UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PLAINTIFF, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. CYTOKINETICS, INCORPORATED and ROBERT I. BLUM, Defendants.	Civil Action No.: **CLASS ACTION** **COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

Plaintiff, individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, inter alia: (a) review and analysis of relevant filings made by Cytokinetics, Incorporated ("Cytokinetics" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Cytokinetics' public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Cytokinetics common stock between December 27, 2023 and May 6, 2025, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Throughout the Class Period, Defendants made materially false and misleading statements regarding the timeline for the New Drug Application ("NDA") submission and approval process for aficamten. Specifically, Defendants represented that the Company expected approval from the U.S. Food and Drug Administration ("FDA") for its NDA for aficamten in the second half of 2025, based on a September 26, 2025 PDUFA date, and failed to disclose material risks related to the Company's failure to submit a Risk Evaluation and Mitigation Strategy ("REMS") that could delay the regulatory process.

3. These misrepresentations began on December 27, 2023, when Cytokinetics announced positive topline results from the SEQUOIA-HCM Phase 3 clinical trial of aficamten, which formed the basis of the NDA submission. Defendants repeatedly affirmed the Company's

progress toward regulatory submissions and commercial readiness, including statements in press releases, earnings calls, and investor presentations, while concealing the FDA's potential requirement for a Risk Evaluation and Mitigation Strategy program due to aficamten's intrinsic properties.

4. The truth began to emerge on March 10, 2025, when Cytokinetics disclosed in a Form 8-K filed with the SEC that the FDA had decided not to convene an advisory committee meeting to review the Company's NDA for aficamten. Then, on May 1, 2025, Cytokinetics announced that the FDA had extended the Prescription Drug User Fee Act ("PDUFA") action date for aficamten's NDA from September 26, 2025 to December 26, 2025 to review a REMS submitted at the FDA's request after the initial NDA filing. This disclosure revealed that Defendants had not included a REMS in the original NDA, despite prior discussions with the FDA about safety and risk mitigation, and that the subsequent REMS submission constituted a major amendment, necessitating a three-month extension.

5. Then, on May 6, 2025, during an earnings call, CEO Robert I. Blum provided additional details, admitting that the Company had multiple pre-NDA meetings with the FDA discussing safety monitoring and risk mitigation but chose to submit the NDA without a REMS, relying on labeling and voluntary education materials. This confirmed Defendants' awareness of potential REMS requirements and their reckless decision to omit it from the initial submission, misleading investors about the regulatory timeline.

6. As a result of Defendants' false and misleading statements, Plaintiff and other Class members purchased Cytokinetics' common stock at artificially inflated prices and suffered significant losses when the truth was revealed. The Defendants' conduct violated the federal securities laws, and Plaintiff seeks to recover damages on behalf of the Class.

JURISDICTION AND VENUE

7. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

8. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

10. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Cytokinetics is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

11. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

12. Plaintiff purchased Cytokinetics common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Cytokinetics is attached hereto.

13. Cytokinetics Corporation is a Delaware corporation with its principal executive offices located at 350 Oyster Point Boulevard, South San Francisco, CA 94080. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "CYTK."

14. Defendant Robert I. Blum ("Blum") was, at all relevant times, the Chief Executive Officer, President, and Direct of Cytokinetics.

15. Defendant Blum is sometimes referred to herein as the "Individual Defendant." Cytokinetics together with the Individual Defendant are referred to herein as the "Defendants."

16. The Individual Defendant, because of his position with the Company, possessed the power and authority to control the contents of Cytokinetics' reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional

investors, *i.e.*, the market. The Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his position and access to material non-public information available to him, the Individual Defendant knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendant is liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the actions of the Individual Defendant.

17. Cytokinetics is liable for the acts of the Individual Defendant, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful act complained of herein were carried out within the scope of their employment with authorization.

18. The scienter of the Individual Defendant, and other employees and agents of the Company are similarly imputed to Cytokinetics under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

19. Cytokinetics is a 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. The Company's research and development efforts are directed toward addressing serious unmet medical needs in cardiovascular and neuromuscular diseases.

