



September 30, 2011

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

RE: *PCAOB Release No. 2011-003, Rulemaking Docket Matter No. 34*

Dear Members and Staff of the Public Company Accounting Oversight Board:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on *Possible Revisions to Reports on Audited Financial Statements*.

BIO is a not-for-profit trade association that represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in 31 other nations. BIO members are involved in the research and development of healthcare, agriculture, industrial, and environmental biotechnology products.

BIO fully appreciates and agrees that strong auditing standards can enhance investor protection and confidence. BIO members strongly support this goal. However, additional regulatory requirements could put emerging biotech companies in a situation wherein funds and efforts that would be otherwise spent for core research and development of new therapies for patients would instead be used to meet these additional requirements. Growing biotechnology companies face a constant struggle to access working capital to fund operations, especially in these companies' development stage of operations. It takes 8 to 12 years and in excess of \$800 million for a breakthrough company to bring a new medicine from discovery through Phase I, Phase II, and Phase III clinical trials and on to FDA approval of a product. Diverting effort and funding from research and development to addressing more stringent regulatory requirements could lead to research programs being delayed; clearly, this is not in our companies' investors' best interest.

Furthermore, the true value of biotech companies is embedded in their development technologies, 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 new standards related to financial statements would outweigh the benefits.

With this in mind, below are BIO's positions on different aspects of the release:

1. BIO does not believe that the inclusion of an auditor's discussion and analysis in our companies' SEC filings would warrant the additional cost or enhance disclosures already provided to investors.

Requiring an auditor's discussion and analysis will almost certainly 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.

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/or 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 in with a company's financial statements and incorporated into the company's 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 an auditor's discussion and analysis section to an SEC filing would appear to be duplicative, of no additional value, and potentially confusing.

Allowing auditors to provide information directly to investors could result in investors receiving disclosures without pertinent qualifying information that only management could provide. The auditors have limited involvement in the day-to-day operations and management of the business, so it would be difficult for them to provide more relevant information than management has already provided in the MD&A.

In addition, the concept of "close calls" could become a point of contention between companies and their auditors because it is only generally defined in the proposal and would require significant judgment. The subjectivity of the matter combined with the vague definition raises questions about whether the requirement to disclose such "close calls" could be consistently applied.

2. BIO believes that requiring the use of emphasis paragraphs in the auditor's report would not add value and perhaps cause confusion or misunderstanding by investors.

Emphasis paragraphs would not be relevant or useful, as incomplete information/disclosure would be provided through the requirement for short emphasis paragraphs in an auditor's report. Highlighting significant matters in the financial statements without providing the appropriate and sometimes lengthy contextual background and basis for conclusion would create greater confusion – not better understanding – for investors.

Furthermore, it would not be appropriate to describe specific audit procedures performed in emphasis paragraphs, since readers would scrutinize and potentially criticize the auditor's described procedures, thereby potentially increasing the auditor's liability. In addition, with the added requirement for emphasis paragraphs, we are concerned that auditors will institute the practice of providing "boilerplate" language to help minimize the auditor's risk/liability, thereby adding negligible additional value to investors. Therefore, BIO does not support the required use of emphasis paragraphs in the standard audit report.

3. BIO believes that requiring auditors to provide assurance on information outside of financial statements, such as the MD&A, would increase audit scope and cost without providing improvements to the quality and reliability of such information.

Similar to our response in #1 above related to the auditor's discussion and analysis, this proposal would make our companies' audits more expensive by increasing the auditor's scope of work while adding, in our opinion, negligible value to investors. Furthermore, auditors would likely charge companies a premium to cover the potential additional liability associated with the providing assurance on other information outside of the financial statements.

As noted above, currently, auditors review and provide comments and feedback to management and the audit committee on a company's MD&A. Furthermore, in practice, for other financial information included outside of a company's financial statements, such as a company's 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. As such, it is a company's expectation that their auditor will provide comments and feedback to management and the audit committee on other issued financial information such as an earnings release. Management and/or the audit committee address auditor comments and feedback as appropriate. In addition, for other information included within an SEC filing that contains an audit opinion, auditors would not permit their audit opinion to be included if the other financial information was inappropriate, inconsistent or incomplete. As a result, we feel strongly that there is no added benefit or value to investors in having such other financial information audited and opined upon by a company's external auditors.

Additionally, the increase in audit scope resulting from this proposal could jeopardize a company's timely issuance of its earnings releases and SEC filings. A company would be forced to provide drafts of other financial information to its auditor at an earlier stage in the

process to ensure that the auditor has sufficient time to conduct their additional audit procedures. This will stress (and potentially stretch) a company's internal resources and, in turn, could have a negative impact on the quality of the information provided to investors. This could apply to a public company of any size, but will certainly impact our small public biotech companies with limited staff who are already operating at full capacity.

4. BIO concurs with the PCAOB proposal to clarify certain language in the auditor's report.

BIO supports amending the auditor's report to better articulate and clarify the responsibilities of management and the external auditor. Furthermore, BIO supports providing additional descriptive language in the auditor's opinion for various terms, such as "reasonable assurance." Such clarifications would be a more cost-efficient way to enhance the auditing reporting model.

BIO looks forward to working with the PCAOB to maintain effective auditing standards that provide value to financial statement users without significantly increasing costs to biotech (and other) companies. If you have further questions or comments, please contact me or Tooshar Swain, Policy and Research Manager, at (202) 962-9200.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan F. Eisenberg". The signature is fluid and cursive, with a large initial "A" and "E".

Alan F. Eisenberg
Executive Vice President
Emerging Companies and Business Development
Biotechnology Industry Organization (BIO)