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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):

November 26, 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))
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**Item 8.01 Other Events.**

On November 26, 2012, Cytokinetics, Inc. issued a press release announcing positive data from a recently completed Phase IIa "Evidence of Effect" clinical trial of tirasemtiv in patients with generalized myasthenia gravis (MG). Tirasemtiv selectively activates the fast skeletal muscle troponin complex by increasing its sensitivity to calcium thereby increasing skeletal muscle force in response to neuronal input and delaying the onset and reducing the degree of muscle fatigue.

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.

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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.

November 26, 2012

Cytokinetics, Incorporated

By: /s/ Sharon Barbari

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*Name: Sharon 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 November 26, 2012

**CYTOKINETICS ANNOUNCES POSITIVE DATA  
FROM A PHASE IIA CLINICAL TRIAL  
OF *TIRASEMTIV* IN PATIENTS WITH MYASTHENIA GRAVIS**

***Myasthenia Gravis Is the Third Disease in which Single Doses of Tirasemtiv  
Have Produced Potentially Clinically Meaningful Pharmacodynamic Effects in Phase II Trials***

**South San Francisco, CA, November 26, 2012** — Cytokinetics, Incorporated (Nasdaq: CYTK) today announced positive data from a recently completed Phase IIA “Evidence of Effect” clinical trial of *tirasemtiv* in patients with generalized myasthenia gravis (MG). *Tirasemtiv* selectively activates the fast skeletal muscle troponin complex by increasing its sensitivity to calcium thereby increasing skeletal muscle force in response to neuronal input and delaying the onset and reducing the degree of muscle fatigue. *Tirasemtiv*, the lead drug candidate from the company’s skeletal muscle contractility program, is being evaluated as a potential treatment for amyotrophic lateral sclerosis (ALS) in BENEFIT-ALS, an international Phase IIb clinical trial that is now enrolling patients.

**Phase IIA Clinical Trial in Patients with Myasthenia Gravis: Design and Results**

This Phase IIA Evidence of Effect clinical trial, known as CY 4023, was a double-blind, randomized, three-period crossover, placebo-controlled, pharmacokinetic and pharmacodynamic study of *tirasemtiv* in patients with generalized MG. Patients enrolled in CY 4023 received single, oral, double-blind doses of placebo, 250 mg, and 500 mg of *tirasemtiv* in random order and approximately one week apart. The main objectives of this trial were to assess the effects of *tirasemtiv* on various measures of muscle strength, muscle fatigue and pulmonary function. Since CY 4023 was a hypothesis-generating trial, no single primary efficacy endpoint was pre-specified.

In CY 4023, at six hours after dosing, improvements (i.e., decreases) in the Quantitative MG score (QMG) were related to the *tirasemtiv* dose in a statistical significant manner (-0.49 QMG points per 250 mg;  $p = 0.02$ ). The QMG is a validated index of disease severity that is often employed as a primary endpoint in clinical trials of patients with MG. In addition, decreases in certain components of the QMG and their relationships to dose were statistically significant or borderline significant. Also at six hours after dosing in CY 4023, increases in the percent predicted forced vital capacity were statistically significantly related to the dose level of *tirasemtiv* (2.2% per 250 mg;  $p = 0.04$ ), as were the individual comparisons of each dose level of *tirasemtiv* versus placebo. Pending further analyses, more complete results from CY 4023 are expected to be submitted for public presentation at an upcoming clinical conference.

Both the 250 mg and 500 mg single oral doses of *tirasemtiv* studied in this Phase IIA clinical trial were well-tolerated by the 32 patients enrolled in CY 4023; there were no premature terminations and no serious adverse events were reported. The most commonly reported adverse event was dizziness which increased in frequency with dose and was reported as mild in all but one case that was classified as moderate.

“This study provides clear evidence of a pharmacodynamic effect of *tirasemtiv* to increase skeletal muscle performance and reduce fatigue in patients with generalized myasthenia gravis,” stated Donald B. Sanders, MD, Professor, Division of Neurology and Founder of the Duke Myasthenia Gravis Clinic and Chair, *Tirasemtiv* in Myasthenia Gravis Study Group. “This Phase IIA clinical trial represents a rigorous evaluation of the novel mechanism of action of *tirasemtiv* in this disease population; these data suggest that *tirasemtiv* may have the potential to meaningfully improve the lives of patients with myasthenia gravis and other neuromuscular diseases.”

