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 13, 2020

Cytokinetics, Incorporated

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50633**	**94-3291317**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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 8.01. Other Events.

On November 13, 2020 Cytokinetics, Incorporated ("Cytokinetics") announced the primary 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 event-driven cardiovascular outcomes clinical trial of *omecamtiv mecarbil*. The results were presented by John Teerlink, M.D., Professor of Medicine, University of California San Francisco, Director of Heart Failure, San Francisco Veterans Affairs Medical Center and Executive Committee Chair, GALACTIC-HF, in a Late Breaking Clinical Trial session at the American Heart Association (AHA) Scientific Sessions 2020, and were simultaneously published in the *New England Journal of Medicine*.[1]

GALACTIC-HF, one of the largest Phase 3 global cardiovascular outcomes trials in heart failure ever conducted, enrolled 8,256 patients who were at risk of hospitalization and death, despite being well treated on standard of care therapy. After a median duration of follow-up of 21.8 months, the trial 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. A first primary endpoint event occurred in 1,523 of 4,120 patients (37.0%) in the *omecamtiv mecarbil* group and in 1,607 of 4,112 patients (39.1%) in the placebo group (hazard ratio, 0.92; 95% confidence interval [CI] 0.86, 0.99; p=0.025). This effect was observed without evidence of an increase in the overall rates of myocardial ischemic events, ventricular arrhythmias or death from cardiovascular or all causes.

The statistically significant reduction in the composite of heart failure events or cardiovascular deaths, without significant imbalances in the overall incidence of adverse events across treatment arms, was observed in one of the broadest and most diverse range of patients enrolled in a contemporary heart failure trial. GALACTIC-HF included both inpatients and outpatients, and with a high representation of participants with moderate to severe heart failure symptoms as well as lower ejection fraction, systolic blood pressure and renal function.

No reduction in the secondary endpoint of time to CV death was observed. Death from cardiovascular causes occurred in 808 (19.6%) patients treated with *omecamtiv mecarbil* and 798 patients (19.4%) assigned to placebo (hazard ratio, 1.01; 95% CI, 0.92 to 1.11; p=0.86). The pre-specified analysis of change from baseline to week 24 in the KCCQ total symptom score by randomization setting (inpatient mean difference [95% CI]: 2.50 [0.54, 4.46], outpatient mean difference: -0.46 [-1.40, 0.48], joint P = 0.028) did not meet the significance threshold of P=0.002 based upon the multiplicity control testing procedure. No other secondary endpoints were met in accordance with the prespecified statistical analysis.

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 ≤28%, n=>4,000, hazard ratio, 0.84; 95% CI 0.77, 0.92; interaction p=0.003). *Omecamtiv mecarbil* also significantly decreased NT-proBNP concentrations by 10 % (95% CI 6-14%) at Week 24 compared to placebo.

The overall safety profile of *omecamtiv mecarbil* in GALACTIC-HF appears to be consistent with data from previous trials. 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. Additionally, there was no significant difference in the change in systolic blood pressure between baseline and at 24 or 48 weeks between the *omecamtiv mecarbil* and placebo groups. There was a small but significant decrease in heart rate in participants assigned to *omecamtiv mecarbil* compared to placebo at both timepoints. Median cardiac troponin I concentration increased 4 ng/L (95% CI 3-5; limit of detection, 6 ng/L) from baseline with *omecamtiv mecarbil* compared to placebo.

Investor/Media Event

Cytokinetics will host an investor and media event on November 13, 2020 at 1:00 PM ET that will be simultaneously webcast and can be accessed at https://wsw.com/webcast/cc/cytk/1388034 as well as from the Investors & Media section of Cytokinetics' website at www.cytokinetics.com. An archived replay of the virtual event will be available via Cytokinetics' website until November 13, 2021.

GALACTIC-HF: Trial Design

GALACTIC-HF,[2] (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure), one of the largest Phase 3 global cardiovascular outcomes studies in heart failure ever conducted, enrolled 8,256 patients in 35 countries across 945 sites with HFrEF, New York Heart Association (NYHA) class II-IV, left ventricular ejection fraction (LVEF) ≤35%, elevated natriuretic peptides and either current hospitalization for heart failure or history of hospitalization or emergency department visit for heart failure within a year. Patients were randomized to either oral placebo or a starting dose of 25 mg *omecamtiv mecarbil* twice daily (maintenance dose of 50 mg, 37.5 mg, or 25 mg twice daily) guided by pharmacokinetic-guided dose selection. A blood test, the QMS *Omecamtiv Mecarbil* Immunoassay (the OM Test) was used to measure plasma levels of *omecamtiv mecarbil* in each patient in order to guide selection of the appropriate maintenance dose.

