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Accounting for FDA Approval Costs: Can They be Capitalized?

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ABSTRACT:

The costs for FDA approval are considered research and development costs. The FASB has never mentioned FDA approval costs in their pronouncements and therefore the method of treatment for these costs was uncertain. The purpose of this paper is to determine what the treatment of FDA approval costs should be and if that method is consistent with the treatment of research and development expenses. The main concern being whether to expense the costs or capitalize the costs as assets. The accounting rules were examined regarding research and development costs, and the definition of FDA costs was determined. Data from companies who incur research, development, and FDA costs was examined to determine what type of treatment they used. After gathering this information, I combined and compared it to determine that the most common, if not only treatment method used by the companies was to expense research, development, and FDA costs.

TABLE OF CONTENTS

ACCOUNTING FOR FDA APPROVAL COSTS: CAN THEY BE CAPITALIZED?

INTRODUCTION

The purpose of this project is to examine the costs associated with the FDA approval process and to determine if such costs meet the criteria of capitalized research and development costs. Under normal circumstances all research and development cost are treated as expenses when incurred. There is an exception to this rule which allows costs to be capitalized if they meet certain requirements. I will explore this area and these requirements to determine if FDA approval costs can be capitalized.

The reason for examining this topic is because often companies are frustrated by expensing all the costs incurred through research and development along with the millions of dollars spent each year on FDA approval. They would prefer to practice the matching principle which states that expenses should be matched with revenues. This would make their company look more profitable by avoiding such large expenses on the income statements until they incur revenues to offset their expenses.

This topic has never been addressed in any articles or books as far as I know. I find it interesting to examine a topic for which there is no one correct answer at this time. It's a topic that many people probably don't consider unless they are in a specific industry that requires FDA approval.

The remainder of this paper will contain the following sections. I will begin by describing the background information related to this topic. In this section I will give detailed explanations of what FDA costs are, what the accounting rules

officially state, and why this is an accounting issue. I will also describe articles that relate to these topics along with company examples from their financial statements.

The next section will examine the different alternatives regarding FDA costs. I will consider whether the reporting options are in accordance with the Financial Accounting Standards Board(FASB)'s pronouncements. I will also state other professionals' opinions and agree with or refute them.

The last section will consist of recommendations made by myself and other professionals. I will also explain the effect the recommendations will have on companies who incur FDA approval costs.

BACKGROUND

RESEARCH AND DEVELOPMENT COSTS

In October 1974, the Financial Accounting Standards Board (FASB) issued a Statement of Financial Accounting Standards No. 2, "Accounting for Research and Development Costs." This is the accounting rule that still exists presently which states that "all research and development costs must be expensed when incurred and the expected value of R&D is zero." (Bierman 48) The exception to this rule is when definite future benefits can be defined, then and only then can they capitalize research and development. This accounting treatment caused an uproar among many professionals along with many companies who spend millions of dollars on research and development every year. Prior treatment of research and development costs allowed more capitalization along with giving

value to research and development.

The FASB's definition of research and development is as follows:

Research is planned search or critical investigation aimed at discovery of new knowledge with the hope that such knowledge will be useful in developing a new product or service, a new process or technique, or in bringing about a significant improvement to an existing product or process.(Keiso & Weygandt 607)

Development is the translation of research findings or other knowledge into a plan or design for a new product or process or for a significant improvement to an existing product or process whether intended for sale or use.(Kieso & Weygandt 607) For specific examples of what costs can be included in research and development costs and which costs must be excluded, see Appendix A.

ACCOUNTING ISSUE

After making the 1974 decision regarding the expensing of research and development costs, the FASB offered the following considerations supporting their decision: "1) Uncertainty of future benefits; 2) Lack of causal relationship between expenditures and benefits; 3) R&D does not meet the accounting concept of an asset; 4) Matching of revenues and expenses; and 5) Relevance of resulting information for investment and credit decisions."(Bierman 48)

One consideration in favor of expensing research and development costs is the uncertainty of future benefits. This view is fairly easy to understand. Many companies begin research projects without knowing whether they are going to succeed or fail

because there is always a high degree of risk involved. It is difficult to determine what the project will be worth several years in the future, if it will be worth anything at all. There is a concept of uncertainty surrounding research and development costs. It's just the nature of this area. On the other hand, the idea of management planning should be considered because management does not want to invest in a project they think will fail. Most companies apply many hours to investment decisions involving research and development along with weighing the costs and benefits involved. Therefore, management engages in research and development with the expectation that future benefits will result. Many argue that the future benefits should be recorded as an asset.

The second factor cited by the FASB is the lack of causal relation between expenditures and benefits. In this case the board implies that there is no relationship between the expenditures for research and development and the subsequent benefits received from research and development. The FASB studies found this case to be true, but several other studies, along with other discipline theories such as economics, have proven false many economic studies performed. It's been concluded that considerable research in the business world does produce benefits to the firm. "Expenditures on R&D to develop new products or improve old ones are likely to be less correlated with market returns than expenditures for expansion into new markets or expanding market capacity."(Bierman 52) Basically, it depends on which view is taken when looking at the relationship.

Third, the FASB believes that research and development costs do not meet the definition of an asset. The FASB defines an asset as probable future economic benefits obtained or controlled by a particular entity as a result of past transactions or events (Bierman 53). They do not believe research and development costs meet the definition of an asset because research and development costs "future economic benefits cannot be identified and objectively measured." (Bierman 53) This is also the reason against capitalization. If it's not an asset, it cannot be capitalized.

Fourth, the issue is the matching of expense and revenue. The FASB uses the matching principle "in favor of expensing R&D." (Bierman 53) Bierman and Duke's opinion of this argument is similar to everyone else's. They argue that "the only reason R&D expenditures are made is to benefit future time periods by generating new revenues in those time periods." They also argue that "the expensing of R&D consistent with matching is a conclusion that is difficult to comprehend and goes against a basic principle of accounting standards - the matching principle." (Bierman 53) This illustrates that the matching principle can be utilized for both sides of the argument.

Finally, the last factor the FASB cited as support is the relevance of resulting information for investment and credit decisions. (Bierman 53) The FASB suggests that there is no purpose in allocating these expenses throughout several periods. They also state that "the capitalization of research and

development costs is not useful in assessment of the earnings potential of the enterprise." (Bierman 53) The FASB translates this to mean that capitalizing research and development costs would not make a substantial difference to investors who use the financial statements. Dukes performed tests relating to the amount of reliance placed on the financial statements regarding research and development costs. He found that there were relationships between research and development costs and the prediction of the future return of a security. His opinion is that when research and development cost are capitalized, it helps an investor predict a return because the investor is aware of possible new discoveries that would increase the value of a company. Research and development costs can be a major expense of a company and can largely affect the financial statements and the earnings per share amount. Tests show that when research and development costs are capitalized, it more accurately reflects the earnings per share than if these costs were expensed.

All the above factors are presented as justification of the FASB's decision to expense research and development costs as opposed to capitalization. The opinion of Bierman and Dukes is that this rule is not based on sound accounting theory but rather is intended to avoid criticism and conflict when the benefit from research and development is determined to be less than the cost outlay. (Bierman 54). Overall, the problem is difficult to solve since determining the future benefits from research and development can be very difficult, if not impossible. The FASB attempts to be

conservative yet, at the same time, is hurting many companies who incur large amounts of expense.

ARTICLES

There have been numerous written opinions regarding the topic of expensing research and developments costs. The bulk of opinions oppose this accounting rule mainly because it violates the matching principle.

In Roula Khalaf's article "Fuzzy Accounting" he states that "the debate whether to expense or defer costs is one of the biggest in accounting."(96) He agrees that the main problem with this accounting rule is that the matching principle is not followed. He also thinks that the rules regarding capitalization are not well-defined. The translation of this opinion is that there needs to be more structure surrounding capitalization rules instead of only stating that those costs which provide economic future benefits can be capitalized. If the rules are more clearly defined, there may be less opposition to the expensing of research and development costs.

This point of view is also shared by Maurice S. Newman in his article "Accounting for Research and Development." His opinion is that the current accounting rule regarding research and development costs violates the matching principle. He feels that this rule has been influenced too much by the Congress and the Internal Revenue Service(IRS). He also understands that it is impossible to find a "simple formula" for research and development because there is a wide variation in the amount of research and development costs

incurred in different industries. For example, the pharmaceutical industry spends the most money on research and development often exceeding billions of dollars. His conclusion is that the FASB should reconsider its pronouncement on research and development expenses. This is the conclusion shared by many individuals both inside and outside the accounting field.

Lynn W. Ellis and Robert G. McDonald express a similar, yet slightly different, opinion about research and development costs. In their article "Reforming Management Accounting to Support Today's Technology" they state that research and development expenses should be considered part of the product cost. Research and development usually makes up a major portion of the product cost. If research and development is not included in product cost, it provides an inaccurate estimate of what the product actually costs to manufacture.

A good point made by Ellis and McDonald is that "growth-enhancing activities such as R&D, market development and manufacturing development, are treated as expenses to be minimized rather than as investments in the future."(31) This is central idea in the area of research and development expenses. It's "research and development that drives the economy." (Newman 6) If research and development is not encouraged no new products will be developed, the rate of technology change will decrease, and the economy and companies will suffer. It is also essential to consumer's well-being to encourage research and development, especially in the pharmaceutical industry. Having companies

expense all research and development costs does not encourage them to incur research and development costs. This treatment of research and development cost could prevent the discovery of vital drugs/products that may save people from serious diseases or other problems.

