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 5, 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 October 5, 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 October 5, 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: October 5, 2018

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

EXHIBIT 99.1

Cytokinetics and Astellas Provide Updates Regarding Collaborative Skeletal Muscle Program

SOUTH SAN FRANCISCO, Calif., and TOKYO, Oct. 05, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK, "Cytokinetics") and Astellas Pharma Inc. (TSE: 4503, "Astellas") today provided an update for their collaborative skeletal muscle program, including clinical trial updates for *reldesemtiv* in neuromuscular and non-neuromuscular conditions. In addition to *reldesemtiv*, the companies are advancing another fast skeletal muscle troponin activator (FSTA) into Investigational New Drug (IND)-enabling studies and continuing their joint research program through 2019. Cytokinetics has been developing *reldesemtiv* as a potential treatment for people with Spinal Muscular Atrophy (SMA), Amyotrophic Lateral Sclerosis (ALS), and other debilitating neuromuscular diseases and conditions associated with skeletal muscle weakness and/or fatigue. In parallel, Astellas has been conducting non-neuromuscular clinical trials with *reldesemtiv* to investigate a potential path forward for the next generation FSTA in patients with Chronic Obstructive Pulmonary Disease (COPD) and Frailty. Cytokinetics and Astellas are also conducting joint research to discover and advance additional small molecule activators of skeletal muscle, which may be developed as drug candidates for a broad array of diseases associated with skeletal muscle weakness and fatigue.

Neuromuscular Program

Spinal Muscular Atrophy (SMA)

- In June, Cytokinetics announced data from a Phase 2 double-blind, randomized, placebo-controlled clinical study in patients with SMA which was designed to determine potential pharmacodynamic effects of a suspension formulation of *reldesemtiv* following 8 weeks of oral dosing in each of two cohorts of 36 patients with Type II, Type III, or Type IV disease. Secondary objectives were to evaluate the safety, tolerability and pharmacokinetics of *reldesemtiv*. The study showed statistically significant concentration-dependent increases in changes from baseline in Six Minute Walk Distance (6MWD), a sub-maximal exercise test of aerobic capacity and endurance. The study also showed statistically significant increases for Maximal Expiratory Pressure (MEP), a measure of strength of respiratory muscles. Other assessments, including the Hammersmith Functional Motor Score - Extended, (a functional motor scale that was assessed in the development program that led to the FDA approval of the first therapy for patients with SMA), Revised Upper Limb Module, Timed Up-and-Go, Forced Vital Capacity, and the SMA Health Index (SMA-HI), a patient reported outcome measure (PROM) developed to comply with FDA standards for PROMs, did not demonstrate differences between *reldesemtiv* versus placebo. Adverse events were similar between groups receiving *reldesemtiv* and placebo.

- Additional results presented at the 2018 Muscle Study Group Scientific Meeting in Oxford, U.K. showed sustained increases in 6MWD and MEP four weeks after discontinuation of study drug (i.e., Follow-up). The mean increase versus placebo in the change from baseline in 6MWD on 450 mg twice daily was 24.89 m after 8 weeks of treatment ($p = 0.0584$) and 30.81 m at Follow-up ($p = 0.0381$). Similarly, the mean increase versus placebo in the change from baseline in MEP on 450 mg twice daily was 13.15 cm H_2O after 8 weeks of treatment ($p = 0.0298$) and 9.47 cm H_2O at Follow-up ($p = 0.1344$).

- A post-hoc analysis also showed that changes from baseline in the 6MWD at 450 mg twice daily were significantly correlated with changes from baseline on certain domains of the SMA-HI intended to reflect improved endurance, especially Fatigue (correlation coefficient [r] = -0.90, $p = 0.01$) and Activity Participation ($r = -0.82$, $p = 0.05$). Of note, decreases in SMA-HI scores reflect reduced disease burden as measured by that PROM; therefore, the negative correlation coefficients indicate that as 6MWD increases, disease burden assessed by that domain of the SMA-HI is reduced.

- Cytokinetics recently convened an expert advisor meeting to discuss the Phase 2 clinical study of *reldesemtiv* in patients with SMA and received encouraging and constructive feedback as well as recommendations to inform potential next steps.

- Cytokinetics will be seeking a Type C regulatory interaction with the FDA this year regarding the acceptability of 6MWD as an endpoint for a potential registration program for *reldesemtiv* in patients with SMA.

Amyotrophic Lateral Sclerosis (ALS)

- Cytokinetics is conducting FORTITUDE-ALS (**F**unctional **O**utcomes in a **R**andomized **T**rial of **I**nvestigational **T**reatment with CK-2127107 to **U**nderstand **D**ecline in **E**ndpoints – in **ALS**) which is expected to enroll 445 patients with ALS and is designed to assess the change from baseline on *reldesemtiv* versus placebo in the percent predicted slow vital capacity (SVC) and other measures of skeletal muscle function after 12 weeks of treatment. Secondary endpoints include the slope of the change from baseline in the mega-score of muscle strength measured by hand held dynamometry (HHD) and handgrip dynamometry; change from baseline in the ALS Functional Rating Scale – Revised (ALSFRS-R); incidence and severity of treatment-emergent adverse events; and plasma concentrations of *reldesemtiv* at sampled time points in the trial.

