
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):

August 19, 2011

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 August 19, 2011, Cytokinetics, Incorporated issued a press release announcing the publication of results from two clinical trials of omecamtiv mecarbil, a novel cardiac myosin activator, in the August 20, 2011 issue of the journal Lancet. These two manuscripts present data regarding the safety, tolerability, pharmacokinetics and pharmacodynamic effects of this investigational drug candidate from a Phase I first-time-in-humans clinical trial in healthy volunteers and a Phase IIa clinical trial in stable heart failure patients, each sponsored by 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.

Cytokinetics, Incorporated

August 19, 2011

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 August 19, 2011

Contact:
Christopher S. Keenan
Director, Investor & Media Relations
(650) 624-3000

CYTOKINETICS ANNOUNCES PHASE I AND PHASE IIA CLINICAL TRIAL RESULTS FOR *OMECAKTIV MECARBIL* PUBLISHED IN THE JOURNAL *LANCET*

Results from These Trials Form the Basis For Ongoing Phase IIb Activities in Collaboration with Amgen

South San Francisco, CA, August 19, 2011 – Cytokinetics, Incorporated (Nasdaq: CYTK) announced today the publication of results from two clinical trials of *omecaktiv mecarbil*, a novel cardiac myosin activator, in the August 20, 2011 issue of the journal *Lancet*. These two manuscripts present data regarding the safety, tolerability, pharmacokinetics and pharmacodynamic effects of this investigational drug candidate from a Phase I first-time-in-humans clinical trial in healthy volunteers and a Phase IIa clinical trial in stable heart failure patients, each sponsored by Cytokinetics. Together, these publications provide evidence for the translation into humans of this unique mechanistic approach to activating cardiac muscle contractility and support the further development of *omecaktiv mecarbil* as a potential treatment for heart failure. Amgen Inc. holds an exclusive, worldwide (excluding Japan) license to *omecaktiv mecarbil* and related compounds, subject to specified development and commercialization participation rights of Cytokinetics.

“We are pleased that these results from earlier clinical trials of *omecaktiv mecarbil*, which demonstrated that this novel drug candidate increased certain measurements of cardiac function, have been recognized by these side-by-side publications in a prestigious peer-reviewed journal,” stated Fady I. Malik, MD, PhD, FACC, Cytokinetics’ Vice President of Biology and Therapeutics. “These two clinical trials have proven especially informative to the further advancement of this novel mechanism drug candidate which is now proceeding in a comprehensive development program under our collaboration with Amgen.”

“These results form the foundation for the larger, international Phase IIb clinical trial of *omecaktiv mecarbil* that is currently enrolling heart failure patients,” stated Scott M. Wasserman, M.D., F.A.C.C., Executive Medical Director at Amgen. “We are enthusiastic about the potential that *omecaktiv mecarbil* may represent for patients suffering from this grievous illness and look forward to advancing the development program in collaboration with Cytokinetics.”

Clinical Trial Publications of *Omecaktiv Mecarbil* in *Lancet*

The first publication, titled “Dose-dependent Augmentation of Cardiac Systolic Function with the Selective Cardiac Myosin Activator, *Omecaktiv Mecarbil*: A First-In-Man Study,” summarizes the results from a Phase I clinical trial of *omecaktiv mecarbil*. The primary objective of this trial was to establish the maximum tolerated dose and plasma concentrations of *omecaktiv mecarbil* in healthy volunteers. The secondary objectives were to evaluate the pharmacodynamic and pharmacokinetic characteristics of *omecaktiv mecarbil* and its safety and tolerability profile. The authors concluded that these first-in-man data showed highly dose- and concentration-dependent augmentation of left ventricular systolic function in response to *omecaktiv mecarbil* and support potential clinical use of the drug candidate in patients with heart failure.

