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 03, 2022

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** **(Address of Principal Executive Offices)**	**94080** **(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 3, 2022, Cytokinetics, Incorporated (the "Registrant") announced its financial results for the third quarter ended September 30, 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)

Exhibit 99.1. Press release dated November 3, 2022.
Exhibit 104. Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 3, 2022

By: /s/ John Faurescu
John Faurescu, Esq.
Vice President, Corporate Legal & Assistant Secretary

CYTOKINETICS REPORTS THIRD QUARTER 2022 FINANCIAL RESULTS

Advisory Committee Meeting to Review NDA for Omecamtiv Mecarbil on December 13, 2022;
PDUFA Target Action Date Set for February 28, 2023

SEQUOIA-HCM Continuing with Results Expected in 2H 2023; Patient Screening for Cohort 4 of REDWOOD-HCM Closed with Data Expected in 1H 2023

COURAGE-ALS Continuing Following First Interim Analysis,
Enrollment Expected to Complete in 1H 2023

SOUTH SAN FRANCISCO, Calif., Nov. 3, 2022 - Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the third quarter of 2022. Net loss for the third quarter was $142.3 million, or $1.52 per share, compared to net loss for the third quarter of 2021 of $76.1 million, or $0.95 per share. Cash, cash equivalents and investments totaled $896.2 million at September 30, 2022.

"During the third quarter, we continued to execute towards our potential transformation to commercialization with expansion of teams and readiness activities in preparation for our upcoming FDA Advisory Committee meeting and the potential launch of *omecamtiv mecarbil*," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "At the same time, the development program for *aficamten* is proceeding with continued conduct of Cohort 4 of REDWOOD-HCM and SEQUOIA-HCM, alongside start up activities for our second Phase 3 clinical trial of *aficamten*. We also are continuing COURAGE-ALS following its first interim analysis marking progress aligned with our commitment to ALS. We have entered the fourth quarter with a strong balance sheet ahead of key corporate milestones."

Q3 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Engaged in further interactions with the U.S. Food and Drug Administration (FDA) related to our New Drug Application (NDA) for *omecamtiv mecarbil*. Continued discussions with FDA regarding matters related to substantial evidence of efficacy, benefit-risk, and dosing.

- Conducted meetings with assigned rapporteurs to discuss the planned submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).

- Continued commercial preparations for the potential U.S. launch of *omecamtiv mecarbil* including convening meetings with national and regional payers, advancing wholesaler agreements for distribution, finalizing third party logistics agreement, completing strategic sourcing of drug substance and drug product contract manufacturing organizations, continuing development of patient services hub, and beginning the final wave of hiring for sales force leaders.

- Expanded the headquarters- and field-based medical affairs team, continued support of independent medical education activities at medical conferences, and initiated planning for our Medical Contact Center.

- Launched "The Heart of Contractility," a disease state education campaign for healthcare providers to build awareness of worsening heart failure and the importance of contractility.

aficamten (cardiac myosin inhibitor)

- Continued clinical trial site activation and enrollment of patients with obstructive HCM in SEQUIOA-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*, with 70 sites now enrolling in the U.S. and Europe.

- Completed screening for patients with non-obstructive HCM to enroll 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**).

- Renamed the open-label extension clinical study of *aficamten* in patients with hypertrophic cardiomyopathy (HCM), previously known as REDWOOD-HCM OLE (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM O**pen **L**abel **E**xtension) to FOREST-HCM (**F**ive-Year, **O**pen-Label, **R**esearch **E**valuation of **S**ustained **T**reatment with *Aficamten* in **HCM**) to reflect the entry of patients from additional clinical trials of *aficamten* including SEQUOIA-HCM.

- Presented data from FOREST-HCM (previously known as REDWOOD-HCM OLE) at the Heart Failure Society of America (HFSA) Annual Scientific Meeting showing that treatment with *aficamten* was associated with substantial and significant symptom improvements as measured by the change in Kansas City Cardiomyopathy Questionnaire (KCCQ) scores.

