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 16, 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 16, 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 16, 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 16, 2018

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

EXHIBIT 99.1

Cytokinetics Unveils Expanded Development Pipeline and Provides Key Updates on Late-Stage Clinical Research Programs at R&D Day

Investigational New Drug Applications Recently Filed for Two New Cardiac Programs: Cardiac Troponin Activator and Cardiac Myosin Inhibitor Advance Toward Phase 1 Studies

Clinical Trial Design Announced for METEORIC-HF, the Second Phase 3 Trial of Omecamtiv Mecarbil

Phase 2 Clinical Trial of Reldesemtiv in Patients with ALS to Complete Enrollment by Year End; Results Expected in First Half of 2019

SOUTH SAN FRANCISCO, Calif., Oct. 16, 2018 (GLOBE NEWSWIRE) -- Cytokinetics, Incorporated (Nasdaq: CYTK) plans to present an expansion of its development pipeline with the progression of two additional cardiac muscle directed drug candidates towards first-in-human clinical trials, at an R&D Day today in New York. The first, a novel cardiac troponin activator, discovered under its joint research program with Amgen, was the subject of an Investigational New Drug Application (IND) that Amgen recently filed with the Food & Drug Administration (FDA). Cytokinetics also has recently filed an IND with the FDA for a cardiac myosin inhibitor which was discovered independently by company scientists. Both of these cardiovascular drug candidates are expected to advance into first-in-human Phase 1 studies before the end of the year.

With respect to progress of its later-stage pipeline, Cytokinetics is presenting the design of METEORIC-HF (**M**ulticenter **E**xercise **T**olerance **E**valuation of ***O****mecamtiv Mecarbil* **R**elated to **I**ncreased **C**ontractility in **H**eart **F**ailure), the second Phase 3 clinical trial of *omecamtiv mecarbil*, its novel cardiac myosin activator, which the company is working towards starting by the end of the year under its collaboration with Amgen. GALACTIC-HF (**G**lobal **A**pproach to **L**owering **A**dverse **C**ardiac Outcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure), the ongoing Phase 3 cardiovascular outcomes trial of *omecamtiv mecarbil*, continues to progress towards the goal of concluding enrollment of 8,000 patients during the first half of 2019.

The company is also providing updates on the progression of *reldesemtiv*, its fast skeletal muscle troponin activator (FSTA), in a neuromuscular development program conducted in collaboration with Astellas. The company expects to conclude enrollment in 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**), an ongoing Phase 2 trial of *reldesemtiv* in patients with ALS, by the end of the year, which should enable reporting results from that trial in the first half of 2019. Additionally, the company recently announced the advancement of CK-3762601, or CK-601, a next generation FSTA, into IND-enabling studies under the collaboration with Astellas.

“Cytokinetics is advancing five compounds in different stages of development, underscoring the breadth of our leadership in the emerging pharmacology of muscle,” said Robert I. Blum, Cytokinetics’ President and Chief Executive Officer. “Potential medicines that we are developing, both independently and in collaboration with partners, have the potential to transform the treatment of severe diseases of muscle dysfunction and weakness. We are pleased to usher in both first-in-class and potentially best-in-class approaches to some of the most devastating and costly diseases.”

“Cytokinetics pioneered the discovery of novel drug candidates that modulate sarcomere function which has translated into our broad pipeline of investigational medicines,” said Fady I. Malik, M.D., Ph.D., Cytokinetics’ Executive Vice President, Research & Development. “Leveraging our longstanding expertise in the screening, biochemistry, biophysics and structural biology of the sarcomere, coupled with extensive experience in the application of advanced chemistries, we have generated development stage, small molecule compounds that distinctively modulate proteins powering muscle contractility. Our refined understanding of muscle function informs how we preferentially optimize drug candidates for mechanistic, pharmacodynamic and pharmacokinetic properties that may translate to leading therapeutics targeting the performance of muscle.”

AMG 594: Cardiac Troponin Activator (Heart Failure)

AMG 594 is a novel, first-in-class, selective, oral, small molecule cardiac troponin activator, discovered under a joint research program with Amgen and for which Amgen recently filed an IND with the FDA. In preclinical models, AMG 594 increases myocardial contractility by binding to cardiac troponin through an allosteric mechanism that sensitizes the cardiac sarcomere to calcium, facilitating more actin-myosin cross bridge formation during each cardiac cycle thereby resulting in increased myocardial contractility. Similar to cardiac myosin activation and unlike traditional inotropic mechanisms, cardiac troponin activation does not change the calcium transient of cardiac myocytes. Cytokinetics expects that Amgen will soon initiate a Phase 1 study program to assess the safety and tolerability of AMG 594 and its potential to increase cardiac function in healthy volunteers. The companies are discussing objectives of a potential subsequent Phase 2 development program for AMG 594 that may include the evaluation of this novel mechanism of action as a potential treatment of patients with heart failure with reduced ejection fraction (HFrEF) and other types of heart failure, such as right ventricular failure or genetic cardiomyopathies, resulting from impaired cardiac contractility. Based on preclinical data, AMG 594 may offer differentiated efficacy and convenience relative to *omecamtiv mecarbil*.

