



April 8, 2016

Brent J. Fields
Secretary
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-0609

Re: File No. 4-692: *Report on the Review of the Definition of "Accredited Investor"*

To whom it may concern:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comment to the Securities and Exchange Commission (SEC) on File No. 4-692, its December 18, 2015, "Report on the Review of the Definition of 'Accredited Investor'" (Report).

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states. Because of the unique capital needs of biotech research (it can take more than a decade and upwards of \$1 billion to bring a single product to patients), BIO members depend on securities laws that increase access to investors and support the early-stage capital formation necessary to fund groundbreaking R&D. Emerging biotechs do not generate product revenue, but a strong capital formation ecosystem provides access to capital and supports their search for the next generation of medical breakthroughs.

BIO applauds the SEC for being willing to reexamine definitions and requirements that affect issuers and investors alike. BIO is concerned, however, that some of the proposed changes to the accredited investor definition would decrease the pool of investors eligible to participate in certain offerings, like those conducted under Regulation D, and would thus negatively impact capital availability for small biotech innovators and delay vital research.

Accredited Investors and Biotech Capital Formation

Policies that encourage capital formation are of paramount importance to growing biotechs, because investment capital is the lifeblood of scientific advancement. It costs \$1-2 billion or more to develop a single life-saving treatment, and most companies spend more than a decade in the lab before their first therapy is approved. During this long development process, virtually every dollar spent by a pre-revenue biotech comes directly from investors.

Because of this capital formation imperative, BIO was a strong supporter of the Jumpstart Our Business Startups (JOBS) Act in 2012, which was designed to increase capital availability and spur fundraising for a wide range of growing businesses. One of the particular provisions that BIO supported was the directive in Title II of the law for the SEC to lift the ban on general solicitation and general advertising then in place for offerings conducted under Regulation D. Regulation D allows small businesses to raise an unlimited amount of capital from an unlimited number of accredited investors and, in light of the reforms directed by the JOBS Act and implemented by the SEC, is an attractive capital formation option for a company seeking early-stage capital.



A large, diverse pool of accredited investors is obviously integral to the success of Regulation D – both the “traditional” Rule 506(b) offering pathway and the new Rule 506(c) pathway authorized by the JOBS Act. BIO supports an accredited investor definition that maintains a substantial group of investors that are able to provide the capital necessary to fund biotech R&D. The goal of the JOBS Act as a whole, and the Title II reforms to Regulation D specifically, was to increase access to capital for emerging companies. Amendments to the accredited investor definition that decrease the pool of investors eligible to participate in Regulation D offerings would be antithetical to the spirit of the JOBS Act.

As the biotech industry has continued to grow, having a diverse universe of investors and funding mechanisms has become even more important. The industry has grown beyond its original home in Boston and San Francisco – BIO has state affiliate organizations in 46 states, and the more than 73,000 biotech companies nationwide can be found in locales as varied as Bozeman, MT; Raleigh, NC; and Austin, TX. However, most “traditional” investors are still based on the coasts.

Communities across the nation have seen the economic impact that a thriving biotech industry can have, and stakeholders ranging from universities to state governments to local chambers of commerce are taking steps to attract emerging biotechs to Middle America. The economic growth that comes with the expansion of biotechnology to all 50 states cannot be supported without buy-in from local investors. Fortunately, investors across the country have an appetite for an industry that has the potential to improve quality of life for millions of patients while also delivering strong returns. However, both income and net worth are much lower (even among wealthier individuals) in the middle of the nation, and dramatic changes to the accredited investor standards could slow the nationwide growth of 21st century industries like biotechnology.

The San Francisco, New York, and Boston metropolitan areas rank first, second, and sixth in median household income. Venture capitalists in these financial hubs will likely not be impacted by a change in the accredited investor definition, but investors across the country who want to support innovative companies could be left out in the cold. The Angel Capital Association (ACA) has reported that nearly 80% of angel investments take place in an angel’s home region – and the Report makes clear that households in the Northeast and West have substantially higher income and net worth than those in the Midwest and South. Meanwhile, a 2014 ACA survey found that 25% of angel investors would no longer qualify as accredited investors if the eligibility thresholds were indexed to inflation – a dramatic impact for early-stage innovators outside of the coastal tech hubs. These angels support the innovation ecosystem in their local communities, and a substantial drop in eligible accredited investors could have a dramatic impact on growing companies.

