CYTOKINETICS INC
Form 8-K
July 27, 2016

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): July 27, 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 July 27, 2016, Cytokinetics, Incorporated (the "Company") and Astellas Pharma, Inc. ("Astellas") entered into an amendment (the "Amendment") to expand their collaboration on the research, development and commercialization of skeletal muscle activators under their existing License and Collaboration Agreement, dated June 21, 2013, as previously amended and restated (the "Agreement").

Under the Amendment, the Company granted Astellas an option to enter into a pre-negotiated agreement for a global collaboration for the development and commercialization of tirasemtiv. If Astellas exercises the option, Astellas will receive exclusive worldwide commercialization rights outside of the Company's commercialization territory of North America, Europe and other select countries. Tirasemtiv is the Company's fast skeletal troponin activator being evaluated in the ongoing Phase 3 clinical trial, VITALITY-ALS, in people living with amyotrophic lateral sclerosis ("ALS"). In addition, the Amendment expands the Company's collaboration with Astellas to include the development of CK-2127107 ("CK-107"), a next-generation fast skeletal troponin activator, for the potential treatment of ALS, as well the possible development in ALS of other fast skeletal regulatory activators licensed to Astellas under the Agreement. Finally, the Amendment extends the existing joint research program focused on the discovery of additional next-generation skeletal muscle activators through 2017, including sponsored research at Cytokinetics.

In connection with the execution of this Amendment, the Company will receive a $15 million non-refundable option fee for the grant of the tirasemtiv option. Prior to Astellas' exercise of the option, the Company will continue the development of tirasemtiv, including the VITALITY-ALS trial, at its own expense to support regulatory approval in the U.S., EU and certain other jurisdictions and will retain the final decision making authority on the development of tirasemtiv. If Astellas exercises the option, the Company will grant Astellas an exclusive license to develop and commercialize tirasemtiv outside the Company's own commercialization territory of North America, Europe and other select countries. Each party would be primarily responsible for the further development of tirasemtiv in its territory and have the exclusive right to commercialize tirasemtiv in its territory.

Also in connection with the execution of the Amendment, the Company will receive a non-refundable upfront amendment fee of $35 million. In addition, the Company will receive the accelerated payment of a $15 million milestone for the initiation of the first Phase 2 clinical trial of CK-107 as the lead compound in ALS that was otherwise provided for in the Agreement, as if such milestone has been achieved upon the execution of the Amendment. The parties will share equally the costs of developing CK-107 in ALS for potential registration and marketing authorization in the U.S. and Europe, provided that (i) Astellas has agreed to solely fund Phase 2 development costs of CK-107 in ALS subject to a right to recoup the Company's share of such costs plus a 100% premium by reducing future milestone and royalty payments to the Company and (ii) the Company may defer (but not eliminate) a portion of its co-funding obligation for development activities after Phase 2 for up to 18 months, subject to certain conditions. The Company has the right to co-fund its share of such Phase 2 development costs on a current basis, in which case there would not be a premium due to Astellas. Cytokinetics will also receive approximately $30 million in additional sponsored research and development funding through 2017 which includes Astellas' funding of Cytokinetics' conduct of the Phase 2 clinical development of CK-2127107 in ALS (approximately $25 million) as well as the continuing research collaboration (approximately $5 million).

Pursuant to the Amendment, the Company and Astellas will collaborate to develop CK-107 in ALS. Astellas will be primarily responsible for the development of CK-107 in ALS, but the Company will conduct the Phase 2 clinical trial of CK-107 in ALS and will share in the operational responsibility for later clinical trials. Subject to specified guiding principles, decision making will be by consensus, subject to escalation and, if necessary, Astellas' final decision making authority on the development (including regulatory affairs), manufacturing, medical affairs and commercialization of CK-107 and other fast skeletal regulatory activators in ALS.

If Astellas exercises its option for a global collaboration for the development and commercialization of tirasemtiv, the Company will receive an option exercise payment ranging from $25 million (if exercise occurs following receipt of data from the VITALITY-ALS trial) to $80 million (if exercise occurs following receipt of FDA approval). In addition, the Company is eligible to receive a potential milestone payment from Astellas associated with the Company's initiation of the planned CY 4033 open-label extension trial for tirasemtiv. Such milestone would be $30 million, provided, however, that the amount will be reduced to $15 million if (i) Astellas elects to pay such milestone payment at the time the trial commences (if prior to Astellas' exercise of its option on tirasemtiv) or (ii) Astellas has exercised said option as of the time the trial commences. The Company will be responsible for the development costs of tirasemtiv during the option period, but if Astellas exercises the option after the defined review period following receipt of data from VITALITY-ALS, Astellas will at the time of option exercise reimburse the Company for a share of any additional costs incurred after such review period.

If Astellas exercises the option for tirasemtiv, the parties will share the future development costs of tirasemtiv in North America, Europe and certain other countries (with Cytokinetics bearing 75% of such shared costs and Astellas bearing 25% of such costs), and Astellas will be solely responsible for the development costs of tirasemtiv specific to its commercialization territory. Contingent upon the successful development of tirasemtiv, the Company may receive milestone payments up to $100 million for the initial indication and up to $50 million for each subsequent indication. If tirasemtiv is commercialized, Astellas will pay the Company royalties (at rates ranging from the mid-teens to twenty percent) on sales of tirasemtiv in Astellas' territory, and the Company will pay Astellas royalties (at rates up to the mid-teens) on sales of tirasemtiv in the Company's territory, in each case subject to various possible adjustments.

The Amendment is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and will become effective on the date of such

clearance (the "Effective Date"). If the Effective Date has not occurred within 120 days or such other time period as the parties may mutually agree, the Amendment may be terminated by either party upon written notice.

On July 27, 2016, the Company also issued a press release announcing the Company's entry into the Amendment. 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.

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

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 March 31, 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.

Cytokinetics, Incorporated

July 27, 2016

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

Exhibit No.	Description
99.1	Press Release, dated July 27, 2016