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): February 25, 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 February 25, 2021, Cytokinetics, Incorporated (the "Registrant") announced its financial results for the fourth quarter ended December 31, 2020. 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 February 25, 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: February 25, 2021

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

EXHIBIT 99.1

Cytokinetics Reports Fourth Quarter 2020 Financial Results

Company Plans to Meet with FDA in Q1 to Discuss Results of GALACTIC-HF

Enrollment Completed in Cohort 2 of REDWOOD-HCM; Results Expected Mid-Year

Company Provides 2021 Financial Guidance; More Than Two Years of Cash Runway

SOUTH SAN FRANCISCO, Calif., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) reported financial results for the fourth quarter and full year 2020. Net loss for the fourth quarter was $43.9 million or $0.62 per share and the net loss for the year 2020 was $127.3 million or $1.97 per share. Net loss for the fourth quarter of 2019 was $30.6 million or $0.52 per share and net loss for the year 2019 was $121.7 million or $2.11 per share. Cash, cash equivalents and investments totaled $501.0 million at December 31, 2020.

"In the fourth quarter, we were pleased to present the results of 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,* with potentially larger treatment effects in patients with increasingly lower ejection fractions. In the next few weeks, we plan to discuss the results of GALACTIC-HF with FDA as may inform a potential registration path," said Robert I. Blum, Cytokinetics' President and Chief Executive Officer. "In addition, we recently progressed REDWOOD-HCM to Cohort 2 following a positive interim analysis and we completed enrollment promptly afterwards. Results from both cohorts are expected mid-year. We believe that we are well positioned for what may be a transformational year for the company as we approach potential commercialization of our first medicine for patients with heart failure and we hope to advance two other programs into pivotal clinical trials."

Q4 and Recent Highlights

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Results 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), the Phase 3 clinical trial of *omecamtiv mecarbil*, were presented and published online.
    - GALACTIC-HF demonstrated a statistically significant effect of treatment with *omecamtiv mecarbil* to reduce risk of the primary composite endpoint of cardiovascular (CV) death or heart failure events (heart failure hospitalization and other urgent treatment for heart failure) compared to placebo in patients treated with standard of care.
    - No reduction in the secondary endpoint of time to CV death was observed and no other secondary endpoints were met in accordance with the prespecified statistical analysis.
    - Adverse events and treatment discontinuation of study drug were balanced between the treatment arms. In general, the overall rates of myocardial ischemia, ventricular arrhythmias and death were similar between treatment and placebo groups.
    - The effect of *omecamtiv mecarbil* was consistent across most prespecified subgroups and with a potentially greater treatment effect suggested in patients with a lower left ventricular ejection fraction (LVEF).
- Supplemental analyses from GALACTIC-HF were presented that demonstrated a greater treatment effect of *omecamtiv mecarbil* in patients with lower LVEF as well as characteristics that may indicate advanced heart failure, such as being hospitalized within the last 3 months, higher N-terminal-pro brain natriuretic peptide levels and lower blood pressures.
- 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*.
- Presented findings from analyses of claims data and electronic health records related to heart failure, including analyses of the high spending and unmet need, underscoring the growing economic burden of this disease.
- Conducted market research with physicians and payors and continued other commercial planning activities for *omecamtiv mecarbil.*

CK-3828136 (CK-136 (formerly referred to as AMG 594), cardiac troponin activator)

- Analyzed data from the completed Phase 1 study of CK-136 conducted by Amgen to inform next steps in its development.

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

- Progressed 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), to Cohort 2 following the conduct of an interim analysis of data from Cohort 1. In December, we opened Cohort 2 in REDWOOD-HCM to screening and it completed patient enrollment in February.

    - The interim analysis of data from Cohort 1 showed that patients experienced substantial reductions in the average resting left ventricular outflow tract gradient (LVOT-G) as well as the post-Valsalva LVOT-G. These clinically relevant decreases in pressure gradients were achieved with only modest decreases in average LVEF; there were no dose interruptions due to LVEF falling below 50%. Pharmacokinetic data were similar to data from Phase 1.

    - Safety and tolerability data were supportive of continued dose escalation with no serious adverse events attributed to study treatment reported by the investigators.

- Received approval of IND submitted in China for conduct of a Phase 1 study of CK-274 under the License and Collaboration Agreement between Cytokinetics and Ji Xing Pharmaceuticals Limited.

