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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*

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*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>
99.1	Press Release, dated July 27, 2016



## **CYTOKINETICS AND ASTELLAS ANNOUNCE OPTION RIGHT FOR *TIRASEMTIV* AND EXPANSION OF GLOBAL COLLABORATION FOR CK-2127107 IN ALS**

*Cytokinetics to Receive \$65 Million in Upfront Payments and \$30 Million in Additional Sponsored R&D;  
Potential for More than \$100 Million in Payments Associated with the Exercise of the Option*

**SOUTH SAN FRANCISCO, Calif. and TOKYO, Japan, July 27, 2016** – Cytokinetics, Inc. (Nasdaq: CYTK, “Cytokinetics”) and Astellas Pharma Inc. (TSE: 4503, “Astellas”) today announced that Cytokinetics and Astellas have expanded their collaboration in skeletal muscle activators to include amyotrophic lateral sclerosis (ALS). Through this expansion, Cytokinetics has granted Astellas an option right for the development and commercialization of *tirasemtiv*, an investigational skeletal muscle activator. The companies have 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.

“We are pleased to further expand our productive and successful collaboration with Astellas in the area of skeletal muscle activators and to align our interests with regard to *tirasemtiv* and ALS,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “Advancing *tirasemtiv* and CK-2127107 for the potential treatment of ALS reinforces our shared commitment to deliver on the promise of fast skeletal troponin activation for people living with ALS who are fighting this dreadful disease.”

“The expansion of our collaboration illustrates Astellas’ commitment to muscle disease as an important and focused therapeutic area for research as announced in our strategic plan,” said Yoshihiko Hatanaka, Astellas’ President and Chief Executive Officer. “ALS is a disease with significant unmet needs worldwide, and we are excited to expand our collaboration with Cytokinetics to include promising drug candidates in ALS which reflect our shared interests in muscle biology.”

### **Option on *Tirasemtiv* and Expanded Collaboration Agreement**

Upon execution of the amended agreement, Cytokinetics will receive \$65 million in committed capital from Astellas which includes upfront payments for Astellas’ option right exercisable for *tirasemtiv* and amended terms of the companies’ collaboration agreement to include ALS for CK-2127107.

Astellas’ decision regarding its option for *tirasemtiv* will depend on its review of results from VITALITY-ALS and potentially other considerations by Astellas including the registration and marketing authorization of *tirasemtiv* in the United States and Europe. If Astellas exercises its option, the parties will enter into a global partnership in which Cytokinetics will continue to develop and commercialize *tirasemtiv* in North America, Europe, and other select countries, and Astellas will develop and commercialize *tirasemtiv* in other countries. Cytokinetics may receive over \$100 million in payments associated with the exercise of the option plus additional milestone payments and escalating double-digit royalties on Astellas’ sales of *tirasemtiv* in its territory. Astellas may be eligible to receive royalties that can reach double-digits on Cytokinetics’ sales of *tirasemtiv* in its territory.

Under this amendment of the collaboration agreement, Cytokinetics and Astellas have also agreed on a development plan for CK-2127107 in ALS. Cytokinetics will receive approximately \$30 million in additional sponsored research and development funding through 2017 which includes Astellas’ sponsorship of Cytokinetics’ conduct of the Phase 2 clinical development of CK-2127107 in ALS as well as the continuing research collaboration. Afterwards, Astellas and Cytokinetics will collaborate in the design and conduct of a potential registration program for CK-2127107 in ALS and the companies will share associated development costs. Cytokinetics would be eligible for additional milestone payments and royalties on sales based on the further development and commercialization of CK-2127107 for ALS.

