PETER THORNTON discusses why the drug delivery sector is

growing faster than the pharmaceutical industry



The benefit of drug delivery is that it provides lifecycle management opportunities through which companies can introduce genuinely improved treatment options for patients, savs Peter Thornton.

THE DRUG DELIVERY MARKET

Why do you think the drug delivery sector is growing faster than the pharmaceutical industry?

THORNTON: This trend is being driven by the challenges the pharma industry faces and the need for improved treatment options for patients as well as improved treatment options for healthcare systems. Productivity is declining in the pharma industry; 75% of all drug approvals by the FDA have been new or improved formulations of existing drugs.

The benefit of drug delivery is that it provides companies with lifecycle management opportunities where companies can introduce genuinely improved treatment options for patients.

Companies are turning to drug delivery especially for poorly soluble molecules in their pipeline. With newer delivery technologies, fewer of these compounds have to be discarded. This increases productivity and also cuts the cost of drug development.

PAYER PERSPECTIVE

How receptive are payers to incrementally improved products?

THORNTON: Historically, many of the lifecycle management activities were compliance improvements, such as moving from a twice-daily tablet to a oncedaily tablet. This approach doesn't cut it with payers these days. Drug delivery can bring a lot of benefit

Pharmaceutical companies are considering drug delivery solutions more widely and earlier in the development cycle, and market growth is outpacing pharmaceutical growth. Peter Thornton, Senior VP, Corporate Development and Business Operations, Elan Drug Technologies, talks about some of the trends impacting drug delivery.

by genuinely improving safety or efficacy or by bringing pharmacoeconomic improvement. If there is a real benefit then payers will look upon the drug favorably.

OUTSOURCING OF DELIVERY

What role do companies such as yours play in this market?

THORNTON: The drug delivery space is growing faster than the overall pharma market. There is a dynamic shift happening in this space similar to what is happening in the CRO segment. Just 15 years ago, the CRO segment was small, but over time that segment has grown dramatically as pharma focused on what it was good at and outsourced clinical development activities to CROs.

The drug delivery sector is beginning to experience that same dynamic. As pharma companies continue to look at their underlying core competitive advantages, they will look at formulation devel-

ABOUT DRUG DELIVERY

- The global top 10 drug delivery technologies market is expected to grow from \$43.8 billion in 2009 to \$81.5 billion in 2015. at an estimated CAGR of 11% from 2010 to 2015.
- The time-release technologies market commands the largest share around 19% of the overall top 10 drug delivery technologies market, owing to immense popularity of once-daily
- Expansion of the applications of non conventional modes of drug delivery such as pulmonary, nasal and transdermal in disease conditions other than respiratory and skin, especially in chronic disease conditions such as diabetes, CNS are also boosting the market

Source: MarketandMarkets

CAREER Highlights

Peter Thornton is Senior VP, Corporate Development and Business Operations, Elan Drug Technologies. He joined Elan in July 2007. He was formerly President and Chief Operating Officer of Circ Pharma Ltd., a specialty pharmaceutical product development company, from 2006 to 2007; Senior VP and Chief Financial Officer of Antigenics, a NASDAQ biotechnology company, from 2004 to 2006; as well as Senior VP of Business Operations at Elan from 1994 to 2004.

opment. The formulation piece is something that can be outsourced to technology providers and service providers that have a depth of experience and expertise.

NEWER DELIVERY TECHNOLOGY

What are some of the applications of Elan's newest technology?

THORNTON: Our NanoCrystal Technology involves reducing the size of drug particles. By reducing particle size, the drug's exposed surface area is increased. The result is a stable drug formulation that exhibits an increased dissolution rate.

The NanoCrystal technology is primarily for small-molecule drugs, although there is some applicability with certain biotech drugs.

There are very early-stage technologies, from a drug delivery point of view, that are using nanoparticulate approaches and nanotechnology for the delivery of large molecules. We are moving into injectable products, and at earlier stages we are focusing on targeting and other bioavailability enhancements.

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The Solubility ISSUE

THE DRUG DELIVERY MARKET

More than 25% of the marketed drugs fail to provide expected commercial returns because of drug distribution and absorption levels within the body (pharmacokinetics) therefore signifying the importance of drug delivery systems, according to a recent report from MarketandMarkets on the Top 10 Drug Delivery Technologies.

