September 18, 2013

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

Re: Release No. 33-9416; Release No. 34-69960; Release No. IC-30595; File No. S7-06-13: *Amendments to Regulation D, Form D and Rule 156 under the Securities Act*

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 S7-06-13: *Amendments to Regulation D, Form D and Rule 156 under 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, 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 was viewed as having the potential to support biotech capital formation. BIO applauds the SEC for finalizing its rule implementing the changes mandated by the JOBS Act, and BIO members look forward to conducting offerings under the new Rule 506(c) when the rule takes effect later this month.

However, BIO is concerned that the recently-proposed rule that makes amendments to Regulation D, Form D, and Rule 156 could damper biotechs' enthusiasm for the reformed offering process. BIO supports strong investor protections and applauds the SEC for making an effort to monitor the usage of Regulation D as a capital formation outlet. Yet BIO is concerned that the data collection mechanisms included in the proposed rule could prove costly and run counter to the intent of Title II of the JOBS Act, which was to increase capital access for job creators.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

In many instances, the proposed rule justifies its modifications to Regulation D as a boon to analysis, tracking, and evaluation. While BIO understands the desire for comprehensive monitoring, its costs should not serve as a roadblock for companies considering a Rule 506 offering to grow their business. Because 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. Any proposed regulatory duties should be judged in this light, particularly those that would be added to a process designed to *increase* capital availability. The proposed amendments to Regulation D, Form D, or Rule 156 should have real world justification beyond the SEC's desire for information.

BIO appreciates the opportunity to comment on the following items in the proposed rule.

Proposed Amendments Relating to Form D

Mandatory Filing of Form D

The first, and most straightforward, change that the rule proposes to make is to require the filing of Form D a precondition of relying on the exemption in Rule 506(c). BIO supports this requirement. Form D as it currently exists is not overly burdensome for issuers to complete and would provide valuable information to the SEC and potential investors about both the issuer and its proposed offering. BIO also supports the usage of an Advance Form D with general information about the issuer, to be amended with complete information about the offering within 15 days after the first sale of securities. BIO applauds the SEC for understanding that some information may not be readily available in advance of an offering and for allowing companies the flexibility to complete their Form D filing after the offering has begun. Additionally, BIO believes that any required filing should have a "cure period" to prevent inadvertent technical errors from disqualifying an issuer from Rule 506(c).

Pre-Filing Requirement

The proposed rule would require that Advance Form D be filed 15 days in advance of the commencement of general solicitation by an issuer. BIO believes that this requirement is not realistic given the demands of the market and the uncertainty inherent in conducting an offering. If the goal of requiring Form D filing is for the SEC to monitor offerings under Rule 506(c), then the due date for said filing should be tied to the actual offering. BIO believes that Advance Form D should be filed with the SEC 15 days before the commencement of the offering, at which point issuers will have more certainty that the offering will actually go forward. This will provide the SEC with the most accurate information about the issuer and its offering while also saving companies from unnecessary paperwork for an offering that might never happen.

Closing Amendment

The final filing requirement that the proposed rule would add is a Form D closing amendment, due to the SEC 30 days after the termination of the offering. The proposal notes that in 1986 the SEC discontinued the requirement that issuers file a closing amendment to Form D, saying that its removal "would have negligible consequences for investors and would result in some savings for both issuers and the Commission." It is not readily apparent that bringing the closing amendment requirement back would have consequences for investors in 2013 any more than it did in 1986. Likewise, achieving cost savings for issuers and the SEC was an admirable goal in 1986, and one that continues to be of import to biotech companies, which lack product revenue to pay for regulatory costs.

The proposed rule justifies this new requirement under the guise of information gathering, noting the SEC's desire to know more about the "size and characteristics of the Rule 506 offering market." BIO admires the SEC's dedication to market-monitoring, but it should not come at the expense of small companies using Rule 506 to grow their business. The proposed rule admits that the closing amendment would be an "additional compliance burden" and notes that the SEC does not want to weigh down companies relying on Rule 504 or Rule 505. This logic should also apply to issuers relying on Rule 506. BIO believes that the proposed closing amendment should not be required of any issuers conducting offerings under Regulation D.

Content of Form D

Changes to Existing Form D

The rule recently finalized by the SEC that creates the new Rule 506(c) exemption added a check box to Form D for issuers to indicate whether they are relying on the new exemption and conducting general solicitation. BIO supported this change, noting that this "non-burdensome step will allow growing companies to take advantage of the reformed Regulation D while also providing the SEC with valuable information." The proposed rule makes several additional changes to Form D, some of which do not meet the same balance of remaining non-burdensome for issuers.

BIO is amenable to the proposed changes to Item 2, Item 4, Item 5, Item 7, and Item 9. These commonsense amendments are simple, easy to implement, and bring Form D up to date for issuers relying on the new Rule 506(c) exemption. However, BIO has concerns with the reforms proposed to Item 3, Item 14, and Item 16.

