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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CELIA SOTO, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. BIOAGE LABS, INC., KRISTEN FORTNEY, DOV GOLDSTEIN, SHANE BARTON, JEAN-PIERRE GARNIER, MICHAEL DAVIDSON, PATRICK ENRIGHT, JAMES HEALY, REKHA HEMRAJANI, ERIC MORGEN, and VIJAY PANDE, Defendants.	Case No. 3:25-cv-00196 **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Demand for Jury Trial

Plaintiff Celia Soto ("Plaintiff") alleges the following upon information and belief, except as to those allegations concerning themselves, which are alleged upon personal knowledge. Plaintiff's information and belief is based on the investigation of their undersigned counsel, which included, among other things, review and analysis of: (a) public statements made by or on behalf of BioAge Labs, Inc. ("BioAge" or the "Company"), including public filings with the U.S. Securities and Exchange Commission ("SEC"); (b) press releases; (c) reports of securities and financial analysts; and (d) news articles. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE CLAIM

1. Plaintiff brings this action pursuant to Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act"), 15 U.S.C. §§ 77k and 77o, on behalf of herself and all other shareholders that purchased stock pursuant and/or traceable to BioAge's registration statement for the initial public offering held on or about September 26, 2024.

2. BioAge introduced itself to investors during its initial public offering as a "clinical-stage biopharmaceutical company" that develops therapeutic product candidates for metabolic diseases, such as obesity, by targeting the biology of human aging. BioAge's lead product candidate, azelaprag, is an orally available small molecule agonist of the apelin receptor APJ. Apelin is an exercise-induced signaling molecule (exerkine) that acts on APJ and has the potential to recapitulate the metabolic benefits of exercise.

3. Defendants' initial public offering documents discussed its collaboration with Eli Lilly and Company ("Lilly") in connection with its ongoing STRIDES clinical trial of azelaprag in combination with GLP-1R agonists to establish proof of concept for enhanced weight loss. Under the terms of the collaboration, Lilly agreed to supply tirzepatide and Lilly's Chorus provided clinical trial design and execution advice.

4. Under the STRIDES trial, azelaprag in combination with tirzepatide was given to approximately 220 obese individuals aged 55 and over, an age group that represents 35-40% of the adult obese population in the U.S. Defendants focused on this age group because the muscle and metabolic benefits of azelaprag observed in BioAge's Phase 1b clinical trial had been achieved in older patients. The goal of the STRIDES clinical trial was to establish proof of concept for enhanced weight loss with its primary endpoint of weight loss at 24 weeks. Defendants anticipated topline results in the third quarter of 2025.

5. BioAge completed its initial public offering on September 27, 2024, selling 12.65 million shares at $18 per share, which included the exercise in full by the underwriters of their option to purchase 1.65 million additional shares. However, less than three months later, on December 6, 2024, BioAge announced that it would discontinue the ongoing STRIDES Phase 2 study of its investigational drug candidate azelaprag after liver transaminitis was observed in some

subjects receiving azelapgrag. An analyst reported on the announcement, noting that the news was surprising that liver tox never appeared across eight Phase 1 studies conducted previously by BioAge. In response to the news, BioAge's stock price declined from $20.09 per share on December 6, 2024 to $4.65 per share on December 7, 2024.

6. Plaintiff and other similarly situated investors bought BioAge stock in the initial public offering based on false and/or materially misleading information concerning its STRIDES Phase 2 clinical trial. These investors sustained damages as a result thereof. This action seeks to compensate those investors and recover the damages they sustained because of Defendants' actions and statements.

JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act, 15 U.S.C. §§ 77k and 77o, respectively.

8. This Court has subject matter jurisdiction over this action under Section 22 of the Securities Act (15 U.S.C. § 77v) and 28 U.S.C. § 1331.

9. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly and/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.

10. Venue is proper in this District pursuant to Section 22 of the Securities Act and 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in this District.

PARTIES

11. Plaintiff purchased BioAge stock pursuant and/or traceable to BioAge's registration statement for the initial public offering and was damaged as a result thereof. Plaintiff's certification evidencing her transaction(s) in BioAge is incorporated herein by reference.

12. Defendant BioAge was founded in 2015 and is incorporated in the State of Delaware. Its principal executive offices are located at 1445A South 50th Street, Richmond,

California 94804. Following its initial public offering, BioAge's stock traded on the Nasdaq under the symbol "BIOA".

