



December 9, 2013

Office of the Secretary
Public Company Accounting Oversight Board
1666 K Street NW
Washington, DC 20006

Re: PCAOB Rulemaking Docket Matter No. 034, Release No. 2013-005

To whom it may concern:

The Biotechnology Industry Organization (BIO) is pleased to submit comments to the Public Company Accounting Oversight Board (PCAOB) on Release No. 2013-005, on proposed auditing standards.

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.

BIO fully supports strong auditing standards, and believes that they can enhance investor protection and confidence. BIO applauds the PCAOB for its dedication to protecting investors and fostering confidence in the market. However, overly stringent regulatory requirements can have a detrimental effect on growing biotechs by causing a diversion of capital from science to compliance.

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. This 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. As such, the efficient use of investment funds is of paramount importance to a growing biotech company. Spending valuable innovation capital on costly regulatory burdens can delay scientific progress and slow the growth of a promising company.

The recent surge in biotech IPOs since the passage of the Jumpstart Our Business Startups (JOBS) Act in April 2012 has brought the compliance requirements of emerging public companies into sharp focus. More than 45 biotech companies have gone public using provisions in the JOBS Act, and they are now subject to the regulatory regime of a public company. One of the key messages of the JOBS Act was that one-size-fits-all compliance burdens are not appropriate for all market participants and can harm growing companies. BIO believes that certain items in the auditing standards proposed by the PCAOB could hurt small innovators by subjecting them to burdensome and unnecessary regulatory requirements.

The true value of biotech companies is embedded in their groundbreaking research, pipeline of product candidates, and their progress in advancing those product candidates toward



regulatory approval and product sales. Investors often make decisions based on these parameters rather than a biotech company's operating results and financial disclosures; therefore, higher costs to comply with the proposed standards would outweigh any potential benefits.

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

Proposed Auditor Reporting Standard

Critical Audit Matters

The proposed critical audit matters standard is substantially similar to requiring AD&A.

In its 2011 concept release, the PCAOB proposed requiring auditor's discussion and analysis (AD&A) in company filings. At the time, BIO commented that an AD&A requirement would "make our companies' audits more expensive, duplicate management's discussion and analysis of its business, operations, and financial results (MD&A), and potentially confuse investors and analysts." BIO believes that the proposed critical audit matters standard is substantially similar to AD&A and that it would be extremely burdensome for pre-revenue biotech issuers.

The AD&A proposal would have required a supplemental report detailing the auditor's perspective about the audit and the company's financial statements. The proposed critical audit matters standard would instead include the auditor's discussion and analysis within the auditor's report itself. Though the new standard would somewhat narrow the scope of what the auditor is asked to identify and report to investors, it remains the case that the auditor is being asked to provide a subjective look into the auditing process that will likely create additional work and expenses.

The proposed critical audit matters approach is also similar to the emphasis paragraphs proposal from the 2011 concept release. BIO opposed this requirement, noting that "emphasis paragraphs would not be relevant or useful." It appears as though the PCAOB has combined AD&A with emphasis paragraphs and titled the result "critical audit matters" – without substantially decreasing the burdens that would be placed on growing companies if the proposal is adopted.

A critical audit matters standard would increase audit costs, is duplicative, and could confuse investors.

The PCAOB release states that the critical audit matters standard would be "cost-sensitive" because "the auditor's determination of critical audit matters is based on the audit already performed." Yet the release also notes that the PCAOB expects "that in most audits, the auditor would determine that there are critical audit matters." The virtual certainty that critical audit matters would be identified belies the PCAOB's assertion that the new standard would not increase audit costs. Additionally, the PCAOB's reassurance that most of the critical audit matters work will be done after the audit is completed is hardly comforting, as this will likely result in a time crunch as auditors and issuers struggle to meet the reporting deadline, increasing the chance for errors or a lower-quality audit. The additional requirement will create additional work, which will be translated into an increase in audit fees to public companies. For growing biotechs, the increased fees will come directly from investment dollars intended for groundbreaking R&D, a diversion of capital that could slow scientific progress.



The problem is further exacerbated by the fact that it is unlikely that the critical audit matters standard will provide any substantial benefits to investors. Currently, auditors review and provide comments and feedback to management and the audit committee on a company's financial statement disclosures and MD&A. During the course of this dialogue, management, the audit committee, and external auditors correspond in detail about identified risks, financial disclosures, management's judgments, estimates, and accounting policies and practices. Management and the audit committee address these auditor comments and feedback and, as required, engage in collaborative discussions regarding the appropriate depth and breadth of the company's disclosures. Auditors, whose opinion is included within a company's financial statements and incorporated into the company's Securities and Exchange Commission (SEC) filings, would not permit their audit opinion to be included with such financial statements if a company's disclosures and discussion of its operating results were inappropriate, inconsistent, or incomplete. Thus, the addition of critical audit matters reporting would appear to be duplicative, of no additional value, and potentially confusing.

