May 16, 2017

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

Re: File No. S7-03-17: Inline XBRL Filing of Tagged Data

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. S7-03-17, its proposed rule to require issuers to submit financial statement information using the Inline version of the eXtensible Business Reporting Language (XBRL) format.

BIO represents more than 1,100 biotech companies across the United States, the vast majority of which are pre-revenue innovators. These emerging biotechs do not generate product revenue, so they turn to the public markets for funding to support the decades-long, billion-dollar search for the next generation of medical breakthroughs. BIO supports a regulatory regime that enhances their access to capital while also allowing these groundbreaking companies to focus investor funds on life-saving research.

BIO appreciates that the SEC is taking steps to reform the XBRL filing requirement. The move from the existing XBRL regime to Inline XBRL should reduce the potential for data errors that often plague XBRL reports. We also appreciate the SEC’s focus on the costs of XBRL compliance for growing issuers; however, we are concerned that the proposed reforms will not result in significant cost savings for emerging biotechs. Ultimately, XBRL data is little-used by biotech investors, so the costs of preparing the data (even if somewhat reduced by the switch to Inline XBRL) likely outweigh any potential benefits.

**Data Integrity**

One of the main issues that small business innovators face under the existing XBRL regime is the quality of the data in the final report. The numerous steps in the current filing process, wherein companies complete an HTML document that is subsequently tagged and copied into the XBRL format, increase the potential for errors. Issues ranging from individual incorrect data points to broader problems like positive numbers being characterized as negative or incorrect scaling (i.e., billions vs. millions) are an ever-present worry for company management. These potential issues make filing the XBRL report a virtual minefield.

Under Inline XBRL, companies would be able to complete their HTML and XBRL filings simultaneously. The updated process would increase the consistency between the two final documents and improve the overall quality of the data reported by issuers – an important step forward for the future of XBRL.
However, the utility of XBRL data for biotech investors remains an issue. The top-line data that is ostensibly comparable among companies (the ultimate goal of XBRL being easier issuer-to-issuer comparison) is heavily weighted toward traditional metrics that might be useful to an investor evaluating profitable multinational corporations – but that provide little to no insight into the health of an emerging, pre-revenue biotech. Investors in these growing businesses instead focus on the company’s science, the diseases it is treating, the patient population, and the FDA approval pathway, among other real-world variables that will actually determine the company’s ultimate success or failure.

Furthermore, as XBRL reports move into the footnotes, the data becomes even less useful, and may even be distracting to investors. Often, footnote disclosure is composed of a significant amount of extended tags that are specific to each issuer, leading to a lack of consistency between filers. These extended tags usually just repeat the information that is already available in the HTML filing, but the XBRL requirement nevertheless compels its inclusion despite its unsuitability to the XBRL format.

Investors largely realize these shortcomings of XBRL and thus do not utilize XBRL reports to evaluate emerging biotech companies. It is unlikely that this dynamic will change under Inline XBRL. BIO does believe that the move to Inline XBRL will improve the accuracy and consistency of the data reported – but these improvements are unlikely to ultimately improve the utility of XBRL reports to biotech investors.

**Costs of Compliance**

Resource efficiency is of paramount importance to emerging biotechs. Because every dollar spent on regulatory compliance is a dollar diverted from scientific advancement, biotech small businesses can be harmed by costly reporting requirements like XBRL. Furthermore, many one-size-fits-all disclosure burdens (again, like XBRL) do not provide meaningful insights for biotech investors, so the resource trade-off between science and compliance is thrown into stark relief.

BIO appreciates the SEC’s efforts to reduce the cost burden of XBRL compliance by moving to Inline XBRL. In the event that Inline XBRL saves even a minimal amount of capital for emerging innovators, those dollars can be pumped into life-saving research. However, BIO is concerned that the cost-savings impact of Inline XBRL will indeed be minimal.

