



# WHITE PAPER



## The benefits of partnering

Don't go alone! Partnering in the US can expand revenues and reduce risks for EU companies

Long ago, biotechnology companies learned the value of partnering or creating alliances with pharmaceutical companies to help them bring their products to market faster-better-cheaper. They learned to take advantage of each other's strengths to fill gaps in their own businesses. Biotech companies provided therapeutic product innovation, and global pharmaceutical companies brought the commercialization expertise and sales reach. Plus, the large firms brought the needed cash for development and manufacturing scale-up.

It's about time that medical device companies saw that partnering makes just as much sense for them, particularly if they want to expand their geographic multi-market reach. The types of partnerships may be different, but they are driven by the same needs: capital conservation and maximizing commercial potential faster. It takes some creativity, but finding new and better ways to speed up or maximize the commercialization potential for medical device companies can be even easier than in the pharmaceutical industry. For reasons we will get into later, medical device companies arguably have to be even faster on their feet than biotechs. Thus, they are often some of the most innovative companies in the life sciences field. Creative deal-making should be just a natural extension of their talents!

We do not want to suggest that there isn't any partnering going on in the medical device industry. In fact, about 50 alliances were reported in "MedTech Insights" and "InVivo" over the last quarter alone. The deals are obviously being done, but what is driving the need to do even more of them?

### **Global economic challenge**

During the economic downturn, raising capital is much more difficult and company budgets have decreased. Most multi-national companies have cut their R&D budgets but still need

new products for their pipelines. Their need for more deals to access cutting edge products generates great opportunities for smaller medical device firms in the US and Europe. At the same time, many small and intermediate sized (development stage) companies (SMEs) can actualize significant benefits by capitalizing on the marketing presence and commercialization expertise that the big, global medical device or diagnostic companies can offer.

### **Slow, uncertain product approvals**

In the United States, the 510(k) approval process for medical devices has slowed because of several factors, including increased demand for ensuring product safety and increased numbers of applications. The same seems to be happening in the European Union and of course, demand for more cost/benefit data has gone up on both sides of the Atlantic. So here you are, a small company with a new innovative medical device, trying to get your product rapidly approved and into the major markets. Your first approval doesn't happen as quickly as you planned; and while you wait for the bureaucracy to act, you're burning critical cash. The perfect reason to explore partnering with an established company that already has regulatory expertise, approved manufacturing sites and sales clout in many markets. Of course, seeking out partners and closing the best deals requires some time to maximize your product valuations, but you can do that while waiting on the MDDD or FDA.

### **Effectiveness research and reimbursement**

It's a crowded marketplace and getting more crowded as governments and insurance firms look for more cost effective medical solutions. Many new products are updated technolo-



**Interactions in the medical device industry become more and more complex. Big companies are motivated to partner if you've got an enabling technology.**

gies with only incremental improvements so health care providers (and their payors) question the need for yet another product with small incremental benefits. You need to give them the answer in the data that show that your product innovation is more effective, safer and/or more economical than currently marketed products. As such, there is the driving need for comparative cost effectiveness research as well as the necessary filings to obtain the product use/reimbursement codes that support higher prices for your better device. In fact, US providers are demanding it as are many EU health budget authorities. An alliance with a larger company that has the research expertise for broader comparative testing as well as a full time reimbursement/insurance approval department could be the smartest approach.

### **Shorter lifecycle for medical devices**

Historically medical devices have much shorter product life spans than pharmaceuticals. The life of a pharmaceutical usually extends as long as the original patent plus extensions, while medical devices life span in the market can be only five to six years. One way to extend that life is by incorporating new technology into a current "old" product. For

example, just look at what the various new materials have done to the orthopedic surgical market. Can your product/technology help extend the life of another company's product or provide an additional indication? Big companies are motivated to partner if you have an enabling technology that can be "bolted on" to an existing product to extend its market reach or a different product that their sales team to add to their line.

In addition, the demand for better therapeutics and more "personalized" medicines are driving a large increase in medical device-pharmaceutical partnerships in this challenging economic environment (who would have predicted Medtronic to be working with drug companies?).

Finally, let's discuss the general types of partnerships or alliances that can be beneficial to medical device companies:

#### **Joint development and commercialization:**

This could be a long term partnership covering everything from early research and clinical trials to regulatory/insurance approval to market introduction; or it could just be an R&D partnership or commercialization partnership in defined territories with a well defined royalty arrangement.

#### **Sales and distribution by territory:**

In most cases, the smartest way to break into the US (and European) markets is to select the best companies to plug into their existing distribution network. There are many experienced distributors/manufacturers covering all healthcare specialties and various regions of Europe and the United States. Partnering with an established firm is a good, economical way to get your product introduced by experienced sales reps and quickly extend your market reach with minimal cash outlay. Plus they have the clinical and institutional contacts to provide immediate feedback on your new product in terms of its acceptance

and reimbursement in a market so you can make adjustments before you launch.

**Large versus small firms:** Sometimes it is to your advantage to do a distribution deal with a large international medical device company to have complete clinical, regulatory and commercialization needs handled. At other times it is best to use a smaller firm or strong networks of distributors that focus on smaller markets and “niche” products with you retaining the regulatory registrations and marketing control. The choice depends on what you (or your market experts) learn during the extensive due diligence and market assessment that you should be doing before making any partnering decisions. For example, a TCG client that had bone regeneration products used distributors for its less complicated, better known products but chose a strategic partner deal for a newer, more complicated product that needed extensive marketing and sales education..

**Licensing versus foreign subsidiary:** If you intend to introduce your product outside of your home country, a local partner can be very beneficial before and after product introduction. The in-country partner knows the marketplace and the approval process and can manage inventory and oversee sales reps. Or if you have the resources and want more control, then set up a subsidiary but still get local expertise to do it correctly. For example TEM international of Germany wanted to launch its ROTEM hemostasis analyzer into major surgery hospitals in the United States. TCG helped them form a subsidiary, Rotem Inc., and then, operated and developed their US business, including sales/marketing, cu-

stomer service, inventory and sales fulfillment for four years.

### How to find good medical device Partners

Fortunately there are many ways to explore the potential of partnering at one of the excellent conferences designed for that purpose at various locations around the world. Examples include EuroMedtech in May, AdvaMed in September, BIO Europe in November and of course, Medica each fall, the largest medical device trade show. The first three meetings focus on helping you to meet dozens of potential partners face to face via confidential 30 minute meetings that are arranged in advance on line. TCG has participated in these conferences and met dozens of companies through them as have the larger medical device firms who often send business development representatives. If you cannot go to the US for AdvaMed or to Europe for EMT, experienced partnering experts like TCG can present your product and explore partnering opportunities without revealing your company name. But most importantly, you need to start now to develop a partnering plan for major geographical territories (United States, European Union, etc.), so your company can monetize your innovations before the competition beats you in those territories.

There has never been a better time to expand your sales particularly if you have a better cost effective product. Starting with a good market assessment and then selecting the most appropriate partner with the best characteristics in the new market are key to your success.

This white paper is published by TCG LLC, Durham, NC.

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