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): October 20, 2014

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))

Item 8.01 Other Events.

On October 20, 2014, Cytokinetics, Incorporated issued a press release providing a program update relating to *tirasemtiv*, the company's lead drug candidate from its skeletal muscle contractility program. The company announced that it has completed its review of results from BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional **I**mprovement with ***T****irasemtiv* in **ALS**) and has concluded that effects observed on Slow Vital Capacity (SVC) in patients treated with *tirasemtiv* are robust and potentially clinically meaningful. In addition, following consultation with clinical and statistical experts, the company believes that data from BENEFIT-ALS support progression of *tirasemtiv* to a potential Phase III clinical trial in patients with amyotrophic lateral sclerosis (ALS). The company also announced that it has begun regulatory interactions with the U.S. Food and Drug Administration (FDA) regarding results from BENEFIT-ALS and has received initial feedback from the FDA. The company believes that effects on SVC could be a Phase III clinical trial endpoint and could support registration of *tirasemtiv* as a potential treatment for patients with ALS. As a result, Cytokinetics has initiated planning for a potential Phase III clinical trial of *tirasemtiv* that could begin in 2015.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

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

October 20, 2014

By: */s/ Sharon Barbari*
Name: *Sharon Barbari*
Title: *Executive Vice President, Finance and Chief Financial Officer*

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated October 20, 2014

Exhibit 99.1

CYTOKINETICS PROVIDES DEVELOPMENT PROGRAM UPDATE FOR *TIRASEMTIV*

Robust Effects of Tirasemtiv on Slow Vital Capacity Observed in BENEFIT-ALS Support Progression to Phase III

Company Believes Effects on Slow Vital Capacity Could Support Registration Path For Tirasemtiv

SOUTH SAN FRANCISCO, CA, October 20, 2014 – Cytokinetics, Incorporated (Nasdaq: CYTK) provided a program update today relating to *tirasemtiv*, the company's lead drug candidate from its skeletal muscle contractility program. The company announced that it has completed its review of results from BENEFIT-ALS (**B**linded **E**valuation of **N**euromuscular **E**ffects and **F**unctional **I**mprovement with ***T****irasemtiv* in **ALS**) and has concluded that effects observed on Slow Vital Capacity (SVC) in patients treated with *tirasemtiv* are robust and potentially clinically meaningful. In addition, following consultation with clinical and statistical experts, the company believes that data from BENEFIT-ALS support progression of *tirasemtiv* to a potential Phase III clinical trial in patients with amyotrophic lateral sclerosis (ALS). The company also announced that it has begun regulatory interactions with the U.S. Food and Drug Administration (FDA) regarding results from BENEFIT-ALS and has received initial feedback from the FDA. The company believes that effects on SVC could be a Phase III clinical trial endpoint and could support registration of *tirasemtiv* as a potential treatment for patients with ALS. As a result, Cytokinetics has initiated planning for a potential Phase III clinical trial of *tirasemtiv* that could begin in 2015.

"We have engaged in an objective and comprehensive review of results from BENEFIT-ALS and have concluded that data favoring the effects of *tirasemtiv* relative to placebo on Slow Vital Capacity from this large, international Phase IIb trial are robust and warrant further investigation. BENEFIT-ALS is the first clinical trial in patients with ALS to demonstrate a positive and potentially clinically meaningful effect on Slow Vital Capacity, an important measure of disease progression and predictor of survival," stated Robert I. Blum, Cytokinetics' President and CEO. "We are encouraged by our initial interactions with the FDA relating to the results of BENEFIT-ALS and believe that our continuing discussions can inform our plans to pursue a potential registration program based on effects observed on respiratory function measured by Slow Vital Capacity in patients with ALS."

Effects of *Tirasemtiv* on SVC in BENEFIT-ALS

In BENEFIT-ALS, treatment with *tirasemtiv* resulted in a statistically significant and potentially clinically meaningful reduction in the decline of SVC, a measure of the strength of the skeletal muscles responsible for breathing that has been shown to be an important predictor of disease progression and survival in prior trials of patients with ALS. This pre-specified secondary efficacy endpoint in BENEFIT-ALS declined less on *tirasemtiv* than on placebo at each assessment time point.

Slow Vital Capacity	Placebo (n = 210)	*Tirasemtiv* (n = 178)	All (N = 388)
Baseline (% Predicted, mean ± SD)	89.7 (17.2)	85.7 (19.3)	87.8 (18.3)
Time Point	Changes from Baseline (Least Square Mean ± Standard Error)		p-value
Week 4	-3.89 (0.62)	-0.99 (0.68)	0.001
Week 8	-5.81 (0.68)	-2.85 (0.77)	0.004
Week 12	-8.66 (0.80)	-3.12 (0.90)	<0.0001
	Slope of decline (Percentage Points per day)		
Week 0 to Week 12	-0.0905	-0.0394	0.0006

In addition, the reduced decline in SVC on *tirasemtiv* versus placebo in BENEFIT-ALS was observed consistently across all subgroups of patients. *Tirasemtiv* reduced the decline in SVC versus placebo by a similar magnitude regardless of age (≥65 versus <65), sex, geographic region (Europe versus North America), *riluzole* use, site of ALS onset (bulbar versus limb), baseline pulmonary function, baseline weight, and baseline BMI. The reduced decline in SVC versus placebo was statistically significant within each subgroup examined except patients enrolled in Europe, those with bulbar onset, and those with a percent predicted SVC less the median at baseline. Outcome measures obtained at 1 and 4 weeks after the last dose of double-blind study medication in BENEFIT-ALS also provide evidence of the durability of the effect of *tirasemtiv* on SVC.