20. Cytokinetics' lead drug candidate, aficamten, is a cardiac myosin inhibitor designed to treat obstructive hypertrophic cardiomyopathy ("oHCM"), a condition where the heart muscle thickens, leading to obstructed blood flow and symptoms such as shortness of breath, chest pain, and fatigue. Aficamten aims to reduce cardiac muscle contractility, thereby improving blood flow and alleviating symptoms.

21. The development of aficamten has been a cornerstone of Cytokinetics' strategy to establish a specialty cardiology franchise. The Company has conducted multiple clinical trials, including the SEQUOIA-HCM Phase 3 trial, to evaluate aficamten's safety and efficacy in patients with oHCM.

The Defendants Materially Misled Investors Concerning Cytokinetics' Timeline for the NDA Submission and Approval Process for Aficamten

December 27, 2023

22. On December 27, 2023, Cytokinetics issued a press release announcing positive topline results from SEQUOIA-HCM (Safety, Efficacy, and Quantitative Understanding of Obstruction Impact of Aficamten in HCM), the pivotal Phase 3 clinical trial of aficamten in patients with symptomatic obstructive hypertrophic cardiomyopathy ("HCM"). In particular, the press release detailed the results as follows:

> The results of SEQUOIA-HCM show that treatment with aficamten significantly improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO2) measured by cardiopulmonary exercise testing ("CPET") by a least square mean difference (95% CI) of 1.74 (1.04 - 2.44) mL/kg/min (p=0.000002). The treatment effect with aficamten was consistent across all prespecified subgroups reflective of patient baseline characteristics and treatment strategies, including patients receiving or not receiving background beta-blocker therapy.
>
> Statistically significant (p<0.0001) and clinically meaningful improvements were also observed in all 10 prespecified secondary endpoints, including Kansas City Cardiomyopathy Questionnaire Clinical Summary Score ("KCCQ-CSS") at weeks 12 and 24, the proportion of patients with ≥1 class improvement in New York Heart Association ("NYHA") functional class at weeks 12 and 24, change in provoked left ventricular outflow tract gradient ("LVOT-G") and proportion <30 mmHg at weeks 12 and 24, as well as exercise workload and guideline-eligibility for septal reduction therapy.
>
> Aficamten was well-tolerated in SEQUOIA-HCM with an adverse event profile comparable to placebo. Treatment emergent serious adverse events occurred in 8 (5.6%) and 13 (9.3%) patients on aficamten and placebo, respectively. Core echocardiographic left ventricular ejection fraction ("LVEF") was observed to be <50% in 5 patients (3.5%) on aficamten compared to 1 patient (0.7%) on placebo. There were no instances of worsening heart failure or treatment interruptions due to low LVEF.

February 27, 2024

23. On February 27, 2024, Cytokinetics published fourth quarter 2023 financial results and recent highlights. As part of the press release, CEO Blum stated, in relevant part:

> We ended 2023 strong with positive results from SEQUOIA-HCM which now propel our company forward to the next stages of planning towards our specialty cardiology business model. As we prepare regulatory submissions for aficamten, we are executing on commercial readiness activities while also conducting Phase 3 clinical trials in patients with oHCM and nHCM which we believe may further generate evidence in support of our next-in-class objectives to reach a broader array of patients struggling with hypertrophic cardiomyopathy. With a strong balance sheet enabling ample cash runway and multiple levers to access capital, we are pleased to be turning the page onto the next chapter for Cytokinetics and all stakeholders.

24. Also as part of the press release, Cytokinetics detailed the aficamten cardiac muscle program and corporate milestones, in pertinent part:

> ***aficamten*** (cardiac myosin inhibitor)
>
> •Announced positive results from SEQUOIA-HCM (Safety, Efficacy, and Quantitative Understanding of Obstruction Impact of Aficamten in HCM) in December demonstrating that treatment with aficamten significantly improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO2) measured by cardiopulmonary exercise testing (CPET) by a least square mean difference (95% CI) of 1.74 (1.04 - 2.44) mL/kg/min ($p=0.000002$). Statistically significant ($p<0.0001$) and clinically meaningful improvements were also observed in all 10 prespecified secondary endpoints. Aficamten was well-tolerated with an adverse event profile comparable to placebo. There were no instances of worsening heart failure or treatment interruptions due to low left ventricular ejection fraction (LVEF).
>
> * * *
>
> •Convened meetings in February with the U.S. Food & Drug Administration (FDA) to discuss the topline results of SEQUOIA-HCM and prepare for the New Drug Application (NDA) submission.
>
> •Engaged in commercial readiness activities for aficamten including market research with hypertrophic cardiomyopathy (HCM) patients and customer account profiling, and held initial conversations with specialty pharmacies and patient hub providers.

