

CYTOKINETICS INC
Form 8-K
October 27, 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):

October 27, 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 positive top-line results 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. The data showed statistically significant improvements in several measures of cardiac function, including systolic ejection time, stroke volume and N-terminal-pro-brain natriuretic peptide, at 20 weeks following randomization. The pharmacodynamic effects of omecamtiv mecarbil were generally dose dependent.

Data from the expansion phase, also showed that pharmacokinetic-based dose titration adequately controlled patient exposure to omecamtiv mecarbil and resulted in statistically significant decreases in cardiac dimensions and heart rate in the dose-titration group.

Adverse events, including serious adverse events, in patients on omecamtiv mecarbil appeared comparable to those on placebo. A small increase in troponin was seen among subjects receiving omecamtiv mecarbil. Events of increased troponin were independently adjudicated and none were determined to be myocardial ischemia or infarction. There was no imbalance in deaths, and cardiac adverse events were generally balanced between placebo and active treatment groups.

The full trial results will be submitted to a future medical conference and for publication.

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

October 27, 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

| <u>Exhibit No.</u> | <u>Description</u> |
|---------------------------|--------------------------------------|
| 99.1 | Press Release Dated October 27, 2015 |