The primary composite endpoint of this double-blind, placebo-controlled, event-driven trial was time to CV death or first heart failure event (heart failure hospitalization and other urgent treatment for heart failure). Secondary endpoints were: time to CV death, patient reported outcomes (measured by Kansas City Cardiomyopathy Questionnaire [KCCQ] Total Symptom Score [TSS]), time to first heart failure hospitalization and time to all-cause death.

About *Omecamtiv Mecarbil* and the Phase 3 Clinical Trials Program

Omecamtiv mecarbil is an investigational selective cardiac myosin activator, the first of a novel class of myotropes[3] designed to directly target the contractile mechanisms of the heart, binding to and recruiting more cardiac myosin heads to interact with actin during systole. Preclinical research has shown that *omecamtiv mecarbil* increases cardiac contractility without increasing intracellular myocyte calcium concentrations or myocardial oxygen consumption.[4-6] Cardiac myosin is the cytoskeletal motor protein in the cardiac muscle cell that is directly responsible for converting chemical energy into the mechanical force resulting in cardiac contraction.

Omecamtiv mecarbil is being developed for the potential treatment of heart failure with reduced ejection fraction (HFrEF) under a collaboration between Amgen and Cytokinetics, with funding and strategic support from Servier. *Omecamtiv mecarbil* is the subject of a comprehensive Phase 3 clinical trials program composed of GALACTIC-HF and METEORIC-HF (Multicenter Exercise Tolerance Evaluation of *Omecamtiv Mecarbil* Related to Increased Contractility in Heart Failure), a Phase 3 clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity.

About Heart Failure

Heart failure is a grievous condition that affects more than 64 million people worldwide[7] about half of whom have reduced left ventricular function.[8,9] It is the leading cause of hospitalization and readmission in people age 65 and older.[10, 11] Despite broad use of standard treatments and advances in care, the prognosis for patients with heart failure is poor.[12] An estimated one in five people over the age of 40 are at risk of developing heart failure, and approximately 50 percent of people diagnosed with heart failure will die within five years of initial hospitalization.[13,14]

About Cytokinetics and Amgen Collaboration

In 2006, Cytokinetics and Amgen entered into a strategic alliance to discover, develop and commercialize novel small molecule therapeutics designed to activate the cardiac sarcomere for the potential treatment of heart failure. *Omecamtiv mecarbil* is being developed by Amgen in collaboration with Cytokinetics, with funding and strategic support from Servier. Amgen holds an exclusive, worldwide license to *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization rights. Cytokinetics is eligible for pre-commercialization and commercialization milestone payments and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. Cytokinetics has co-invested with Amgen in the Phase 3 development program of *omecamtiv mecarbil* in exchange for increased royalties from Amgen on worldwide sales of *omecamtiv mecarbil* outside Japan and co-promotion rights in institutional care settings in North America. Amgen has also entered an alliance with Servier for exclusive commercialization rights for *omecamtiv mecarbil* in Europe as well as the Commonwealth of Independent States, including Russia. Servier contributes funding for development and provides strategic support to the program.

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 collaborating with Amgen Inc. (Amgen) to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of an international clinical trials program in patients with heart failure including GALACTIC-HF, of which topline results were recently reported, and METEORIC-HF, which is ongoing. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is developing *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA) for the potential treatment of ALS and other neuromuscular indications following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is considering potential advancement of *reldesemtiv* to Phase 3 pending ongoing regulatory interactions. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to research, develop and commercialize other novel mechanism skeletal sarcomere activators (not including FSTAs). Licenses held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies. Cytokinetics has granted Ji Xing Pharmaceuticals Limited an exclusive license to develop and commercialize CK-274 in China and Taiwan, in accordance with Cytokinetics' planned global registration programs. Cytokinetics is conducting REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. 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 disclaims any intent or obligation to update these forward-looking statements and 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 the GALACTIC-HF clinical trial; statements relating to the METEORIC-HF clinical trial; the potential benefits of *omecamtiv mecarbil*, including its ability to represent a novel therapeutic strategy to increase cardiac muscle function and restore cardiac performance; the potential approval of *omecamtiv mecarbil* by the FDA or any other regulatory authority; Cytokinetics' and its partners' research and development activities; the design, timing, results, significance and utility of preclinical and clinical results; and the properties and potential benefits of Cytokinetics' other 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, 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; Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; the nature of Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; standards of care may change, rendering Cytokinetics' drug candidates obsolete; competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target; and risks and uncertainties relating to the timing and receipt of payments from its partners, including milestones and royalties on future potential product sales under Cytokinetics' collaboration agreements with such partners. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

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Contact:
Cytokinetics
Diane Weiser
Senior Vice President, Corporate Communications, Investor Relations
(415) 290-7757

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CYTOKINETICS, INCORPORATED

Date: November 13, 2020

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