

Trends 2010

Medtech Industry Continues Strong Growth

The pharmaceutical and medical device industries are projected to grow 6.1 and 8.9 percent respectively. Growth remains strong because of demographic trends and in spite of expected declines in the number of new product FDA approvals, pharmaceuticals losing patent protection, and the recession-driven decrease in hospital budgets and elective surgeries. Since individual sectors are, more or less, affected by buying patterns and other market dynamics specific to each sector, it will be crucial to obtain a timely, critical understanding of the markets you will be doing business in before you launch products.

Mature Companies Will Thrive

Venture capitalists have shown declining interest in younger companies the last few years. Mature, innovative companies that capitalize on the situation and use their foresight and flexibility will thrive in the next two years. The reasons are tied to the following factors.

- Perceived market and regulatory risks are high, and uncertainty in reimbursements and the impact of US healthcare reform are both more significant risks for earlier stage companies. More experienced companies will have the motivation and opportunity to deal with the risks and position themselves for the future. Their management teams will be most attractive to Wall Street and to corporate partners needing deals to stay afloat and get their products on the market.
- Potential exit/liquidity has been limited by the absence of the IPO market and dramatic downturn in M&A activity this past year. In a market with poor liquidity and IPO possibilities, companies with relatively secure market shares will be prime investor targets.

Weaker Dollar Presents Opportunity in US

Massive US government spending and low US interest rates will continue to depress the dollar in 2010, compared to other currencies. History shows the dollar has been very cyclical in comparison to the Euro, and a reversal of US dollar weakness is only a matter of time. Because we will be at the bottom of the cycle in 2010, this represents a good time for European companies to enter the US market. They will be spending market development dollars when the Euro is strong, and reaping the rewards in a few years when the dollar is stronger.

New Medical Device Directives Helps EU Companies Enter the US Market

The Medical Device Directive goes into effect in March of 2010 and will have an impact on both European and US firms. To comply, European companies will have to follow more stringent and well-defined standards. For example, some devices previously classified as "lower risk" will be reclassified as higher risk Class III devices. Devices may also be subject to post-market surveillance, and software validation will be required in more devices. The most significant change is that some level of clinical evaluation will be required for all devices. While companies might have to work harder to get their products approved for the European market, they will often be better prepared for submission to the FDA, thus easing the cost and time of US market entry.

US Healthcare Reform Expands Insurance Coverage and Increases Size of Overall Market

Companies will use 2010 to prepare for changes that will be coming because of US Health Care Reform. These laws will mainly change the way insurance is purchased in the United States. They will do very little to change the cost, delivery, or overall healthcare. The actual impact will be a significant increase in insured individuals — up to 30 million more patients. This means an even larger market for medical device and pharmaceutical companies. And, because insurers will not be allowed to discriminate against unhealthy individuals, there will be a greater emphasis on preventing disease, thus creating markets for cost-effective preventive products and services.

Regenerative Medicine Market Excitement

Tissue regeneration products rank at or near the top in terms of growth potential. The most significant opportunities for the next couple of years will likely be in orthopedics and spinal devices. Numerous biomaterials that promote growth in bone and soft tissue have debuted in the last year and more are expected. Perhaps the biggest opportunity is in cartilage repair where no single product has proven to be very effective, and a huge unmet need exists. We agree with Robin Young's comments in the June 23, 2009, issue of *Orthopedics This Week* that adult stem cells will play an increasing role in various tissue regenerative modalities.

New Biosimilars Approval Pathway Creates Opportunity

A few years ago, large international pharmaceutical companies began developing and marketing lower-cost versions of their rivals' biological medicines (biosimilars) to compete as soon as patents expire. In 2010, we will see White House signature of the new product approval pathway for these products. Both the Senate and House versions of the bill provide for 11-year exclusivity, which will help ensure good returns on research investments. This will help decrease development risks, spur more product development and increase investor interest.

US Economic Slowdown Offers Opportunity

The great recession of 2009 may have hit bottom, but a slow recovery will continue throughout most of 2010. Many companies have cut back on their advertising, promotion and product development. The good news is that for companies with the resources and courage to invest in new products and marketing programs, 2010 will offer an excellent opportunity to gain share from more cautious and less well-financed competitors.

Tougher FDA Enforcement will Help Innovative Products

FDA has new staff in key positions and has vowed to move away from yesterday's hands-off policies, particularly as they apply to product recalls and suspected adverse effects. Companies will need to update monitoring programs and re-evaluate their filing strategies especially for products being reviewed under the 510(K) process. This presents an excellent opportunity for companies whose products have strong clinical (and cost) data. These products will move through with minimal delays. Those that are "me too," with weak data, can expect delays.

International Policies Drive Adoption of More Electronic Data Management

The recent health care debate has focused increased attention on the chaotic state of US medical records and is driving efforts to reduce administrative costs and errors. Hospital IT systems, as well as private medical offices, will be moving even faster toward Electronic Medical Records (EMR), funded in part by \$2B in grants from the Obama administration. FDA will also push the effort, requiring manufacturers to file adverse event reports by EMR. Meanwhile, more countries (such as Germany) will explore digital signatures and uniform insurance cards to better synchronize patient information.

Comparative Trials will be Required

Both FDA and the Office of Management and Budget (OMB) are pushing for more comparative trials to improve safety and reduce costs. Efforts to test Class III devices and drugs against the current "standards of care" will start in 2010 and the final US health care reform bill will establish either a private or governmental institute to enforce and oversee these efforts. Companies that are planning clinical trials for the next year can get an advantage over their competition by considering the implications of these new requirements.

To our Subscribers: If you want to generate more sales by launching your product on the other side of the Atlantic, please contact Robert Keefer or Reinhard Merz for a free consultation and to see if we might be of assistance. In today's fast-pitched world and pinched economy, every new market can bring tangible value to you. We can help you think through your options, and we would enjoy working with you. Our phone number in NC is 919-941-0700, and in Germany it is +49 6221-27262.

Upcoming Events:

"Doing Business in the US"

Four (4) Experts will be presenting valuable information and insights you can use regarding FDA approvals, US Market Assessments and Strategic Planning, Health Care Reform & Reimbursement, and US Partnering and Cultural Issues.

Cambridge, UK, February 3, 2010
Frankfurt, Germany, February 5, 2010

Click here for workshop details and to [register online](#). Enter promotional code 6295.

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