- Presented data from FOREST-HCM at the 2022 HCM Society Scientific Sessions demonstrating in patients treated with *aficamten* the successful reduction or withdrawal of standard of care therapies.

- Published a manuscript entitled “A Phase 1 Dose-Escalation Study of the Cardiac Myosin Inhibitor *Aficamten* in Healthy Participants” in *JACC: Basic to Translational Science.*

Skeletal Muscle Program

reldesemtiv (fast skeletal muscle troponin activator (FSTA))

- 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 and recommended that conduct of the Phase 3 trial continue.

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 in the next year.

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

Corporate

- Raised $523.6 million in net proceeds from a 3.50% convertible senior notes offering (due 2027), after deducting underwriters’ discounts and transaction fees, and before repurchasing approximately $117 million of previously outstanding 4.00% convertible senior notes (due 2026).

- Announced a new release of the Pooled Resource Open-Access ALS Clinical Trials (PRO-ACT) database updated with clinical data from Cytokinetics’ completed clinical trials in ALS.

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

Upcoming Corporate Milestones

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Participate in Advisory Committee meeting to review the NDA for *omecamtiv mecarbil* on December 13, 2022.

- Launch *omecamtiv mecarbil* in the U.S. subject to FDA approval in Q1 2023.
- Submit Marketing Authorization Application (MAA) to the European Medicines Agency by the end of 2022.

aficamten (cardiac myosin inhibitor)

- Continue enrolling patients with obstructive HCM in SEQUOIA-HCM through 1H 2023 with results expected in 2H 2023.
- Complete enrolling patients with non-obstructive HCM in Cohort 4 of REDWOOD-HCM with data expected in 1H 2023.
- Begin second Phase 3 clinical trial of *aficamten* in obstructive HCM in Q4 2022.

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

- Begin Phase 1 study of CK-136 in Q4 2022.

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 1H 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.
- Continue enrolling patients with ALS in COURAGE-ALS and expect to complete enrollment in 1H 2023.

Financials

Revenues for the three and nine months ended September 30, 2022 were $2.5 million and $92.6 million, respectively, compared to $5.4 million and $14.8 million for the corresponding period in 2021. The increase in revenues for the nine months ended September 30, 2022 was primarily due to the recognition of $87.0 million of deferred revenue for royalties on the net sales of products containing *mavacamten* as a result of the extinguishment of royalty obligations.

Research and development expenses for the three and nine months ended September 30, 2022 increased to $62.7 million and $165.8 million, respectively, compared to $48.4 million and $116.4 million for the same period in 2021. The changes were primarily due to increases in spending for clinical development

activities for COURAGE-ALS and SEQUOIA-HCM, and for our other cardiac muscle inhibitor and early research programs.

General and administrative expenses for the three and nine months ended September 30, 2022 increased to $48.2 million and $124.0 million, respectively, from $26.2 million and $63.0 million for the same period in 2021 due primarily to higher outside services spending in anticipation of the potential commercial launch of *omecamtiv mecarbil*, and an increase in personnel related costs including stock-based compensation.

During the quarter, we recognized a loss of $22.2 million related to the conversion and partial settlement of our 2026 Convertible Notes.

