# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

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# FORM 8-K

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## 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 10, 2018

**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.**

On December 10, 2018, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

Exhibit 99.1. Press release dated December 10, 2018

**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: December 10, 2018

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

**EXHIBIT 99.1**

# Cytokinetics Announces New Data Presented at the International Symposium on ALS/MND

**Baseline Characteristics and Demographics from FORTITUDE-ALS Similar to Other Recent Large Trials in ALS**

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) today announced that new data were presented at the 29th International Symposium on ALS/MND in Glasgow, Scotland, UK, including patient baseline characteristics and demographics from FORTITUDE-ALS, the Phase 2 clinical trial of *reldesemtiv* in patients with ALS. In addition, posters presented at the conference contained data from an analysis of the correlation between slow vital capacity (SVC) measured at home and in the clinic in FORTITUDE-ALS, additional analyses from VITALITY-ALS, the Phase 3 clinical trial of *tirasemtiv* in patients with ALS, new results from IMPACT ALS, a patient and caregiver survey conducted by The ALS Association and funded in part by Cytokinetics, and results from analyses conducted by Origent Data Sciences on the validation of machine learning models to predict ALS disease progression using data from VITALITY-ALS.

FORTITUDE-ALS, a Phase 2 clinical trial of *reldesemtiv* designed to assess the change from baseline in percent predicted SVC and other measures of skeletal muscle function after 12 weeks of treatment with *reldesemtiv* in patients with ALS, completed enrollment in November 2018. The trial enrolled 458 patients with ALS from centers in the U.S., Canada, Europe and Australia.

Baseline characteristics of patients enrolled in FORTITUDE-ALS are similar to those of other recent large clinical trials in ALS, including BENEFIT-ALS and VITALITY-ALS. Patients enrolled in FORTITUDE-ALS were on average 58.7 years of age, 60.7 percent male, 8.4 months from diagnosis, 22.9 months from their first symptom and had an average percent predicted SVC of 86.8 percent. Regarding other therapies for ALS, the majority of patients were taking only Rilutek® (*riluzole*) (259, 56.6%), while 19 (4.1%) were taking only Radicava® (*edaravone*), 94 (20.5%) were taking both *riluzole* and *edaravone*, and 86 (18.8%) were taking neither. Demographics and baseline characteristics were similar among patients who received *riluzole* alone, *edaravone* alone, received both or received neither.

“We are encouraged to see that the baseline characteristics from FORTITUDE-ALS are consistent with previous ALS trials, and are pleased to be able to share them with the ALS community,” Jeremy Shefner, M.D., Ph.D., Lead Investigator of FORTITUDE-ALS, Professor and Chair of Neurology at Barrow Neurological Institute, and Professor and Executive Chair of Neurology at the University of Arizona, Phoenix. “With enrollment now complete in this trial, we look forward to learning how *reldesemtiv* may impact slow vital capacity and other measures of skeletal muscle function to potentially complement current therapies for patients bravely battling ALS.”

**Home SVC Measurements Correlate with Clinic Measurements for Patients with ALS**

Data from an analysis comparing SVC measurements taken at home by patients enrolled in FORTITUDE-ALS and SVC measurements taken for the same patients in the clinic were presented in a poster session by Stacy Rudnicki, M.D., Senior Director, Clinical Research, Neurology at Cytokinetics. These data showed that SVC measured at home appeared highly correlated to SVC measured in the clinic. Both SVC in liters and percent predicted SVC measured at home and in the clinic were significantly correlated; the Pearson correlation coefficients were 0.94 and 0.88, respectively (n=695 and p<0.0001 for both). SVC measured at home (hSVC), however, was consistently and significantly greater than SVC measured in clinic (cSVC); the mean difference was 0.153 liters (SD=0.361; p<0.0001), translating to differences in percent predicted SVC of more than 10 percentage points. These results suggest that a significant discrepancy exists between hSVC and cSVC and suggests substituting hSVC for cSVC and decreasing the frequency of in-clinic trial visits may not be advisable. An updated analysis regarding the utility of this exploratory outcome measure will be provided when FORTITUDE-ALS is completed.

**Additional Analyses from VITALITY-ALS May Help Inform Future Clinical Trial Design**

Two poster presentations included additional analyses from VITALITY-ALS, the Phase 3 clinical trial of *tirasemtiv* in patients with ALS. Andrew Wolff, M.D., Senior Vice President and Chief Medical Officer at Cytokinetics, presented results from sub-group analyses of the impact of time from diagnosis on the efficacy of *tirasemtiv.* In patients with a time from diagnosis <6.1 months (the median time from diagnosis in the population, n=274), the change from baseline in percent predicted SVC significantly favored *tirasemtiv* vs. placebo at 24 weeks (LS mean difference; 5.04 percentage points, p=0.0253), but was not significantly different from placebo in patients with a time from diagnosis ≥6.1 months (n=287, LS mean difference; -2.23, p=0.2670), <1 year (n=451, LS mean difference; 1.82, p=0.2826), or ≥1 year (n=110, LS mean difference; -2.20, p=0.5047). Results from this subgroup analysis of VITALITY-ALS suggest better outcomes with *tirasemtiv* in ALS patients with a shorter time since disease diagnosis. Future studies in ALS may consider a shorter allowable time since ALS diagnosis (e.g., 1 year instead of 2).

