

Growing Headwinds For Pharmaceutical Companies

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Key Highlights

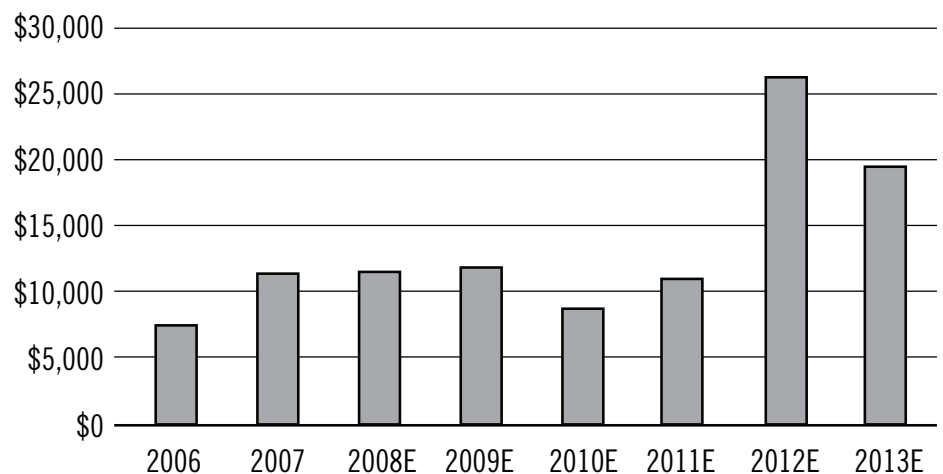
- Pharmaceutical companies face a multi-year headwind due to the loss of revenue from patent expirations of branded drugs.
- The companies face the challenge of replacing this revenue, a difficult task when trying to develop new drugs from scratch. Declining research and development productivity does not provide us encouragement that they will be successful.
- In general, we see the stocks of pharmaceutical companies as appropriate for more conservative, income oriented investors.

Executive Summary

In this edition of Capital Ideas, we examine the issues looming over the pharmaceutical industry in coming years. Extensive patent expirations

for key revenue-producing drugs will act as a headwind to sales and earnings growth across the pharmaceutical industry. Considering the challenges involved in developing new drugs and the trend of declining research and

Figure 1. Major Pharmaceutical Revenues Expected To Be Lost Due To Patent Expirations (millions)



Source: IMS Health, JP Morgan Research

development success in the industry, we will show that companies will have a difficult time replacing lost revenues. The industry will attempt to offset the gaps with cost cutting and acquisitions, although these measures will not solve their long term problems. We conclude with the investment implications of the industry's challenges and where we see opportunities.

Patent Cliff Problem

The main challenge facing the drug companies over the next several years stems from the loss of patent exclusivity for branded drugs and the effect this will have on their revenues. The timeline varies by drug, but in general when a company develops a new drug idea they get it patented. They then spend years developing and testing the new drug with the ultimate goal of having it approved by the Food and Drug Administration (FDA). After the drug is approved by the FDA, the Hatch-Waxman Act allows for a period of market exclusivity that often extends beyond the expiration of the patent. The period of patent protection and the extended exclusivity period reward the company for the risk and expense they undertook in developing the drug. This protection usually gives the company a period of very strong profitability for the product. A very successful drug can grow over

time to be a substantial portion of a company's sales. When the exclusivity period expires, the majority of those sales evaporate due to competition from generic drug companies, leaving a large hole in the company's revenue stream.

The pharmaceutical industry is facing a period of substantial patent expirations over the next several years. It can be difficult to pinpoint the exact timing of when a drug will face generic competition due to patent challenges, but we know the numbers will be very large in the years to come. According to estimates from JP Morgan Research, the dollar amount of sales that will likely be lost over the next several years for the industry is substantial (see Figure 1). In the worst hit years, 2012 and 2013, they expect the industry as a whole to lose 12% and 9% of their revenues, respectively. Figure 1 illustrates that the loss of patents has been a headwind for the group over the last few years. This trend is expected to accelerate.