- This trial has now enrolled more than 350 patients with ALS and enrollment is expected to be completed in Q4 2018 with results from the clinical trial expected in the first half of 2019.

Non-Neuromuscular Program

Chronic Obstructive Pulmonary Disease (COPD)

- Astellas recently completed a Phase 2 clinical trial designed to assess the potential effect of *reldesemtiv* compared to placebo on exercise tolerance, assessed as change from baseline in Constant Work Rate (CWR) endurance time over two weeks, in approximately 40 patients with COPD. Additionally, the trial assessed other cardiopulmonary and neuromuscular effects and resting spirometry. In addition, the safety, tolerability and pharmacokinetics of *reldesemtiv* were assessed.

- This trial of *reldesemtiv* did not meet the primary endpoint and did not demonstrate a statistically significant treatment difference in any of the secondary endpoints. Adverse events were similar between groups receiving *reldesemtiv* and placebo.

Limited Mobility/Frailty

- Astellas has been conducting a Phase 1b clinical trial designed to assess the effect of *reldesemtiv* versus placebo on skeletal muscle fatigue in approximately 60 subjects who are 70 to 89 years of age and who have limited mobility. Endpoints measured include the change from baseline versus 14 days of treatment in sum of peak torque during isokinetic knee extensions. Additionally, the trial is designed to assess the effects of *reldesemtiv* on physical performance as well as the safety, tolerability and pharmacokinetics of *reldesemtiv*.

- An interim analysis of this study was recently conducted, and the Independent Data Monitoring Committee determined that the pre-defined criteria for lack of efficacy of *reldesemtiv* had been met; Astellas has notified investigators to halt further enrollment in the trial.

Other Research & Development

As recently announced, Cytokinetics and Astellas are advancing a next-generation FSTA into IND-enabling studies, which triggers a $2 million milestone payment from Astellas to Cytokinetics. This potential drug candidate was designed to have different physicochemical properties than *reldesemtiv* and may be developed for the treatment of diseases and conditions associated with non-neuromuscular etiology and pathogenesis. The companies are also continuing their joint research program with Astellas providing sponsorship of Cytokinetics' activities through 2019.

About *Reldesemtiv*

Skeletal muscle contractility is driven by the sarcomere, the fundamental unit of skeletal muscle contraction and a highly ordered cytoskeletal structure composed of several key proteins. Skeletal muscle myosin is the motor protein that converts chemical energy into mechanical force through its interaction with actin. A set of regulatory proteins, which includes tropomyosin and several types of troponin, make the actin-myosin interaction dependent on changes in intracellular calcium levels. *Reldesemtiv*, a next-generation fast skeletal muscle troponin activator (FSTA) arising from Cytokinetics' skeletal muscle contractility program, slows the rate of calcium release from the regulatory troponin complex of fast skeletal muscle fibers, which sensitizes the sarcomere to calcium, leading to an increase in skeletal muscle contractility. *Reldesemtiv* has demonstrated pharmacological activity that may lead to new therapeutic options for diseases associated with muscle weakness and fatigue. In non-clinical models of SMA, a skeletal muscle activator has demonstrated increases in submaximal skeletal muscle force and power in response to neuronal input and delays in the onset and reductions in the degree of muscle fatigue. *Reldesemtiv* 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. Mid-stage clinical trials in patients with SMA, COPD and elderly adults with limited mobility have been completed. Cytokinetics is currently conducting a Phase 2 clinical trial in patients with amyotrophic lateral sclerosis (ALS).

About Cytokinetics and Astellas Collaboration

In 2013, Cytokinetics and Astellas formed a partnership focused on the research, development, and potential commercialization of skeletal muscle activators. The primary objective of the collaboration is to advance novel therapies for diseases and medical conditions associated with muscle impairment and weakness. Under the collaboration, Cytokinetics exclusively licensed to Astellas rights to co-develop and potentially co-commercialize *reldesemtiv* and other FSTAs in non-neuromuscular indications. In 2014, Astellas and Cytokinetics agreed to expand the collaboration to include certain neuromuscular indications, including SMA, for *reldesemtiv* and other FSTAs and to advance *reldesemtiv* into Phase 2 clinical development, initially in SMA. Under the agreement as further amended in 2016, Astellas has exclusive rights to co-develop and commercialize *reldesemtiv* and other FSTAs in non-neuromuscular indications and certain neuromuscular indications (including SMA and ALS) and other novel mechanism skeletal muscle activators in all indications, subject to certain Cytokinetics' development and commercialization rights; Cytokinetics may co-promote and conduct certain commercial activities in North America and Europe under agreed scenarios.

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 *reldesemtiv*, a next-generation 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 SMA which showed increases in measures of endurance and stamina

consistent with the mechanism of action. Cytokinetics is conducting a Phase 2 clinical trial of *reldesemtiv* in patients with amyotrophic lateral sclerosis. Astellas holds an exclusive worldwide license to develop and commercialize *reldesemtiv*. Licenses held by Amgen and Astellas are subject to Cytokinetics' specified co-development and co-commercialization rights. Cytokinetics continues its 20-year history of innovation with three new muscle biology directed compounds advancing from research to development in 2018. For additional information about Cytokinetics, visit www.cytokinetics.com.

Cytokinetics 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 SMA 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.

About Astellas Pharma Inc.

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at https://www.astellas.com/en

Astellas Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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