



December 6, 2010

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

Re: *Release No. 34-63108; File No. s7-29-10*

Dear Chairman Schapiro:

On behalf of its members, the Biotechnology Industry Organization (BIO) is pleased to provide comments on the SEC study regarding compliance with Section 404(b) of the Sarbanes-Oxley Act (SOX).

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, renewable fuels, and a cleaner and safer environment.

BIO applauds the 111th Congress and the SEC for passage and implementation of a permanent exemption from Section 404(b) of SOX for companies with public floats of \$75 million or less as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act. This is a good first step in acknowledging the cost burdens that many small public companies face in complying with Section 404(b). BIO further commends Congress and the SEC for conducting a study of how the Commission can reduce the burden of complying with Section 404(b) for companies whose public float is between \$75 million and \$250 million.

BIO fully appreciates and agrees with the congressional intent behind Section 404 – to enhance investor protection and confidence. While BIO members strongly support this goal, the implementation of Section 404 has gone awry. Many emerging biotech companies face a situation where funds that would be otherwise spent for core research and development of new therapies for patients are instead used for overly complex controls or unnecessary evaluation of internal controls.

The scale of the problems that Section 404(b) has created suggests that Congress and the SEC should continue closely monitoring the implementation of these revisions to ensure that SOX's original intent is achieved. It is critical that Congress and the SEC ensure that these new rules provide the greatest possible flexibility and scalability for small public companies.

Promising biotechnology research has a long, arduous road from preclinical research, through Phase I, Phase II, and Phase III clinical trials, and ultimately to FDA approval of a therapy. It is estimated that it takes over a decade to bring a biotechnology therapy to market and it costs over \$1 billion. Capital-intensive, innovative industries like biotechnology generally have very low revenues despite large market capitalizations because the business model relies heavily on research and development. For example, it is not uncommon for newly public biotechnology companies to have a public float of \$250 million but have product revenues of \$1 million or less. For most biotechnology companies, the actual costs of Section 404 compliance (including both internal costs and external auditor costs) are substantial. For smaller companies, the opportunity costs of Section 404 can be even greater, as the costs of compliance impede the ability to invest in and, in some cases, to continue critical research and development activities for treatments for an array of diseases, from cancer to multiple sclerosis. Further, most of these companies have very limited staff, multiplying the burdens even more.

While transparency is paramount to promoting robust capital markets, costly regulatory rules without proper adjustments for smaller companies can take away already scarce financial resources that would otherwise be used for research and development. Scaling certain regulatory measures that provide for adequate transparency while minimizing the financial burden on small companies must be an achievable goal in today's economic climate. In 2010, the industry has had 15 IPOs. However, the majority of these IPOs did not raise the amount that was originally filed. Currently, 66 percent of public biotech companies fall under the \$250 million public float threshold. The overwhelming majority of these companies do not have revenue and are years away from putting a product on the market. An exemption from Section 404(b) for companies with public floats of \$250 million or less would help these companies continue to grow during this rough economic climate.

We appreciate your efforts and your leadership in the Section 404(b) study you are about to undertake. We would welcome the opportunity to meet with your staff to discuss our concerns further, as well as provide you with additional information on our industry. In the meantime, 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)