CELL GENESYS

May 1, 2006

Chairman Christopher Cox
U.S. Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549

Acting Chairman Bill Gradison
Public Company Accounting Oversight Board
1666 K Street, NW
Washington, DC 20006-2803

Mr. Chairman and Mr. Acting Chairman:

On behalf of the Biotechnology Industry Organization (BIO), I would like to thank the Securities and Exchange Commission (SEC) and the Public Accounting Oversight Board (PCAOB) for providing this opportunity to submit comments on the second-year implementation of the Section 404 of the Sarbanes-Oxley Act of 2002. As the Chairman and Chief Executive Officer of Cell Genesys, Inc. and as a Director and Treasurer of BIO as well as Chairman of BIO's Emerging Companies Section, I also appreciate the opportunity to participate in the SEC-PCAOB roundtable discussions on May 10, 2006.

Cell Genesys is a biotechnology company focused on the development and commercialization of the next generation of biological therapies for cancer. Our lead program, GVAX® immunotherapy for prostate cancer is in Phase 3 human clinical trials. We are also engaged in human clinical trials with other products for leukemia, pancreatic cancer and bladder cancer. These products are based on our two novel, proprietary product platforms, GVAX® cancer immunotherapies and oncolytic virus therapies.

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 BIO member companies are small, research and development-oriented companies pursuing innovations

that have the potential to improve human health, expand our food supply, and provide new sources of energy.

As representatives of one of the most innovative high growth sectors of the nation's economy -- one in which the Unites States still maintains a global leadership position-- BIO's Section 404 comments are tailored to the issues currently faced, or to be faced, by emerging companies in the biotech sector – the microcap and smallcap companies who are among the driving forces of our innovation and competitiveness in the global market place.

Need to Focus on Microcap and Smallcap Companies

BIO believes the 2006 joint roundtable of the SEC and PCOAB will be critical to focusing the discussion on Section 404 and its impact on microcap and smallcap companies – both for those companies that are "accelerated filers," and thus in their second year of Section 404 compliance, and those that are not "accelerated filers," preparing for the July 15, 2007 compliance date. BIO believes the time is right for a roundtable discussion of these issues given the final recommendations recently submitted to the SEC by the Advisory Committee on Smaller Public Companies. The 2005 Section 404 roundtable did not address, to any significant degree, the particular issues facing microcap and smallcap companies but rather focused on PCAOB Audit Standard No. 2 (AS2) and a variety of general issues and definitions. Today, the Advisory Committee has just finalized its review, and now the SEC and PCAOB have the opportunity to consider that review and the Committee's recommendations.

One Size Does Not Fit All

As stated in its April 3, 2006 letter to the Advisory Committee, BIO supports the Advisory Committee's reform framework embodied in its recommendations relating to Section 404 and its application to microcap and smallcap companies. These recommendations were the result of a thorough and thoughtful 13-month period of reviews, comments, discussions and testimonials regarding the unique issues facing smaller companies in complying with Section 404. Ultimately, a substantial majority of the Advisory Committee concluded that Section 404, as currently structured and implemented, constitutes a clear problem for smaller public companies and their investors and one that requires urgent attention.

The one-size-fits-all current approach of Section 404 is highly burdensome to smaller companies, and such companies are bearing disproportionate costs on a relative basis. This has been recognized, and documented, not only by the Advisory Committee in its Final Report, but also through surveys of BIO member companies. The reason for this increased cost is the imposition of an inflexible Section 404 on companies with fewer personnel, less revenue and fewer resources. Simply put, if the current 404 implementation continues to be imposed, or, in the case of non-accelerated filers, is imposed in the future, microcap and smallcap companies in our industry and other industries will be forced to endure internal processes and organizational changes that are

completely contrary to the rapidly changing and highly-competitive markets in which they operate.

The Costs of the One-Size-Fits-All Approach

For most biotechnology companies, the cost burdens associated with Section 404 compliance including both internal costs as well as external auditor costs have been very substantial. For example, majority of smaller companies have had to consistently spend well over 1000 staff hours on internal control work in both 2004 and 2005 while many larger biotech companies have spent over 10,000 staff hours on internal control work related to Section 404. In terms of costs, the majority of the smaller companies have sustained costs of $500,000 to $1 million on Section 404 compliance without a significant reduction from 2004 to 2005. Moreover, for the majority of the smaller companies, cost burdens specifically due to Section 404 implementation have increased by as much as 250% since the initiation of the requisite procedures.

The opportunity costs of Section 404 for smaller companies can be even greater in terms of impeding the ability to invest in and even sometimes, to continue ongoing, critical research and development activities. Significant time and money are spent to put in place complex systems and processes dictated by AS2 and required by external auditors. If the current system is not changed, these effects will also be felt by non-accelerated filers as they prepare for compliance next year, as well as private companies preparing for an initial public offering of their stock.

As a specific example, one of BIO's member companies had five employees working on Section 404 compliance at a cost of approximately $1 million. This company estimated that its controller spent approximately 35% of his time on Section 404 in year two, while the CFO spent approximately 20% of his time. To complete the mandated internal control processes and the "checklist" dictated by AS2, the company had to increase its accounting staff by 40%. Further, this company reports only a 7% decrease in costs in year two as compared to its first year of compliance.

Another public company member's experience shows the impact of Section 404 with respect to opportunity cost. This company not only spent approximately $500,000 on its external attestation of internal controls but also had to endure additional costs in terms of (i) the reassignment of laboratory research personnel to perform internal control work dictated by AS2 and the company's external auditors, and (ii) the postponement of the hiring of as many as 10 additional researchers. Such diversion of resources away from research activities can delay critical product development work and have in turn a deleterious effect on a company's ability to raise capital. To say the least, this is clearly an unintended and unfortunate consequence of Section 404.

