



April 20, 2009

The Honorable Mary L. Schapiro
Chairman
U.S. Securities and Exchange Commission
100 F Street, NE
Washington, D.C. 20549-1090

Re: Release No. 33-8982; File No. S7-27-08; Roadmap for the Potential Use of Financial Statements Prepared in Accordance with International Financial Reporting Standards by U.S. Issuers

Dear Chairman Schapiro:

The Biotechnology Industry Organization (BIO) is pleased to have the opportunity to comment on the Securities and Exchange Commission's (SEC or Commission) proposed roadmap to implement a global set of financial accounting standards.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 50 U.S. states and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. The majority of our member companies are small, research and development intensive companies that are eager to attract scientific talent and investments to continue growing as part of the new economy. International Financial Reporting Standards (IFRS) has a substantial impact on our emerging companies, and the manner in which the SEC plans to address implementation of IFRS may profoundly affect the vitality of the biotechnology industry in the United States and globally.

BIO believes that a global set of accounting standards is both achievable and worthwhile. A unified system of financial reporting should allow for U.S. businesses to more easily raise capital abroad without complex accounting disparities impeding transactions. It takes an estimated 8 to 12 years to bring a biotechnology therapy to market and costs between \$800 million to \$1.2 billion. In order to raise capital to further research and development, biotechnology companies often reach out to international investors or enter into collaborative agreements with other larger biotechnology or pharmaceutical companies. During this process, biotechnology companies often spend a significant amount of time educating foreign investors to the nuances of Generally Accepted Accounting Principles (GAAP) and SEC interpretations which could potentially impede a biotechnology company's ability to reach a final agreement. For these reasons, a single

set of global accounting standards will likely allow for a greater number of international transactions, enhancing the potential for growth for emerging biotechnology companies.

While BIO strongly supports a unified set of global accounting rules as an option for companies seeking capital abroad, there are some areas of the SEC's roadmap that we believe need further consideration. Before the SEC considers moving forward with implementation of IFRS, the following issues should be taken into consideration.

1. SEC should consider cost burdens to smaller companies when implementing the IFRS roadmap.

While BIO generally agrees with eventual IFRS implementation, the SEC needs to provide assurances that ample consideration is given to the cost burdens that may harm smaller companies. Before making any final decisions on mandatory implementation of IFRS, the SEC should perform a thorough analysis on the transition costs associated with implementation of IFRS by smaller companies.

Smaller companies are concerned that IFRS implementation will have disproportionately higher conversion costs. A recent Accenture survey shows that smaller companies with revenues between \$1 billion and \$4 billion will spend 0.731 percent of their revenue to convert to IFRS.¹ On the other hand, larger companies with over \$50 billion in revenues will spend .103%.² Since biotechnology companies have significantly less revenue than those surveyed, and no product revenues, implementation of IFRS could provide significant cost burdens on emerging companies.

2. SEC should not move forward on mandatory IFRS implementation until FASB and IASB have reached their goals.

The Commission will vote again in 2011 to determine whether the Financial Accounting Standards Board (FASB) and the International Accounting Standards Board (IASB) have sufficiently met the goals outlined in the FASB/IASB 2006 Memorandum of Understanding (MOU)³. The MOU outlines both short-term and long-term goals which are to be accomplished within this timeframe. BIO applauds the work done to this point by the FASB and IASB. If these goals are met, the Commission should proceed in 2011 with further consideration of the SEC's proposed roadmap and determine what steps should be taken to move forward with a single set of accounting standards. Without a collaborative effort between FASB and IASB taking hold, BIO does not believe the SEC should move forward in approving any proposals that would mandate the implementation of IFRS.

¹ Accenture, *Preparing for IFRS: An Opportunity for Financial Transformation*, Mar. 31, 2009, at 8.

² *Id.* at 8.

³ A Roadmap for Convergence between IFRSs and US GAAP—2006-2008, (Feb. 27, 2006), <http://www.iasb.org/NR/rdonlyres/874B63FB-56DB-4B78-B7AF-49BBA18C98D9/0/MoU.pdf>

BIO believes that FASB and IASB are both moving in the right direction in establishing a single set of global accounting standards. Meeting the goals outlined in the 2008 MOU update⁴ is essential to the Commission's determination of moving to an official single set of standards. We believe that the FASB and IASB can meet their goals within this time frame, and that meeting those goals might allow for U.S. companies to more easily move to a new set of accounting standards with less cost.

