Industry Landscape

Bridging the Gap Between Drug Delivery & Specialty Pharma

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Introduction

What is the difference between a Drug Delivery company and a Specialty Pharma company? Classifying companies into the two groups can prove to be difficult. For more than a handful of companies, the lines are blurring as companies in each segment continue to morph and adapt to the competitive pressures they face.

Changing How People Take Their Medicines

The drug delivery industry comprises more than 200 companies, many of which are in direct competition with each other. While a number are publicly traded or wholly owned by other companies, the majority are relatively small, with a single technology, and annual revenues well below $25 million. Companies tend to build expertise in a particular area of drug delivery and, due to resource constraints, are often limited to competing primarily in that technology. There are, however, several notable exceptions, such as ALZA (now a part of the Johnson & Johnson Group of Companies) and Elan, both of which grew into fully integrated billion-dollar-plus pharmaceutical companies.

Products based on novel drug delivery technologies have changed the way people take their medicine. Drug delivery companies (eg, Biovail, SkyePharma, Nektar, and Alkermes) generated more than $2 billion last year, making drugs safer, more effective, or more convenient. These companies are also optimizing the effect of drugs on the body with such techniques as controlling the rate of absorption and targeting a specific organ for drug release. Advanced delivery technologies that control the release of medicine or enhance its absorption can deliver drugs orally, or through the skin, mucus, eyes, or lungs. Drug delivery technology makes drugs safer, more effective, or more convenient for patients.

Big Pharma companies invest 10 or more years and up to $1 billion developing new medicines, according to the Tufts Center for the Study of Drug Development, while drug delivery companies invest a fraction of that amount and still retain the benefits of patent protection for their drugs that win approval. Branded pharmaceutical companies (eg, Pfizer, Johnson & Johnson) find drug delivery technology so valuable that they often partner with or acquire drug delivery companies to extend the patent lives of their older products facing generic competition. Developing products based on these advanced delivery technologies has proven to be a good business model because techniques that improve drug safety, efficacy, or convenience can command a premium price. For example,

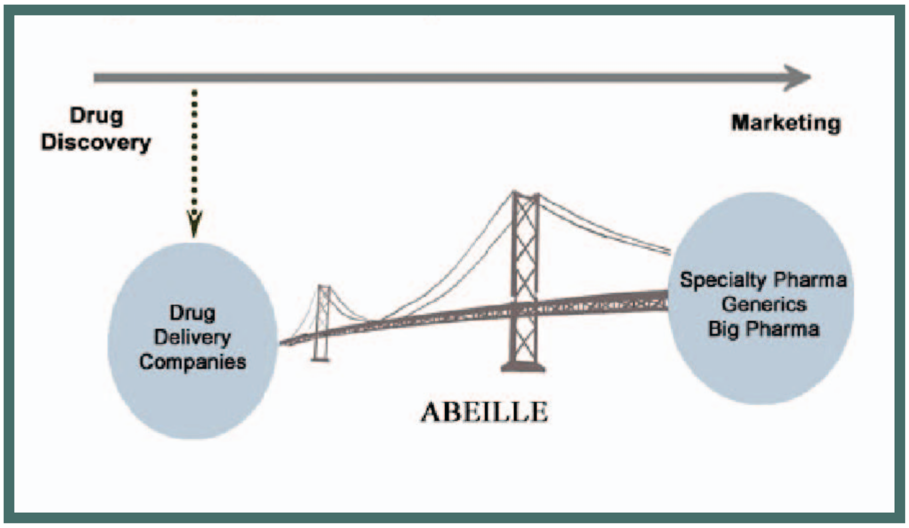

Figure 1. Bridging The Product Gap

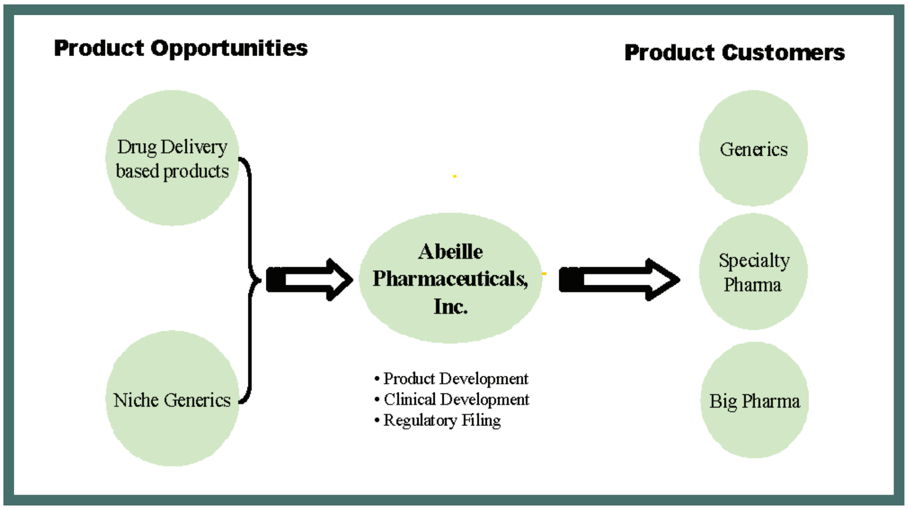

Figure 2. Abeille's Business Model

Johnson & Johnson sells its once-a-day incontinence medicine Ditropan XL (oxybutynin) for more than $3 per pill, compared to about 20 cents per pill for the generic dose taken several times a day.