CK-3773274 – (CK-274): Cardiac Myosin Inhibitor (Hypertrophic Cardiomyopathy)

CK-274 is a novel, oral, small molecule cardiac myosin inhibitor that company scientists discovered independent of its collaborations and for which Cytokinetics recently filed an IND with the FDA. CK-274 arose from an extensive next-generation chemical optimization program conducted with careful attention to therapeutic index and pharmacokinetic properties and as may

translate into best-in-class potential in clinical development. In preclinical models, CK-274 reduces myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site preventing myosin from entering a force producing state. CK-274 reduces the number of active actin-myosin cross bridges during each cardiac cycle and consequently reduces myocardial contractility as may be therapeutically effective in conditions characterized by excessive hypercontractility, such as hypertrophic cardiomyopathy (HCM). In preclinical models of cardiac function, CK-274 reduced cardiac contractility in a predictable dose and exposure dependent fashion. In preclinical models of disease, CK-274 reduced compensatory cardiac hypertrophy and cardiac fibrosis. The preclinical pharmacokinetics of CK-274 were evaluated with the objective to maximize potential ease of use in the clinic setting. Cytokinetics expects to initiate a first-in-human Phase 1 study to assess the safety and tolerability, pharmacokinetics and effect of CK-274 on cardiac function by the end of the year. A potential subsequent Phase 2 clinical study will examine its ability to reduce the left ventricular outflow tract obstruction (LVOTO) in patients with HCM. LVOTO limits cardiac output and results from excessive hypertrophy and thickening of the cardiac muscle during systole (particularly in the region of the interventricular septum). The initial development program will focus on an extensive characterization of the pharmacokinetic/pharmacodynamic relationship of CK-274 as has been a hallmark of Cytokinetics' industry-leading development programs in muscle pharmacology. The overall development program will assess the potential of CK-274 to improve exercise capacity and relieve symptoms in patients with hyperdynamic ventricular contraction due to HCM.

METEORIC-HF: Second Phase 3 Clinical Trial of *Omecamtiv Mecarbil* (Heart Failure)

METEORIC-HF is a Phase 3, randomized, placebo-controlled, double-blind, parallel group, multicenter clinical trial designed to evaluate the effect of treatment with *omecamtiv mecarbil* compared to placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET) following 20 weeks of treatment. This trial, to be conducted by Cytokinetics in collaboration with Amgen, is designed to enroll approximately 270 patients with HFrEF at sites throughout the U.S., Canada and Europe. In order to be eligible to participate in METEORIC-HF, patients should have a left ventricular ejection fraction (LVEF) ≤ 35%, be New York Heart Association (NYHA) heart failure class II or III, and have reduced exercise capacity compared to age matched controls. Patients will be randomized in a 2:1 fashion to *omecamtiv mecarbil*, which will be started at 25 mg twice daily and titrated to 25, 37.5 or 50 mg twice daily based on the same PK-guided dosing regimen as is used in GALACTIC-HF, or to placebo. The primary endpoint is the change in peak oxygen uptake (pVO_2) on CPET from baseline to Week 20. Secondary endpoints include the change in total workload during CPET from baseline to Week 20 and the change in the average daily activity units measured over a 2-week period from baseline (Week -2 to Day 1) to Week 18-20 as determined using accelerometry. Cytokinetics is working together with Amgen towards the objective of starting METEORIC-HF by the end of 2018.

At today's Cytokinetics R&D Day, a panel of cardiovascular experts including John Teerlink, M.D., Professor of Clinical Medicine at the University of California San Francisco and Director of Heart Failure at the San Francisco Veterans Affairs Medical Center, and Gregory Lewis, M.D., Section Head, Heart Failure; Medical Director, Heart Transplant Program and Director of Cardiopulmonary Exercise Testing, Massachusetts General Hospital, will discuss opportunities and perspectives for a new generation of muscle-biology directed cardiovascular therapies.

***Reldesemtiv:* Next-Generation FSTA (SMA, ALS)**

Cytokinetics recently announced data from a Phase 2 clinical study of *reldesemtiv* in patients with spinal muscular atrophy (SMA) that showed statistically significant and concentration-dependent increases from baseline in Six Minute Walk Distance (6MWD), a sub-maximal exercise test of aerobic capacity and endurance, and statistically significant increases for Maximal Expiratory Pressure (MEP), a measure of the strength of respiratory and abdominal muscles, both of which were sustained four weeks after discontinuation of study drug.

The company plans to conduct an additional Phase 1 study of *reldesemtiv* in healthy volunteers to assess higher doses than were evaluated in the Phase 2 study of patients with SMA and to evaluate exposure related proportionality and linearity. In addition, Cytokinetics will be engaging FDA in Type C interactions regarding the acceptability of 6MWD as an endpoint suitable for registration of *reldesemtiv* for the treatment of SMA. Both initiatives are intended to inform the potential progression of *reldesemtiv* towards a registration program in patients with SMA.

