1,200	—	1,300	—
Change in fair value of liabilities related to RPI Transactions	(4,600)	—	(19,600)	—
Net loss before income taxes	(150,020)	(136,896)	(589,526)	(526,244)
Income tax benefit	—	—	—	—
Net loss	$ (150,020)	$ (136,896)	$ (589,526)	$ (526,244)
Net loss per share — basic and diluted	$ (1.26)	$ (1.38)	$ (5.26)	$ (5.45)
Weighted-average shares in net loss per share — basic and diluted	118,075	99,067	111,979	96,524

Source: Cytokinetics, Incorporated