It is the experience of BIO members that the current problems with Section 404 are not merely growing pains where the costs and burdens will decrease once the auditors and companies become more familiar with the process and requirements. The current implementation of Section 404 imposes the same requirements, steps and reviews on all

companies, by the same individuals year after year. As a result, the costs are fixed and ongoing, impacting the long-term investment resources of microcap and smallcap companies.

Scaled Reform Needed for Smaller Public Companies

BIO believes that the Commission and the PCAOB are aware of the concerns of smaller public companies regarding Section 404 and further believes Section 404 and its application to smaller public companies is not consistent with a guiding principle in the adoption of regulations – achieving the maximum benefit with the least amount of cost and intrusion into corporate decision-making. While BIO appreciates the SEC's prior two delays of the Section 404 compliance date for non-accelerated filers, the time has come to implement a workable, long-term solution and framework for these smaller companies, and BIO urges the Commission and PCAOB to promptly consider the following reform framework.

As noted by the Advisory Committee, it is critical that the Section 404 reform framework establishes a risk-based approach that provides scaled reforms based on a "revenue filter" condition. This approach recognizes that the level of risk and the level of product revenues are clearly interrelated and that product revenues should drive the complexity of internal control procedures. An approach that scales Section 404 requirements based on the level of product revenues also provides a risk-based approach, more appropriate for microcap and smallcap companies in our industry. Biotechnology start-up companies early in their histories may have very limited product revenues compared to their market capitalizations. For example, it is not uncommon for a public biotechnology company to have a market capitalization of $700 million or greater with product revenues of $1 million, or less.

Thus, BIO urges the Commission and PCAOB to, as expeditiously as possible, take the necessary steps to adopt the following reform framework:

- As per the Advisory Committee's recommendations, establish risk-based, scaled Section 404 reform for smaller public companies based on the level of product revenues (as defined in Section 5-03 of SEC Regulation S-X, 17 CFR 210.5-03, excluding revenues from license fees, and research and development payments, milestone payments, and other payments received from an unrelated third party before product sales have commenced under the terms of a collaborative contractual agreement to develop a product).

    - Provide full Section 404 relief for smallcap companies with less than $10 million in annual product revenues and microcap companies with less than $125 million in annual revenues.

    - Provide relief from the auditor attestation requirements of Section 404 and AS2 for microcap companies with between $125 million and $250 million in annual revenues, and for smallcap companies with less than $250 million in

annual revenues, but greater than $10 million in annual product revenues.

- Require that in order to take advantage of the above reforms, microcap and smallcap companies would be required to (i) comply with the audit committee requirements under Section 10A-3 of the Securities Exchange Act of 1934, and (ii) adopt (and disclose) a code of ethics applicable to directors, officers and employees in addition to other required corporate governance standards.

- If the Commission and PCAOB ultimately determine that an auditor attestation requirement is necessary for microcap and/or smallcap companies, it is imperative that the PCAOB re-open AS2 to revise the standards to devise a cost-effective, risk based standard that is tailored to the product revenue size and the level of complexity of smaller companies.

- For the smaller public companies, as defined by level of product revenues, the above reform framework should focus on the internal controls necessary for CEO and CFO certifications of company financials as currently required under Section 302 of SOX. The proposed reform supports management's incentive to maintain effective systems of internal controls and produce accurate financial reports which are most important to the investors. Section 13(b)(2)(B) of the Exchange Act requires, as it has since 1977, that public companies maintain a system of internal controls that provide reasonable assurances as to the accuracy of financial reports. The proposed reform would continue to provide assurances to investors based on the degree of risk and cost effectiveness while providing Section 404 relief for smaller public companies.

The comprehensive reform framework proposed above and the accompanying corporate governance conditions should not be implemented in a vacuum. Microcap and smallcap public companies would still be required to adhere to the other elements of the SOX protections and penalties, including the whistleblower protections, officer and director bars, and auditor independence standards. In addition, the vital work of the PCAOB and its inspection and enforcement powers, would also continue to apply and serve as a deterrent against, and remedy for, financial fraud. BIO firmly believes that these protections, coupled with the proposed reform framework, appropriately balance the costs and benefits of Section 404 with the resource challenges faced by smaller public companies.

As stated above, with the delivery of the Final Report of the Advisory Committee on April 23, 2006, BIO believes the time has arrived for the Commission to act on the recommendations of the Committee. BIO respectfully requests that the Commission act as quickly as possible and well before the July 15, 2007 compliance deadline for non-accelerated filers. If not, the current Section 404 framework will continue to impose substantial costs on smaller companies as a result of external auditors continuing to apply the same standards and methods across all companies, large and small. Non-accelerated filers will incur costs as they continue to plan and prepare for compliance next year, based upon the current framework. Even private companies will feel the disproportionate cost in terms of the impact on their potential opportunities to become public companies.

In closing, I would like to state that BIO appreciates the opportunity to provide feedback to the Commission and the PCAOB as it reviews year two compliance with Section 404 and, the opportunity to lend our support to the recommendations of the Advisory Committee on Smaller Companies with respect to modifications of Section 404 for microcap and smallcap companies. If you have additional questions, please feel free to contact me or Lauren Choi, BIO Director of Policy for Capital Formation and Emerging Companies at (202) 962-6632.

Sincerely,

/S/ Stephen A. Sherwin
Stephen A. Sherwin, M. D.
Chairman and Chief Executive Officer
Cell Genesys, Inc.

Board Member and Treasurer, Chairman of the Emerging Companies Section
Biotechnology Industry Organization

cc: Commissioner Cynthia A. Glassman
Commissioner Paul S. Atkins
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