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Outsourcing/Offshoring Trends in the Orthopaedic Industry

With rapid growth of an aging population and the growing epidemic of obesity, along with technological advances, orthopaedic companies must continually develop innovative products to gain market share and ultimately, to maintain a competitive edge in this growing market. Innovation trends in hip, knee and spine implants plus increasing interest in improved devices for extremities continue to attract capital and private investors to inject more funding particularly for innovative start-up companies, in a market that has been estimated to be over \$35 billion worldwide.

Not only are orthopaedic companies undoubtedly forced more than ever before to develop innovative products to meet market demands, they must also get these products into market, quicker and at lower prices, to stay ahead of their competitors. To do so and because of potential cost benefits, orthopaedic companies have considered turning to U.S.-based outsourcing partners as well as international partnerships to find ways to exploit the efficiencies that outsourcing might offer. While this may seem like a reasonable approach to reduce costs and improve efficiency, companies need to be aware of potential risks and obstacles far in advance to avoid any costly mistakes in the future. In other words, they need to do their homework and evaluate all of the options before making any decision.

With growth in the orthopaedic industry, it's no surprise that the overall orthopaedic outsourcing market is growing as well (at an estimated average rate of 13 percent per Wachovia Capital Markets). As a rule of thumb, important factors such as high quality, reduced costs and quicker time-to-market have always been top priorities for orthopaedic OEMs in any outsourcing process. However, since the medical device industry is by nature highly regulated, manufacturers need to learn more on a

potential partner's background, as any miscalculation in the process can adversely affect the entire process. In any outsourcing model, a few key criteria should be always considered in the potential partner. Some of these criteria include regulations, accountability, cost structure and resource optimization. That said, the decision to outsource will also depend on other crucial factors beyond

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the outsourcing supplier. These key factors include but are not limited to company size, internal capabilities and most importantly the long term strategic value of the intended outsourcing Partnership. A company may strategically choose to keep outsourcing certain products in order to focus on their own core competencies. In addition, product life cycle is always a determining factor in the entire outsourcing process. For instance, a company like Smith & Nephew would rather focus on the production of its newer product in-house while outsourcing the legacy products that have been in market for a while and are at the end of product life cycle. Exhibit 1 summarizes key factors in the outsourcing decision process.

Trends in Outsourcing Companies

Along with orthopaedic industry consolidations, outsourcing companies have also consolidated over the past few years. While specialty component outsourcing suppliers are still important in certain areas of the industry, the overall trend in the outsourcing process has shifted more towards one-shop, "total solutions" approaches, wherein all outsourcing services can be accomplished under one roof. This approach not only may help with better management of the process, but also with potential quality issues such that those can be resolved more efficiently as opposed to OEMs dealing with quality issues from multiple suppliers. Today, orthopaedic companies

Exhibit 1: Key driving factors in outsourcing

<i>Cost & margin pressure</i>
<i>Focus and investment on internal core competencies</i>
<i>Acceleration of time-to-market</i>
<i>High production and volume requirements</i>
<i>Accommodation of excess demand</i>
<i>Leveraging external expertise</i>
<i>Technology advancement</i>
<i>Industry consolidation</i>

may choose to employ outsourcing partners who offer full services like design and engineering services due to higher efficiency. This is undoubtedly even more significant for start-up companies that have limited resources. Due to a high potential in the spine fusion market, today we see many small venture funded start-ups turning to outsourcing partners who have broader services in design and engineering. Many of these companies do not have any internal manufacturing capability and have no intention of putting that infrastructure in place.

Why Offshoring?

Before orthopaedic companies decide to offshore, they need to ask some basic but fundamental questions. Does Offshoring make sense to their organization, and why? Most importantly, if offshoring is perceived to save cost in labor force, they need to determine the proportion of labor costs in the entire offshoring process cost structure. They need to look at product complexity levels and determine if automation can be a viable option, or if it requires skilled labor forces.

Offshoring and near-shoring are generally appealing simply because they are intended to save costs and are perceived to improve the overall efficiency in product development. Ironically, though, many orthopaedic companies still prefer near-shore or U.S.-based outsourcing options. This may be due to reasons such as lack of required expertise in offshore destinations compared to outsourcing partners in the U.S. Another explanation could be the nature of orthopaedic products that are historically more complex, with low volume and high mix. Especially for newer generation products, relying on offshore expertise can be quite costly as may just not be there. In fact, many companies around the world choose U.S.-based outsourcing partners because the U.S. has a stronger base of technology in the orthopaedic marketplace, as well as higher orthopaedic expertise. At the end of the day, everything will ultimately depend on the categories and complexity level of orthopaedic products to be offshored and the culture and size of the orthopaedic company seeking offshoring opportunities.

Conclusion

Many factors and parameters need to be evaluated and assessed prior to offshoring. Once these steps are taken, companies also need to account for economic and political stability of offshoring destinations. Good business

standards, facilities, logistics, medical expertise and stable legal systems as well as Intellectual Property protection are all important and should be carefully examined.

Prior to formulating, and executing the offshoring strategy, though, companies need to fully understand and track the complete cost structure and market needs. They need to know that low cost labor regions in offshoring may not always be the answer. As for regional capabilities in an offshoring model, some of the key factors to be considered are:

- Local infrastructure
- Technology base
- Logistic capability
- Supply base
- Manufacturing capacity

OEMs need to tabulate all strengths and drawbacks for potential offshoring locations, and by evaluating the total cost structure, proactively predict and manage all challenging areas to ensure that a successful offshoring strategy is in place.

Analyst Marco Bafan partners with medical device companies to develop R&D solutions. His industry expertise includes both the business strategy and hands-on research of commercial biomedical and medical device industries. He can be reached at mbafan@nerac.com.

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