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): March 01, 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 March 1, 2023, Cytokinetics, Incorporated announced its financial results for the fourth quarter and for the year ended December 31, 2022. 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

Exhibit Number	Description
99.1	Press release dated March 1, 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: March 1, 2023

By: /s/ Ching Jaw
Ching Jaw
Senior Vice President, Chief Financial Officer

CYTOKINETICS REPORTS FOURTH QUARTER 2022 FINANCIAL RESULTS

Company Received Complete Response Letter from FDA for New Drug Application for Omecamtiv Mecarbil

Data from Cohort 4 of REDWOOD-HCM to be Presented at the American College of Cardiology Scientific Sessions; Results Expected from SEQUOIA-HCM in Q4 2023

Second Interim Analysis of COURAGE-ALS Expected to Occur in Q2 2023

Company Provides 2023 Financial Guidance; More than 2 Years of Cash Runway

SOUTH SAN FRANCISCO, Calif., Mar. 1, 2023 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the fourth quarter and full year 2022. Net loss for the fourth quarter was $137.4 million or $1.45 per share and the net loss for the year 2022 was $389.0 million or $4.33 per share. Net loss for the fourth quarter of 2021 was $30.6 million or $0.36 per share and net loss for the year 2021 was $215.3 million or $2.80 per share. Cash, cash equivalents and investments totaled $829.3 million at December 31, 2022.

"*Aficamten* remains our top priority and is advancing in a broad development program with emphasis on the conduct of SEQUOIA-HCM, our pivotal Phase 3 clinical trial in obstructive HCM, and the start of two additional Phase 3 trials." said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "At the same time, COURAGE-ALS, our Phase 3 clinical trial of *reldesemtiv,* is continuing to enroll with the planned second interim analysis expected to occur in the second quarter. These activities will continue as company priorities while we will also assess potential next steps for *omecamtiv mecarbil*. We entered 2023 with a strong balance sheet as we advance multiple late-stage programs as well as make progress in our early-stage pipeline, continuing our 25-year commitment to bringing forward potential new medicines for patients in need."

Q4 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Cytokinetics 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*, stating that GALACTIC-HF is not sufficiently persuasive to establish substantial evidence of effectiveness for reducing the risk of heart failure events and cardiovascular death in adults with chronic heart failure with

reduced ejection fraction, in lieu of evidence from at least two adequate and well-controlled clinical investigations.

- The European Medicines Agency (EMA) accepted the Marketing Authorization Application (MAA) for *omecamtiv mecarbil* for the treatment of advanced or worsening HFrEF.

- Ji Xing Pharmaceuticals announced that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the People's Republic of China has accepted the submission of the New Drug Application (NDA) for *omecamtiv mecarbil* for the treatment of heart failure with reduced ejection fraction (HFrEF) in China.

- Presented results from two additional analyses 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 2022, including one showing that the estimated cost reduction due to heart failure events avoided due to treatment with *omecamtiv mecarbil* averaged $6,052 per patient (26.9% reduction) at three years, and one that showed that women had lower quality of life at baseline and a lower rate of the primary composite outcome, but the treatment benefit of *omecamtiv mecarbil* did not differ between men and women (interaction p=0.68).

aficamten (cardiac myosin inhibitor)

- Continued enrolling patients with obstructive hypertrophic cardiomyopathy (HCM) in SEQUOIA-HCM (**S**afety, **E**fficacy, and **Q**uantitative **U**nderstanding of **O**bstruction **I**mpact of ***A****ficamten* in **HCM**), our first Phase 3 trial of *aficamten* in the U.S. and Europe.

- Completed enrollment of patients with non-obstructive HCM in 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**).

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

- Hired a U.S. marketing leader and continued to advance the go-to-market strategy for *aficamten* in the U.S.

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

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

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Continued enrolling patients with ALS in COURAGE-ALS (**C**linical **O**utcomes **U**sing ***R**eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS**), the Phase 3 clinical trial of *reldesemtiv*.

- Announced that the Data Monitoring Committee (DMC) for COURAGE-ALS (**C**linical **O**utcomes **U**sing ***R**eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS**) convened to review unblinded data from the clinical trial for the first interim analysis and recommended that conduct of the Phase 3 trial continue.

- Presented results from an additional analysis from FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**nvestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**), the Phase 2 clinical trial of *reldesemtiv* showing that the ENCALS predicted risk scores are strongly correlated with the rate of decline in ALSFRS-R.

- Published a manuscript entitled "MiToS and King's staging as clinical outcome measures in ALS: a retrospective analysis of the FORTITUDE-ALS trial" in *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration.*

Pre-Clinical Development and Ongoing Research

- Continued to advance new muscle directed compounds and conduct IND-enabling studies with the expectation of our potentially moving 1-2 drug candidates into clinical development this year.

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

- Published a manuscript entitled "Distinct Mechanisms for Increased Cardiac Contraction Through Selective Alteration of Either Myosin or Troponin Activity" in the *Journal of the American College of Cardiology: Basic to Translational Science*.

Corporate

- 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 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

omecamtiv mecarbil (cardiac myosin activator)

- Request meeting with FDA to understand what may be required to support potential approval of *omecamtiv mecarbil* in the United States.

