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 21, 2017

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.

Cytokinetics, Incorporated today announced that VITALITY-ALS (Ventilatory Investigation of Tirasemtiv and Assessment of Longitudinal Indices after Treatment for a Year in ALS), the international Phase 3 clinical trial of tirasemtiv in patients with amyotrophic lateral sclerosis (ALS), did not meet the primary endpoint of change from baseline in slow vital capacity (SVC) which was evaluated at 24 weeks following randomization or any of the secondary endpoints in the trial which were evaluated at 48 weeks. A copy of the press release is attached as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated November 21, 2017

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 21, 2017

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

EXHIBIT 99.1

Cytokinetics Announces Negative Results From VITALITY-ALS

Phase 3 Clinical Trial of Tirasemtiv in Patients with ALS
Did Not Meet Primary or Secondary Endpoints

Results to be Presented December 8th at 28th International Symposium on ALS/MND

Conference Call Today at 8:30 a.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., Nov. 21, 2017 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq:CYTK) today announced that VITALITY-ALS (**V**entilatory **I**nvestigation of ***T****irasemtiv* and **A**ssessment of **L**ongitudinal **I**ndices after **T**reatment for a **Y**ear in **ALS**), the international Phase 3 clinical trial of *tirasemtiv* in patients with amyotrophic lateral sclerosis (ALS), did not meet the primary endpoint of change from baseline in slow vital capacity (SVC) which was evaluated at 24 weeks following randomization or any of the secondary endpoints in the trial which were evaluated at 48 weeks.

No new safety or tolerability findings related to *tirasemtiv* were identified in VITALITY-ALS. Serious adverse events were similar between patients who received *tirasemtiv* or placebo but more patients discontinued double-blind treatment on *tirasemtiv* than on placebo primarily due to non-serious adverse events related to tolerability. The decline in SVC from baseline to 24 weeks was smaller in patients who received any dose of *tirasemtiv* in VITALITY-ALS compared to the decline in patients receiving placebo. The largest differences from placebo were observed in patients randomized to the mid- and high-dose groups of *tirasemtiv* who could tolerate and remain on their target dose, although those differences were not statistically significant.

"While we are deeply disappointed by the results of VITALITY-ALS, we remain committed to people with ALS who are fighting this devastating disease and who need new therapies to slow the decline of respiratory function and muscle strength that are key hallmarks of disease progression," said Robert I. Blum, Cytokinetics' President and CEO. "We have decided to suspend the development of *tirasemtiv*. While we believe that VITALITY-ALS demonstrated pharmacologic activity for the mechanism of action, we also believe that limitations of *tirasemtiv* may be addressed with our next-generation fast skeletal muscle activator, CK-2127107. Based on previous Phase 1 clinical studies, we believe CK-2127107 will be better tolerated and potentially more effective than *tirasemtiv* in patients with ALS and look forward to Phase 2 trial results in 2018. We are grateful to the trial investigators, site personnel, patients and caregivers who participated in VITALITY-ALS."

The results of VITALITY-ALS will be presented on December 8, 2017 at the 27th Annual International ALS/MND Symposium in Boston, MA by Jeremy 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 University of Arizona, Phoenix.

About VITALITY-ALS and VIGOR-ALS

VITALITY-ALS was a multi-national, randomized, double-blind, placebo-controlled trial in patients with possible, probable or definite ALS, diagnosed within 24 months, and with SVC at baseline ≥ 70 percent predicted. The primary endpoint of the trial assessed change from baseline in SVC, after 24 weeks of double-blind, placebo-controlled treatment. Secondary endpoints, assessed at 48 weeks, included change from baseline in the score of the three respiratory items of the ALSFRS-R (i.e., the sum of items 10, 11 and 12) at 48 weeks; slope of the mega-score of muscle strength at 48 weeks; time to the first occurrence of a decline from baseline in percent predicted SVC ≥20 percentage points or the onset of respiratory insufficiency or death through 48 weeks; time to the first occurrence of a decline in SVC to ≤50% predicted or the onset of respiratory insufficiency or death through 48 weeks; change from baseline in the ALSFRS-R total score at 48 weeks; and time to the first use of mechanical ventilatory assistance or death through 48 weeks. Patients enrolled in VITALITY-ALS received two-weeks of open-label treatment with *tirasemtiv* administered at 250 mg/day. Patients were 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 3:2:2:2 ratio. After 48 weeks of randomized, double-blind, placebo-controlled treatment, patients who received *tirasemtiv* during those 48 weeks of double-blind treatment were randomized to continue the dose of *tirasemtiv* 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 continued to receive placebo during the double-blind, *tirasemtiv* withdrawal phase.

Following their participation in VITALITY-ALS, patients were eligible to participate in an open-label extension study of *tirasemtiv,* VIGOR-ALS (**V**entilatory **I**nvestigations in **G**lobal **O**pen-label **R**esearch in **ALS**), designed to assess the long-term safety and tolerability of *tirasemtiv* in patients with ALS. Currently, over 200 patients are receiving *tirasemtiv* in VIGOR-ALS. Cytokinetics will seek advice from the academic leadership of VITALITY-ALS and its clinical investigators, regulatory authorities and other consultants before making decisions about continuing treatment with *tirasemtiv* in VIGOR-ALS.

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* and CK-2127107

Tirasemtiv is a fast skeletal muscle troponin activator (FSTA) 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.

CK-2127107 is a next-generation FSTA arising from Cytokinetics' skeletal muscle contractility program. CK-2127107 was derived from a different chemical structural class and was designed to have certain advantages relative to *tirasemtiv*. CK-2127107 appears to be more potent than *tirasemtiv* in preclinical models and in humans and appears better tolerated compared to *tirasemtiv*. CK-2127107 has demonstrated pharmacological activity that may lead to new therapeutic options for diseases associated with muscle weakness and fatigue. CK-2127107 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. CK-2127107 is the subject of an ongoing clinical development program in neuromuscular and non-neuromuscular diseases and conditions associated with muscle dysfunction and weakness, including three Phase 2 trials currently underway in patients with each of SMA, ALS, or COPD, as well as a Phase 1b trial in elderly subjects with limited mobility.

Cytokinetics Conference Call / Webcast

Cytokinetics will host a conference call today 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' website. 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 2396807. An archived replay of the webcast will be available via Cytokinetics' website until November 28, 2017. The replay will also be available via telephone from November 21, 2017 at 11:30 a.m. Eastern Time until November 28, 2017 by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (International) and typing in the passcode 2396807.

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 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 collaborating with Astellas Pharma Inc. (“Astellas”) to develop CK-2127107, a next-generation FSTA. CK-2127107 has been granted orphan drug designation by the FDA for the potential treatment of SMA. CK-2127107 is the subject of three ongoing Phase 2 clinical trials enrolling patients with spinal muscular atrophy, chronic obstructive pulmonary disease and ALS. Astellas is also conducting a Phase 1b clinical trial of CK-2127107 in elderly adults with limited mobility. Astellas holds an exclusive worldwide license to develop and commercialize CK-2127107. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization rights. For additional information about Cytokinetics, visit 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 our continuing review and assessment related to the results from VITALITY-ALS, our evaluation, in consultation with the FDA and other regulatory authorities of future development plans for *tirasemtiv* and the process and timing of anticipated future development of *tirasemtiv*; the design, results, significance and utility of preclinical study results; and the properties and potential benefits of CK-2127107 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, 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; Astellas’ decisions with respect to the design, initiation, conduct, timing and continuation of development activities for CK-2127107; 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.

Contact:
Cytokinetics
Diane Weiser
Vice President, Corporate Communications, Investor Relations
(415) 290-7757