“We have now completed Evidence-of-Effect studies of *tirasemtiv* in three different diseases, all of which involve impaired muscle function. In each one, single doses of *tirasemtiv* appeared to be well-tolerated and produced potentially clinically meaningful pharmacodynamic effects,” stated Andrew A. Wolff, MD, FACC, Cytokinetics’ Senior Vice President of Clinical Research and Development and Chief Medical Officer. “While Cytokinetics’ current focus is the rapid completion of BENEFIT-ALS, we believe these new results in patients with MG provide further validation of the potential therapeutic utility of fast skeletal muscle troponin activators across a broad spectrum of diseases characterized by muscle weakness or fatigue.”

Cytokinetics has been awarded \$3.5 million in grants (Award Number RC3NS070670) from the National Institute of Neurological Disorders and Stroke (NINDS) to fund research and development of *tirasemtiv* in MG. Through September 30, 2012, Cytokinetics has incurred \$4.1 million in research and development expense associated with its MG program, and has received \$2.9 million or 69% of the program’s funding from the NINDS. The content of this press release is solely the responsibility of Cytokinetics and does not necessarily represent the official views of the NINDS or the National Institutes of Health.

**Background on Myasthenia Gravis**

Myasthenia gravis is a progressive, chronic neuromuscular disease that commonly strikes people between the ages of 40 and 70 and afflicts between 50,000 and 85,000 people in the United States. Approximately 13,600 new cases of myasthenia gravis are diagnosed each year. Myasthenia gravis is an autoimmune disease in which the immune system attacks the junction between nerve and muscle, targeting either the muscle cell’s acetylcholine receptor (which receives signals from the associated nerve cell) or the muscle-specific kinase, a protein that helps to organize acetylcholine receptors on the muscle cell. The cause of myasthenia gravis is unclear. Researchers suspect viruses or bacteria might trigger the autoimmune response; the thymus gland also sometimes seems to play a role in the disease. Symptoms include fatigue and weakness of voluntary muscles, including partial paralysis of eye movements, double vision, droopy eyelids, and weakness and fatigue in neck and jaws with problems in chewing, swallowing and holding up the head. This weakness usually fluctuates each day but tends to spread and progress over the course of a few years, especially if untreated.

**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 United States Food and Drug Administration and orphan medicinal product designation by the European Medicines Agency for the potential treatment of ALS.

In October 2012, Cytokinetics announced that it opened enrollment for BENEFIT-ALS, a Phase IIb, multi-national, double-blind, randomized, placebo-controlled clinical trial designed to evaluate the safety, tolerability and potential efficacy of *tirasemtiv* in patients with ALS. This trial is designed to enroll approximately 400 patients who will be randomized to 12 weeks of double-blind treatment with *tirasemtiv* or placebo dosed twice daily. The primary analysis of BENEFIT-ALS 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 respiratory and skeletal muscle function. Cytokinetics plans to conduct BENEFIT-ALS at over 70 sites across the United States, Canada, and several European countries.

Data from two completed randomized, double-blind, placebo-controlled, multiple-dose, Phase II clinical trials were presented at the April 2012 American Academy of Neurology 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*, 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 the two 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 in this trial were 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. In addition, in December 2010, data from a Phase IIa clinical trial evaluating single doses of *tirasemtiv* were presented at the 21<sup>st</sup> International Symposium on ALS and Motor Neurone Diseases. In all three of these Phase II clinical trials, *tirasemtiv* appeared to be safe and well-tolerated, and 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*, 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. Both of these drug candidates have arisen from Cytokinetics' muscle biology focused 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](http://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 the progress, conduct, design and results of clinical trials; the significance and utility of clinical trial results, expected presentations of clinical trial results, and the potential for BENEFIT-ALS to support the registration of tirasemtiv for the treatment of ALS; and the properties and potential benefits of tirasemtiv and Cytokinetics' other drug candidates and potential 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, 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.*

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