
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):

December 9, 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 8.01 Other Events.

On December 9, 2016, Cytokinetics, Inc. announced that new data was presented at the 27th International Symposium on ALS/MND in Dublin, Ireland, including patient baseline characteristics from VITALITY-ALS and results of an international physician survey on the use of noninvasive ventilation (NIV) in the treatment of ALS.

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.

Cytokinetics, Incorporated

December 9, 2016

By: /s/ Sharon A. Barbari

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

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated December 9, 2016



CYTOKINETICS ANNOUNCES NEW DATA PRESENTED AT THE INTERNATIONAL SYMPOSIUM ON ALS/MND

Patient Baseline Characteristics from VITALITY-ALS Comparable to BENEFIT-ALS

Physician Survey Shows Regional Variability in Use of Noninvasive Ventilation

SOUTH SAN FRANCISCO, Calif., Dec. 9, 2016 - Cytokinetics, Inc. (Nasdaq: CYTK) today announced that new data was presented at the 27th International Symposium on ALS/MND in Dublin, Ireland, including patient baseline characteristics from VITALITY-ALS and results of an international physician survey on the use of noninvasive ventilation (NIV) in the treatment of ALS.

VITALITY-ALS, a multi-national, randomized, double-blind, placebo-controlled Phase 3 clinical trial designed to assess the effects of *tirasemtiv* versus placebo on slow vital capacity (SVC) and other measures of respiratory and skeletal muscle function in patients with ALS, completed enrollment in August 2016. The trial screened 866 patients, enrolled 744 and randomized 566 patients.

Baseline characteristics of patients enrolled in VITALITY-ALS are similar to those from BENEFIT-ALS and other recently conducted clinical trials in patients with ALS. Patients enrolled in VITALITY-ALS are on average 57.6 years of age, 65 percent male, 7.7 months from diagnosis, 20.6 months from their first symptom and had an average percent predicted SVC of 90.7 percent. Like other trials of *tirasemtiv*, the most common adverse events (AEs) observed to date are dizziness, fatigue and nausea. Approximately 24 percent of patients withdrew from VITALITY-ALS during the two week open-label phase, primarily due to AEs, similar to what was observed during the first two weeks of *tirasemtiv* treatment in BENEFIT-ALS, the Phase 2 clinical trial of *tirasemtiv* in patients with ALS.

“We’re pleased to provide the first look at the patient population from VITALITY-ALS and note the consistency with previously conducted large-scale ALS trials,” said Jeremy M. Shefner, M.D., Ph.D., Lead Investigator of VITALITY-ALS, Professor and Chair of Neurology at Barrow Neurological Institute, and Professor and Executive Chair of Neurology at the University of Arizona, Phoenix. “We look forward to sharing full results from VITALITY-ALS in late 2017 and remain hopeful that treatment with *tirasemtiv* may slow the decline of SVC and other measures of muscle strength including measures of respiratory function.”

Vital Capacity Key Driver to Initiating Noninvasive Ventilation

Results of an international physician survey on the use of NIV in the treatment of ALS presented by Terry Heiman-Patterson, M.D., Director of the Center for Neurodegenerative Disorders, and Professor of the Department of Neurology at the Lewis Katz School of Medicine at Temple University, revealed similarities in best practices for initiating NIV in North America and Europe, yet differences in the time to initiation. Among ALS specialists including physicians, nurse practitioners, and physician assistants, US specialists rank upright FVC, supine FVC, and symptoms of orthopnea and/or dyspnea as the three most important factors influencing NIV initiation, while EU specialists prioritize symptoms of orthopnea and/or dyspnea, sleep-related symptoms, and supine SVC.

Regional variations were observed in the timing of NIV initiation, in part influenced by varying insurance coverage and regulations. In the US, 70 percent of specialists indicated that insurance regulations and national health care coverage impact time to NIV initiation, compared to 47.5 percent of EU specialists. The FVC/SVC value at which specialists reported initiating NIV also differed regionally, with many US specialists citing an upright FVC/SVC <50 percent vital capacity, and EU specialists more often initiating NIV at a higher upright FVC/SVC of <70 percent or <80 percent.

“Although we found geographic differences in how and when noninvasive ventilation is used, vital capacity remains one of the most important measures influencing the decision,” said Terry Heiman-Patterson, M.D., Director of the Center for Neurodegenerative Disorders, and Professor of the Department of Neurology at the Lewis Katz School of Medicine at Temple University. “These results help us understand what additional research is needed to optimize NIV use in all patients, and may help inform the design of future clinical trials in ALS.”

About VITALITY-ALS

VITALITY-ALS is a multi-national, randomized, double-blind, placebo-controlled clinical trial in patients with possible, probable or definite ALS, diagnosed within 24 months, and with percent predicted SVC at baseline 70 percent. The primary endpoint of the trial will assess change from baseline in SVC, to be assessed after 24 weeks of double-blind, placebo-controlled treatment. Secondary endpoints, to be assessed at 48 weeks, include time to decline from baseline in percent predicted SVC by 20 percentage points or the onset of respiratory insufficiency or death; time to decline from baseline in percent predicted SVC to 50 percent predicted or the onset of respiratory insufficiency or death; time to first occurrence of any use of assisted ventilation or death; time to decline in any of the three respiratory domains of the ALSFRS-R or death; and change in the Mega-Score of muscle strength. Patients enrolled in VITALITY-ALS receive two-weeks of open-label treatment with *tirasemtiv* administered at 250 mg/day. Patients are then randomized into a double-blind treatment phase to placebo or one of three target *tirasemtiv* dose levels (250 mg/day, 375 mg/day, 500 mg/day) in a 3:2:2 ratio. After

48 weeks of randomized, double-blind, placebo-controlled treatment, patients who received *tirasemtiv* during those 48 weeks of double-blind treatment will be randomized to continue the *tirasemtiv* dose at which they completed the 48 weeks of double-blind treatment or to placebo for a four-week double-blind, *tirasemtiv* withdrawal phase. Patients who received placebo during the 48 weeks of double-blind treatment will continue to receive placebo during the double-blind, *tirasemtiv* withdrawal phase. Following their participation in VITALITY-ALS, patients are eligible to participate in an open-label extension study of *tirasemtiv*.

About ALS

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that afflicts approximately 30,000 people in the United States and a comparable number of patients in Europe. Approximately 6,000 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 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 *Tirasemtiv*

Tirasemtiv, a novel skeletal muscle activator, 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 currently the subject of VITALITY-ALS, a Phase 3 clinical trial, designed to confirm and extend findings on measures of respiratory function and muscle strength from prior studies.

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 an option held by Astellas Pharma Inc. Cytokinetics is also collaborating with Astellas to develop CK-2127107, a fast skeletal muscle activator, for the potential treatment of spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Cytokinetics is collaborating with Amgen Inc. to develop *omecamtiv mecarbil*, a novel cardiac muscle activator, for the potential treatment of heart failure. 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/>.

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, progress and timing of results of 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 *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 FDA 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; 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; and 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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