- Presented preclinical data for CK-274 showing that it reduced contractility and left ventricular outflow tract peak pressure gradient in cats with naturally occurring HCM and left ventricular outflow tract obstruction.

CK-3772271 (CK-271, second cardiac myosin inhibitor)

- Presented preclinical data for CK-271 demonstrating that, in the Dahl/Salt sensitive rat model of heart failure with preserved ejection fraction (HFpEF), CK-271 attenuated the development of fibrosis and diastolic dysfunction.

- Completed the planned Phase 1, single-dose pharmacokinetic evaluation and tolerability assessments of CK-271 in healthy volunteers and determined it to be suitable for further development. We are evaluating its potential for further development in connection with plans to conduct a broad development program for our cardiac myosin inhibitor(s) in HCM and other indications.

Skeletal Muscle Program

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

- Additional data from FORTITUDE-ALS, the Phase 2 clinical trial of *reldesemtiv* in patients with ALS, were presented showing that the effect of *reldesemtiv* was more apparent in faster progressing patients, supporting the rationale and design of COURAGE-ALS, the planned Phase 3 clinical trial of *reldesemtiv* in patients with ALS.

- The design of COURAGE-ALS was also presented, and we conducted readiness activities in preparation for the potential start of the trial.

Pre-Clinical Development and Ongoing Research

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

- Continued research in collaboration with Astellas directed to the discovery of next-generation skeletal muscle activators under a joint research program extended through March 31, 2021.

- Continued research activities directed to our other muscle biology research programs which we expect to continue in 2021.

Corporate

- Announced we will regain worldwide rights to develop and commercialize *omecamtiv mecarbil* and CK-136 in May 2021.

- Named Nancy Wysenski and Muna Bhanji to the company's Board of Directors.

- Received $85 million upon the closing of the sale of a royalty on *mavacamten*, being developed by Bristol-Myers Squibb Company (formerly by MyoKardia, Inc.), to RTW Royalty Holdings Designated Activity Company.

2021 Corporate Milestones

Cardiac Muscle Programs

omecamtiv mecarbil (cardiac myosin activator)

- Plan to meet with FDA to discuss GALACTIC-HF in Q1 2021.

- Expect enrollment in METEORIC-HF to be completed in 1H 2021.

- Develop a "go-to-market" strategy and potential commercial launch plan in 1H 2021.

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

- Expect a Phase 1 study of CK-274 in China, conducted under the License and Collaboration Agreement between Cytokinetics and Ji Xing Pharmaceuticals Limited, to start in Q1 2021.
- Expect to begin an open label extension study for patients who complete REDWOOD-HCM in Q2 2021.
- Expect to announce results from both cohorts in REDWOOD-HCM by mid-year 2021.
- Plan to engage regulatory authorities regarding a potential registration path in 2H 2021.
- Expect to begin a potential Phase 3 clinical trial of CK-274 by the end of 2021.

Skeletal Muscle Program

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

- We expect to conduct start-up activities for COURAGE-ALS in 2021 and may open the trial to enrollment in 2H 2021, subject to our plans relating to advancing *omecamtiv mecarbil* towards commercialization and CK-274 to a potential Phase 3 clinical trial in patients with oHCM.

Financials

Revenues for the three and twelve months ended December 31, 2020 were $6.7 million and $55.8 million, respectively, compared to $5.2 million and $26.9 million for the corresponding periods in 2019. The increase in revenues for the year ended December 31, 2020 was primarily due to $36.5 million of license revenue recognized in the third quarter 2020 for the RTW transactions.

Research and development expenses for the three and twelve months ended December 31, 2020 increased to $29.2 million and $97.0 million, respectively, compared to $18.3 million and $86.1 million for the same periods in 2019, respectively, due primarily to increased spending for our cardiac myosin inhibitor programs and increased spending on readiness for *reldesemtiv* offset by a study that concluded on *reldesemtiv* in 2019.

General and administrative expenses for the three and twelve months ended December 31, 2020 increased to $13.9 million and $52.8 million from $10.6 million and $39.6 million in 2019 due primarily to an increase in personnel related costs including stock-based compensation and higher outside spending for commercial readiness.