With this impact in mind, BIO urges the SEC to be extremely cautious as it considers modifications to the accredited investor definition. The Report does not identify any specific investor protection red flags that have arisen under the current definition – indeed, it concedes that, despite the growth in the pool of accredited investors since 1982, SEC staff “is not aware of evidence suggesting that individuals qualifying as accredited investors under the current financial thresholds and participating in the Regulation D market require the protections of registration.” Absent a compelling investor protection concern, BIO believes that the existing definition suffices to limit the universe of investors eligible to participate in Regulation D offerings without negatively impacting capital availability for emerging innovators.

Preserving Eligibility for Investors Meeting the Current Accredited Standards

To the extent that the SEC makes changes to the accredited investor definition, BIO believes that it is imperative to maintain eligibility for the existing universe of accredited investors.



With regard to an issuer's current investors, BIO supports the Report's proposal that the SEC grandfather, for any and all of the issuer's future offerings, any investors who continue to meet the current accredited investor standards. Biotech investors often participate in successive rounds of financing as a therapeutic candidate moves through the clinical trial process; kicking investors out of upcoming rounds because of regulatory changes at the SEC would dilute their investment and punish, rather than reward, them for taking a chance on an early-stage innovator.

BIO also believes that the current financial thresholds should be maintained in some form for all investors (not just those grandfathered into a specific issuer's offerings). Completely removing a substantial portion of current investors from the accredited pool could have an immediate, drastic, and potentially devastating impact on capital availability for emerging companies. For example, an increase in the annual income test to \$500,000 for individuals and \$750,000 for married persons coupled with an increase in the net worth test to \$2.5 million (as proposed in the Report) would decrease the size of the accredited investor pool by nearly 65% if no provisions are included for investors meeting the current standards. Maintaining some eligibility for today's accredited investors would reduce the shock to the system while also preserving an investment outlet for individuals across the country who want to participate in the innovation economy.

The Report suggests allowing investors who meet the current standards but would fail the proposed standards to maintain their accredited investor status but be limited in their per-issuer investments to 10% of their income or net worth in a 12-month period. BIO believes that further research needs to be conducted into what percentage of their income or net worth accredited investors typically invest in Regulation D offerings in order for the SEC to fully understand the impact that the 10% limitation would have on capital availability. With that being said, however, BIO is concerned that the proposed limitation could be too restrictive.

Consider an angel investor in Kansas City with annual income of \$250,000 and net worth of \$900,000. Her income allows for substantial savings and investments given her location, yet she would just barely qualify as a conditional accredited investor despite her substantial net worth. A \$25,000 per-issuer investment limitation could impose an unfair cap on this individual's investment potential. At a minimum, BIO strongly believes that limited accredited investors should be able to invest up to 10% of *the greater of* their income or net worth, as is the case for non-accredited investors participating in Tier 2 offerings under Regulation A. (The Report is unclear on how the proposed 10% limitation would work, but it appears to read as a limitation based on the financial metric that the investor used to qualify as accredited. For the Kansas City investor, the Report would seem to apply the 10% limit to her \$250,000 income; BIO believes the limit should apply to her \$900,000 net worth.) BIO would also support an investment limit higher than 10% that would allow greater flexibility for angel investors and the start-ups they support.

In its proposed form (a 10% limit on the financial qualifier used to meet the accredited standards), BIO is concerned that the 10% metric will entirely foreclose participation by conditional accredited investors in certain offerings. It is not as simple as forcing investors to contribute a reduced amount to an offering – many financing rounds have minimum investment limits, so reducing an investor's contribution potential below that minimum would prevent them from investing *at all* rather than just limiting their investment. If the Kansas City investor above wants to participate in a Regulation D offering with minimum contributions of \$50,000, she cannot simply reduce her investment to \$25,000 – she must instead take a pass on the investment opportunity entirely (despite her \$900,000 net worth), robbing her of potential returns and the company of critical funds. This investor will have met all of the SEC's standards to qualify as accredited, but she will still be prohibited from investing. In order to ensure that investors in all areas of the country continue to have a stake in the innovation



economy, BIO encourages the SEC to consider reforming the Report's 10% proposal by applying the limitation to the greater of an investor's income or net worth and/or by increasing the 10% limit.