13. Defendant Kristen Fortney ("Fortney") was at all relevant times BioAge's Chief Executive Officer. Fortney signed BioAge's registration statement for the initial public offering.

14. Defendant Dov Goldstein ("Goldstein") was at all relevant times BioAge's Chief Financial Officer.

15. Defendant Shane Barton ("Barton") was at all relevant times BioAge's Vice President of Finance.

16. Defendants Jean-Pierre Garnier, Michael Davidson, Patrick Enright, James Healy, Rekha Hemrajani, Eric Morgen, and Vijay Pande were at all relevant times members of BioAge's Board of Directors. Collectively, these defendants are referred to as the "Director Defendants."

17. Fortney, Goldstein, Barton, and the Director Defendants:

a. directly participated in the management of BioAge;

b. were directly involved in the day-to-day operations of BioAge at the highest levels;

c. were directly or indirectly involved in drafting, producing, reviewing, and/or disseminating the false and misleading statements and information alleged herein;

d. were directly or indirectly involved in the oversight or implementation of BioAge's business and/or finances, medical, or scientific research;

e. and/or approved or ratified these statements in violation of the federal securities laws.

18. As officers of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the federal securities laws of the United States, Fortney, Goldstein, Barton, and the Director Defendants each had a duty to disseminate prompt, accurate, and truthful information with respect to the Company's deteriorating relationship with Moderna and to correct any previously-issued statements that had become materially misleading or untrue.

19. Fortney, Goldstein, Barton, and the Director Defendants, because of their positions with BioAge, possessed the power and authority to control the contents of BioAge's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Fortney, Goldstein, Barton, and the Director Defendants had the ability and opportunity to prevent their issuance or cause them to be corrected.

SUBSTANTIVE ALLEGATIONS

20. On October 26, 2023, Defendants issued a press release announcing plans to initiate a Phase 2 trial of its oral apelin receptor agonist BGE-105 (azelaprag) co-administered with the GLP-1/GIP receptor agonist tirzepatide for treatment of obesity.

21. In the same press release, Defendant Fortney stated, in relevant part:

> We are thrilled to work directly with the clinical development experts at Chorus and benefit from Lilly's expertise in obesity drug development. Our Phase 2 trial is designed to assess whether azelaprag can substantially increase the weight loss achieved with drugs of the incretin class. This combination could enhance the performance of both injectable and oral incretin drugs. The oral route of administration of azelaprag makes it particularly exciting as a combination partner for next-generation oral incretins currently in development. As an additional benefit, azelaprag may help promote healthier weight loss. Treating obesity has the potential to prevent or delay multiple diseases of aging and increase healthspan for a large segment of the population.

22. The press release further stated that in December 2022, BioAge announced positive topline results from a Phase 1b clinical trial showing that azelaprag treatment resulted in statistically significant prevention of muscle atrophy and maintenance of muscle protein synthesis in healthy volunteers aged 65 or older after 10 days of strict bed rest. "Azelaprag was well tolerated in this study and at all doses tested to date in 227 subjects, with a safety profile consistent with the findings of prior phase 1 trials conducted by Amgen."

23. On July 29, 2024, Defendants issued a press release that the that the first patient had been dosed in the STRIDES Phase 2 clinical trial evaluating BioAge's lead product candidate azelaprag in combination with tirzepatide for the treatment of obesity in adults aged 55 and older.

24. The press release further stated, in relevant part:

> STRIDES is a randomized, double-blind, placebo-controlled Phase 2 clinical trial of azelaprag in combination with tirzepatide that will enroll approximately

> 220 obese individuals aged 55 years and older. The trial will evaluate the efficacy, safety, and tolerability of two oral doses of azelaprag (300 mg once or twice daily) in combination with tirzepatide (5 mg subcutaneous injection once weekly). The primary endpoint is mean percent change in body weight at 24 weeks. Additional exploratory endpoints include body composition, glycemic control, obesity-related biomarkers, and patient-reported outcomes related to health and quality of life. Top-line results are anticipated in the fourth quarter of 2025.

25. In the same press release, Defendant Fortney stated, in pertinent part:

> We believe combining azelaprag, an exercise mimetic, with tirzepatide, a GLP-1/GIP receptor agonist that decreases food intake, could provide a powerful pharmacological parallel to the exercise and diet interventions that form the foundation of obesity management. The STRIDES trial aims to demonstrate that activating apelin signaling with azelaprag is a potent complementary mechanism that can deliver increased weight loss efficacy in patients on incretins. In addition, this trial will provide a direct read-through to azelaprag's potential as an orally available small molecule to achieve efficacy on par with injectable weight loss drugs when combined with incretins in an all-oral regimen.

