

## NEWS RELEASE

# Cytokinetics Reports Second Quarter 2025 Financial Results and Provides Business Update

2025-08-07

*Regulatory Reviews of Aficamten for Obstructive HCM Progressing in U.S., E.U. and China; Late-Cycle Meeting with U.S. FDA Scheduled for September Ahead of December 26, 2025 PDUFA Date*

*Primary Results from MAPLE-HCM to be Presented in a Hot Line Session at the European Society of Cardiology Congress 2025*

*~\$1.0 Billion in Cash, Cash Equivalents and Investments as of June 30, 2025*

SOUTH SAN FRANCISCO, Calif., Aug. 07, 2025 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported a management update and financial results for the second quarter of 2025.

"Following solid progress in the first half of the year, we are looking forward to several key corporate milestones. Our primary focus remains on preparations for the potential FDA approval of *aficamten* in late December and subsequent commercial launch in early 2026," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "Additionally, we are pleased to be sharing results from MAPLE-HCM later this month, which we believe will provide important information related to the standard-of-care in obstructive HCM. With our current balance sheet and additional access to capital, we are well-positioned to execute on both the commercialization and potential label expansion opportunities of *aficamten* while also advancing our later-stage specialty cardiovascular pipeline."

## Q2 and Recent Highlights

### Cardiac Muscle Programs

#### *aficamten* (cardiac myosin inhibitor)

- Continued to support the review of the New Drug Application (NDA) for *aficamten* for the treatment of patients with obstructive hypertrophic cardiomyopathy (HCM) by the U.S. Food and Drug Administration (FDA). With the three-month extension of the Prescription Drug User Fee Act (PDUFA) target action date to December 26, 2025, the late cycle meeting is now scheduled to occur in September.

- Prepared responses to the 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; submission on track to meet the clock stop timeline agreed with EMA. We expect a potential EMA decision regarding the MAA in 1H 2026.
- Completed all Good Clinical Practice (GCP) inspections for applications under review.
- 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*:
  - Announced positive topline results from MAPLE-HCM (*Metoprolol vs Aficamten* in Patients with LVOT Obstruction on Exercise Capacity in HCM). The primary results will be presented in a Hot Line Session in August at the European Society of Cardiology Congress 2025.
  - Continued conduct of ACACIA-HCM (Assessment Comparing *Aficamten* to Placebo on Cardiac Endpoints In Adults with Non-Obstructive HCM), a pivotal Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM. We expect to share topline results of the primary cohort (excluding Japan) in 1H 2026. Dosed the first patient in the Japan cohort of ACACIA-HCM.
  - Dosed the first patient in CAMELLIA-HCM, a Phase 3 clinical trial of *aficamten* in Japanese patients with obstructive HCM. CAMELLIA-HCM is being conducted by Bayer in collaboration with Cytokinetics to support potential marketing authorization in Japan.
  - Continued enrolling patients in CEDAR-HCM (Clinical Evaluation of Dosing with *Aficamten* to Reduce 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.
- Presented new analyses at the European Society of Cardiology Heart Failure 2025 Congress from SEQUOIA-HCM on the effect of *aficamten* between patients with mild and moderate-to-severe symptoms, and across geographic regions.
- Expanded U.S. commercial readiness activities for *aficamten* including sales force recruitment, final stages of implementing patient support programs and finalization of our promotional launch campaign. Continued payer engagement to educate on the clinical data supportive of *aficamten* and the clinical and economic burden of HCM.
- Advanced European commercial readiness activities including hiring key leadership positions in our European headquarters and other EU and UK geographies, preparing Health Technology Assessment (HTA) dossiers and ensuring launch readiness for potential approval in Germany in 1H 2025.
- Published the following manuscripts:
  - "A Plain Language Summary of the SEQUOIA-HCM Study: *Aficamten* for Symptomatic Obstructive Hypertrophic Cardiomyopathy" in *Future Cardiology*
  - "Efficacy of *Aficamten* in Patients with Obstructive Hypertrophic Cardiomyopathy and Mild Symptoms: Results from the SEQUOIA-HCM Trial" in the *European Heart Journal*
  - "Associations of Sex on Economic Burden in Patients with Symptomatic Obstructive Hypertrophic Cardiomyopathy: Results from Medical and Pharmacy Claims Data in *Frontiers in Cardiovascular Medicine*

- “*Aficamten* Treatment for Symptomatic Obstructive Hypertrophic Cardiomyopathy: 48-weeks Results From FOREST-HCM” in the *Journal of the American College of Cardiology – Heart Failure*
- “Concomitant *Aficamten* and *Disopyramide* in Symptomatic Obstructive Hypertrophic Cardiomyopathy” in the *Journal of the American College of Cardiology – Heart Failure*
- “Clinical Evaluation of the Effect of *Aficamten* on QT/QTc Interval in Healthy Participants” in *Clinical and Translational Science*

#### ***omecamtiv mecarbil*** (cardiac myosin activator)

- Continued conduct of COMET-HF (Confirmation of *Omecamtiv Mecarbil* Efficacy Trial in Heart Failure), 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 late 2026.

#### ***ulacamten*** (CK-4021586, cardiac myosin inhibitor)

- Received approval from the International Nonproprietary Names (INN) Program of the World Health Organization for *ulacamten* to be used as the nonproprietary name for CK-4021586.
- Continued conduct of AMBER-HFpEF (Assessment of CK-586 in a Multi-Center, Blinded Evaluation of Safety and Tolerability Results in HFpEF), a Phase 2 clinical trial of *ulacamten* in patients with symptomatic heart failure with preserved ejection fraction (HFpEF) with left ventricular ejection fraction (LVEF)  $\geq 60\%$ . We expect to complete patient enrollment of the first two cohorts in 2H 2025.

