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): October 5, 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 October 5, 2020 Cytokinetics, Incorporated ("Cytokinetics") announced that new data were presented at the Heart Failure Society of America (HFSA) Virtual Annual Scientific Meeting 2020. The first presentation provided analyses of outcomes research in patients with heart failure with reduced ejection fraction (HFrEF) whose characteristics were similar to those patients who met eligibility criteria for 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 second presentation provided post hoc analyses of effects of *omecamtiv mecarbil* on right ventricular function arising from COSMIC-HF (**C**hronic **O**ral **S**tudy of **M**yosin Activation to **I**ncrease **C**ontractility in **H**eart **F**ailure), the Phase 2 clinical trial evaluating *omecamtiv mecarbil* in patients with HFrEF.

Characteristics and Outcomes of a Real-World Population with HFrEF Representative of Patients Enrolled in GALACTIC-HF

De-identified electronic health records from 2006-2019 of inpatients and outpatients at the Vanderbilt University Medical Center were used to create two real-world cohorts of HFrEF patients. The "clinical cohort" included 3,955 patients matching the eMERGE network phenotype of HFrEF, with a left ventricular ejection fraction (LVEF) ≤ 40%. A "GALACTIC-HF-like cohort" included 1,541 patients identified by mirroring the eligibility criteria of the trial, including hospitalizations, medications, laboratory values and a LVEF ≤ 35%. Approximately 40% of real-world HFrEF patients met the eligibility criteria for GALACTIC-HF in this database. The median age at index date for the clinical cohort was 65, and 61 for the GALACTIC-HF-like cohort. Both cohorts were approximately two-thirds male and 80% white. Aside from a higher median N-terminal B-type natriuretic peptide (NT-proBNP) level in the GALACTIC-HF-like cohort (821 pg/mL vs. 506 pg/mL in the clinical cohort), blood pressure and heart rate of the two cohorts were similar. Comorbidities including chronic kidney disease (31% vs. 21%) and atrial fibrillation (32% vs. 29%) were somewhat higher in the GALACTIC-HF-like cohort than in the clinical cohort, as was utilization of cardiac resynchronization or implantable cardioverter defibrillator (26% vs. 23%). The heart failure hospitalization rate (per 1000 patient-years) was 242 (203, 280; 95% confidence interval [CI]) in the clinical cohort and 396 (350, 442; 95% CI) in the GALACTIC-HF-like cohort during median follow up of 2.7 and 4.1 years, respectively. The rates of HF hospitalization in both cohorts, and in particular the GALACTIC-HF-like cohort, indicates a high-risk population with significant unmet need.

New Results from COSMIC-HF Demonstrate Improvement in Right Ventricular Function During Treatment with *Omecamtiv Mecarbil*

In COSMIC-HF, 448 patients with stable, symptomatic heart failure and left ventricular ejection fraction (LVEF) <40% were randomly assigned to *omecamtiv mecarbil* [25 mg twice daily (n=150); or 25 mg twice daily with pharmacokinetic-guided dose selection to 50 mg twice daily (PK titration group, n=149)] or placebo (n=149) in a double-blind fashion for 20 weeks. Previously reported results showed improvements in measures of left ventricular function in the PK group. This post-hoc analysis assessed the effect of *omecamtiv mecarbil* on right ventricular structure and function. Patients in the PK titration group who received *omecamtiv mecarbil* had improved measures of right ventricular function, including right ventricular systolic ejection time (RV-SET) ($p<0.001$), right ventricular end-systolic area (RV-ESA) ($p=0.012$), and right ventricular outflow tract velocity time integral (RVOT-VTI) ($p=0.002$). Additionally, measures of right ventricular pulmonary arterial coupling were also improved, including pulmonary arterial systolic pressure (PASP) ($p=0.008$), tricuspid annular plane systolic excursion (TAPSE)/PASP ratio ($p=0.002$), and RVOT-VTI/PASP ratio ($p=0.002$), indicating improved blood flow from the right ventricle was not met with increased pulmonary arterial resistance.

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[1], 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.[2-4] 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.

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 and METEORIC-HF. 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. Cytokinetics is collaborating with Astellas Pharma Inc. (Astellas) to research, develop and commercialize other novel mechanism skeletal sarcomere activators (excluding 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 (HCM). 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 filing 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 expected timing of the availability of top-line results; 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; 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.

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: October 5, 2020

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