July 21, 2020

Vanessa Countryman  
Secretary  
Securities and Exchange Commission  
100 F Street NE  
Washington, DC 20549-0609


Dear Secretary Countryman,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments to the Securities and Exchange Commission’s (SEC) proposed amendments to the exempt offering framework to promote capital formation for entrepreneurs and simplify the current exempt offering reporting structure while increasing opportunities for investors and enhancing protections.

BIO represents nearly 1,000 companies in the biotechnology industry across the United States. Our members are responsible for innovating the next generation of treatments, diagnostics, and cures that will secure the health and safety of our Nation. Even in today’s uncertain times, America’s small biotechnology (biotech) companies, both public and private, continue to lead efforts to address the most devastating health risks and diseases in the world.

In fact, 76% of all global research and development (R&D) aimed at tackling the COVID-19 pandemic is generated by small biotech companies.¹ Small biotech companies are also responsible for 80% of all scientific R&D.² Almost all of these companies started as a revolutionary idea in a laboratory that was nurtured by private market financing, such as exempt offerings.

The Central Role of Private Markets in Entrepreneurship and Innovation

BIO members are some of the biggest beneficiaries of the current structure and function of funding markets in the United States. Private markets are instrumental in helping biotechnology companies get started on the 10 to 15-year journey needed to gain regulatory approval and introduce novel products to markets. Private offerings allow entrepreneurs to take that first step out of the lab and into the real world where few pass the rigorous regulatory, but those that do will provide therapies and products that will offer patients, farmers, and consumers across the world a better standard of living. Importantly, exempt offerings help support the first few critical years of research, team building, and enterprise maturity required to graduate to venture rounds and ultimately public markets.

The entrepreneurs BIO represents do not view fundraising as a binary decision between public or private capital, but rather as a continuum where regulatory burdens grow in tandem with access to larger pools of capital. As such, expanding private markets need not constitute a de facto deterrent to public markets. Both private and public markets are accessed based on company specific needs for financing.

Therefore, BIO applauds the SEC for its ongoing efforts to improve capital formation for companies, particularly early-stage and emerging growth companies. Access to capital at various stages of growth is necessary to foster American innovation in an increasingly competitive global market, particularly for the next generation of scientific and technological discoveries.

Exempt offerings, such as from Regulation Crowdfunding (Reg. CF) and Regulation A (Reg. A), have broadened access to capital for entrepreneurs including from their local communities and previously unavailable sources.

The exempt offerings framework, however, has become increasingly complex over the years. This regulatory complexity has created challenges to resource-constrained entrepreneurs as they consider new funding rounds. BIO supports and commends the SEC’s efforts to harmonize, streamline, and simplify the exempt offering framework and increase offering limits to encourage entrepreneurship in America and investment in American innovation. BIO also offers two recommendations that the SEC should consider as it finalizes changes to the exempt offering framework.

**Summary of recommendations:**

- **Raise Regulation A Tier 2 funding limits to $100 million and streamline reporting requirements.**
- **Promote secondary liquidity for exempt offerings by preempting state securities regulations on secondary sales, encouraging the participation of institutions in exempt offerings, allowing the securitization of exempt offerings for retail investors, and by reducing Rule 144 holding periods.**

The combination of these measures will ensure a more stable, more efficient, and more resilient ecosystem of entrepreneurial funding sources as accredited investors and institutions are able to transfer risk among each other over their respective investment horizons while allowing some access for retail participants via pooled investment vehicles and other such securitized structures. A system such as this will maintain existing accredited investor protections, maximize corporate maturity before IPO, accelerate American innovation, and lower the aggregate cost of capital in the economy.

**Discussion**

BIO supports transparent and reliable capital markets, both private and public, that allow companies to efficiently “graduate” or transition across funding structures while minimizing overlap in reporting and disclosure burdens. Disclosures and reporting obligations should scale as a company matures and seeks to access ever-broader pools of diverse investors.

BIO contends that private markets should not to be regulated in the same manner as public markets, as this defeats the foundational premise upon which private markets are based—mainly, that this is an area for professional persons with the knowledge and risk tolerance to participate. In short, disclosures and reporting obligations should fit each successive level of corporate maturity and adequately balance against the sophistication of the investors but, moreover, the mix of investors in a pool of capital. This belief supports the intent of the SEC’s proposed amendments and buoys the following recommendations.
Raise Regulation A Tier 2 funding limits to $100 million and streamline reporting requirements.

