
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):

April 4, 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 April 4, 2016 Cytokinetics, Inc. announced the start of a double-blind, randomized, placebo-controlled, multi-center Phase 2 clinical trial to evaluate the safety, pharmacokinetics and efficacy of omecamtiv mecarbil in Japanese subjects with heart failure and reduced ejection fraction. Omecamtiv mecarbil, a novel investigational cardiac myosin activator that increases cardiac contractility, is being developed by Amgen in collaboration with Cytokinetics for the potential treatment of 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.

April 4, 2016

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 April 4, 2016



CYTOKINETICS ANNOUNCES START OF PHASE 2 CLINICAL TRIAL OF *OMECAMTIV MECARBIL* IN JAPANESE SUBJECTS WITH HEART FAILURE

SOUTH SAN FRANCISCO, Calif. Apr. 4, 2016 – Cytokinetics, Inc. (Nasdaq: CYTK) today announced the start of a double-blind, randomized, placebo-controlled, multi-center Phase 2 clinical trial to evaluate the safety, pharmacokinetics and efficacy of *omecamtiv mecarbil* in Japanese subjects with heart failure and reduced ejection fraction. *Omeamtiv mecarbil*, a novel investigational cardiac myosin activator that increases cardiac contractility, is being developed by Amgen in collaboration with Cytokinetics for the potential treatment of heart failure.

“Advancing the clinical investigation of *omeamtiv mecarbil* in Japan represents an important step for our novel cardiac myosin activator program,” said Fady I. Malik, MD, PhD, Cytokinetics’ Executive Vice President, Research and Development. “*Omeamtiv mecarbil* holds promise as a potential new treatment for patients with heart failure and we look forward to learning about its clinical application in Japanese patients.”

Phase 2 Clinical Trial Design

The ongoing Phase 2 clinical trial of *omeamtiv mecarbil* in Japan will evaluate approximately 80 subjects with chronic stable heart failure with reduced ejection fraction over 16 weeks randomized 1:1:1 to receive either placebo or *omeamtiv mecarbil* twice daily at 25 mg, 37.5 mg or 50 mg. Subjects randomized to 37.5 mg or 50 mg will be up-titrated using a PK-guided dose titration strategy. The primary objectives of the trial are to assess the pharmacokinetics, safety, and tolerability of *omeamtiv mecarbil* in Japanese subjects with heart failure and reduced ejection fraction. The secondary objective is to measure changes from baseline in systolic ejection time measured at week 16. Additional information can be found at clinicaltrials.gov.

About *Omeamtiv Mecarbil*

Omeamtiv 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. *Omeamtiv mecarbil* is being developed by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to *omeamtiv mecarbil* and related compounds, subject to Cytokinetics’ specified development and commercialization rights. Les Laboratoires Servier obtained an exclusive option to commercialize *omeamtiv mecarbil* in Europe.

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*. Cytokinetics is collaborating with Amgen Inc. to develop *omeamtiv mecarbil*, a novel 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 *omeamtiv 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, plans and timing of the ongoing Phase 2 clinical trial of *omeamtiv mecarbil* and a potential Phase 3 clinical trial of *omeamtiv mecarbil*; the potential for eventual regulatory approval, commercialization and launch of Cytokinetics’ product candidates; and the properties and potential benefits of Cytokinetics’ 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 Amgen’s decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omeamtiv 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 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; and 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; 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.

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Contact:

Cytokinetics

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