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 6, 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 February 6, 2020, Cytokinetics, Incorporated ("Cytokinetics" or the "Company") announced the publication of a manuscript relating to the design 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), the Phase 3 event driven cardiovascular outcomes clinical trial of *omecamtiv mecarbil* in the *Journal of American College of Cardiology: Heart Failure (JACC: HF)*. *Omecamtiv mecarbil*, a selective cardiac myosin activator, is being developed for the potential treatment of heart failure with reduced ejection fraction under a collaboration between Amgen and Cytokinetics, with funding and strategic support from Servier.

GALACTIC-HF: Designed to Enroll High Risk Patients from Inpatient and Outpatient Settings

GALACTIC-HF is designed to evaluate whether treatment with *omecamtiv mecarbil*, dosed twice-daily in accordance with a pharmacokinetic-guided dose selection regimen, when added to standard of care, reduces the risk of heart failure events (heart failure hospitalization or other urgent, unscheduled treatment for heart failure) and cardiovascular (CV) death in patients with chronic heart failure and reduced ejection fraction. GALACTIC-HF opened to enrollment in late 2016 and was designed to enroll approximately 8,000 heart failure patients with reduced ejection fraction at over 1,000 sites in 35 countries who are either currently hospitalized for a primary reason of heart failure or have had a hospitalization or admission to an emergency room for a primary reason of heart failure within one year prior to screening. Patients were also required to have a left ventricular ejection fraction (LVEF) £35% and elevated natriuretic peptides. GALACTIC-HF completed enrollment in 2019, having enrolled 8,256 patients in 35 countries. Approximately 25% of patients in GALACTIC-HF were hospitalized at the time of randomization.

GALACTIC-HF: Designed to Provide 90% Statistical Power to Assess Risk of Cardiovascular Death

The primary efficacy endpoint in GALACTIC-HF is the composite of time to CV death or first heart failure event, whichever occurs first. However, the trial is statistically powered based on a hypothesis relating to the first secondary endpoint, time to CV death. An accrual of 1,590 CV deaths provides 90% power to detect a hazard ratio of 0.8 for CV death. A sample size of 8,000 patients was chosen assuming the following: an annualized rate of CV death of 10% in the first year and 7% thereafter, a 24-month enrollment period, total study duration set to 48 months, a 3-month treatment lag with a treatment effect hazard ratio of 0.8 thereafter, 10% annual rate of study drug discontinuation, and 10% of subjects lost to endpoint determination either through non-CV death or study discontinuation over the course of the trial. The overall type I error is 0.05 for 2-sided testing. Assuming the rates for experiencing either a heart failure event or CV death are double those for CV death alone, and the same other assumptions as for CV death alone, the primary composite endpoint is expected to have greater than 99% statistical power.

GALACTIC-HF: Second Interim Analysis Expected to Occur in Q1 2020

According to protocol, the first and second interim analyses in GALACTIC-HF are to be conducted by the Data Monitoring Committee (DMC) following the accrual of approximately one-third and two-thirds respectively of the targeted 1,590 CV deaths. In March 2019, the DMC completed the first planned interim analysis which could have provided for the early stopping of the trial for futility. The DMC reviewed data from the trial and recommended that the trial continue without changes to its conduct. The second interim analysis is expected to occur in Q1 2020 and the DMC will assess for both futility and superiority. The statistical analysis plan provides guidance for the DMC to recommend stopping the trial for superiority if the primary composite endpoint and the secondary endpoint of time to CV death are both highly statistically significant. The DMC may also stop the trial for futility if there is a low likelihood of the trial demonstrating a statistically significant benefit on the primary endpoint.

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

Omecamtiv mecarbil is a novel investigational selective cardiac myosin activator that binds to the catalytic domain of myosin. Preclinical research has shown that cardiac myosin activators increase cardiac contractility without affecting intracellular myocyte calcium concentrations or myocardial oxygen consumption.[1-3] 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 comprised 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), a large, Phase 3 global event driven cardiovascular outcomes study, and 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), a Phase 3 clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity.

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 is an independent international pharmaceutical company, governed by a non-profit foundation, with its headquarters in France.

Forward-Looking Statements

This current report 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, including the planned timing of a second interim analysis for superiority; the potential benefits of *omecamtiv mecarbil*, including its ability to represent a novel therapeutic strategy to increase cardiac muscle function and restore cardiac performance; 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' 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; 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.

References

1 Planelles-Herrero VJ, Hartman JJ, Robert-Paganin J. et al. Mechanistic and structural basis for activation of cardiac myosin force production by omecamtiv mecarbil. *Nat Commun*. 2017;8:190.

2 Shen YT, Malik FI, Zhao X, et al. Improvement of cardiac function by a cardiac myosin activator in conscious dogs with systolic heart failure. *Circ Heart Fail*. 2010; 3: 522-27.

3 Malik FI, Hartman JJ, Elias KA, Morgan BP, Rodriguez H, Brejc K, Anderson RL, Sueoka SH, Lee KH, Finer JT, Sakowicz R. Cardiac myosin activation: a potential therapeutic approach for systolic heart failure. *Science*. 2011 Mar 18;331(6023):1439-43.

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 7, 2020

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