The Ellis and McDonald article also mentioned the violation of the matching principle and how there is now less disclosure in research and development endeavors. They share the opinion of others that feel research and development costs need a detailed analysis keeping in mind those businesses who incur excessive research and development costs.

A final viewpoint is that of David E. Nix and Paul E. Nix in their article "It's Time to Change the Financial Accounting Treatment of R&D Expenditures." Once again they follow the opinions of the others stated above. They believe that the accounting treatment is obsolete and that new methods should be developed. They concur with the others' opinion that the matching principle is violated by the FASB ignoring sound accounting theory. They go on to state that the United States is at a competitive disadvantage because of their treatment of research and development since many other countries, such as Australia and Canada, are allowed to defer their research and development expenses.

The difference in this article from all the others is that they offer an alternative approach. This approach involves placing all research and development expenses incurred into a contra stockholder's equity account instead of expensing the costs. This

approach looks more at the long-term expenses because research and development projects almost always last more than one year. This approach will be discussed more thoroughly later.

All the articles cited basically express the same view point that the accounting rules need to be changed. This is the main area of conflict surrounding research and development costs. It seems as if the majority of people do not side with the FASB on this issue.

My conclusions from the analysis of these articles leads me to believe that there are some definite misunderstandings between the FASB and accountants in general. The main area is with the matching principle. The matching principle is defined as the expense recognition that is tied to revenue recognition. The expenses should be matched with revenue whenever it is reasonable and practical to do so. It also goes on to say that this type of expense recognition pattern involves assumptions about the benefits that are being received as well as the costs associated with those benefits. Also, some costs are charged to expense in the current period simply because no confection with revenue can be determined. (Kieso & Weygandt 607-8)

This definition clearly explains why the FASB is able to advocate their research and development costs treatment. The clause about no connection between the costs and benefits partially supports the FASB's opinion and the opposition's opinion. There is no connection currently but in the long-term outlook there is a connection.

The other clause that the FASB seems to use to support its opinion are the words "reasonable and practical." The FASB does not support the view that capitalizing research and development is reasonable and practice. Their opinion is that capitalizing research and development costs causes more harm then good and its only fair to have one standard way of handling these costs.

FDA APPROVAL COSTS

The next area of investigation is the definition of FDA approval costs. This includes describing the purpose of the FDA, defining FDA costs, determining if these costs meet the qualifications for research and development expenses, and finally analyzing if these costs can be capitalized or expensed.

First we must look at the FDA's purpose. The Food & Drug Administration(FDA) is a "scientific regulatory Agency responsible for the safety of the Nation's foods, cosmetics, drugs, medical devices, biologics, and electronic radiological products."(Campbell 3) The federal government controls this Agency whose main purpose is for public interest, that being safety and welfare. The FDA "monitors the industry and provides the consumer the best assurances possible that the industry is meeting its responsibility"(Campbell 3), the industry's responsibility being to make sure their products are safe. It is important to understand that the FDA is not responsible for creating safe products, but only to test and monitor products to be confident that they are harmless. For many of these products it is required that they obtain FDA approval before the products can be used legally.

Step	Average review time, months: Current	After reform	Time saved, months
Preclinical testing	18	15	3
IND[a] approval	1	1	0
IND phase I (Healthy volunteers)	6	6	0
IND phase II (Hundreds of patient volunteers)	18	34	20
IND phase III (Thousands of patient volunteers)	36		
NDA[b] preparation time	8	4	4
FDA approval Process	30	6	24
TOTAL TIME	**117** (9.75 years)	**66** (5.5 years)	**51** (4.25 years)

a Investigational New Drug. b New Drug Application.

(Ember, Lois C&EN November 25, 1991 page 4)

Each of the phases contain numerous procedures which all require a large amount of time and capital. There has been a recent push to speed up the approval process for new drugs/products. Unfortunately, along with the speedy process comes an increase in costs. The cost of getting a new drug/product to the market can range from at least $150 million to several billion dollars depending on the type of research findings needed and the risks involved.

The procedures for each step of the FDA approval process are as follows(as related to drug approvals):

--Preclinical Testing: This step includes analyzing the drug/products's composition and the first stages of animal testing. The worthiness of human testing must be determined.

--IND Approval: The new drug is preliminary approved for human clinical trials. In order to get approval for clinical testing, the company must show: 1)the protection of the human research subject, 2)the adequacy of animal studies already completed, 3)the

scientific merits of the research plan, 4)the qualifications of the investigator. (Lucas 80)

--IND Phase I: This phase includes profiling the safety and pharmacological activity of a drug. These procedures are performed on a small number of healthy volunteers(non-patients). This stage determines what constitutes a safe dosage, how long the effects of the drug last, and the way the drug is absorbed, distributed, metabolized, and excreted. The situations in this phase are highly controlled.

--IND Phase II: This stage begins the efficacy tests on patients, which are "tests providing that a drug is ineffective as it is purported to be, without harmful or disagreeable side effects, safety being stressed." (Grabowski 22) These test are conducted on volunteer patients, approximately between 200-300 patients. Animal and human studies for safety are performed coincidently.

--IND Phase III: This stage is usually the most extensive of all the trials. The goal in this stage is to confirm the efficacy results from Phase II in patients afflicted with the specific disease. Further, they identify low-incidence adverse effects.

--NDA Preparation Time: This step includes gathering all the data from the pre-clinical and clinical studies along with information about the chemical structure, scientific rationale and purpose, and formulation and manufacturing details. This application is usually thousands of pages long.

--FDA Approval Process: This step includes a final review and analysis from all the information included in the New Drug

Application(NDA). It is at this stage that the final approval/disapproval is given. The FDA uses a team approach to review the application.

(The above information adapted from C&EN February 25, 1991 page 30)

As mentioned above there has been a move towards decreasing the time needed to approve new drugs/products, especially those drugs which are used to treat life-threatening illnesses. For life-threatening illnesses, the FDA will allow the drug to be used for treatment as long as it is in the marketing approval stage. In conjunction with this situation to the decrease in approval time is the adoption of user fees. User fees are additional fees added on to various stages in the FDA approval process. The reason for the adoption of this bill is that "traditional sources of funding are no longer enough to do with reasonable speed the job that needs to be done."(Hanson 6) With the additional funds the FDA will be receiving, they will be able to hire additional scientists, physicians, and administrative staff. This means the approval process time will be reduced because there are more professionals. The new staff will help to reduce the current workload which is already somewhat overbearing and prepare for the future which predicts an increase in the number of product applications.

As of the end of 1992, the user fees were apportioned as follows: 1) $150,000 for each new drug application, 2) $50,000 for each drug company annually, and 3) $5,000 for each product a company has on the market. These amounts are to be phased in over a five-year period beginning in 1993 and will bring in revenues to

the FDA totaling approximately $75 million per year.(Adapted from Hanson 6-7) This may pose a problem for the smaller companies who are unable to afford such high costs when they are already performing costly research methods. The federal government is looking at allowing smaller companies to defer these fees up to one year after gaining approval which will allow for the companies to recognize some income.

FDA COSTS AS RESEARCH AND DEVELOPMENT

The next area regarding FDA approval costs is whether they are considered research and development costs. First we must refer to the definition of research and development. According to this definition, and looking at the list of what constitutes research and development activities, it is easy to determine that the seven FDA approval stages are considered research and development. The definition of research says that it is an investigation that hopes to discover useful knowledge to bring about an improvement. Development is the translation of research findings into knowledge for a new product intended for use. These definitions are what FDA costs accomplish. FDA approval seeks to gain new knowledge about a product that is being developed and make sure that the product is safe for the market. There is much research involved in FDA approval as explained above. Therefore, from the definitions it can be assumed that FDA costs are considered part of research and development costs.

The activities I am referring to that relate to research and development are "1) testing in search for or evaluation of product

or process alternatives, 2) laboratory research aimed at discovery of new knowledge, and 3) conceptual formulation and design of possible product or process alternatives."(Kieso & Weygandt 607-608) All these research and development activities are what is performed during the stages of FDA approval, so therefore the costs from these stages are classified as research and development costs.

The second set of costs to analyze are the newly-proposed user fees. These fees are administrative in nature because accompany paperwork procedures. Nothing in the definition of research and development or in the listing of research and development activities relates to straight fees charged by an agency. Therefore these costs are not considered research and development costs and are expensed as administrative costs when incurred.

The final area to analyze for FDA costs is whether they should be expensed or capitalized. No articles have been published specifically on this issue which makes it difficult to determine exactly what the FASB's opinion would be on this matter although, the FASB's opinion on research and development costs was stated earlier. This discussion relates to the explanation of when research and development costs can be capitalized which leads to the attempt to specify definite future benefits. This topic will be discussed later along with the different alternatives relating to the options of capitalization or expensing.

COMPANY DATA

The third and background section brings in specific examples of the treatment of FDA approval costs by various companies. When

looking at the companies for which I have collected data, the general consensus seems to be expensing of research and development costs along with the costs associated with FDA approval. The data collected is from financial statements, notes to the financial statements, and managers notes.

I took a sample of fifteen financial statements from companies that have extensive research and development costs and are also experiencing an increase in FDA approval costs. Insertions from the companies financial statements are found in Appendix C. I will refer to a few that have significant information.

The first company to be investigated is Houston Biotechnology Inc. This company "engages in the development of pharmaceutical products to treat or prevent a variety of common ophthalmic and neurological diseases and disorders."(Financial Footnotes) Their products involve a high degree of risk and uncertainty and therefore require a large investment in cash and technical resources before the product can enter the commercial market. Commercialization requires FDA approval on the products which can take many years. Because of the risk and uncertainty, Houston Biotechnology Inc. will not realize its research and development investment until the FDA gives approval to market the drug and profits are generated at a future date. Therefore, since this company does not measure or realize an investment until the product is approved for market, they expense all research and development costs when incurred, including FDA approval costs.