First, as the proposing release notes, the costs of transition to Inline XBRL will “disproportionately burden smaller filers.” Biotech small businesses, having already settled into a reporting system for XBRL, will face an initial uptick in costs to fund the transition to Inline XBRL. In order to implement Inline XBRL, growing companies will face both time and cost pressure, both internally and via their external printers. These costs will extend to potential new review and reporting processes for the new compliance requirement, including the possibility of increased audit fees related to the attestation of the XBRL data now required to be included in the HTML file.

Furthermore, BIO members do not expect to see a significant drop in compliance costs once the transition is complete. The proposing release itself notes that the SEC “do[es] not expect Inline XBRL to significantly affect the overall costs of compliance with XBRL requirements.” As such, BIO remains concerned about the costs of XBRL compliance in the face of minimal benefits to issuers or investors.
Because of the potential for cost increases during the transition period, BIO supports a phase-in period for smaller issuers similar to the one outlined in the proposing release. However, the SEC’s current proposal does not include emerging growth companies (EGCs), of which there have been more than 200 in the biotech industry since the passage of the JOBS Act. We believe that EGCs should be included in the final year of the phase-in period along with smaller reporting companies (SRCs) and non-accelerated filers.

A more effective way to keep costs down for growing businesses would be to provide an optional XBRL exemption for certain smaller companies. Even with the shift to Inline XBRL, pre-revenue biotechs will face a considerable cost burden to comply; as such, BIO supports making XBRL compliance optional for EGCs, SRCs, and non-accelerated filers. Given the lack of utility that XBRL reports have for investors in growing biotechs, we believe such an exemption would meaningfully reduce compliance costs for emerging businesses without damaging investor protections.

For both the phase-in period in the proposed rule and the small company exemptions that BIO supports, we remain concerned that the SEC’s current company classifications do not accurately reflect the true nature of America’s small businesses, and thus that exemptions or phase-ins based on these categorizations will fail to fully achieve their desired ends. Specifically, BIO believes that the current SRC and non-accelerated filer classifications are outdated, with the $75 million public float marker in both definitions setting an artificially low cap that most biotechs exceed despite their pre-revenue nature.

This issue has broader implications than XBRL compliance costs, but XBRL is a telling window into the problem. The costs of filing an XBRL report (even under Inline XBRL) have a substantial impact on growing biotechs, whether their public float is $50 million or $500 million. These growing businesses are virtually all pre-revenue – they may be highly valued for their future potential to deliver life-saving treatments, but at present they rely solely on investor dollars to fund their research. The outdated SRC and non-accelerated filer definitions force these growing businesses to divert innovation capital from science to compliance, potentially slowing their growth and hampering their ability to advance groundbreaking research.

Last summer, the SEC issued a proposed rule that would increase the public float cap for SRCs, but not non-accelerated filers, to $250 million. This proposal is an important first step, but BIO strongly believes that the SRC and non-accelerated filer definitions should be consistent at $250 million in public float. Additionally, we believe that revenue is a more appropriate arbiter of company size (and, importantly, of a company’s ability to pay for expensive compliance burdens), so a revenue-only test should be added to both definitions as an alternative to the existing public float standard.

**Conclusion**

BIO applauds the SEC for taking steps to reform XBRL. The likely improvements to data quality under Inline XBRL will be a welcome change from the current XBRL landscape. However, given that biotech investors generally do not utilize XBRL when making investment decisions, we remain concerned that the costs associated with XBRL compliance, even under Inline XBRL, outweigh the benefits. In the face of transition costs and a subsequent annual cost burden, growing innovators will be forced to siphon off innovation capital to spend on a reporting requirement that does not meaningfully protect investors or encourage life-saving innovation.
The public capital markets are a vital component of the 21st century innovation ecosystem, and we encourage the SEC to continue to examine ways to support capital formation and reduce regulatory burdens for small business innovators. BIO looks forward to working with the SEC as it considers how to make XBRL reporting more cost-efficient for emerging issuers. If you have further questions or comments, please contact Charles Crain, Director of Tax & Financial Services Policy, at [Contact Information].

Sincerely,

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Director, Tax & Financial Services Policy

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