March 11, 2014

Elizabeth M. Murphy
Secretary
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-1090

Re: File No. S7-11-13: *Proposed Rule Amendments for Small and Additional Issues Exemptions Under Section 3(b) of the Securities Act*
(Release No. 33-9497; Release No. 34-71120; Release No. 39-2493)

To whom it may concern:

The Biotechnology Industry Organization (BIO) is pleased to submit comments to the Securities and Exchange Commission (SEC) on File Number S7-11-13: *Proposed Rule Amendments for Small and Additional Issues Exemptions Under Section 3(b) of the Securities Act*.

BIO is a not-for-profit trade association that represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states. BIO members are working toward groundbreaking cures and treatments for devastating diseases, developing technologies for advanced biofuels and renewable chemicals, and researching novel gene traits for identifying food sources that could help combat global hunger.

In the biotechnology industry, it can take more than a decade and over $1 billion to bring a single life-saving treatment from laboratory bench to hospital bedside. Further, the entire process is undertaken without the benefit of product revenue. Early-stage biotech companies do not have the luxury of using the sale of one product to finance the development of another. Rather, the entire cost of drug development is borne by external investors.

For this reason, growing biotech companies had reason to be optimistic when Congress passed the Jumpstart Our Business Startups (JOBS) Act in 2012, which was designed to increase capital availability and spur fundraising for a wide range of businesses. In particular, BIO was optimistic about the directive in Title IV of the law for the SEC to create a new class of securities under Section 3(b)(2) of the Securities Act modeled after those eligible for the existing Regulation A exemption authorized by Section 3(b)(1).

This new exemption, colloquially known as Regulation A+ but now titled Tier 2 by the proposing release, will allow issuers to conduct offerings of up to $50 million without incurring the onerous compliance burdens of an Exchange Act reporting company. BIO believes that the increased offering limit of $50 million – a significant change from the $5 million limit under the existing Regulation A exemption (now called Tier 1) – will provide a valuable fundraising option for capital-intensive biotech companies. The relative ease of conducting a Tier 2 offering is extremely important to growing biotechs given their need to efficiently use investment capital, and the increased offering limit will better reflect the reality that groundbreaking research is a costly endeavor.

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BIO applauds the SEC for taking action to implement Title IV of the JOBS Act. Once the proposed rule becomes final, it will open up a new avenue to capital formation to fund groundbreaking research at small businesses across the country. BIO appreciates the opportunity to comment on the following items in the proposed rule.

Qualified Purchaser Definition

Pursuant to Section 401(b) of the JOBS Act, securities purchased in a Tier 2 offering would be treated as covered securities if they are either offered or sold on a national securities exchange or offered or sold to a qualified purchaser. The law gives the SEC latitude to define qualified purchaser.

Because these securities will likely not be traded on the national exchanges, the qualified purchaser definition chosen by the SEC will be extremely impactful on the utility of Tier 2 for emerging biotechs. Covered securities are exempt from state securities restrictions and regulations, and benefit from a uniform set of rules governing their offering. The complexity inherent in complying with divergent securities law in all 50 states could discourage issuers from conducting Tier 2 offerings. BIO strongly believes that there should be one national standard for securities offered or sold using the new exemption under Regulation A.

The proposed rule would define qualified purchaser as any offeree or purchaser in a Tier 2 offering. **BIO strongly supports the SEC's proposed qualified purchaser definition.** This definition would preempt state securities law for Regulation A offerings and avoid a costly roadblock for emerging biotechs considering such an offering.

The proposing release notes that "the cost of state securities law compliance…would discourage market participants from using the new exemption." BIO agrees. Because emerging biotechs do not generate product revenue, capital spent on regulatory burdens comes directly from investment dollars – a costly diversion of funds from science to compliance. Given that the goal of the JOBS Act was to *increase* capital availability, requiring issuers to spend dollars to "analyze and comply with separate registration or qualification requirements, or to identify and comply with applicable exemptions, in each state in which they intend to offer or sell securities under revised Regulation A" would fly in the face of Congressional intent. Thankfully, the SEC has recognized this reality and the proposed rule would not subject issuers to 50 levels of state review. BIO applauds this decision and strongly supports maintaining the proposing release's qualified purchaser definition in the final rule.

