

## Outsourcing: A Model Whose Time Has Come

In earlier days, companies often turned to outsourcing so that they could concentrate on their core competencies, cut costs and increase product speed to market. Indeed, for many companies, those reasons continue to prevail. Rather than invest in new factory space or equipment, OEMs find it more beneficial to use their people and capital resources on developing new IP.

Today's increased customer demand from an aging population and growing global markets, coupled with warp-speed innovations in technology and heightened competition, create an even greater impetus for outsourcing. Last year, Pittiglio Rabin Todd & McGrath (PRTM) Management Consultants, based in Waltham, MA, surveyed high-growth companies in cardiology, in vitro diagnostics, ortho-pedics and endoscopy. It found that those companies outsourced 10% to 60% of their cost of goods (cogs), and almost all of them expected to ratchet that up another 10 points (ie, to 20% to 70% of cogs) over the next two to three years. The companies in these segments are growing at 10% to 15% annually, compared with the 6% to 8% yearly growth experienced by companies across the whole medical device sector.

"Higher-growth companies look at outsourcing for volume flexibility and cost advantages, but they also use outsourcing to support a more strategic focus, to differentiate themselves in the market," explained John Lamb, PRTM director. "They are looking to work faster and with more partners to get more complex products and more integrated solutions that incorporate more technology. They recognize they can't be experts in all technologies, so they partner with companies that are."

However, he continued, "Both the OEMs and the contract manufacturers also know that they are not set up to do this effectively yet. It will take significant strategic alignment and operational innovation on both sides to make this work well."

Increasingly, experts say, more companies will outsource to support faster growth. Keene has noticed this developing trend among Avail's customers. "A number of our customers outsource only a small percentage of their functions, and they've gotten mandates to outsource 30% to 40% [of their activities] over the next half dozen years," Keene said. "The mandate to outsource more is coming from the CEO/CFO/COO level. They're looking at their businesses and needing to grow by at least large single-digit percentages each year to keep pace with their competitors. To get ahead of other players, they need strong double-digit growth. If you're growing 15% each year, the company will double in size in five years. Most companies don't want to build new factories or add the additional infrastructure necessary to support that growth."

It's really a return-on-investment issue, said George Blank, president of The MedTech Group, Inc. in South Plainfield, NJ. "Companies eventually realize that the assets deployed to nonessential functions would be better spent growing their IP," he explained. "They can get a much better ROI by outsourcing activities that aren't part of their core of excellence."

In addition to allowing companies to grow faster and focus resources more cost effectively and efficiently, outsourcing also provides access to best-in-class capabilities. An outsourcing firm's designers and manufacturing pros serve clients in a variety of sectors, thus expanding the number of technologies and techniques in which they have expertise. Further, they are performing their functions daily, creating systems to turn art into science, noted Keene.

Consider product launches. Keene said that the average medical device company launches one or two new products each year. Avail launches 12 to 16 for its clients; therefore, it has created very robust processes in the area.

As another example, while most companies move manufacturing plants infrequently, Avail relocated four in 2005 and had moved five more facilities between January and April 2006. "It's a scientific process for us," Keene said. "We've created systems for many functions that allow our customers to gain great value from outsourcing."

Indeed, in the evolution of outsourcing, while companies first will outsource a component or established device to save money, over time they will outsource for the value they receive in return. Perhaps outside designers can devise a slight tweak that makes a product easier to use or manufacture, or fresh outside thinking can come up with new marketing suggestions to fuel higher sales. Increasingly, outsourcing companies are looking at their menu of offerings and adding new services and capabilities to provide their customers with more value.

"We provide value by enabling our OEM customers to focus on design and manufacturing issues for their next-generation products through communication with end users. This is accomplished by our taking care of all of their manufacturing and supply chain concerns as an extension of the OEM," said Jim LaVersa, manager of business development for Harmac Medical Products, Inc. in Buffalo, NY.