The proposed rule adds a new disclosure requirement to Item 3 for individuals who directly or indirectly control the issuer, defined as "owners of 10% or more of a class of the issuer's equity securities." Currently, Item 3 disclosures are limited to executive officers, directors, and promoters, but the proposed change would expand the "related persons" definition to include all 10% equity owners. In 2008, the SEC deleted this requirement, noting that it was able to "collect sufficient information to satisfy the regulatory objectives for Form D" without it. Further, the SEC specifically acknowledged the privacy concerns of potential investors as companies seek to raise capital. Indeed, the proposed rule continues to recognize these privacy concerns for issuers conducting offerings under Rule 504, Rule 505, and Rule 506(b). The only group of issuers subject to the newly-reinstated disclosure requirement are those conducting Rule 506(c) offerings. The goal of the JOBS Act in mandating the Rule 506(c) exemption was to support capital formation for issuers conducting Rule 506(c) offerings – not to burden said issuers and their investors and thus divert them to other offering types. BIO opposes amending the definition of "related persons" to include 10% equity owners.

Item 14 requires a new table analyzing the participation of investors in a Rule 506 offering, including the number of accredited and non-accredited investors, whether the individual investors are natural persons or legal entities, and the amount raised from each category. The goal of conducting an offering under Regulation D is to raise capital, not to provide analysis to the SEC on a company's investor base. Rule 506 allows issuers to raise capital from an unlimited amount of accredited investors, and up to 35 non-accredited investors (or, in the case of Rule 506(c), zero non-accredited investors). Other than verifying that the appropriate number of non-accredited investors purchased in an offering, issuers should not be obligated to conduct further research into offering participants for the SEC. The

current Item 14 only requires disclosure of whether securities were sold to non-accredited investors and the total number of investors who purchased in the offering. No further information or analysis should be required.

The change proposed to Item 16 would require an issuer to report to the SEC what percentage of offering proceeds will be used for various company functions. While most issuers likely have a specific goal in mind when conducting an offering, day-to-day business operations, the fluctuating market, and factors completely outside of a company's control will likely determine how offering proceeds are actually spent. A quarter of slow sales might divert offering proceeds to company operations intended to be funded by sales revenue, falsifying an issuer's Form D filing. In the biotech industry, the extreme uncertainty surrounding scientific research means that funds could be diverted at any point depending on clinical trial failure or success. It is likely that most biotechs will earmark offering proceeds for "working capital," but BIO does not believe the proposed rule provides justification for issuers to provide this (speculative) information to the SEC at all.

New Information Required by Form D

The new items that the proposed rule plans to add to Form D are specifically targeted at issuers that take advantage of the new Rule 506(c) exemption, although, in most cases, any issuer who conducts an offering under Rule 506 would be required to provide the information.

First, BIO has concerns that Item 17, like Item 14, requires unnecessary analysis of the shareholder base by issuers. Separating the investors by accreditation status and then further dividing the accredited investors by type would require a fair amount of post-offering time and capital but would provide no benefit to the issuer or its investors. Information intended solely to monitor the Rule 506 market should not be collected at the price of dampening the enthusiasm for participating in a Rule 506 offering.

The key proposed items are Item 21 and Item 22, which would monitor the new facets intrinsic to the Rule 506(c) exemption. Item 21 would require issuers to report what types of general solicitation were used in the offering. BIO believes that Item 21 should not be required to be included on Advance Form D. Companies conducting Rule 506(c) offerings will likely react to market conditions when determining general solicitation methods – they might have a plan when solicitation commences (at which point Advance Form D will already be filed with the SEC), but it could change depending on investor interest and the success of the offering. As such, requiring issuers to pre-judge what general solicitation methods will succeed is unrealistic. However, allowing Item 21 to be completed via an amendment to Form D within 15 days after the first sale of securities would allow companies to retrospectively list the solicitation methods used in the offering. While still imposing a marginal cost and time burden, this requirement is unlikely to be overly cumbersome, provided that the SEC accepts categorical descriptions of general solicitation methods (*e.g.*, "newspaper advertisements") rather than unnecessarily specific descriptions (*e.g.*, "quarter-page advertisement, *New York Times*, May 5").

Item 22 calls for disclosure of the steps taken by an issuer to verify accredited investor status. As both the text of the JOBS Act and the finalized SEC rule on Rule 506(c) make it clear that issuers must take reasonable steps to verify that all purchasers in an offering are accredited investors, disclosing those steps to the SEC seems fair. Upon implementation, the SEC should recall that overly-rigid enforcement could hamper Rule 506(c) offerings. The finalized rule implementing the JOBS Act reforms establishes a non-exclusive safe harbor for investor verification methods – simply listing the verification method(s) used by

the issuer should suffice to fulfill the requirement in Item 22. Again, as with Item 21, it is vital that the SEC accept categorical descriptions rather than requiring detailed information on each individual verification step.

