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): May 04, 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 May 4, 2023, Cytokinetics, Incorporated (the "Registrant") announced its financial results for the first quarter ended March 31, 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 May 4, 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: May 4, 2023

By: /s/ John Faurescu

John Faurescu, Esq.
Vice President, Associate General Counsel &
Corporate Secretary

CYTOKINETICS REPORTS FIRST QUARTER 2023 FINANCIAL RESULTS

SEQUOIA-HCM Nearing Completion of Enrollment;
On Track for Results in Q4 2023

Additional Data from Cohort 4 of REDWOOD-HCM
to be Presented in Late-Breaking Clinical Trial Session
at European Society of Cardiology Heart Failure 2023 Congress

Company to Reduce Spending by More Than 10% in 2023 to Maintain Over 2 Years of Cash Runway

SOUTH SAN FRANCISCO, Calif., May 4, 2023 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the first quarter of 2023. Net loss for the first quarter was $131.3 million, or $1.38 per share, compared to net loss for the first quarter of 2022 of $89.4 million, or $1.05 per share. Cash, cash equivalents and investments totaled $704.4 million at March 31, 2023.

"In the first quarter we continued to prioritize the broad development program for *aficamten* for the potential treatment of obstructive and non-obstructive HCM and with focus to SEQUOIA-HCM, our pivotal Phase 3 clinical trial in obstructive HCM. We expect to complete patient enrollment in the coming weeks and read out the results later this year," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In parallel, we continue to deepen our specialty cardiology pipeline with the advancement of CK-136 and CK-586 in earlier phase clinical trials. Finally, as good stewards of shareholder capital, we are reducing our spending to ensure we maintain over two years of cash runway."

Q1 and Recent Highlights

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- 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 the American College of Cardiology 72nd Annual Scientific Session (ACC.23), showing that treatment with *aficamten* resulted in significant

improvements in heart failure symptoms as measured by New York Heart Association (NYHA) Class, as well as in NT-proBNP and high-sensitivity troponin I, cardiac biomarkers.

- Presented 48-week data from FOREST-HCM (**F**ollow-up, **O**pen-Label, **R**esearch **E**valuation of **S**ustained **T**reatment with *Aficamten* in **HCM**) at ACC.23 showing that long-term treatment with *aficamten* was associated with sustained treatment effect, well-tolerated with no treatment-related serious adverse events, and was associated with rapid and sustained improvements in echocardiographic hemodynamics paralleled by significant improvements in NYHA class.

- Continued enrolling patients 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).

- Continued preparations for 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 of *aficamten* as monotherapy in patients with obstructive HCM.

- Began preparations for the Phase 3 clinical trial of *aficamten* in non-obstructive HCM.

- Published the following manuscripts:

    - "Phase 2 Study of *Aficamten* in Patients with Obstructive Hypertrophic Cardiomyopathy" in the *Journal of the American College of Cardiology*.

    - "Effects of *Aficamten* on Cardiac Contractility in a Feline Translational Model of Hypertrophic Cardiomyopathy" in *Scientific Reports.*

    - "Pharmacokinetics of a Single Dose of *Aficamten* (CK-274) on Cardiac Contractility in a A31P MYBPC3 Hypertrophic Cardiomyopathy Cat Model" in the *Journal of Veterinary Pharmacology and Therapeutics.*

omecamtiv mecarbil (cardiac myosin activator)

- Announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for *omecamtiv mecarbil*.

- Continued to support review of the Marketing Authorization Application (MAA) for *omecamtiv mecarbil* by the European Medicines Agency (EMA) for the treatment of advanced or worsening HFrEF.

- Published the following manuscripts:

- "*Omecamtiv Mecarbil* in Black Patients with Heart Failure and Reduced Ejection Fraction: Insights From GALACTIC-HF" in the *Journal of the American College of Cardiology: Heart Failure*.

- "Efficacy of *Omecamtiv Mecarbil* in Heart Failure with Reduced Ejection Fraction According to N-terminal pro-B-type Natriuretic Peptide Level: Insights from the GALACTIC-HF Trial" in the *European Journal of Heart Failure*.

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

- Completed 3 single ascending dose cohorts in the Phase 1 study of CK-136 in healthy volunteers.

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Announced that COURAGE-ALS (**C**linical **O**utcomes **U**sing ***R****eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS**) met criteria for futility at the second planned interim analysis. The company will conclude study conduct and plans to discontinue treatment with *reldesemtiv* in all patients, including those in the open-label extension study, COURAGE-ALS OLE.

Pre-Clinical Development and Ongoing Research

- Received U.S. Food & Drug Administration (FDA) clearance for the Investigational New Drug (IND) application to initiate a Phase 1 study of CK-4021586 (CK-586).

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

Corporate

- Released inaugural Corporate Responsibility Report outlining the Company's commitment to social and environmental responsibility, ethics and governance and patient and community engagement.

