
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):

September 23, 2013

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 September 23, 2013, Cytokinetics, Inc. issued a press release announcing the presentation of additional data from the ATOMIC-AHF (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure) clinical trial at a Late Breaking Clinical Trials Session at the Heart Failure Society of America (HFSA) Annual Scientific Meeting in Orlando, Florida. The presentation was made by John R. Teerlink, MD, Director of the Heart Failure Program and of the Clinical Echocardiography Laboratory at the San Francisco Veterans Affairs Medical Center, Professor of Medicine at University of California San Francisco and the Principal Investigator in ATOMIC-AHF.

ATOMIC-AHF was conducted by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to develop and commercialize omecamtiv mecarbil and related compounds, subject to Cytokinetics' specified development and commercialization participation rights.

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.

September 23, 2013

Cytokinetics, Incorporated

By: /s/ Sharon Barbari

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

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 23, 2013

**Cytokinetics Announces Presentation of Data from ATOMIC-AHF at Heart Failure Society of
America Annual Scientific Meeting**
**CYTOKINETICS ANNOUNCES PRESENTATION OF DATA FROM ATOMIC-AHF
AT HEART FAILURE SOCIETY OF AMERICA ANNUAL SCIENTIFIC MEETING**

Additional Safety and Pharmacodynamic Results Presented in Late Breaking Clinical Trials Session

South San Francisco, CA, September 23, 2013 – Cytokinetics, Incorporated (NASDAQ:CYTK) today announced the presentation of additional data from the ATOMIC-AHF (Acute Treatment with *omecamtiv mecarbil* to Increase Contractility in Acute Heart Failure) clinical trial at a Late Breaking Clinical Trials Session at the Heart Failure Society of America (HFSA) Annual Scientific Meeting in Orlando, Florida. The presentation was made by John R. Teerlink, MD, Director of the Heart Failure Program and of the Clinical Echocardiography Laboratory at the San Francisco Veterans Affairs Medical Center, Professor of Medicine at University of California San Francisco and the Principal Investigator in ATOMIC-AHF.

ATOMIC-AHF was a randomized, double-blind, placebo-controlled Phase II clinical trial that enrolled 613 patients hospitalized with acute heart failure (AHF) treated for 48 hours with an intravenous formulation of *omecamtiv mecarbil* or placebo and designed to evaluate the safety, pharmacokinetics, pharmacodynamics, and potential efficacy of *omecamtiv mecarbil* in patients with AHF. Data presented at HFSA included details of the adjudicated myocardial infarctions in ATOMIC-AHF and additional data from the pharmacokinetic/pharmacodynamic relationship between increasing concentrations of *omecamtiv mecarbil* and increases in echocardiographic measurements of systolic ejection time in patients hospitalized with heart failure.

ATOMIC-AHF was conducted by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights.

Results from ATOMIC-AHF Presented at HFSA Annual Meeting

Initial results from ATOMIC-AHF were recently presented at the ESC Congress 2013, organized by the European Society of Cardiology. Additional data from ATOMIC-AHF presented today at the HFSA Annual Scientific Meeting showed that systolic ejection time, the echocardiographic signature of *omecamtiv mecarbil*, increased in a concentration-dependent manner similar to that previously reported in healthy volunteers and stable heart failure patients. Results from ATOMIC-AHF presented at the ESC Congress 2013 showed that rates of adverse events (AEs), serious AEs, adjudicated deaths and hospitalizations were similar between *omecamtiv mecarbil* and placebo groups. There were seven post-randomization myocardial infarctions in the treatment groups receiving *omecamtiv mecarbil* compared with three in the placebo groups (2.3 percent vs. 1.0 percent, respectively). Data from ATOMIC-AHF presented today at the HFSA Annual Scientific Meeting showed that four of the myocardial infarctions were observed to be temporally remote from investigational product administration. The estimated plasma concentrations near the time of these events are zero. Three of these events occurred in patients who received *omecamtiv mecarbil* and one occurred in a patient who received placebo. One myocardial infarction occurred subsequent to a percutaneous coronary intervention in a patient who received *omecamtiv mecarbil*. One myocardial infarction occurred in a patient with sepsis who received placebo.

