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

Re: File Number DSP-3 — Comments on SEC Draft Strategic Plan for Fiscal Years 2026–2030

Dear Secretary Countryman:

I am writing in response to the Securities and Exchange Commission's Draft Strategic Plan for Fiscal Years 2026–2030. Thank you for the opportunity to provide comments on the Commission's priorities relating to capital formation, innovation, investor protection, and regulatory modernization.

My name is Jim Wu. I am the Founder and CEO of SaniMed Science Group, a Houston-based life science investment and commercialization platform, and I am also a Lifetime Founding Member of BLPN. Through my work, I engage with biotechnology, medical technology, diagnostics, AI healthcare, CRO/CDMO, and cross-border life science innovation companies, as well as investors, founders, clinicians, scientists, and strategic partners. My comments reflect practical experience in the life sciences ecosystem rather than legal or technical securities advice.

Life science companies face capital formation challenges that are materially different from many other startup sectors. Biotechnology, medical device, diagnostics, and advanced healthcare technology companies often require significant capital long before they generate revenue. These companies must fund intellectual property protection, preclinical research, regulatory planning, FDA interactions, CMC development, clinical trials, quality systems, manufacturing scale-up, and commercialization preparation. The development timeline can often span many years, and capital needs may be substantial even before a product reaches patients or the market.

For these reasons, a one-size-fits-all approach to small company financing may not fully serve the needs of life science innovation. A software or consumer startup may be able to validate a product and reach early revenue with limited capital. By contrast, a promising life science company may need millions of dollars simply to reach an IND-enabling study, a first-in-human trial, a regulatory milestone, or a manufacturing readiness milestone. Financing delays in this sector do not only affect company growth; they may delay new therapies, diagnostics, medical technologies, manufacturing capabilities, high-quality jobs, and ultimately patient access to innovation.

I respectfully recommend that the SEC recognize the unique capital formation needs of life science companies as it develops its strategic priorities for the next five years. In particular, the Commission should consider modernizing pathways such as Regulation Crowdfunding and Regulation A to better support capital-intensive innovation while maintaining strong investor protections.

First, the SEC should consider increasing the annual Regulation Crowdfunding limit for life science and similarly capital-intensive innovation companies. The current $5 million annual limit may be too low for many biotechnology, medtech, diagnostics, and healthcare technology companies to reach meaningful development milestones. A higher limit, such as $20 million, could make Regulation Crowdfunding more

useful for companies that have strong scientific foundations, clear development plans, and responsible disclosure practices. Any increase should be accompanied by appropriate safeguards, including clear risk disclosures, anti-fraud protections, use-of-proceeds disclosure, milestone reporting, and balanced communication standards.

Second, the SEC should create smoother pathways from Regulation Crowdfunding to Regulation A and other larger financing structures. Life science companies often need staged financing. A company may begin with smaller investors, patient communities, physicians, scientists, or syndicate investors, but then require larger pools of capital to advance clinical development, manufacturing, or commercialization. A clearer and more efficient pathway from early exempt offerings to larger offerings would reduce legal uncertainty and transaction friction, helping companies raise capital in a more disciplined and transparent manner.

Third, the SEC should simplify communications rules so that founders, scientists, and executives can educate potential investors while still maintaining strong investor protections. Life science companies often involve complex science, long development timelines, regulatory risks, clinical risks, and reimbursement considerations. Investors need clear, understandable, and balanced information. Overly complex or uncertain communication rules may discourage responsible investor education and increase legal costs, especially for smaller companies. The Commission should encourage practical disclosure frameworks that allow companies to explain the science, development plan, risks, and milestones in plain language.

Fourth, regulatory certainty should be treated as a competitive advantage for the United States. Life science innovation is increasingly global. Capital, talent, clinical development, manufacturing, and licensing opportunities can move across borders. If U.S. capital formation rules are clear, modern, and appropriately tailored, the United States can remain the leading environment for life science entrepreneurship, patient-focused innovation, and responsible investment. If the rules are overly uncertain or unnecessarily costly, early-stage companies may delay development, seek capital elsewhere, or move important innovation activity outside the United States.

I strongly support the SEC's continued commitment to investor protection. Modernizing capital formation rules should not mean weakening protections. Rather, the goal should be to create a more effective balance: allowing legitimate life science companies to access sufficient capital while ensuring that investors receive clear disclosures, realistic risk explanations, and protection against fraud or misleading claims.

I respectfully encourage the Commission to engage directly with biotechnology founders, medical technology entrepreneurs, patient advocates, physicians, university researchers, CROs, CDMOs, manufacturers, syndicate investors, and other life science ecosystem participants when evaluating capital formation policy. These stakeholders can provide real-world insight into how securities regulations affect innovation, patient access, manufacturing, and U.S. competitiveness.

Thank you again for the opportunity to comment. I appreciate the Commission's consideration of the unique financing challenges facing biotechnology and other life science companies as it develops its strategic priorities for fiscal years 2026 through 2030.

Respectfully submitted,

Jim Wu
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BLPN Lifetime Founding Member