

CYTOKINETICS INC
Form 8-K
December 23, 2014

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):

December 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 1.01 Entry into a Material Definitive Agreement.

On December 22, 2014, Cytokinetics, Incorporated ("Cytokinetics") entered into an Amended and Restated Collaboration and License Agreement (the "Amended Agreement") with Astellas Pharma Inc. ("Astellas"), replacing in full the Collaboration and License Agreement entered into between the Company and Astellas on June 21, 2013 (the "Original Agreement"). The Amended Agreement expands the objective of the collaboration of advancing novel therapies for diseases and medical conditions associated with muscle weakness to now include spinal muscle atrophy ("SMA") and potentially other neuromuscular indications, in addition to the non-neuromuscular indications provided for in the Original Agreement.

Under the Amended Agreement, Cytokinetics expanded the existing exclusive license previously granted Astellas to co-develop and commercialize CK-2127107, a fast skeletal troponin activator drug candidate, for potential application in non-neuromuscular indications worldwide to now include certain neuromuscular indications as well. CK-2127107 will continue to be developed jointly by Cytokinetics and Astellas. In connection with the expanded collaboration, the companies have agreed to advance CK-2127107 into Phase II clinical development. Cytokinetics will conduct the initial Phase II clinical trial in patients with SMA, which is anticipated to be initiated in 2015. The development program may include other neuromuscular indications as the companies may agree. Cytokinetics and Astellas will jointly develop and may jointly commercialize CK-2127107 and other fast skeletal troponin activators in neuromuscular indications. Astellas will be responsible for the costs associated with the development of all collaboration products, including CK-2127107, subject to Cytokinetics' option to co-fund certain development costs as described below.

The parties have extended their joint research program to identify next-generation skeletal muscle activators to be nominated as drug candidates through 2016. This research will be conducted at Astellas' expense. Under the Amended Agreement, 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 the U.S., Canada and Europe under agreed scenarios.

Cytokinetics retains an option to conduct early-stage development for certain agreed indications at its initial expense, subject to reimbursement if development continues under the collaboration. Under the Amended Agreement, Cytokinetics also retains an option to co-promote collaboration products containing fast skeletal muscle activators for neuromuscular indications in the U.S., Canada and Europe, in addition to its option to co-promote other collaboration products in the U.S. and Canada as provided for in the Original Agreement. Astellas will reimburse Cytokinetics for certain expenses associated with its co-promotion activities. The Amended Agreement also provides for Cytokinetics to lead certain activities relating to the commercialization of collaboration products for neuromuscular indications in the U.S., Canada and Europe under particular scenarios.

Cytokinetics will receive an upfront payment of \$30 million in connection with the execution of the Amended Agreement. In addition, Cytokinetics will receive a \$15 million as a milestone payment in connection with Astellas' decision to advance CK-2127107 into Phase II clinical development. Cytokinetics is also eligible to potentially receive over \$20 million in reimbursement of sponsored research and development activities during the next two years of the collaboration. Based on the achievement of pre-specified criteria, Cytokinetics may receive over \$600 million in milestone payments relating to the development and commercial launch of collaboration products, including up to \$112 million (of which Cytokinetics has now received \$17 million) relating to early development of CK-2127107 and for later-stage development and commercial launch milestones for CK-2127107 in non-neuromuscular indications, and over \$100 million in development and commercial launch milestones for CK-2127107 in each of SMA and other neuromuscular indications. Cytokinetics may also receive up to \$200 million in payments for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Amended Agreement. In the event Astellas commercializes any collaboration products, Cytokinetics will also receive royalties on sales of such collaboration products, including royalties ranging from the high single digits to the high teens on sales of products containing CK-2127107. Cytokinetics also holds an option to co-fund certain development costs for CK-2127107 and other compounds in exchange for increased milestone payments and royalties; such royalties may increase under certain scenarios to exceed twenty percent. In addition to the foregoing development, commercial and sales milestones, Cytokinetics may also receive payments for the achievement of pre-specified milestones relating to the joint research program.

Cytokinetics retains the exclusive right to develop and commercialize tirasemtiv, a fast skeletal troponin activator currently in Phase II clinical trials, for the potential treatment of amyotrophic lateral sclerosis and certain other neuromuscular disorders independently from the Amended Agreement.

The above description of the Amended Agreement is a summary of its material terms, does not purport to be complete, and is qualified in its entirety by reference to the Amended Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2014, or in another report filed with the Securities and Exchange Commission.

In conjunction with the Amendment, Cytokinetics also entered into a Common Stock Purchase Agreement with Astellas (the "CSPA"), which provides for the sale of 2,040,816 shares of Cytokinetics' common stock at a price per share of \$4.90 and an aggregate purchase price of approximately \$10.0 million. Pursuant to the CSPA, Astellas has agreed to certain trading and other restrictions with respect to Cytokinetics'

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common stock.

On December 23, 2014, Cytokinetics also issued a press release announcing Cytokinetics' entry into the Amended Agreement. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 1.01.

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 Astellas' planned research and development activities; potential milestone payments, royalties and other payments; the expected roles of Cytokinetics and Astellas under the collaboration and in developing or commercializing drug candidates or products subject to the collaboration; and the indications to be pursued under the collaboration. 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 September 30, 2014.

Item 3.02 Unregistered Sales of Equity Securities.

The information under Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 3.02.

Item 9.01 Financial Statements and Exhibits.

A copy of the CSPA is attached hereto as Exhibit 10.46, and is incorporated by reference into this Item 1.01.

A copy of the December 23, 2014 joint press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 1.01.

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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

December 23, 2014

By: *s/Sharon A. Barbari*

Name: s/Sharon A. Barbari

Title: Executive Vice President, Finance and Chief Financial Officer

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
10.46	Common Stock Purchase Agreement by and between Cytokinetics, Incorporated and Astellas Pharma Inc. dated December 22, 2014
99.1	Press Release, Dated December 23, 2014