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 16, 2020

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 8.01. Other Events.

On November 16, 2020, Cytokinetics, Incorporated ("Cytokinetics" or the "Registrant") announced that new findings from analyses of claims data and electronic health records related to heart failure and hypertrophic cardiomyopathy (HCM) were shared in three poster presentations at the American Heart Association (AHA) Scientific Sessions 2020. Two posters related to heart failure included one detailing analyses of outcomes highlighting the high unmet need in these patients with reduced ejection fraction (HFrEF) and a worsening heart failure event, and another one presenting data on spending for hospitalized Medicare patients with heart failure underscoring the high costs of their healthcare. An additional poster presented demographics and clinical characteristics of patients with HCM.

Findings in Heart Failure Detail High Risk Population and High Spending Among Hospitalized Patients

The first analysis, conducted in collaboration with Duke Clinical Research Institute, characterized outcomes of patients with HFrEF and a recent worsening heart failure event (WHF), defined as an emergency department visit or hospitalization with heart failure as the primary discharge diagnosis within 12 months prior to their index echocardiogram. A total of 3,867 patients aged 18-85 with chronic symptomatic HFrEF were identified via electronic health records from the Duke University Health System between January 2008 to December 2018. 1,668 (43.1%) had a WHF event in the year prior to index echocardiogram. Patients with a recent WHF event had more comorbidities, including the presence of renal disease (40.5% vs. 26.7%; $p<0.001$) as well as higher rates of mortality (hazard ratio 1.59; $p<0.001$), all-cause hospitalization (hazard ratio 1.51; $p<0.001$), and heart failure hospitalization (hazard ratio 1.85; $p<0.001$). Patients with a recent WHF event also had lower ejection fraction (EF) (63.5% with EF <25% vs. 48.4%; $p<0.001$) and higher NT-proBNP (3864 vs. 2443; $p<0.001$). Use of heart failure medication was statistically significantly higher in those with a recent WHF event (% on ACE-I, ARB, ARNI/Beta-Blocker/Mineralocorticoid antagonist was 87/76/53 for the WHF group and 78/71/35 for non-WHF). These results suggest that despite broad use of heart failure medication in patients who experienced a worsening heart failure event, a significant unmet need remains for new therapies.

The second analysis, conducted in collaboration with Yale University School of Medicine, examined payments spanning the index hospitalization through 30-days post-discharge for Medicare beneficiaries with heart failure (HF). Using Medicare fee-for-service administrative claims data, patients hospitalized with HF from 2016-2018 were identified with the following primary discharge diagnoses (ICD-10 codes): systolic HF (50.2 and 50.4), diastolic HF (50.3), hypertensive heart disease (HHD) with HF (I11), and HHD with HF and chronic kidney disease (CKD) (I13). Of the 935,962 patients hospitalized with HF included in the analysis, 365,274 (39.0%) were hospitalized with HHD with HF and CKD, 226,929 (24.2%) with HHD with HF, 165,156 (17.6%) with diastolic HF, and 178,603 (19.1%) with systolic HF. Over time, there was a substantial increase in hospital admissions with a primary diagnosis of HHD with HF with or without CKD. Payments varied across HF diagnosis, with the highest payments for patients with HHD with HF and CKD. The total estimated mean Medicare 30-day payments for HF care were approximately $16.5 billion over the 3-year study period, with little change in spending year to year. These results underscore the high cost of heart failure related health care, especially for hospitalizations.

Demographics and Clinical Characteristics of Patients with Obstructive HCM

In a retrospective analysis of demographics and clinical characteristics of adult patients with obstructive HCM (oHCM), patients were identified from electronic health records from 39 Integrated Delivery Networks (IDN) in the IBM Explorys database from 2010 through 2018. Of 8,792 patients, 53.0% were female, and 81.2% Caucasian (mean index age: 61.8 years). Primary insurance type was private (58.9%) and 54.9% of patients lived in the Midwest. Mean BMI at index was 30.4 and 30.9% were nondrinkers. The mean Quan-Charlson Comorbidity Index was 6.35% with the most common comorbidities being congestive heart failure (31.9%), chronic pulmonary disease (20.1%), and diabetes without chronic complications (16.9%). Cardiovascular (CV) drug rates included beta blockers (80.5%), calcium channel blockers (46.0%), ACE inhibitors (27.7%), ARBs (18.8%), disopyramide (2.4%) and amiodarone (13.0%). Surgical procedure rates included septal myectomy (22%), ablation (19.8%), implantable cardioverter defibrillator (11.2%), and heart transplantation (0.3%). Major residual side effects subsequent to surgical procedures included atrial fibrillation (31.4%) and reintervention (15.6%). Common reintervention procedures included ablation and septal myectomy. The results from this analysis of a large, diverse, national sample of patients with obstructive HCM may be used to compare the characteristics of patients with obstructive HCM in the general population and those treated in centers of excellence.

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, including the results thereof; 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 timing and likelihood of regulatory approval for *omecamtiv mecarbil*, 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:
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(415) 290-7757

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: November 16, 2020

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