The proposing release discusses the coordinated review program put forth by the North American Securities Administrators Association (NASAA). BIO commented on this proposal, and commends NASAA for taking steps to lessen the review burden on issuers considering a Tier 2 offering. However, BIO has serious concerns about the utility and usability of a coordinated review program. It is unclear at this point to what standard the examiners in the program would adhere – consolidating review would do little good if NASAA or the examiners simply adopt the most stringent, burdensome option available. Further, the comments or corrections submitted by the participating jurisdictions to the lead examiner could lead to a morass of conflicting, state-specific questions for the issuer.

BIO believes that the SEC's proposed qualified purchaser definition is a much simpler and more effective approach to "protect offerees and investors in Regulation A securities, while streamlining compliance and reducing transaction costs." BIO's strong preference is to

preempt state securities law by maintaining a qualified purchaser definition that encompasses all offerees and purchasers in a Tier 2 offering, regardless of whether NASAA moves forward in implementing a coordinated review program at the state level.

A requirement to comply with 50 sets of regulations, even under the guise of coordinated review, could dissuade growing biotechs from considering a Tier 2 offering as a capital formation option and undercut the effectiveness of Title IV of the JOBS Act. The SEC should maintain its proposed qualified purchaser definition.

Testing the Waters and Confidential Filing

The proposed rule would echo Title I of the JOBS Act by allowing Regulation A issuers to submit a draft offering statement for non-public review by the SEC and to conduct testing the waters meetings to gauge investor interest in a potential offering. These two provisions are already available to emerging growth companies (EGCs) conducting a public offering under Title I's IPO On-Ramp, and biotech issuers have greatly benefited from the new rules. **BIO supports both testing the waters and confidential filing for issuers conducting Regulation A offerings.**

Testing the Waters

More than 70 small biotechs have gone public since the JOBS Act became law in April 2012, and the vast majority have utilized the ability to conduct testing the waters meetings. Biotech CEOs have reported that testing the waters substantially increased investor awareness of their company and also helped them generate investor interest, anticipate potential investor concerns in advance of the roadshow, and determine target pricing for their offering. For growing biotech companies, which conduct intricate scientific research and development for more than a decade and are then subject to the complicated process of FDA approval, testing the waters meetings are extraordinarily beneficial. The additional time with investors allows companies to clarify questions relating to their technology, regulatory pathway, and commercial story in a way that is simply not possible in a traditional roadshow meeting.

BIO believes that companies considering Regulation A offerings would see similar benefits from testing the waters and applauds the SEC for maintaining the ability of issuers to conduct these meetings. BIO also believes it is important to maintain the ability to conduct testing the waters meetings both before and after an offering statement is filed.

BIO does not, however, support the SEC's proposal that solicitation materials from testing the waters meetings be required to be filed and be made available to the public. Any relevant information about the offering would already be included in the offering statement, which would of course be reviewed by the SEC and made available to the public. Requiring solicitation materials to be filed would create a new compliance burden for small issuers and could decrease the effectiveness of testing the waters meetings. The proposing release notes that such a requirement would be a departure from the treatment of solicitation materials under IPO On-Ramp testing the waters, but the overwhelming success of that provision as it exists should caution the SEC not to complicate it for Regulation A offerings.

If the SEC does require that solicitation materials be filed with the SEC and be made public, BIO supports the proposed amendment to Rule 254 that would rescind the requirement that issuers submit the materials at or before the time of first use. Allowing solicitation materials to be submitted to the SEC when the offering statement is either submitted for non-public review or filed would still provide information to the SEC and the public without

requiring issuers to maintain rolling submission of materials with each testing the waters meeting.

Further, BIO does not believe that filing solicitation materials should be a condition of the Regulation A exemption. Because these materials will likely not provide much additional insight for investors or the SEC beyond the offering statement, inadvertently omitting them should not disqualify an issuer from conducting a Regulation A offering. Additionally, BIO believes that there should be a cure period for inadvertent failures to submit or file solicitation materials.