		Changes from Baseline		
Outcome Measure	Baseline	After 12 Weeks Double-Blind	1 Week after Last Double-Blind Dose	4 Weeks after Last Double-Blind Dose
SVC (% predicted)				
Placebo	89.7	-8.66	-8.03	-10.30
Tirasemtiv	85.7	-3.12	-3.75	-5.39
p-value		<0.0001	0.0002	0.0002

Cytokinetics has performed extensive statistical analyses as well as simulations and sensitivity tests on data from BENEFIT-ALS. In addition, the company has consulted with neuromuscular and pulmonary specialists and key opinion leaders, both in the United States and internationally, and has concluded that the results from BENEFIT-ALS provide compelling evidence that *tirasemtiv* may preserve respiratory function in patients with ALS that warrants investigation in a potential Phase III trial.

Ongoing Regulatory Interactions and Next Steps

Cytokinetics has received feedback from the FDA following initial communications regarding *tirasemtiv* and BENEFIT-ALS. The company believes that the FDA may be willing to consider a potential registration path for *tirasemtiv* relating to effects on SVC. The company expects to have additional interactions with the FDA and other regulatory authorities. In addition, the company has commenced Phase III readiness activities including designing a potential Phase III clinical trial in order to inform plans, timelines and costs associated with the further development of *tirasemtiv*.

About *Tirasemtiv* and BENEFIT-ALS

Tirasemtiv selectively activates the fast skeletal muscle troponin complex by increasing its sensitivity to calcium and, in preclinical studies and early clinical trials, increased skeletal muscle force in response to neuronal input and delayed the onset and reduced the degree of muscle fatigue. BENEFIT-ALS was a Phase IIb, multi-national, double-blind, randomized, placebo-controlled, clinical trial designed to evaluate the safety, tolerability and efficacy of *tirasemtiv* in patients with ALS. BENEFIT-ALS enrolled 711 patients from 73 centers in 8 countries. 605 patients were subsequently randomized 1:1 to double-blind treatment with either *tirasemtiv* or placebo for 12 weeks. The primary outcome measure, the ALS Functional Rating Scale in its revised form (ALSFRS-R), and secondary outcome measures of respiratory performance and other measures of skeletal muscle function and fatigability were assessed after 4, 8, and 12 weeks of double-blind treatment, and again at 1 and 4 weeks after the last dose of double-blind treatment. The results from double-blind treatment were presented in April 2014 at the Annual Meeting of the American Academy of Neurology. In June 2014, outcome measures obtained at 1 and 4 weeks after last dose of double-blind study medication were presented at the Joint Congress of European Neurology. In July 2014, data demonstrating that the effects of *tirasemtiv* on SVC appeared to be consistent across patient subgroups were presented at the International Congress on Neuromuscular Diseases.

The primary efficacy endpoint in BENEFIT-ALS, the change from baseline to the average of the ALSFRS-R total scores obtained after 8 and 12 weeks of double-blind treatment, was not statistically different between the treatment groups. Treatment with *tirasemtiv* resulted in a statistically significant and potentially clinically meaningful slowing of the rate of decline of SVC versus placebo; the reduction from baseline in SVC was statistically significantly smaller on *tirasemtiv* versus placebo at each time point. The difference in the reduction from baseline in SVC in patients treated with *tirasemtiv* versus those on placebo persisted for at least four weeks following the last dose of double-blind medication.

About Amyotrophic Lateral Sclerosis

Amyotrophic lateral sclerosis is a progressive neurodegenerative disease that afflicts approximately 25,000 people in the United States and a comparable number of patients in Europe. Approximately 5,600 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% 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 therapeutic options to address the symptoms and modify the disease progression of this grievous illness.

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 to develop and commercialize *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization participation rights. Cytokinetics is independently developing *tirasemtiv*, a fast skeletal muscle activator, as a potential treatment for diseases and medical conditions associated with neuromuscular dysfunction. *Tirasemtiv* is 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 (ALS). Cytokinetics is collaborating with Astellas Pharma Inc. to develop CK-2127107, a skeletal muscle activator structurally distinct from *tirasemtiv*, for non-neuromuscular indications. All 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.

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' research and development activities, including the potential significance and utility of the results from BENEFIT-ALS and other studies of tirasemtiv; the potential conduct of a Phase III clinical trial of tirasemtiv and the timing for the initiation of such a trial; the use of effects on slow vital capacity as a Phase III clinical trial endpoint; planned interactions with regulatory authorities and the outcomes of such interactions; the potential size of markets for tirasemtiv; and the properties and potential benefits 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 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 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 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; Amgen's and Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for omecamtiv mecarbil and CK-2127107, respectively; Cytokinetics may incur unanticipated research and development and other costs or be unable to obtain additional financing necessary to conduct development of its products; 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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