



November 15, 2008

Mr. Robert Herz
Chairman
Financial Accounting Standards Board
401 Merritt 7
P.O. Box 5116
Norwalk, CT 06856-5116

RE: Exposure Draft on Amendments to FASB Interpretation of FIN 46(R)

Dear Chairman Herz:

On behalf of its members, the Biotechnology Industry Organization (“BIO”) is pleased to provide comments on the FASB’s proposed amendments to FIN 46(R), *Consolidation of Variable Interest Entities*. As part of the public comment process, BIO would like to highlight the impact of FIN 46(R) on collaborative arrangements between emerging biotechnology companies and pharmaceutical companies. Collaborative arrangements remain an important financing mechanism for emerging companies to further their research and development. Given the financial turmoil in the markets, biotechnology companies are increasing the use of these arrangements to raise substantial capital, but the complexity and uncertainty surrounding the current FIN 46(R) guidance has indirectly affected biotechnology and pharmaceutical companies entering into these agreements.

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.

Collaborations are essential for many biotechnology companies to continue their research and development of life saving therapies

Research and development in the biotechnology industry has a long and arduous road. Biotechnology companies are often lacking funds for research and development of early stage products. It takes an estimated 8 to 12 years to bring a biotechnology therapy to market and costs between \$800 million and \$1.2 billion. Due to the capital intensive nature of bringing a new therapy to market, collaborative arrangements for the biotechnology industry are a critical mechanism to finance the development of new therapeutics. Collaborations usually involve an

emerging biotechnology company partnering with a pharmaceutical company in which both parties typically agree to share technology, research costs, and resulting profits. Such arrangements allow the emerging biotechnology companies to access additional funding and commercialization networks.

At a fundamental level, emerging biotechnology companies are engaging in the commercialization of cutting edge science. As scientific progress is an endeavor that requires a large amount of resources, biotechnology companies will collaborate with one another to pursue their research and development objectives. Furthermore, collaborative arrangements provide an opportunity for specialization so that emerging biotechnology companies may focus on scientific innovation while a larger pharmaceutical company may have a greater expertise in downstream clinical trial management. Under these arrangements, often a biotechnology company may license its intellectual property of a certain therapeutic product to a pharmaceutical company in exchange for a combination of upfront payments, payments for achieved milestones, or reimbursements for research and development undertaken. These arrangements are pervasive throughout the industry with duration ranging from several years to indefinite. However, depending on the terms of the arrangement, the arrangement could trigger FIN 46(R) forcing the pharmaceutical company to consolidate a biotechnology's financial statements into its own financial statements.

Clarification to FIN 46(R) is necessary to accurately reflect the economics of collaborations

BIO applauds FASB's efforts to promote financial accuracy and transparency to provide "meaningful" financial statements for investors. However, the current FIN 46(R) guidance does not reflect the underlying economics of a collaborative arrangement particularly when both companies have a vested interest in jointly developing a product. One company may hold the license and know-how of developing a product, while the other has superior research and development capabilities. Should a product gain FDA approval and enter the marketplace, they typically share royalties. Under the FIN 46(R) guidance, if the pharmaceutical company is the primary beneficiary of the biotechnology company because it is exposed to a majority of the expected losses of the biotechnology company during the development of the particular product under the collaboration, then it would have to consolidate the biotechnology's company financial statements. Full consolidation of the biotech company's activities into the pharmaceutical company results in the activities of all the biotech's products, including those not in the collaborations agreement being reported into the results of the pharmaceutical company. Similarly, consolidation results in assets and liabilities of the biotechnology company not related to the collaboration being reported as if they are "controlled" and used in the operations of the pharmaceutical company. Such a requirement results in the accounting not matching the actual economics of the transaction.

If the economics of a transaction are not properly reflected in the financial statements, how can those financial statements be meaningful to investors? Furthermore, we are concerned that subjecting collaborations to FIN 46(R) could make these arrangements less attractive for pharmaceutical company because collaborations could negatively affect their financial statements. FIN 46(R) can cause pharmaceutical companies to hesitate in entering into collaborations regardless of the science but because of the complex and potentially adverse accounting ramifications. Biotechnology companies could lose an important financing

mechanism in their research and development and the ultimate result would be delaying innovation of life saving therapeutics.

BIO would like to see more clarity on how to consolidate financial statements if a company complying with FIN 46(R) must consolidate a collaborative partner. Currently, paragraph 22 of FIN 46(R) states that the principles of consolidated financial statements in ARB 51 should be applied as if the entity were consolidated based on voting interest. This is very difficult to apply in our industry because consolidation is based on a collaboration agreement where neither a voting interest (control) nor ownership exists.

BIO looks forward to working with the FASB on revising FIN 46(R) guidance that would provide meaningful financial information to investors and reflect the underlying economics of collaborations. 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,

A handwritten signature in black ink, appearing to read "Alan Eisenberg". The signature is fluid and cursive, with the first name "Alan" being more prominent and the last name "Eisenberg" following in a similar style.

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