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Panel 6: Critical Audit Matters Related to the Audits of Small Companies

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Good afternoon Chairman Doty, Members of the Board, ladies, and gentlemen. My name is Cartier Esham, and I am the Executive Vice President of Emerging Companies at the Biotechnology Industry Organization (BIO). BIO represents more than 1,100 innovative biotech companies, and about 90% of those make up our Emerging Companies Section. These growing businesses must have less than $25 million in annual revenue to qualify for our small company membership, but in truth most of them have revenues closer to $0 than $25 million. This is because the vast majority of BIO's membership, and the biotech industry writ large, is made up of pre-revenue companies whose research is still in the lab or the clinic.

These small businesses – virtually all of which employ fewer than 100 workers – spend more than a decade conducting R&D in their search for groundbreaking medicines and life-saving treatments. During this years-long process of research and clinical trials, biotechs do not have any products to sell. Revenue does not fund the biotech development process – which can cost upwards of $1 billion. Instead, emerging biotech companies rely on outside investors for innovation capital. From angel investors to venture capitalists to the public markets, biotechs are constantly searching for the next round of financing to support the next stage of research.

The overwhelming capital burden of next generation science highlights the importance of a functioning public market. A late-stage clinical trial can cost upwards of $200 million, a sum that is difficult to raise with just private investors. The public market has a broader capital reach, and growing biotechs often turn to an IPO to fund the expensive Phase III trials required for FDA approval. As such, the Jumpstart Our Business Startups (JOBS) Act, designed to increase capital availability for emerging growth companies (EGCs) entering the market, was tremendously important for the growth and success of the biotech industry. The JOBS Act was signed into law two years ago by President Obama, and in that time it has stimulated nearly 80 biotech IPOs. In the two years prior to the JOBS Act, there were just over 30 IPOs in our industry. The law has been successful because it institutes a commonsense regulatory burden for small issuers both during the IPO process and when they are new to the public market. To put it more bluntly, the JOBS Act veers away from the one-size-fits-all approach that dominates capital markets regulation.

This change has had such an impact on the biotech industry because of the utmost importance of resource efficiency for growing companies. Because they lack product

revenue, any dollar spent on unnecessary red tape is, by definition, lost to innovation. Small businesses are the innovative heart of the biotech industry, conducting most early-stage, groundbreaking research, so regulations that harm them have a large-scale effect on scientific advancement. Expensive compliance requirements take investment dollars earmarked for R&D and divert them to the accounting department, a costly burden for emerging companies and a waste of the funds that investors provided to fund breakthrough research. The JOBS Act allows enhanced access to investors, increasing the capital potential of an offering, and then institutes a relaxed regulatory burden, decreasing the amount of capital diverted from research. This one-two punch is critical for biotech innovators and has increased the viability of the public market for a growing company looking to fund its capital-intensive development program.

A public market that is an attractive avenue to capital formation is vital for the health of the biotech industry – and, of course, the health of the patients waiting on the treatments being developed – both because it allows companies to raise enough capital to fund expensive research and expand their pipeline and because it can give small businesses leverage in M&A negotiations with larger pharmaceutical partners. It is imperative that Congress, the SEC, the PCAOB, and other regulators view any proposed compliance burdens through this lens. The JOBS Act has shown that instituting commonsense regulations removes a barrier to entry for the emerging companies most in need of the capital available on the public market.

Unfortunately, the critical audit matters standard recently proposed by the PCAOB does not meet this standard. Expanding the scope of the audit report by requiring the auditor of an emerging growth company to identify and report on critical audit matters would violate the spirit and the letter of the JOBS Act, siphoning off research dollars for a one-size-fits-all requirement that will do nothing to support scientific advancement or breakthrough cures and treatments.

Critical Audit Matters and Emerging Growth Companies

Cost Burden on EGCs

First and foremost, adopting a critical audit matters standard would increase audit costs for emerging growth companies. The proposing release notes that it is virtually certain that an auditor would identify critical audit matters based on the proposed standard in any given audit report, meaning that we can be similarly certain that audit costs will go up. Quite simply, the new proposed standard would increase the scope of work necessary to complete an audit, as well as the level of subjective analysis required of the auditor. These costs will be passed on to emerging growth companies, which can ill-afford such a substantial capital diversion.