The second company is Pharmaceutical Resources Inc. This

company primarily manufactures and distributes generic pharmaceuticals, mainly the oral solid form(tablet and capsule). At their financial statement date, they were waiting for FDA approval on one product line. The FDA insisted that they avoid submitting any more new drug applications until the FDA has a chance to perform a validity assessment program on those current products waiting FDA approval. Because a management is unable to predict what the outcomes of this program will have on the product lines or operations in general, they expense all costs when they are incurred. As the definition of research and development costs states, Pharmaceutical Resources Inc.'s costs must be expensed since they are unable to define the value of the benefits they may receive.

The third and company is Helix Biocore, Inc. This company operates in the cardiovascular field, more specifically the production and development of heart valves. The unusual aspect of this company is that they are able to give a definite estimate of future benefits. They state in their 1992 financial statements: "today, estimates are that the world market for heart valves is $410 million." They go on to state that the United States market will be limited at first because they still must obtain FDA approval. Helix Biocore, Inc. decided to expense all their research and development costs as incurred, even though they would have a valid argument if they wanted to capitalized their costs. I feel that the reason they expense their costs is because it's the norm to treat research and development costs in that manner, and

also because they must still obtain FDA approval in the United States. Since the costs of FDA approval are enormous and difficult to estimate, it was easier to expense all the costs associated with research and development.

After reviewing my sample of financial statements, I reached the conclusion that all the companies I looked at expensed their research and development costs, which includes their FDA approval costs. The most commonly stated reasons were the inability to measure the possible future benefits of their research and development investments and to determine if their product will receive FDA approval. Appendix B recaps the conclusions of the financial statements. It shows the reasons the companies give for their treatment of research, development, and FDA costs, and what their treatment is for research, development, and FDA costs.

The next section of the paper will consider the reporting alternatives.

ALTERNATIVES

There are two alternative as to the treatment of research and development costs mainly the costs of FDA approval. One alternative is to treat research, development, and FDA approval costs as expenses. The other alternative is to treat these costs as assets and capitalize the costs over a number of years. The FASB's definition of research and development costs is narrow meaning it does not allow many companies to treat the research and development costs as assets, when actually these costs often become revenue-producing assets. The FASB makes no mention of FDA

approval costs; it never addresses the issue. It is the companies and accountants responsibility to determine if these FDA approval costs can be considered assets or expenses.

EXPENSES

The majority, if not all, the companies(especially the companies I reviewed) treated their research and development costs as expenses. They included their costs of FDA approval in the research and development category which is appropriate because FDA approval costs are considered the "final end" of research and development costs. The question is why do all the companies choose to expense the enormous costs associated with FDA approval when the treatment of these costs as assets would be more beneficial to the company? The answer is the rules and guidelines set by the FASB.

As mentioned in the background section, the FASB's reasons for treating the majority of research and development costs as expenses were stated, along with the strict opposition to this treatment of costs. The five reasons stated again are: "1) Uncertainty of future benefits; 2) Lack of causal relationship between expenditures and benefits; 3) R&D does not meet the accounting concept of an asset; 4) Matching of revenues and expenses; 5) Relevance of resulting information for investment and credit decisions." (Bierman 48) Because it was previously determined that FDA approval costs are considered part of research and development costs, the FASB guidelines also apply to FDA approval costs. All the reasons are applicable in this situation. It is difficult to determine if a company's product will be approved, much less to

determine what the expected benefit will be. It is easier to see the relationship between FDA approval costs and benefits. Many drugs cannot be marketed unless they receive FDA approval, therefore the expenditures provide a benefit, although if the drug is not approved, there is no relationship. This information gives a good reason why these costs should be treated as expenses.

Another important factor why FDA costs should be expensed is conservatism. When dealing with FDA costs, a company cannot be certain that they will receive FDA approval much less when they will receive that approval. This involves a great deal of uncertainty. It is safe and more conservative to give the expected value of research, development, and FDA costs a value of zero, thereby expensing all the costs they incur. (Bierman 48) This treatment avoids making many adjustments if the FDA doesn't approve the product or the research and development does not produce any revenues.

One area of FDA costs that should always be considered expenses are the newly adopted user fees. These costs are administrative in nature because they are costs attached to the use of facilities and applications. They are a set amount and are the same for every product no matter how long the approval process lasts nor how much money the company has. Because these costs are not considered part of the definition of research and development, and therefore not part of the definition of FDA approval costs, they will always be treated as expenses and separated from the other FDA costs.

Expensing FDA costs is not only more conservative, it is also simpler to apply. There is no need to calculate and determine amortization amounts. The FASB only requires brief disclosure regarding research and development expenses, including FDA expenses. The disclosure could be as brief as one line on the income statement listing research and development expenses for the year to paragraphs explaining what the research, development, and FDA costs are for and what they consist of.

The previous factors are the reasons why FDA costs should be expensed or why it would be beneficial to expense the costs. It seems to be the alternative most companies tend to follow.

ASSETS

The other alternative is that of treating FDA costs as assets, which is the least common alternative. Many opinions back this alternative because it seems to be the better approach for companies to follow.

The reason most commonly stated in accordance with the asset alternative is that of the matching principle. Once again, the matching principle states that expenses should be matched against the revenues in the period the revenues are earned. In the case of FDA approval costs, this could be a time period of over ten years. Maurice S. Newman states "in an accounting sense, assets are created and these costs should be matched against future revenues when the R&D brings forth fruit." (Newman 6) The same could be said for FDA costs. FDA costs produce assets if the FDA approves the product. The revenues produced by products with FDA approval

cannot be offset by expenses of the products because the expenses were incurred probably many years before and have already been removed from the income statement.

Related to the matching principle is the length of time and the amount of cash investment required for FDA approval. In 1991, it took an average of three years for the FDA to approve a drug (FDA approval stage - one of the last phases), and it took an average of twelve years to get the drug from the lab to the market. (Hanson 28) The amount of cash investment needed to gain FDA approval begins at $125 million and quickly increases, the average being around $400 million for one product. It was said that in order to compete the pharmaceutical industry will invest approximately $8 billion. (Ember 6) This is a long time and an enormous amount of money to expense every year. It would make more sense to capitalize the costs and spread they out evenly over the life of the product. If in the future it is determined that the there were more cost than revenues, then expense the excess costs.

Ellis and McDonald have an opinion that says "a consequence of this erroneous focus is that growth-enhancing activities such as R&D, market development, and manufacturing development, are treated as expenses to be minimized rather than investments in the future." (Ellis 31) They make a valid point about the economics of product development. We as consumers want companies to develop new and better products to increase our quality of life. We would also prefer that the costs be kept down so all consumers could share in the new technology. When companies have to expense all their

costs, these costs are passed on to the consumer, whereas if they were capitalized the companies would have less expenses and therefore less costs to the consumers. This statement is not saying that all projects should be considered valid and be capitalized, yet it is implying that projects be analyzed more closely to determine if they have a good chance of being approved by the FDA. If the product does have a good chance of approval, then determine if the product will be profitable in the marketplace. If this favorable outcome can be concluded from the current company information, the product costs, especially those relating to FDA approval, should be capitalized. If the product is terminated before it is placed on the market or before FDA approval, then all the costs can be expensed.

More disclosure is required for treating FDA approval costs as assets. In the financial statements a company must show the value of the asset and the amount that has been capitalized. In the notes to the financial statements a company must show the capitalization schedule and give a detailed description of the asset being capitalized. FDA approval could be considered an asset because it most often provides for future economic benefit. If a product gains FDA approval, it is almost 100 percent certain that the product will be marketed.

The previous paragraphs gave reasons in favor of treating FDA approval costs as assets. It is probably the most practical solution for most companies to adopt. Unfortunately it is also the least common approach to utilize.

As can be determined from the arguments stated above, there is a thin line between treating FDA approval costs as expenses or assets. Just because one method is more common does not mean that the method is the best for that company. Which alternative a company uses usually depends on how they fit the FASB's guidelines for research and development costs.

RECOMMENDATIONS

In my opinion, FDA approval costs, along with research and development cost should be capitalized. There should still be restrictions, but these restrictions should be narrowed allowing for more cost to be capitalized, thereby fueling the economy for additional research and development leading to FDA approvals.

In many cases companies will not enter a research and development/FDA project unless they are sure of success. They can perform many tests - scientific and financial. Through preliminary analysis a company can usually get a good indication of whether the project will succeed or fail. Granted that this analysis is not always 100 percent accurate, yet it is highly consistent and provides a valid estimation of the overall picture of the project. This provides support for the asset theory of the treatment of FDA approval costs. Companies are not, for the most part, going to enter a multi-million dollar project blind. For this reason I recommend that companies put additional pressure on the FASB for a change in their accounting policy regarding research and development costs. In particular the FASB should address the area of FDA approval costs.

Another recommendation is to consider selling the product under review in foreign countries who do not have as strict of regulations as the United States does. This approach is demonstrated by Biospherics, Inc. They decided to sell/release drugs in other countries to generate the revenues needed for them to gain FDA approval in the United States. This approach would be useful after extensive testing of the drug has been completed so that the possibility of harm to consumers using the product is decreased.

