Update -- Overview of Pharmaceutical Industry Research and Development Vehicles (6/6/00)

Since CFRA’s earlier reports on pharmaceutical companies which use research and development vehicles, certain of such companies have initiated action to repurchase their R&D vehicles. In addition, there have been some further developments regarding FASB’s review of the use of this approach.

CFRA believes that certain pharmaceutical companies obtain a boost to revenue and earnings by recording revenue from transactions with certain related-party entities (called “off-balance sheet R&D vehicles” or “R&D vehicles”). The Financial Accounting Standards Board (FASB) is currently holding meetings to review this approach and is expected to issue a Statement which will generally disallow the treatment of R&D vehicles as separate entities. Upon the adoption of this new accounting rule by FASB, CFRA believes that such companies will be required to consolidate such R&D vehicles, thus eliminating this revenue source. Furthermore, CFRA notes that such rule, in its current form, suggests that such consolidation would be retroactive, thus eliminating this revenue source from past financial statements as well.

In addition, CFRA believes that if these companies were to consolidate such R&D vehicles, the bulk of the related expenses (e.g., R&D, depreciation, amortization, salaries, and insurance) would remain on the pharmaceutical companies’ income statement. However, the pharmaceutical companies’ revenue would be reduced by the amount attributable to each respective R&D vehicle. Thus, CFRA disagrees with the claim of many of these pharmaceutical companies that such R&D vehicles do not contribute significantly to operating income, since the pharmaceutical companies make that assertion on the basis of both the revenue and expenses associated with the R&D vehicles -- whereas, in reality, the consolidation of R&D vehicles would generally eliminate only the revenue, and not the expenses.

Background. CFRA has identified Allergan, Inc. (“AGN”), Alza Corporation (“AZA”), BioChem Pharma Inc. (“BCHE”), Biovail Corporation International (“BVF”), Dura Pharmaceuticals, Inc. (“DURA”), Elan Corporation, plc (“ELN”), and Forest Laboratories, Inc. (“FRX”); collectively, “the pharmaceutical companies”); as pharmaceutical companies which have used/are using off-balance sheet R&D vehicles. R&D vehicles are typically created by these companies and either spun off as initial public offerings or spun off to shareholders as taxable distributions. The pharmaceutical companies retain an option to purchase this R&D vehicle.

The pharmaceutical company funds the R&D vehicle with cash which is designed to be returned to the pharmaceutical company as payments for the pharmaceutical company performing research over a specified period of time for the R&D vehicle. The pharmaceutical company typically generates this revenue through a development agreement, under which the R&D vehicle reimburses the pharmaceutical company on a cost-plus basis for certain R&D, and a technology license agreement, under which the pharmaceutical company grants the R&D vehicle a license to certain of the pharmaceutical company’s technology in exchange for periodic fee. Such agreements are typically not negotiated in an arm’s-length manner. CFRA believes that pharmaceutical companies created these entities as vehicles for the channeling of funds used to support research and development of certain of the companies pharmaceutical products.
FASB Position Statement. A FASB position statement would disallow the recording of revenue from entities such as R&D vehicles, which are created and controlled by these pharmaceutical companies. FASB issued an Exposure Draft in February 1999 with a comment period that expired on May 24, that “would require a parent to consolidate all entities that it controls (subsidiaries) unless control is temporary at the date it is acquired or otherwise obtained.” FASB originally indicated that the proposed Statement would be effective for financial statements for annual periods beginning after December 15, 1999 (but FASB later decided that it would not retain this effective date and reported that it had not yet discussed a specific effective date for a final Statement) and would be applied retroactively by restatement of comparative financial statements for earlier periods.

Despite discussions in September and October 1999 in which different guidance for implementing the definition of control was considered, FASB decided at its February 23, 2000 meeting to retain the Exposure Draft approach which “identifies several factors that provide compelling evidence pointing toward the existence of control and provide a basis for rebuttable presumptions of control.” FASB reported that it was continuing its deliberations and plans to issue a Statement early in the third quarter of 2000.

Some Pharmaceutical Companies Exercising Purchase Option. No doubt at least partially as a result of FASB’s recent actions to force pharmaceutical companies to consolidate such R&D vehicles, certain pharmaceutical companies have recently exercised their options to purchase their R&D vehicles. Specifically, ELN announced that it had exercised its option to acquire both of its R&D vehicles, Axogen Limited and Neuralab Limited, in December 1999 and January 2000, respectively. In addition, BCHE announced that it planned to purchase its R&D vehicle, CliniChem Development, Inc., when its funding is exhausted, expected to be sometime in 2000.

Commentary. CFRA believes that pharmaceutical companies should not record any revenue from their transactions with the off-balance sheet R&D vehicles, both because of the apparent lack of validity of any such revenue and in light of the apparent imminent disallowance by FASB of the reporting of such revenue. Specifically, we believe that the pharmaceutical companies should report financial results for the R&D vehicles in a consolidated manner, both going forward and retroactively, which would prohibit the possibility of recording any revenue from these entities.

We conclude that this revenue lacks validity because of the following factors: R&D vehicles are created as shell companies in order for the pharmaceutical company to record revenue which exceeds the expenses that the pharmaceutical company would incur to perform R&D; the R&D vehicles lack independent economic substance, as its underlying agreements with the pharmaceutical companies are generally not completed on arm’s-length basis’s, and because the pharmaceutical companies retain the right to repurchase the R&D vehicles; and the R&D vehicles’ capability to pay the pharmaceutical company rests on the funding provided by the pharmaceutical company to the R&D vehicle.

We also believe that the new FASB ruling will disallow the reporting of revenue from an off-balance sheet R&D vehicle structure. Based on the clarified definitions appearing in FASB’s draft statement, the pharmaceutical companies appear to control the R&D vehicles through their direction of the ongoing use of their assets to obtain benefits from the R&D vehicles, while also limiting losses from R&D activities. Moreover, the pharmaceutical companies’ right to acquire the R&D vehicle appears to satisfy FASB’s “Presumption of Control” criteria.