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): August 03, 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 August 3, 2023, Cytokinetics, Incorporated (the "Registrant") announced its financial results for the second quarter ended June 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 August 3, 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: August 3, 2023

By: /s/ John O. Faurescu

John O. Faurescu, Esq., VP, Associate General Counsel & Secretary

CYTOKINETICS REPORTS SECOND QUARTER 2023 FINANCIAL RESULTS

Completed Enrollment in SEQUOIA-HCM,
Pivotal Phase 3 Trial of Aficamten in Obstructive HCM;
On Track for Topline Results by the End of the Year

Initiated Enrollment in MAPLE-HCM,
a Phase 3 Clinical Trial Comparing Aficamten and Metoprolol in Obstructive HCM

ACACIA-HCM, a Pivotal Phase 3 Clinical Trial of Aficamten in Non-Obstructive HCM,
Expected to Start in September 2023

Company Reduces Projected Spending by Approximately 15% and
Revises 2023 Financial Spending Guidance

SOUTH SAN FRANCISCO, Calif., Aug. 3, 2023 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the second quarter of 2023. Net loss for the second quarter was $128.6 million, or $1.34 per share, compared to net loss for the second quarter of 2022 of $19.8 million, or $0.23 per share. Cash, cash equivalents and investments totaled $592.6 million at June 30, 2023.

“In the second quarter we made substantial progress across our pipeline, with notable advancements in the development program of *aficamten*, including our completing enrollment in SEQUOIA-HCM, with 282 patients, making it the largest randomized trial of an investigational therapy in HCM. We are pleased with ongoing study conduct and expect topline results from SEQUOIA-HCM by year end,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “During the quarter we also started a second Phase 3 clinical trial of *aficamten* in obstructive HCM, MAPLE-HCM, furthered preparations for ACACIA-HCM, our Phase 3 clinical trial in non-obstructive HCM expected to start next month and began a Phase 1 study of CK-586, a cardiac myosin inhibitor, that we plan to develop for the potential treatment of heart failure with preserved ejection fraction. Finally, in the second quarter, we prioritized company activities and reduced expected operating expenses for 2023 by approximately 15 percent in order to further extend our cash runway through key corporate milestones.”

Q2 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Completed patient enrollment in 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), enrolling a total of 282 patients.

- Announced the start of MAPLE-HCM (**M**etoprolol vs ***A****ficamten* in **P**atients with **L**VOT Obstruction on **E**xercise Capacity in **HCM)**, the second Phase 3 clinical trial in patients with symptomatic obstructive HCM, comparing *aficamten* as monotherapy to *metoprolol* as monotherapy.

- Continued preparations for 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.

- Presented data from Cohort 4 of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM**), a Phase 2 clinical trial of *aficamten* in patients with non-obstructive hypertrophic cardiomyopathy, at Heart Failure 2023, showing that treatment with *aficamten* resulted in significant improvements in Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Symptom Score (CSS), New York Heart Association (NYHA) Functional Class, angina frequency as measured by the Seattle Angina Questionnaire Angina Frequency (SAQ-AF), NTpro-BNP and high-sensitivity troponin I.

- Recently published a manuscript entitled "*Aficamten* for Drug-Refractory Severe Obstructive Hypertrophic Cardiomyopathy in Patients Receiving Disopyramide: REDWOOD-HCM Cohort 3" in the *Journal of Cardiac Failure*.

omecamtiv mecarbil (cardiac myosin activator)

- Participated in a Type A meeting with the U.S. Food and Drug Administration (FDA) to understand the FDA's views related to the Complete Response Letter (CRL) received on February 28, 2023.

- Continued to support reviews and address questions related to the marketing applications for *omecamtiv mecarbil* for the treatment of advanced or worsening heart failure with reduced ejection fraction (HFrEF) with the European Medicines Agency (EMA) and the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA).

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

- Completed two additional single ascending dose cohorts in the Phase 1 study of CK-136 in healthy volunteers.

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

- Initiated Phase 1 study of CK-586 in healthy volunteers.

Pre-Clinical Development and Ongoing Research

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

Upcoming Corporate Milestones

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Expect topline results from SEQUOIA-HCM by the end of 2023.
- Continue enrollment of MAPLE-HCM.
- Start ACACIA-HCM in September 2023.
- Continue advancing go-to-market strategy for *aficamten.*

omecamtiv mecarbil (cardiac myosin activator)

- Continue to pursue potential international approvals for *omecamtiv mecarbil* in Europe and China.

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

- Expect single ascending dose data from the Phase 1 study of CK-136 in 2H 2023.

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

- Continue enrollment of the Phase 1 study of CK-586.