26. On November 7, 2024, Defendants issued a press release in which Defendant Fortney reiterated the importance of BioAge's Phase 2 STRIDES stating, "The STRIDES trial is a critical step in our mission to improve outcomes for patients with obesity. We're developing an oral therapy that has the potential to enhance the weight loss benefits of incretin drugs while promoting healthy body composition."

FALSE AND MATERIALLY MISLEADING STATEMENTS

27. On September 3, 2024, Defendants filed a registration statement on Form S-1 with the SEC in connection with the Company's initial public offering. BioAge amended the registration statement on September 18, 2024 and September 25, 2024. On September 26, 2024, BioAge filed its final prospectus for the Company's initial public offering, which was incorporated into the registration statement, and listed for sale 11 million shares of BioAge common stock at an offering price of $18 per share.

28. BioAge's final prospectus for the initial public offering represented the significance and benefits of azelaprag for the treatment of obesity in older adults. In pertinent part, the Company detailed the arrangement as follows:

We are a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases, such as obesity, by targeting the biology of human aging. Our technology platform and differentiated human datasets enable us to identify promising targets based on insights into molecular changes that drive aging. Our primary focus is metabolic disease, one of the greatest global healthcare challenges. Azelaprag, our lead product candidate, is an orally available small molecule that has been well-tolerated in 265 individuals across eight Phase 1 clinical trials. In preclinical obesity models, azelaprag demonstrated the ability to more than double the weight loss induced by a glucagon-like-peptide-1 receptor (GLP-1R) agonist while also restoring healthy body composition and improving muscle function. These preclinical results are supported by our Phase 1b clinical trial in older adults on bed rest where we observed decreased muscle atrophy, preservation of muscle quality and improved metabolism in subjects treated with azelaprag over a 10-day period. We plan to assess azelaprag's potential to drive significant improvements in weight loss when combined with a GLP-1R agonist in two Phase 2 clinical trials. While the results of these preclinical studies and early clinical trials have demonstrated the potential use of azelaprag for the treatment of metabolic disease, they may not be predictive of the results of later-stage clinical trials. ***The ongoing STRIDES clinical trial will assess azelaprag in combination with tirzepatide, marketed as Zepbound® by Eli Lilly (Lilly), with topline results anticipated in the third quarter of 2025.***

. . .

We are building a pipeline of platform-derived therapeutics targeting chronic metabolic disease. Our lead product candidate, azelaprag, is an orally available small molecule agonist of the apelin receptor (APJ) where activation has the potential to recapitulate many of the benefits of exercise. We are developing azelaprag for the treatment of obesity in combination with GLP-1R agonists with the goal of increasing overall weight loss, with the potential to also improve tolerability and body composition. We have initiated one Phase 2 clinical trial of azelaprag in combination with tirzepatide and plan to initiate a second Phase 2 clinical trial of azelaprag in combination with semaglutide in the first half of 2025 and topline results expected in the second half of 2026.

. . .

We are initiating two Phase 2 clinical trials of azelaprag in combination with GLP-1R agonists. The first of these trials, STRIDES, is an ongoing clinical trial of azelaprag in combination with tirzepatide in approximately 220 obese individuals aged 55 and over, an age group that represents 35-40% of the adult obese population in the U.S. We are initially focusing on these older patients because the muscle and metabolic benefits of azelaprag observed in our Phase 1b clinical trial were achieved in older patients. ***The goal of the STRIDES clinical trial is to establish proof of concept for enhanced weight loss. The primary endpoint of this trial will be weight loss at 24 weeks. In addition, biomarkers, changes in body composition and glucose control will be assessed as exploratory endpoints. We anticipate topline results in the third quarter of 2025.***

We have a material transfer agreement with Lilly, under which Lilly has agreed to provide us with tirzepatide in connection with our STRIDES clinical trial of azelaprag in obesity. Lilly's Chorus clinical development organization is advising and assisting on all aspects of the Phase 2 STRIDES clinical trial design and execution, enabling us to benefit from Lilly's extensive clinical experience in this space, while retaining all rights to azelaprag.

. . .