Rapid enhancements in drug discovery technologies have led to developments in proteomics and genomics and a great impact on drug delivery technology market.

The changing market trends, with quick cycle of innovations have compelled market participants to clearly understand changing dynamics and focus on emerging technology and enhance market positions in terms of revenue, growth, and geographical presence.

The increasing demand for effective delivery of novel biopharmaceuticals is driving the growth of the global top 10 drug delivery technologies market. Patent expirations of drugs, need for faster drug development, and greater drug approvals are further fuelling market growth.

The global top 10 drug delivery technologies market is expected to grow from \$43.8 billion in 2009 to \$81.5 billion in 2015, at an estimated CAGR of 11% from 2010 to 2015. The time-release technologies market commands the largest share around 19% of the overall top 10 drug delivery technologies market, owing to immense popularity of once-daily formulations.

Drug delivery technologies are revenue boosters for the pharmaceutical industry as they enhance drug lifecycles in the market by extending patent rights, adding a competitive edge to the drug by enhancing their safety and efficacy. Further, expansion of the applications of non conventional modes of drug delivery, such as pulmonary, nasal, and transdermal in disease conditions other than respiratory and skin, especially in chronic disease conditions, such as diabetes and CNS are also boosting the market. In addition, innovations, such as microneedle transdermal patches and novel intelligent inhalers, are also adding to the market growth.

Source: MarketandMarkets.

For more information, visit marketsandmarkets.com.

It is estimated that between 40% and 50% of compounds in development suffer from poor solubility, making them difficult to develop and resulting in a significant number of potentially beneficial compounds being discarded in development each year.

One company working to address this issue is Elan Drug Technologies. The company's NanoCrystal Technology involves reducing the size of drug particles, typically to less than 2,000 nanometres. By reducing particle size, the drug's exposed surface area is increased. The nanoparticles are then stabilized to maintain their reduced particle size. The result is a stable drug formulation that exhibits an increased dissolution rate.

Peter Thornton, senior VP, corporate development and business operations, Elan Drug Technologies, says the NanoCrystal technology is primarily for small-molecule drugs, not biotech drugs, although there is some applicability with certain biotech drugs.

"There are very early-stage technologies, from a drug delivery point of view, that are using nanoparticulate approaches and nanotechnology to the delivery of large molecules," he says. "We are moving into injectable products and at earlier stages we are focusing on targeting and other bioavailability enhancements."

The nanotechnology drug delivery market is expected to grow at a CAGR of 21.7% for the period 2009 to 2014, reaching almost \$16 billion by 2014, according to Business Insights.

EDT's commercialized products using the NanoCrystal technology include:

Rapamune. An immunosuppressant, Wyeth's (now Pfizer) Rapamune received marketing approval from the FDA in 2000. Rapamune was previously available only as an oral solution in bottles or sachets. The oral solution requires refrigeration storage, and must be mixed with water or

orange juice before administration. The new tablet developed using NanoCrystal technology provides patients with more convenient administration and storage than Rapamune oral solution. The development of a NanoCrystal formulation of sirolimus enabled the preparation of a solid dose form.

Emend. The product was approved by the FDA in March 2003 and was launched by Merck in April 2003. Emend is a capsule containing 80 mg or 125 mg of aprepitant formulated as NanoCrystal drug particles. While Rapamune was an improved formulation of an already marketed drug, Emend was developed as an NCE in a NanoCrystal formulation.

TriCor 145. The product was launched in December 2004 by Abbott in the United States following FDA approval. The new formulation of TriCor incorporating NanoCrystal technology provides the benefits of a lower dose, simplified, flexible dosing regime and allows for administration with or without food. The old formulation had to be taken with food.

Megace ES. The product was approved in July 2005 by the FDA. Megace ES uses NanoCrystal technology to improve the rate of dissolution, increase the rate of absorption and improve on the bioavailability of the original Megace Oral Suspension.

Invega Sustenna. The product was approved by the FDA in July 2009 and is marketed by Janssen in the United States. This new once-monthly extended-release injectable formulation incorporates the NanoCrystal technology. Major benefits include, monthly dosing using a small bore needle with small volume needle, negating the need for a power injector, which can all help to improve compliance for schizophrenic patients. This is the first injectable product launched using the NanoCrystal technology. ◆



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