A new approach was recommended by David E. and Paul E. Nix in their article "Its Time to Change the Financial Accounting Treatment of R&D Expenditures." In their approach they utilize a contra-stockholder's equity account that is considered a permanent account appearing on the balance sheet as a deduction from stockholder's equity. They proposed to capitalize all research and development expenditures as incurred during the year in this contra-stockholder's equity account(unless the expenditures had absolutely no future benefits in which case they would be expensed immediately). At year-end, a fixed percent of the remaining balance in the contra account from prior years research and development expenditures would be expensed for the current year. This could result in a greater emphasis on research and development, and even FDA approval, of products because none of the current years research and development expenses would be reported on this years financial statements.

According to the authors of the article, "the advantages of

APPENDIX A

R & D ACTIVITIES

a) Laboratory research aimed at discovery of new knowledge.

b) Searching for applications of new research findings.

c) Conceptual formulation and design of possible product or process alternatives.

d) Testing in search for or evaluation of product or process alternatives.

e) Modification of the design of a product or process.

f) Design, construction, and testing of pre-production prototypes and models.

g) Design of tools, jigs, molds, and dies involving new technology.

h) Design, construction, and operation of a pilot plan not useful for commercial production

i) Engineering activity required to advance the design of a product to the manufacturing stage.

(from Kieso and Weygandt 608)

ACTIVITIES NOT CONSIDERED R & D

a) Engineering follow-through in any early phase of commercial production.

b) Quality control during commercial production including routine testing.

c) Trouble-shooting breakdowns during production.

d) Routine, on-going efforts to refine, enrich, or improve the qualities of an existing product.

e) Adaptation of an existing capability to a particular requirement or customer's need.

f) Periodic design changes to existing products.

g) Routine design of tools, jigs, molds, and dies.

h) Activity, including design and construction engineering related to the construction, relocation, rearrangement, or start-up of facilities or equipment.

i) Legal work on patent applications, sale, licensing, or litigation.

APPENDIX B

COMPANY NAME	FDA COSTS	REASON FOR TREATMENT
MEDCO RESEARCH	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
BARR LABORATORIES	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
HELIX BIOCORE	EXPENSE	ABLE TO ESTIMATE FUTURE BENEFITS - CHOOSE TO EXPENSE
GULL LABORATORIES	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
STAAR SURGICAL	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
VISX	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
K V PHARMACEUTICAL	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
A L LABORATORIES	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
DOW CORNING	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
BIOPHAMACEUTICS	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
PHARMACEUTICAL RESOURCES	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
HOUSTON BIOTECH	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
HALSEY DRUG	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
BIOSPERICS	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS
UNIVERSITY PATENTS	EXPENSE	UNABLE TO ESTIMATE FUTURE BENEFITS

APPENDIX C

BARR LABORATORIES INC

BARR LABORATORIES, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
Years ended June 30, 1992, 1991 and 1990

	1992	1991	1990
Net sales (including sales to related parties of $2,842,000 in 1992, $1,938,000 in 1991 and $1,165,000 in 1990) (note 8)	100,790,419	93,984,088	70,305,651
Costs and expenses:			
Cost of sales (note 5)	70,595,112	60,686,779	48,699,168
Distribution	3,413,237	3,132,698	2,911,554
Marketing and sales	6,756,290	5,981,440	4,289,990
Research and development	7,436,027	5,908,793	3,965,961
General and administrative	12,403,294	9,506,368	5,567,896
Interest expenses	2,165,265	1,716,187	1,944,951
Other expense (income), net (note 10)	1,485,182	-3,788	1,398,396
Earnings (loss) before income tax expense (benefit)	-3,463,988	7,055,611	1,527,735
Income tax expense (benefit) (note 6)	-1,555,000	2,531,000	451,000
Net earnings (loss)	-1,908,988	4,524,611	1,076,735

See accompanying notes to consolidated financial statements.

(e) Research and Development-Research and development costs, which consists principally of product development costs, are charged to operations as incurred.

(12) Other Matters-Food and Drug Administration (FDA) Litigation-After completion of lengthy inspections of the Company's facilities in the fall of 1991 and again in the spring of 1992, the FDA determined that the Company was not in compliance with current good manufacturing practice regulations (cGMP). Upon learning of the FDA's position, the Company vigorously disputed the findings because it believed that it was in substantial compliance with all applicable regulations. Furthermore, the Company did not believe that the FDA had the right to impose certain sanctions which are imposed automatically when a company is deemed to be out of compliance with cGMP regulations. Although the parties met numerous times to discuss the issues raised by the FDA and the Company, those discussions were not fruitful because of the insistence by the FDA that the Company agree at the outset to a consent decree which would have caused the Company to cease all operations until such time as the alleged deficiencies had been remedied to the FDA's satisfaction.

When it became clear that the Company and the FDA would not be able to negotiate an end to their dispute, the Company undertook several actions. First, in an effort to reach a swift settlement with the FDA and address its regulatory and compliance issues, the Company temporarily reduced its product line in April 1992. This reduction resulted in the suspension of the marketing of a significant number of the Company's products. The Company believes that all of its products, including those that were suspended, are safe and effective for their intended use and conform to all applicable pharmaceutical industry standards.

Second, in April 1992, the Company commenced an action in Federal District Court in Newark, New Jersey (the Barr Action) seeking judicial clarification of Barr's cGMP obligations and an injunction preventing the FDA from enforcing ambiguous and shifting interpretations of the cGMP regulations. In addition, the Company is seeking a judicial declaration that the FDA's Alert List and the corresponding sanctions imposed upon the Company by the FDA associated with the Alert List are illegal. The Company has moved for a preliminary injunction against its inclusion on the Alert List and the sanctions imposed by the FDA as

a result of being included on the Alert List.

As of the date hereof, the cases are ongoing and, based on the information currently available, it is not possible to determine the possible effect of these actions on the Company's financial position or results of operations.

PRESIDENT'S LETTER:
(FROM ANNUAL REPORT TO SHAREHOLDERS)
DEAR FELLOW SHAREHOLDER:

Optimism is high at the Company for a number of reasons. First, the Company is poised to take advantage of new opportunities emerging in the generic marketplace. Because of FDA's new interpretation of old regulations and the increasing costs of regulatory compliance, many of our traditional competitors are being forced to close their doors. FDA's actions have not only reduced the number of competitors but also ensured that the new generic marketplace will remain small. Barr Laboratories is far ahead of its remaining competitors vis-a-vis these "new" regulations. This, combined with our production capacity and ability to produce high quality pharmaceuticals, provides the Company with an enormous strategic advantage.

Secondly, the Company continues to develop new products. Our research and development activities, while having slowed during the dispute with FDA, will be back in full operation shortly. In addition, the Company is currently awaiting approval from FDA to market a significant number of new products. Although it is not possible to predict when these new approvals will be granted to FDA, we are optimistic that following the resolution of the legal proceedings between Barr and FDA, approvals for these new applications will be forthcoming.

Lastly, as shareholders of Barr Laboratories, Inc., you can be proud of the effort and commitment of our highly skilled work force. Their efforts, not only in production, scientific and marketing achievements, but those required during our ongoing dispute with FDA, have truly been extraordinary.

Research and development expenses for the fiscal year ended June 30, 1992 were $7,436,027, compared to $5,908,793 for the comparable period last year. This increase of 25.8% is primarily attributable to increases in salaries. The Company also increased staff and incurred additional regulatory compliance expenses.

Research and development expenses were $5,908,793 or 6.3% of net sales for the fiscal year ended June 30, 1991 as compared to $3,965,961 or 5.6% of net sales for the fiscal year ended June 30, 1990. This increase of 49.0% is primarily attributed to an increase in outside clinical studies, salaries and raw material consumed in the development of new products.

BIOPHARMACEUTICS INC

BIOPHARMACEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended September 30

	1992	1991	1990
Sales	2,375,371	6,244,443	5,599,861
Costs and expenses:			
Cost of sales	3,008,651	5,823,758	5,186,242
Selling, general and administrative	974,956	1,216,344	1,113,632
Research and development	NA	NA	90,467
Interest	258,140	235,268	164,996
	4,241,747	7,275,370	6,555,337
	-1,866,376	-1,030,927	-955,476
Other income (deductions):			
Gain on sale of equipment	75,751	NA	NA
Settlement of claims with affiliate and past management (Note 14)	1,078,752	NA	NA
Recovery (write-off) of:			

Goodwill (Note 15)	NA	NA	-473,483
Drug licensing receivable (Note 16)	NA	69,945	-104,950
	1,154,503	69,945	-578,433
Loss from continuing operations	-711,873	-960,982	-1,533,909
Loss from discontinued operations (Note 3)	NA	NA	-808,006
Net loss	-711,873	-960,982	-2,341,915
Primary loss per share (Note 10):			
Continuing operations	-.09	-.12	-.18
Discontinued operations	NA	NA	-.10
Net loss	-.09	-.12	-.28

The accompanying notes are an integral part of these financial statements.

FINANCIAL FOOTNOTES:

-NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

f. Research and development expenses-The Company expenses research and development costs as incurred.

Note 2. Basis of Preparation-The Company has incurred losses in six consecutive years, which have resulted in a decline in stockholders' equity to a deficit of approximately $453,000 at September 30, 1992.

On January 10, 1992, the Company was approved to commence operations as a drug repacker, after being shut-down for approximately two months in compliance with a temporary restraining order obtained by the Food and Drug Administration ("FDA") on November 1, 1991. The Company is currently seeking approval to resume its manufacturing operations pursuant to an amended decree of permanent injunction for alleged current good manufacturing practice deficiencies in its drug manufacturing activities. Upon achieving this approval, the Company intends to develop prescription products which do not require the approval of the FDA, but carry higher profit margins than the over-the-counter products previously sold by the Company. In addition, the Company plans to apply for FDA approval of prescription drugs, which both require bioavailability studies or do not require bioavailability studies.