The Research and Development Challenge

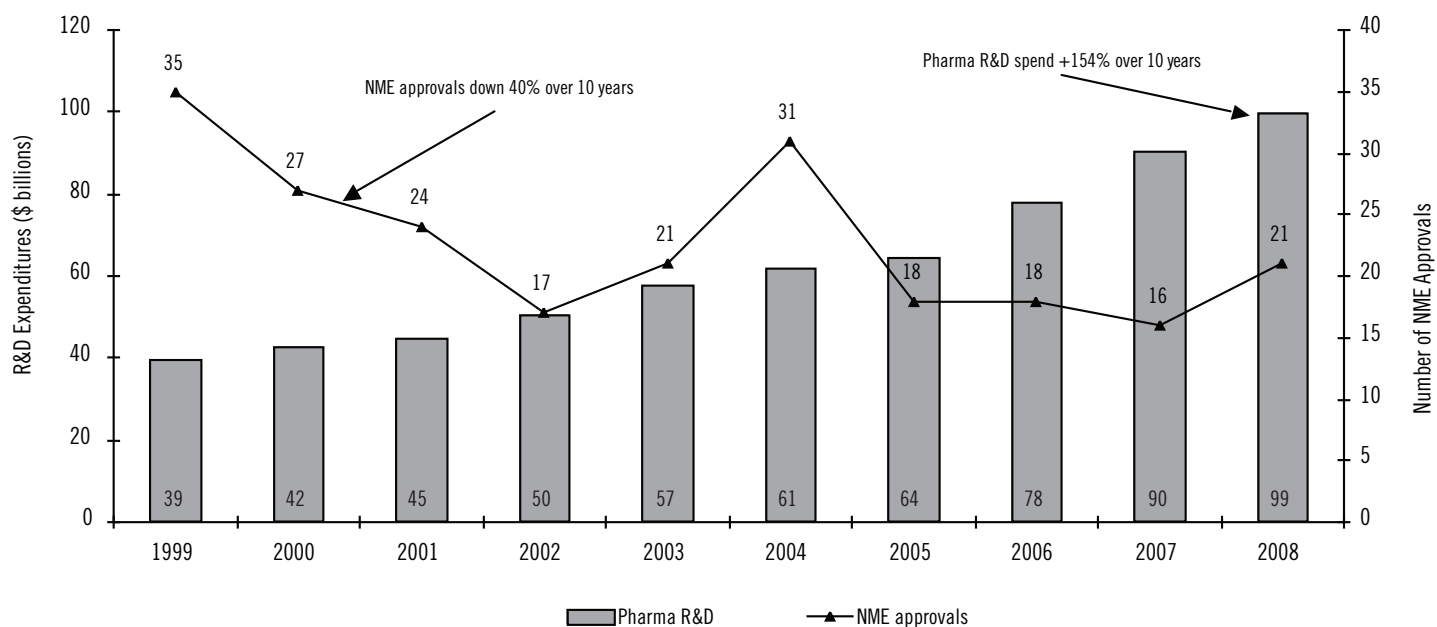
The patent expirations faced by the pharmaceutical companies are a normal aspect of their business. The companies are constantly engaged in research and development (R&D) in an effort to create the next big drug that

will reach blockbuster status. Unfortunately, the development of a new drug is a monumental task, with a very low rate of success and FDA approval adds another layer of difficulty to the process. According to the Pharmaceutical Research and Manufacturers of America, one out of every ten thousand potential new drug ideas from American pharmaceutical companies is ultimately approved by the FDA and makes it to the commercial market¹. It takes a great deal of time to bring a new product to market; a typical drug may take nearly twelve years to go from the discovery process to approval by the FDA. Research and development is also very expensive; academic research on the subject estimates the cost to develop a new drug at more than \$800 million dollars². This estimate includes the opportunity costs of other investments and the costs of drugs that fail during various stages of the development process. Some candidates are rejected after years of testing and large amounts of investment. Even after a drug makes it through the development and testing process, it still must

