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When Should Companies Disclose Drug Safety Risks?

***In re BioAge Labs, Inc., Securities Litigation*, No. 25-cv-00196, 2025 WL 3038991 (N.D. Cal. Oct. 30, 2025)**

Case Highlights

In October 2025, a federal district court dismissed securities claims against a biopharmaceutical company, BioAge Labs, Inc., arising from disclosures in connection with its initial public offering (IPO) concerning the safety of the company's lead drug candidate, azelaprag, which was intended to facilitate weight loss by mimicking the physiological effects of exercise. The court held that the plaintiff failed to plausibly allege that BioAge's IPO offering documents were misleading because they omitted discussion of a potential liver-related safety risk.

At the time of the IPO, BioAge was conducting a Phase 2 clinical trial of azelaprag. Approximately nine weeks after the IPO, BioAge discontinued the trial after 11 participants who received azelaprag developed transaminitis—elevated liver enzyme levels that can indicate injury to the liver. Following that announcement, BioAge's stock price dropped, and investors brought a class action under Sections 11 and 15 of the Securities Act of 1933.

The plaintiff alleged that BioAge's IPO offering documents were misleading because they failed to disclose that transaminitis posed a serious risk to the development and commercialization of azelaprag. Specifically, the plaintiff claimed that transaminitis was "virtually certain" to occur in the Phase 2 trial because a single patient in an earlier, Phase 1 trial experienced transaminitis

and, therefore, it was not possible to accurately discuss the risk that side effects of azelaprag might derail the drug's prospects without expressly disclosing the risk posed by transaminitis.

The court disagreed, identifying both legal and factual deficiencies in the complaint.

First, as a matter of law, the court emphasized that Section 11 does not impose a freestanding duty to disclose all material risks. Here, the plaintiff did not identify any statement in which BioAge affirmatively downplayed or mischaracterized the risk of transaminitis. Instead, the plaintiff argued that by discussing the general risk of adverse events, BioAge implicitly represented that no "expected" or "typical" safety risks existed. The court rejected this argument, holding that a company does not assume an obligation to disclose every conceivable safety signal merely because it elects to discuss clinical trial risks in general terms.

Second, the court found that the plaintiff failed to plausibly allege that transaminitis was "inevitable" at the time of the IPO. The complaint relied heavily on non-serious liver enzyme elevation in one of 265 participants across eight Phase 1 trials, which resolved without treatment and did not disrupt development. The court held that this isolated observation did not establish a trend, much less make liver toxicity "virtually certain" to derail Phase 2 testing. The complaint also pointed to the fact that BioAge tracked liver enzyme levels in mice that were dosed with azelaprag in a 27-week mouse study. But the court found that study actually showed that azelaprag lowered liver enzyme levels, and nothing in the mouse study would have indicated that transaminitis was inevitable.

Key Takeaways

BioAge provides helpful guidance on a pharmaceutical company's obligation to disclose drug-safety risks, particularly when reporting clinical trial results. The decision underscores that the omission of isolated adverse events may not, standing alone, render otherwise accurate descriptions of general trial risks and outcomes misleading. At the same time, BioAge serves as a reminder that once a company elects to speak about a specific risk, it assumes a duty to disclose additional context to avoid providing investors with "half-truths." Importantly, the more serious and prevalent the undisclosed safety risk, the more likely it is that general statements about clinical trial risks may be rendered misleading. This is particularly so under Section 11, where Items 105 and 303 of Regulation S-K impose affirmative disclosure obligations regarding known trends, uncertainties, and material risk factors. Companies should carefully calibrate their risk disclosures with these principles in mind and consult experienced counsel when drafting public statements about drug development programs and observed safety events.

**Update: Following the court's October 2025 decision, the plaintiff filed an amended complaint. On March 2, 2026, the court granted BioAge's motion to dismiss the amended complaint with prejudice.*

In the amended complaint, the plaintiff advanced a new theory: that the company's risk disclosures—stating that serious, severe, atypical side effects "may" impact drug development—were misleading because the company allegedly already knew that transaminitis had affected drug development. In essence, the plaintiff argued that describing this risk as hypothetical was false because it had already materialized.

The court rejected this argument. It found that the challenged disclosure concerned atypical side effects, whereas the plaintiff had consistently alleged that transaminitis was a typical side effect of the drug. The court further held that, regardless, the plaintiff failed to plausibly allege that the risk of transaminitis had materialized at the time of the alleged misstatement.

The plaintiff filed a notice of appeal to the Ninth Circuit on March 27, 2026.

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