

October 22, 2010

Technical Director
File Reference No. 1820-100
Financial Accounting Standards Board
401 Merritt 7
P.O. Box 5116
Norwalk, Connecticut 06856-5116

Re: Comments regarding Revenue Recognition (Topic 605) Exposure Draft, "Revenue from Contracts with Customers"

Dear Sir or Madam:

On behalf of its members, the Biotechnology Industry Organization (BIO) is pleased to provide comments on the Exposure Draft entitled *Revenue from Contracts with Customers*.

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 collaboration agreements. At a fundamental level, the biotechnology industry is engaging in the commercialization of cutting edge science. Due to the significant (i) capital investments, (ii) research and development costs, (iii) risks, and (iv) length of time from discovery to commercialization associated with bringing new therapies to market, biotechnology companies will most often collaborate with one another or with pharmaceutical companies to obtain funding, share or mitigate risk, and allow biotechnology companies to pursue their research, development, and commercialization objectives. Furthermore, collaborative arrangements often provide the opportunity for smaller biotechnology companies to contribute scientific innovation and research, whereas larger collaborators may contribute their expertise in later-stage clinical development, commercialization, and manufacturing drug supplies. Collaboration agreements often include up-front licensing payments, reimbursements for (or cost-sharing of) research and development activities, development milestone payments (such as for initiating a clinical trial of a product candidate), royalties or sharing of profits/losses, and sales milestone payments. Collaboration agreements are essential and pervasive throughout the

biotechnology industry, and vary in complexity. The term of these agreements may be finite or flexible based on the collaborators' joint determination as to if and when the collaboration should be discontinued.

BIO supports the efforts of the Financial Accounting Standards Board (FASB) and the International Accounting Standards Board (IASB) to establish more uniform standards for revenue recognition across various industries. Collaboration agreements, however, present unique challenges from a revenue recognition perspective which raise industry concerns regarding the proposed provisions of the Revenue Recognition Exposure Draft (ED). Below are some of the biotechnology industry's specific concerns.

1. Should the Provisions of the ED apply to Collaborations in the Life Sciences industry?

The ultimate goal of a collaboration in the life sciences industry is to advance scientific understanding which will lead to the sale of products. Therefore, it is not clear whether the ED would apply to collaboration agreements since both parties to the collaboration generally work together to develop and, ultimately, commercialize a product candidate (i.e., is a biotech collaborator really a "customer" of a biotech company, or is it simply a development partner?). In addition, if the ED would not be applicable to such collaborations, based on the facts and circumstances, then what accounting guidance should our industry follow instead? It appears that more clarity in the ED is needed to address this concern.

2. The ED does not allow Multiple Revenue Recognition Methods for Various Performance Obligations in a Collaboration Agreement.

Under the ED, performance obligations are separated based on whether they are "distinct," similar to the current "stand-alone value" concept in the U.S. generally accepted accounting principles (GAAP). In many biopharmaceutical collaborations, performance obligations during the research and development phase may contain various elements such as an up-front licensing payment, reimbursement for or sharing of costs for research and development (R&D) activities, and development milestone payments. Currently, biotech companies account for these various elements, based on facts and circumstances, under different revenue recognition methods. For example, the up-front licensing payment may be recognized over time, reimbursements for or cost-sharing of costs for R&D activities as such costs are incurred, and development milestones, which are deemed substantive, upon their achievement.

However, the ED seems to provide that only a single method of revenue recognition may be used for a particular unit of accounting, meaning that all amounts allocated to that unit must be recognized using a single pattern. Such methodology would appear, therefore, to negate the FASB's recently issued guidance validating the recognition of substantive performance milestones upon their achievement under (the former) EITF 08-9. In addition, reimbursements for R&D activities as the related costs are incurred might not be allowed, which is contrary to the basic principle of matching revenues to expenses in the same period and would be confusing to explain to investors who rely on financial statements. As a result, the biotechnology industry supports more flexibility in applying varying methods of revenue recognition to each

performance obligation under a collaboration, based on each collaboration's facts and circumstances.

In addition, the biotechnology industry strongly supports the continued validation of the substantive milestone method for recognition of applicable milestones in these agreements. BIO applauded the Emerging Issues Task Force in its development of EITF 08-9. We believed that this was as an important codification of a revenue recognition principle that best aligned the business intent of industry collaborations in consideration of the significant R&D efforts, risks of achievement and accretion of value in connection with achieving substantive development milestones related to those agreements. There is significant uncertainty in achieving such milestones which is inherent in developing drug product candidates (for example, achieving favorable clinical trial results or regulatory approval).

We are especially concerned that the substantive milestone method, as originally codified under EITF 08-9, may no longer be allowable under the ED. Furthermore, it appears that the ED may require a company to potentially recognize revenue in advance of achieving a substantive milestone based upon the requirement for the company to estimate the probability of such milestone's achievement at a reporting date. Due to the serendipitous nature of research and development in the biotechnology industry and the high degree of uncertainty in achieving such milestones for reasons described above, such requirement to make estimates of the probability achieving development milestones would be extraordinarily difficult and highly susceptible to errors in judgment. Thus, BIO continues to strongly support the recognition of substantive milestone payments in full upon their achievement.

3. The ED lacks clarity on how the biotech industry would recognize upfront payments.

In general, the biotech industry considers up-front payments to be attributable to development activities and, therefore, prefers to recognize these payments as revenue over a collaboration's development period. It is not clear from the ED that this would be an acceptable way to recognize upfront payments. Furthermore, we are concerned about whether a portion of an upfront payment would have to be allocated to "contingent obligations" once product candidates are approved for commercialization. Additionally, BIO is concerned that companies would have to anticipate what they might achieve or be obligated to do in order to report revenue related to up-front payments under the ED. Such estimates would be extraordinarily difficult given the high degree of uncertainty in developing and achieving regulatory approval of a product candidate.

4. Retrospective application of the ED would be overly burdensome.

BIO is strongly opposed to the retroactive application of the ED. The retrospective application of the ED would be very burdensome to emerging biotechnology companies that lack the internal and financial resources needed to restate up to five years of financial statements. In addition, the ED requires companies to estimate the stand-alone value of each performance obligation at the onset of an agreement. Since companies will not have up to five years of actual experience with their agreements, in hindsight, such estimates could be materially different than if they are

prepared when the ED is enacted. As described above, there is a significant amount of uncertainty (and, therefore, estimation) related to collaboration agreements.

BIO would strongly support prospective application of the ED, with appropriate disclosures explaining the impact of the enacted guidance on the Company's revenue arrangements and its financial statements.

5. Example 10 in the ED is not completely reflective of the collaborations that occur in the industry.

BIO appreciates inclusion of a collaboration involving technology licensing with research and development services. However, example 10 addresses an overly simplistic scenario. Under the presumption that collaboration agreements would be scoped into the ED, we would suggest the inclusion of a more complex collaboration arrangement, with multiple elements, in the ED, which is much more common in the biopharmaceutical industry.

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. Additionally, BIO would appreciate the opportunity to have a representative at the round table being held on November 4th to discuss the Exposure Draft. 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)