¹ *Pharmaceutical Research and Manufacturers of America, www.phrma.org/innovation, 2009.*

² *"The Price of Innovation: New Estimates of Drug Development Costs" Joseph DiMasi, Ronald Hansen, & Henry Grabowski. Journal of Health Economics 22 (2003).*

Figure 2. Pharmaceutical Pipelines – Productivity Declining



Source: Nature Biotechnology, company reports, Bernstein analysis

be approved by the FDA. This key step is where many potential drugs are rejected, meaning they never make it to the marketplace. As a result, the pharmaceutical companies face an uphill battle in introducing new drugs to consumers.

R&D Success Has Waned

With the expectation of patent cliffs ahead, many of the pharmaceutical companies have proactively ramped up their research and development efforts

in order to replace expiring products. The problem is that the companies' R&D efforts appear less effective than in years past. There are not enough new drugs in their pipelines to offset the revenues from the drugs that are losing their patents. A good deal of work has been done on this subject and we see two trends: R&D spending is on the rise and approvals for new drugs are on the decline. This point is illustrated in Figure 2. The chart shows that over the last ten years research and development spending

has increased about 154%, but new molecular entity (NME) approvals have declined 40% over the same period. The year by year comparison here is difficult because the long lag time needed to develop a new drug means that research costs in a given year may not see any economic benefit for several years down the road. The FDA also makes the analysis difficult because they have been known to delay approvals for various reasons. Some speculate that the FDA is acting more conservatively due to scrutiny over prior

product recalls and, perhaps, they are overloaded because of understaffing³. The longer term trends impacting the success or failure of R&D are important, and they do not bode well for the pharmaceutical companies' ability to develop new replacement products. In the end, the industry is creating fewer new products to replace those that are being lost to patent expirations.

Understanding Rising R&D Costs

We have shown how research and development spending has been on the rise, but it may not all be due to companies simply spending more to develop new products. Some of these changes may be more secular in nature. For instance, a Congressional Budget Office (CBO) paper addresses the topic of rising R&D costs, proposing several possibilities that may explain why companies are spending more in recent years. Pharmaceutical companies may be shifting their focus away from acute illnesses and more toward chronic illnesses. This shift would require longer clinical trials.

³ Bethan Hughes. "2007 FDA Drug Approvals: A Year of Flux." *Nature Reviews Drug Discovery* 7 (February, 2008): 107-109.

⁴ "Research and Development in the Pharmaceutical Industry" A CBO Study, David H. Austin et al., October 2006.

Pharmaceutical companies are also conducting more studies to compare their drugs to those of competitors for marketing purposes. Clinical trials also seem to be getting longer and involving more participants. Finally, the CBO noted that a higher rate of failure in clinical trials over time has increased the costs associated with new drug development⁴. Some of the increased spending on R&D is being driven by the need to develop new products and some is driven by structural changes in the industry. The end result is the same – expenses are rising and output has been stagnating.

The Impact Of "Me-Too" Drugs

One aspect of the pharmaceutical industry that is worth noting is the rise of the so called "me-too" drugs. These are drugs that are very similar to currently approved drugs, but may be different in some slight manner. The "me-too" drug is developed to treat the same condition as its predecessor. In order to be approved by the FDA, a "me-too" drug must be shown to pass safety and efficacy standards. It need not prove more beneficial than the drug it is mimicking. A "me-too" drug can be less beneficial for treating a condition than a previously approved drug, yet it can end up costing more money for the consumer. Of course, a "me-too" drug

can also lead to increased competition and put downward pressure on product pricing.

The "me-too" drugs are not without merit, as they can actually end up leading to a new therapy that is either more beneficial or safer than the original. They have accounted for a large portion of the research and development money that has been spent over the years, and they can cause one to question the ability of the drug companies to generate novel products. If the industry's pipelines contain too many "me-too" drugs they may not have the same revenue potential as a pipeline of truly innovative products.