“ATOMIC-AHF extends the previously reported, encouraging results from clinical studies of *omecamtiv mecarbil* conducted in healthy volunteers and in patients with chronic stable heart failure to now include data in hospitalized patients with acute heart failure, a group of patients with a high unmet need for a safe compound that improves cardiac performance,” stated John Teerlink, MD. “Findings from ATOMIC-AHF provide important data to inform the design of future efficacy trials with the intravenous formulation of *omecamtiv mecarbil* and also provide support for COSMIC-HF which is currently enrolling patients with chronic heart failure receiving the oral formulation of this promising compound.”

“We are pleased to have these additional data regarding the safety and pharmacodynamic effects from ATOMIC-AHF presented at this important heart failure conference,” stated Andrew A. Wolff, MD, Cytokinetics' Senior Vice President of Clinical Research and Development and Chief Medical Officer. “These data contribute to the ongoing review of results from ATOMIC-AHF and add to our confidence that *omecamtiv mecarbil* appeared generally well-tolerated in a high risk heart failure population. We look forward to additional data from the ongoing development of this novel drug candidate which holds promise for the potential treatment of heart failure.”

Initial Results from ATOMIC-AHF Presented at ESC Congress

ATOMIC-AHF is a completed Phase II clinical trial designed to evaluate an intravenous formulation of *omecamtiv mecarbil* in 613 patients enrolled in three sequential, ascending-dose cohorts. In each cohort, patients were randomized 1:1 to *omecamtiv mecarbil* or placebo. The primary objective of this trial was to evaluate the effect of 48 hours of intravenous *omecamtiv mecarbil* compared to placebo on dyspnea in patients with left ventricular systolic dysfunction hospitalized for AHF. The secondary objectives were to assess the safety and tolerability of the three dose levels of *omecamtiv mecarbil* compared with placebo and to evaluate the effects of 48 hours of treatment with intravenous *omecamtiv mecarbil* on additional clinical and pharmacodynamic measures.

Initial results from ATOMIC-AHF were recently presented at the ESC Congress 2013, organized by the European Society of Cardiology. ATOMIC-AHF enrolled three, sequential, dose escalation cohorts of patients treated for 48 hours with *omecamtiv mecarbil* or placebo. The primary efficacy endpoint of dyspnea symptom response was not met; however, the study demonstrated favorable trends between the dose and plasma concentration of *omecamtiv mecarbil* and dyspnea response. The incidence of worsening heart failure within seven days of initiating treatment appeared lower in each of the cohorts on *omecamtiv mecarbil* compared to the pooled placebo group of patients. Rates of adverse events (AEs), serious AEs, adjudicated deaths and hospitalizations were similar between *omecamtiv mecarbil* and placebo groups. *Omeclamtiv mecarbil* was not associated with an increased incidence of tachyarrhythmias nor were heart rate or blood pressure adversely affected.

Additional information about clinical trials of *omecamtiv mecarbil* can be found at www.clinicaltrials.gov.

About *Omeclamtiv Mecarbil*

Omeclamtiv 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 in 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 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' lead drug candidate from its cardiac muscle contractility program, *omecamtiv mecarbil*, is in Phase II clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing *tirasemtiv*, a fast skeletal muscle activator, as a potential treatment for diseases and medical conditions associated with neuromuscular dysfunction. *Tirasemtiv* is currently the subject of a Phase II clinical trials program and 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 amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment. Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a skeletal muscle activator structurally distinct from *tirasemtiv*, for non-neuromuscular indications. 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 www.cytokinetics.com.

Forward Looking Statement

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 Amgen's research and development activities, including the conduct and design of clinical trials; the significance and utility of clinical trial results from ATOMIC-AHF; and the properties and potential benefits of omecamtiv mecarbil and Cytokinetics' other drug candidates, including the potential utility of omecamtiv mecarbil in the potential treatment of heart failure. 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: Cytokinetics anticipates that it will be required to conduct at least one confirmatory Phase III clinical trial of tirasemtiv in ALS patients which will require significant additional funding, and it 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; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil and CK-2127107, 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.

Contacts:

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