The proposing release notes these "unintended consequences," but BIO believes that they should be more of a cause for consternation than the PCAOB seems to give them credit for. The release mentions that the critical audit matters standard "could result in additional effort involving both one-time costs and recurring costs." Investors "could misunderstand the meaning of a critical audit matter" because they are not accustomed to reviewing or analyzing financial statements in such a manner. Lower quality audits could be the result of the reduced time available to the auditor under the new standard. These concerns are not trivial, and should give the PCAOB pause before adopting this costly and unnecessary regulation.

Because biotechs do not generate product revenue during the R&D phase, capital spent on regulatory burdens comes directly from funds earmarked for innovation. Any proposed regulatory duties should be judged in this light, particularly those with the ostensible goal of protecting the very investors providing those funds. The critical audit matters standard would increase audit fees without providing much, if any, valuable information to investors, so its costs far outweigh any alleged benefits.

BIO believes the JOBS Act precludes application of a critical audit matters standard to EGCs.

The PCAOB release calls for further examination and discussion of whether the proposed standards and amendments should be applied to emerging growth companies (EGCs) as defined by the JOBS Act. It is BIO's belief that the proposed critical audit matters standard should not, and cannot, be applied to EGCs.

One of the goals of the JOBS Act was to avoid a one-size-fits-all regulatory regime. The law targets growing companies during the first five years after their IPO and provides certain exemptions and allowances to ease their transition to the public market and reduce some of the cost barriers of public reporting. Applying the proposed critical audit matters standard to all issuers, regardless of EGC status, would violate the spirit of the IPO On-Ramp by subjecting smaller issuers to this costly requirement. EGCs should not be required to comply.

Further, irrespective of the costs of the critical audit matters standard to EGCs, BIO believes that the JOBS Act specifically curtails the PCAOB's authority to enact such a requirement. The proposing release notes that Section 104 of the JOBS Act requires the SEC to determine whether any new rules adopted by the PCAOB should apply to EGCs. The release solicits comment on this issue, which BIO addresses in full on page 5 of this letter. However, the release fails to mention the sentence immediately preceding the highlighted one in Section



104, which forbids the PCAOB from requiring of EGCs “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.” The JOBS Act parenthetically identifies this potential supplement as AD&A, but it is clear that Congress was attempting to forestall any efforts by the PCAOB to require this type of additional information and analysis on the audit of an EGC.

Despite the name change from AD&A to critical audit matters, and the slightly narrower scope, BIO believes that these two provisions are substantially similar. The JOBS Act forbids the PCAOB from requiring additional information about an EGC’s audit and financial statements, and the critical audit matters standard would do just that. As such, applying this proposed requirement to the audits of EGCs would be in direct violation of the JOBS Act. If the critical audit matters standard is adopted (and BIO’s position is that it should not be), the PCAOB should provide for an exception for EGCs. This exemption is required by the JOBS Act, and following Congress’s directive will prevent additional regulatory burdens from weighing down the progress of emerging biotech innovators.

Proposed Other Information Standard

Under current PCAOB standards, auditors must “read and consider” certain other information contained in Exchange Act annual reports and other documents to which the auditor devotes attention. The proposed other information standard would both increase the amount of information auditors are required to analyze and expand the procedures associated with reporting the other information.

A significant change in the proposal is in the amount and type of information for which auditors are responsible. The proposed standard would require auditors to review “Selected Financial Data, Management’s Discussion & Analysis (“MD&A”), exhibits, and certain information incorporated by reference,” among other items. Auditors are currently required to review information related to the audit in the annual report, but this expansion would substantially broaden the scope of the auditor’s responsibilities. Issuers would see a corresponding increase in audit fees as auditors struggle with the new workload.

As previously noted, auditors currently review and provide comments and feedback to management and the audit committee on a company’s MD&A. For other financial information included outside of an issuer’s financial statements (such as an earnings release), the auditor will perform certain procedures to satisfy themselves that the information is accurate and not inconsistent with the company’s financial statements. For other information included within an SEC filing that contains an audit opinion, auditors do not permit their audit opinion to be included if the other financial information is inappropriate, inconsistent, or incomplete. BIO believes that this process is sufficient, and that there is no added benefit or value to investors in having auditors expand the other information or processes for which they are responsible.

In addition to the broader definition of “other information,” the proposed standard would also hold auditors accountable for a greater degree of analysis. The current “read and consider” standard is sufficient to garner relevant information and relay it to investors in a practical manner. The proposed “read and evaluate” standard increases auditor responsibility and liability – and audit fees. These new required audit procedures specified to support the auditor’s conclusions with regard to the other information identified are complex and burdensome.

