October 5, 2012

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

Re: Release No. 33-9354, File No. S7-07-12: *Eliminating the Prohibition against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings*

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 S7-07-12: *Eliminating the Prohibition against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings*.

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.

These funds can be raised in any number of ways – and one of the goals of the Jumpstart Our Business Startups (JOBS) Act was to open up even more avenues to capital formation for growing companies. To that end, Title II of the new law requires the SEC to lift the ban on general solicitation and general advertising for offers and sales of securities made under Rule 506 of Regulation D. BIO strongly supported this change because Regulation D has not been, up to this point, useful to emerging biotech companies. The ban on general solicitation restricts growing businesses to a curtailed pool of accredited investors, mostly comprised of friends and family. In an industry with such significant capital requirements, the limited fundraising potential of Regulation D in its current form barely makes a dent in the total cost of developing a drug.

BIO applauds the SEC for proposing straightforward amendments to Rule 506 of Regulation D that would lift the existing ban on general solicitation and general advertising. Once the proposed amendments are made final, growing biotech companies will benefit from an expanded fundraising base, stimulating capital formation and speeding the development of groundbreaking medicines.

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BIO also supports the proposed revision to Form D which would add a separate checkbox for issuers to indicate whether they are using general solicitation or general advertising in their Regulation D offering. This non-burdensome step will allow growing companies to take advantage of the reformed Regulation D while also providing the SEC with valuable information about the process of conducting an offering under Rule 506.

Reasonable Steps to Verify Accredited Investors and Reasonable Belief that All Purchasers are Accredited Investors

The JOBS Act requires the SEC to write the new exemption from the general solicitation rules such that they would still require that the issuer "take reasonable steps to verify that purchasers of the securities are accredited investors." The law gives the SEC leeway to determine the appropriate methods for this verification.

The SEC proposed rule sets forth the conditions that the issuer must take reasonable steps to verify that purchasers are accredited investors and that all purchasers must be accredited investors, either because they fall within a category of persons defined as such or because the issuer has reasonable belief that they do. These conditions are obviously aligned with the intent of the JOBS Act, but they do not expand upon the legislative text in any meaningful way – the term "reasonable" is not defined in relation to either steps or belief. The rule states that establishing reasonableness "would be an objective determination, based on the particular facts and circumstances of each transaction." The goal of this ambiguity is to "provide sufficient flexibility" to cover various types of issuers and investors.

The SEC has indicated that it believes that evaluating reasonableness on a case-by-case basis would give issuers and market participants the flexibility to adopt different approaches to verification depending on the circumstances, to adapt to changing market practices, and to implement innovative approaches to meeting the verification requirement. BIO agrees with this assessment.

BIO applauds the SEC for not implementing a one-size-fits-all approach in determining what verification steps and what level of belief qualify as reasonable. The unique nature of companies in the biotech industry often makes it impractical to comply with overly stringent regulatory requirements, and implementing a generally applicable and burdensome requirement for reasonableness would reduce the impact of the changes to Regulation D.

Because emerging biotech companies undertake their development process without the benefit of product revenue, every dollar spent on regulatory compliance is an investment dollar diverted from innovation. A burdensome verification standard would impose a significant cost burden on these small innovators. Growing R&D-intensive businesses considering offerings under Rule 506 could balk at overly restrictive requirements, decreasing the usefulness of the reformed Regulation D. As the proposed rule notes, "uniform verification methods" could be "ill-suited or unnecessary to a particular offering or purchaser" – and would thus undercut the legislative intent of the JOBS Act-mandated changes. BIO appreciates the SEC's efforts to maintain the applicability and worth of Regulation D for a wide variety of issuers.

BIO agrees with the SEC that a specific list of approved methods may be overly prescriptive and would not account for the uniqueness of each offering, but an absence of guidelines on the acceptability of various verification options will cause issuers undue hesitation when considering a capital raise under the revised Regulation D. BIO urges the SEC to maintain its flexible approach while also providing staff guidance on verification standards, allowing

emerging biotech companies to effectively plan for their growth. Uncertainty about whether the SEC will approve an issuer's "reasonable steps" or question its "reasonable belief" could lead issuers to forgo Regulation D offerings altogether.

Further, though BIO supports the flexibility inherent in evaluating Rule 506 offerings on a case-by-case basis, biotech companies will not benefit if the SEC uses said flexibility to employ overly stringent requirements for investor verification, whether via official guidance or staff practice. Pre-revenue biotech companies requiring massive amounts of capital to fund their R&D need assurance that the SEC will not negate the capital formation potential of the reformed Regulation D by implementing its proposed flexible standards in a restrictive manner. If biotech innovators see their industry colleagues try and fail at Rule 506 offerings due to overly stringent or unnecessarily opaque verification standards, appetite for capital formation under Regulation D will dissipate, negating its potential benefits for speeding the delivery of breakthrough medicines to patients. As the SEC moves to implement its case-by-case standard, BIO urges that it be mindful of the legislative intent of Title II of the JOBS Act – providing greater access to capital for job creators.

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 lifesaving cures and treatments. BIO also anticipates further engagement with the SEC during the rulemaking process for the increased exemption for Regulation A offerings – another JOBS Act reform that has the potential to spur fundraising in the biotech sector. If you have further questions or comments, please contact me or Charles Crain, Manager of Policy and Research, at (202) 962-9218.

Sincerely,

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