B. Braun noted that one of its product lines benefits some of its customers' portfolios. "OEMs are now required by the states to have safety products in their lines," explained Joel Bartholomew, manager of

research and development for B. Braun's OEM Division. "We have a full line of safety products and can provide them to our customers, bringing value to their product lines."

### **A Maturing Menu of Options**

Just as outsourcing has matured from a cost-saving to a value-adding operation, it also has grown in other ways. For starters, the relationship between OEM and supplier has changed dramatically.

Years ago, a smaller base of people at the OEM—perhaps just purchasing and senior management—would determine which outside company got a contract. Today, a full team evaluates potential suppliers. Employees with backgrounds in engineering, manufacturing, marketing and operations have joined their purchasing and senior management colleagues in choosing which companies will help the OEM move its products to market with the highest quality, reliability and speed. Once a company is selected, the day-to-day interaction is much more intense than in the past.

"Today, outsourcing companies are considered to be OEMs' strategic manufacturing partners. It's a whole different relationship," noted Andrew Kinross, managing consultant for Navigant Consulting in Burlington, MA. "It's a much tighter relationship. There are set expectations, strong communication and idea sharing, common goals. Compare that with the component buyer of five years ago, who would simply fax in a work order every month."

Certainly, strong communication and planning are essential to a successful product development and launch, said Thomas Taylor, president of Medical Products Group for Nypro, Inc. in Clinton, MA. "OEMs and their contract manufacturers need to be extremely open with each other in regards to information, costs and program requirements," he said.

The OEM-supplier relationship also has shifted in response to OEM needs. "We're not just a vertically integrated supplier; we are committed to long-term relationships," said Jim Wagner, vice president of engineering for Harmac. He pointed out that not only does Harmac work with clients to choose materials, manufacturing processes and marketing plans, its experts also visit clinical sites to see how the product is used and its goals so that they can make the final product most beneficial for the end user.

The relationship extends further. "We've met with our customers' end users as part of the OEMs' customer relationship program so that we can explain the benefits of the product, how it's used, etc.," Wagner explained. "We've also seen customers wind down manufacturing sites in other parts of the world and locate them at our facility because it was a mature product line, and they wanted to focus on the clinical and marketing aspects of a new product line instead." By supporting customer needs at every stage of the product life cycle, outsourcing firms and their OEM customers can both focus on what they do best and grow.

Thomas Osypka, president and CEO of Oscor, Inc. in Palm Harbor, FL, has noticed a change in how OEMs interact with his company, too. "Over the past 10 years, the relationship has changed from being merely a supplier to a customer to being partners in product development," he said. "We're involved early in the product development cycle now to help speed the product to market—to ensure the product is designed with the optimal materials, manufacturing processes and marketing techniques in mind. Both companies gain from the success of the product, and we work together more closely than before to ensure that success."

Success also is made more likely by limiting the number of partners involved. "An OEM must be completely vertically integrated to be competitive, and if it is dealing with too many outside companies, it can lose its grip on cost and speed," Osypka explained. Therefore, OEMs' outsourcing partners have taken over supply chain management responsibilities, and in many cases, they've increased their own capabilities so that they will have more control over formerly outside functions, such as sterilization.

"It used to be very seldom that we would have the capability to do every single thing a customer wanted with a product," Keene recalled. "The customer would have to help us learn a portion of the technology. Today, after completing project after project, year after year, we have a more robust knowledge base."

Experts say OEMs understand that their outsourcing partners may not be able to supply in-house, for example, all 10 of 10 functions needed to produce a product. However, OEMs would much rather work with a company that can provide seven of those capabilities than with one that can offer only three.

"Successful companies in full service outsourcing need to be integrated suppliers with product design, mold building, injection molding, supply chain management, technology development, assembly and contract manufacturing capabilities," said Taylor.

As a result, in the quest to provide one-stop shopping, another trend is unfolding.

### **Is Consolidation Coming?**

In the evolution of any industry, a predictable pattern prevails. A new opportunity is recognized; multiple players flock into the space to meet the need; some players morph into market leaders, others carve out their spaces in niche markets and others just fade away. Some experts say that the 3,000-plus companies

currently offering medical outsourcing services today will become fewer in number in the future, even as market revenues continue to grow.

