CYTOKINETICS INC
Form 8-K
November 09, 2015

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 8, 2015

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)

Registrant s telephone number, including area code: (650) 624 - 3000

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))

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Item 8.01 Other Events.

Cytokinetics, Inc. and Amgen announced the presentation of data from the expansion phase of COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure), a Phase 2 trial evaluating omecamtiv mecarbil in patients with chronic heart failure, in a Late-Breaking Clinical Trial session at the American Heart Association (AHA) Scientific Sessions 2015 in Orlando, Fla. The trial met its primary pharmacokinetic objective and demonstrated statistically significant improvements in all pre-specified secondary measures of cardiac function in the treatment group employing pharmacokinetic-based dose titration. Omecamtiv mecarbil, a novel investigational cardiac myosin activator, enhances cardiac function by increasing cardiac contractility and is being developed for the potential treatment of heart failure.

The expansion phase of COSMIC-HF was designed to evaluate the pharmacokinetics, pharmacodynamics, safety and tolerability of oral omecamtiv mecarbil in 448 patients with chronic heart failure and left ventricular systolic dysfunction. Patients were randomized 1:1:1 to receive either placebo or treatment with omecamtiv mecarbil 25 mg twice daily or a dose titration group where 25 mg twice daily dosing could be increased to 50 mg twice daily depending on plasma concentrations of omecamtiv mecarbil after two weeks of treatment with the 25 mg dose. Data from the expansion phase showed that dose titration controlled patient exposure to omecamtiv mecarbil. Approximately 60 percent of patients in the dose titration group escalated dosing to 50 mg twice daily.

Following 20 weeks of treatment, statistically significant improvements were observed in pre-specified secondary endpoint measures of cardiac function in the dose titration group, compared to placebo. Systolic ejection time increased by 25.0 msec ($p<0.001$), stroke volume increased by 3.63 mL ($p=0.022$) and heart rate decreased by 2.97 beats per min ($p=0.007$). Left ventricular end-systolic and end-diastolic dimensions decreased by 1.79 mm ($p=0.003$) and 1.29 mm ($p=0.013$), respectively, and were associated with statistically significant reductions in left ventricular end-systolic and end-diastolic volumes. N-terminal pro-brain natriuretic peptide (NT-proBNP) decreased by 970 pg/mL ($p=0.007$). Additionally, in the 25 mg twice daily group, there were statistically significant increases in systolic ejection time and stroke volume and a decrease in NT-proBNP. All changes are from baseline compared to placebo. The pharmacodynamic effects of omecamtiv mecarbil were generally dose dependent and larger in patients that received oral dosing with 50 mg twice daily.

Adverse events (AEs), including serious AEs, in patients on omecamtiv mecarbil were comparable to placebo. The incidence of adjudicated deaths (2.7 percent died on placebo, 1.4 percent died on omecamtiv mecarbil), myocardial infarction (1.34 percent on placebo, 0.34 percent on omecamtiv mecarbil) and unstable angina (0 percent on placebo, 0.34 percent on omecamtiv mecarbil) was similar. Other cardiac AEs were generally balanced between placebo and active treatment groups. In the omecamtiv mecarbil groups, compared to placebo, cardiac troponin increased by 0.001 ng/mL and 0.006 ng/mL (median change from baseline at week 20) in the 25 mg twice daily group and dose titration group, respectively. Events of increased troponin (n=278 across all treatment groups) were independently adjudicated and none were determined to be myocardial ischemia or infarction.

Omecamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to omecamtiv mecarbil and related compounds, subject to Cytokinetics' specified development and commercialization rights. Additionally, Les Laboratoires Servier obtained an exclusive option to commercialize omecamtiv mecarbil in Europe.

Item 9.01 Financial Statements and Exhibits.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

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SIGNATURES

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

November 9, 2015

By: /s/ Sharon A. Barbari

Name: Sharon A. Barbari
Title: Executive Vice President, Finance and Chief Financial Officer

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Exhibit Index

Exhibit No.	Description
99.1	Press Release Dated November 8, 2015