BIOSPHERICS INC

Consolidated Statements of Operations
Years ended December 31

	1992	1991
Revenues		
Contract revenues (Note 1)	16,685,489	15,096,221
Product and process sales	47,085	29,096
Total revenues	16,732,574	15,125,317
Costs and Expenses Operating Expenses		
Direct costs and operating expenses, excluding depreciation and amortization	13,215,878	12,385,697
Selling, general and administrative	1,832,016	1,773,428
Research and development	58,293	250,094
Depreciation and amortization (Note 4)	581,172	582,058
Uncollectible accounts	20,000	52,000
Total operating expenses	15,707,359	15,043,277
Income from operations	1,025,215	82,040
Other Income (Expenses)		
Other income (Note 11)	103,577	438,477
Interest expense	-87,342	-177,087
Income before income taxes and extraordinary item	1,041,450	343,430
Provision for income taxes (Note 6)	360,703	137,371
Income before extraordinary item	680,747	206,059
Extraordinary item (Note 9)	NA	-76,429
Net Income	680,747	129,632

The accompanying notes are an integral part of the financial statements

MANAGEMENT DISCUSSION:
ITEM 6. Management's Discussion of Financial Condition and Results of Operations

The BioTech Programs Unit generated revenues from royalties and sales of its specialty chemicals of $149,000 in 1992, compared with $467,000 in 1991. Research and Development expenditures were $270,000 and $250,000 for 1992 and 1991, respectively. The spending in 1992 was related to new studies in support of its patented nonfattening sugar, D-tagatose, and safe-for-humans pesticide.

There are a number of factors that could potentially have a significant impact on future earnings and the financial condition of the Company. As previously discussed in Item 1, the Company is continuing its effort to bring D-tagatose and the safe-for-humans pesticide to market. Research and Development costs are expected to increase in 1993 as part of this effort. Full-scale toxicity test on D-tagatose have begun, which, upon completion, should clear the way for sales of the product overseas. Profits generated from these sales will be utilized to fund the testing necessary to obtain FDA approval, thus opening the U.S. market.

Cash generated from operations will continue to be utilized to fund the ongoing research and development effort. An example of this was the Company's ability to fund the full-scale toxicology test for D-tagatose in the first quarter of 1993. Consistent with the Company's policy, excess profits will be retained within the Company to help bring these products to market.

DOW CORNING CORP

DOW CORNING CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND RETAINED EARNINGS
(in millions of dollars except per share amounts)
Year ended December 31

	1992	1991	1990
NET SALES	1,955.7	1,845.4	1,718.2
OPERATING COSTS AND EXPENSES:			
Manufacturing cost of sales	1,343.2	1,195.5	1,105.2
Marketing and administrative expenses	410.4	397.3	351.6
Implant costs	69.0	25.0	NA
Special items	40.0	29.0	NA
	1,862.6	1,646.8	1,456.8
OPERATING INCOME	93.1	198.6	261.5
OTHER INCOME (EXPENSE):			
Interest income, currency gains (losses) and other, net	-20.6	31.9	18.2
Interest expense	-22.5	-21.5	-18.7
INCOME BEFORE INCOME TAXES	50.0	209.0	261.0
Income taxes	10.1	58.3	80.1
Minority interests' share in income	11.5	14.1	9.8
INCOME BEFORE CUMULATIVE EFFECTS OF CHANGES IN ACCOUNTING PRINCIPLES (1992 - $11.36 per share; 1991 - $54.64 per share; 1990 - $68.44 per share)	28.4	136.6	171.1
NET INCOME (LOSS) (1992 - $(28.80) per share; 1991 - $61.16 per share; 1990 - $68.44 per share)	-72.0	152.9	171.1

The Notes to Consolidated Financial Statements are an integral part of these financial statements.

FINANCIAL FOOTNOTES:
-NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Research and Development Costs-Research and development costs are charged to operations when incurred and are included in manufacturing cost of sales. These costs totalled $161.2 in 1992, $148.7 in 1991 and $139.8 in 1990.

NOTE 2 - CONTINGENCIES-Breast Implant Business-Prior to January 6, 1992, the Company, directly and through its wholly-owned subsidiary, Dow Corning

Wright Corporation, was engaged in the manufacture and sale of silicone gel breast implants. As part of a process initiated in 1991 of review by the United States Food and Drug Administration (FDA) of Premarket Approval Applications (PMAA) for silicone gel breast implants, on January 6, 1992 the FDA asked breast implant producers and medical practitioners to halt the sale and use of silicone gel breast implants, pending further review of the safety and effectiveness of such devices, and the Company voluntarily suspended shipments of implants. Subsequently, the Company announced that it would not resume the production or sale of silicone gel breast implants and that it would withdraw its PMAA for silicone gel breast implants from consideration by the FDA.

GULL LABORATORIES INC

Gull Laboratories, Inc
Consolidated Statements of Operations
Years Ended December 31

	1992	1991
Sales	8,606,508	6,492,130
Cost of sales	2,964,836	2,324,205
	5,641,672	4,167,925
Expenses:		
Selling, general and administrative	2,153,000	1,665,015
Research and development	696,561	582,515
Total expenses	2,849,561	2,247,530
Other income (expense):		
Interest expense	-245,482	-292,778
Other	43,124	-7,264
Total other income (expense)	-202,358	-300,042
Income from continuing operations before provision for income taxes	2,589,753	1,620,353
Income tax provision (Note 7)	854,500	559,000
Income from continuing operations	1,735,253	1,061,353
Discontinued operations - loss of USANA, Inc. to be spun off (net of income tax benefit) (Notes 2 and 7)	-670,332	-521,404
Net income (loss)	1,064,921	539,949
Earnings (loss) per share:		
Continuing operations	.32	.20
Discontinued operations	-.12	-.10
Earnings per common and common equivalent share (Note 10)	.20	.10

See accompanying notes.

MANAGEMENT DISCUSSION:
ITEMS 6: MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS

Research and development costs increased 20% in 1992 from $582,515 to $696,561. In 1992 the Company's research and development efforts decreased as the new ELISA product line was transferred out of research and development to production. During 1992 the Company renewed its research and development efforts to find new test to supplement its existing product line.

Research & development costs decreased 46% in 1991 to $582,515 compared with $1,070,055 in 1990. This decreased is primarily due to the successful completion of development of the Company's new ELISA product line and the transfer of many of the employees working on the development project to product manufacturing.

HALSEY DRUG CO INC

Halsey Drug Co., Inc. and Subsidiaries
CONSOLIDATED STATEMENTS OF EARNINGS
Year ended December 31

	1992	1991	1990
Net sales (Note A)	49,867,563	37,462,130	26,354,399
Cost of goods sold	35,769,162	27,343,828	18,615,413
Gross profit	14,098,401	10,118,302	7,738,986
Research and development	1,090,000	783,000	592,000
Selling, general and administrative expenses	8,616,274	5,722,340	4,480,876
Provision for product recall (Note J)	2,000,000	NA	NA
Earnings from operations	2,392,127	3,612,962	2,666,110
Investment loss	NA	NA	-293,689
Interest expense	-372,681	-509,144	-558,590
Earnings before income taxes and minority interest	2,019,446	3,103,818	1,813,831
Provision for income taxes (Notes A and F)	1,128,000	1,340,000	810,000
Earnings before minority interest	891,446	1,763,818	1,003,831
Minority interest in net loss (earnings) of subsidiaries (Note B)	36,994	-36,994	NA
NET EARNINGS	928,440	1,726,824	1,003,831
Earnings per common share (Note A)	.13	.26	.16
Average number of outstanding shares	7,157,871	6,579,061	6,356,527

The accompanying notes are an integral part of these statements.

FINANCIAL FOOTNOTES:

MANAGEMENT DISCUSSION:
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The Company's continued increased sales are linked to expanding sales of existing products as no new products were introduced by the Company in 1992, although Houba received a supplemental approval for one new product. The Company's increase in sales is a result of increased sales of previously existing products through improved marketing and manufacturing and an expansion of the Company's customer base.

Research and Development Expenses Research and development expenses for fiscal years 1992, 1991 and 1990 were approximately $1,090,237, $783,000 and $592,000, respectively, which, expressed as a percentage of sales, were 2.2%, 2.1% and 2.3%, respectively. The Company's research and development efforts during 1992 were predominantly directed at the development of Biotin and Zidovudine (AZT) raw materials at the Indiana facility. The Company has and in the future will, to the extent possible, continue to take an aggressive position in the development of new products coming off of patent protection or expected to become available in the near future. The Company also has chemical products at various stages of development and production.

HELIX BIOCORE INC

PRESIDENT'S LETTER:
(FROM ANNUAL REPORT TO SHAREHOLDERS)
To Our Shareholders and Friends:
And what a year it was. In 1991, we vigorously pursued our entry into

the heart valve market. As you may know, our management team and employees have extensive experience in the cardiovascular field, many having been previously involved in the development of implantable devices, including heart valves. This has allowed us to develop a new heart valve with a new pivot concept which is designed to reduce thromboembolism and thrombosis; problems long recognized as the scourge of heart valves. Under a development agreement with CarboMedics, Inc., the world's largest and most experienced manufacturer of heart valve components, we will develop, manufacture and market our new open pivot, bileaflet, pyrolytic carbon heart valve. The design, which is protected by two issued U.S. patents and six issued overseas patents together with additional patent applications, is being prepared for our first human implant which we anticipated will occur in Europe in the first half of 1992.

