UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 20, 2026

BIOAGE LABS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-42279**	**47-4721157**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
5885 Hollis Street Suite 370 Emeryville, California		**94608**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 510 806-1445

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.00001 Par Value Per Share	BIOA	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On January 20, 2026, BioAge Labs, Inc. (the "Company") issued a press release announcing indication expansion for oral NLRP3 inhibitor BGE-102, with plans to initiate Phase 1b/2a proof-of-concept clinical trial in patients with diabetic macular edema in mid-2026.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events

Planned proof-of-concept clinical trial in DME

On January 20, 2026, the Company announced indication expansion for oral NLRP3 inhibitor BGE-102.

- Growing preclinical and clinical evidence points to central role of the inflammasome in multiple retinal diseases where inflammation is a key feature, including diabetic macular edema ("DME")
    - In a preclinical model of DME, oral BGE-102 demonstrated dose-dependent preservation of retinal vascular integrity, achieving near-complete protection from vascular leakage and up to 90% preservation of microvascular integrity
- BGE-102 has demonstrated favorable tolerability to date in ongoing Phase 1 trial, with robust reductions in key inflammatory biomarkers including hsCRP, IL-6, and IL-1β
- Proof-of-concept ("POC") trial in DME is designed to demonstrate ocular target engagement, supporting future development across inflammation-driven retinal diseases

Anticipated Clinical Milestones for BGE-102

- **1H 2026**:
    - Completion of Phase 1 trial with full data readout, including two additional multiple ascending dose cohorts in obese participants with elevated hsCRP
    - Initiation of Phase 2a POC trial in patients with obesity and cardiovascular ("CV") risk factors
- **Mid-2026**:
    - Initiation of Phase 1b/2a POC trial in patients with DME
- **2H 2026**:
    - CV risk Phase 2a POC trial data readout
- **Mid-2027**:
    - DME Phase 1b/2a POC trial data readout

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by BioAge Labs, Inc. dated January 20, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the Company’s plans to develop and commercialize its product candidates, including BGE-102, the potential for BGE-102 as a treatment for cardiovascular and retinal diseases, including DME, and the expected timeline for future data readouts from our ongoing Phase 1 clinical trial. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “potential,” “possible,” “will,” “would,” and other words and terms of similar meaning. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: the Company’s ability to develop, obtain regulatory approval for and commercialize its product candidates; the timing and results of preclinical studies and clinical trials; the risk that positive results in a clinical trial may not be replicated in subsequent trials or success in early stage clinical trials may not be predictive of results in later stage clinical trials; risks associated with clinical trials, including its ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of its drug candidates; the occurrence of adverse safety events; failure to protect and enforce its intellectual property, and other proprietary rights; failure to successfully execute or realize the anticipated benefits of its strategic and growth initiatives; risks relating to technology failures or breaches; its dependence on collaborators and other third parties for the development of product candidates and other aspects of its business, which are outside of the Company’s full control; risks associated with current and potential delays, work stoppages, or supply chain disruptions, including due to the imposition of tariffs and other trade barriers; risks associated with current and potential future healthcare reforms; risks relating to attracting and retaining key personnel; changes in or failure to comply with legal and regulatory requirements, including shifting priorities within the U.S. Food and Drug Administration; risks relating to access to capital and credit markets; and the other risks and uncertainties that are detailed under the heading “Risk Factors” included in the Company’s Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on November 6, 2025, and Company’s other filings with the SEC filed from time to time. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOAGE LABS, INC.

Date: January 20, 2026

By: /s/ Dov Goldstein
Dov Goldstein, M.D.
Chief Financial Officer

Exhibit 99.1

BioAge announces indication expansion for oral NLRP3 inhibitor BGE-102, with plans to initiate Phase 1b/2a proof-of-concept clinical trial in patients with diabetic macular edema in mid-2026

BGE-102 has the potential for therapeutic retinal exposure with oral delivery, reducing treatment burden in ocular indications currently treated with intravitreal therapies

Growing preclinical and clinical evidence points to central role of the inflammasome in multiple retinal diseases where inflammation is a key feature, including diabetic macular edema (DME)

BGE-102 has demonstrated favorable tolerability to date in ongoing Phase 1 trial, with robust reductions in key inflammatory biomarkers including hsCRP, IL-6, and IL-1β

Proof-of-concept trial in DME is designed to demonstrate ocular target engagement, supporting future development across inflammation-driven retinal diseases

DME trial, with results anticipated mid-2027, to run in parallel with the BGE-102 Phase 2a cardiovascular risk trial, with results anticipated 2H26

EMERYVILLE, Calif.--(BUSINESS WIRE)--BioAge Labs, Inc. (Nasdaq: BIOA) ("BioAge", “the Company”), a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases by targeting the biology of human aging, today announced expansion of its BGE-102 development program into ophthalmology, with an initial proof-of-concept (POC) study in patients with diabetic macular edema (DME). BGE-102 is a potent, structurally novel, orally administered small molecule NLRP3 inhibitor with potential for therapeutic retinal exposure.

NLRP3 inflammasome activation is a central pathological feature in a range of retinal diseases. In DME, activation of NLRP3 by hyperglycemia leads to vascular leakage and compromised vision. DME represents the initial proof-of-concept indication for BGE-102 in ophthalmology, with potential for expansion into additional NLRP3-driven retinal diseases, including geographic atrophy.