Compounding the problem, these additional costs will not improve audit quality. A critical audit matters requirement will not provide insightful or relevant information for investors in emerging growth companies. EGCs in the biotech industry have few employees and a simple corporate structure, so it does not require detailed analysis to understand the inner workings of their business. Each year's financials show millions of dollars in losses – a steadily declining balance from the latest round of financing. BIO member CEOs have noted that they cut relatively few checks per year, virtually all of which are personally approved by senior management. The existing audit procedures are sufficient to analyze this business model and ensure that a company's disclosures are appropriate, consistent, and complete. In fact, most investors are much less concerned with the audit report (beyond the pass/fail designation) than they are with a company's scientific progress and clinical trial results.

BIO fully supports strong investor protections, but the true value of a biotech company is found in its scientific disclosures rather than the audit report – especially one made unduly expensive by new, burdensome standards.

BIO believes that the critical audit matters standard will impose a cost burden that is proportionately far greater than any benefit it is intended to generate. It is important to reiterate that this cost burden is oppressive not only because of the amount of capital that will be spent to comply – which could be significant in its own right – but because of where that capital will be coming from. Without product revenue, growing biotechs will be forced to ask investors to pay for the increased audit fees instead of funding vital research. Spending capital on regulatory burdens can slow the development process, increasing the time it takes to reach the important milestones that trigger the new investments that will take the research even further. A critical audit matters standard will prove too costly for emerging growth companies, in the biotech industry and elsewhere, and BIO believes that the PCAOB should not apply it to EGCs.

JOBS Act Section 104

Taking a step back from the specific downsides of the proposed critical audit matters standard, BIO's opposition also stems from a close reading of Section 104 of the JOBS Act, which details how PCAOB rules will be applied to emerging growth companies. Specifically, it precludes the PCAOB from requiring "a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer." BIO believes that the proposed critical audit matters standard meets this definition.

Though not a *supplement* in the traditional sense of the word (as the critical audit matters would be identified within the audit report rather than as a separate addendum), the standard would certainly require *supplemental* information about the audit and the issuer's financial statements. This extra information is key – the JOBS Act prohibits the PCAOB from requiring superfluous information that would increase the regulatory burden on emerging growth companies. The restriction in Section 104 is clearly a directive from Congress that should forestall any efforts by the PCAOB to require this type of additional information and analysis on the audit of an EGC.

In 2011, the PCAOB proposed requiring auditor's discussion and analysis (AD&A) in company filings. The JOBS Act parenthetically mentions this specific proposal as an example of a supplement that would fall under Section 104's prohibitions, but BIO does not believe that the prohibition is limited to AD&A. The proposed critical audit matters standard requires a similar level of discussion and analysis as the supplement required by AD&A, which would have included a report detailing the auditor's perspective about the audit and the company's financial statements, including any potential areas of concern. Moving the analysis from a supplement to within the audit report itself does not change the work required by the auditor or the cost burden for the audited company. The level of information required is substantially similar, so BIO believes both AD&A and critical audit matters are proscribed by Section 104.

The JOBS Act clearly precludes application of any rule that would require additional information about an EGC's audit and financial statements, and the proposed critical audit matters standard would do just that. BIO believes that requiring an auditor to report on critical audit matters in the audit of an emerging growth company would violate both the letter and spirit of the JOBS Act, and we encourage the PCAOB to exempt EGCs from any such burden.

Conclusion

For EGCs in the biotech industry, a fair and cost-sensitive regulatory burden is of paramount importance. As I have mentioned, biotech companies face a decade-long, billion-dollar development timeline, and their research is supported by outside investment capital rather than product revenue. Any funds spent complying with costly and complicated new audit regulations like critical audit matters would be lost to the scientists and innovators working in labs and hospitals to cure disease and improve patients' quality of life.

The cost burden of the proposed critical audit matters standard, and therefore the amount of capital diverted from R&D, could be significant. BIO urges the PCAOB not to apply this standard to emerging growth companies, which thrive under a commonsense regulatory regime rather than a one-size-fits-all burden that slows development and stifles growth. For growing biotech companies, reducing barriers to capital formation on the public market better enables scientific advancement and the search for novel medicines and life-saving treatments for patients in need.