Conference Call and Webcast Information

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 Q3 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 readying for the potential commercialization of *omecamtiv mecarbil*, its cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is also developing *aficamten*, a next-generation 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). Cytokinetics continues its over 20-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 commercially launch *omecamtiv mecarbil* by any particular date, if ever, 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 initiate a second phase 3 clinical trial of *aficamten* in patients with obstructive HCM by the fourth quarter of 2022 or to initiate a phase 1 clinical trial of CK-136 in the fourth quarter of 2022, our ability to conduct a second interim analysis of COURAGE-ALS in the first half of 2023, our ability to complete enrollment and announce results of SEQUOIA-HCM in the second half of 2023, our ability to complete enrollment and announce the results of Cohort 4 of REDWOOD-HCM in the first half of 2023, our ability to complete enrollment of COURAGE-ALS in the first half of 2023, our ability to submit a Marketing Authorization Application (MAA) to the European Medicines Agency by the end of 2022, the significance and utility of pre-clinical study and clinical trial results, including, but not limited to, the results of GALACTIC-HF in respect of *omecamtiv mecarbil*, SEQUOIA-HCM and REDWOOD-HCM in respect of *aficamten*, or COURAGE-ALS in respect of *reldesemtiv*, 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, including, but not limited to, our Advisory Committee for *omecamtiv mecarbil* scheduled for December 13, 2022, the likelihood of FDA's approval of the company's NDA for *omecamtiv mecarbil* by the PDUFA target action date of February 28, 2023 or at any other time, if ever; decisions by the FDA or other regulatory authorities to condition our approval of *omecamtiv mecarbil* on the need or approval of a dosage selection test for the personalized dose optimization of *omecamtiv mecarbil* in patients, our ability or the ability of any third party to develop or commercialize such a dosage selection test, or the timing, prospects, process or likelihood of the approval of such a dosage selection test, 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' Quarterly Report on Form 10-Q for the second quarter 2023. 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)

	September 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and short term investments	$ 867,664	$ 471,638
Other current assets	16,611	64,034
Total current assets	884,275	535,672
Long-term investments	28,544	152,050
Property and equipment, net	80,302	73,271
Operating lease right-of-use assets	75,076	73,138
Other assets	7,764	7,188
Total assets	$ 1,075,961	$ 841,319
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 54,658	$ 55,457
Short-term operating lease liabilities	16,056	14,863
Other current liabilities	5,782	1,540
Total current liabilities	76,496	71,860
Term loan, net	63,544	47,367
Convertible notes, net	544,986	95,471
Liabilities related to revenue participation right purchase agreements, net	291,260	179,072
Long-term deferred revenue	—	87,000
Long-term operating lease liabilities	114,405	112,229
Other non-current liabilities	1,247	4,457
Total liabilities	1,091,938	597,456
Commitments and contingencies		
Stockholders' equity:		
Common stock	93	84
Additional paid-in capital	1,438,103	1,452,268
Accumulated other comprehensive income	(5,559)	(869)
Accumulated deficit	(1,448,614)	(1,207,620)
Total stockholders' equity	(15,977)	243,863
Total liabilities and stockholders' equity	$ 1,075,961	$ 841,319

Cytokinetics, Incorporated

Condensed Consolidated Statements of Operations

(in thousands except per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2022	**September 30, 2021**	**September 30, 2022**	**September 30, 2021**
Revenues:				
Research and development revenues	$ 2,515	$ 437	$ 4,631	$ 9,828
Milestone revenues	—	5,000	1,000	5,000
Realization of revenue participation right purchase agreement	—	—	87,000	—
Total revenues	2,515	5,437	92,631	14,828
Operating expenses:				
Research and development	62,734	48,436	165,795	116,440
General and administrative	48,222	26,202	124,008	62,997
Total operating expenses	110,956	74,638	289,803	179,437
Operating loss	(108,441)	(69,201)	(197,172)	(164,609)
Interest expense	(6,804)	(4,161)	(12,357)	(12,222)
Loss on settlement of debt	(22,246)	—	(24,939)	—
Non-cash interest expense on liabilities related to revenue participation right purchase agreements	(8,963)	(2,955)	(22,530)	(8,621)
Interest and other income	4,144	231	5,423	708
Net loss	$ (142,310)	$ (76,086)	$ (251,575)	$ (184,744)
Net loss per share — basic and diluted	$ (1.52)	$ (0.95)	$ (2.85)	$ (2.48)
Weighted-average number of shares used in computing net loss per share — basic and diluted	93,758	80,329	88,195	74,460