The Response: Cost Cutting and Acquisitions

So how are the pharmaceutical companies dealing with their issues in light of less than optimal pipeline opportunities? They have been turning more and more toward cost cutting and acquisitions. The cost cutting opportunities are obvious. If a company is having a difficult time maintaining a certain level of sales and it wants to minimize the impact to its profits, it must cut its expenses. We have seen this from numerous companies in the industry and will likely see this trend continue in the future. For example, some blockbuster drugs have entire sales forces dedicated solely to one product. If the

economics of the product evaporate after the loss of a patent, that sales force is a good place to cut costs.

Cost cutting is important, but it is a short term solution to a company's problems. Long run earnings growth will only come from new product innovation. Since often the pharmaceutical companies have large amounts of cash and insufficient pipelines, they may acquire other companies to fill in the product gaps. Some large pharmaceutical companies have purchased smaller biotech companies and others have merged with their pharmaceutical peers. The biotech industry offers attractive longer term appeal as they can open doors for new treatments, but the industry is also in the beginning stages of generic legislation that may lead to patent cliffs of their own. These acquisitions also bring significant cost cutting opportunities. Although, in some cases the acquirers do little more than spend large amounts to maintain the status quo as far as revenues are concerned. Acquisitions are very risky endeavors and often do little more than destroy shareholder value. Nevertheless, it would not be surprising to see the trend of acquisitions continue in the future.

Investment Implications

With the issues looming over the industry over the next several years,

what place do the stocks of major pharmaceutical companies have in an investment portfolio? To begin, the companies in the sector are very defensive in nature because drug volumes tend to hold up well during a recession. This attribute can be appealing during times of economic uncertainty. This recession, however, has illustrated that the pharmaceutical companies are resilient, but not immune to the economy as consumers have been skipping prescriptions and cutting pills to make their medications last longer. The stocks also tend to have high and stable dividend yields, making them suitable for those clients with a need for current income. So we tend to view these stocks as conservative, with current valuations that largely reflect the weak sales outlooks and good for income oriented investors.

Not all drug companies are created equal. Some drug companies have better pipelines than others. Some will lose a smaller percentage of their revenues to patents than others. Some of the companies in the industry have proven to be better at research and development. Some are more diversified than their peers, and are less susceptible to the loss of revenues when their drugs lose their patents. We prefer these companies over their more pure-play cousins since they tend to have an abil-

ity to offset the losses in revenues with other product lines.

The story does not end here, however, as the problems for pharmaceutical companies may present opportunities for others. For instance, generic pharmaceutical companies should benefit over the next several years from the large increase in the number of available generic drugs. Drugstores and pharmacy benefit managers should also benefit as these companies earn a higher margin on generic drugs than they do on the branded versions. Consumers and those paying for prescription drugs should also benefit from the increased number of drugs going generic due to the lower absolute dollar cost compared to the branded counterparts.

Conclusion

The road ahead for numerous pharmaceutical companies will be rocky. The loss of revenues due to patent expirations of key products will create problems the companies may not be able to easily offset in a world of declining R&D efficiency and dwindling pipelines. In order to compensate for slowing revenue growth, pharmaceutical companies will likely continue to cut costs and engage in acquisitions. This approach will create an ever changing landscape as new companies are formed from mergers. This strat-

egy does not promise new innovative products. Beyond the healthy dividend payments there is little for us to be excited about in the way of earnings growth. Though some pharmaceuti-

cal companies are better positioned than others, ultimately we believe the real winners are those companies that will profit from the big pharmaceutical companies' woes.

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We look forward to serving you. For more information, please contact us at 1-866-917-8730.

About the author



Derek Peterson is an equity analyst covering the Consumer Staples and Health Care sectors. As an equity analyst he helps oversee the Total Return Opportunity Portfolio, the Equity Income Opportunity Portfolio, and the Small Cap Value Portfolio. He has been an equity analyst since February 2006 and served as an equity trader for one year prior to that. He earned a Bachelor's degree of Business Administration in Finance from the University of Georgia. Mr. Peterson is a CFA charterholder and a member of the CFA Society of Alabama.

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