Doctors are more likely to prescribe medicines that are safer, more effective, or more convenient than other alternatives. Patients prefer drugs with fewer side effects and improved convenience. In addition, people are more likely to take their medicine with less frequent dosing, a key aim of drug delivery technology. The combination of these factors leads to favorable pharmacoeconomics for these advanced delivery-based drug products, which in turn helps address reimbursement issues. Sales of pure-play drug delivery companies were approximately $2.1 billion this past year and are on track to grow 16% per year to $5 billion by 2008, compared to approximately 10% growth for Big Pharma companies, according to the Drug Delivery Technology Industry Report from Raymond James & Associates. While these numbers are encouraging, the dynamics of the drug delivery market are changing. Pharmaceutical companies are bringing drug delivery capabilities in-house, and reformulation technologies and life-cycle management strategies are being incorporated at earlier stages of the product life cycle. This suggests that for drug delivery companies to remain competitive, they will need to develop and possess unique capabilities and technologies that can add value through multiple stages in the drug development cycle. A greater diversification of drug delivery technologies and the development of additional new technologies will support drug delivery companies' expanding business development activities (eg, the transformation of Inhale Therapeutics into what is now Nektar Therapeutics). Expertise in a range of drug delivery techniques will enable superior performance and greater competitiveness, according to DataMonitor.

Adopting A New Business Model

The Specialty Pharma sector encompasses a range of company types, but all share the same end goal: To be fully integrated pharmaceutical companies (FIPCOs). The late 1990s and early 2000 saw a surge in the number of Specialty Pharma companies that were formed around a strategy of acquiring under-resourced and under-promoted products that no longer were of strategic interest to Big Pharma companies. The majority of these products are believed to have peak sales potential of $200 million or less. Historically, a growth-by-acquisition strategy has enabled these Specialty Pharma companies to achieve this goal, but leading Specialty Pharma companies must now move downstream to fill pipeline gaps with proprietary products.

Most Specialty Pharmaceutical companies generate annual sales of less than $1 billion and have limited therapeutic, geographic, and operational capabilities. These companies have relied on low marketing and selling costs (but relatively high revenue) of a single product and product acquisitions. A new product will jump-start specialty company growth in the first 2 years following its acquisition. After this point, growth peters out, new drivers are required, and therefore, more product acquisitions must be made. This continued need for acquisitions has two major effects: High cash burn and an over-reliance on each acquisition for company growth. In addition, as a Specialty Pharmaceutical company grows, the difficulty increases in finding targets that fit with its therapeutic strategy, and are large enough (and cheap enough) to sustain previous growth rates.

For Specialty Pharmaceutical companies to reduce their dependence on Big Pharma for growth, they will need to work more closely together, and establish partner networks to access products and resources. A network of partners is key to sustained growth. Greater collaboration between niche pharmaceutical companies will make them more competitive against larger players. The companies operating in the same therapeutic areas should pool their resources to diversify risk, speed drug development, and increase drug-market penetration. Their ultimate goal should be to construct a portfolio of shared products that are developed and promoted more efficiently than by one company alone. Specialty Pharmaceutical companies will need to adopt a new business model that includes enhanced development capabilities. This enables them to take on pre-commercial product development activities. Additionally, industry insiders claim that companies will need to reinvent some of these products through drug delivery strategies.

Generic companies within the Specialty Pharma sector face different pressures. The number of Chinese- and Indian-based companies entering the US market will continue to rise in the coming years as they seek to capitalize on their capabilities of being fully integrated. As competition increases in the commodity generic sector, companies that move into the high-value generic research and development segments, and combine generic product portfolios with broad branded product lines that promote innovation, are expected to become the most successful.

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The Need Today—Products, Products, Products!

Specialty pharmaceutical, generic, and drug delivery companies continue to evolve. Many of these companies have built a product portfolio, achieving sales and earnings growth. However, obstacles remain, and these companies need to implement unique business strategies that sustain their growth. For example, Specialty Pharmaceutical companies have to adapt to the changing climate and become fully integrated to maintain a robust product portfolio and sustain growth rates. Generic companies need to maximize market penetration and focus on product innovation and globalization to maintain growth rates in an increasingly competitive environment. Drug delivery companies have to become more independent in product development and marketing to maintain a greater share of the product revenues.

No matter what business model is being pursued, the companies need proprietary products with high growth potential to sustain or improve growth rates. Even more pertinent is the fact that Specialty Pharma, generic companies, and Big Pharma prefer to in-license finished products and products in late-stage development, as opposed to partnering on a technology-based product at an early stage of development. However, the drug delivery business model, driven primarily by resource constraints and a risk-management strategy, has been to seek partners at an early stage of development. This divergence in priorities and focus has created an opportunity in the market for companies like Abeille Pharmaceuticals. Its business model, which is to develop technology-based products and advance them through the clinical development before seeking to license them out to the end marketers, bridges the gap between Drug delivery companies and end marketers: Specialty Pharma and generic companies. The firms that can bridge the product divide will achieve great value.

SURESH BORSADIA

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Mr. Suresh Borsadia has more than 14 years experience in the pharmaceutical and drug delivery industries, with expertise and experience in R&D and business/corporate development activities. Mr. Borsadia has a demonstrated record of successfully managing multiple projects and building R&D organizations in early-stage companies. Prior to founding Abeille Pharmaceuticals, Inc., he was with Lavipharm for 7 years, where he played a leading role in the company's R&D, in-licensing, and out-licensing activities. He was part of the Senior Management team involved in M&A and fundraising activities. Prior to that, he worked at 2 other leading drug delivery companies, TheraTech, Inc., (now Watson Pharmaceuticals), and Bertek, Inc., (now Mylan Technologies, a Division of Mylan Labs.). His professional background is in Pharmacy & Pharmaceutics.