- Joined with the European Organisation for Rare Diseases (EURORDIS) and the National Organization for Rare Disorders (NORD) to recognize Rare Disease Day®, an international campaign elevating the public understanding of rare diseases.

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

2023 Corporate Milestones

Cardiac Muscle Programs

aficamten (cardiac myosin inhibitor)

- Present additional data from Cohort 4 of REDWOOD-HCM at the European Society of Cardiology Heart Failure 2023 Congress on May 20, 2023.
- Complete patient enrollment in SEQUOIA-HCM in Q2 2023, with results expected in Q4 2023.
- Begin MAPLE-HCM, the second Phase 3 clinical trial of *aficamten* as monotherapy compared to *metoprolol* in patients with obstructive HCM, in Q2 2023.
- Begin a Phase 3 clinical trial of *aficamten* in non-obstructive HCM in 2H 2023.
- Advance U.S. 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)

- Expect to advance CK-586 into a first-in-human study in Q2 2023.

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Conclude clinical trial conduct and complete majority of close-out activities for COURAGE-ALS in Q2 2023; expect to share results from COURAGE-ALS in 2H 2023.

Financials

Revenues for the first quarter 2023 were $4.6 million compared to $1.1 million for the corresponding period in 2022. The increase in revenues is due to our recognizing a $2.5 million milestone from Ji Xing Pharmaceuticals in anticipation of the start of a Phase 3 trial on nHCM.

Research and development expenses for the first quarter 2023 increased to $79.4 million compared to $45.9 million for the same period in 2022, due primarily to increased spending for our clinical development activities for our cardiac myosin inhibitor programs and COURAGE-ALS.

General and administrative expenses for the first quarter 2023 increased to $49.7 million from $33.1 million for the same period in 2022 due primarily to higher personnel related costs including stock-based compensation and precommercial launch expenses.

The company expects to reduce spending in 2023, primarily through a reduction in planned outsourced services and headcount growth, thereby resulting in projected savings of more than 10% relative to forecasted spending for 2023.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first 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 Q1 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. Cytokinetics is developing *aficamten*, a next-in-class cardiac myosin inhibitor, currently the subject of SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in non-obstructive HCM and the company plans to begin a Phase 3 trial later this year. Cytokinetics is also developing *omecamtiv mecarbil*, a cardiac muscle activator in patients with heart failure. 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 complete patient enrollment in SEQUOIA-HCM in the second quarter of 2023 or issue topline results of SEQUOIA-HCM in the fourth quarter of 2023, our ability to begin MAPLE-HCM in the second quarter of 2023 or to begin a phase 3 trial of *aficamten* in patients with non-obstructive HCM in the second half of 2023, our ability to conclude clinical trial conduct and complete majority of close-out activities for COURAGE-ALS in the second quarter of 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; and statements relating to our cash balance at any particular date or the amount of cash runway such cash balance represents 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)

	March 31, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and short term investments	$ 663,962	$ 782,577
Other current assets	16,667	12,609
Total current assets	680,629	795,186
Long-term investments	40,406	46,708
Property and equipment, net	78,859	80,453
Operating lease right-of-use assets	81,802	82,737
Other assets	8,119	9,691
Total assets	$ 889,815	$ 1,014,775
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued liabilities	$ 52,989	$ 69,707
Short-term operating lease liabilities	14,263	12,829
Other current liabilities	7,968	2,081
Total current liabilities	75,220	84,617
Term loan, net	64,110	63,810
Convertible notes, net	546,513	545,808
Liabilities related to revenue participation right purchase agreements, net	306,814	300,501
Long-term operating lease liabilities	125,341	126,895
Other non-current liabilities	837	1,044
Total liabilities	1,118,835	1,122,675
Commitments and contingencies		
Stockholders' deficit:		
Common stock	94	94
Additional paid-in capital	1,489,814	1,481,590
Accumulated other comprehensive loss	(1,645)	(3,590)
Accumulated deficit	(1,717,283)	(1,585,994)
Total stockholders' deficit	(229,020)	(107,900)
Total liabilities and stockholders' deficit	$ 889,815	$ 1,014,775

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

	Three Months Ended	
	March 31, 2023	March 31, 2022
Revenues:		
Research and development revenues	$ 2,113	$ 1,148
Milestone revenues	2,500	—
Total revenues	4,613	1,148
Operating expenses:		
Research and development	79,421	45,935
General and administrative	49,665	33,070
Total operating expenses	129,086	79,005
Operating loss	(124,473)	(77,857)
Interest expense	(6,961)	(2,746)
Loss on extinguishment of debt	—	(2,693)
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(6,280)	(6,564)
Interest and other income, net	6,425	415
Net loss	$ (131,289)	$ (89,445)
Net loss per share — basic and diluted	$ (1.38)	$ (1.05)
Weighted-average number of shares used in computing net loss per share — basic and diluted	95,164	84,996