•Advanced profiling of HCM treatment programs, began development of payor clinical value proposition and continued support of medical education activities at medical conferences.

* * *

•Published manuscript entitled "Exercise Capacity in Patients with Obstructive Hypertrophic Cardiomyopathy: SEQUOIA-HCM Baseline Characteristics and Study Design" in the Journal of the American College of Cardiology: Heart Failure.

* * *

aficamten (cardiac myosin inhibitor)

•Expect to present primary results from SEQUOIA-HCM at a medical conference in Q2 2024.

•Expect to submit a New Drug Application (NDA) to the FDA in Q3 2024 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in Q4 2024.

•Complete enrollment of MAPLE-HCM in Q3 2024.

•Continue enrollment of ACACIA-HCM in 2024.

•Continue advancing go-to-market strategies for *aficamten.*

May 8, 2024

25. On May 8, 2024, Cytokinetics issued a press release reporting the Company's first quarter 2024 financial results and recent highlights. As part of the press release, Cytokinetics published updates on aficamten, in relevant part:

> Primary Results and Two Additional Analyses from SEQUOIA-HCM to be Presented in a Late-Breaking Clinical Trial Session at the European Society of Cardiology Heart Failure 2024 Congress.

May 13, 2024

26. On May 13, 2024, Cytokinetics published a press release announcing primary results from SEQUOIA-HCM, in pertinent part:

> SEQUOIA-HCM enrolled 282 patients with obstructive HCM. The baseline characteristics of patients in SEQUOIA-HCM were well-matched between treatment groups and consistent with a symptomatic patient

population that had high resting and post-Valsalva gradients (mean [SD]; 55.1 [29.6] and 83.1 [32.3] mmHg, respectively) reflective of substantial burden of disease. Background therapies consisted of beta-blockers (61.3%), calcium channel blockers (28.7%), and disopyramide (12.8%), with combination background therapies permitted.

The results from SEQUOIA-HCM showed that treatment with aficamten for 24 weeks significantly improved exercise capacity compared to placebo, increasing peak oxygen uptake (pVO_2) measured by cardiopulmonary exercise testing (CPET) by 1.8 ml/kg/min compared to baseline in patients treated with aficamten versus 0.0 ml/kg/min in patients treated with placebo (least square mean (LSM) difference [95% CI] of 1.74 mL/kg/min [1.04 - 2.44]; p=0.000002) (Figure 1).

* * *

Statistically significant improvements were observed in all 10 prespecified secondary endpoints, with functional and symptomatic improvements occurring within two weeks of initiating treatment with aficamten and sustained throughout the treatment period. Compared to baseline, at Week 24 patients treated with *aficamten* experienced significant improvements in post-Valsalva left ventricular outflow tract gradient (LVOT-G) with an LSM difference of -50 mmHg ($p<0.0001$) versus placebo. *Aficamten* also substantially reduced the burden of symptoms compared with placebo, with a significant improvement observed in Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) (LSM difference = 7 points; $p<0.0001$) and with 34% of patients experiencing ≥1 class improvement in New York Heart Association (NYHA) Functional Class ($p<0.0001$) (Figure 3). Treatment with *aficamten* substantially reduced the proportion of patients eligible for septal reduction therapy (SRT). Among those eligible for SRT at baseline, over the duration of 24 weeks of treatment, patients receiving *aficamten* spent 78 fewer days eligible for SRT compared with those treated with placebo ($p<0.0001$). Additionally, from baseline to Week 24, treatment with *aficamten* reduced NT-proBNP, a biomarker of cardiac wall stress, by 80% relative to placebo (Figure 4).

