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 10, 2012

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))

Top of the Form

Item 8.01 Other Events.

On September 10, 2012, Cytokinetics, Inc. issued a press release announcing that, following interactions with regulatory authorities, the company is proceeding to initiate a Phase IIb, international, randomized, double-blind, placebo-controlled, clinical trial designed to evaluate the safety, tolerability and efficacy of tirasemtiv (formerly CK-2017357) in patients with amyotrophic lateral sclerosis (ALS). The company plans to initiate this clinical trial, known as CY 4026, in the fourth quarter of 2012.

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.

Top of the Form

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 10, 2012

By: /s/ Sharon Barbari

Name: Sharon Barbari
Title: Executive Vice President, Finance and Chief Financial Officer

Top of the Form

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated September 10, 2012

Contact:
Jodi L. Goldstein
Manager, Marketing & Corporate Communications
(650) 624-3000

CYTOKINETICS PREPARES TO INITIATE REGISTRATION PROGRAM FOR *TIRAMSEMTIV* (CK-2017357) IN AMYOTROPHIC LATERAL SCLEROSIS FOLLOWING RECENT REGULATORY INTERACTIONS

South San Francisco, CA, September 10, 2012 – Cytokinetics, Incorporated (Nasdaq: CYTK) announced that, following interactions with regulatory authorities, the company is proceeding to initiate a Phase IIb, international, randomized, double-blind, placebo-controlled, clinical trial designed to evaluate the safety, tolerability and efficacy of *tirasemtiv* (formerly CK-2017357) in patients with amyotrophic lateral sclerosis (ALS). The company plans to initiate this clinical trial, known as CY 4026, in the fourth quarter of 2012.

In recent months, Cytokinetics submitted the CY 4026 protocol to the U.S. Food and Drug Administration (FDA) and also met with the European Medicines Agency (EMA) Scientific Advice Working Party to seek advice and protocol assistance in order to include European countries in CY 4026. Based on feedback from these interactions, the company is now preparing to initiate CY 4026. This clinical trial is designed to enroll approximately 400 patients who are expected to receive *tirasemtiv* or placebo for three months. The primary analysis of CY 4026 will compare the mean change from baseline in the ALS Functional Rating Scale in its revised form (ALSFRS-R) on *tirasemtiv* versus placebo. Secondary endpoints will include Maximum Voluntary Ventilation (MVV) and other measures of repiratory and skeletal muscle function. Patients will receive *tirasemtiv* or placebo dosed twice daily; patients taking *riluzole* at the time of enrollment, and who are randomized to receive *tirasemtiv,* will receive *riluzole* at a reduced dose of 50 mg daily, in a blinded manner.

"We are pleased to further evaluate *tirasemtiv* in patients with ALS, building upon our prior clinical experience obtained in trials of shorter duration," stated Andrew A. Wolff, MD, FACC, Cytokinetics' Senior Vice President of Clinical Research and Development and Chief Medical Officer. "Our recent interactions with regulatory authorities in the United States and Europe have informed this progress to the next stage of clinical development for *tirasemtiv.* We look forward to initiating this important clinical trial later this year."

Development Status of *Tirasemtiv*

Tirasemtiv (formerly CK-2017357) is currently the subject of a Phase II clinical trials development program and has been granted orphan drug designation and fast track status by the FDA and orphan medicinal product designation by the EMA for the potential treatment of ALS.

As reported previously, data from two completed randomized, placebo-controlled, multiple-dose, Phase II clinical trials were presented at the April 2012 American Academy of Neurology (AAN) Annual Meeting. In one of these trials, *tirasemtiv* appeared to be generally safe and well-tolerated when dosed daily for two weeks at 125 mg, 250 mg, or 375 mg, first in a cohort of patients not receiving *riluzole*, and then in a cohort of patients receiving *riluzole* at a reduced dose of 50 mg daily. Adverse events and clinical assessments during treatment with *tirasemtiv* appeared similar, with or without co-administration of *riluzole*. While the trial was not designed or powered to evaluate statistically the effects of *tirasemtiv* on the various outcome measures that were assessed during the study, a combined analysis of patients from two separate cohorts suggested encouraging trends in the ALSFRS-R and in MVV that appeared dose-related and potentially clinically meaningful in magnitude. In the other Phase II clinical trial, a twice-daily dose titration regimen of *tirasemtiv* also appeared to be generally safe and well-tolerated. The majority of patients could be titrated successfully to a *tirasemtiv* dose level of 250 mg twice daily. While this trial also was not designed or powered to evaluate statistically the effects of *tirasemtiv* on the various outcome measures that were assessed during the study; increases were observed in ALSFRS-R that were similar in direction, and in MVV that were similar in direction and magnitude, to those observed in the aforementioned trial.

Also as previously reported, in December 2010, data from a Phase IIa clinical trial evaluating single doses of *tirasemtiv* were presented at the 21st International Symposium on ALS/MND in Orlando. In all three of these previously conducted Phase II clinical trials, *tirasemtiv* appeared to be safe and well tolerated, and has demonstrated encouraging trends to improvement in patients' functional abilities, and in measures of respiratory and skeletal muscle strength and endurance.

About Cytokinetics

Cytokinetics is a clinical-stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics that modulate muscle function for the potential treatment of serious diseases and medical conditions. Cytokinetics' lead drug candidate from its cardiac muscle contractility program, *omecamtiv mecarbil*, is in Phase II clinical development for the potential treatment of heart failure. Amgen Inc. holds an exclusive license worldwide (excluding Japan) to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing *tirasemtiv* (formerly CK-2017357), a skeletal muscle activator, as a potential treatment for diseases and conditions associated with aging, muscle wasting or neuromuscular dysfunction. *Tirasemtiv* is currently the subject of a Phase II clinical trials program and 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 amyotrophic lateral sclerosis, a debilitating disease of neuromuscular impairment in which treatment with *tirasemtiv* produced potentially clinically relevant pharmacodynamic effects in Phase II trials. Cytokinetics is also conducting research on compounds that inhibit smooth muscle contractility and which may be useful as potential treatments for diseases and conditions associated with excessive smooth muscle contraction, such as bronchoconstriction associated with asthma and chronic obstructive pulmonary disease. All of these drug candidates and potential drug candidates have arisen from Cytokinetics' research activities and are directed towards the cytoskeleton. The cytoskeleton is a complex biological infrastructure that plays a fundamental role within every human cell. Additional information about Cytokinetics can be obtained at www.cytokinetics.com.

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' research and development activities, including plans for and the timing, initiation, conduct, size, design and results of clinical trials for tirasemtiv (CK-2017357); the significance and utility of clinical trial results for tirasemtiv; and the properties and potential benefits of tirasemtiv and Cytokinetics' other drug candidates and potential drug candidates, including tirasemtiv's potential utility in the treatment of patients with amyotrophic lateral sclerosis (ALS). 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, Cytokinetics will require significant additional funding to conduct a registration program for tirasemtiv for the potential treatment of ALS and may be unable to obtain such additional funding on acceptable terms, if at all; 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 trials 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 (FDA) or foreign regulatory agencies may delay or limit Cytokinetics' or its partners' ability to conduct clinical trials, regulatory authorities may not grant tirasemtiv orphan drug exclusivity in ALS even if it is approved for marketing; Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; Cytokinetics may incur unanticipated research and development and other costs; 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.

###