UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 02, 2023

Cytokinetics, Incorporated

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-50633**	**94-3291317**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
350 Oyster Point Boulevard South San Francisco, California		**94080**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 624-3000

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	CYTK	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 2, 2023, Cytokinetics, Incorporated (the "Registrant") announced its financial results for the third quarter ended September 30, 2023. The full text of the press release issued in connection with this announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information furnished under this Item 2.02 shall not be considered "filed" under the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any future filing under the Securities Act of 1933, as

amended, or under the Securities Exchange Act of 1934, as amended, unless the Registrant expressly sets forth in such future filing that such information is to be considered “filed” or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated November 2, 2023
104 The cover page of this report has been formatted in Inline XBRL

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CYTOKINETICS, INCORPORATED

Date: November 2, 2023

By: /s/ John O. Faurescu
John O. Faurescu, Esq.
Vice President, Associate General Counsel &
Corporate Secretary

CYTOKINETICS REPORTS THIRD QUARTER 2023 FINANCIAL RESULTS

On Track for Topline Results from SEQUOIA-HCM
a Pivotal Phase 3 Clinical Trial of Aficamten in Obstructive HCM,
in Late December

Long-Term Data from FOREST-HCM,
the Open-Label Extension Study of Aficamten,
Show Sustained Improvements in Clinical Efficacy Endpoints
and No Treatment Interruptions for Low Ejection Fraction

Initiated Enrollment in ACACIA-HCM,
a Pivotal Phase 3 Clinical Trial of Aficamten in Non-Obstructive HCM

SOUTH SAN FRANCISCO, Calif., Nov. 2, 2023 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the third quarter of 2023. Net loss for the third quarter was $129.4 million, or $1.35 per share, compared to net loss for the third quarter of 2022 of $142.3 million, or $1.52 per share. Cash, cash equivalents and investments totaled $554.7 million on September 30, 2023.

“During the third quarter we made considerable progress across our specialty cardiology franchise, with *aficamten* remaining our top priority. Of note, the baseline characteristics of patients enrolled in SEQUOIA-HCM met our objectives for the trial and align with our goal to assess *aficamten* as a potential next-in-class cardiac myosin inhibitor in a population with a substantial deficit in exercise capacity and significant symptom burden despite existing standard of care,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “In addition, we recently shared longer-term data from FOREST-HCM that demonstrate durable reductions in pressure gradients and cardiac biomarkers as well as improved symptoms in patients with obstructive HCM. During the quarter we also started ACACIA-HCM, a pivotal Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM. Alongside these increasing commitments to *aficamten*, we are approaching the end of 2023 in a strong position with the resources and pipeline to execute on our goals in service to both patients and shareholders.”

Q3 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Presented baseline characteristics from SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A****ficamten* in **HCM**), the first Phase 3 trial of *aficamten* in obstructive hypertrophic cardiomyopathy (HCM), at the HCM Society Scientific Sessions 2023.

- Shared new long-term data 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, at the Company's recent Investor and Analyst Day, demonstrating sustained reductions in left ventricular outflow tract (LVOT) gradients with no treatment interruptions for low left ventricular ejection fraction (LVEF) due to *aficamten*. Additionally, patients experienced sustained reductions in cardiac biomarkers and improved symptoms. *Aficamten* has been generally well-tolerated, with no treatment-related serious adverse events (SAEs) as assessed by investigators, and no patient deaths.

- Announced the start 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.

- Published a manuscript entitled "*Aficamten* in Patients with Drug-Refractory Obstructive Hypertrophic Cardiomyopathy Receiving Disopyramide: REDWOOD-HCM Cohort 3 Analysis" in the *Journal of Cardiac Failure*.

- Published a manuscript entitled "Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Doses of *Aficamten* in Healthy Chinese Participants: a Randomized, Double-blind, Placebo-controlled, Phase 1 Study" in the *Frontiers of Pharmacology*.

