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): May 08, 2024

Cytokinetics, Incorporated

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-50633**	**94-3291317**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
350 Oyster Point Boulevard South San Francisco, California		**94080**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 624-3000

N/A
(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, $0.001 par value	CYTK	The Nasdaq Global Select Market

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.

On May 8, 2024, Cytokinetics, Incorporated (the "Company") announced that CEDAR-HCM (**C**linical **E**valuation of **D**osing with ***A**ficamten* to **R**educe Obstruction in a Pediatric Population in **HCM)**, a clinical trial of *aficamten* in a pediatric population with symptomatic obstructive hypertrophic cardiomyopathy (HCM), is open to enrollment. *Aficamten* is a next-in-class cardiac myosin inhibitor in development for the potential treatment of HCM.

CEDAR-HCM: Clinical Trial Design

CEDAR-HCM is a multi-center, randomized, double-blind, placebo-controlled and open-label extension clinical trial to evaluate the efficacy, pharmacokinetics (PK) and safety of *aficamten* in a pediatric population with symptomatic obstructive HCM. The primary endpoint is the change in Valsalva left ventricular outflow tract gradient (LVOT-G) from baseline to Week 12. Secondary endpoints include the change from baseline to Week 12 in resting LVOT-G, New York Heart Association (NYHA) Functional Class, pharmacokinetics and cardiac biomarkers including NT-proBNP and hs-cTnI.

CEDAR-HCM is expected to enroll two cohorts, beginning with an initial cohort of approximately 40 adolescent patients aged 12 to 17. Adolescent patients enrolled in CEDAR-HCM must have LVEF ≥ 60%, Valsalva LVOT-G ≥ 50 mmHg and NYHA Functional Class ≥ II. Patients will be randomized on a 2:1 basis to receive *aficamten* or placebo, and those receiving *aficamten* will begin with 5 mg dosed once daily. At weeks 2, 4 and 6 patients will receive an echocardiogram to determine if they will be up-titrated to escalating doses of 10, 15 or 20 mg. Dose escalation will occur only if a patient has a Valsalva LVOT-G ≥ 30 mmHg and an LVEF ≥ 55%. Safety, efficacy and PK data obtained from at least 20 adolescent patients who have completed 12 weeks of double-blind treatment will support the decision to open enrollment in a second cohort of approximately 8 to 10 younger patients (aged 6 to 11). The protocol will be amended to include eligibility criteria and dose selection for the younger pediatric cohort. After 12 weeks of double-blind treatment, eligible patients will rollover into the open label extension period of CEDAR-HCM. Additional information can be found on www.clinicaltrials.gov.

About *Aficamten*

Aficamten is an investigational selective, small molecule cardiac myosin inhibitor discovered following an extensive chemical optimization program that was conducted with careful attention to therapeutic index and pharmacokinetic properties and as may translate into next-in-class potential in clinical development. *Aficamten* was designed to reduce the number of active actin-myosin cross bridges during each cardiac cycle and consequently suppress the myocardial hypercontractility that is associated with hypertrophic cardiomyopathy (HCM). In preclinical models, *aficamten* 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.

Forward-Looking Statements

This filing 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 express or implied relating to the properties or potential benefits of *aficamten* or any of our other drug candidates and our ability to fully enroll CEDAR-HCM. 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 the risks related to Cytokinetics’ business outlines in Cytokinetics’ filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and Cytokinetics’ actual results of operations, financial condition and liquidity, and the development of the industry in which it operates, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that Cytokinetics makes in this press release speak only as of the date of this press release. Cytokinetics assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

SIGNATURES

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: May 8, 2024

By: /s/ John O. Faurescu

John O. Faurescu, Esq., Associate General Counsel & Secretary