* * *

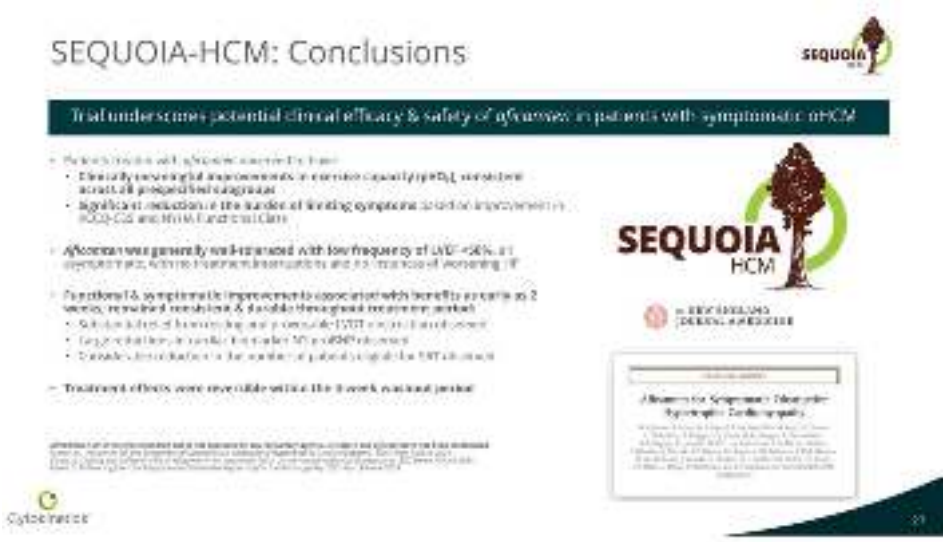
Aficamten was well-tolerated in SEQUOIA-HCM with an adverse event profile comparable to placebo. Treatment emergent serious adverse events occurred in 5.6% and 9.3% of patients on aficamten and placebo, respectively. Core echocardiographic left ventricular ejection fraction (LVEF) was observed to be <50% in 5 patients (3.5%) on *aficamten* compared to 1 patient (0.7%) on placebo. One of the 5 patients on *aficamten* with low LVEF had LVEF <40% following infection with COVID-19 but did not interrupt treatment as the site-read LVEF remained greater than 40% and the patient did not have symptoms of heart failure

due to systolic dysfunction. Overall, there were no instances of worsening heart failure or treatment interruptions due to low LVEF.

(Emphasis added).

May 22, 2024

27. On May 22, 2024, Cytokinetics published an investor presentation detailing the conclusions from SEQUOIA-HCM phase 3 trial and regulatory submissions, in relevant part:



August 8, 2024

28. On August 8, 2024, Cytokinetics issued a press release reporting second quarter 2024 financial results. As part of the press release, Cytokinetics detailed the Company's NDA submission for aficamten, in pertinent part:

> Participated in a Type B meeting with the U.S. Food and Drug Administration (FDA) to discuss potential strategies related to safety monitoring and risk mitigation for *aficamten* and included a review of how results from SEQUOIA-HCM and intrinsic properties of *aficamten* may inform risk mitigation. The Company expects to propose a distinct risk mitigation approach specific to *aficamten* with the New Drug Application (NDA) for which the rolling submission is underway. The Company is on track to complete the rolling NDA submission for *aficamten* in Q3 2024.

December 2, 2024

29. On December 2, 2024, Cytokinetics issued a press release announcing that the U.S. Food & Drug Administration (FDA) accepted the Company's New Drug Application (NDA) for aficamten, a next-in-class cardiac myosin inhibitor, for the treatment of obstructive hypertrophic cardiomyopathy (HCM). Particularly, the press release detailed that the FDA assigned the NDA a standard review with a Prescription Drug User Fee Act (PDUFA) target action date of September 26, 2025 and that the FDA was not currently planning to hold an advisory committee meeting to discuss the application. As part of the press release, CEO Robert Blum issued a statement detailing the NDA acceptance, in pertinent part:

> The NDA acceptance for aficamten by FDA is a significant milestone that moves our company another step closer to hopefully translating our pioneering science to the potential benefit of patients suffering from obstructive HCM. The results from SEQUOIA-HCM, the pivotal Phase 3 clinical trial, which form the foundation of the NDA, demonstrated that aficamten has a positive impact on exercise capacity, clinical outcomes, symptom burden and cardiac biomarkers in patients with HCM, with a consistent effect across all prespecified subgroups and a favorable safety and tolerability profile. If approved by FDA, we believe aficamten may expand utilization of cardiac myosin inhibitors and become the preferred choice amongst physicians and patients while also anchoring our emerging specialty cardiology franchise arising from Cytokinetics' industry-leading muscle biology directed research.