3. All companies should have the option to choose whether to use IFRS or U.S. GAAP in 2011.

BIO believes that the Commission's desire to limit early use of IFRS to the top 20 companies in any one industry is misguided. If the Commission determines that one segment of U.S. companies should have the ability to file using IFRS in 2011, then all U.S. companies should have the ability to file. This allows for companies to make the best decision for their shareholders, as well as to have companies of all sizes and all industries to participate in the benefits of one system of accounting.

We recognize that a scenario in which smaller companies would become early adopters of IFRS is unlikely. However, BIO does not think it is the role of the SEC to give larger companies preferences not available to smaller companies.

4. SEC should not mandate IFRS implementation without Congressional approval.

While some have suggested that the Commission should consider earlier adoption of IFRS, any mandatory implementation would be harmful to most smaller companies. BIO believes that any consideration of a government mandate should be done only after an explicit action by the United States Congress that affirms its intent to use one international set of accounting principles for U.S. companies. Any action taken by the SEC without a directive from Congress should be done through a voluntary manner only using incentives to encourage companies to use IFRS. Without an explicit mandate from Congress, the SEC should at most provide incentives for firms to move toward IFRS. As we have seen with the transition by companies to file using XBRL, the Commission does have the ability to provide companies with incentives to make a transition and should continue down this path⁵.

5. If mandatory implementation is adopted, the SEC should amend Securities Exchange Act Rule 12b-2.

Should Congress or the SEC mandate the use of IFRS, BIO believes that the SEC should revisit Securities Exchange Act Rule 12b-2⁶. As BIO expressed in letters to the SEC and the Public Company Accounting Oversight Board (PCAOB) during the drafting and proposal of PCAOB

⁴ Completing the February 2006 Memorandum of Understanding: A Progress Report and Timetable for Completion, (Sept. 2008), http://www.fasb.org/intl/MOU_09-11-08.pdf

⁵ SEC Offers Incentives for Using XBRL in Filings, (Jan. 2006), <http://www.sec.gov/news/press/2006-7.htm>

⁶ 17 CFR 240.12b-2.

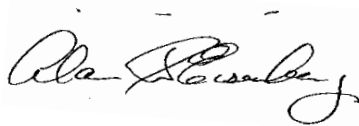
Accounting Standard No. 5 (AS-5)⁷, we believe that smaller public companies should not only be defined by their market capitalization but also by their annual revenues, as suggested by the SEC's Advisory Committee on Smaller Public Companies.⁸

The SEC disregarded the Advisory Committee's recommendations and did not include revenues in the criteria used to decipher between accelerated and non-accelerated filers. BIO believes that Rule 12b-2 should be amended to exempt companies with market capitalizations of less than \$700 million and less than \$250 million in gross annual revenues from the accelerated filer status.

Furthermore, any mandatory use of IFRS should not require a company to provide three years of audited financial statements. Instead, companies should only have to file one audited financial statement for the first year of IFRS implementation, two prior years of unaudited financial statements using IFRS, and two prior years of audited financial statements under GAAP. This will result in three sets of audited financials without the increased burden of two additional audits. This is the best option given that the purpose of the audit is to protect investors from fraud, not to act as a sign of confidence in a company.

Continued attention by the SEC, FASB and IASB to the success of this proposal will be integral to achieving their goals and to understand what further steps should be taken to ensure that our capital markets and public companies operate with the integrity and efficiency required by a truly global economy. BIO looks forward to working with the SEC toward a successful transition to IFRS. If you have further questions, please contact me or Shelly Mui-Lipnik, Director of Capital Formation and Financial Services Policy, at (202) 962-9200.

Sincerely,



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

⁷BIO letter to SEC PCAOB Rulemaking Docket Number 021, (July 12, 2007), <http://sec.gov/comments/pcaob-2007-02/pcaob200702-27.pdf>

⁸ SEC Final Report of the Advisory Committee on Smaller Public Companies, (Apr. 23, 2006), <http://sec.gov/info/smallbus/acspc/acspc-finalreport.pdf>