“Full service outsourcing companies are differentiating themselves based on offerings and scale,” Kinross said. “OEMs are more likely to go with a larger company [that has expertise in numerous service and technology areas], so many of the larger companies will continue to move farther ahead of the competition. The trend will be toward more consolidation. The evolution of any industry is a little Darwinian, actually. Some companies get more successful, and they acquire other successes.”

Tom Podesta, vice president of healthcare for The Tech Group in Scottsdale, AZ, noted “Most of The Tech Group’s sites and capabilities were built from the ground up and not acquired, and this makes a difference. It takes longer to build from the ground up, and if you can do that, organically and culturally your systems will be set up in concert with all the other systems and people in your company, allowing a more integrated, cohesive whole.”

Whether acquiring other companies to increase their overall market share, the capabilities they can offer to clients, their geographic footprint or for other reasons, more full service companies are expected to participate in mergers and acquisitions for the foreseeable future. Mid-size companies also may enter the fray, for as the definition of a large company becomes even larger, it creates an impetus for other firms to consider joining forces to become bigger and more competitive themselves.

### **Future Opportunities**

Of course, not every company wants to partner with a Goliath. Therefore, smaller companies with proven track records in quality, on-time delivery and competitive pricing will continue to thrive.

In fact, mid-sized companies in the OEM area represent an area of opportunity, according to Kinross. “Small OEM companies sometimes won’t go with the big companies because they’re concerned they won’t get the same level of attention as the supplier’s other, much larger customers,” he said. “But these small companies grow, and over time, they may find their small vendor can’t necessarily handle all of their needs as a mid-sized company. This creates a vacuum and an opportunity for vendors to target that segment of the market.”

Kinross noted that overseas markets represent another big growth opportunity for outsourcing firms. “Most of the new plants that are constructed won’t be built in the United States, but overseas,” he said. “The United States will remain the dominant location for manufacturing—half of all dollars spent on outsourcing are spent in the United States, after all—but other places will become more prevalent. Certainly, Mexico, China and India will see more plant construction. It remains to be seen how sophisticated these latter markets can become, but their markets are expanding rapidly.”

Design services, testing and providing supporting documentation for 510k and PMAs are currently among the most requested items from full service outsourcing firms. Assembly work also is soaring in popularity. “A big opportunity has been in assembly,” Podesta noted. “Four or five years ago, 10% of our [clients] requested assembly services, and today 60% to 80% of incoming jobs have assembly attached.” Two of the company’s 13 manufacturing sites are dedicated solely to contract assembly, and there are plans to continue expansion of those sites in early 2007.

More OEMs also are starting to express interest in outside R&D assistance, but this offering isn’t widely used yet.

Nypro’s Taylor believes full service outsourcing will be much more entrenched within the fabric of medical technology innovation in the future. Five years from now, “the majority of integrated suppliers will offer a comprehensive global footprint, differentiated technology, supply chain excellence and advanced quality systems that better integrate with large OEMs,” he predicted.

The move toward full service outsourcing is resulting in one final opportunity that benefits not only suppliers and OEMs, but patients as well: OEMs seeking their outside partners’ assistance in developing new materials and technologies to continue to push the limits of innovation.

Through its increased supply chain capabilities and additional resources of new parent company West Pharmaceutical, The Tech Group is seeing opportunities to develop custom blends of thermoplastic elastomers that are compatible with specific drugs and reagents, Podesta reported. He added, “The end result is multi-material assemblies that are designed for integrated manufacturing and, ultimately, improved quality, performance and reliability while reducing total cost.”

Certainly, as OEMs outsource more products and processes, their outside partners’ capabilities will continue to evolve and be refined. “New opportunities require us to develop new skills,” Blank concluded. “Developing trends such as product miniaturization presents both new challenges and new opportunities to develop technologies and materials that will allow great gains in patient care. It’s an exciting time to be in the industry.”