The effectiveness of the amended agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

### **Cytokinetics Conference Call / Webcast**

Cytokinetics will host a conference call on July 27, 2016 at 8:30 a.m. Eastern Time. The conference call will be simultaneously webcast and will be accessible in the Investors & Media section of Cytokinetics’ Web site; for further information please go to [www.cytokinetics.com](http://www.cytokinetics.com). The live audio of the conference call is also accessible via telephone to investors, members of the news media and the general public by dialing either (866) 999-2985 (CYTK) (United States and Canada) or (706) 679-3078 (International) and typing in the passcode 55539648. An archived replay of the webcast will be available via Cytokinetics’ website until August 3, 2016. The replay will also be available via telephone from July 27, 2016 at 11:30 a.m. Eastern Time until August 3, 2016 by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (International) and typing in the passcode 55539648.

## 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 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. In connection with the expanded collaboration, the companies also agreed to extend their joint research program through 2016.

Under the recently 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 ALS) 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.

## About *Tirasemtiv* and CK-2127107

*Tirasemtiv* and CK-2127107 have demonstrated pharmacological activity that may lead to new therapeutic options for diseases associated with muscle weakness and fatigue. *Tirasemtiv* is a novel skeletal muscle activator that selectively activates the fast skeletal muscle troponin complex by increasing its sensitivity to calcium and, in preclinical studies and early clinical trials, demonstrated increases in skeletal muscle force in response to neuronal input and delays in the onset and reductions in the degree of muscle fatigue. *Tirasemtiv* has been studied in clinical trials that have enrolled over 1000 people internationally. *Tirasemtiv* is the subject of VITALITY-ALS, an ongoing Phase 3 clinical trial designed to confirm and extend findings on measures of respiratory function and muscle strength from prior studies. CK-2127107, a next-generation skeletal muscle activator has been the subject of five Phase 1 clinical trials in healthy volunteers, which evaluated safety, tolerability, bioavailability, pharmacokinetics and pharmacodynamics. CK-2127107 is being studied in Phase 2 studies in patients with SMA and chronic obstructive pulmonary disease (COPD).

## About ALS

Amiotrophic lateral sclerosis (ALS) is a progressive degenerative neuromuscular disease that afflicts approximately 30,000 people in the United States and a comparable number of patients in Europe<sup>1</sup>. Approximately 6,000 new cases of ALS are diagnosed each year in the United States. In people living with ALS, motor neurons progressively die and the brain can no longer communicate with the muscles through the spinal cord. As muscles are used less and less frequently, they can atrophy, causing people with ALS to lose the ability to perform everyday activities, such as walking, speaking, and eating. The average life expectancy of an ALS patient is approximately three to five years after diagnosis and only 10% of patients survive for more than 10 years. Death is usually due to respiratory failure because of diminished strength in the skeletal muscles responsible for breathing. Few treatment options exist for these patients, resulting in a high unmet need for new therapies to address functional deficits and disease progression.

## 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 Astellas' option. 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, chronic obstructive pulmonary disease and ALS. 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/>.

## About Astellas Pharma Inc.

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at [www.astellas.com](http://www.astellas.com).

## Cytokinetics 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, COPD and ALS and the VITALITY-ALS Phase 3 clinical trial of tirasemtiv in patients with ALS; the significance and utility of preclinical study and clinical trial results; and the properties and potential efficacy and safety profile of CK-2127107, tirasemtiv 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; Astellas’ decisions with respect to the design, initiation, conduct, timing and continuation of development activities for CK-2127107 and tirasemtiv, including Astellas’ decisions with respect to its option to enter into a global collaboration for the development and commercialization of tirasemtiv; 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; 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.

#### **Astellas Forward-Looking Statements**

This press release includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future. Statements made in the future tense, and words such as “anticipate,” “expect,” “project,” “continue,” “believe,” “plan,” “estimate,” “pro forma,” “intend,” “potential,” “target,” “forecast,” “guidance,” “outlook,” “seek,” “assume,” “will,” “may,” “should,” and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Actual results may differ materially depending on a number of factors. This press release contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these pharmaceuticals nor provide medical advice of any kind.

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<sup>1</sup> Amyotrophic Lateral Sclerosis Association. (2016). Media Facts and Key Facts. Retrieved from: <http://www.alsa.org/news/media/quick-facts.html> and <http://www.alsa.org/about-als/facts-you-should-know.html>