The ongoing STRIDES clinical trial is the first of these and aims to establish proof of concept in obesity and evaluate the ability of azelaprag to enhance weight loss in combination with tirzepatide in adults aged 55 and above with obesity, an age group that represents 35-40% of the adult obese population in the U.S. We chose to initially establish proof of concept in these older patients given the strong muscle and metabolic benefits of azelaprag observed in our Phase 1b clinical trial in older patients.

We have selected a 5 mg dose of tirzepatide in the STRIDES clinical trial given it approximates oral efficacy. Our ultimate goal is to develop azelaprag as part of an all-oral obesity combination therapy. The 5 mg dose of tirzepatide achieves similar weight loss as the most advanced oral in development, oral semaglutide. Tirzepatide 5 mg achieved 15.0% overall weight loss at 72 weeks; oral semaglutide 50 mg, achieved 15.1% weight loss after 68 weeks.

We plan to investigate two doses of azelaprag, 300 mg QD and 300 mg BID (which has potential for 600 mg QD dose formulation) in combination with tirzepatide as compared to tirzepatide alone. The doses were selected based on a completed Phase 1 oral pharmacokinetic trial; they are intended to result in azelaprag exposures (area under the curve) that bracket the similar exposure achieved in the Phase 1b bed rest trial and diet-induced obesity preclinical studies. These doses will be administered orally in combination with weekly subcutaneous tirzepatide. We are collaborating with Lilly's Chorus clinical development organization, which will provide clinical trial design and execution expertise, and Lilly, which is supplying tirzepatide. We retain all rights to azelaprag.

. . .

The primary endpoint of the STRIDES clinical trial is mean percent weight loss at 24 weeks with exploratory endpoints focused on body composition, glycemic control, patient-reported outcomes / quality of life, biomarkers, and rebound weight gain. We set the primary endpoint at 24 weeks because there is lower variability in tirzepatide monotherapy weight loss compared to later time points in clinical trials, and because Lilly has found weight loss at 24 weeks to be predictive for weight loss at 72 weeks (one year of treatment once the maintenance dose is reached). The trial has 90% power to detect a 3.3% difference between treatment groups (azelaprag plus tirzepatide versus tirzepatide alone) in weight loss at 24 weeks of treatment, which is expected to correspond to 5% at one year of treatment. FDA's 2007 draft guidance for

> development of weight management products states that a 5% treatment difference compared to placebo can be evidence of effectiveness in Phase 3 trials. A 5%+ benefit in weight loss for azelaprag could also translate into potential 20%+ overall weight loss in an oral combination, a competitive efficacy benchmark; for reference, the most advanced oral incretin in development, oral semaglutide, achieves 15.1% overall weight loss at 68 weeks.
>
> ***We anticipate topline results from this trial in the third quarter of 2025.***

(Emphasis added).

29. The statements identified above were false and/or materially misleading. Defendants touted its lead product candidate azelaprag in connection with the Company's ongoing STRIDES with expectations of topline results in 2025. Defendants also mentioned its collaboration with Lilly's Chorus clinical development organization who would be advising and assisting on all aspects of the STRIDES trial design and execution. Defendants further discussed the potential for a second Phase 2 clinical trial combining azelaprag and semaglutide to treat obesity in individuals ages 18 years and older. Therefore, the initial public offering represented to the public that there were no safety concerns and the Company expected top line results and to meet its primary endpoint goals in connection with its STRIDES clinical trial.

30. Contrary to these representations, BioAge discontinued the ongoing STRIDES Phase 2 study of its investigational drug candidate azelaprag after several subjects showed elevated levels of liver enzymes warning of potential organ damage. As a result, Defendants discontinued the clinical trial and halted further enrollment. Given the fact that Defendants failure to disclose the potential for liver transaminitis in any of its previous clinical Phase 1 trials and various preclinical tox studies, Defendants' statements in BioAge's registration statement were false and/or materially misleading at the time of the initial public offering.

31. Following the announcement, analysts and news outlets reported on the development. In pertinent part, one analyst reported that the news was surprising noting that liver tox never appeared across eight Phase 1 studies conducted previously by BioAge. In response to the news, BioAge's stock price declined from $20.09 per share on December 6, 2024 to $4.65 per share on December 9, 2024.

32. BioAge's stock currently trades at or around $5.82 per share, which is well below its $18 per-share initial public offering price.

