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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.

1 **NATURE OF THE CLAIM**

2 1. Plaintiff brings this action pursuant to Sections 11 and 15 of the Securities Act of
3 1933 (the “Securities Act”), 15 U.S.C. §§ 77k and 77o, on behalf of herself and all other
4 shareholders that purchased stock pursuant and/or traceable to BioAge’s registration statement for
5 the initial public offering held on or about September 26, 2024.

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

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

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

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

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

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

10 **JURISDICTION AND VENUE**

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

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

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

19 10. Venue is proper in this District pursuant to Section 22 of the Securities Act and
20 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and
21 dissemination of materially false and/or misleading information, occurred in this District.

22 **PARTIES**

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

26 12. Defendant BioAge was founded in 2015 and is incorporated in the State of
27 Delaware. Its principal executive offices are located at 1445A South 50th Street, Richmond,
28

1 California 94804. Following its initial public offering, BioAge’s stock traded on the Nasdaq under
2 the symbol “BIOA”.

3 13. Defendant Kristen Fortney (“Fortney”) was at all relevant times BioAge’s Chief
4 Executive Officer. Fortney signed BioAge’s registration statement for the initial public offering.

5 14. Defendant Dov Goldstein (“Goldstein”) was at all relevant times BioAge’s Chief
6 Financial Officer.

7 15. Defendant Shane Barton (“Barton”) was at all relevant times BioAge’s Vice
8 President of Finance.

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

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

- 13 a. directly participated in the management of BioAge;
- 14 b. were directly involved in the day-to-day operations of BioAge at the
15 highest levels;
- 16 c. were directly or indirectly involved in drafting, producing, reviewing,
17 and/or disseminating the false and misleading statements and information
18 alleged herein;
- 19 d. were directly or indirectly involved in the oversight or implementation of
20 BioAge’s business and/or finances, medical, or scientific research;
- 21 e. and/or approved or ratified these statements in violation of the federal
22 securities laws.

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

28

1 220 obese individuals aged 55 years and older. The trial will evaluate the
2 efficacy, safety, and tolerability of two oral doses of azelaprag (300 mg once or
3 twice daily) in combination with tirzepatide (5 mg subcutaneous injection once
4 weekly). The primary endpoint is mean percent change in body weight at 24
5 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.

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

7 We believe combining azelaprag, an exercise mimetic, with tirzepatide, a GLP-
8 1/GIP receptor agonist that decreases food intake, could provide a powerful
9 pharmacological parallel to the exercise and diet interventions that form the
10 foundation of obesity management. The STRIDES trial aims to demonstrate that
11 activating apelin signaling with azelaprag is a potent complementary mechanism
12 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.

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

18 **FALSE AND MATERIALLY MISLEADING STATEMENTS**

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

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

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

23 ...

24 We are building a pipeline of platform-derived therapeutics targeting chronic
25 metabolic disease. Our lead product candidate, azelaprag, is an orally available
26 small molecule agonist of the apelin receptor (APJ) where activation has the
27 potential to recapitulate many of the benefits of exercise. We are developing
28 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.

29 ...

30 We are initiating two Phase 2 clinical trials of azelaprag in combination with
31 GLP-1R agonists. The first of these trials, STRIDES, is an ongoing clinical trial
32 of azelaprag in combination with tirzepatide in approximately 220 obese
33 individuals aged 55 and over, an age group that represents 35-40% of the adult
34 obese population in the U.S. We are initially focusing on these older patients
35 because the muscle and metabolic benefits of azelaprag observed in our Phase
36 1b clinical trial were achieved in older patients. ***The goal of the STRIDES
37 clinical trial is to establish proof of concept for enhanced weight loss. The
38 primary endpoint of this trial will be weight loss at 24 weeks. In addition,
39 biomarkers, changes in body composition and glucose control will be assessed
40 as exploratory endpoints. We anticipate topline results in the third quarter of
41 2025.***

1
2 We have a material transfer agreement with Lilly, under which Lilly has agreed
3 to provide us with tirzepatide in connection with our STRIDES clinical trial of
4 azelaprag in obesity. Lilly's Chorus clinical development organization is
5 advising and assisting on all aspects of the Phase 2 STRIDES clinical trial design
6 and execution, enabling us to benefit from Lilly's extensive clinical experience
7 in this space, while retaining all rights to azelaprag.

8 ...

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

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

22 We plan to investigate two doses of azelaprag, 300 mg QD and 300 mg BID
23 (which has potential for 600 mg QD dose formulation) in combination with
24 tirzepatide as compared to tirzepatide alone. The doses were selected based on
25 a completed Phase 1 oral pharmacokinetic trial; they are intended to result in
26 azelaprag exposures (area under the curve) that bracket the similar exposure
27 achieved in the Phase 1b bed rest trial and diet-induced obesity preclinical
28 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

1 development of weight management products states that a 5% treatment
2 difference compared to placebo can be evidence of effectiveness in Phase 3
3 trials. A 5%+ benefit in weight loss for azelaprag could also translate into
4 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.

5 ***We anticipate topline results from this trial in the third quarter of 2025.***

6 (Emphasis added).

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

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

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

- 1 (a) whether the federal securities laws were violated by the Defendants’
- 2 respective acts as alleged herein;
- 3 (b) whether the price of BioAge’s securities during the Class Period was
- 4 artificially inflated because of the Defendants’ conduct complained of
- 5 herein; and
- 6 (c) whether the Class members have sustained damages and, if so, what is the
- 7 proper measure of damages.

8 38. A class action is superior to all other available methods for the fair and efficient
9 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the
10 damages suffered by individual Class members may be relatively small, the expense and burden
11 of individual litigation make it impossible for members of the Class to individually redress the
12 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

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

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

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

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

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

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

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

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

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

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

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1 **COUNT II**

2 **Violation of Section 15 of the Securities Act**

3 **against Thomas, Wapnick, and the Director Defendants**

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

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

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

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

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

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

20 **PRAYER FOR RELIEF**

21 WHEREFORE, Plaintiff prays for relief and judgment as follows:

- 22 (a) Determining that this action is a proper class action, certifying Plaintiff as a
23 class representative under Federal Rule of Civil Procedure 23 and Plaintiff's
24 counsel as class counsel;
- 25 (b) Awarding compensatory damages in favor of Plaintiff and the other Class
26 members against all Defendants, jointly and severally, for all damages
27 sustained as a result of the Defendants' wrongdoing, in an amount to be
28 proven at trial, including interest thereon;

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- (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: