
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):

March 13, 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.

On March 13, 2015, Cytokinetics, Inc. announced that COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) has completed enrollment of the approximately 450 patients planned in the expansion phase of the clinical trial. In addition, the company announced that over 200 patients have completed the protocol-specified 20-week duration of dosing in this phase of the trial and reaffirmed that results from COSMIC-HF are expected to be available in the second half of 2015. COSMIC-HF is being conducted by Amgen in collaboration with Cytokinetics.

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.

March 13, 2015

Cytokinetics, Incorporated

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 March 13, 2015

CYTOKINETICS ANNOUNCES COMPLETION OF ENROLLMENT IN COSMIC-HF

Results Expected Later This Year to Inform Potential Progression of Omecamtiv Mecarbil to Phase III

SOUTH SAN FRANCISCO, CA, March 13, 2015 – Cytokinetics, Incorporated (Nasdaq: CYTK) announced today that COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) has completed enrollment of the approximately 450 patients planned in the expansion phase of the clinical trial. In addition, the company announced that over 200 patients have completed the protocol-specified 20-week duration of dosing in this phase of the trial and reaffirmed that results from COSMIC-HF are expected to be available in the second half of 2015. COSMIC-HF is being conducted by Amgen in collaboration with Cytokinetics.

“We are pleased to reach this milestone in the development program for *omecamtiv mecarbil*,” stated Fady I. Malik, M.D., Ph.D., Cytokinetics’ Senior Vice President, Research and Development. “COSMIC-HF will provide important information that will inform the potential progression of *omecamtiv mecarbil* to Phase III. We look forward to data from COSMIC-HF later this year and continue to prepare with Amgen for the initiation of a potential Phase III registration program.”

Omecamtiv mecarbil is the company’s lead drug candidate from its cardiac muscle contractility program. Amgen holds an exclusive, worldwide license to *omecamtiv mecarbil* and related compounds, subject to Cytokinetics’ specified development and commercialization rights. Additional information on COSMIC-HF and other completed Phase II clinical trials of *omecamtiv mecarbil* can be found at www.clinicaltrials.gov.

COSMIC-HF: Phase II Clinical Trial of Oral *Omecamtiv Mecarbil* in Patients with Heart Failure

COSMIC-HF is a double-blind, randomized, placebo-controlled, multicenter, study with two parts, a dose escalation phase and an expansion phase. The dose escalation phase assessed the pharmacokinetics and tolerability of three oral modified-release formulations of *omecamtiv mecarbil* in patients with heart failure and left ventricular systolic dysfunction and was used to select one formulation for further evaluation. During the dose escalation phase approximately 40 patients were randomized 1:1:1 to placebo or one of three different oral formulations of *omecamtiv mecarbil* in each of two ascending dose escalation cohorts. The dose of *omecamtiv mecarbil* was 25 mg twice daily in the first escalation cohort and 50 mg twice daily in the second escalation cohort. The dose escalation phase of COSMIC-HF completed in 2013 and informed progression to the expansion phase.

The ongoing expansion phase of the trial has enrolled approximately 450 patients randomized 1:1:1 to receive placebo, 25 mg, or 50 mg twice daily of *omecamtiv mecarbil*. Escalation to the 50 mg dose depends on the plasma concentration of *omecamtiv mecarbil* following 2 weeks of dosing with 25 mg twice daily. The primary objective of the expansion phase of COSMIC-HF is to characterize the safety, tolerability, and pharmacokinetics of oral *omecamtiv mecarbil* during 20 weeks of treatment. Secondary objectives are to assess changes from baseline in systolic ejection time, stroke volume, left ventricular end-systolic diameter, left ventricular end-diastolic diameter, heart rate and N-terminal pro-brain natriuretic peptide (a biomarker associated with the severity of heart failure) during 20 weeks of treatment.

About *Omecamtiv Mecarbil*

Omecamtiv mecarbil is a novel cardiac myosin activator and is the subject of a collaboration between Cytokinetics and Amgen. 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 contractility is driven by the cardiac sarcomere, a highly ordered cytoskeletal structure composed of cardiac myosin, actin and a set of regulatory proteins, which is the fundamental unit of muscle contraction in the heart. Cardiac myosin activators have been shown preclinically to work in the absence of changes in intracellular calcium in cardiac myocytes by a novel mechanism that directly stimulates the activity of the cardiac myosin motor protein. Cardiac myosin activators appear 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 this mechanism does not increase the velocity of cardiac contraction, but instead, increases the systolic ejection time, resulting in an increase in cardiac contractility and cardiac function in a potentially more oxygen-efficient manner.

About Heart Failure

Heart failure is a debilitating syndrome affecting over 5 million people in the United States. Over 3 million patients are hospitalized each year with a primary or secondary diagnosis of heart failure in the United States. Heart failure is among the most common causes of hospitalization in patients over 65 years of age and is the leading cause of rehospitalization in Medicare beneficiaries. Despite available therapies, readmission rates for patients remain high within one year of hospital discharge and mortality rates exceed 50% over the five-year period following a diagnosis of heart failure. The prevalence of heart failure is increasing with the aging population and the increased likelihood of survival following acute myocardial infarction. The limited effectiveness of current therapies points to the urgent need for next-generation therapeutics.

About Cytokinetics

Cytokinetics is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Cytokinetics is developing *tirasemtiv*, a fast skeletal muscle activator, as a potential treatment for amyotrophic lateral sclerosis (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 is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a cardiac muscle activator, for the potential treatment of heart failure. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy. 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. All of these drug candidates have arisen from Cytokinetics’ muscle biology focused research activities and are directed towards the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Additional information about Cytokinetics can be obtained at <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 conduct, design, enrollment, progress and results of clinical trials, the significance and utility of preclinical data and clinical trial results, anticipated timing for the availability of results from COSMIC-HF, the initiation of a potential Phase III registration program for *omecamtiv mecarbil*; the properties and potential benefits of Cytokinetics’ drug candidates, including *omecamtiv mecarbil*; and the potential market for *omecamtiv**

mecarbil. 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, additional clinical trials or non-clinical studies of omecamtiv mecarbil may be required prior to its progression into Phase III development; further clinical development of tirasemtiv will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding on acceptable terms, if at all; 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 current and past results of clinical trials or preclinical studies may not be indicative of future clinical trials results, 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; Astellas' and Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for CK-2127107 and omecamtiv mecarbil, respectively; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; Cytokinetics may be unable to enter into future collaboration agreements for its drug candidates and programs on acceptable terms, if at all; 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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