BIO would also encourage the SEC, after determining that an issuer's verification steps were reasonable, to study which steps it is most often approving in order to determine the common market practices used to verify accredited investor status. As mentioned in BIO's comment letter on the now-finalized general solicitation rule, issuers may be skeptical of participating in the reformed Regulation D if it is unclear what methods of verification the SEC will accept. By monitoring the most common methods approved for use, and expanding the existing non-exclusive safe harbor as the market evolves, the SEC can support the growth of Rule 506(c) as an important capital formation outlet.

Proposed Rule and Rule Amendments Relating to General Solicitation Materials

The proposed rule requires that issuers include a legend in any written general solicitation materials distributed to the public. This legend would include notifications about the risk inherent in the offering, as well as what investors are eligible to participate. While BIO generally believes that accredited investors are already aware of the information that would be included in the legend, requiring its inclusion in written general solicitation materials is unlikely to be overly burdensome. Upon implementation, the SEC should not be overly rigid about the size, placement, or exact wording of the legend incorporated with any given solicitation, but BIO is amenable to the requirement that it be included, and expects such language to become somewhat boilerplate.

However, BIO does not believe that compliance with this requirement should be a condition of the Rule 506(c) exemption. Because the legend is likely providing potential investors with information they already know, inadvertently leaving it off should not disqualify an issuer from conducting a Rule 506(c) offering. Further, BIO believes that there should be a cure mechanism for inadvertent errors in, or the omission of, the legend associated with written general solicitation materials.

Proposed Temporary Rule for Mandatory Submission of Written General Solicitation Materials

The proposed rule would create a new Rule 510T that would, for two years, require issuers relying on the Rule 506(c) exemption to provide their written general solicitation materials to the SEC. BIO is supportive of this rule, provided that compliance is not a precondition of eligibility to conduct a Rule 506(c) offering. Allowing issuers to provide general solicitation materials to the SEC via an online portal that is not made available to the public would assist the SEC's data collection and monitoring efforts while not proving too cumbersome for issuers conducting an offering.

However, BIO opposes the requirement that the materials be submitted "no later than the date of first use of such materials in the offering." If the goal of the data collection is truly to study the marketplace, it should suffice for issuers to collect written materials during the course of solicitation and the offering itself and submit them to the SEC at a specified date after the offering is complete. There is no need for companies to rush to the online portal the day an advertisement is used when the SEC could garner the same information, at a decreased burden to the issuer, by waiting for a singular data dump after the offering is complete.

Comment on the Definition of "Accredited Investor"

The proposed rule solicits comments on the definition of accredited investor as it relates to natural persons. BIO applauds the SEC for being willing to reexamine definitions and requirements that affect issuers and investors alike. BIO does not, however, support any changes to the accredited investor definition. 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. Amending the accredited investor definition would decrease the pool of investors eligible to participate in Rule 506 offerings and would be antithetical to the spirit of the reforms mandated by the JOBS Act. The current definition is sufficient to protect investors, and in its existing form limits participation in Rule 506(c) offerings to those investors who best understand the risks of said offerings and are more able to withstand any potential losses.

In the biotech industry, an informed investor is a good one. BIO members take great strides to inform their investors of the high degree of risk inherent in groundbreaking R&D. However, it remains the case that groundbreaking R&D is costly – the average biotech company will spend over $1 billion developing a single life-saving therapy. Shrinking the pool of available investors by amending the accredited investor definition would negatively impact capital availability for small biotech innovators and could delay vital research.

Conclusion

The efficient use of investment funds is of paramount importance for innovative biotechnology companies. The extended development period and groundbreaking science intrinsic to biotech research require a massive amount of funding to bring a single technology to the market. As such, biotech investors demand efficiency and streamlined processes that direct their investment dollars straight to R&D. Dedicating funds to research means swifter progress toward scientific advancements – which leads to treatments for patients and returns for investors. This imperative is especially apparent when it comes to compliance burdens associated with an offering. Each new regulation takes capital raised from the offering and diverts it away from the laboratory. This diversion does not benefit investors, issuers, or patients.

As the SEC considers amendments to Regulation D, Form D, and Rule 156, it should keep in mind this key facet of the capital formation market for growing innovators. BIO appreciates the SEC's desire to collect information on the new processes now available to companies under Regulation D, but diminishing the efficacy of Rule 506(c) offerings in the name of data collection runs counter to the intent of the JOBS Act and will not support capital formation in the long term. The SEC should carefully consider whether the requirements it has proposed will truly benefit both investors and issuers participating in Rule 506 offerings.

BIO looks forward to working with the SEC to effectively implement the changes to Regulation D so that it will stimulate important capital formation to support the ongoing search for groundbreaking medicines, advanced biofuels, and other next generation technologies. BIO members are eager to take advantage of the new Rule 506(c) offering process and BIO would like to again thank the SEC for finalizing that rule.

If you have further questions or comments, please contact me or Charles Crain, Manager of Policy and Research, at (202) 962-9218.

Sincerely,

Shelly Mui-Lipnik
Senior Director, Tax and Financial Services Policy
Biotechnology Industry Organization (BIO)