July 14, 2015

Brent J. Fields
Secretary
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-1090

Re: *Disclosure Effectiveness Review*

To whom it may concern:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comment to the Securities and Exchange Commission (SEC) on its ongoing disclosure effectiveness project. An effective disclosure regime should provide important information to investors without instituting undue compliance burdens, particularly on emerging companies. BIO appreciates the steps the SEC is taking toward that goal.

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 – growing companies often turn to the public market for capital formation. A disclosure regime that supports this public capital formation is critical to the success of the biotech industry and America's 21st century economy.

The vast majority of biotech companies are growth-stage innovators. A typical biotech has fewer than 50 employees (most of whom are scientists) and is dedicating vast sums of investment capital to the decades-long, billion-dollar R&D pathway intrinsic to groundbreaking medical advancement. These small businesses operate without the benefit of product revenue to fund their work, so they place a high value on policies that incentivize investment in innovation and prioritize resource efficiency. Any policy that increases the flow of innovation capital to emerging companies could lead to funding for a new life-saving medicine – while any policy that diverts capital to unnecessary and costly regulatory burdens could lead to the same treatment being left on the laboratory shelf.

The Jumpstart Our Business Startups (JOBS) Act is a significant example of smart policymaking leading to right-sized regulations that support company growth. This important law allows enhanced access to investors, increasing the capital potential of a public offering, and then reduces the regulatory burden on emerging growth companies, decreasing the amount of capital diverted from R&D. This one-two punch is critical for biotech innovators and has increased the viability of the public market for growth-stage businesses looking to fund their capital-intensive development programs.

Since the JOBS Act was signed into law, there have been more than 160 IPOs in the biotech industry. For comparison, the three years prior to the JOBS Act saw fewer than 40 biotech IPOs. It is clear that policy decisions can have an impact on the capital formation ecosystem for innovative companies, and BIO thanks the SEC for continuing to look for ways to create an effective disclosure regime that protects investors while allowing small companies to focus precious funds on advancing their business.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

Reviewing Regulation S-K and Regulation S-X and making specific changes to Forms 10-K, 10-Q, and 8-K in order to reduce, scale, or eliminate duplicative, overlapping, outdated, or unnecessary reporting requirements will significantly reduce the cost burden of being a public company and therefore free up funds to support the search for the next generation of medical breakthroughs. Additionally, smart disclosure requirements provide a long-term benefit to investors. After all, investors invest in companies in the hope that their work will be successful and provide a strong return. Disclosure reform that allows companies to focus on their work instead of spending money on reports that investors do not want or need will speed a company's progress and enhance returns for investors. This is especially true in the biotech industry, where each dollar spent on burdensome filings represents a damaging diversion of capital from science to compliance.

For small biotech companies, there are two main roadblocks to growth – the complexity of advanced science and the high costs of breakthrough research. The science of saving lives is complicated, and policymaking cannot make genetic targeting or protein modification any less difficult. On the other hand, policymaking can certainly make it easier to fund the research and clinical trials necessary to discover and develop a life-saving medicine. BIO believes that a successful disclosure effectiveness project will spur capital formation and support groundbreaking R&D if it institutes commonsense compliance burdens without an overreliance on one-size-fits-all reporting requirements.

Smaller reporting companies and non-accelerated filers

As the SEC continues to analyze the existing disclosure regime, and specifically Regulation S-K, BIO is hopeful that it will pay particular attention to the universe of companies to which various disclosure requirements apply. Specifically, BIO urges the SEC to reform the smaller reporting company (SRC) and non-accelerated filer definitions in order to more accurately reflect the nature of small and emerging issuers on the public market.

Item 10(f) of Regulation S-K defines a smaller reporting company as any issuer with a public float below $75 million. Rule 12b-2 applies the same definition to non-accelerated filers. Collectively, these two definitions are intended to encompass the entire pool of small public companies. As such, SRCs and non-accelerated filers are eligible for a panoply of reductions to and exemptions from certain compliance requirements, including reports on selected financial data, executive compensation, and market risk as well as more onerous regulatory burdens like management discussion and analysis (MD&A) and Sarbanes-Oxley (SOX) Section 404(b).

However, many businesses that would be considered "small" by any reasonable observer are excluded from the SRC/non-accelerated universe because investors are optimistic about their future progress and thus value them highly. A high valuation means a high public float, and a corresponding loss of SRC and non-accelerated filer status. Because these definitions do not accurately capture what makes a company "small," emerging biotechs must often endure a compliance burden identical to that faced by commercial leaders and multinational corporations.