"The efficacy observed with injectable IL-6 inhibitors in retinal disease validates targeting the inflammatory cascade in the eye,” said Kristen Fortney, PhD, CEO and co-founder of

BioAge. “NLRP3 sits at the apex of this cascade, and BGE-102 offers the potential to deliver broader anti-inflammatory benefit in an oral formulation, which could meaningfully reduce treatment burden for patients with serious, sight-threatening conditions who currently require frequent intravitreal injections. In our ongoing Phase 1 trial, BGE-102 has already demonstrated the potential for best-in-class reductions in inflammatory markers of cardiovascular risk, our primary development focus, with a Phase 2a readout anticipated in 2H26. Together, these promising features position BGE-102 as a potential 'pipeline in a pill': a single oral therapy to address NLRP3-driven inflammation across cardiovascular, CNS, and ocular diseases."

Preclinical evidence supporting development of BGE-102 for retinal disease

In a preclinical model of DME, oral BGE-102 demonstrated dose-dependent preservation of retinal vascular integrity, achieving near-complete protection from vascular leakage and up to 90% preservation of microvascular integrity. In retinal diseases more broadly, published studies [1, 2] have shown that deletion or inhibition of NLRP3 provides complete protection of the retinal pigment epithelium against pro-inflammatory challenges. And in preclinical studies performed by BioAge in a natural model of aging, NLRP3 inhibition reduced age-related accumulation of lipofuscin — a toxic aggregate linked to pathogenesis of retinal diseases including geographic atrophy — by approximately 80%.

Clinical evidence supporting anti-inflammatory approach in retinal disease

A growing body of clinical data supports the therapeutic rationale for targeting inflammation in inflammatory diseases of the retina. In macular edema patients (diabetic and/or uveitis), intravitreal IL-6 inhibitors have demonstrated sustained gains in visual acuity both as monotherapy and as incremental benefit when added to VEGF inhibitor therapy.

Planned proof-of-concept clinical trial in DME

BioAge plans to initiate a Phase 1b/2a POC trial in patients with DME in mid-2026. The randomized, controlled trial will evaluate patients across three arms to evaluate the efficacy of BGE-102 as a monotherapy and in combination with a VEGF inhibitor.

The goal of the POC trial will be to demonstrate target engagement and pharmacodynamics (PD) for BGE-102 in the eye to motivate future clinical development in retinal diseases driven by inflammation. The primary endpoint will be percent change in intraocular IL-6, with additional exploratory endpoints including best-corrected visual

acuity (BCVA), central subfield thickness (CST) and intraocular and plasma biomarkers. Results are anticipated in mid-2027.

Additional details on preclinical data, clinical rationale, and trial design are available in the Company's corporate presentation at https://ir.bioagelabs.com.

Anticipated clinical milestones for BGE-102

- **1H 2026:**
  - Completion of Phase 1 trial with full data readout, including two additional MAD cohorts in obese participants with elevated hsCRP
  - Initiation of Phase 2a POC trial in patients with obesity and cardiovascular (CV) risk factors.
- **Mid-2026**:
  - Initiation of Phase 1b/2a POC trial in patients with DME
- **2H 2026:**
  - CV risk Phase 2a POC trial data readout
- **Mid-2027**:
  - DME Phase 1b/2a POC trial data readout

Background on BGE-102 and NLRP3

BGE-102 is a potent, orally available, brain-penetrant small molecule NLRP3 inhibitor being developed for diseases of inflammation including elevated cardiovascular risk. BGE-102 represents a structurally novel class of NLRP3 inhibitors developed by BioAge with a unique mechanism and binding site. NLRP3 is a key driver of age-related inflammation that has been implicated in a broad range of diseases, including cardiovascular disease, neurodegeneration, and metabolic disorders. In an ongoing Phase 1 clinical trial, the compound has demonstrated a favorable safety profile and robust reductions in key inflammatory biomarkers IL-6, hsCRP, and IL-1β in patients with obesity and elevated cardiovascular risk.

About BioAge Labs, Inc.

BioAge is a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases by targeting the biology of human aging. The Company's lead product candidate, BGE-102, is a potent, orally available, brain-penetrant small-molecule NLRP3 inhibitor being developed for cardiovascular risk and retinal diseases. A Phase 1 SAD/MAD trial of BGE-102 is underway, with topline data including additional MAD cohorts anticipated in 1H26. The Company is also developing long-acting injectable and oral small molecule APJ agonists for obesity. BioAge’s

additional preclinical programs, which leverage insights from the Company’s proprietary discovery platform built on human longevity data, address key pathways involved in metabolic aging.

Forward-looking statements

This press release contains "forward-looking statements" within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our plans to develop and commercialize our product candidates, including BGE-102, the potential for BGE-102 as a treatment for cardiovascular and retinal diseases including DME, the expected timing of clinical trials, the timing and results of our clinical activities, risks associated with clinical trials, including our ability to adequately manage clinical activities, the timing of and our ability to obtain and maintain regulatory approvals and the clinical utility of our product candidates. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "potential," "possible," "will," "would," and other words and terms of similar meaning. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our ability to develop, obtain regulatory approval for and commercialize our product candidates; the timing and results of preclinical studies and clinical trials; the risk that positive results in a preclinical study or clinical trial may not be replicated in subsequent trials or success in early stage clinical trials may not be predictive of results in later stage clinical trials; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events; failure to protect and enforce our intellectual property, and other proprietary rights; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; risks relating to technology failures or breaches; our dependence on collaborators and other third parties for the development of product candidates and other aspects of our business, which are outside of our full control; risks associated with current and potential delays, work stoppages, or supply chain disruptions, including due to the imposition of tariffs and other trade barriers; risks associated with current and potential future healthcare reforms; risks relating to attracting and retaining key personnel; changes in or failure to comply with legal and regulatory requirements, including shifting priorities within the U.S. Food and Drug Administration; risks relating to access to capital and credit

markets; and the other risks and uncertainties that are detailed under the heading "Risk Factors" included in BioAge's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) on November 6, 2025, and BioAge's other filings with the SEC filed from time to time. BioAge undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Contacts

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