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

FORM 8-K/A

(AMENDMENT NO. 1)

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): July 19, 2021

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))

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. ☐

Explanatory Note

On July 19, 2021, Cytokinetics, Incorporated filed a Current Report on Form 8-K (the "Original Report") to report topline results from its clinical trial. This Current Report on Form 8-K/A is being filed to correct an error in the Original Report which stated that "reductions in LVOT-G occurred within two weeks of initiating treatment with CK-274, were maximized within two to six weeks of the ***end*** of dose titration, and were sustained until the end of treatment at 10 weeks." The correct statement that should have been in the Original Report is: "reductions in LVOT-G occurred within two weeks of initiating treatment with CK-274, were maximized within two to six weeks of the ***start*** of dose titration, and were sustained until the end of treatment at 10 weeks." For convenience of the reader, this filing restates the entire contents of the Original Report and replaces the erroneous statement with the correct statement.

Item 8.01. Other Events.

On July 19, 2021 Cytokinetics, Incorporated (the "Registrant" or "Cytokinetics") announced positive topline results from Cohorts 1 and 2 of REDWOOD-HCM (**R**andomized **E**valuation of **D**osing **W**ith CK-274 in **O**bstructive **O**utflow **D**isease in **HCM**), the Phase 2 clinical trial of CK-3773274 (CK-274), an investigational next-generation cardiac myosin inhibitor in development for the potential treatment of hypertrophic cardiomyopathy (HCM). The results of REDWOOD-HCM inform dose selection and support progression of CK-274 to a planned Phase 3 registrational clinical trial which is expected to start before year end.

Results from Cohorts 1 and 2 of REDWOOD-HCM demonstrated that treatment with CK-274 for 10 weeks resulted in statistically significant reductions from baseline compared to placebo in the average resting left ventricular outflow tract pressure gradient (LVOT-G) ($p=0.0003$, $p=0.0004$, Cohort 1 and Cohort 2, respectively) and the average post-Valsalva LVOT-G ($p=0.001$, $p<0.0001$, Cohort 1 and Cohort 2, respectively). The majority of patients treated with CK-274 (78.6% in Cohort 1 and 92.9% in Cohort 2) achieved the target goal of treatment, defined as resting gradient <30 mmHg and post-Valsalva gradient <50 mmHg at Week 10 compared to placebo (7.7%). Reductions in LVOT-G occurred within two weeks of initiating treatment with CK-274, were maximized within two to six weeks of the start of dose titration, and were sustained until the start of treatment at 10 weeks. The observed reductions in LVOT-G were dose dependent, with patients achieving greater reductions of LVOT-G with increasing doses of CK-274.

Treatment with CK-274 in REDWOOD-HCM was generally well tolerated. The incidence of adverse events was similar between treatment arms. No serious adverse events were attributed to CK-274 and no treatment interruptions occurred on CK-274. No new cases of atrial fibrillation in patients treated with CK-274 were reported. In this dose-range finding trial, one patient experienced a transient decrease in left ventricular ejection fraction (LVEF) that required dose adjustment but not dose interruption. LVEF returned to baseline within two weeks after the end of treatment in both cohorts, which was consistent with the reversibility of LVEF decreases that were similarly observed in healthy participants in the Phase 1 study of CK-274.

REDWOOD-HCM: Clinical Trial Design

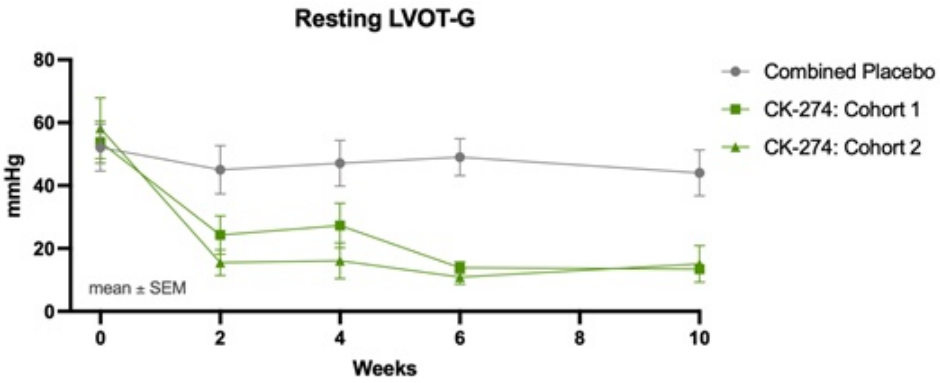
REDWOOD-HCM is a multi-center, randomized, placebo-controlled, double-blind, dose finding clinical trial of CK-274 in patients with symptomatic obstructive HCM (oHCM) on background medical therapy. The primary objective of the trial is to determine the safety and tolerability of CK-274. The secondary objectives are to describe the concentration-response relationship of CK-274 on the resting and post-Valsalva left ventricular outflow tract gradient as measured by echocardiography during 10 weeks of treatment, to describe the dose response relationship of CK-274, and to evaluate the plasma concentrations of CK-274 in patients with oHCM. Seventeen investigative sites in North America and Europe screened for patients to enroll in Cohort 1 and 2 of REDWOOD-HCM.

