



January 23, 2009

Mr. Russell G. Golden
Chairman of Emerging Issues Task Force
Financial Accounting Standards Board
401 Merritt 7
Norwalk, Connecticut 06856-5116

Re: BIO submits comments to EITF 08-1

Dear Mr. Golden:

On behalf of its members, the Biotechnology Industry Organization ("BIO") is pleased to provide comments on the Emerging Issues Task Force (EITF) Issue No. 08-1, "Revenue Arrangements with Multiple Deliverables."

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.

Revenue recognition continues to be an area of concern in the biotechnology industry, particularly as it relates to collaborative agreements. At a fundamental level, the biotechnology industry is engaging in the commercialization of cutting edge science. Due to the capital intensive nature of bringing a new therapy to market, biotechnology companies will collaborate with one another to pursue their research and development objectives. Furthermore, collaborative arrangements provide an opportunity for specialization so that small biotechnology companies may focus on scientific innovation while a larger company may have greater expertise in downstream clinical trial management. These agreements often involve upfront payments for entering into the collaboration, milestones payments for achieving developmental events, and payments for research and development services performed. These agreements are pervasive throughout the industry with duration ranging from several years to indefinite. As such, BIO has the following comments regarding EITF 08-1:

1. While EITF 08-1 is a step in the right direction, FASB should provide guidance on acceptable methods for evidence of fair market value.

BIO commends FASB's recent efforts to allow the use of an estimated selling price for undelivered elements for purposes of separating elements included in multiple-element

arrangements. While FASB's proposed action should allow more entities in a multiple-element arrangement to be separately accounted for, in the biotechnology industry, certain issues, such as ownership rights to technology and joint steering committees, are unable to be separated as a single entity from a multiple element arrangement.

Furthermore, it appears that there are no substantial changes to example 12 in EITF 08-1 from EITF 00-21. In example 12, it appears that a biotechnology company still will not be able to separate technology ownership rights as a single entity. This could cause significant revenue deferrals for multiple payments in biotechnology collaborative agreements, and many of the payments may not be able to be recognized until the agreement expires.

2. Additional FASB efforts are necessary for revenue recognition to accurately reflect the underlying economics of collaborations.

BIO applauds FASB's continuous efforts to promote financial accuracy and transparency to provide "meaningful" financial statements for investors. EITF 08-1 is a step in the right direction toward this goal. However, changes made under EITF 08-1 will not allow many biotechnology companies to accurately reflect the underlying economics of a collaborative arrangement in their financial statements. When the accounting treatment differs significantly from the underlying arrangement economics, biotechnology companies will need to provide statements in accordance with the Generally Accepted Accounting Principles (GAAP), but they may also need to provide financial information that aligns with the economics of the transaction. Aligning revenue recognition in financial statements with the compelling economics of collaborative arrangements makes those financial statements more relevant and meaningful for investors.

BIO looks forward to working with the FASB on revenue recognition changes 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".

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