Additionally, Stacy Rudnicki, M.D., Senior Director, Clinical Research, Neurology at Cytokinetics, presented results of analyses of non-invasive ventilation (NIV) prescribing practices and patient compliance during the conduct of VITALITY-ALS. Of 565 patients randomized and dosed with placebo or *tirasemtiv* in VITALITY-ALS, 195 (34.5%) were prescribed NIV during the study and 153 (78.5%) used it for ≥2 hours/24 hours. The three most commons reasons NIV was prescribed were decline in vital capacity, respiratory symptoms, and sleep-related symptoms. During the trial, 179 (31.1%) of patients had a decline in SVC below 50%, and of these patients, 122 (68.2%) were prescribed NIV; i.e., despite allowing for NIV initiation at any point following randomization in VITALITY-ALS, only two out of three patients whose SVC fell below 50% were prescribed NIV. These results may inform future ALS trial design and encourage best practices in NIV use at ALS centers.

**Survey Results Reveal ALS Patient and Caregiver Perspectives on Burden of Disease, Treatment and Clinical Trial Participation**

Amy Laverdiere, Director, New Product Planning & Business Analysis at Cytokinetics, presented new results from IMPACT ALS, a cross-sectional self-report, online survey of ALS patients and caregivers in the United States designed to gather quantitative and qualitative information regarding perspectives on burden of disease, functional outcomes, views on treatment and clinical trial participation. The survey was developed based on collaborative input from The ALS Association, regulatory and methodology experts, ALS clinical thought leaders, a person with ALS, a caregiver, and representatives from industry partners, with financial support from Biogen, Inc., Ionis Pharmaceuticals, Inc., and Cytokinetics. Preliminary results were presented in 2017 at the 28th International Symposium on ALS/MND. 1,534 people participated, including 813 persons with ALS, 74 people assisting persons with ALS and 647 caregivers responding from their own point of view. Survey results showed that within the previous two weeks, nearly every person with ALS experienced at least one symptom, including muscle-related symptoms, balance issues, speech problems and shortness of breath. Among responders who indicated which outcomes were most preferred in a new treatment, stopping the progression of disease was the most commonly chosen item (48%), and responders specifically preferred improvements in breathing/respiratory function (86%), muscle weakness (70%) and mobility (67%). A majority of persons with ALS offered participation in a clinical trial did participate (71%), and the highest ranked reason for participating was to contribute to the greater good. Among the 29% who had not participated in a trial, the

highest ranked reason was not qualifying. Among 383 caregivers, 65% rated their health as somewhat or much worse compared to before they began caring for the person with ALS, and 94% reported medium, high or maximum stress levels of the previous two weeks. These results may inform drug development in areas of greatest patient burden and highest unmet need, decision-making by the FDA and health insurers and other policy issues. A similar European survey is currently in development to characterize patient experience and inform global ALS drug development.

**Validation of Machine Learning Models to Predict ALS Disease Progression**

Dave Ennist, Chief Science Officer at Origent Data Sciences, presented results on the validation of machine learning models to predict ALS disease progression, using data from VITALITY-ALS and BENEFIT-ALS, with support from The ALS Association. The poster reported on the development of regression models for the ALSFRS-R total score and subscores (including bulbar function, fine and gross motor function & respiratory function), vital capacity in liters and percent expected vital capacity, as well as the development of time-to-event models which predict loss of speech, wheelchair use, use of feeding tube, time to 50% expected vital capacity, and survival. As the Origent models were created using the PRO-ACT database of clinical trials conducted from 1996-2010, this external validation with contemporary trials supports the application of these models to increase the efficiency of future clinical trials in ALS.

**About Cytokinetics**

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and best-in-class muscle inhibitors 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 impact 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 also collaborating with Amgen to develop AMG 594, a first-in-class cardiac troponin activator, discovered under the companies’ joint research program. Further development of AMG 594 is subject to the collaboration agreement between Amgen and Cytokinetics. Cytokinetics is collaborating with Astellas Pharma Inc. (“Astellas”) to develop *reldesemtiv*, a fast skeletal muscle troponin activator (FSTA). *Reldesemtiv* has been granted orphan drug designation by the FDA for the potential treatment of spinal muscular atrophy. *Reldesemtiv* was the subject of a positive Phase 2 clinical study in patients with spinal muscular atrophy which showed increases in measures of endurance and stamina consistent with the mechanism of action. *Reldesemtiv* is currently the subject of FORTITUDE-ALS, a Phase 2 clinical trial in patients with amyotrophic lateral sclerosis. Cytokinetics is also advancing CK-601, a next-generation FSTA into IND-enabling studies under the collaboration with Astellas. Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to specified co-development and co-commercialization rights of Cytokinetics. Cytokinetics is also developing CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations, for the potential treatment of hypertrophic cardiomyopathies. Cytokinetics continues its 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

For additional information about Cytokinetics, visit www.cytokinetics.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

**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 Cytokinetics’ and Astellas’ joint research program and the Phase 2 clinical study of *reldesemtiv* in patients with ALS and its potentially beneficial effects; the timing, enrollment and results of Cytokinetics’ and its partners clinical trials; the timing and receipt of milestone payments; and the properties and potential benefits of Cytokinetics’ 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; Astellas’ decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *reldesemtiv*; 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.

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