MASSBIO

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July 6, 2026

Ms. Vanessa Countryman
Secretary
U.S. Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-1090

Re: Semiannual Reporting Proposed Rule; File Number S7-2026-15

Dear Ms. Countryman:

The Massachusetts Biotechnology Council (MassBio) appreciates the opportunity to comment on the Commission's proposed rule to allow reporting companies the option of filing semiannual reports on new Form 10-S in lieu of quarterly reports on Form 10-Q. MassBio represents more than 1,600 members across the Massachusetts life sciences ecosystem, including hundreds of small and emerging biotechnology companies working to discover and develop the next generation of treatments for patients. We write today in strong support of this proposal, which offers a meaningful opportunity to right-size disclosure obligations for these companies without compromising the investor protections at the heart of our public markets.

An Opportunity to Right-Size Regulation for Small and Emerging Biotechs

The vast majority of publicly traded biotechnology companies are small, pre-revenue enterprises. They have no products on the market, no sales to report, and no earnings to announce. Their value is instead built on scientific progress: advancing candidates through preclinical development, initiating and completing clinical trials, and reaching regulatory milestones. For these companies, the quarterly reporting regime designed with mature, revenue-generating corporations in mind imposes obligations that are poorly matched to their business reality.

Each Form 10-Q requires significant time from a small company's finance, legal, and executive teams, along with meaningful outside expenditures on auditors, counsel, and consultants. For a large company, these costs are absorbed with little notice. For an emerging biotech operating on finite investor capital and a fixed cash runway, every dollar spent on compliance is a dollar not spent on research and development. The proposal would allow these companies to redirect substantial compliance savings toward their scientific programs, extending runway and, ultimately, improving the odds that promising medicines reach patients.

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Right-sizing regulations like this may also improve the calculus for private biotechs weighing an initial public offering. Going public offers access to the deep pools of capital that drug development requires, but that benefit comes at the price of significant ongoing compliance and reporting costs, a price that weighs heaviest on small, pre-revenue companies. By reducing that burden without diminishing the information available to investors, the proposal makes the public markets a more attractive source of funding for the companies that need them most, supporting capital formation across the sector.

Biotech Investors Are Focused on Clinical Milestones, Not Quarterly Readouts

The Commission correctly observes in the proposing release that investors in pre-revenue biotechnology companies focus primarily on progress in product development and regulatory decisions rather than interim financial results. Our members' experience confirms this. Biotech investors are sophisticated and long-term oriented by necessity: drug development is measured in years, not quarters. A clinical trial may take two to five years to read out, and the financial statements filed in the interim change little from one quarter to the next, typically reflecting only operating expenses and cash position against a story that investors already understand.

The information that actually moves a biotech company's valuation, including trial initiations, enrollment progress, data readouts, and partnership transactions, is already disclosed promptly when these events occur. Companies announce material developments through press releases and current reports filed with the Commission on Form 8-K, typically due within four business days of the triggering event, and Regulation FD ensures that any material information shared with analysts or investors is simultaneously made available to the entire market. This framework delivers information to investors within days, not months.

Quarterly reports for these companies rarely convey new decision-useful information to investors; they largely restate what the market already knows, at real cost to the company. A semiannual cadence, supplemented by the robust current-reporting system that has developed over the past several decades, is well suited to how biotechnology companies are analyzed and valued in today's markets.

An Optional Regime Preserves Choice for Companies and Investors Alike

Critically, the proposal mandates nothing. It is an optional reporting regime that allows companies to determine a reporting cadence that best serves their shareholders. Management teams and boards who are best positioned to weigh the preferences of their particular investor base would simply gain the flexibility to make that judgment for themselves.

This flexibility is a win for biotechnology companies and investors alike. Companies gain the ability to align their disclosure obligations with the realities of their business model and stage of development.

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Investors retain timely access to all material information through the current-reporting framework, along with the assurance that any move to semiannual reporting reflects a considered judgment by the company's management about what best serves its shareholders. And the market itself will provide discipline: companies whose investors value quarterly reporting will face strong incentives to maintain it.

The experience of other jurisdictions bears this out. As the Commission notes in the proposing release, when the United Kingdom eliminated its quarterly reporting requirement in 2014, fewer than 10 percent of companies stopped issuing quarterly reports in the period that followed. The European Union, the United Kingdom, Hong Kong, and Japan all operate on semiannual reporting regimes today, and their capital markets continue to attract investment. Given flexibility, companies will still make disclosure decisions that reflect the expectations of their investors.

Conclusion

MassBio commends the Commission for advancing a thoughtful, balanced proposal that recognizes one size does not fit all in interim reporting. For small and emerging biotechnology companies, the option of semiannual reporting would reduce unnecessary compliance costs, free resources for the research that drives value for patients and investors, and better align disclosure with the long timelines on which drug development actually operates. We encourage the Commission to adopt the proposal, and we would welcome the opportunity to serve as a resource as the Commission finalizes this rulemaking.

Thank you for your consideration.

Respectfully,

Kendalle Burlin O'Connell
President & CEO
Massachusetts Biotechnology Council