- Published a manuscript entitled "Exercise Capacity in Patients With Obstructive Hypertrophic Cardiomyopathy: SEQUOIA-HCM Baseline Characteristics and Study Design" in the *Journal of the American College of Cardiology: Heart Failure*.

omecamtiv mecarbil (cardiac myosin activator)

- Submitted a Formal Dispute Resolution Request to the Office of New Drugs (OND) of the U.S. Food and Drug Administration (FDA) regarding the Complete Response Letter (CRL) for *omecamtiv mecarbil* with objective to appeal the FDA's conclusion, as stated in the CRL, that

substantial evidence of effectiveness had not been established to support approval of *omecamtiv mecarbil.*

- Submitted responses to the Day 120 questions to the European Medicines Agency (EMA) in connection with its review of the marketing application for *omecamtiv mecarbil* for the treatment of advanced or worsening heart failure with reduced ejection fraction (HFrEF).

- Ji Xing Pharmaceuticals submitted a request for voluntary withdrawal of the NDA for *omecamtiv mecarbil* to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the People's Republic of China, subject to potential re-submission upon receipt of favorable feedback from EMA or FDA with regard to potential drug approval for *omecamtiv mecarbil* in the EU or U.S., respectively.

CK-3828136 (CK-136, cardiac troponin activator)

- Completed the single ascending dose (SAD) cohorts of the Phase 1 study of CK-136 in healthy participants. Initiated analyses of the SAD data to inform potentially proceeding to the multiple ascending dose (MAD) cohorts of the Phase 1 study.

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

- Completed the SAD cohorts of the Phase 1 study of CK-586 in healthy participants. Completed analyses of the SAD data which are supportive of proceeding to the MAD cohorts of the Phase 1 study in Q4 2023.

Pre-Clinical Development and Ongoing Research

- Continued research activities directed to our other muscle biology research programs.

Corporate

- Announced a call for proposals for the sixth annual Cytokinetics Communications Grant Program. The program awards five grants worth $20,000 each to patient advocacy organizations serving the HCM, heart failure or ALS communities, and is intended to support increased capacity in communications and outreach.

Upcoming Corporate Milestones

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Expect topline results from SEQUOIA-HCM in late December.
- Continue enrollment of MAPLE-HCM.
- Continue enrollment of ACACIA-HCM.
- Continue advancing go-to-market strategy for *aficamten.*

omecamtiv mecarbil (cardiac myosin activator)

- Continue to pursue potential approval for *omecamtiv mecarbil* in Europe.

CK-3828136 (CK-136, cardiac troponin activator)

- Analyze SAD data from the Phase 1 study of CK-136 to inform potentially proceeding with the MAD cohorts in the Phase 1 study.

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

- Proceed to the MAD cohorts in the Phase 1 study of CK-586.

Financials

Revenues for the three and nine months ended September 30, 2023 were $0.4 million and $5.9 million (inclusive of $2.5 million milestone, in the nine months ended, from Ji Xing Pharmaceuticals upon the start of ACACIA-HCM), respectively, compared to $2.5 million and $92.6 million (inclusive of $87 million from the sale of our royalty on *mavacamten*) for the corresponding periods in 2022.

Research and development expenses for the three and nine months ended September 30, 2023 increased to $82.5 million and $245.2 million, respectively, compared to $62.7 million and $165.8 million for the same periods in 2022, respectively, due primarily to increased spending for our cardiac myosin inhibitor programs.

General and administrative expenses for the three months ended September 30, 2023 decreased to $40.1 million from $48.2 million from the three months ended September 20, 2022, primarily due to lower outside services spend. General and administrative expenses for the nine months ended September 30, 2023 increased to $129.5 million from $124.0 million from the nine months ended September 20, 2022,

primarily due to higher personnel related cost including stock-based compensation offset by lower outside service spend.