In keeping with the spirit of the JOBS Act, the SEC’s mission, and the SEC’s proposed amendments to the exempt offering framework, BIO recommends that the SEC raise the Regulation A Tier 2 limits to $100 million instead of $75 million.

Regulation A (Reg A) has been in existence since 1936 but it was not until JOBS Act reforms were implemented in 2015 that the offering saw increased uptake. Despite these increased volumes, however, Reg A remains an underdeveloped offering, particularly for biotechnology companies. By increasing the offering limit to $100 million, the amount of funding raised would enable biotech startups to gather more evidence for their scientific endeavors and build out a mature company structure before becoming public companies, a process that has been rushed due to the lack of stability, liquidity, and cost efficiency in private funding markets.

The beauty and utility of Regulation A Tier 2 offerings is in that they introduce companies to the obligations and expectations of a mature, reporting company. In addition to a Tier 2 offering having to be qualified by SEC staff, companies are required to submit audited financial statements and are subject to ongoing reporting requirements, such as annual and semiannual reports. This provides founders with an on-ramp to ease into the reporting framework of the Exchange Act.

However, there is little reason for reporting under Exchange Act Sections 12(b) and 12(g) at the early stage in the lifecycle of a company. BIO recommends a permanent exemption from Section 12(b) and Section 12(g) reporting for Regulation A Tier 2 offerings as this contradicts the spirit of the JOBS Act by treating exempt securities as registered securities. At an early stage in the lifecycle of a company, there is little to report to accredited investors every quarter. Further, the burden of reporting under Exchange Act Section 13(d), Section 13(e), Section 14, and Section 16 is unwarranted for a small company, particularly small biotechs that do not generate revenue until therapies are approved and introduced to markets (a journey that can take a decade or more). This disincentivizes the uptake of Regulation A Tier 2 offerings and pushes companies to enter public markets at a time when they are not mature enough to do so.

Evidence of this has been shown in Nasdaq’s report of companies that chose to complete both a Nasdaq listing and a Reg A offering in tandem. Nasdaq subsequently issued a requirement for a certain minimum operating history for Regulation A companies prior to listing on the exchange.

One of the key drawbacks faced by biotech companies that go public too early is the threat of class action lawsuits brought at the state level by public securities investors. These lawsuits are due to a lack of sufficient safe harbors for the uncertainties tied to the FDA approval process and due to the fact that securities class action jurisdiction remains at the state level, per the Securities Act of 1933, instead of at the federal level, as made explicit for claims brought in relation to the Exchange Act of 1934.

Raising the offering limit to $100 million would extend the runway for biotechnology companies to mature both their science and their management team before going public and would help mitigate the losses from frivolous lawsuits once they are public.

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3 SEC Release No. 33-632, January 21, 1936
enhances the spirit of the JOBS Act and Regulation A offerings, in particular, as a “mini IPO” or “IPO onramp.”

If the intention of Reg A offerings is to serve as an on-ramp to public markets, then the disclosure and reporting structure should reflect this. The validity of the program is drastically diminished when the benefits are completely countered by the reporting requirements of the offering and the amount of resources required to comply. BIO urges the Commission to align exemptive relief with reporting obligations to maintain the spirit of the JOBS Act and allow the Reg A market to come to fruition.

Finally, private and public markets have distinct reporting and disclosure requirements precisely because there is a higher standard applied to the investors that directly participate in private markets. Companies are required to conduct adequate due diligence to verify that these persons are indeed accredited investors, which by their very classification as defined by the SEC, should have the risk tolerance, investing history, and knowledge to bare the risks associated with exempt offerings of new and early ventures.

BIO encourages the SEC to ensure that private markets and public markets do not converge in reporting and disclosure requirements as this would eventually lead to demise of one market or the other. Enhancing liquidity in exempt markets is a great method for ensuring that novice accredited investors have the ability to transfer risk to more seasoned investors while lowering the cost of capital and barrier to entry of entrepreneurship.

**Promote secondary liquidity for exempt offerings by preemting state securities regulations on secondary sales, encouraging the participation of institutions in exempt offerings, allowing the securitization of exempt offerings for retail investors, and by reducing Rule 144 holding periods.**

Expanding the Regulation A Tier 2 exempt offering will also require careful consideration for the liquidity requirements of accredited investors that participate in these markets. BIO supports the SEC’s efforts to address secondary market liquidity for both exempt and listed securities. As noted in the SEC’s Concept Release on Harmonization of Securities Offering Exemptions, “an investor’s willingness to participate in an exempt offering and the price he or she would be willing to pay may depend on the investor’s assessment of whether, when, and on what terms the security can be resold.”