February 27, 2025

30. On February 27, 2025, Cytokinetics issued a press release reporting fourth quarter 2024 financial results and business updates. As part of the press release, CEO Blum issued a statement regarding the Company's progress related to aficamten, in pertinent part:

> The fourth quarter of 2024 capped off a momentous year for Cytokinetics with progress and achievements across our business. With regulatory submissions on file in the U.S., Europe and China for *aficamten* and regulatory review activities underway, we are approaching a key inflection point, and our commercial readiness activities are on track to support planned launch activities. During recent months, we also started important clinical trials advancing later-stage development programs, setting us up to potentially deliver multiple new medicines to patients over the next several years. With a strong balance sheet and additional access to investment capital, we are well-funded to execute the potential commercial launch of *aficamten* in 2025, while we advance our pipeline and continue investing in research for the benefit of all stakeholders.

31. The press release also detailed Cytokinetics' NDA with the FDA for aficamten and other commercialization updates, in relevant part:

> The U.S. Food & Drug Administration (FDA) accepted our New Drug Application (NDA) for aficamten, a next-in-class cardiac myosin inhibitor, for the treatment of obstructive hypertrophic cardiomyopathy (HCM). The NDA was assigned standard review with a Prescription Drug User Fee Act (PDUFA) target action date of September 26, 2025. We are responding to information requests from FDA and preparing for clinical site and other inspections. We expect to participate in a mid-cycle meeting with FDA in March.
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> * * *
>
> ***aficamten*** (cardiac myosin inhibitor)
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> •Advance NDA review activities with U.S. FDA to support the potential U.S. approval of *aficamten* in 2H 2025.
>
> •Advance go-to-market strategies and prepare to commercially launch *aficamten* in the U.S. in 2H 2025, subject to approval by FDA.
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> •Continue go-to-market plans in Germany and expand commercial readiness activities in Europe in 2025, in preparation for potential approval by the EMA in 1H 2026.
>
> •Coordinate with Sanofi to support the potential approval of *aficamten* in China in 2H 2025, pending approval by the NMPA.

32. The above statements in Paragraphs 22 to 31 were false and/or materially misleading. Defendants created the false impression that aficamten had been completely and properly submitted as a NDA to the FDA. In truth, Defendants had knowingly or recklessly

omitted a REMS from the initial NDA submission, despite prior FDA discussions about safety and risk mitigation, and that the subsequent REMS submission necessitated a three-month delay in the FDA's process for potential approval.

The Truth Emerges

March 10, 2025

33. On March 10, 2025, Cytokinetics published a Form 8-K announcing the Company's intent to furnish information pertaining to its new drug application for aficamten at upcoming investor conferences. As part of the regulatory disclosure, Cytokinetics included the following information relating to aficamten, in relevant part:

> 1. Cytokinetics has completed its midcycle review with the Food and Drug Administration ("FDA") with respect to the New Drug Application ("NDA") for aficamten for the treatment of obstructive hypertrophic cardiomyopathy.
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> 2. FDA has informed Cytokinetics that it does not plan to convene an advisory committee meeting to review the Company's NDA for aficamten.
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> 3. We expect the Late Cycle meeting with FDA to occur in June 2025.
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> We maintain our expectation for a differentiated label and risk mitigation profile for aficamten, if approved by FDA.
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> As previously stated, the Company does not plan to share detailed updates on its communications with the FDA.

May 1, 2025

34. On May 1, 2025, after market hours, Cytokinetics published a press release announcing that the FDA extended the PDUFA action date for the NDA for aficamten for the treatment of patients with obstructive hypertrophic cardiomyopathy ("oHCM") from September 26, 2025 to December 26, 2025. According to the press release, the FDA notified Cytokinetics that additional time is required to conduct a full review of the Company's proposed Risk Evaluation and Mitigation Strategy ("REMS"). As part of the press release, Cytokinetics stated, in relevant part:

> Following pre-NDA discussions with FDA in which safety and risk mitigation were discussed, Cytokinetics submitted the NDA for aficamten

> in oHCM without an accompanying REMS, and the FDA accepted the NDA for filing. Recently, during the NDA review, the FDA requested that Cytokinetics submit a REMS, based on the inherent characteristics of aficamten, which the company provided. The submission of a REMS has now been determined by FDA to be a Major Amendment to the NDA resulting in a standard three-month extension to the original PDUFA action date. No additional clinical data or studies have been requested of Cytokinetics by FDA.