- Engage with EMA regarding the MAA for the treatment of HFrEF.

aficamten (cardiac myosin inhibitor)

- Present data from Cohort 4 of REDWOOD-HCM at the American College of Cardiology's 72nd Annual Scientific Session.
- Present data from 48 weeks of treatment with *aficamten* in FOREST-HCM at the American College of Cardiology's 72nd Annual Scientific Session.
- 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 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.*

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

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

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- Expect the Data Monitoring committee to conduct the second interim analysis from COURAGE-ALS in Q2 2023, which will assess for futility and allow for a fixed increase in total enrollment, if deemed necessary, to augment the statistical power of the trial.
- Complete patient enrollment in COURAGE-ALS in Q2 2023, subject to second interim analysis.

Pre-Clinical Development and Ongoing Research

- Expect to advance CK-4021586, an additional cardiac myosin inhibitor, into clinical development in 1H 2023.

Financials

Revenues for the three and twelve months ended December 31, 2022 were $2.0 million and $94.6 million, respectively, compared to $55.6 million and $70.4 million for the corresponding period in 2021. The increase in revenues for the prior year was primarily due to the recognition of $54.9 million of license revenue recognized for the transaction with Ji Xing.

Research and development expenses for the three and twelve months ended December 31, 2022 increased to $75.0 million and $240.8 million, respectively, compared to $43.5 million and $159.9 million for the same period in 2021.

The changes were primarily due to increases in current year activities for clinical development for COURAGE-ALS and our cardiac myosin inhibitor programs.

General and administrative expenses for the three and twelve months ended December 31, 2022 increased to $54.0 million and $178.0 million, respectively, from $33.8 million and $96.8 million for the same period in 2021 due to higher outside service spending in anticipation of the potential launch of *omecamtiv mecarbil* and an increase in personnel related cost including stock-based compensation.

2023 Financial Guidance

The company today announced financial guidance for 2023. The company anticipates revenue will be up to $5 million, driven by Astellas reimbursement of the costs of COURAGE-ALS. In addition, we expect to receive $50 million in a milestone payment from Royalty Pharma upon the start of the pivotal Phase 3 clinical trial of *aficamten* in nHCM. Operating expenses will be in the range of $420 to $450 million, and net cash utilization will be approximately $350 to $375 million. Our current cash balance of approximately $830 million represents more than 2 years of forward cash based on our projected 2023 operating expenses and net cash utilization.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth quarter 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 homepage and in 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 2022 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 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 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 muscle function and contractility. Cytokinetics is developing *omecamtiv mecarbil*, a cardiac muscle activator in patients with heart failure. Cytokinetics is also 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 in Cohort 4 of the Phase 2 clinical trial, REDWOOD-HCM. Cytokinetics is also developing *reldesemtiv*, an investigational fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS). 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 remedy any of the deficiencies contained in FDA's complete response letter to our NDA for *omecamtiv mecarbil* or 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 conduct IND-enabling studies and to advance new muscle directed compounds into clinical development in the next year, if at all, 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 conduct a second interim analysis of COURAGE-ALS in the second quarter of 2023 or to complete patient enrollment in 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 first half 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*, *reldesemtiv* 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
Diane Weiser
Senior Vice President, Corporate Communications, Investor Relations
(415) 290-7757

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and short-term investments	$ 782,577	$ 471,638
Other current assets	12,609	64,034
Total current assets	795,186	535,672
Long-term investments	46,708	152,050
Property and equipment, net	80,453	73,271
Operating lease right-of-use assets	82,737	73,138
Other assets	9,691	7,188
Total assets	$ 1,014,775	$ 841,319
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 69,707	$ 55,457
Short-term lease liability	12,829	14,863
Other current liabilities	2,081	1,540
Total current liabilities	84,617	71,860
Term loan, net	63,810	47,367
Convertible notes, net	545,808	95,471
Liabilities related to revenue participation right purchase agreements, net	300,501	179,072
Long-term deferred revenue	—	87,000
Long-term operating lease liabilities	126,895	112,229
Other non-current liabilities	1,044	4,457
Total liabilities	1,122,675	597,456
Commitments and contingencies		
Stockholders' (deficit) equity:		
Common stock	94	84
Additional paid-in capital	1,481,590	1,452,268
Accumulated other comprehensive loss	(3,590)	(869)
Accumulated deficit	(1,585,994)	(1,207,620)
Total stockholders' (deficit) equity	(107,900)	243,863

Total liabilities and stockholders' (deficit) equity	$	1,014,775	$	841,319

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Research and development revenues	$ 1,957	$ 744	$ 6,588	$ 10,572
License revenues	—	54,856	—	54,856
Milestone revenues	—	—	1,000	5,000
Realization of revenue participation right purchase agreement	—	—	87,000	—
Total revenues	1,957	55,600	94,588	70,428
Operating expenses:				
Research and development	75,018	43,498	240,813	159,938
General and administrative	53,969	33,806	177,977	96,803
Total operating expenses	128,987	77,304	418,790	256,741
Operating loss	(127,030)	(21,704)	(324,202)	(186,313)
Interest expense	(7,057)	(4,218)	(19,414)	(16,440)
Loss on settlement of debt	—	—	(24,939)	—
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(9,212)	(4,271)	(31,742)	(12,892)
Interest and other income (loss), net	5,919	(377)	11,342	331
Net loss before income taxes	(137,380)	(30,570)	(388,955)	(215,314)
Income tax benefit	—	—	—	—
Net loss	$ (137,380)	$ (30,570)	$ (388,955)	$ (215,314)

Net loss per share — basic and diluted	$ (1.45)	$ (0.36)	$ (4.33)	$ (2.80)
Weighted-average shares in net loss per share — basic and diluted	94,681	84,087	89,825	76,886