The second publication, titled “The Effects of the Cardiac Myosin Activator, *Omecaktiv Mecarbil*, on Cardiac Function in Systolic Heart Failure: A Double-Blind, Placebo-Controlled, Crossover, Dose-Ranging Phase II Trial,” summarizes the results from a Phase IIa clinical trial of *omecaktiv mecarbil*. The primary objective of this clinical trial was to assess the safety and tolerability of *omecaktiv mecarbil* in patients with stable heart failure due to systolic dysfunction. The secondary objectives were to evaluate the relationship between the plasma concentration of *omecaktiv mecarbil* and its echocardiographic effects and to define a range of pharmacodynamically active, well tolerated target plasma concentrations for subsequent clinical trials. The authors concluded that *omecaktiv mecarbil* improved cardiac function in these patients with heart failure caused by left ventricular systolic dysfunction and could be the first in a new class of therapeutics for the treatment of heart failure.

Development Status of *Omecaktiv Mecarbil*

Omecaktiv mecarbil, a novel cardiac muscle myosin activator, is currently the subject of a clinical trials development program designed to evaluate the safety, tolerability, pharmacodynamic and pharmacokinetic profiles of both intravenous and oral formulations of *omecaktiv mecarbil* for the potential treatment of heart failure across the continuum of care, in both hospital and outpatient settings. In April 2011, a Phase IIb clinical trial of an intravenous formulation of *omecaktiv mecarbil* opened to enrollment. This trial is being conducted by Amgen in collaboration with Cytokinetics and is designed to evaluate the safety and efficacy of an intravenous formulation of *omecaktiv mecarbil* in patients with left ventricular systolic dysfunction hospitalized for acute heart failure. Cytokinetics and its partner Amgen are discussing plans for the initiation of additional studies designed to assess the safety, tolerability and pharmacokinetics of multiple oral formulations of *omecaktiv mecarbil*, to occur first in healthy volunteers and then in stable heart failure patients.

Prior to the ongoing Phase IIb clinical trial, *omecaktiv mecarbil* was the subject of a clinical trials program conducted under Cytokinetics’ sponsorship. Two Phase IIa clinical trials of *omecaktiv mecarbil* were completed in patients with systolic heart failure. In addition, five Phase I clinical trials of *omecaktiv mecarbil* were completed in healthy volunteers: a first-time-in-humans study evaluating an intravenous formulation, an oral bioavailability study evaluating both intravenous and oral formulations, and three studies of oral formulations: a drug-drug interaction study, a dose proportionality study and a study evaluating modified-release formulations. Data from each of these trials have been reported previously.

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, *omecaktiv mecarbil* (formerly CK-1827452), is in clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide (excluding Japan) to develop and commercialize *omecaktiv mecarbil* and related compounds, subject to Cytokinetics’ specified development and commercialization participation rights. Cytokinetics is independently developing CK-2017357, a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or neuromuscular dysfunction. CK-2017357 is currently the subject of a Phase II clinical trials program and has been granted orphan-drug designation by the U.S. Food and Drug Administration for the potential treatment of amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment in which CK-2017357 demonstrated potentially clinically relevant pharmacodynamic effects in a Phase IIa trial. Cytokinetics is also conducting research and non-clinical development of compounds that inhibit smooth muscle contractility and which may be useful as potential treatments for diseases and conditions associated with excessive smooth muscle contraction, such as bronchoconstriction associated with asthma and chronic obstructive pulmonary disorder (COPD). In addition, prior Cytokinetics’ research generated three anti-cancer drug candidates that have progressed into clinical development: *ispinesib*, SB-743921 and GSK-923295. All of these drug candidates and potential drug candidates have arisen from Cytokinetics’ 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.

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 plans for and the initiation, conduct, design and scope of omecamtiv mecarbil clinical trials, the significance and utility of clinical trial results for omecamtiv mecarbil; and the properties and potential benefits of omecamtiv mecarbil (including the use of omecamtiv mecarbil as a potential treatment for heart failure) and Cytokinetics' other drug candidates and potential drug candidates. 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, 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 decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products on acceptable terms, if at all; 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.