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2012 promises to be a year of new and different innovations from the Life Sciences industry as companies are forced to respond to unique and difficult challenges that have not previously been characteristic of this market yet have been looming in the background for the last decade. Many large pharmaceutical companies continue to face expiring patents, pressure from stockholders to streamline spending on research and development (R&D), and continued merger and acquisition (M&A) activity. While many of these companies are seeing a decrease in top line revenue in the United States, these same companies are attempting to increase sales abroad, especially in emerging markets. Unlike with pharmaceuticals, the medical device industry was able to sustain profitability through the challenges of the past year and produce an impressive rate of return on investments, 6 percent versus 2 percent loss from the pharmaceutical market. (Based on $100 investment from 1999-2009 in S&P 500 Medical Equipment and Pharmaceutical Index)[1] The Life Sciences industry faces a multitude of issues and threats moving into 2012, but within each challenge lies great opportunity to make the next year a success.

Waiting on a blockbuster?

Threat

During the 2011 fiscal year, the FDA approved 35 new medicines,[2] and speculation is abound on which of these has the potential to reach blockbuster status. However, within the industry, companies are questioning for the first time whether the pursuit of blockbusters provides a valuable return on the enormous investment it takes to get drugs through clinical trials. Estimated at $1.05 billion, the cost to bring a drug to market is higher than ever, a 25 percent increase over the previous year alone.[3] Of those drugs projected as blockbusters, many are not doing as well as anticipated. This can often be attributed to a slower than expected adoption rate from physicians who are waiting for more data on the long term effectiveness of newly approved drugs. With costs this high and generics waiting in the queue for patent expirations, pharmaceutical companies must work harder than ever to justify the benefits of their drug to the consumer.

Identifying the main customer also continues to be a challenge in all segments of the Life Sciences industry; is it the physicians, paying organizations, or consumers who need the most attention in marketing and educational efforts? Pfizer, faced with a patent expiration of its major blockbuster, Lipitor, took a new approach and began targeting the individual patients instead of focusing on other stakeholders. Pfizer has taken a new approach, lowering prices to be competitive with the generic brands and soliciting individuals to order Lipitor directly from the company.[4] Moves like this could change the game for blockbusters and, if the strategy is successful, once again justify the quest for such drugs. Because each type of customer has his or her individual interests at hand, all Life Sciences companies must also look to obtain not only more data on their products, but also the correct package of data that will be most effective to prove that the product is bringing superior value to each customer.

What to consider in 2012

- *How are you executing on an integrated strategy to all of the customers of your business? Do you know the needs of the physicians, payers, and patients?*
- *How successful has the execution of your M&A activity been? Do you have an M&A playbook that addresses people, processes, technology, and culture?*
- *Do you view all of your CMOs as partners? Do you have access to the data needed to best determine whether the relationship is working?*

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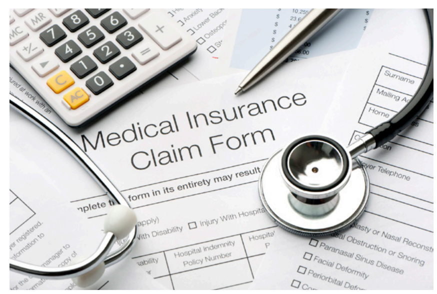

Opportunity

To achieve annual sales worthy of blockbuster status there is an increased need to know your customer and their needs. The following is a breakdown on three primary customers – the patient, the doctor, and the payer – and what to consider when reaching out to them.

- **The Patient**: In the information age and the growing influence of social media, reaching the patient has taken on even greater importance. However, at the same time this can be a risky regulatory move. For now, having a social media strategy that allows flexibility and the ability to quickly adjust as regulatory guidance is given will be key to successful execution of the strategy.
- **The Doctor**: How the industry collaborates and educates doctors has changed over the course of the last few years. With more doctors restricting visits from the pharmaceutical sales reps in their offices, the industry is looking for new ways to reach doctors. Doctors are looking for less marketing and more data around the various drugs, as was found in a recent Clarkston survey of doctors.
- **The Payer**: Reaching the payer is the biggest of these challenges. Payers are requiring additional testing and data to prove the benefits of the new drug are greater than that of current treatments, and more cost effective than current treatments. Sanofi is trying to address this as part of the clinical trial design by partnering with Medco Health Solutions to help design their clinical studies so that they gather improved comparative effectiveness data and streamline the path to gain access to formularies.

The key to reaching these customers is data and more data; specifically, data that addresses their questions and concerns, but also demonstrates the value of the product. Companies will need a segmented strategy that addresses the needs of each customer, while overall pulls together the value proposition of the product to all customers.

Buy or sell?

Threat

Anyone watching the news in the past few years has seen the volume of mergers and acquisitions within the Life Sciences industry. In addition to this activity, companies are now thinking critically about where to place their focus. Pressure from shareholders to pursue only the most profitable and promising avenues for drug development are causing many organizations to carve off pieces of their non-core business. Examples of this can be seen with Pfizer's sale of Capsugel, Mead Johnson's spin-off from Bristol-Myers or Medco Health's from Merck.[5] Traditionally, the acquisition strategy was used to bring new and profitable drugs into a company's portfolio after their own pipeline of innovative products began looking scarce or patent expirations loomed. Instead, companies now seem to be acknowledging that their investment dollars are not well spent pursuing every type of product, but could be more effective focusing on a few core treatment areas. The question for many then is which areas? In the shadows of such major pharmaceutical expansion, it seems counterintuitive to limit the scope of a company's portfolio. However, this focus could be the key to success for many. Limiting the breadth of offerings could drive more – and better – investment and innovation in a few core areas.

