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): November 27, 2018

Cytokinetics, Incorporated
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50633**	**94-3291317**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

280 East Grand Avenue, South San Francisco, California 94080
(Address of Principal Executive Offices) (Zip Code)

(650) 624-3000
(Registrant's telephone number, including area code)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 8.01. Other Events.

On November 27, 2018, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated November 27, 2018

SIGNATURE

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

Date: November 27, 2018

By: /s/ Peter S. Roddy
Peter S. Roddy
Senior Vice President, Chief Accounting Officer

EXHIBIT 99.1

Cytokinetics Completes Enrollment in FORTITUDE-ALS, Phase 2 Clinical Trial of Reldesemtiv in Patients With ALS

Clinical Trial Results Expected First Half 2019

SOUTH SAN FRANCISCO, Calif., Nov. 27, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced the completion of patient enrollment in FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**nvestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**), the Phase 2 clinical trial designed to assess the change from baseline in the percent predicted slow vital capacity (SVC) and other measures of skeletal muscle function after 12 weeks of treatment with *reldesemtiv* (formerly CK-2127107). In collaboration with Astellas Pharma Inc. (TSE:4503) ("Astellas"), Cytokinetics is developing *reldesemtiv*, a next-generation fast skeletal muscle troponin activator (FSTA), as a potential treatment for people living with debilitating diseases and conditions associated with skeletal muscle weakness and/or fatigue.

"Completion of enrollment in FORTITUDE-ALS marks an important step forward towards our advancing the first potential muscle-directed medicine for people living with ALS who desperately need new therapies that may increase muscle force, power and the time to muscle fatigue," said Robert I. Blum, Cytokinetics' President and CEO. "We would like to thank all the dedicated investigators and clinical site coordinators who are working diligently to conduct this trial and to the people living with ALS and their caregivers who are participating. With this trial, Cytokinetics has now enrolled more than 2,000 people living with ALS into clinical trials in recent years, underscoring our industry-leading commitment to advancing the science and treatment possibilities for this community. We look forward to reporting results in the first half of 2019."

"There remains an urgent need in ALS to slow the decline of respiratory function, and to maintain stamina and muscle strength so that patients can sustain essential functionality for as long as possible," said Jeremy Shefner, M.D., Ph.D., Lead Investigator of FORTITUDE-ALS, Professor and Chair of Neurology at Barrow Neurological Institute, and Professor and Executive Chair of Neurology at University of Arizona, Phoenix. "Fast skeletal muscle troponin activation may offer an important new approach to preserve strength in the presence of ongoing nerve loss and potentially complement current treatments for patients suffering from this dreadful disease. FORTITUDE-ALS is a large, international trial that was designed to answer key questions relating to this novel mechanism."

About FORTITUDE-ALS

FORTITUDE-ALS is a Phase 2, double-blind, randomized, placebo-controlled, parallel group, dose ranging study of *reldesemtiv* in patients with ALS. Approximately 450 eligible ALS patients from centers in the U.S., Canada, Europe and Australia were randomized (1:1:1:1) to receive either 150 mg, 300 mg or 450 mg of *reldesemtiv* dosed orally twice daily or placebo for 12 weeks. The primary efficacy endpoint is the change from baseline in the percent predicted SVC at 12 weeks. Secondary endpoints include slope of the change from baseline in the mega-score of muscle strength measured by hand held dynamometry (HHD) and handgrip dynamometry in patients on *reldesemtiv;* change from baseline in the ALS Functional Rating Scale – Revised (ALSFRS-R); incidence and severity of treatment-emergent adverse events (TEAEs); and plasma concentrations of *reldesemtiv* at the sampled time points during the study.

In addition, exploratory endpoints will be measured including the effect of *reldesemtiv* versus placebo on self-assessments of respiratory function made at home by the patient with help as needed by the caregiver; disease progression through quantitative measurement of speech production characteristics over time; disease progression through quantitative measurement of handwriting abilities over time; and change from baseline in quality of life (as measured by the ALSAQ-5) in patients on *reldesemtiv*.