However, the issue with Regulation A Tier 2 offerings is that secondary sales face a complex web of disparate state securities regulations, leaving investors and companies searching for the most appropriate state in which to conduct such sales. **BIO, therefore, supports the preemption of state securities requirements governing the secondary sale of Regulation A Tier 2 exempt offerings.** The SEC’s Small Business Forum has recommended this proposal for two consecutive years.6,7

This would lower costs for companies raising capital and accredited investors alike while expanding liquidity of Reg A Tier 2 exempt offerings. Enhanced liquidity in the exempt offering market can also increase participation in offerings as larger deal sizes pave the way for the participation of institutions.

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6 [https://www.sec.gov/info/smallbus/gbfor37.pdf](https://www.sec.gov/info/smallbus/gbfor37.pdf)
While private markets have become incrementally more liquid for accredited investors, the expansion of access to exempt offerings and private markets to retail investors through various investment vehicles has also incrementally improved. But more can be done.

**BIO supports the SEC’s efforts to democratize the wealth creation potential these offerings present and recommends incrementally expanding access to these investment opportunities to Main Street investors via pooled investment vehicles, interval funds, business development companies, and mutual fund vehicles.**

As the United States Department of the Treasury stated in a recent report, “in addition to encouraging companies to become public, it is equally important to consider methods to increase investor exposure and opportunity to the private markets as well.**

Larger deal sizes and enhanced secondary market liquidity may help mutual funds overcome limitations that have historically prevented their participation in exempt securities and in the equity ownership of small capitalization companies. The prevalence of liquid alternatives in the mutual fund and asset management industries provide an existing structure from which to argue the case for the securitization of Reg A Tier 2 exempt offerings to offer retail investors some exposure to the private market.

Pooled investments of private securities, in general, pose no greater risk than highly leveraged exchange-traded funds, exchange-traded funds linked to front-month commodity futures contracts, or exchange-traded notes linked to volatility derivatives, which despite catastrophic market dynamics, continue to trade on exchanges and are provided to retail investors. While it is impossible to expect intraday liquidity for private offerings, there are existing equity structures with more adequate provisions to address the liquidity limitations of the exempt offerings.

The United States Department of the Treasury recently suggested that due to “limited redemption rights, closed-end funds can more easily invest in thinly traded securities and private startup companies.** Thus interval funds and closed-end funds can make ideal vehicles for providing Main Street investors with the economic exposure and diversification offered by exempt offerings while providing the private market much needed liquidity.

The SEC should, at minimum, implement a pilot program extending the ability of retail investors to participate in pooled investment vehicles of private securities to gauge investor interest, the ability for public markets to absorb these securities, and the liquidity enhancements in private markets.

Of note, non-accredited retail investors are already participating in other exempt offerings provided that broker dealers serve as intermediaries. This provides sufficient evidence and case to recommend a pilot program for the securitization of a pool of private securities into retail products.

Finally, **BIO recommends a reduction in the holding period requirements of Rule 144,** which are applied to securities of reporting companies that also offering exempt securities, the holding period of which is six months, and restricted securities of non-reporting companies, the holding period of which is twelve months. BIO recommends a reduction in the holding period to three months and six months, respectively. This reduction would further enhance liquidity and support growth for small biotechs.

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Conclusion

The SEC’s proposals are a crucial step in making the exempt offering system of funding more efficient for companies and more liquid for investors, which can lower the cost of capital in the innovation economy and for all entrepreneurs who dare to take the leap from idea to product.

BIO supports and praises the SEC’s efforts to harmonize, streamline, and simplify the exempt offering framework; to increase exempt offering limits; and to expand access to these investment vehicles to more investors as these policies will encourage American entrepreneurship, investment in American innovation, and extend the potential for wealth creation to more Americans. BIO’s proposed amendments will provide time for companies to mature before entering public markets, will lower the cost of capital, and will make a company’s transition from early-stage venture to exchange-listed company in a more efficient and more prudent manner while maintaining investor protections that are most appropriate at each stage of investment.

BIO believes that the combination of increasing the limits for Regulation A Tier 2 offerings, facilitating the secondary trading of Reg A securities, and creating incentives for participation of mutual funds and other institutions in the exempt market will unleash a new wave of capital formation for small business innovators and expand wealth creation opportunities for investors across the spectrum.

BIO looks forward to working with the SEC on these important issues. If we can provide further information regarding these comments, please contact me at cpasseri@bio.org.

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