2021 Financial Guidance

The company today announced financial guidance for 2021. The company anticipates revenue will be in the range of $23 to $28 million, operating expenses will be in the range of $195 to $205 million, and net cash utilization will be approximately $160 to 170 million. Our current cash balance of $501 million represents more than two years of forward cash based on our projected operating expenses and this net cash utilization range. The net cash utilization range includes approximately $35 million of non-recurring, building construction and related costs; it also includes receipt of a potential $45 million from RTW Royalty Holdings Designated Activity Company in exchange for a low single digit royalty on CK-274 in connection with the funding agreement signed in July 2020, subject to conditions for payment being fulfilled. Should we not exercise our option to receive the $45 million, we expect our net cash utilization range will be increased. We expect to revise our financial guidance mid-year once we finalize strategies and potential commercial launch plans for *omecamtiv mecarbil*. Significant additional expenses may arise from our executing on those strategies and plans that are not included in the current financial guidance.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will review the company's fourth quarter 2020 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 6555297.

An archived replay of the webcast will be available via Cytokinetics' website until March 11, 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 6555297 from February 25, 2021 at 7:30 PM Eastern Time until March 11, 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 preparing for 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 1H 2021 and the release of results of METEORIC-HF by the end of 2021, 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 discussions related to the potential NDA submission and prospects of regulatory approval for, and if approved, potential commercialization of *omecamtiv mecarbil* and discussions in preparation for a potential Phase 3 clinical trial and registration program for *reldesemtiv* in patients with ALS; 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*, including, but not limited to, any development and regulatory activities associated with the immunoassay used in GALACTIC-HF and METEORIC-HF and the potential purchase of drug substance related to *omecamtiv mecarbil*, the expected timing of events and milestones; the properties and potential benefits of Cytokinetics' drug candidates; and our ability to meet any conditions required for the disbursement of $45 million under our funding agreement with RTW Royalty Holdings Designated Activity Company. 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:
Cytokinetics
Diane Weiser
Senior Vice President, Corporate Communications, Investor Relations
(415) 290-7757

Cytokinetics, Incorporated
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and short term investments	$ 464,060	$ 225,112
Other current assets	10,161	8,640
Total current assets	474,221	233,752

Long-term investments	36,954	42,650
Property and equipment, net	13,346	4,530
Operating lease right-of-use assets and other assets	9,282	8,882
Total assets	$ 533,803	$ 289,814
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 27,365	$ 20,283
Short-term lease liability	2,785	4,616
Other current liabilities	1,049	1,124
Total current liabilities	31,199	26,023
Term loan, net	46,209	45,052
Convertible notes, net	89,504	84,205
Liability related to the sale of future royalties, net	166,068	143,276
Long-term deferred revenue	87,000	—
Long-term lease liability	440	2,195
Total liabilities	420,420	300,751
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock	70	59
Additional paid-in capital	1,105,470	853,341
Accumulated other comprehensive income	149	679
Accumulated deficit	(992,306)	(865,016)
Total stockholders' equity (deficit)	113,383	(10,937)
Total liabilities and stockholders' equity (deficit)	$ 533,803	$ 289,814

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

	Three Months Ended December 31,			Years Ended December 31,		
	2020	**2019**	**2018**	**2020**	**2019**	**2018**
Revenues:						
Research and development revenues	$ 4,222	$ 5,212	$ 9,377	$ 16,527	$ 26,868	$ 26,368
License revenues	—	—	—	36,501	—	5,133
Milestone revenues	2,500	—	—	2,800	—	—
Total revenues	6,722	5,212	9,377	55,828	26,868	31,501
Operating expenses:						
Research and development	29,221	18,334	23,278	96,951	86,125	89,135
General and administrative	13,908	10,584	7,558	52,820	39,610	31,282
Total operating expenses	43,129	28,918	30,836	149,771	125,735	120,417
Operating loss	(36,407)	(23,706)	(21,459)	(93,943)	(98,867)	(88,916)
Interest expense	(4,018)	(2,731)	(1,170)	(15,963)	(6,623)	(3,797)
Non-cash interest expense on liability related to sale of future royalties	(5,651)	(5,533)	(4,740)	(22,713)	(20,737)	(17,767)
Interest and other income, net	2,146	1,330	900	5,329	4,535	4,191
Net loss before income taxes	(43,930)	(30,640)	(26,469)	(127,290)	(121,692)	(106,289)
Income tax benefit	—	—	—	—	—	—
Net loss	$ (43,930)	$ (30,640)	$ (26,469)	$(127,290)	$(121,692)	$(106,289)
Net loss per share — basic and diluted	$ (0.62)	$ (0.52)	$ (0.48)	$ (1.97)	$ (2.11)	$ (1.95)
Weighted-average shares in net loss per share — basic and diluted	70,833	59,133	54,689	64,524	57,575	54,420