

TCG's Forecast for 2011 and Beyond

TCG's goal is to create measurable value for the companies we work with. With that in mind, we will take this opportunity to focus on the trends that will affect you and your business in 2011-2012. As we do that, one overall theme we are compelled to note is an even sharper focus on de-risking the business enterprise. In fact, one could argue that this attitude represents a shift in thinking that will persevere for some time to come, given the uncertainty that remains in the global economy, and with health care and regu-

latory reforms. In today's changing global medical market, the key questions have become "what's the opportunity?", and "how can we reduce our risk as we increase the value of our assets and grow our revenues and profits?" As opposed to the past decade, when companies in our industry literally expected that customers would adopt virtually all new products, if enough money was thrown into marketing, the reality now is very different. For proof, we only need to look at the data:

Currency fluctuations

Currency fluctuations for the dollar and Euro are affecting the debt status of nations. As a result medical companies view multiple revenue sources from international markets as a proven way of de-risking the business. Even small to medium size companies in Europe are looking to US revenue sources, and vice versa.



Government issues

Government budget reductions in Europe and the US are favoring cost effective innovation and new products that offset medical care costs. Before product development is complete, smart companies know which innovations will help them meet these goals, and then complete the product, marketing, and financing plans.



Good economic policies

Good economic policies implemented by the more stable European countries are driving expansion into overseas markets. As an example, Germany's medtech exports grew by 5.5% last year and now represent 40% of total turnover. To de-risk their business, German manufacturers are developing US markets by picking and choosing selected customers and markets that generate attractive profits in the fastest way possible.



Virtual teams

Emerging firms, including US startup subsidiaries of established European companies, have increasingly moved to the virtual model to be more flexible and less capital intensive while launching products. While technical expertise is still a core competency, these virtual teams often include customer focused market and product development experts charged with ensuring the products will meet the market's true needs before major marketing dollars are committed.



Operations efficiency

To increase flexibility and operations efficiency, medical firms are down-sizing and outsourcing manufacturing, R&D, and sales forces. In this environment, companies are doing more partnering deals and acquisitions of advanced and more proven products.

New EU Directive

The EU Medical Device Directive is increasing global harmonization and reducing regulatory risk even though it will increase the cost of regulatory approval for certain products. US companies launching first in Europe will increase in number, but the more informed executives have learned that Europe is not a unified market because of different reimbursement schemes in each country. They develop very specific, yet fully comprehensive European launch plans.

The bottom line is that companies of all sizes are learning how to de-risk their business because of the world's economic conditions and because customers, patients, regulatory agencies and payors are demanding it. Companies can't assume that just because they have regulatory approval, and money for marketing, or have signed up a

Venture capital

Venture capital remains scarce and the firms still investing are interested primarily in reducing risk, while the number of IPO's remains relatively low as well. This means that investors will be primarily focused on exits via acquisition, but this option won't exist unless the products or technologies are targeting a true, proven, customer need.



510k changes

FDA changes in the 510K approval process, along with proposed user fees, are galvanizing increased interest in launching first in Europe. This is also driving small to medium European medical companies to develop more thoughtful US market entry plans and commercial strategies. No longer do they view signing up with a distributor as some sort of guarantee of success.

distributor in a new market they will be successful. Innovative companies have found that it is possible to increase both focus and flexibility – two key risk reducers – by leveraging outside experts to help commercialize their truly innovative products with proven cost effective marketing and sales plans.

Your TCG Expert Team

TCG partners are all experienced former senior operating executives. We work closely with CEOs and other business leaders to develop effective commercialization strategies for their new and innovative medical products. Our specialty is in helping firms develop their US and European markets and business for the medical device, pharmaceutical, diagnostics, and biotechnology industries. We deliver results that translate into measureable value for your business.

Our approach is much more than advisory. We apply our substantial industry experience and “lessons learned” to deliver keen insights that help our clients avoid many of the traditional missteps others make when developing new markets. You won’t waste time educating us. The hallmarks of our style and approach are collaboration and high frequency of communication. Above all, there are no “cookie cutter” approaches. Each new project is a unique collaboration bound together by our clients specific needs, capabilities, and culture.



Dennis Burns

Mr. Burns has 25 years of management, market development, R&D and licensing experience in large and small firms including three divisions of Johnson & Johnson.



Kenneth West

Mr. West’s background includes 25 years of business development experience in medical devices, specialty materials, veterinary, and information technology.



Robert Keefer

Dr. Keefer has 20 plus years experience in business, finance, and marketing in a number of emerging biotech, diagnostic and pharmaceutical companies.



James Woodward

Mr. Woodward has spent over 25 years in medical device, diagnostic, and healthcare service companies with strong experience in financial direction and management.



Ray Swanson

Mr. Swanson has more than 20 years of senior commercial operations leadership experience in the US and abroad for medical technology and diagnostics.



Reinhard Merz

Based in our European office in Heidelberg, Germany, Dr. Merz has twenty years of experience in medical research, health-care marketing and e-business.

We help you survive and thrive in the new medical market. Call or contact us.
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