



June 16, 2020

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

Re: File No. S7-25-19: Amending the "Accredited Investor" Definition

Dear Secretary Countryman,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments to the Securities and Exchange Commission (SEC) proposed amendments to the definition of "accredited investor" in the Commission's rules and the definition of "qualified institutional buyer" in Rule 144A under the Securities Act of 1933.

BIO represents nearly 1,000 biotechnology companies across the United States, the vast majority of which are small, pre-revenue companies that, by their very nature, are in a highly specialized sector of the economy populated by subspecialties, all of which require decades of study to acquire expertise. Biotechnology investors also tend to be very specialized, with most having scientific backgrounds in order to properly assess, understand, and price the risks associated with a scientific endeavor, the timelines involved, and the probabilities associated with the regulatory approval process. As a result, emerging biotechnology companies must rely on a very narrow segment of available capital from these investors for seed funding and capital raising efforts.

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 discoveries. Private market offerings are instrumental in helping biotechnology companies get started on the 10 to 15-year journey to FDA approval and introduction to markets. Even in today's uncertain times, America's small biotechnology companies continue to lead global 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 coming from small biotechnology companies, and American companies account for 51% of all global COVID-19 R&D.¹ It should also be noted that small biotech companies are responsible for 80% of the R&D for novel therapeutics to address the myriad of debilitating diseases affecting society.²

BIO, therefore, welcomes the SEC's proposed expansion of the current Accredited Investor Definition, and offers additional recommendations to enhance the *Definition* to accommodate the unique circumstances of emerging biotechnology companies.

¹ <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/therapeutic-development/bio-covid-19-therapeutic-development-tracker>

² <https://www.iqvia.com/insights/the-iqvia-institute/reports/emerging-biopharmas-contribution-to-innovation>

Summary of recommendations:

- Expand the proposed test of demonstrating an individual's background and understanding in the areas of securities and investing to also include demonstrated background and understanding in the areas of the hard sciences for the specific purpose of participating in seed and early stage funding of biotechnology companies.
- Expand the professional certifications and credentials test to include possessing a Doctor of Philosophy (PhD) in the hard sciences, Medical Doctor degrees (MD), or Master of Science (MS) in hard sciences for the specific purpose of participating in the seed and early stage funding of biotechnology companies.

Discussion

Similar to how other jurisdictions are launching initiatives to address and support the specialized needs of biotechnology, such as Hong Kong's Chapter 18A listing regime^{3,4}, we believe that a narrow carve-out for biotechnology and life sciences investments is a positive step in the right direction towards facilitating capital formation for these critical companies. This notion also forms the basis for our recommendations outlined below and the philosophy guiding BIO's efforts to enhance access to capital and market liquidity for those companies that seek to change the world tomorrow but need help in financing their operations today.

Expand the "background and understanding" test to also include demonstrated knowledge in the hard sciences for the purposes of biotechnology and life sciences seed investing.

BIO supports creating additional categories of natural persons who qualify as accredited investors. BIO also seeks to democratize access to biotechnology companies in their growth stages by opening investment specifically to experts in the field that may not meet the current income limits and remain outside the scope of the current *Proposal*.

While these experts may not possess the financial sophistication posited by the *Definition*, they possess the technical sophistication needed to participate in seed and early stage capital raising efforts for biotechnology companies. In this regard, they stand above most of the investing and general population. These professionals have the expertise necessary to understand the value proposition, feasibility, and, importantly, the science behind therapeutics being developed by startup biotechnology companies. For this reason, BIO believes that the background and understanding of these professionals should be deemed adequate for the *Definition* in the narrow carve-out for biotechnology investments.

BIO shares a similar view to that expressed in many comment letters from the investment industry which posit that despite professional certifications and deep experience conducting financial research and due diligence to make recommendations to accredited investors, investment analysts cannot participate in the offerings themselves. BIO agrees that these investment research staff possess the technical expertise and sophistication required to invest in certain vehicles.

³ The Hong Kong Exchange (HKEX) Chapter 18A initiative was launched in 2018 and includes a specialized set of listing rules and disclosure requirements crafted specifically for pre-revenue biotechnology and medical devices companies and their investors.

<https://en-rules.hkex.com.hk/node/5193>

⁴ HKEX Guidance Letter, HKEX-GL107-20,

https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/g/l/gl10720.pdf



Similarly, BIO believes scientific professionals deserve the same treatment in the specific case of investing in early stage biotechnology companies. Scientific professionals are uniquely knowledgeable and experienced in this specialized field and can more accurately assess the risks of a scientific endeavor than the vast majority of investors, including many investment research analysts included in the *Proposal*.

