

Advice to Medical Device Companies: Don't Go It Alone

Take a lesson from biotech and pharmaceutical companies on the benefits of partnering

By Dr. Robert C. Keefer

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 product innovation, and pharmaceutical companies brought the commercialization expertise and sales reach. Plus, the large firms brought needed cash!

It's about time medical device companies saw that partnering makes just as much sense for them, too. The types of partnerships may be different, but they are driven by the same needs: capital conservation and maximizing the commercial potential. 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 I will get into later, medical device companies arguably have to be even faster on their feet. 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!

I don't 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?

1. **Global economic crisis:** During this economic crisis, the cost of capital has increased and company budgets have decreased. Most big companies slashed 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. At the same time, many small and intermediate sized companies and development stage companies can actualize significant benefits by capitalizing on the marketing presence and commercialization expertise that the big global companies can offer.
2. **Slow, uncertain product approvals:** In the United States, the 510(k) approval process for medical devices has slowed down because of several factors, including increased demand for ensuring product safety. The same seems to be happening in the European Union. So here you are, a small company with a new innovative medical device, thinking you are going to get your product rapidly approved and to market. It doesn't happen; and while you wait for the bureaucracy to act, you're burning critical cash - another excellent reason to partner with a company that has regulatory expertise, approved manufacturing sites and marketplace clout. Of course, seeking out partners and closing deals requires good timing to maximize your valuations, but you can do that!

3. **Pressure for comparative effectiveness research:** It's a crowded marketplace — getting more crowded. Many new products are old technology with only incremental improvements. Insurance companies and providers question the need for yet another product with incremental benefits. You need to give them the answer, and the answer is in the data that show that your innovation is more effective, safer or more economical than the current product. This is driving the need for comparative cost effectiveness research to justify a new medical device. In fact, it is becoming apparent that U.S. health care reform will mandate it! An alliance with a company with the research expertise and the budget for broader testing might be the answer.
4. **Shorter lifecycle for medical devices:** Historically medical devices have shorter product life spans than pharmaceuticals. The life of a pharmaceutical usually extends as long as the patent, while medical devices are being created so fast that the life span 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 drug eluting approaches have done to the cardiac stent 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've got an enabling technology that can be bolted on to an existing product to extend its life cycle or market reach.

Those are the hot-button issues today that have compelled medical device companies to partner in this challenging economic environment. Now let's turn our attention to the general types of partnerships or alliances that can be beneficial to medical device companies:

1. **Joint development and commercialization:** This could be a soup-to-nuts partnership covering everything from research and clinical trials through to market introduction or just an R&D partnership or commercialization partnership in defined territories.
2. **Sales and distribution:** In most cases, the smartest way to break into the U.S. (and European) markets is to plug into a company's existing distribution network. There are hundreds of experienced distributors (who may also be manufacturers in their own right) covering all healthcare specialties and various regions of the United States. Partnering with a distributor is a good, economical way to get your product introduced by experienced sales reps and extend your market reach. But it's really important that you don't assume a distributor has the marketing expertise, product knowledge and budget to launch an advanced technology-based product. In many cases, especially with advanced technology products, it is wise to retain the marketing responsibility. Further, sometimes it is to your advantage to do a distribution deal with a large medical device company, and other times it is best to use strong networks of smaller distributors that focus on smaller markets and niche products. It all depends on what you (or your market experts) learn in the extensive due diligence you should be doing before making any decisions.
3. **Component or end-product manufacturing:** Medical device components made of biomaterial must be manufactured in accordance with the FDA's GMP (Good Manufacturing Practices) or, in Europe, ISO standards. Both of these manufacturing protocols require expertise and are expensive. It can be more cost-effective, and faster to market, to employ a licensed contract manufacturer.
4. **Foreign subsidiaries:** If you intend to introduce your product outside of your homeland, an in-country 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. Rotem AG, for example, partnered with TCG to introduce its products to the United States. TCG formed a subsidiary, Rotem Inc., and set up the U.S. operation, including sales/marketing, customer service, inventory and sales fulfillment.

A good place to start to explore the idea of partnering is at one of the excellent conferences designed for that purpose. These 2010 meetings also allow you to meet dozens of potential partners face to face:

- **EuroMedtech** (www.ebdgroup.com/emt): "Europe's leading international medical technology partnering conference, connects smaller medtech firms with large company decision makers and investors through an online networking platform." June 1-2 in Leipzig, Germany.
- **ERBI Conference** (www.erbiconference.co.uk): "ERBI's Annual BioPartnering Exchange is the most successful regional biotechnology event in the UK. This gathering of leading life science opinion formers has become a major highlight in the European conference calendar." June 2-4 in Cambridge, England.
- **AdvaMed** (www.advamed2010.com): "Premier U.S. conference for networking, partnering and educating policymakers. The 2009 conference had 1,400 attendees and featured over 600 one-on-one partnering sessions." October 18-20 in Washington, D.C.
- **BioEurope, BioPharm America** and the annual **Biotechnology Industry Organization Meeting (BIO)**: While these conferences are mostly for pharmaceutical and biopharmaceutical companies, a growing fraction of participating companies are in diagnostic and other medical device segments.

TCG has participated in these conferences in the past and can act as your representative to explore partnering opportunities. 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 to the punch. And comprehensive Opportunity Assessments are critically important to identify the very best ways and means to do that. If you choose a partner that has the financial wherewithal but not the commercial reach, for example, you may not get all the benefits you need. Due diligence, as always, is the key.

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