Under the proposed standard, the auditor must read and evaluate the other information for material inconsistencies and/or material misstatements of fact. Regardless of the auditor’s



findings, the auditor is required to identify the information evaluated, the auditor's responsibility regarding the other information, and the procedures used to evaluate the other information. The auditor must then communicate any conclusions in the auditor's report. This striking increase in auditor responsibility – extending so far that auditors are required to report even on information they do not believe is inconsistent or misstated – will create a new burden for auditors and issuers. The proposing release concedes that there will likely be an increase in cost and auditor effort because the proposed procedures go far beyond the current "read and consider" approach. The corresponding fees imposed on issuers could be damaging to company growth.

BIO believes that the existing other information standard is sufficient to protect investors. It balances disclosure standards with the needs of growing businesses – as directed by their investors – to efficiently use investment capital. The PCAOB should not adopt the costly, onerous other information standard described in the proposing release.

Considerations Regarding Audits of Emerging Growth Companies

As noted in the proposing release, Section 104 of the JOBS Act states that any new PCAOB rules "shall not apply to an audit of any emerging growth company, unless the [SEC] determines that the application of such additional requirements is necessary or appropriate in the public interest." According to the release, the PCAOB will make an initial determination as to whether it should recommend that the proposed standards and amendments be applicable to EGCs. If the PCAOB does recommend that the proposal apply to EGCs, the SEC will make a separate, binding determination on the issue. The PCAOB is soliciting comment to guide its initial determination. It is BIO's strong belief that the PCAOB should not recommend to the SEC that the proposed standards and amendments apply to the audits of EGCs.

The JOBS Act has been successful in spurring IPO activity amongst EGCs. The various provisions in the IPO On-Ramp have eased the IPO process and reduced the regulatory burden that newly-public companies face. The biotech industry has seen more than 50 IPOs since the law passed, a striking increase from the past two years when the market was essentially closed. It is clear that commonsense regulatory obligations play a part in the decision to go public. If growing companies face one-size-fits-all compliance burdens, they risk being dragged down by government red tape. These fears contribute to a reluctance to go through with an IPO and could harm a company's progress once it is public.

For EGCs in the biotech industry, an awareness of an issuer's potential regulatory burden is of paramount importance. As previously discussed, biotech companies face a decade-long, billion-dollar development timeline, and their research is supported by private investment capital rather than product revenue. Any funds spent complying with costly and complicated new audit regulations would be, by definition, lost to innovation.

Spending capital on regulatory burdens can slow the development process, increasing the time it takes to reach the important milestones that trigger new investments. Without product revenue, most biotech EGCs would be forced to ask investors to pay for the new audit requirements rather than scientific research. The cost burden of the proposed standards, and therefore the amount of capital diverted from R&D, could be significant.

These traits are shared by small businesses and growing innovators in all segments of the economy. Congress created the EGC definition as a means to protect these vital job creators and support their growth. The five year transition period onto the market, targeted specifically at small and emerging companies, circumvents the existing one-size-fits-all



regulatory regime and instead implements commonsense, tailored regulations that are indicative of the unique nature of EGCs. The PCAOB should not undercut this important facet of the JOBS Act, and it should not recommend that the proposed audit standards apply to the audits of EGCs.

Conclusion

The proposed change to the audit report is presumably intended to inform, and therefore protect, investors, and BIO supports this goal. In the biotech industry, an informed investor is a good one. However, the information that these investors want and need does not always align with what would be disclosed under the proposed standards. The true value of a biotech company is found in scientific milestones and clinical trial advancement rather than financial disclosures.

The business model of biotechnology is simple – growing innovators take in millions of dollars to fund their research and often do not earn a single penny in product revenue for more than a decade. Their science is the complicated part of their business, and it is the most important aspect for investors to understand. Investors mainly make their decisions based on scientific results and development milestones, not financial disclosures: tracking cash and expenses is fairly straightforward. The proposed audit changes would not provide much insight for potential investors, meaning that the high cost of compliance would far outweigh its benefits.

From a scientific perspective, biotech companies are innovators expanding the world's understanding of human life. As corporations, they strive to stay as simple as possible so that the maximum amount of investment dollars can flow directly to R&D. Disrupting that flow by diverting research funds to the unnecessary and complicated proposed audit standards could slow research and hamper growth – all while failing to increase investor confidence or spur capital formation.

As such, BIO believes that the PCAOB should not adopt the proposed critical audit matters or other information standards. These onerous requirements would stall the progress of companies at all stages of scientific development. Further, BIO believes that the proposed rule in its entirety would have a unique and damaging effect on EGCs. These growing businesses, both in the biotech industry and elsewhere, have been identified by Congress for a tailored regulatory regime. The PCAOB should not revert to a one-size-fits-all approach by applying the proposed standards to EGCs.

BIO looks forward to working with the PCAOB to enhance investor protections through the audit report without impeding innovation and growth at research-intensive small businesses. If you have further questions or comments, please contact me or Charles Crain, Manager of Policy and Research, at (202) 962-9218.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Cartier Esham".

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