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 6, 2021

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)	(I.R.S. Employer Identification No.)

280 East Grand Avenue
South San Francisco, California 94080
(Address of Principal Executive Offices) (Zip Code)

(650) 624-3000
(Registrant's telephone number, including area code)

Not Applicable
(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, par value $0.001	CYTK	The Nasdaq Stock Market LLC

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 6, 2021, Cytokinetics, Incorporated (the "Registrant") announced its financial results for the first quarter ended March 31, 2021. 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.

Exhibit 99.1	Press release dated May 6, 2021.
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 6, 2021

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

EXHIBIT 99.1

Cytokinetics Reports First Quarter 2021 Financial Results

Secondary Analysis from GALACTIC-HF to be Presented in Late Breaking Clinical Trial Session at ACC.21

Company Plans to Submit NDA for Omecamtiv Mecarbil following Recent Meeting with FDA

Results from REDWOOD-HCM Expected Mid-Year; Open Label Extension Study and Phase 3 Clinical Trial Planning Underway

SOUTH SAN FRANCISCO, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the first quarter of 2021. Net loss for the first quarter was $47.1 million, or $0.66 per share, compared to net loss for the first quarter of 2020 of $39.4 million, or $0.66 per share. Cash, cash equivalents and investments totaled $460.2 million at March 31, 2021.

"We continued to execute well in the first quarter against our ambitious plans. We recently convened a meeting with FDA related to *omecamtiv mecarbil* and GALACTIC-HF and are proceeding towards additional planned meetings this quarter with an expected NDA submission in the second half of the year," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "We look forward to the presentation of a secondary analysis from GALACTIC-HF which will shed further light on the impact of ejection fraction on patient outcomes. Additionally, we were pleased to complete enrollment in Cohort 2 of REDWOOD-HCM and more recently begin enrollment in the open-label extension study. We expect results from REDWOOD-HCM mid-year and are planning to initiate a pivotal Phase 3 trial by year-end."

Q1 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Met with the U.S. Food and Drug Administration (FDA) in Q1 and anticipate additional regulatory interactions in Q2 to inform plans to submit a New Drug Application (NDA) for *omecamtiv mecarbil* in 2H 2021. The planned regulatory filing is expected to be based on a single pivotal trial, GALACTIC-HF, which demonstrated a positive effect on the primary composite endpoint of cardiovascular death or heart failure events in patients receiving standard of care plus *omecamtiv mecarbil*

- Announced that data from a secondary analysis of 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) assessing the effect of *omecamtiv mecarbil* on clinical outcomes in relationship to patient baseline ejection fraction will be presented in a Late Breaking Clinical Trial session at the American College of Cardiology 70th Annual Scientific Session & Expo (ACC.21).

- Continued conduct of METEORIC-HF (**M**ulticenter **E**xercise **T**olerance **E**valuation of ***O****mecamtiv Mecarbil* **R**elated to **I**ncreased **C**ontractility in **H**eart **F**ailure), the second Phase 3 trial of *omecamtiv mecarbil*. Expect to complete enrollment in Q2 and report results in early 2022.

- Conducted market research, forecasting and other planning activities in support of the potential commercialization of *omecamtiv mecarbil.*

- Published a manuscript entitled, "Effect of Varying Degrees of Renal Impairment on the Pharmacokinetics of *Omecamtiv Mecarbil"* in *Clinical Pharmacokinetics*.

CK-3773274 (CK-274, cardiac myosin inhibitor)

- Dosed the first patient in Cohort 2 of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM**), the Phase 2 clinical trial designed to determine the safety and tolerability of CK-274 in patients with obstructive hypertrophic cardiomyopathy (oHCM). We subsequently completed enrollment in Cohort 2 of REDWOOD-HCM in Q1.

- Opened enrollment in Cohort 3 of REDWOOD-HCM for patients whose background therapy includes disopyramide.

- Activated the first site for enrollment in REDWOOD-HCM OLE, the open label extension clinical study designed to assess the long-term safety and tolerability of CK-274 in patients with symptomatic oHCM who have participated previously in REDWOOD-HCM.

- Received orphan drug designation for CK-274 for the potential treatment of symptomatic HCM from the FDA.

- Prepared for regulatory interactions with FDA to occur in Q2 and continuing into the second half of 2021 to inform preparations for a pivotal Phase 3 clinical trial of CK-274 in HCM, expected to begin by year-end.

- Recently presented data related to the optimization of CK-274, including the first disclosure of its chemical structure, at the American Chemical Society Spring 2021 Virtual Meeting.

- Enrolled the first patient in a Phase 1 study of CK-274 in China under the License and Collaboration Agreement between Cytokinetics and Ji Xing Pharmaceuticals Limited.

Skeletal Muscle Program

reldesemtiv (next-generation fast skeletal muscle troponin activator (FSTA))

- Conducted start-up activities, including regulatory and institutional review board submissions, for COURAGE-ALS (**C**linical **O**utcomes **U**sing ***R**eldesemtiv* on **A**LSFRS-R in a **G**lobal **E**valuation in **ALS**), the planned Phase 3 clinical trial of *reldesemtiv* in patients with ALS, in preparation for the potential opening of the trial to patient enrollment in 2H 2021.

- Completed joint research program under collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators.

- Published a manuscript entitled "*Reldesemtiv* in Patients with Spinal Muscular Atrophy: A Phase 2 Hypothesis-Generating Study" in *Neurotherapeutics.*

Pre-Clinical Development and Ongoing Research

- Continued to advance new chemical entities and to conduct IND-enabling studies with expectation of our potentially advancing 1-2 potential drug candidates in development over the next year.

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

Corporate

- Conducted planning activities related to the termination of the Collaboration and Option Agreement with Amgen and the transition of rights to develop and commercialize *omecamtiv mecarbil*, effective May 20, 2021.