During 1991, we received encouragement and comments from the medical community, which confirms our belief that we will succeed in the heart valve market. Let us review some of those thoughts:

Today, estimates are that the world market for heart valves is $410 million. Our initial commercial introduction into the U.S. market will be limited, as we must conduct clinical trials and seek FDA regulatory approval. In the international market, however, we feel that we will be able to introduce our valve and begin to generate revenues in 1992.

MANAGEMENT DISCUSSION:
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Research, development and engineering expenses related to the heart valve operations increased by 96% from 1990 to 1991. The increase resulted from a full year's development under the heart valve program which the Company commenced in November 1990. The expenses incurred in 1991 and 1990 included $404,331 and $383,000, respectively, in payments to outside vendors for development work related to the ATS Medical valve. The Company expects that research, development and engineering expenses will increase substantially during 1992 as the Company continues testing of the Valve and meets additional milestone for payments to outside vendors.

FINANCIAL STATEMENT TEXT:

NA; Income Statement Data provided only for NYSE, AMEX, NASD and Fortune 1,000 companies.

FINANCIAL FOOTNOTES:
NA; Data provided only for NYSE, AMEX and Fortune 1,000 companies.

HOUSTON BIOTECHNOLOGY INC

HOUSTON BIOTECHNOLOGY INCORPORATED
STATEMENTS OF OPERATIONS
Year Ended December 31

	1992	1991	1990
REVENUES:			
Research and development contracts:			
Houston Biotech Partners, L.P.	1,067,469	2,813,027	2,986,906
Other	NA	NA	1,000,000
Investment income	159,778	142,934	119,306
Other income	237,831	104,984	88,557
Total revenues	1,465,078	3,060,945	4,194,769
COSTS AND EXPENSES:			
Research and development - contract	981,541	2,590,938	2,755,350
Research and development -			

proprietary	2,013,261	247,958	535,933
General and administrative	719,452	330,640	287,616
Writedown of capitalized construction costs	43,834	NA	455,363
Total costs and expenses	3,758,088	3,169,536	4,034,262
INCOME (LOSS), before income taxes and extraordinary item	-2,293,010	-108,591	160,507
Income taxes	NA	NA	59,940
INCOME (LOSS), before extraordinary item	-2,293,010	-108,591	100,567
EXTRAORDINARY ITEM, utilization of net operating loss carryforward	NA	NA	59,940
NET INCOME (LOSS)	-2,293,010	-108,591	160,507

The accompanying notes are an integral part of these financial statements.

FINANCIAL FOOTNOTES:

--(1) Organization-HBI is a biotechnology company engaged in the development of pharmaceutical products to treat or prevent a variety of common ophthalmic and neurological diseases and disorders, with a primary focus in ophthalmology. The principal objective of the Company is to develop biopharmaceutical products to treat conditions for which no effective pharmaceutical treatment is currently available or for which such products may provide advantages over existing treatments. The Company's most advanced product is an immunotoxin for the prevention of secondary cataract (the "4197X-RA Immunotoxin").

Until April 30, 1992, substantially all of the Company's research and development activities related to contract research performed for Houston Biotech Partners, L.P. (the "Partnership"), a research and development partnership.

Revenues resulting from the 4197X-RA Immunotoxin had not commenced as of December 31, 1992, and are not expected to do so, if at all, for at least several years. Development of pharmaceutical products takes many years and involves a high degree of risk and uncertainty. There can be no assurance that any revenues will ever be generated from development efforts. In addition, it is probable that current funds available to invest in research and development will be insufficient to complete the 4197X-RA Immunotoxin to commercialization.

Contract Research Revenues-Contract research revenues consist of nonrefundable amounts earned under contractual agreements to perform research and development of specific scientific projects and are recognized as revenues as the research is performed or as milestones are achieved (see Note 3). As a result of the Combination, contract research is no longer conducted on behalf of the Partnership, and therefore contract research revenues related to contract research on behalf of the Partnership were no longer recognized.

Research and Development Costs-HBI performed contract research on behalf of the Partnership through April 30, 1992, as well as its own independent proprietary research. Research and development costs are expensed when incurred. These costs consist of direct costs associated with specific projects including costs associated with the operation of laboratories performing such research, and in the case of contract research, an allocation of general and administrative costs associated with administering these activities. As a result of the Combination, contract research is no longer conducted on behalf of the Partnership, and therefore HBI no longer allocated general and administrative costs. See Note 10.

MANAGEMENT DISCUSSION:

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the Financial Statements and related notes contained elsewhere herein.

Product Development Development of biopharmaceutical products involves a high degree of risk and uncertainty and requires a large investment of cash and technical resources before commercialization. The Company's realization of its investment in its research and development efforts will not occur unless and

until regulatory approval to market is obtained and profits are generated at a future date. The FDA requires compliance with strict regulatory procedures before it will grant approval for a pharmaceutical product to be marketed in the United States. These regulatory procedures require, among other things: (i) preclinical development and filing an IND with the FDA, (ii) Phase I human clinical trials to test safety, which normally take from one to three years, (iii) Phase II and III human clinical trials to confirm the results of Phase I safety studies, prove efficacy and observe any low-incidence adverse effects, which normally take from two to three years each, and (iv) filing a PLA with the FDA containing the results of the human clinical trials for review and approval by the FDA, a process which normally takes approximately two to three years. There is no assurance that FDA approval of the 4197X-RA Immunotoxin or any product candidate can be obtained within these time frames, if at all.

The Company filed the IND with respect to the 4197X-RA Immunotoxin in August 1990, filed a Phase I report with the FDA in January 1992 and commenced a Phase I/II human clinical study in April 1992. Primarily because of an unacceptable level of patient enrollment by doctors recruited by the CRO engaged by the Company for the purpose, HBI closed its initial investigational site and terminated its relationship with the CRO performing the study. HBI has redesigned the study to facilitate patient recruiting and simplify study execution without compromising patient safety. Patient enrollment began in March 1993. See "Business-Secondary Cataract-Human Clinical Trials."

Operating expenses for the year ended December 31, 1992 were $3,758,088, an 18% increase from $3,169,536 incurred in the same period in 1991. This increase was due to increased research and development on Company projects other than th 4197X-RA Immunotoxin and the writedown of capitalized construction costs.

MEDCO RESEARCH INC

Medco Research, Inc.
Consolidated Statements of Operations
Year Ended August 31

	1992	1991	1990
Revenues:			
Royalty revenue (Note 5)	4,782,744	2,947,127	777,367
Interest income	1,295,686	108,732	118,657
Other income	281	570	2,147
	6,078,711	3,056,429	898,171
Costs and expenses:			
Royalty expense (Note 5)	2,391,372	1,473,564	388,684
Research and development costs	2,160,634	298,286	438,023
General and administrative expenses	1,088,602	671,133	1,304,079
	5,640,608	2,442,983	2,130,786
Income (loss) before income taxes	438,103	613,446	-1,232,615
Provision for income taxes	42,600	1,950	1,200
Net income (loss)	395,503	611,496	-1,233,815

See accompanying notes.

PRESIDENT'S LETTER:
(FROM ANNUAL REPORT TO SHAREHOLDERS)

Dear Shareholder:

Medco remains dedicated to a strategy of identifying and licensing additional pharmaceutical products of promising potential.

Approval of Adenoscan(R) by the Health Protection Branch of Canada's Health and Welfare Department for marketing in Canada, with commercialization to commence following the grant of an export license by the U.S. Food and Drug Administration to Medco's licensee, Fujisawa USA, Inc.

Continued clinical trials of adenosine (MEDR 640) as a cardioprotectant in patients who have suffered a heart attack, and initiation of such trials in patients who are undergoing coronary artery bypass surgery

Commencement of Phase II clinical trials of IPPA, a nuclear cardiac diagnostic agent

Commencement of Phase I clinical trials of adenosine triphosphate (ATP), which is being studied for treatment of cancer and cancer-related cachexia (weight loss and body-wasting syndrome)

Commencement of multicenter clinical trials for the oral antiarrhythmic drug, NAPA(R), for the treatment of two types of arrhythmia in the atria (upper chambers of the heart)

Commencement of development of Bidil(TM) as a vasodilator therapeutic for patients suffering from congestive heart failure.

With an array of products in the late stages of clinical development, principally for the treatment of cardiovascular diseases and cancer, we believe Medco is moving closer to the point of commercial breakthrough.

We are disappointed that the Food and Drug Administration has not yet approved Adenoscan(R) in the United States. Our progress has been delayed by issues arising from the drug-manufacturing activities of Lyphomed Inc., which was subsequently acquired by Fujisawa USA, our Adenoscan(R) manufacturing and marketing partner. Fujisawa USA has advised Medco that it is working diligently to satisfy any Food and Drug Administration concerns with respect to the manufacture of its products.

MANAGEMENT DISCUSSION:

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

During fiscal year 1992, the Company's principal activities consisted of the continued development of, and regulatory submissions for, its adenosine products and the identification and acquisition of new products. In November 1991, the Company entered into an exclusive worldwide license agreement to research, develop, manufacture and market Bidil for patients with CHF. In April 1992, the Company entered into an agreement for the development and marketing of IPPA in the United States. The Company's research and development expenses increased substantially in fiscal year 1992 due to acceleration or initiation of clinical trials for the development of MEDR 640, NAPA, ATP, Bidil and IPPA.

During fiscal year 1991, the Company focused on filing New Drug Submission applications to the Canadian Health Protection Branch (HPB) for Adenocard and Adenoscan and on investigating potential new indications for adenosine. Attention was also directed to recruiting senior staff personnel and licensing new products for development by the Company. During fiscal year 1991, the Company entered into an exclusive worldwide license agreement to research, develop, manufacture and market ATP for use in cancer treatment.

