

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): June 16, 2022

Cytokinetics, Incorporated

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-50633

(Commission File Number)

94-3291317

(I.R.S. Employer Identification Number)

350 Oyster Point Boulevard, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	CYTK	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Today, June 16, 2022, Cytokinetics, Incorporated (the “Company” or “Cytokinetics”) announced the start of COURAGE-ALS OLE (Clinical Outcomes Using *Reldesemtiv* on ALSFRS-R in a Global Evaluation in ALS Open Label Extension), an open-label extension clinical study designed to assess the long-term safety and tolerability of *reldesemtiv* in people with amyotrophic lateral sclerosis (ALS). Patients will be eligible for COURAGE-ALS OLE after completing their participation in COURAGE-ALS, the Phase 3 clinical trial of *reldesemtiv*, a next-generation fast skeletal muscle troponin activator (FSTA) for the potential treatment of ALS.

COURAGE-ALS OLE: Clinical Study Design

COURAGE-ALS OLE is an open-label extension clinical study of *reldesemtiv* in people with ALS who have completed participation in COURAGE-ALS. Following enrollment in COURAGE-ALS OLE, participants will continue to receive 300 mg of *reldesemtiv* dosed orally twice daily for 48 weeks after which they may transition into the Managed Access Program. The primary endpoint is the incidence of adverse events. Secondary endpoints include the time to the first occurrence of respiratory insufficiency or death, time to the first hospitalization, combined assessment of change in ALSFRS-R total score, time to onset of respiratory insufficiency, and survival time, changes in ALSFRS-R total score, and the slope of changes in ALSFRS-R total score. Additional information on COURAGE-ALS OLE can be found at clinicaltrials.gov.

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 the troponin complex, make the actin-myosin interaction dependent on changes in intracellular calcium levels. *Reldesemtiv* is an investigational, selective, small molecule fast skeletal muscle troponin activator (FSTA) arising from Cytokinetics’ skeletal muscle contractility program. *Reldesemtiv* was designed to slow 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.

The development program for *reldesemtiv* is assessing its potential for the treatment of ALS and includes FORTITUDE-ALS and COURAGE-ALS, the ongoing Phase 3 clinical trial designed to evaluate the effect of treatment with *reldesemtiv* compared to placebo on measures of disease progression, functional outcomes and survival.

About ALS

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that afflicts approximately 27,000 people in the United States and a comparable number of patients in Europe. Approximately 6,300 new cases of ALS are diagnosed each year in the United States. The average life expectancy of a person with ALS is approximately three to five years after diagnosis and only approximately 10 percent of people with ALS survive for more than 10 years. Death is usually due to respiratory failure because of diminished strength in the skeletal muscles responsible for breathing. Few treatment options exist for these patients, resulting in a high unmet need for new therapies to address functional deficits and disease progression.

About Cytokinetics

Cytokinetics is a late-stage biopharmaceutical company focused on discovering, developing and commercializing first-in-class muscle activators and next-in-class muscle inhibitors as potential treatments for debilitating diseases in which muscle performance is compromised. 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 readying for the potential commercialization of *omecamtiv mecarbil*, its cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is also developing *aficamten*, a next-generation cardiac myosin inhibitor, currently the subject of SEQUOIA-HCM, the Phase 3 clinical trial of *aficamten* in patients with symptomatic obstructive hypertrophic cardiomyopathy (HCM). *Aficamten* is also being evaluated in non-obstructive HCM in Cohort 4 of the Phase 2 clinical trial, REDWOOD-HCM. Cytokinetics is also developing *reldesemtiv*, an investigational fast skeletal muscle troponin activator, currently the subject of COURAGE-ALS, a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS). Cytokinetics continues its over 20-year history of pioneering innovation in muscle biology and related pharmacology focused to diseases of muscle dysfunction and conditions of muscle weakness.

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 any of our other clinical trials, statements relating to the potential benefits of *omecamtiv mecarbil*, *aficamten*, or any of our other drug candidates. Cytokinetics' research and development activities; the design, timing, results, significance and utility of preclinical and clinical results; and the properties and potential benefits of Cytokinetics' other 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; Cytokinetics' drug candidates may have adverse side effects or inadequate therapeutic efficacy; the FDA or foreign regulatory agencies may delay or limit Cytokinetics' ability to conduct clinical trials; Cytokinetics may be unable to obtain or maintain patent or trade secret protection for its intellectual property; standards of care may change, rendering Cytokinetics' drug candidates obsolete; and competitive products or alternative therapies may be developed by others for the treatment of indications Cytokinetics' drug candidates and potential drug candidates may target. For further information regarding these and other risks related to Cytokinetics' business, investors should consult Cytokinetics' filings with the Securities and Exchange Commission.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CYTOKINETICS, INCORPORATED

Date: June 16, 2022

By: /s/ Ching Jaw
Ching Jaw
Senior Vice President, Chief Financial Officer