Additionally, Cytokinetics is providing an update on enrollment in FORTITUDE-ALS, the Phase 2 clinical trial of *reldesemtiv* in patients with ALS. This trial has now enrolled 375 patients and is expected to complete enrollment in Q4 2018 with results from FORTITUDE-ALS expected in the first half of 2019.

CK-3762601 – (CK-601): Next-Generation Fast Skeletal Muscle Troponin Activator (FSTA)

Cytokinetics recently announced the advancement of CK-601, a next-generation FSTA into IND-enabling studies under the collaboration with Astellas. This potential drug candidate was designed in a joint research program conducted by the companies' scientists to have different pharmacokinetics and physicochemical properties than *reldesemtiv* which may inform its development for the treatment of diseases and conditions associated with both neuromuscular and non-neuromuscular etiology and pathogenesis.

At today's Cytokinetics R&D Day, a panel of neuromuscular experts, including John Day, M.D., Ph.D., Professor of Neurology and Pediatrics (Genetics), Stanford University Medical Center (via video), Jacqueline Montes, PT, EdD, NCS, Assistant Professor of Clinical Rehabilitation and Regenerative Medicine, Columbia University Irving Medical Center and Jinsy Andrews, M.D., M.Sc., Assistant Professor of Neurology, Director of Neuromuscular Clinical Trials, Columbia University, will share perspectives and insights on the promise of FSTAs in neuromuscular disease.

About Cytokinetics and Amgen Collaboration

Omecamtiv mecarbil is being developed under a collaboration with Amgen. In 2006, Amgen and Cytokinetics entered into a strategic alliance to discover, develop, and commercialize novel small molecule therapeutics designed to activate the cardiac sarcomere for the potential treatment of heart failure. Initially, following Amgen's option exercise in 2009, the collaboration was worldwide, excluding Japan. The companies expanded the collaboration in 2013 to provide Amgen with worldwide rights to develop and commercialize *omecamtiv mecarbil* and related compounds subject to development and commercial participation rights of Cytokinetics. Amgen holds an exclusive, worldwide license to *omecamtiv mecarbil* and related compounds, subject to Cytokinetics' specified development and commercialization rights, including the right to co-promote *omecamtiv mecarbil* in institutional care settings in North America, with reimbursement from Amgen for certain sales force activities. A joint commercial operating team comprised of representatives of Cytokinetics and Amgen will be responsible for the day-to-day management of the commercialization program of *omecamtiv mecarbil*. Under the collaboration agreement between Amgen and Cytokinetics, Cytokinetics is eligible for pre-commercialization and commercialization milestone payments and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. Amgen has also entered an alliance with Servier for exclusive commercialization rights in Europe as well as the Commonwealth of Independent States, including Russia. Servier contributes funding for development and provides strategic support to the program. AMG 594 is an additional cardiac sarcomere activator discovered under a joint research program conducted between Amgen and Cytokinetics scientists. Its further development and commercialization is subject to the collaboration agreement between Amgen and Cytokinetics.

About Cytokinetics and Astellas Collaboration

Reldesemtiv is being developed under a collaboration with Astellas. In 2013, Cytokinetics and Astellas formed a partnership focused on the research, development, and potential commercialization of activators of the skeletal muscle sarcomere. 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. Under the collaboration agreement between Astellas and Cytokinetics, Cytokinetics is eligible for pre-commercialization and commercialization milestone payments and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. CK-601 is an additional compound discovered under a joint research program conducted between Astellas and Cytokinetics. Its further development and commercialization is subject to the collaboration agreement between Astellas and Cytokinetics.

Conference Call and Webcast Information

Interested parties may access the live webcast of this presentation by visiting the Investors & Media section of Cytokinetics' website at www.cytokinetics.com. The live audio of the conference call can also be accessed by telephone by dialing either (866) 999-CYTK (2985) (United States and Canada) or (706) 679-3078 (international) and typing in the passcode 9765799.

An archived replay of the webcast will be available via Cytokinetics' website until October 30, 2018. The replay will also be available via telephone by dialing (855) 859-2056 (United States and Canada) or (404) 537-3406 (international) and typing in the passcode 9765799 from October 16, 2018 at 2:30 PM Eastern Time until October 30, 2018.

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 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 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 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 recently filed an IND for CK-274, a novel cardiac myosin inhibitor that company scientists discovered independent of its collaborations. 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.

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; the timing of enrollment of patients in Cytokinetics' and its partners' clinical trials; the design, timing, results, significance and utility of preclinical and clinical results; 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, 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 FDA 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; Astellas' decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *reldesemtiv;* Amgen's decisions with respect to the design, initiation, conduct, timing and continuation of development activities for *omecamtiv mecarbil*; 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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