
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 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 1.01 Entry into a Material Definitive Agreement.

On August 29, 2016, Cytokinetics, Incorporated ("Cytokinetics") entered into a Letter of Agreement (the "Letter Agreement"), with Amgen Inc. ("Amgen"), Les Laboratoires Servier ("LLS") and Institut de Recherches Internationales Servier (together with LLS, "Servier").

On September 1, 2016, Amgen and Servier announced Servier's decision to exercise its option to commercialize omecamtiv mecarbil in Europe as well as the Commonwealth of Independent States (the "CIS"), including Russia.

As previously disclosed, in July 2013, Amgen granted to Servier, with Cytokinetics' consent, an option to commercialize omecamtiv mecarbil in Europe pursuant to an Option, License and Collaboration Agreement (the "Servier Agreement"). The option and related commercialization sublicense to Servier is subject to the terms and conditions of that certain Collaboration and Option Agreement, dated December 29, 2006, by and between Cytokinetics and Amgen, as amended (the "Amgen Agreement"). The Letter Agreement of August 29, 2016 (i) expands the territory of the sublicense to Servier to include specified countries in the CIS and (ii) provides that, if Amgen's rights under the Amgen Agreement are terminated with respect to the territory of such sublicense, the sublicensed rights previously granted by Amgen to Servier under the Servier Agreement will remain in effect and become a direct license or sublicense of such rights by Cytokinetics to Servier, on substantially the same terms as set forth in the Servier Agreement, including but not limited to Servier's payment of its share of agreed development costs and future milestone and royalty payments to Cytokinetics. The Letter Agreement does not otherwise modify Cytokinetics' rights and obligations under the Amgen Agreement or create any additional financial obligations of Cytokinetics, unless it otherwise agrees in writing. Amgen remains responsible for the performance of its obligations under the Amgen Agreement relating to Europe and the CIS, including the payment of milestones and royalties relating to the development and commercialization of omecamtiv mecarbil in Europe and the CIS.

The above description of the Letter Agreement is a summary of its material terms, does not purport to be complete and is qualified in its entirety by reference to the Letter Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2016.

Item 8.01 Other Events.

On September 1, 2016, Cytokinetics announced the advancement of omecamtiv mecarbil into a Phase 3 clinical development program with a cardiovascular outcomes clinical trial expected to initiate in the fourth quarter of 2016. A copy of the press release, titled "Cytokinetics and Amgen to Advance Omecamtiv Mecarbil into Phase 3 Clinical Development" is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 Press Release, dated September 1, 2016, titled "Cytokinetics and Amgen to Advance Omecamtiv Mecarbil into Phase 3 Clinical Development."

Forward-Looking Statements:

This Current Report on Form 8-K contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). The Company 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 planned research and development activities, including with respect to the proposed Phase 3 clinical development program of omecamtiv mecarbil and the potential for commercialization of omecamtiv mecarbil. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties. For further information regarding these and other risks related to Cytokinetics' business, investors should refer to the Risk Factors set forth in the Company's Quarterly Report on Form 10-Q filed with Securities and Exchange Commission for the quarter ended June 30, 2016.

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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 1, 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 September 1, 2016



CYTKINETICS AND AMGEN TO ADVANCE *OMECAMTIV MECARBIL* TO PHASE 3 CLINICAL DEVELOPMENT

Company Expects the Initiation of Phase 3 Cardiovascular Outcomes Clinical Trial in Q4 2016

SOUTH SAN FRANCISCO, Calif. Sept. 1, 2016 – Cytokinetics, Inc. (Nasdaq:CYTK) today announced the advancement of *omecamtiv mecarbil* to Phase 3 clinical development with a cardiovascular outcomes clinical trial expected to initiate in the fourth quarter of 2016. *Omeclamtiv mecarbil*, a novel investigational cardiac myosin activator, enhances cardiac function by increasing cardiac contractility and is being developed for the potential treatment of patients with chronic heart failure.

The decision to proceed to Phase 3 development follows the review of results from prior clinical trials, including COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure), a Phase 2 clinical trial evaluating *omecamtiv mecarbil* in patients with chronic heart failure. Data from COSMIC-HF were first presented in a Late-Breaking Clinical Trial session at the American Heart Association Scientific Sessions 2015. COSMIC-HF met its primary pharmacokinetic objective and demonstrated statistically significant improvements in all pre-specified secondary measures of cardiac function in the treatment group employing pharmacokinetic-based dose titration. In addition, Amgen and Cytokinetics have convened meetings with regulatory authorities to inform plans for *omecamtiv mecarbil* in a Phase 3 clinical trials program.

“Progression of *omecamtiv mecarbil* to Phase 3 is a major milestone for our company as well as our collaboration with Amgen and reflects our collective commitment to the heart failure community,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “We are pleased that the comprehensive clinical trials program that we have jointly conducted for *omecamtiv mecarbil* has contributed data that provide a compelling rationale to advance the development of our cardiac myosin activator to an international outcomes trial for the potential treatment of patients with chronic heart failure.”

The Phase 3 outcomes trial will be conducted by Amgen in collaboration with Cytokinetics. As part of the Phase 3 clinical trials program, Cytokinetics and Amgen are also planning a potential exercise performance/cardiac function clinical trial to be conducted by Cytokinetics. Cytokinetics has the opportunity to earn increased royalties by sharing certain Phase 3 development costs. In that case, Cytokinetics could co-promote *omecamtiv mecarbil* in North America and would have an agreed role in commercialization activities.

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 *Omeclamtiv Mecarbil*

Omeclamtiv 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.

Omeclamtiv mecarbil is being developed by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to *omeclamtiv mecarbil* and related compounds, subject to Cytokinetics’ specified development and commercialization rights.

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 *omeclamtiv 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 significance and utility of COSMIC-HF clinical trial results and the likelihood and timing for the progression of *omecamtiv mecarbil* to Phase 3 development; 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 *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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