Confidential Filing

Similar to testing the waters, the vast majority of the 70-plus biotech EGCs that have undertaken an IPO since the JOBS Act passed have filed their registration statements confidentially with the SEC for non-public review. Decision-makers in these small businesses have said that the confidential review process led to decreased scrutiny from the media while their company waited for the right market conditions to finalize the offering. They have also reported a more constructive dialogue with the SEC during the revisions process and a reduced risk of market perception failure if the company decided not to go forward with the offering. The ability to file confidentially has been very helpful to biotech IPOs, and BIO believes that it should be extended to Regulation A offerings.

Eligible Issuers

Potential Limits on Issuer Size

The proposing release solicits comment on whether the SEC should adopt any limitations on the size of issuers eligible to rely on the Regulation A exemption. Any such restriction would limit Regulation A to only the smallest of issuers. While most biotech companies would pass the "eye test" to be considered a small business, the existing definitions that categorize issuer size are wildly inaccurate and do not reflect the true nature of emerging biotech companies. Limiting eligibility for Regulation A and/or Tier 2 to companies that meet an outdated size definition would exile from the exemption the very companies for which Congress intended to open new capital formation outlets. **BIO opposes restricting Regulation A eligibility based on issuer size.**

The proposing release specifically suggests the smaller reporting company definition as an option to restrict Regulation A eligibility, which would limit the exemption to companies with a public float below $75 million. Despite their simple corporate structure, few employees, and lack of product revenue, many biotech companies have a relatively high public float. Groundbreaking research is costly and biotech IP is valuable, but judging small companies solely by their market value leads to an inaccurate classification and subjects them to an outsized regulatory burden. In this case, it could stymie their research by prohibiting them from conducting an offering under Regulation A.

BIO has long supported reform of the smaller reporting company and non-accelerated filer definitions. The proposing release mentions a recommendation of the SEC's Advisory Committee on Small and Emerging Companies that would reform the definition to include issuers with a public float of up to $250 million. The SEC's Government-Business Forum on Small Business Capital Formation has for years supported a similar recommendation. BIO's position is that the smaller reporting company and non-accelerated filer definitions should be reformed to include any issuer with a public float below $250 million. BIO also believes that a revenue test should be added to the definitions, so that any issuer with annual

revenues below $100 million that is not a large accelerated filer would be considered a non-accelerated filer or smaller reporting company.

Regardless of the parameters for smaller reporting companies and non-accelerated filers (on which BIO urges the SEC to take separate action), BIO does not believe that issuer size should be a determining factor in eligibility for the Regulation A exemption. The statutory limit on the size of Tier 2 offerings suffices to limit the pool of interested companies without unfairly banishing valuable biotechs that are in dire need of capital to fund their research.

Reporting Companies

The proposed rule would maintain the existing prohibition on reporting companies conducting offerings under Regulation A. The current exemption only allows a capital raise of up to $5 million, so the reporting company prohibition does not bar many issuers from Regulation A because few would consider $5 million to be an impactful influx of capital. However, the new capital limits under Tier 2 enhance the utility of Regulation A, and reporting companies might want to consider a raise of up to $50 million under the new exemption. BIO believes that the SEC should consider allowing reporting companies to conduct Tier 2 offerings, provided that they are current on their existing reporting requirements. Reporting companies do have capital formation options through Forms S-1 and S-3, but the new Tier 2 exemption could provide them with a new avenue to capital formation.

Capital Efficiency and the Regulatory Burden under Regulation A

As previously noted, emerging biotech companies operate without product revenue to fund the decade-plus, billion-dollar R&D timeline intrinsic to scientific advancement. A biotech small business considering a Regulation A offering will want to use its capital as efficiently as possible in order to maximize the available offering proceeds to be used for research. The $50 million capital influx available under the new Tier 2 would have a dramatic impact on a growing biotech innovator, so the SEC should ensure that any rules and regulations attached to the offering process do not present an overwhelming or unnecessary cost burden for small businesses seeking research funding.

Form and Content

The proposing release makes several changes to Form 1-A, which is required of all issuers conducting a Regulation A offering. BIO supports the proposed modifications to Part I of Form 1-A and applauds the SEC for moving to a convenient online submission requirement.

However, BIO has concerns with the proposed changes to Part II of Form 1-A. The offering circular is the most important part of the Form and changes to it will have a direct impact on companies considering a Regulation A offering. The proposed rule would eliminate Model A, which under the existing Regulation A allows companies to provide narrative information about their business using a simplified question-and-answer format. Removing Model A as an option reduces company flexibility and imposes a heightened burden on small businesses filing for an offering.