Topline results from REDWOOD-HCM include data from two sequentially conducted cohorts, Cohort 1 (n=21) and Cohort 2 (n=20) which randomized treatment of patients 2:1 to CK-274 or placebo. Patients received up to three escalating doses of CK-274 once daily (5, 10, 15 mg in Cohort 1 and 10, 20, 30 mg in Cohort 2) or placebo. Patients had an echocardiogram after two weeks of treatment at each dose to determine potential up-titration to the next higher dose. Overall, treatment duration for each patient in REDWOOD-HCM was 10 weeks with an echocardiogram conducted 2 weeks after the last dose.

REDWOOD-HCM: Topline Results

For patients on CK-274 in Cohort 1 (n=14), the average resting LVOT-G changed from 53.8 mmHg at baseline to 13.4 mmHg at 10 weeks; for patients on CK-274 in Cohort 2 (n=14) the average resting LVOT-G changed from 58.2 mmHg at baseline to 15.1 mmHg at 10 weeks; and for patients in the combined placebo group (n=13) the average resting LVOT-G changed from 52.1 at baseline to 44.0 mmHg at 10 weeks (Figure 1, p=0.0003 for Cohort 1, p=0.0004 for Cohort 2 in comparison to placebo at 10 weeks).

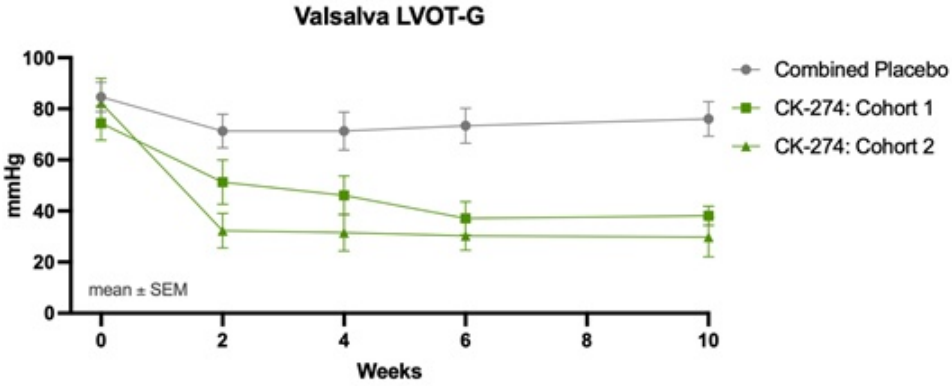
Figure 1



Mean ± SEM	Resting LVOT-G (mmHg)				
	Baseline	Week 2	Week 4	Week 6	Week 10
Placebo (n=13)	52.1	45.0	47.1	49.0	44.0
Cohort 1 (n = 14)	53.8	24.3	27.3	13.9	13.4
p-value vs placebo	-	0.007	0.025	<0.0001	0.0003
Cohort 2 (n = 14)	58.2	15.5	16.1	10.9	15.1
p-value vs placebo	-	0.0002	0.0006	<0.0001	0.0004

For patients on CK-274 in Cohort 1 (n=14) the average Valsalva LVOT-G changed from 74.4 mmHg at baseline to 38.1 mmHg at 10 weeks; for patients on CK-274 in Cohort 2 (n=14) the average Valsalva LVOT-G changed from 82.3 mmHg at baseline to 29.8 mmHg at 10 weeks; and for patients in the combined placebo group (n=13) the average Valsalva LVOT-G changed from 84.6 at baseline to 76.0 mmHg at 10 weeks (Figure 2; p=0.001 for Cohort 1, p<0.0001 for Cohort 2 in comparison to placebo at 10 weeks).

Figure 2



Mean ± SEM	Valsalva LVOT-G (mmHg)				
	Baseline	Week 2	Week 4	Week 6	Week 10
Placebo (n=13)	84.6	71.3	71.3	73.4	76
Cohort 1 (n = 14)	74.4	51.3	46.1	37.1	38.1
p-value vs placebo	-	0.097	0.038	0.0003	0.001
Cohort 2 (n = 14)	82.3	32.3	31.5	30.3	29.8
p-value vs placebo	-	0.0005	0.0005	<0.0001	<0.0001

The average ejection fraction for patients on CK-274 in Cohort 1 (n=14) changed from 73.2% at baseline to 67.4% at 10 weeks; for patients on CK-274 in Cohort 2 (n=14) the average ejection fraction changed from 75.4% at baseline to 64.1% at 10 weeks, and for patients in the combined placebo group (n=13) the average ejection fraction changed from 74.5% at baseline to 74.9% at 10 weeks (p=0.007 for Cohort 1, p=<0.0001 for Cohort 2 in comparison to placebo at 10 weeks).