Research and development costs increased seven-fold, from $298,286 to $2,160,634, reflecting the Company's planned acceleration of research and development activities, including contract manufacturing and clinical research contracts, for NAPA, ATP, Bidil, IPPA, MEDR 640 and bethanidine sulfate, and salary and overhead expenses directly related thereto. Research and development costs are expected to continue to be substantially higher than those incurred in prior years.

Research and development costs decreased from $438,023 to $298,286, a decrease of 32%, primarily due to a substantial reduction in direct clinical trial expenses associated with the completion of the development of Adenoscan, for which an NDA was submitted to the FDA in February 1990. Salary and overhead expenses directly related to research and development activities remained virtually unchanged as the Company focused on (a) preparing plans for the clinical development of several of its other products; (b) conducting early stage clinical trials of selected adenosine products; and (c) monitoring and updating additional clinical data relating to Adenoscan, none of which required significant direct clinical trial expense. Research and development costs are expected to increase substantially during fiscal year 1992 from fiscal year 1991 as the Company begins or accelerates clinical trials for MEDR 640, NAPA, ATP, Bidil, IPPA, bethanidine sulfate, MEDR 340 and MEDR 240.

The Company is continuing with its planned acceleration of the development of its products by significantly increasing its research and development expenditures for preclinical development activities and clinical testing of its products and the recruitment of additional scientific, administrative and

support personnel. Accordingly, until such time as Adenoscan is approved by the FDA and marketing of this products commences, the acceleration of research and development will have a material affect of the Company's earnings and could result in reduced net income or net losses in the future. The Company is also exploring the possibility of developing within the next several years a limited, specialized sales force for the marketing of certain of its products, which would require significant additional expenditures. The Company believes that it has more than sufficient cash reserves to fund its current operations, including the accelerated development of its products, the recruitment of additional personnel and the development of a limited sales force as described above.

Except for Adenocard, which has been approved and marketed in the United States, the United Kingdom and Switzerland, the Company will not generate revenues from its products until it receives approval from the FDA or corresponding agencies in other countries to market these products. In October 1992 the Canadian Health Protection Branch ("HPB") approved the marketing of Adenoscan in Canada. Commercialization of this drug in that country will not commence until the FDA grants an export license for the manufacture of this product by Fujisawa USA, which must resolve certain of the manufacturing issues with the FDA referred to below the license will be granted. The FDA's review of the Adenoscan NDA has been delayed as the result of certain manufacturing issues raised by the FDA with respect to various products including Adenoscan manufactured by Lyphomed, Inc. (the Company's original manufacturing and marketing partner for adenosine products which was acquired by Fujisawa USA in April 1990.) Fujisawa has advised the Company that it has successfully completed its internal validity assessment of the Adenoscan manufacturing data, and that it is working diligently with the FDA to resolve the outstanding issues with the FDA so that the FDA can then complete its review of the NDA. It is possible, however, that delays in resolving these issues, including those relating to other Fujisawa products, could affect the timing of any FDA approval of the Adenoscan NDA.

As with any new drug, including those currently under development by the Company, the Company cannot predict the research results or the timing of any potential marketing approval, nor can assurances be given that the FDA or corresponding agencies in other countries will approve any of the Company's products.

FINANCIAL FOOTNOTES:

5. Patent, Trademark and Distribution Rights-The Company is engaged in the development of new prescription drugs in pursuit of obtaining governmental marketing approvals in the United States and other countries. The Company acquires exclusive rights to develop and market various drugs from third parties, including related patents and trademarks (where applicable), and develops drugs and seeks patents and trademarks for its products on a proprietary basis. The costs of acquiring rights from third parties and major costs associated with the perfection and protection of patents and trademarks are capitalized by the Company. Agreements under which the Company acquires such rights from third parties generally require the Company to finance the costs of clinical trials and the filing of New Drug Applications (NDAs) with the United States Food and Drug Administration (FDA) and, in some instances, comparable applications with appropriate regulatory agencies in other countries. The Company is also typically required to pay royalties to such third parties based on sales of the applicable approved drugs and, pursuant to certain agreements and under certain circumstances, the Company is obligated to make advance royalty payments to such third parties.

In October 1989, the Company received FDA approval to market Adenocard(R) in the United States. The Company entered into agreements with Fujisawa USA, Inc. (Fujisawa) for the manufacture and marketing of Adenocard(R) in the United StateS and Canada.

PHARMACEUTICAL RESOURCES INC

CONSOLIDATED STATEMENTS OF OPERATIONS AND RETAINED EARNINGS (DEFICIT)
Year Ended October 3, 1992

	Oct 3 1992	Sep 28 1991	Sep 29 1990
Net sales	52,493,000	34,226,000	22,884,000
Other income	142,000	649,000	1,133,000
Total revenues	52,635,000	34,875,000	24,017,000
Costs and expenses:			
Cost of goods sold	32,769,000	26,798,000	20,434,000
Product development	978,000	1,546,000	1,948,000
Selling, general and administrative	11,404,000	12,146,000	10,940,000
Interest	923,000	1,175,000	1,102,000
Settlements of legal proceedings	230,000	12,465,000	NA
Regulatory review costs, recalls and other matters	82,000	408,000	1,706,000
	46,386,000	54,538,00	36,130,000
Income (loss) from continuing operations before income taxes	6,249,000	-19,663,000	-12,113,000
Provision (credit) for income taxes	2,150,000	-1,736,000	-5,000,000
Income (loss) from continuing operations	4,099,000	-17,927,000	-7,113,000
Discontinued operations:			
Loss from operations	NA	-11,648,000	-7,640,000
Estimated gain (loss) on disposition	1,696,000	-12,510,000	NA
Income (loss) before extraordinary item	5,795,000	-42,085,000	-14,753,000
Extraordinary item--tax benefit of utilization of net operating loss carryforward	2,150,000	NA	NA
Net income (loss)	7,945,000	-42,085,000	-14,753,000

The accompanying notes are an integral part of these statements.

FINANCIAL FOOTNOTES:
(SOURCE 10-K)
NOTES TO FINANCIAL STATEMENTS

The Company operates in one business segment, the manufacture and distribution of generic pharmaceuticals. Products are marketed principally in oral solid (tablet and capsule) form.

Product Development:-Product development expenses consist primarily of research and development costs. All such costs are expensed as incurred.

MANAGEMENT DISCUSSION:
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Operating Expenses Product Development Product development costs for the year ended October 3, 1992 of $978,000 decreased or 37% from fiscal 1991 costs. The decrease was due to management's decision during the prior year to suspend all product development efforts relating to the oral liquid and topical product lines, as well as to curtail efforts relating to the oral solid product line. Management has decided to revitalize its product development efforts in fiscal 1993 relating to the oral solid product line, including hiring additional personnel, purchasing raw material and contracting with outside laboratories to conduct biostudies and, accordingly, expects related costs to increase substantially from current levels. In addition, the Company is actively pursuing alternatives to supplement its internal product development efforts, such as joint ventures, licensing agreements and the reintroduction of additional products from the distribution moratorium (see "Results of Operations--Sales" above). There can be no assurance that these efforts will be successful.

FDA has advised Par that FDA will not review new product applications submitted by Par, nor will Par be eligible to receive new drug application approvals, before the conclusion of the validity assessment process (see "Notes

to Financial Statements--Contingencies and Other Matters--Validity Assessments by FDA"). The Company has been taking, and intends to continue to take, any necessary steps to conclude the validity assessment process. Management is unable to predict the impact that the validity assessment process will have on future results of operations.

Product development costs in fiscal 1991 of $1,546,000 decreased $402,000 or 21% from $1,948,000 in the fiscal 1990 year. Such decrease was due to management's decision during fiscal 1991 to suspend all product development efforts relating to the oral liquid and topical products lines, as well as curtail efforts relating to the oral solid product line.

Although the major portion of the regulatory audits being conducted by the Company's outside consultant is complete, the Company is unable to predict the length of time that it will take for the balance of the regulatory reviews and audits to be concluded, nor is it able to predict the extent or magnitude of any additional corrective actions that may be necessary due to review or audit findings or the results of FDA's validity assessments (see "Notes to Financial Statements--Contingencies and Other Matters--Validity Assessments by FDA"). Accordingly, it is possible that the Company will incur additional costs to be reported under this item, and such costs may be material.

STAAR SURGICAL CO

FINANCIAL STATEMENT TEXT:

NA; Income Statement Data should be available by 07/26/93.

FINANCIAL FOOTNOTES:
NA; Data provided only for NYSE, AMEX and Fortune 1,00 companies.

MANAGEMENT DISCUSSION:
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview Since its inception in 1992, the Company has directed its efforts to providing products, systems, procedures, and technology that restore vision through small incision cataract surgery, save vision through glaucoma surgery, and now provide better vision through implantable contact lenses.

The new management team effected a turn-around in the Company by: 1) obtaining pre-market approval from the FDA in September 1991 for the unrestricted sale in the United States of the Company's ELASTIC(tm) and ELASTIMIDE(tm) foldable IOL's, 2) obtaining approvals to market the same products in most other countries, 3) resolving and settling significantly all of the Company's substantial and costly litigation, 4) licensing the Company's technology to generate approximately $11.6 million in non-dilutive capital to eliminate the Company's capital deficiency and to provide cash flow for various corporate purposes until such time as the Company generates a profit, and 5) raising capital from private placements of the Company's securities, also for the purpose of eliminating the Company's capital
deficiency and to provide cash flow for various corporate purposes pending profitability.

This significant sales growth resulted primarily from increased sales of the Company's foldable IOLs which were approved by the FDA in September 1991 for marketing and sales in the United States. The sales growth when considering only foldable IOL's was over 300%.