The proposed rule would also modify Model B to make it more like Part I of Form S-1. By eliminating Model A and moving Model B toward Form S-1, the SEC is severely restricting the options that issuers have when filing for a Regulation A offering. In enacting Title IV of the JOBS Act, Congress sought to create an offering method separate and distinct from the traditional IPO process. Yet the proposed rule takes steps to conform the Regulation A filing

requirements with those of an IPO. BIO believes that Part I of Form S-1 should remain a disclosure option for Regulation A filings, but eliminating or marginalizing the other existing options makes for a poor menu of choices for issuers.

Financial Statements and XBRL

The proposing release solicits comment on whether issuers conducting Tier 2 offerings should be required to provide their financial statements to the Commission and on their corporate websites in interactive data format using the eXtensible Business Reporting Language (XBRL). **BIO strongly opposes an XBRL filing requirement for issuers conducting Tier 2 offerings.** The existing XBRL requirement places unnecessary burdens on biotech reporting companies, and it should not be extended to issuers under Regulation A.

Emerging biotech companies have limited financial and personnel resources in their compliance and finance departments, and any unnecessary compliance burdens increase their workload and costs for the company. Without product revenue, biotech companies conducting a Regulation A offering would be forced to ask investors to pay for XBRL reporting rather than scientific research.

In addition to instituting a new compliance burden for a small company's accounting department, XBRL is actually its own computing language – one that requires specific expertise outside the bounds of traditional financial or accounting training. Companies need experts in the XBRL language to properly file the appropriate reports, so small issuers turn to external contractors to complete their XBRL filings. The cost of an external XBRL contractor is significant for an emerging company, reducing the capital available for more vital functions like research and development.

Further, the information included in an XBRL report is often not indicative of the health of a smaller issuer. A biotech investor would be better served by comparing clinical trial results between companies rather than focusing on XBRL filings that do not tell the whole story of a company's progress. Because XBRL reporting does not provide much insight for potential investors in growing companies, the high cost of compliance far outweighs its benefits.

BIO supports an exemption from XBRL compliance for small public companies, and urges the SEC to take separate action to free them from a costly regulatory burden that does more harm than good. Irrespective of any action taken (or not taken) to provide regulatory relief to reporting companies, BIO opposes efforts to impose an XBRL requirement on issuers conducting Tier 2 offerings under Regulation A. The cost burden of such a requirement, and therefore the amount of capital diverted from R&D, would be significant – a harmful burden that would divert capital raised in the offering to reporting rather than research.

Conclusion

BIO applauds the SEC for taking action to implement Title IV of the JOBS Act and open up a new fundraising avenue for emerging biotech companies searching for the next generation of medical breakthroughs. BIO believes that the expanded Regulation A exemption could have an important impact on capital formation for the biotech industry and urges the SEC to expeditiously finalize the proposed rule.

As the SEC moves toward a final rule, BIO asks that it be mindful of the importance of resource efficiency for pre-revenue biotechs conducting costly and time-consuming

research. Small biotech companies are successful when they can dedicate investment capital to R&D, not bureaucratic red tape. BIO applauds the SEC for recognizing this reality by preempting state securities law through the proposed qualified purchaser definition. BIO is hopeful that the SEC will maintain this definition and allow growing biotechs to avoid the compliance burden that would come with a state-level filing requirement.

Capital formation is vital to the success of growing innovators conducting breakthrough R&D, and BIO is also hopeful that the SEC will not enact undue restrictions on issuer eligibility for Regulation A that would limit the universe of biotech job creators that could take advantage of the exemption.

BIO looks forward to working with the SEC to effectively implement reforms to Regulation A so that it will stimulate important capital formation to support the ongoing search for life-saving cures and treatments. If implemented successfully, the expanded Regulation A exemption will spur capital availability, company growth, and next generation research at innovative small businesses. If you have further questions or comments, please contact me or Charles Crain, Senior Manager of Tax & Financial Services Policy, at (202) 962-9218.

Sincerely,

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Biotechnology Industry Organization (BIO)