- 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, ALS and SMA communities to support increased capacity in communications, disease awareness and community engagement.

- Convened inaugural Heart Failure Advisory Council meeting with patients and caregivers with heart failure to inform the ongoing development of the company's heart failure directed pipeline.

Financials

Revenues for the first quarter 2021 increased to $6.5 million from $3.8 million for the first quarter 2020 due to increased research and development revenue from our collaborations with Amgen and Astellas.

Research and development expenses for the first quarter 2021 increased to $31.6 million from $21.7 million for the first quarter of 2020. The changes were primarily due to increases in spending for COURAGE-ALS and our clinical development activities for our cardiac muscle inhibitor programs.

General and administrative expenses for the first quarter of 2021 increased to $15.6 million from $12.4 million for the first quarter in 2020, due primarily to an increase in personnel related costs including stock-based compensation and higher outside spending for commercial readiness.

We expect to revise our financial guidance mid-year once we finalize strategies and potential commercial launch plans for *omecamtiv mecarbil*. Executing on those strategies and plans may result in our incurring significant additional expenses that were not included in our current financial guidance. We expect that some or all of those potential expenses could be covered by our accessing additional capital through strategic partnership(s) with near term cash infusions or by equity and/or debt financings if deemed appropriate.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's first quarter 2021 results via a webcast and conference call today at 4:30 PM Eastern Time. The webcast can be accessed through the Investors & Media section of the Cytokinetics website at www.cytokinetics.com. The live audio of the conference call can also be accessed by telephone by dialing either (866) 999-CYTK (2985) (United States and Canada) or +1 (706) 679-3078 (international) and typing in the passcode 6097958.

An archived replay of the webcast will be available via Cytokinetics' website until May 20, 2021. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or +1 (404) 537-3406 (international) and typing in the passcode 6097958 from May 6, 2021 at 7:30 PM Eastern Time until May 20, 2021.

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 and/or declining. 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 conducting regulatory interactions for *omecamtiv mecarbil*, its novel cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is conducting METEORIC-HF, a second Phase 3 clinical trial of *omecamtiv mecarbil*. Cytokinetics is also developing CK-274, a next-generation cardiac myosin inhibitor, for the potential treatment of hypertrophic cardiomyopathies (HCM). Cytokinetics is conducting REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. Cytokinetics is also developing *reldesemtiv*, a fast skeletal muscle troponin activator for the potential treatment of ALS and other neuromuscular indications following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is preparing for the potential advancement of *reldesemtiv* to a Phase 3 clinical trial in 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 are not limited to, statements relating to Cytokinetics' and its partners' research and development and commercial readiness activities, including the initiation, conduct, design, enrollment, progress, continuation, completion, timing and results of clinical trials, including the completion of enrollment in METEORIC-HF in Q2 2021 and the release of results of METEORIC-HF in early 2022, the availability of results from the first and second cohorts of patients in REDWOOD-HCM by mid-year 2021, the commencement of a Phase 3 clinical trial of CK-274 by year-end 2021, the significance and utility of pre-clinical study and clinical trial results, including the results of GALACTIC-HF in respect of *omecamtiv mecarbil*; the timing of interactions with regulatory authorities in connection to any of Cytokinetics' drug candidates and the outcomes of such interactions, including the submission of an NDA for *omecamtiv mecarbil* in the second half of the year, and the prospects of regulatory approval for, and if approved, potential commercialization of *omecamtiv mecarbil*; our decision to engage in or execute, and the cost and expenses to be incurred in connection with, any particular transition activities from Amgen related to *omecamtiv mecarbil* and any particular commercial launch readiness activities for *omecamtiv mecarbil* ; the potential opening of COURAGE-ALS to patient enrollment in 2H 2021; and the properties and potential benefits of Cytokinetics' drug candidates. 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. 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.

Contact:
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Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2021	December 31, 2020

	(unaudited)	
ASSETS		
Current assets:		
Cash and short term investments	$ 425,577	$ 464,060
Other current assets	7,540	10,161
Total current assets	433,117	474,221
Long-term investments	34,664	36,954
Property and equipment, net	23,198	13,346
Operating lease right-of-use assets and other assets	86,083	9,282
Total assets	$ 577,062	$ 533,803
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 22,572	$ 27,365
Current portion of long-term debt	5,625	—
Short-term lease liabilities	5,295	2,785
Other current liabilities	2,438	1,049
Total current liabilities	35,930	31,199
Term loan, net	40,874	46,209
Convertible notes, net	90,889	89,504
Liability related to the sale of future royalties, net	168,890	166,068
Long-term deferred revenue	87,000	87,000
Long-term lease liability	85,633	440
Total liabilities	509,216	420,420
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	71	70
Additional paid-in capital	1,107,135	1,105,470
Accumulated other comprehensive income	50	149
Accumulated deficit	(1,039,410)	(992,306)
Total stockholders' equity (deficit)	67,846	113,383
Total liabilities and stockholders' equity (deficit)	$ 577,062	$ 533,803

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

	Three Months Ended	
	March 31, 2021	**March 31, 2020**
Revenues:		
Research and development revenues	$ 6,548	$ 3,825
Total revenues	6,548	3,825
Operating expenses:		
Research and development	31,561	21,738
General and administrative	15,598	12,449
Total operating expenses	47,159	34,187
Operating loss	(40,611)	(30,362)
Interest expense	(3,988)	(4,077)
Non-cash interest expense on liability related to the sale of future royalties	(2,795)	(5,689)
Interest and other income	290	723
Net loss	$ (47,104)	$ (39,405)
Net loss per share — basic and diluted	$ (0.66)	$ (0.66)
Weighted-average number of shares used in computing net loss per share — basic and diluted	71,195	59,270