Additionally, BIO is hopeful that implementation of an investment limit will not impose compliance obligations on companies conducting Regulation D offerings. Issuers relying on the Rule 506(c) exemption are already required to take "reasonable steps" to ensure that purchasers in their offerings are accredited investors. Some companies are concerned that even this requirement is too onerous and are instead reverting back to the pre-JOBS Act Rule 506(b) – would the Report's 10% proposal require companies to verify, not only an investor's accredited status, but also her specific income or net worth and the percentage thereof that she plans on investing? Such a requirement would further discourage issuers who are considering a Regulation D offering to fund their research.

BIO's positions on both the grandfathering proposal and the 10% proposal are consistent with BIO's belief that the existing financial standards are sufficient to protect investors while still supporting capital formation – and that the current metrics continue to enhance investment in capital-intensive industries. To the extent that changes are made to the income and net worth thresholds, the SEC should not indiscriminately remove a large universe of investors from eligibility – which, as discussed, could have a drastic impact on start-ups in undercapitalized areas of the country. Instead, the SEC should exercise caution, allowing individuals who have \$200,000 in income or \$1 million in net worth to maintain their accredited eligibility, even if their investment potential is more limited going forward. Regardless of how conditional accredited status is implemented, BIO strongly believes that the existing universe of accredited investors should remain accredited.

Other Measures of Sophistication

BIO applauds the SEC staff for including in the Report proposals of numerous alternative methods for individuals to qualify as an accredited investor. BIO believes that these potential standards reflect the reality that income and net worth are not the only measures of an individual's financial sophistication, and we appreciate the commonsense solutions offered by the Report.

One group of potential sophistication measures would evaluate an investor's investment experience – for instance, by permitting individuals with a minimum of \$750,000 in investments or investments in 10 exempt offerings to qualify as accredited investors. Another group of measures would allow individuals with certain professional certifications to qualify as accredited, including the Series 7, Series 65, and Series 82 exams. The Report also floats the idea of an accredited investor exam administered by the SEC.

BIO has not taken a position on any one measure of sophistication, but, taken as a group, these methods would ensure that qualified individuals would be eligible for accredited investor status, irrespective of their income or net worth. In a world where the SEC is considering increasing the income and net worth thresholds, BIO believes that it is vitally important for alternative sophistication methods to be available for investors who are willing and able to support the capital formation ecosystem necessary to fund biotech research.

Conclusion

As the SEC considers changes to the accredited investor definition, BIO urges it to be mindful of the legislative intent of Title II of the JOBS Act (and, indeed, the JOBS Act as a whole) – providing greater access to capital for job creators. Modifications that drastically reduce the accredited investor pool or place burdens on potential accredited investors could reduce the



flow of capital to early-stage businesses. In the biotech industry, a lack of financing could mean that promising therapeutic candidates are left to gather dust on the laboratory shelf.

On the other hand, reforms to the accredited investor definition that reflect the reality that a diverse universe of individuals across the country want to invest in exciting, innovative industries like biotechnology – and are ready, willing, and able to do so – could enhance capital formation and support the search for the next generation of medical breakthroughs.

BIO looks forward to working with the SEC to ensure that any changes to the accredited investor definition result in a strong capital formation ecosystem for groundbreaking R&D. If you have further questions or comments, please contact me or Charles Crain, Senior Manager of Tax & Financial Services Policy, at [REDACTED].

Sincerely,

A handwritten signature in black ink, which appears to read "E. Cartier Esham". The signature is fluid and cursive, with a large initial "E" and a long, sweeping tail.

E. Cartier Esham
Executive Vice President, Emerging Companies
Biotechnology Innovation Organization (BIO)