35. The aforementioned press release is in direct contrast to the statements made by Cytokinetics and the Individual Defendant during the Company's quarterly earnings reports and investor presentations. These press releases and presentations provided affirmations that Defendants' NDA for aficamten was progressing according to the timeline presented by Cytokinetics and failed to include any indications that this timeline may be disrupted due to the Company's failure to include all relevant portions of the NDA submission.

36. Investors and analysts reacted immediately to Cytokinetics' revelation. The price of Cytokinetics' common stock plummeted $5.57 per share or approximately 13% to close at $37.35 on May 2, 2025.

37. On May 1, 2025, CGS International issued a report following Cytokinetics' news that aficamten received a PDUFA delay. The report stated, in relevant part:

> Thursday evening, after market close, Cytokinetics announced that the PDUFA for aficamten in obstructive hypertrophic cardiomyopathy (oHCM) was delayed three months to December 26, 2025. Cytokinetics disclosed that they recently submitted a proposed REMS and that they had not included a REMS protocol in the initial NDA submission, with the delay related to the REMS review. Much like the Phase 3 SEQUOIA-HCM data, the FDA decision will now be a Christmas gift for investors.
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> * * *
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> ***The delay is for review of a major amendment following the submission by Cytokinetics of a proposed REMS protocol, per FDA request.*** Recall mavacamten (Camzyos) also had a 3-month PDUFA delay, likely related to determination of the REMS. It is our speculation that the mavacamten delay was related to negotiation of an echo monitoring titration protocol vs a PK titration protocol (as was used in the mavacamten EXPLORER-HCM Phase 3 study). It is unclear to us any specific reason why FDA would need additional time to review the aficamten REMS, though we note the

> proposed REMS not being in the initial submission for aficamten is puzzling. We anticipate negative investor sentiment on the execution/transparency of the submission, which could bleed through into expectations for the launch, though in our view the delay does not change the likelihood of launch success in any meaningful way.
>
> The delay will drive uncertainty on the REMS, which investors had already started to discount as an advantage for aficamten given the recent label update for mavacamten permitting q6m maintenance cardiac echo and relaxation of DDI verbiage. We still see meaningful difference for aficamten and mavacamten on ease-of-use and the likely advantages on the REMS/label for aficamten namely; 1) Faster titration, 2) lack of dose down titration due to Valsalva LVOT-G <20 mmHg, 3) wider permissible echo window, 4) dose reduction on LVEF <50% vs interruption/discontinuation, 5) lack of meaningful DDIs. ***However, the delay will put more emphasis on the REMS review, and we think spur speculation on just how much differentiation there will be and how meaningful it is to clinical utilization.***

[Emphasis added].

38. Also on May 1, 2025, UBS published a report titled "Cutting PT further on a series of setbacks:

> Differentiation increasingly a pipe dream" cutting Cytokinetics' price target to $41 from $47. As part of the report, UBS stated, in relevant part:
>
> We see the FDA's 3-mo PDUFA extension for aficamten as a further concern, especially given that the agency has requested the sponsor to submit a REMS. Cytokinetics PR noted that agency requires additional time to do a full review of proposed REMS. We see this update as increasing the chances of a REMS (even if a simplified one) for aficamten; this could potentially be due to conservative FDA stance around "class label".

May 6, 2025

39. On May 6, 2025, Cytokinetics published a press release reporting first quarter 2025 financial results and business updates. As part of the press release, CEO Blum issued a statement detailing the FDA's decision to extend the Company's PDUFA date for aficamten, in pertinent part:

> In the first quarter, we made progress towards commercial readiness and advanced our specialty cardiology pipeline. Recently, our PDUFA date for *aficamten* in obstructive HCM was extended by FDA to provide time to review a REMS submission made at the Agency's request subsequent to

> the initial NDA filing acceptance. We remain confident in the distinct benefit-risk and pharmaceutic profile of *aficamten*, and our top priority is bringing this potential therapy to patients. This month, we also expect to report topline results from MAPLE-HCM, and we continue conduct of ACACIA-HCM, for which we have now completed enrollment of patients. With a strong balance sheet and prudent attention to capital deployment, we are well positioned to deliver across regulatory, clinical and commercial milestones.