Opportunity

Strategy is key, but that goes without saying. Execution is where a successful scenario for M&A, whether it is buying or divesting, defines its value. Assess your core business to determine the best investments in your product portfolio to drive opportunistic growth, and those that are not in alignment. Then develop a playbook to take advantage of opportunities to grow your business through acquisition or key partnerships. Achieving the return on your investment through a successful integration allows the business to achieve the goals of the strategy. The time between acquisition of businesses, integration of similar departments, and the integration of new and existing intellectual capital while limiting disruption of existing operations is key to the success of these deals. Companies that focus on these aspects of deal making will gain the most from the opportunities they embark on in 2012. Having the playbook that addresses the organization's people, processes, technology, and culture will assist in making the acquisitions and divestitures a success in 2012. The most important of which is cultural integration of two companies so that intellectual capital is not lost and the full benefits of the merger are realized. This involves thoughtful consideration of both company cultures while purposely combining the best pieces of both entities to ensure that everyone is operating with the same organizational values, structure and management practices.

Do you have a playbook that addresses the organization's people, processes, technology, and culture that will assist in making your acquisitions and divestures a success in 2012?

Outsourcing it all

Threat

Over the last few years, pharmaceutical companies have turned to CMOs to provide a more cost-effective and compliant approach to manufacturing, especially in the final stages of filling and packaging drug product.[6] The rationale being that an organization focused solely on manufacturing would have the infrastructure, processes, and procedures already in place to perform these activities. As venture capital funding decreases and new medical device taxes increase, medical device companies are also being forced to strategically outsource portions of the product manufacturing pipeline. This strategy allows them to maintain their focus on innovation, a critical component in the industry in meeting the diverse and growing needs of the customer. This CMO relationship provides challenges of its own; however, many major players in the industry have already moved in this direction. In addition, many pharmaceutical companies use contract, or clinical, research organizations (CROs) to manage and track their clinical trials. Pfizer's partnership with Parexel and Sanofi's partnership with Covance are only two examples of industry-wide moves to strategically outsource core business processes. This has resulted in a 9 percent rise in CRO market penetration in 2011, up to 38 percent from 27 percent in 2010.[9]

What is newer to the industry is a trend of outsourcing that has moved further up the supply chain to the R&D competencies of an organization. This year the rate of return on R&D activities dropped from 11.8 percent to 8.4 percent.[7] Pharmaceutical companies are under scrutiny to invest the right resources on the right research for the right periods of time. Some companies are fostering new partnerships with peer organizations or educational institutions while others are investing in new R&D facilities closer to hotbeds of scientific talent. Still others are looking to cut costs in this area and outsource the innovation to a contract organization. Research in this area has shown that the level of investment in R&D is not necessarily tied to the number of new products brought to market. Pfizer, for example, tripled its spending over the last ten years but saw a decline in the number of new medicines.[8] After cries from shareholders, Pfizer recently responded by slashing spending on R&D. These realities create a compelling argument to consider outsourcing what was once thought to be the most important and sacred aspect of an organization.

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Opportunity

There is not a one-size-fits-all solution for outsourcing. The needs, capabilities, and opportunities for each organization are different, and understanding where your organization is at will determine the best path to pursue.

- Evaluate your organization's capabilities and alignment with the organizational strategy, taking into consideration your customer, the customer locations, quality, cost, and business continuity. Based on this evaluation, determine where to invest internally versus the investments needed externally.
- Determine the best mix or who the right "partners" are for the organization. The difference between developing a partnership and simply executing a contract can be the difference between success and a long bumpy road. Developing the criteria for selecting your partners will help the organization evaluate and choose partners that will help them achieve their objectives.
- Data, data, and more meaningful data is how organizations are able to get comfortable with their partners and create a trusted relationship. Data that drives confidence in the partner's service and quality are key components to building this trust. Working together with your partners to establish common metrics and data sharing will also drive success at both organizations and help your organization to realize the ROI you are expecting.

Consider this in 2012

As you move into executing your plans for 2012, think about what has changed in your organization over the last year. 2011 proved to be a year where companies questioned and challenged industry practices that in the past had been considered sacred. Pfizer stepped up direct sales and marketing practices to patients in order to challenge the looming generic brands knocking at their door. Outsourcing continues to increase, even within core areas of the business, such as R&D. And the blockbuster drug strategy that once drove the industry is a thing of the past. Faced with these game-changing issues, consider these questions as you move into the New Year:

- How are you executing on an integrated strategy to all of the customers of your business? Do you know the needs of the physicians, payers, and patients?
- How successful has the execution of your M&A activity been? Do you have an M&A playbook that addresses people, processes, technology, and culture?
- Do you view all of your CMOs as partners? Do you have access to the data needed to best determine whether the relationship is working?

About the Author

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