### **Pre-Clinical Development and Ongoing Research**

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

### **Second Quarter 2025 Financial Results**

#### **Cash, Cash Equivalents and Investments**

- As of June 30, 2025, the company had approximately \$1.0 billion in cash, cash equivalents and investments compared to \$1.1 billion at March 31, 2025. Cash, cash equivalents and investments declined by \$52.6 million during the second quarter of 2025. The Company received \$75 million in proceeds from the drawing on Tranche 4 of the Royalty Pharma Multi Tranche Term Loan in the second quarter of 2025.

#### **Revenues**

- Total revenues for the second quarter of 2025 were \$66.8 million compared to \$0.2 million for the same period in 2024. Revenues in the second quarter of 2025 included the recognition of \$52.4 million related to the Company's license and collaboration agreement for *aficamten* in Japan with Bayer, and \$11.7 million for the achievement of clinical milestones in the non-obstructive HCM and obstructive HCM trials in Japan.

### Research and Development (R&D) Expenses

- R&D expenses for the second quarter of 2025 were \$112.6 million, which included \$13.5 million of non-cash stock-based compensation expense, compared to \$79.6 million for the same period in 2024, which included \$11.5 million of non-cash stock-based compensation expense. The increase was primarily due to advancing our clinical trials, higher personnel-related costs, and medical affairs-related activities.

### General and Administrative (G&A) Expenses

- G&A expenses for the second quarter of 2025 were \$65.7 million, which included \$14.0 million of non-cash stock-based compensation expense, compared to \$50.8 million for the same period in 2024, which included \$13.1 million of non-cash stock-based compensation expense. The increase was primarily due to investments toward commercial readiness and higher personnel-related costs.

### Net Income (Loss)

- Net loss for the second quarter of 2025 was \$134.4 million, or \$(1.12) per share, basic and diluted, compared to a net loss of \$143.3 million, or \$(1.31) 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 second 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](http://www.cytokinetics.com) or directly at the following link: [Cytokinetics Q2 2025 Earnings Conference Call](#). An archived replay of the webcast will be available via Cytokinetics' website for six 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), *ulacamten*, 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](http://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 announce the results of ACACIA-HCM in the first half of 2026, 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, 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' Quarterly Report on Form 10-A for the quarter ended March 31, 2025. 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)

	<u>June 30, 2025</u> (unaudited)	<u>December 31,</u> <u>2024</u>
<b>ASSETS</b>		
Current assets:		
Cash and short term investments	\$ 858,135	\$ 1,076,014
Other current assets	28,407	31,926
Total current assets	886,542	1,107,940
Long-term investments	178,201	145,055
Property and equipment, net	70,219	65,815
Operating lease right-of-use assets	76,120	75,158
Other assets	14,553	7,705
Total assets	<u>\$ 1,225,635</u>	<u>\$ 1,401,673</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 68,543	\$ 75,692
Short-term operating lease liabilities	19,585	18,978
Current portion of long-term debt	14,400	11,520
Derivative liabilities measured at fair value	17,600	11,300
Deferred revenue	1,344	52,370
Other current liabilities	9,592	9,814
Total current liabilities	131,064	179,674
Term loan, net	159,058	93,227

Convertible notes, net	553,987	552,370
Liabilities related to revenue participation right purchase agreements, net	489,503	462,192
Long-term operating lease liabilities	111,028	112,582
Liabilities related to RPI Transactions measured at fair value	147,700	137,000
Other non-current liabilities	2,015	—
Total liabilities	<u>1,594,355</u>	<u>1,537,045</u>
Commitments and contingencies		
Stockholders' deficit		
Common stock	119	118
Additional paid-in capital	2,628,829	2,563,876
Accumulated other comprehensive (loss) income	(158)	2,398
Accumulated deficit	<u>(2,997,510)</u>	<u>(2,701,764)</u>
Total stockholders' deficit	<u>(368,720)</u>	<u>(135,372)</u>
Total liabilities and stockholders' deficit	<u>\$ 1,225,635</u>	<u>\$ 1,401,673</u>

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

	Three Months Ended		Six Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
Revenues:				
Collaboration revenues	\$ 2,416	\$ 249	\$ 3,995	\$ 1,084
License and milestone revenues	64,353	—	64,353	—
Total revenues	<u>66,769</u>	<u>249</u>	<u>68,348</u>	<u>1,084</u>
Operating expenses:				
Research and development	112,554	79,597	212,395	161,167
General and administrative	65,721	50,824	123,090	96,324
Total operating expenses	<u>178,275</u>	<u>130,421</u>	<u>335,485</u>	<u>257,491</u>
Operating loss	<u>(111,506)</u>	<u>(130,172)</u>	<u>(267,137)</u>	<u>(256,407)</u>
Interest expense	(11,084)	(12,732)	(19,952)	(19,835)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(13,181)	(11,567)	(27,259)	(21,785)
Interest and other income, net	13,001	11,553	26,702	19,466
Change in fair value of derivative liabilities	3,000	(600)	2,600	(600)
Change in fair value of liabilities related to RPI Transactions	<u>(14,600)</u>	<u>200</u>	<u>(10,700)</u>	<u>200</u>
Net loss	<u>\$ (134,370)</u>	<u>\$ (143,318)</u>	<u>\$ (295,746)</u>	<u>\$ (278,961)</u>
Net loss per share — basic and diluted	<u>\$ (1.12)</u>	<u>\$ (1.31)</u>	<u>\$ (2.49)</u>	<u>\$ (2.63)</u>
Weighted-average number of shares used in computing net loss per share — basic and diluted	<u>119,457</u>	<u>109,240</u>	<u>118,979</u>	<u>106,013</u>

Source: Cytokinetics, Incorporated