40. The same day, Cytokinetics hosted an earnings call, wherein CEO Blum provided additional details related to the FDA's decision to extend the Company's PDUFA date for aficamten, in relevant part:

> As we disclosed last week, the FDA extended the PDUFA date for the NDA for aficamten for the treatment of patients with oHCM to December 26, 2025, to provide additional time to conduct a full review of our proposed REMS. And to be clear, we had a series of three meetings with FDA ahead of our NDA submission for aficamten during which we discussed a range of topics related to the content of our submission, including safety monitoring and risk mitigation strategies. These included a top line meeting to review the results of SEQUOIA-HCM, a pre-NDA meeting to cover specific topics related to our submission and a Type B meeting during which we discussed strategies related to safety monitoring and risk mitigation in support of our NDA submission. Attending all 3 of these meetings were representatives from the Division of Cardiology and Nephrology as well as representatives from the Division of Risk Management within the Office of Surveillance and Epidemiology of FDA.
>
> As we've previously shared, these interactions provided the opportunity to discuss in detail the data supporting the safety and intrinsic pharmaceutic properties of aficamten and how they may inform approaches to manage risk and gain insight into FDA's perspectives on this matter. Given these interactions, we considered it reasonable to propose a distinct risk mitigation approach specific to aficamten and based on labeling and other tools such as voluntary education materials. However, we understood from FDA that the potential need for REMS would be a focus of the agency's review. We made the determination to take this approach because under the circumstances, we thought it was reasonable given the profile of aficamten. However, as a contingency, we developed our distinct REMS proposal, and we were well prepared to submit it, if necessary. During the NDA review, given the mechanism of aficamten, the FDA requested that we submit a REMS specific to its intrinsic properties, which we promptly provided.
>
> As we communicated last week, we recently learned from FDA that our subsequent submission of the REMS constitutes a major amendment to the

> NDA and will now require a standard 3 month extension to the original PDUFA action date. To remind you, please, we discovered and developed aficamten with objective to advance it as a potential next-in-class cardiac myosin inhibitor. Based on its inherent characteristics, we evaluated it in preclinical and clinical studies to understand how its half-life, its rapid onset, its reversibility as well as an optimized relationship between PK and PD could enable a unique convenient dosing regimen. We extensively studied its DDI profile to similarly ensure that it was enabling of a distinct clinical profile to support potential differentiation. We believe the results of our clinical studies, including SEQUOIA-HCM and FOREST-HCM, support a potential label and risk mitigation profile that, if approved by FDA, will differentiate aficamten. Nothing has changed in that regard. And again, to confirm, no additional clinical data or studies were requested by FDA.
>
> As we disclosed in an 8-K filing in March, during the first quarter, we completed a mid-cycle review with FDA. During the meeting, FDA confirmed that the agency does not plan to convene an advisory committee meeting, which is consistent with prior communications to us and that our late cycle meeting is expected to occur in June. While the PDUFA extension does delay the potential approval of aficamten, it does not change our confidence in its distinct benefit risk and pharmaceutic profile, nor does it change our expectation for a potentially differentiated label and risk mitigation profile upon potential approval. Given the FDA review of the NDA is ongoing, we do not intend to provide further color or detailed updates on our communications with FDA.

41. The aforementioned press releases and statements made by the Individual Defendant are in direct contrast to statements they made during the press releases and associated earnings calls held on December 27, 2023, February 27, 2024, May 8, 2024, May 13, 2024, August 8, 2024, December 2, 2024, and February 27, 2025. During the earnings calls and related statements, Cytokinetics' executives continually touted the progress the Company had made relating to aficamten, including the steps that Company had taken pertaining to the NDA submission with the FDA for aficamten. In actuality, Cytokinetics knowingly failed to include a REMS in its NDA submission for aficamten, an omission that Defendants should have known would constitute a major amendment, which, in turn, caused a three-month delay.

42. As a result, investors and analysts reacted immediately to Cytokinetics' revelations. The price of Cytokinetics' stock declined another $0.93 per share to close at $33.04 on May 7, 2025.

