
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):

December 1, 2016

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.

On December 1, 2016 Cytokinetics, Inc. announced the activation of the first clinical site and the start of GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure), the Phase 3 cardiovascular outcomes clinical trial of omecamtiv mecarbil which is being conducted by Amgen, in collaboration with Cytokinetics. Coincident with the start of the trial, Amgen will make a \$26.7 million milestone payment to Cytokinetics. In clinical studies, omecamtiv mecarbil, a novel investigational cardiac myosin activator, has been shown to enhance cardiac function by increasing cardiac contractility and is being developed for the potential treatment of patients with chronic heart failure.

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

December 1, 2016

By: /s/ Sharon A. Barbari

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

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated December 1, 2016



CYTOKINETICS ANNOUNCES START OF GALACTIC-HF, A PHASE 3 CLINICAL TRIAL OF *OMECAMTIV MECARBIL*

Trial to be Conducted Under Special Protocol Assessment with the FDA

Company Earns \$26.7 Million Milestone Payment from Amgen

SOUTH SAN FRANCISCO, Calif. Dec. 1, 2016 – Cytokinetics, Inc. (Nasdaq: CYTK) today announced the activation of the first clinical site and the start 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), the Phase 3 cardiovascular outcomes clinical trial of *omecamtiv mecarbil* which is being conducted by Amgen, in collaboration with Cytokinetics. Coincident with the start of the trial, Amgen will make a \$26.7 million milestone payment to Cytokinetics. In clinical studies, *omecamtiv mecarbil*, a novel investigational cardiac myosin activator, has been shown to enhance cardiac function by increasing cardiac contractility and is being developed for the potential treatment of patients with chronic heart failure.

The primary objective of this double-blind, randomized, placebo-controlled multicenter clinical trial is to determine if treatment with *omecamtiv mecarbil* when added to standard of care is superior to standard of care plus placebo in reducing the risk of cardiovascular death or heart failure events in patients with high risk chronic heart failure and reduced ejection fraction. GALACTIC-HF will be conducted under a Special Protocol Assessment (SPA) with the U.S. FDA.

“We are pleased that GALACTIC-HF is underway and we are grateful for the participation of investigators and their staff at the many hundreds of clinical sites worldwide who will be managing the care of the chronic heart failure patients in this pivotal trial,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “We will look forward to the results of this Phase 3 trial which is designed to assess whether the increases in cardiac function observed in prior trials of *omecamtiv mecarbil* will translate into improved cardiovascular outcomes for patients living with chronic heart failure.”

GALACTIC-HF: Trial Design

GALACTIC-HF is planned to enroll approximately 8,000 symptomatic chronic heart failure patients in over 800 sites in 34 countries who are either currently hospitalized for a primary reason of heart failure or have had a hospitalization or admission to an emergency room for heart failure within one year prior to screening. In order to be eligible to participate in GALACTIC-HF patients should have an LVEF 35%, be NYHA class II to IV, and have an elevated BNP or NT-proBNP. Patients will be randomized to either placebo or *omecamtiv mecarbil* with dose titration up to a maximum dose of 50 mg twice daily based on the plasma concentration of *omecamtiv mecarbil* after initiation of drug therapy. The primary endpoint is a composite of time to cardiovascular death or first heart failure event, which is defined as either a hospitalization for heart failure or other urgent treatment for worsening heart failure. Secondary endpoints include time to cardiovascular death; patient reported outcomes as measured by the Kansas City Cardiomyopathy Questionnaire Total Symptom Score; time to first heart failure hospitalization; and all-cause death. For additional information, please visit <http://bit.ly/2fC2wtp>.

About Heart Failure

Heart failure is a grievous condition that affects more than 23 million people worldwide, about half of whom have reduced left ventricular function. It is the leading cause of hospitalization and readmission in people age 65 and older. Despite broad use of standard treatments and advances in care, the prognosis for patients with heart failure is poor. An estimated one in five people over the age of 40 are at risk of developing heart failure, and approximately 50 percent of people diagnosed with heart failure will die within five years of initial hospitalization.

About *Omecamtiv Mecarbil*

Omecamtiv mecarbil is a novel cardiac myosin activator. 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. Cardiac myosin activators are thought to accelerate the rate-limiting step of the myosin enzymatic cycle and shift the enzymatic cycle in favor of the force-producing state. Preclinical research has shown that cardiac myosin activators increase contractility in the absence of changes in intracellular calcium in cardiac myocytes. *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. Amgen has granted a sublicense to Servier to commercialize *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 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 increase muscle function and contractility. Cytokinetics' lead drug candidate is *tirasemtiv*, a fast skeletal muscle troponin activator, for the potential treatment of ALS. *Tirasemtiv* has been granted orphan drug designation and fast track status by the U.S. Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS. Cytokinetics retains the right to develop and commercialize *tirasemtiv*, subject to an option held by Astellas Pharma Inc. Cytokinetics is also collaborating with Astellas to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. Amgen holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and Astellas holds an exclusive license worldwide to develop and commercialize CK-2127107. Both licenses are subject to Cytokinetics' specified development and commercialization participation rights. For additional information about Cytokinetics, visit <http://www.cytokinetics.com/>.

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 Cytokinetics' and its partners' research and development activities, including the design, results, significance and utility of GALACTIC-HF clinical trial results and the likelihood and timing for the progression of *omecamtiv mecarbil*; and the properties and potential benefits of Cytokinetics' drug candidates; and Cytokinetics' receipt of milestone payments from Amgen, including the timing of such payments. 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 Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; 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, including risks that patient enrollment for or conduct of clinical trials may be difficult or delayed, Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy, the U.S. Food and Drug Administration or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, and Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; standards of care may change, rendering Cytokinetics' drug candidates obsolete; and competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics' actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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