Financials

Revenues for the three and six months ended June 30, 2023 were $0.9 million and $5.5 million, respectively, compared to $89.0 million and $90.1 million for the corresponding periods in 2022. The changes in revenues are due primarily to the recognition of $87.0 million in 2022 of deferred revenues for royalties on the net sales of products containing *mavacamten*.

Research and development expenses for the three and six months ended June 30, 2023 increased to $83.2 million and $162.6 million, respectively, compared to $57.1 million and $103.1 million for the same periods in 2022. The changes were primarily due to increased spending for our cardiac myosin inhibition programs.

General and administrative expenses for the three months ended June 30, 2023 decreased to $39.7 million from $42.7 million from the three months ended June 30, 2022, primarily due to lower outside service spend. General and administrative expenses for the six months ended June 30, 2023 increased to $89.4 million from $75.8 million the six months ended June 30, 2022, primarily due to higher outside service spend and an increase in personnel related costs including stock-based compensation recorded during the period.

Revised 2023 Financial Guidance

The company today revised its financial guidance due to the reduction in expected operating expenses following the receipt of a CRL from the FDA regarding the New Drug Application for *omecamtiv mecarbil* and the discontinuation of COURAGE-ALS, the Phase 3 trial of *reldesemtiv.* The company anticipates operating expenses for 2023 will be in the range of $390 to $410 million, and net cash utilization will be approximately $310 to $320 million, resulting in projected savings of approximately 15% relative to forecasted spending for 2023. The company expects to end 2023 with more than $510 million, representing nearly two years of forward cash based on its 2023 projected net cash utilization.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's second 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 Q2 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 two Phase 3 clinical trials: SEQUOIA-HCM, evaluating *aficamten* in patients with obstructive hypertrophic cardiomyopathy (HCM), and MAPLE-HCM, evaluating *aficamten* as monotherapy compared to metoprolol as monotherapy in

patients with obstructive HCM. ACACIA-HCM, an additional Phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM, is expected to start soon. 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 Twitter, 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, our ability to start ACACIA-HCM, our phase 3 clinical trial of *aficamten* in patients with non-obstructive HCM in September 2023, our ability to announce the results of the phase 1 clinical trial of CK-136 in the second half of 2023, our ability to advance CK-586 into clinical development in the second quarter 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 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 sale proceeds or 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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Contact:
Cytokinetics
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Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and short term investments	$ 565,722	$ 782,577
Other current assets	20,853	12,609
Total current assets	586,575	795,186
Long-term investments	26,871	46,708
Property and equipment, net	77,248	80,453
Operating lease right-of-use assets	80,866	82,737
Other assets	8,339	9,691
Total assets	$ 779,899	$ 1,014,775
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 44,031	$ 69,707
Short-term operating lease liabilities	15,701	12,829
Other current liabilities	5,885	2,081
Total current liabilities	65,617	84,617
Term loan, net	62,492	63,810
Convertible notes, net	547,288	545,808
Liabilities related to revenue participation right purchase agreements, net	313,163	300,501
Long-term operating lease liabilities	123,829	126,895
Other non-current liabilities	625	1,044
Total liabilities	1,113,014	1,122,675
Commitments and contingencies		
Stockholders' deficit:		
Common stock	94	94
Additional paid-in capital	1,514,169	1,481,590
Accumulated other comprehensive loss	(1,458)	(3,590)
Accumulated deficit	(1,845,920)	(1,585,994)
Total stockholders' deficit	(333,115)	(107,900)
Total liabilities and stockholders' deficit	$ 779,899	$ 1,014,775

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

	Three Months Ended		Six Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Revenues:				
Research and development revenues	$ 867	$ 968	$ 2,980	$ 2,116
Milestone revenues	—	1,000	2,500	1,000
Realization of revenue participation right purchase agreement	—	87,000	—	87,000
Total revenues	867	88,968	5,480	90,116
Operating expenses:				
Research and development	83,194	57,126	162,615	103,061
General and administrative	39,722	42,716	89,387	75,786
Total operating expenses	122,916	99,842	252,002	178,847
Operating loss	(122,049)	(10,874)	(246,522)	(88,731)
Interest expense	(7,045)	(2,807)	(14,006)	(5,553)
Loss on extinguishment of debt	—	—	—	(2,693)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(6,322)	(7,003)	(12,602)	(13,567)
Interest and other income, net	6,779	864	13,204	1,279
Net loss	$ (128,637)	$ (19,820)	$ (259,926)	$ (109,265)
Net loss per share — basic and diluted	$ (1.34)	$ (0.23)	$ (2.72)	$ (1.28)
Weighted-average number of shares used in computing net loss per share — basic and diluted	95,755	85,731	95,461	85,366