Loss Causation and Economic Loss

43. During the Class Period, as detailed herein, Cytokinetics and the Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Cytokinetics' common stock and operated as a fraud or deceit on Class Period purchasers of Cytokinetics' common stock by materially misleading the investing public. Later, when Cytokinetics and Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Cytokinetics' common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Cytokinetics' common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

44. Cytokinetics' stock price fell in response to the corrective events on May 1, 2025 and May 6, 2025, as alleged *supra*. On May 1, 2025 and May 6, 2025, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Cytokinetics' NDA submission to the FDA for aficamten.

45. In particular, on May 1, 2025, Cytokinetics published a press release announcing the FDA's decision to delay the Company's PDUFA date for aficamten by three months, from September 26, 2025 to December 26, 2025. Then, on May 6, 2025, during a quarterly earnings call, Cytokinetics' management disclosed that the Company had participated in multiple meetings with the FDA regarding its aficamten NDA and had even prepared a REMS, but chose not to submit it to the FDA.

Presumption of Reliance; Fraud-On-The-Market

46. At all relevant times, the market for Cytokinetics' common stock was an efficient market for the following reasons, among others:

(a) Cytokinetics' common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

(b) Cytokinetics communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) Cytokinetics was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Cytokinetics was reflected in and incorporated into the Company's stock price during the Class Period.

47. As a result of the foregoing, the market for Cytokinetics' common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Cytokinetics' stock price. Under these circumstances, all purchasers of Cytokinetics' common stock during the Class Period suffered similar injury through their purchase of Cytokinetics' common stock at artificially inflated prices, and a presumption of reliance applies.

48. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

49. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with materially misleading statements about its operational plans while at the same time omitting then existing material adverse information concerning the Company's regulatory

filings. Defendants provided the public with information about their operations that failed to account for negative realities concerning their undisclosed conduct.

50. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

51. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Cytokinetics who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

52. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Cytokinetics' common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

53. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Cytokinetics' common stock were actively traded

on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Cytokinetics or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of February 26, 2025, there were 118.4 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

54. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

55. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

56. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Cytokinetics;

(c) whether the Individual Defendant caused Cytokinetics to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Cytokinetics' common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

57. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Against All Defendants for Violations of Section 10(b) and Rule 10b-5 Promulgated Thereunder

58. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

59. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

60. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Cytokinetics common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Cytokinetics' securities at artificially inflated prices. In furtherance of this

unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

61. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Cytokinetics' securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

62. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

63. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior manager and/or director of the Company, the Individual Defendant had knowledge of the details of Cytokinetics' internal affairs.

64. The Individual Defendant is liable both directly and indirectly for the wrongs complained of herein. Because of his position of control and authority, the Individual Defendant was able to and did, directly or indirectly, control the content of the statements of the Company. As officer and/or director of a publicly-held company, the Individual Defendant had a duty to disseminate timely, accurate, and truthful information with respect to Cytokinetics' businesses, operations, future financial condition and future prospects. As a result of the dissemination of

the aforementioned false and misleading reports, releases and public statements, the market price of Cytokinetics' common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Cytokinetics' common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

65. During the Class Period, Cytokinetics' common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Cytokinetics' common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Cytokinetics' common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Cytokinetics' common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

66. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

67. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendant
for Violations of Section 20(a) of the Exchange Act

68. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

69. During the Class Period, the Individual Defendant participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of his senior position, he knew the adverse non-public information about Cytokinetics' misstatements.

70. As officer and/or director of a publicly owned company, the Individual Defendant had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Cytokinetics which had become materially false or misleading.

71. Because of his positions of control and authority as senior officer, the Individual Defendant was able to, and did, control the contents of the various reports, press releases and public filings which Cytokinetics disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendant exercised his power and authority to cause Cytokinetics to engage in the wrongful acts complained of herein. The Individual Defendant therefore, was a "controlling person" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in the unlawful conduct alleged which artificially inflated the market price of Cytokinetics' common stock.

72. The Individual Defendant, therefore, acted as a controlling person of the Company. By reason of his senior management positions and/or being director of the Company, the Individual Defendant had the power to direct the actions of, and exercised the same to cause, Cytokinetics to engage in the unlawful acts and conduct complained of herein. The Individual Defendant exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

73. By reason of the above conduct, the Individual Defendant and/or Cytokinetics are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.