CYTOKINETICS INC
Form 8-K
April 29, 2014

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): April 29, 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.

Cytokinetics, Inc. announced additional results from BENEFIT-ALS (Blinded Evaluation of Neuromuscular Effects and Functional Improvement with Tirasemtiv in ALS), which will be presented later today during the 66th Annual Meeting of the American Academy of Neurology at the Pennsylvania Convention Center in Philadelphia by Jeremy M. Shefner, M.D., Ph.D., Professor and Chair, Department of Neurology at the Upstate Medical University, State University of New York and the Lead Investigator for BENEFIT-ALS.

In BENEFIT-ALS, 711 patients with amyotrophic lateral sclerosis (ALS) were enrolled into the open-label phase; subsequently 605 patients were randomized 1:1 to double-blind treatment with either tirasemtiv or placebo for 12 weeks. As previously announced, BENEFIT-ALS did not achieve its primary efficacy endpoint, the mean change from baseline in the ALS Functional Rating Scale in its revised form (ALSFRS-R). Secondary endpoints evaluated measures of respiratory performance and other measures of skeletal muscle function and fatigability.

Treatment with tirasemtiv resulted in a statistically significant and potentially clinically meaningful reduction in the decline of Slow Vital Capacity (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 also declined less on tirasemtiv than on placebo at each assessment time point.

	Placebo	***Tirasemtiv***	**All**
Slow Vital Capacity	**(n = 210)**	**(n = 178)**	**(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

The analyses of other pre-specified secondary efficacy endpoints in BENEFIT-ALS produced mixed results. The Muscle Strength Mega-Score, a measure of strength combining the data from several muscle groups in each patient, declined more slowly on tirasemtiv versus placebo (p = 0.016 for the difference in slope of decline); however, there were no differences at any time point that reached statistical significance. The rate of decline for Sniff Nasal Inspiratory Pressure (SNIP) was not statistically significant different (p = 0.21); however, SNIP decreased more on tirasemtiv compared with placebo in a statistically significant manner at 4 and 12 weeks (p values at 4, 8, and 12 weeks were 0.012, 0.066, 0.050, respectively). No differences in Maximum Voluntary Ventilation and Hand Grip Fatigue were observed on tirasemtiv versus placebo.

Serious adverse events (SAE) during double-blind treatment were more frequent on tirasemtiv than on placebo (9.0% vs. 5.4%). The most common SAE was respiratory failure which occurred in 1 patient on tirasemtiv and 3 patients on placebo, while confusional state and delirium occurred in 2 patients on tirasemtiv and no patients on placebo. More patients on tirasemtiv withdrew from the trial following randomization than on placebo (99 vs. 33 patients, respectively). Adverse events more common on tirasemtiv than on placebo (>10% difference) were dizziness (50.8%

vs. 19.7%), fatigue (33.2% vs. 14.2%), and nausea (21.9% vs. 7.8%).

Patients on tirasemtiv lost more weight than patients on placebo (change from baseline to Week 12: -1.70 kg vs. -0.79 kg; p = 0.006). Weight loss was significantly greater in patients with gastrointestinal adverse events (e.g. nausea and decreased appetite) which occurred more frequently on tirasemtiv than on placebo (43.5% vs. 25.8%). The weight loss on tirasemtiv appeared to negatively impact the effect of tirasemtiv on the ALSFRS-R when compared to placebo (p value for weight change-by-treatment interaction = 0.052). ALSFRS-R declined less on tirasemtiv than on placebo in those patients treated with tirasemtiv who lost less weight.

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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release.

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

April 29, 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 April 29, 2014