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): April 05, 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 April 5, 2024, Cytokinetics, Incorporated (the "Company" or the "Registrant") announced additional 48-week data from FOREST-HCM (**F**ollow-up, **O**pen-Label, **R**esearch **E**valuation of **S**ustained **T**reatment with *Aficamten* in **HCM**), the open label extension clinical study of *aficamten* in patients with hypertrophic cardiomyopathy (HCM), at the 73rd Annual American College of Cardiology (ACC) Scientific Session taking place from April 6, 2024 –April 8, 2024 in Atlanta, GA.

FOREST-HCM enrolled 213 patients with obstructive HCM from May 28, 2021 through October 31, 2023. Previously presented data from 17 patients who had been enrolled through 48 weeks in FOREST-HCM showed that prolonged treatment with *aficamten* was associated with significant and sustained reductions in left ventricle outflow tract gradient (LVOT-G), and improvements in symptoms and cardiac biomarkers. The updated data set presented at ACC in Atlanta focuses on 46 patients from FOREST-HCM that had completed 48 weeks of follow-up at the time of the current interim analysis.

At Week 48, 75% of these patients were receiving the 15 mg or 20 mg dose of *aficamten*. Treatment with *aficamten* for 48 weeks resulted in substantial and sustained reductions in average resting LVOT-G (mean change from baseline (SD) = -39.6 mmHg (34), $p<0.0001$) and Valsalva LVOT-G (mean change from baseline (SD) = -53.2 mmHg (38.6), $p<0.0001$). Statistically significant improvements in New York Heart Association (NYHA) Functional Class from baseline were observed, with 82.2% of patients improving by ≥1 NYHA class with no instances of worsening NYHA class. Additionally, there were significant improvements in NT-proBNP, a biomarker of cardiac wall stress, with an average decrease of 63% from baseline to week 48 ($p<0.001$). Treatment with *aficamten* also resulted in statistically significant improvements in measures of cardiac structure and function including decreases in maximum wall thickness (mean change from baseline (SE) = -0.12 cm (0.02), $p<0.0001$), left atrial volume index (mean changes from baseline (SE) = -3.5 mL/m^2 (0.98), $p=0.0008$) and lateral E/e' (mean change from baseline (SE) = -2.2 (0.92), $p=0.02$). While 19 of these 46 patients in FOREST-HCM met guideline eligibility criteria for septal reduction therapy (SRT) at baseline, only one patient remained eligible for SRT after six months of treatment with *aficamten,* representing a 94% reduction in SRT-eligibility.

In FOREST-HCM, *aficamten* appears to be well-tolerated, with no treatment-related serious adverse events (SAEs). There was a modest reduction in left ventricular ejection fraction (LVEF) from baseline to Week 48 (mean change from baseline (SD) = -5.1 mg (5.9), $p<0.0001$). As has been previously reported, three patients underwent dose down-titration due to LVEF <50%. Two patients were asymptomatic, and one dose down-titration occurred due to recurrent alcohol-induced atrial fibrillation.

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 express or implied relating to the properties or potential benefits of *aficamten* or any of our other drug candidates and our ability to obtain regulatory approval for *aficamten* for the treatment of obstructive hypertrophic cardiomyopathy or any other indication from FDA or any other regulatory body in the United States or abroad. 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: April 5, 2024

By: /s/ John O. Faurescu

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