During the quarter we also received a $50 million cash milestone payment from Royalty Pharma plc upon the start of ACACIA-HCM, treated as a liability on our balance sheet in accordance with GAAP.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's third quarter 2023 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 2023 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 first-in-class muscle activators and next-in-class muscle inhibitors 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. *Aficamten* is a next-in-class cardiac myosin inhibitor, currently the subject of three Phase 3 clinical trials: SEQUOIA-HCM, evaluating *aficamten* in patients with obstructive hypertrophic cardiomyopathy (HCM), MAPLE-HCM, evaluating *aficamten* as monotherapy compared to metoprolol as monotherapy in patients with obstructive HCM and ACACIA-HCM, evaluating *aficamten* in patients with non-obstructive HCM. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac muscle activator, in patients with heart failure. Additionally, Cytokinetics is developing CK-136, a cardiac troponin activator for the potential treatment HFrEF and other types of heart failure, such as right ventricular failure, resulting from impaired cardiac contractility, and CK-586, a cardiac myosin inhibitor with a mechanism of action distinct from *aficamten* for the potential treatment of HFpEF. In 2023, Cytokinetics is celebrating its 25-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

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 obtain approval of our marketing authorisation application for *omecamtiv mecarbil* in the E.U., our ability to publish topline results of SEQUOIA-HCM by the end of 2023, 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 regarding the potential outcome of our Formal Dispute Resolution Request to FDA regarding the Complete Response Letter (CRL) for *omecamtiv mecarbil*, statements relating to the potential patient population who could benefit from *omecamtiv mecarbil*, *aficamten*, CK-136, CK-586 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 2023, and statements relating to our cash balance at year-end 2023 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 2022. 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)

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and short term investments	$ 539,239	$ 782,577
Other current assets	22,177	12,609
Total current assets	561,416	795,186
Long-term investments	15,468	46,708
Property and equipment, net	75,614	80,453
Operating lease right-of-use assets	79,929	82,737
Other assets	8,187	9,691
Total assets	$ 740,614	$ 1,014,775
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 46,750	$ 69,707
Short-term operating lease liabilities	17,236	12,829
Other current liabilities	13,737	2,081
Total current liabilities	77,723	84,617
Term loan, net	60,885	63,810
Convertible notes, net	548,134	545,808
Liabilities related to revenue participation right purchase agreements, net	370,049	300,501
Long-term operating lease liabilities	122,216	126,895
Other non-current liabilities	408	1,044
Total liabilities	1,179,415	1,122,675
Commitments and contingencies		
Stockholders' deficit:		
Common stock	94	94
Additional paid-in capital	1,537,321	1,481,590
Accumulated other comprehensive loss	(874)	(3,590)
Accumulated deficit	(1,975,342)	(1,585,994)
Total stockholders' deficit	(438,801)	(107,900)
Total liabilities and stockholders' deficit	$ 740,614	$ 1,014,775

Cytokinetics, Incorporated

Condensed Consolidated Statements of Operations

(in thousands except per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenues:				
Research and development revenues	$ 378	$ 2,515	$ 3,358	$ 4,631
Milestone revenues	—	—	2,500	1,000
Realization of revenue participation right purchase agreement	—	—	—	87,000
Total revenues	378	2,515	5,858	92,631
Operating expenses:				
Research and development	82,532	62,734	245,147	165,795
General and administrative	40,111	48,222	129,498	124,008
Total operating expenses	122,643	110,956	374,645	289,803
Operating loss	(122,265)	(108,441)	(368,787)	(197,172)
Interest expense	(7,136)	(6,804)	(21,142)	(12,357)
Loss on extinguishment of debt	—	(22,246)	—	(24,939)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(6,860)	(8,963)	(19,462)	(22,530)
Interest and other income, net	6,839	4,144	20,043	5,423
Net loss	$ (129,422)	$ (142,310)	$ (389,348)	$ (251,575)
Net loss per share — basic and diluted	$ (1.35)	$ (1.52)	$ (4.07)	$ (2.85)
Weighted-average number of shares used in computing net loss per share — basic and diluted	96,071	93,758	95,666	88,195