
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 8, 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 September 8, 2016 Cytokinetics, Inc. announced the initiation of IND-enabling studies for a next-generation fast skeletal muscle activator under Cytokinetics' collaboration with Astellas. The initiation of IND-enabling studies triggers a \$2 million milestone payment from Astellas to Cytokinetics under the terms of the collaboration agreement between the companies established in June 2013, expanded in 2014, and again in 2016.

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

September 8, 2016

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 8, 2016



CYTKINETICS ANNOUNCES NEXT-GENERATION FAST SKELETAL MUSCLE ACTIVATOR ENTERING IND-ENABLING STUDIES

Triggers Milestone Payment from Astellas; Expands Portfolio of Skeletal Muscle Activators

SOUTH SAN FRANCISCO, Calif., Sept. 8, 2016 – Cytokinetics, Inc. (Nasdaq: CYTK) today announced the initiation of IND-enabling studies for a next-generation fast skeletal muscle activator under Cytokinetics' collaboration with Astellas. The initiation of IND-enabling studies triggers a \$2 million milestone payment from Astellas to Cytokinetics under the terms of the collaboration agreement between the companies established in June 2013, expanded in 2014, and again in 2016.

“Moving an additional potential drug candidate into IND-enabling studies expands our growing portfolio of skeletal muscle activators and provides an opportunity to explore an array of potential clinical applications of this class of compounds,” said Fady I. Malik, Cytokinetics' Executive Vice President and Head of Research & Development. “We're proud of the success we have achieved in our collaborative research program with Astellas and pleased that we share a mutual commitment to continue discovery in parallel with our development programs.”

About Cytokinetics and Astellas Collaboration

In 2013, Astellas and Cytokinetics formed a partnership focused on the research, development, and commercialization of skeletal muscle activators. The primary objective of the collaboration is to advance novel therapies for diseases and medical conditions associated with muscle impairment and weakness. Under the collaboration, Cytokinetics exclusively licensed to Astellas the rights to co-develop and potentially co-commercialize CK-2127107, a fast skeletal troponin activator, in non-neuromuscular indications.

In 2014, Astellas and Cytokinetics agreed to expand the collaboration to include certain neuromuscular indications, including spinal muscular atrophy (SMA), and to advance CK-2127107 into Phase 2 clinical development, initially in SMA. Under the amended collaboration, Astellas has exclusive rights to co-develop and commercialize CK-2127107 and other fast skeletal troponin activators in non-neuromuscular indications and certain neuromuscular indications (including SMA) and other novel mechanism skeletal muscle activators in all indications, subject to certain Cytokinetics' development and commercialization rights; Cytokinetics may co-promote and conduct certain commercial activities in North America and Europe under agreed scenarios.

In July 2016, Cytokinetics and Astellas announced further expansion of the collaboration to include amyotrophic lateral sclerosis (ALS). Through this expansion, Cytokinetics granted Astellas an option right for the development and commercialization of *tirasemtiv*; if Astellas exercises the option, Astellas will receive exclusive worldwide commercialization rights outside of Cytokinetics' commercialization territory of North America, Europe and other select countries. The companies also agreed to amend their collaboration agreement to enable the development of CK-2127107 for the potential treatment of ALS and to extend their joint research focused on the discovery of additional next-generation skeletal muscle activators through 2017.

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 *omecamtiv 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 and COPD. 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 conduct, design, enrollment and progress of the Phase 2 clinical trial

of CK-2127107 in patients with SMA; the significance and utility of preclinical study and clinical trial results; and the properties and potential efficacy and safety profile of CK-2127107 and Cytokinetics' other 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, further clinical development of *tirasemtiv* in ALS patients will require significant additional funding, and Cytokinetics may be unable to obtain such additional funding on acceptable terms, if at all; the FDA and/or other regulatory authorities may not accept effects on slow vital capacity as a clinical endpoint to support registration of *tirasemtiv* for the treatment of ALS; 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 trial 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.

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