Per the SEC's Investor Advisory Committee, an accredited investor must satisfy three factors: (1) the ability to access necessary information; (2) whether an individual can bear the economic risks, including illiquidity risks and potential loss of principal; and (3) whether an individual has sufficient knowledge and experience to evaluate the opportunity to make an informed investment decision without the full disclosure provided in a public offering.⁵

In the case of biotechnology investments, the scientific community stands out as the most qualified to understand the risks and make informed decisions on investments in novel sciences and trailblazing therapeutics. Scientists, by virtue of their decades of experience in academia, also know that time and a significant amount of capital are required to make these discoveries.

It is BIO's view that creating a carve-out for biotechnology investments and expanding the *Definition* to include scientific professionals will broaden the opportunities for capital raising efforts of biotechnology companies who must already contend with a very narrow, specialized sliver of capital allocators. We further believe that these modifications align with the SEC's intentions in the *Proposal* and with the spirit of Chair Clayton's stated mission to benefit the long-term interests of Main Street investors.⁶

Expand the "professional certifications and credentials" test to include PhDs in the physical sciences, MDs, and select MS degrees with research-driven thesis work in the physical sciences in the Accredited Investor carve-out for biotechnology and life sciences investments.

BIO acknowledges that, in the general terms of the *Proposal* as written, the category of *scientific* sophistication falls outside of the scope of the *Definition*, which is specifically written with respect to financial prowess. However, within the scope of biotechnology and life sciences investing, no financial designation or investment certification equals the degree of sophistication and expertise gained via graduate or professional education in the physical sciences or medicine.

As mentioned above, BIO agrees that industry analysts, whether they be in financial services research or in clinical research, should be able to invest in the products that they help to create. Indeed, in these scenarios, research analysts are relied upon for the development of products for accredited investors and in doing so have become knowledgeable and sophisticated in their respective fields. The *Proposal* acknowledges the gap in financial research but not in scientific research. It is our view that the Committee should expand the *Definition* to include professional and graduate degrees that demonstrate expertise in the scientific field for the purposes of biotechnology and life sciences investments.

Similar to how Chartered Financial Analyst® and FINRA designations are being proposed to certify financial expertise,⁷ we believe a PhD in a physical science, a MD, a PharmD, and/or a MS in a physical science provide a superior verification of sophistication and knowledge in the field of biotechnology and life sciences. No designation or certification can replace the

⁵ <https://www.sec.gov/spotlight/investor-advisory-committee-2012/investment-advisor-accredited-definition.pdf>

⁶ <https://www.sec.gov/news/testimony/testimony-clayton-2019-12-10>

⁷ <https://www.sec.gov/comments/s7-25-19/s72519-7159328-216511.pdf>



expertise of a PhD or the clinical relevance of a MD as these credentials are limited to the few who have studied for decades and have passed several exams to prove their expert-level of knowledge. While these professionals may not always meet the income and wealth tests in the current definition, they do possess unparalleled expertise in the field. BIO agrees with the comments made by the U.S. Chamber of Commerce that not allowing these subject matter experts to participate only exacerbates “disparities in income and wealth⁸” for these men and women who have dedicated their lives to solving society’s most pressing issues.

BIO also notes that most seed and venture investors that participate in biotechnology and life science capital raising efforts tend to have backgrounds in the physical sciences. This causes the industry to rely on a very small, specialized segment of capital owners. This means that the amount of capital and number of investors that can participate is inherently limited. By expanding the *Definition* to include credentialed scientific professionals with verified graduate or professional degrees in the sciences, it will unlock an opportunity set for capital raising and foster further innovation.

The SEC’s proposal is a crucial first step in expanding the universe of individuals that can participate in private markets. BIO’s proposed amendments will extend the opportunity for wealth creation to those who are innovating the next generation of therapeutics. Finally, BIO’s proposed amendments will benefit startups and their investors by expanding the investor base, thus providing more capital for biotechnology and life sciences companies so that they invest in hiring scientists and pursuing research and development. After all, there would be no better signal for the market than physicians and scientists supporting their own work and that of their colleagues by investing in these exempt offerings.

BIO looks forward to working with the SEC on this important issue and others that benefit the biotech sector entering and staying in the public markets. If we can provide further information regarding these comments, please contact me at cpasseri@bio.org.

Carlo Passeri
Director of Capital Markets and Financial Services Policy
Biotechnology Innovation Organization

⁸ <https://www.sec.gov/comments/s7-25-19/s72519-6960329-212743.pdf>