

CYTOKINETICS INC
Form 8-K
October 20, 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): October 20, 2014

Cytokinetics, Incorporated

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-50633
(Commission

File Number)

94-3291317
(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 *Tirasemtiv* 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 |