CLASS ACTION ALLEGATIONS

33. Plaintiff bring this action on behalf of himself and all other shareholders that purchased stock pursuant and/or traceable to BioAge's registration statement for the initial public offering held on or about September 26, 2024, and were damaged thereby (the "Class"). Excluded from the Class are Defendants each of their immediate family members, legal representatives, heirs, successors or assigns, and any entity in which any of the Defendants have or had a controlling interest.

34. The Class members are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown 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 Class members may be identified from records maintained by BioAge 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. In the initial public offering itself, BioAge sold 12.65 million shares. Upon information and belief, these shares are held by hundreds or thousands of individuals located throughout the world. Joinder would be highly impracticable.

35. Plaintiff's claims are typical of the claims of the Class members as all Class members are similarly affected by the Defendants' respective wrongful conduct in violation of the federal laws complained of herein.

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

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

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

(b) whether the price of BioAge's securities during the Class Period was artificially inflated because of the Defendants' conduct complained of herein; and

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

38. 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

Violation of Section 11 of the Securities Act against Defendants

39. Plaintiff specifically disclaims any allegations that are based on fraud, recklessness, or intentional misconduct.

40. This count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of Plaintiff and other members of the Class against Defendants.

41. BioAge's registration statement and prospectus for the initial public offering were inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein.

42. BioAge is the issuer of the securities purchased by Plaintiff and other members of the Class. As such, BioAge is strictly liable for the materially untrue statements contained in the registration statement and prospectus and their failure to be complete and accurate.

43. Thomas, Wapnick, and the Director Defendants each signed the registration statement filed by BioAge for its initial public offering. As such, each is strictly liable for the materially inaccurate statements contained therein and the failure of the registration statement and

prospectus to be complete and accurate. Thomas, Wapnick, and the Director Defendants named herein were responsible for the contents and dissemination of the registration statement and prospectus, which were inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein. Thomas, Wapnick, and the Director Defendants each had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the registration statement and prospectus and ensure that they were true and accurate and not misleading. In the exercise of reasonable care, Thomas, Wapnick, and the Director Defendants should have known of the material misstatements and omissions contained in the registration statement and prospectus. Accordingly, Thomas, Wapnick, and the Director Defendants are liable to Plaintiffs and the other members of the Class.

44. By reason of the conduct alleged herein, Defendants violated Section 11 of the Securities Act.

45. Plaintiff and the other members of the Class acquired BioAge common stock pursuant or traceable to the Company's registration statement and prospectus filed in conjunction with the initial public offering and without knowledge of the untruths and/or omissions alleged herein. Plaintiff and the other members of the Class sustained damages, and the price of BioAge's shares declined substantially due to material misstatements in the registration statement and prospectus.

46. This claim was brought within one year after the discovery of the untrue statements and omissions and within three years of the date of the initial public offering.

47. By virtue of the foregoing, Plaintiff and the other members of the Class are entitled to damages under Section 11, as measured by the provisions of Section 11(e), from the Defendants and each of them, jointly and severally.

COUNT II

Violation of Section 15 of the Securities Act

against Thomas, Wapnick, and the Director Defendants

48. Plaintiff repeats and realleges each and every allegation contained in Count I, *supra*. Plaintiff specifically disclaims any allegations that are based on fraud, recklessness, or intentional misconduct.

49. This Count is brought by Plaintiff against Thomas, Wapnick, and the Director Defendants pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of the Class.

50. This Count is asserted against Thomas, Wapnick, and the Director Defendants, each of whom possessed the power to control, and did control, directly and/or indirectly, the actions of BioAge at all relevant times.

51. Thomas, Wapnick, and the Director Defendants were each control persons of BioAge by virtue of their positions as directors, senior officers, and/or authorized representatives of the Company. Thomas, Wapnick, and the Director Defendants had the power and authority to control the contents of BioAge's registration statement and prospectus and had the ability and opportunity to prevent their issuance or cause them to be corrected.

52. As a direct and proximate result of said wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchase of BioAge securities.

53. This claim is brought within the applicable statute of limitations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

(a) Determining that this action is a proper class action, certifying Plaintiff as a class representative under Federal Rule of Civil Procedure 23 and Plaintiff's counsel as class counsel;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

In accordance with Fed. R. Civ. P. 38(b), Plaintiff demands a jury trial of all issues involved, now, or in the future, in this action.

Dated: January 7, 2025

Respectfully submitted,

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