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 2, 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 October 2, 2020, Cytokinetics, Incorporated ("Cytokinetics") announced that a manuscript detailing the baseline characteristics 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*, was published in the *European Journal of Heart Failure*. *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 is designed to evaluate whether treatment with *omecamtiv mecarbil*, dosed twice-daily in accordance with a pharmacokinetic-guided dose optimization 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 (HFrEF). Patients enrolled in GALACTIC-HF were required to have a diagnosis of HFrEF with left ventricular ejection fraction (LVEF) ≤35% and elevated natriuretic peptides. Patients were either currently hospitalized for heart failure (25% of total enrollment), or had a recent hospitalization, or a visit to an emergency room or urgent care facility for heart failure within the preceding year.

	Overall (8256)	**Current HF Hospitalization ("Inpatient") (N=2084)**	**Recent HF Hospitalization or ED Visit Within One Year ("Outpatient") (N=6172)**
Demographics			
Age (years), mean (SD)	64.5 (11.3)	65.0 (11.3)	64.4 (11.4)
Sex, female, n (%)	1756 (21.3)	411 (19.7)	1345 (21.8)
Race, n (%)			
White	6421 (77.8)	1706 (81.9)	4715 (76.4)
Asian	710 (8.6)	184 (8.8)	526 (8.5)
Black or African American	562 (6.8)	105 (5.0)	457 (7.4)
Other*	563 (6.8)	89 (4.3)	474 (7.7)
Ethnicity, Hispanic/Latino n (%)	1771 (21.5)	355 (17.0)	1416 (22.9)
Geographic Region, n (%)			
Eastern Europe/ Russia	2705 (32.8)	915 (43.9)	1790 (29.0)
Western Europe/ South Africa/ Australasia	1921 (23.3)	486 (23.3)	1435 (23.3)
Latin and South America	1574 (19.1)	326 (15.6)	1248 (20.2)
US and Canada	1386 (16.8)	180 (8.6)	1206 (19.5)
Asia	670 (8.1)	177 (8.5)	493 (8.0)
Clinical Characteristics			
Medical Conditions, n (%)			
Coronary artery disease	5144 (62.3)	1317 (63.2)	3827 (62.0)
Peripheral artery disease	847 (10.3)	215 (10.3)	632 (10.2)
Stroke	753 (9.1)	197 (9.5)	556 (9.0)
Atrial fibrillation or flutter history	3472 (42.1)	995 (47.7)	2477 (40.1)
Hypertension	5800 (70.3)	1495 (71.7)	4305 (69.8)
Hypercholesterolemia	4553 (55.1)	1094 (52.5)	3459 (56.0)
Type 2 diabetes mellitus	3313 (40.1)	870 (41.7)	2443 (39.6)
Heart Failure History			
LVEF (%), mean (SD)	26.6 (6.3)	26.5 (6.4)	26.6 (6.2)
MAGGIC Score, mean (SD)	23.3 (6.3)	25.0 (6.3)	22.8 (6.3)
NYHA classification, n (%)			
Class II	4391 (53.2)	767 (36.8)	3624 (58.7)
Class III	3616 (43.8)	1190 (57.1)	2426 (39.3)
Class IV	248 (3.0)	126 (6.0)	122 (2.0)
Ischemic heart failure etiology, n (%)	4458 (54.0)	1148 (55.1)	3310 (53.6)
KCCQ Total Symptom Score, mean (SD)	66.4 (25.1)	52.6 (25.4)	71.0 (23.2)
Vitals and Laboratory Parameters			
NT-proBNP (pg/mL), median (Q1-Q3)	1971 (961-4033)	2457 (1185-5073)	1858 (900-3749)
hsTnI (ng/mL), median (Q3)	0.030 (0.049)	0.036 (0.066)	0.029 (0.044)
eGFR (mL/min/1.73m2), median (Q1-Q3)	59 (41-74)	54 (41-70)	60 (45-75)
Stage ≤2; >60	3922 (47.7)	838 (40.2)	3084 (50.0)
Stage 3: 30-59	3806 (46.1)	1077 (51.7)	2729 (44.2)
Stage 4: 15-29	523 (6.3)	169 (8.1)	354 (5.7)
Stage 5: <15	5 (<0.1)	0 (0.0)	5 (<0.1)
Medications and Cardiac Devices, n (%)			
ACEi, ARB or ARNi	7161 (86.7)	1729 (83.0)	5432 (88.0)
ARNi	1594 (19.3)	328 (15.7)	1266 (20.5)
BB	7763 (94.0)	1931 (92.7)	5832 (94.5)
MRA	6358 (77.0)	1686 (80.9)	4672 (75.7)
(ACEi, ARB, or ARNi) + MRA + BB	5367 (65.0)	1360 (65.3)	4007 (64.9)
SGLT2 Inhibitors	219 (2.7)	56 (2.7)	163 (2.6)
Ivabradine	533 (6.5)	156 (7.5)	375 (6.1)

Cardiac Resynchronization Therapy	1156 (14.0)	267 (12.8)	889 (14.4)
Implantable Cardioverter Defibrillator	2614 (31.7)	598 (28.7)	2016 (32.7)
*Includes American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, or Multiple self-identified races			

Data are as published in the manuscript and may change with final review

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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cytokinetics, Incorporated

Date: October 2, 2020

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