Growing biotechs are uniquely harmed by the small company classifications in Regulation S-K and Rule 12b-2 because of the groupings' overreliance on public float as a determinant of company size. The high cost of biotech research coupled with strong investor interest in life-saving medical advancements means that growing biotechs often have a high public float despite their simple corporate structure and lack of product revenue. The dependence on public float as a marker for size begs the question: what does a pre-revenue biotech

company with a public float of $400 million truly have in common with a $400 million widget-maker? The biotech is highly valued because it is working toward a groundbreaking treatment that may, *years from now*, save millions of lives. The widget-maker, on the other hand, is highly valued because it is manufacturing millions of widgets *today*. These two companies have little in common beyond their valuations, yet are bound by the same disclosure regime.

As such, BIO believes that the SEC should move away from its existing reliance on public float to determine a company's compliance obligations. BIO supports changes to Regulation S-K and Rule 12b-2 to define any issuer with annual revenues below $100 million as a smaller reporting company and a non-accelerated filer, regardless of how the market values their stock. This revenue test should exist separately from any public float marker in Regulation S-K or Rule 12b-2, ensuring that highly valued small companies with little or no revenue are not erroneously grouped with larger corporations.

BIO supports adding a revenue component to these definitions in order to give the SEC more accurate company classifications and reduce the regulatory burden on growing businesses. BIO also believes that the $75 million public float ceiling for SRCs and non-accelerated filers is outdated and does not reflect today's market – and thus should be increased to $250 million.

In short, a company should be considered a non-accelerated filer and a smaller reporting company if it has either a public float below $250 million or revenues below $100 million. Such a change would more accurately reflect the nature of small public companies and provide important regulatory relief – both laudable goals for the disclosure effectiveness project.

Reforms to the SRC and non-accelerated filer definitions have been endorsed by a variety of market participants – all of which support the goal of expanding the universe of SRCs and non-accelerated filers in order to more accurately reflect what the market considers "small." The SEC Government-Business Forum on Small Business Capital Formation recommended expanding the definitions for SRCs and non-accelerated filers in its report in 2014, 2013, 2012, 2011, 2010, and 2009. The SEC Advisory Committee on Small and Emerging Companies recommended similar changes in 2013. Indeed, the very existence of the Advisory Committee implies that the SEC itself would support reforms to its small company definitions – the founding charter of the Committee defines the small companies within its jurisdiction as those with "less than $250 million in public market capitalization." The $75 million public float cap for SRCs and non-accelerated filers is clearly outdated, and the disclosure effectiveness project is the perfect opportunity to update it.

Growing biotechs retain a simple corporate structure through most of their development timeline. They may grow from 15 scientists in a lab to 50 scientists in lab, but the core essence of the business model is a capital-intensive, laser-focused drive toward medical advancement. Yet the existing small company definitions found in Regulation S-K and Rule 12b-2 treat these small businesses as large companies, diverting dollars from the lab and slowing scientific progress. BIO urges the SEC to reform both the SRC and the non-accelerated filer definitions in order to enhance the capital formation ecosystem and incentivize funding for the next generation of breakthrough medicines.

Conclusion

The most damaging facet of a one-size-fits-all regulatory regime for the biotech industry is the diversion of investment funds from science to compliance in the absence of product

revenue. Biotech small businesses place a high value on capital efficiency, so BIO applauds the SEC for undertaking its disclosure effectiveness project and remains hopeful that it will result in commonsense reporting requirements for emerging companies. If the project is successful for growing biotechs, these smaller issuers will have increased access to investors on the public market and will not be forced to siphon off innovation capital to spend on costly compliance burdens.

BIO strongly supports reforms to the smaller reporting company and non-accelerated filer definitions in order to more accurately classify companies and provide important regulatory relief for small businesses. Specifically, BIO believes that an overreliance on public float (especially the existing far-too-low $75 million public float ceiling) has been damaging to smaller issuers, and we urge the SEC to make reforms in order to take revenue into account when determining a company's compliance burden. Expanding the SEC's small company definitions will support the growth of these businesses, incentivizing scientific advancement and sustaining small innovators as they continue their efforts to bring life-saving treatments to patients who desperately need them.

BIO looks forward to working with the SEC as it considers how to implement an effective, cost-efficient disclosure regime for emerging companies that 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 [redacted].

Sincerely,

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