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 topline data from the Phase 1 study of CK-4021586 (CK-586). The study met its primary and secondary objectives to assess the safety, tolerability and pharmacokinetics (PK) of single and multiple oral doses of CK-586. The data support the advancement of CK-586 to a Phase 2 clinical trial in patients with heart failure with preserved ejection fraction (HFpEF) which is expected to begin in Q4 2024. CK-586 is a cardiac myosin inhibitor in development for the potential treatment of a subgroup of patients with HFpEF.

Phase 1 Design and Key Findings

The primary objective of this Phase 1 double-blind randomized, placebo-controlled, multi-part single and multiple ascending dose clinical study was to evaluate the safety, tolerability and PK of CK-586 when administered orally as single or multiple doses to healthy participants. The study design included seven single ascending dose cohorts (10 mg to 600 mg) comprised of 10 participants each, and two multiple-dose ascending cohorts (100 and 200 mg once daily) comprised of 10 participants each. The study met the primary objective, demonstrating that CK-586 was safe and well tolerated in healthy participants with linear PK. Pharmacodynamics were evaluated using echocardiography and consistent with expectations. No serious adverse events were observed, and the stopping criteria were not met in the study.

About CK-4021586 (CK-586)

CK-4021586 (CK-586) is a novel, selective, oral, small molecule cardiac myosin inhibitor designed to reduce the hypercontractility associated with heart failure with preserved ejection fraction (HFpEF). In preclinical models, CK-586 reduced cardiac hypercontractility by decreasing the number of active myosin cross-bridges during cardiac contraction thereby reducing the contractile force, without effect on calcium transients. In some patients, HFpEF is a condition that resembles non-obstructive hypertrophic cardiomyopathy (HCM) in that the patients have higher ejection fractions, thickened walls of their heart, elevated biomarkers, and symptoms of heart failure. In a Phase 2 clinical trial in patients with non-obstructive HCM, *aficamten*, a cardiac myosin inhibitor also developed by the Company, was well tolerated, improved patient reported outcomes (Kansas City Cardiomyopathy Questionnaire (KCCQ) and New York Heart Association (NYHA) Functional Class) and biomarkers, measures that are also relevant to HFpEF, lending support for this mechanism of action in HFpEF.

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 potential benefits of CK-586 for patients with heart failure with preserved ejection fraction (HFpEF) and our ability to commence a Phase 2 clinical trial of CK-586 in the fourth quarter of 2024, if ever. 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.

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 08, 2024

By: /s/ John O. Faurescu

John O. Faurescu, Associate General Counsel & Secretary