About ALS

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that afflicts approximately 20,000 people in the United States and a comparable number of patients in Europe. Approximately 5,000 new cases of ALS are diagnosed each year in the United States. The average life expectancy of an ALS patient is approximately three to five years after diagnosis and only approximately 10 percent 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 *Reldesemtiv*

Skeletal muscle contractility is driven by the sarcomere, the fundamental unit of skeletal muscle contraction and a highly ordered cytoskeletal structure composed of several key proteins. Skeletal muscle myosin is the motor protein that converts chemical energy into mechanical force through its interaction with actin. A set of regulatory proteins, which includes tropomyosin and several types of troponin, make the actin-myosin interaction dependent on changes in intracellular calcium levels. *Reldesemtiv*, a next-generation FSTA arising from Cytokinetics' skeletal muscle contractility program, slows the rate of calcium release from the regulatory troponin complex of fast skeletal muscle fibers, which sensitizes the sarcomere to calcium, leading to an increase in skeletal muscle contractility. *Reldesemtiv* has demonstrated pharmacological activity that may lead to new therapeutic options for diseases associated with muscle weakness and fatigue. In non-clinical models of spinal muscular atrophy (SMA), a skeletal muscle activator has demonstrated increases in submaximal skeletal muscle force and power in response to neuronal input and delays in the onset and reductions in the degree of muscle fatigue. *Reldesemtiv* has been the subject of five completed Phase 1 clinical trials in healthy volunteers, which evaluated the safety, tolerability, bioavailability, pharmacokinetics and pharmacodynamics of the drug candidate. Mid-stage clinical trials in patients with SMA, COPD and elderly adults with limited mobility have been completed. In the Phase 2 clinical study in patients with SMA, patients treated with *reldesemtiv* demonstrated increases in measures of endurance and stamina consistent with the mechanism of action.

About Cytokinetics and Astellas Collaboration

Reldesemtiv is being developed under a collaboration with Astellas. In 2013, Cytokinetics and Astellas formed a partnership focused on the research, development, and potential commercialization of activators of the skeletal muscle sarcomere. 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 *reldesemtiv* and other FSTAs in non-neuromuscular indications. In 2014, Astellas and Cytokinetics agreed to expand the collaboration to include certain neuromuscular indications,

including SMA, for *reldesemtiv* and other FSTAs and to advance *reldesemtiv* into Phase 2 clinical development, initially in SMA. Under the agreement as further amended in 2016, Astellas has exclusive rights to co-develop and commercialize *reldesemtiv* and other FSTAs 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. Under the collaboration agreement between Astellas and Cytokinetics, Cytokinetics is eligible for pre-commercialization and commercialization milestone payments and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. CK-601 is an additional compound discovered under a joint research program conducted between Astellas and Cytokinetics. Its further development and commercialization is subject to the collaboration agreement between Astellas and Cytokinetics.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and best-in-class muscle inhibitors 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 impact muscle function and contractility. Cytokinetics is collaborating with Amgen Inc. ("Amgen") to develop *omecamtiv mecarbil*, a novel cardiac muscle activator. *Omecamtiv mecarbil* is the subject of GALACTIC-HF, an international Phase 3 clinical trial in patients with heart failure. Amgen holds an exclusive worldwide license to develop and commercialize *omecamtiv mecarbil* with a sublicense held by Servier for commercialization in Europe and certain other countries. Cytokinetics is also collaborating with Amgen to develop AMG 594, a first-in-class cardiac troponin activator, discovered under the companies' joint research program. Further development of AMG 594 is subject to the collaboration agreement between Amgen and Cytokinetics. Cytokinetics is collaborating with Astellas Pharma Inc. ("Astellas") to develop *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA). *Reldesemtiv* has been granted orphan drug designation by the FDA for the potential treatment of spinal muscular atrophy. *Reldesemtiv* was the subject of a positive Phase 2 clinical study in patients with spinal muscular atrophy which showed increases in measures of endurance and stamina consistent with the mechanism of action. *Reldesemtiv* is currently the subject of a Phase 2 clinical trial in patients with amyotrophic lateral sclerosis. Cytokinetics is also advancing CK-601, a next-generation FSTA into IND-enabling studies under the collaboration with Astellas. Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics recently filed an IND for CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations. Cytokinetics continues its 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

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 Cytokinetics' and Astellas' joint research program and the Phase 2 clinical study of *reldesemtiv* in patients with ALS and its potentially beneficial effects; the timing, enrollment and results of Cytokinetics' and its partners clinical trials; the timing and receipt of milestone payments; 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, 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; Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *reldesemtiv*; 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.

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