

Letter of Comment No: 16
File Reference: 1082-194R
Date Received: 5/25/99

May 21, 1999

Director of Research and Technical Activities FINANCIAL ACCOUNTING STANDARDS BOARD of the Financial Accounting Foundation 401 Merritt 7 P.O. Box 5116 Norwalk, Connecticut 06856-5116

Re: File Reference: 194-B

Proposed Statement of Financial Accounting Standards — Consolidated Financial Statements : Purpose and Policy

The following is in response to your request for comments regarding the above captioned proposal.

BioChem Pharma Inc.

BioChem Pharma Inc. is an international biopharmaceutical company dedicated to the research, development and commercialization of innovative products for the prevention and treatment of human diseases, with a focus in cancer and infectious diseases. The company is headquartered in Laval, Québec, Canada. Its common shares are authorized for quotation in the United States on the NASDAQ National Market and are traded in Canada on the Montreal Exchange and the Toronto Stock Exchange. The company's market capitalization is some US\$2.3 billion.

BioChem's most significant therapeutic product is its anti-HIV drug marketed under the brand name 3TC or Epivir and developed with Glaxo Wellcome. Looking back to 1997, about 44% of total revenues came from royalties resulting from sales of 3TC. Another 42% of sales came from a well-established diagnostics business. Most of BioChem's 1997 net income was attributable to its therapeutic business.

In 1998, BioChem Pharma was the sponsor of the creation of CliniChem Development Inc. which was subsequently distributed as a dividend to BioChem shareholders. CliniChem was formed for the purpose of researching and developing certain cancer and infectious disease products for human use which have been licensed from BioChem. BioChem is conducting R&D for CliniChem. BioChem has the option to license each CliniChem product, and has an option to purchase all of the CliniChem Class A common shares at a price set according to a predetermined formula.



At the beginning of 1998, BioChem found itself in the fortunate position of having several products emerge through the pre-clinical research stage ready for further development including clinical trials in humans. The magnitude of the costs of these trials, which will last for several years, were such that the nature of BioChem's existing business would have been significantly transformed. The formation of CliniChem and the undertakings between BioChem and CliniChem allowed for the separation of the development risk in the new product portfolio, which was licensed to CliniChem, from the existing business. BioChem's near term financial results would continue to reflect principally its existing businesses. Thus shareholders were given the opportunity of choosing the degree of risk they wished to hold by varying their level of investment in CliniChem.

Research & Development

Pharmaceutical and biotechnology research and development is unique from the point of view of time, cost and risk with these distinguishing features:

- i) R&D time is roughly 12 years from start of the discovery process to final approval of a drug for marketing.
- ii) Cost to develop a single drug varies widely but the average is some U.S. \$300 million.
- iii) The risk from discovery to approval is 10,000 to 1. Starting with 10,000 drug compounds:
 - 20 show promise
 - 10 make it to the initial Phase of testing in humans
 - 5 make it to the second Phase of clinical trials
 - 2 make it to Phase III clinical trials
 - 1 gets regulatory approval

It is these characteristics, and the need to pay attention to the risk/reward requirements of shareholders, that have led biotechnology companies to sponsor special purpose R&D vehicles. Such vehicles have also been an effective financing means for development work. Risk and income separation has a legitimate business purpose for the drug development industry due to the unique profile noted above and will continue to be important in the future, and changing the reporting requirements of these entities to require consolidation of both entities will be to the ultimate detriment of shareholders.

Furthermore, existing vehicles have been carefully designed to give control to the special purpose entity's board of directors and shareholders under current standards. Reversing the accounting treatment for existing vehicles that have been structured properly and approved by independent accounting firms and the S.E.C. is both unfair and inappropriate. These should be exempted from the proposed standard. Changing the reporting requirements will result in unnecessary confusion and instability in the securities markets.

While fully integrated, biopharmaceutical companies might be able to balance the risk of product development in their existing product and activity portfolio, emerging biopharmaceutical companies will continue to need to separate risks in their portfolios to meet the expectations of their shareholders.

Determination of Control

With regard to determination of the existence of control, we are of the opinion that <u>presumption</u> of control is an inappropriate principle that leads to total conjecture on the part of financial statement preparers. It would appear to us that <u>demonstrated</u> control is by far a more solid foundation. In this light, we agree with the points outlined in the Alternative View contained in the Exposure Draft on this issue.

Regarding the existence of an option to acquire voting shares, this clearly does not confer any additional decision making power to the option holder, an issue cited as a key control consideration. Furthermore, the presumption that control is being exerted, because of the existence of an option or will, in future, be exerted by exercise of the option, has no economic basis. An option holder has the right but no obligation to act and only by exercising the option does he obtain a voting right. Currently, BioChem's economic interest in CliniChem is 0.04%. If the portfolio of drug candidates in a special purpose R&D vehicle has limited or no future value, then the option holder will not exercise. The existence of an option as a proof of control is clearly unfounded in economics. Only by exercise of the option and demonstration of control can the case be unambiguously made.

Next we refer to the existence of an option and the question of a parents' ability to use its power to increase the benefits it derives and limit the losses that it suffers from the activities of that subsidiary. In the case of CliniChem, approximately \$25M has been spent to date in R&D. The current option exercise price by BioChem is \$175 M - \$25 M = \$150 M. It is hard to see, then, how the exercise of the option today, which would effectively deliver proceeds of \$150M to the CliniChem shareholders, could be seen as increasing the benefits to BioChem from the activities of that subsidiary.

The scope and content of FASB definition of "control" in the current proposed statement is excessively broad, and should be reworked to limit control to demonstrated control and should not encompass the mere holding of an option by a party. At the very least, if the holding of an option is to be reflected in the definition of control, the current bargain purchase option concept should be retained.

Fiduciary Responsibilities

The CliniChem Board clearly has a fiduciary responsibility to the CliniChem shareholders and only to them. CliniChem is a public company, with its own shareholders, many of whom have changed over since the initial distribution to BioChem shareholders. This Board has the right to agree to work plans and to the budget for each product and has a predetermined dispute resolution process. Presupposing that BioChem can influence the CliniChem Board's view of its fiduciary duties is a wrong approach. It is easier and more appropriate to presume that CliniChem will act in its

own best interest, which assumption does not confer "decision making ability that is not shared with others" on BioChem.

In summary, we believe that the concept of presumed control will not benefit users of financial statements. The concept is ambiguous, lacks a basis in economic reality, will produce a lack of comparability between entities and hence is a step in the wrong direction. There is no way the accounting profession should be expected to enforce comparability under a regime of ambiguity or presumption. We believe that demonstrated control is a far more economically sound foundation to underpin control considerations.

Yours truly,

Fred Andrew

Chief Financial Officer