Research and Development Research and Development costs nominally increased 13.4% over the 1991 level. The Company's R&D efforts have been focused on reducing the cost to manufacture current products; making current products easier to use, making current products less invasive during surgery, and developing new products for better vision care. The Company has reduced its costs of manufacturing, and has designed and introduced products that are easier to use than any other competitive products in the marketplace. As a direct result of these R&D efforts, the Company has recently announced two new lens products, the TORIC(tm) foldable IOL used for patients with astigmatism,

and the implantable contract lens (ICL) which is aimed at the general vision care marketplace. All of these technological advancements should enhance the future sales growth of the Company. The Company continues to demonstrate its technological leadership in vision care marketplace.

Research and Development Research and development expenses decreased by approximately 8.3% for 1991 compared to 1990. The decrease was primarily due to the fact that most of the research required for FDA approval of the ELASTIC(tm) and ELASTIMIDE(tm) IOLs was completed in 1990.

UNIVERSITY PATENTS INC

UNIVERSITY PATENTS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
For the years ended July 31, 1992, 1991 and 1990

	1992	1991	1990
Revenues:			
Retained royalties	504,143	450,578	423,297
Computer-based education services	2,030,291	1,193,643	621,344
	2,534,434	1,644,221	1,044,641
General and administrative expenses, including costs of technology management business of which $60,000, $89,000 and $200,000 were paid to related parties	1,103,717	1,214,968	1,281,255
Costs of computer-based education services, including $92,000, $143,000 and $120,000 paid to related parties	2,577,298	1,912,340	1,518,001
Reversal of accrued rent liability	NA	-960,400	NA
	3,681,015	2,166,908	2,799,256
Operating loss	-1,146,581	-522,687	-1,754,615
Gain on issuance of shares by subsidiary	44,018	NA	NA
Net gain on sale of investments	28,037	NA	17,194
Interest income	85,313	249,852	253,520
Interest expense	-73,329	-18,003	-597
Losses related to equity method affiliates	-503,882	-1,303,155	-886,686
Loss from continuing operations before income taxes and minority interest	-1,566,424	-1,593,993	-2,371,184
Provision (benefit) for income taxes	-60,000	18,715	14,457
Loss from continuing operations before minority interest	-1,506,424	-1,612,708	-2,385,641
Minority interest in losses of consolidated subsidiary	339,409	316,504	273,782
Loss from continuing operations	-1,167,015	-1,296,204	-2,111,859
Discontinued operations:			
Gain (loss) on disposal	180,504	NA	-491,079
Net loss	-986,511	-1,296,204	-2,602,938

See accompanying notes

FINANCIAL FOOTNOTES:

Income and Expenses-Expenditures made in connection with evaluating the marketability of inventions, pursuing patent applications, licensing patents and patent litigation are charged to operations as incurred.

PRESIDENT'S LETTER:

FROM ANNUAL REPORT TO SHAREHOLDERS)

Dear Shareholder:

Subsequent to the end of fiscal 1992, University Patents made a major strategic move. It returned to the university-based technology transfer business and now actively seeks new university clients whose technologies it will attempt to commercialize. This comes at a time when corporate research and development is on the wane and universities continue to maintain their preeminence as America's greatest source of basic research.

The acquisition of 80% of Lehigh University's technology unit, Competitive Technologies, Inc. (CTI) in October, 1992, was the culmination of a strong corporate inclination to return to what University Patents does best -- evaluate, license and commercialize inventions arising fro university research. When UPI sold its technology transfer business in 1988, the environment was much different -- the entrepreneurial spirit was sweeping campus administrations and industry was investing heavily in R&D. But that climate has now changed, leading UPI to believe that the time is right to reenter the field, but with a different set of rules and priorities.

UPI's previous modus operandi was to work with universities on a totally contingent basis, with UPI bearing all the expenses of evaluating, patenting technologies and searching for licensees to further develop the technologies and bring them to market. With the purchase of CTI, UPI has created a partnership with Lehigh University for the management of the university's new inventions. CTI has a five-year contract (subject to conditions) under which the university pays an annual fee to CTI and provides facilities and resources to help defray some of the costs associated with the commercialization process. At the same time, CTI retains a healthy interest in the successful conclusion of licenses obtained on those technologies. The Lehigh-UPI partnership creates an environment that reduces operating costs and risks for both parties. UPI plans to use the CTI partnership as a model for contracts it hopes to strike with other universities and Federal agencies/labs with technology to offer. CTI has also brought to UPI a number of government relationships with groups such as the National Science Foundation and the U.S. Department of Defense under revenue-producing tech transfer and collaborative R&D management contracts.

An important UPI technology - the anti-photoaging product Retin-A - is now before the Food and Drug Administration. Once FDA approval is granted to Johnson & Johnson, its producer, and sales volume begins to build, we except that this product will generate significant royalty income for our Company.

VISX INC

VISX, Incorporated and Subsidiaries
ONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 1992, 1991 and 1990
(In thousands, except per share data)

	1992	1991	1990
Revenues:			
Product sales	9,368	11,182	5,977
Product sales to Alcon, a related party	9,566	1,678	NA
Development revenues	24	61	572
Service and other revenues	1,327	250	72
Total revenues	20,285	13,171	6,621
Costs and Expenses:			
Cost of sales	12,551	8,285	4,126
Marketing, general and administrative	6,846	4,624	6,034
Research, development and regulatory	5,445	2,664	4,472
Purchased research and development	6,017	NA	NA
Total costs and expenses	30,859	15,573	14,632
Loss from Operations	-10,574	-2,402	-8,011
Other Income (Expense):			
Interest expense	-20	-4	-12

would require treatment for both nearsightedness and astigmatism in order to achieve optimum visual acuity and to eliminate the need for corrective lenses.

MANAGEMENT DISCUSSION:
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Research, development and regulatory expenses increased $2,781,000, or 104%, in 1992 compared to 1991. This increase reflects the Company's continued investment in research, development and regulatory personnel, increases in material costs, increases in regulatory expenses associated with the FDA studies and the addition of Questek's research and development organization. Research, development and regulatory expenses decreased $1,808,000, or 40%, in 1991, compared to the prior year. This decrease reflects reductions in research, development and regulatory personnel consultants and product development material expenses resulting from the consolidation of operations after the Merger.

K V PHARMACEUTICALS

K V PHARMACEUTICAL COMPANY AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended March 31, 1992, 1991, and 1990

	1992	1991	1990
Revenues:			
Net Sales	41,368,435	34,457,148	30,147,069
Investment Income	650,171	663,195	1,440,791
Total Revenues	42,018,606	35,120,343	31,547,860
Costs and Expenses:			
Manufacturing Costs	27,808,368	23,959,032	22,152,713
Research and development	4,880,180	4,218,469	3,926,743
Selling and administrative	8,468,429	7,036,148	5,617,371
Interest expense	1,009,785	1,329,255	900,288
Total Costs and Expenses	42,166,762	36,543,904	32,597,115
Loss before income taxes	-148,156	-1,423,561	-1,049,255
Provision for income taxes	NA	NA	NA
Net Loss	-148,156	-1,423,561	-1,049,255

MANAGEMENTS DISCUSSION

During fiscal 1992, research and development costs increased to $4,880,180, an increase of 16% over the prior year. As a percent of revenue, these costs remained at 12%. Research and development expenses were $4,219,469 in fiscal 1991 and $3,926,743 in fiscal 1990. These costs are linked directly to the expansion of the Company's drug delivery technologies and new product development. The Company expects these expenditures to continue at a relatively high level related to proprietary new products.

Compared to a new drug entity, which is a drug molecule that has never been approved by the FDA or commercially marketed, an Improved Drug Entity(TM) is a patented or off-parent drug (already approved by the FDA for marketing in its original form) which has been converted by a K V drug delivery system technology to have differentiated and improved benefits.

The Company expects to continue a relatively high level of expenditures and investment for research, clinical, and regulatory efforts relating to development and commercialization of proprietary new and Improved Drug Entities(TM) and their approval for marketing. Delays in FDA approvals have been experienced industry-wide by pharmaceutical companies in general and there can be no assurance such delays will not continue.

A. L. LABORATORIES, INC.
A. L. LABORATORIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF INCOME
(In thousands)
Years Ended December 31

	1992	1991	1990
Total revenue	295,112	257,129	241,375
Cost of sales	116,947	144,283	131,121
Gross profit	128,165	112,846	110,254
Selling, general and administrative expenses	99,671	99,156	78,063
Operating income	28,494	13,690	32,191
Interest expense	-10,134	-12,098	-11,652
Other income (expense), net	-785	174	709
Income from continuing operations	17,575	1,766	21,248
Provision for income taxes	6,208	1,187	8,025
Income from continuing operations	11,367	579	13,223
Income from discontinued operations	4,809	4,502	883
Net Income	16,176	5,081	14,106

MANAGEMENTS DISCUSSION

Reasons for the decision included the delays experience by the Company in obtaining drug approvals by the FDA, while maintaining an increased level of expenses related to personnel, research, product development, and clinical testing necessary to support regulatory submissions and approvals.

The development, manufacturing and marketing of the Company's products are subject to regulation which includes inspections and controls over manufacturing practices and procedures, requires approval to market products, and can result in the recall of products and suspension of production. In the United States the Food and Drug Administration(FDA), has imposed increasingly comprehensive oversight and more stringent regulatory requirements on the pharmaceutical industry, with the result of substantially increasing the cost of regulatory compliance incurred in the production and marketing of pharmaceutical products.

Operating expenses in 1991 included costs for regulatory compliance.

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