October 17, 2005

Mr. Jonathan G. Katz
Committee Management Officer
Securities and Exchange Commission
100 F Street, NE
Washington DC 20549-9303

File No.: 265-23

Dear Mr. Katz:

On behalf of the Biotechnology Industry Organization (BIO), I want to thank the Advisory Committee on Smaller Public Companies (Committee) for providing this opportunity to submit our comments on the Committee's agenda and to express our concerns on some of the key provisions affecting the smaller biotechnology companies. Our hope is to continue our dialogue with the Committee and to be a resource to the Committee as it prepares its final recommendations to the SEC.

The Biotechnology Industry Organization (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 health-care, agricultural, industrial and environmental biotechnology products. Many of our member companies are small, research- and- development oriented companies that are eager to attract scientific talent, investment, and corporate partners to grow into the next generation of Fortune 500 firms. The issues discussed in this letter are very important to our member companies, and the manner in which they are addressed by the SEC may profoundly affect the vitality of the biotechnology industry in the United States and around the world.

Internal Controls under Section 404 of Sarbanes-Oxley Act:

Although we recognize the benefits that arise from the internal control report and related quarterly and annual disclosures, we believe that compliance with the new rules are time-consuming, inefficient and cost prohibitive for many smaller biotechnology companies.

1) Additional Cost Burden for Smaller Companies: For many of our companies, the primary responsibility for the documenting and testing falls to their internal audit departments. As most do not have full-time employees assigned to the internal audit function, these companies are forced to either hire additional internal audit personnel or engage external consultants to perform the required internal controls. As a result, many of our companies have incurred additional annual audit fees related to the attestation reports issued by their public accounting firms. For

instance, for many of the smaller biotechnology companies, they have to redirect 10 percent of their full time employee resources (in most cases double their accounting department resources) and/or hire outside firms. The increase in cost of compliance is estimated to be between $300,000 to $500,000 for internal auditors and approximately $800,000 to $1M for external auditors.

The additional costs of complying with Section 404 ultimately affects the ability of biotechnology companies to access the public capital markets, which are a critical source of funding for research and development expenditures. Most emerging biotechnology companies cannot initially fund their research and development expenditures with revenue from products or services. The need for public capital is exacerbated by recent trends in the drug discovery process that shifted many early-stage research and development expenditures from pharmaceutical companies to biotechnology companies.

We support the enhanced disclosures mandated by Section 404 and believe that the internal control report requirement will improve financial reporting. However, we believe that many small companies, including biotechnology companies, are disproportionately bearing the additional fixed compliance costs associated with being a public company. We believe the Commission should consider the additional costs that are imposed on smaller public companies in connection with the future implementation and interpretation of the Section 404 rules.

2) Need for Risk Based Approach: Although the SEC's rules provide for some flexibility based on circumstances of the companies and the significance of the controls, the prescriptive nature of the Public Company Accounting Oversight Board (PCAOB)'s Standard No.2 deters both management and auditors from taking a risk based approach to prioritizing their key financial controls under Section 404. The standards fail to recognize the value of cumulative knowledge and the importance of staggering internal control assessments for many of our companies. We believe that the Commission should provide clear guidance that would enable management and auditors to take a more risk-based approach to Section 404 compliance.

Definition of an Accelerated Filer:

The current accelerated filer definition places an additional burden on the shoulders of many of the smaller companies. Vast majority of BIO's smaller public company members have market capitalization rates of between $75M to $750M. Very few, if any, of these companies have significant product revenues and most are forced to conserve their cash to finance their ongoing lead product clinical development work. Thus, with the additional compliance requirements and resource constraints, it would be critical for the Commission to reexamine the proposed accelerated filer definition. We would recommend a substantial increase in the "public float" standards of the accelerated filer definition from the proposed $75M to $700M range to $500M to $999M. This definition change would provide additional time for many of the smaller biotechnology firms under $500M market capitalization to meet their compliance requirements, providing some relief for many of our smaller companies.

Expensing of Stock Options:

The proposed Financial Accounting Standards Board (FASB) rule requiring companies to expense their stock-based employee compensation, including stock option grants, through the use of the fair value based method is of great concern to the small biotechnology companies. Most small companies that operate in growth sectors of the economy often use stock option plans as one incentive to attract top employees from more mature industries. As a result, the use of appropriate accounting methods is a critical matter for companies in the biotechnology industry. If the accounting treatment of options is inappropriate, we believe the biotechnology industry will

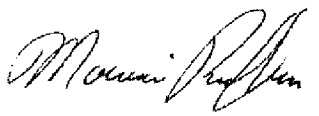
be discouraged from utilizing stock options as an incentive to attract top personnel from other industries.

The proposed rule also creates uncertainty and added compliance burdens in the biotechnology industry's efforts to provide accurate and transparent financial reports that meet the expectations of the investor community. Given the event-driven nature of our industry and the huge volatility in our industry's stock prices, reliance upon either of the proposed valuation methodologies – Black Scholes or the Binomial Lattice model – would provide an enormous range of option expense numbers as to be of little value to the investors. Additionally, most smaller companies are currently ill prepared to make their assessments, most having to invest upwards of $100,000 in additional accounting software and personnel costs.

Given the lack of industry standards and the variability of the valuation methods, we would recommend that the Commission work with the industry to develop alternative solutions to the existing framework that meet the needs of smaller companies and not rely on a more blanket, one-size-fits-all approach.

We appreciate the opportunity to comment on the Advisory Committee's agenda and BIO would welcome the opportunity to work with the Committee further. BIO is also currently working on a comprehensive survey on the impact of the Sarbanes-Oxley Act on our industry and we would welcome the opportunity to share the survey results with the Committee. If you have further questions, please contact me or my staff, Lauren Choi, Director of Capital Formation and Business Development Policy at (202) 962-9200.

Sincerely,



Edmund M. Ruffin
Executive Vice President
Capital Formation Sector and Business Development
Biotechnology Industry Organization