Overall, the incidence of adverse events was similar between treatment arms. Treatment with CK-274 in REDWOOD-HCM was generally well tolerated in patients being treated with current standard of care with adverse events reported as mild or moderate in severity. There were no treatment related serious adverse events reported by investigators.

No patients who received CK-274 in Cohort 1 had an LVEF <50%. In Cohort 2, one patient with an LVEF at baseline of 58% was up-titrated to 20 mg of CK-274 and experienced transient LVEF reduction to <50% (remaining above 40%) requiring down titration. No interruptions or discontinuations of treatment with CK-274 occurred in any patients across both cohorts.

The distribution (Table 1) of patients across doses of CK-274 in REDWOOD-HCM informs dose selection for the planned Phase 3 trial with the objective to assess clinical outcomes at the lowest effective individualized dose of CK-274.

Table 1

		Final Dose Achieved (N)					
		Cohort 1			Cohort 2		
	Placebo	5 mg	10 mg	15 mg	10 mg	20 mg	30 mg
Cohort 1+2 (N=41)	13	4	5	5	9	4	1

Results of REDWOOD-HCM will be submitted to a future medical conference and for publication.

Conference Call and Webcast Information

Members of Cytokinetics' senior management team will host a conference call and webcast today at 8:30 AM Eastern Time. The webcast can be accessed through the Investors & Media section of the 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 2984784.

An archived replay of the webcast will be available via Cytokinetics' website until August 2, 2021. 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 2984784 from July 19, 2021 at 11:30 AM Eastern Time until August 2, 2021.

About CK-274

CK-274 is a novel, oral, small molecule cardiac myosin inhibitor that company scientists discovered independent of its collaborations. CK-274 arose from an extensive chemical optimization program conducted with careful attention to therapeutic index and pharmacokinetic properties that may translate into next-in-class potential in clinical development. CK-274 was designed to reduce the hypercontractility that is associated with hypertrophic cardiomyopathy (HCM). In preclinical models, CK-274 reduced myocardial contractility by binding directly to cardiac myosin at a distinct and selective allosteric binding site, thereby preventing myosin from entering a force producing state. CK-274 is designed to reduce the number of active actin-myosin cross bridges during each cardiac cycle and consequently reduce myocardial contractility. This mechanism of action may be therapeutically effective in conditions characterized by excessive hypercontractility, such as HCM.

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.

About Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a disease in which the heart muscle (myocardium) becomes abnormally thick (hypertrophied). The thickening of cardiac muscle leads to the inside of the left ventricle becoming smaller and stiffer, and thus the ventricle becomes less able to relax and fill with blood. This ultimately limits the heart’s pumping function, resulting in symptoms including chest pain, dizziness, shortness of breath, or fainting during physical activity. A subset of patients with HCM are at high risk of progressive disease which can lead to atrial fibrillation, stroke and death due to arrhythmias. There are no FDA approved medical treatments that directly address the hypercontractility that underlies HCM.

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 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 preparing a U.S. NDA submission of *omecamtiv mecarbil*, its novel cardiac muscle activator, following positive results from GALACTIC-HF, a large, international Phase 3 clinical trial in patients with heart failure. Cytokinetics is conducting METEORIC-HF, a second Phase 3 clinical trial of *omecamtiv mecarbil*. Cytokinetics is also developing CK-274, a next-generation cardiac myosin inhibitor, for the potential treatment of hypertrophic cardiomyopathies (HCM). The company has announced positive topline results from Cohorts 1 and 2 in REDWOOD-HCM, a Phase 2 clinical trial of CK-274 in patients with obstructive HCM. Cytokinetics expects to start a Phase 3 clinical trial of CK-274 in patients with obstructive HCM by year end. Cytokinetics is also developing *reldesemtiv*, a fast skeletal muscle troponin activator for the potential treatment of ALS following conduct of FORTITUDE-ALS and other Phase 2 clinical trials. The company is advancing *reldesemtiv* to a Phase 3 clinical trial called COURAGE-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 the timing and design of Cytokinetics’ Phase 3 clinical trial of CK-274; the potential benefits of CK-274; Cytokinetics’ research and development activities; 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’ 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; 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, particularly under the caption “Risk Factors” in Cytokinetics’ latest Quarterly Report on Form 10-Q.

SIGNATURE

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

CYTOKINETICS, INCORPORATED

Date: July 19, 2021

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