

CMOs need structure as well as size!

Written by John Brosky - 2017

The major orthopedic players continue to manufacture in-house at a higher rate than other industries. Because they have no robust alternative for outsourcing to companies unable to absorb the volume. In the first part of this interview Ali Madani from Avicenne Medical suggests the need for bringing structure to the CMO sector. Other key issues include:

- **The vast opportunities for growth in partnering with OEMs**
- **The prospect of greater OEM divestiture of production facilities.**



Ali Madani, Chief Executive Officer & Founder, Avicenne Consulting

The market for orthopedic implants can be seen as mature with basic products that have reached the commodity stage of competition. Yet the orthopedic industry itself is relatively young, having emerged only 20 years ago, according to Ali Madani, the founder and managing partner of Avicenne Medical.

From this point of view, he says, the constant consolidation among contract manufacturing organisations (CMOs) over 15 years can be seen as the normal and healthy development of an industry in its adolescence. And like a teenager, we can expect to see continued, even faster expansion as this vital segment of the orthopedics industry strives to realize its full potential.

Ahead of the IMPLANTS 2017 conference on June 8 in Paris, Madani focused in this interview on a study of trends in outsourcing of product manufacturing by major orthopedic companies and he shares his perspectives on how the CMO market needs to evolve, and quickly, to capture a vast opportunity.

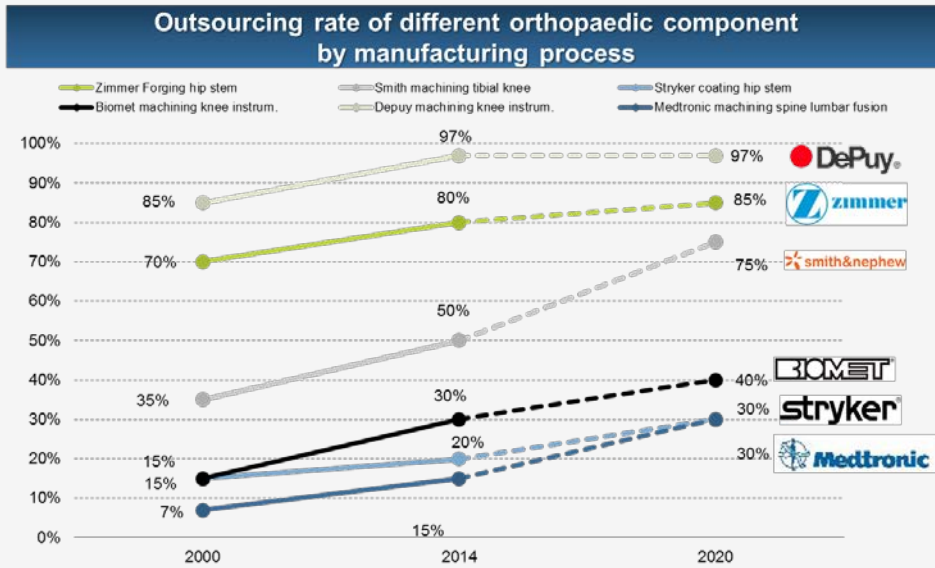
IMPLANTS: We have seen a non-stop expansion of a few major CMOs, Is there no end in sight?

Ali Madani: There has been a tremendous concentration among CMOs through acquisitions. Industry leaders like Tecomet, Orchid or Greatbatch have been built over 15 years by an aggressive acquisition of smaller contract Manufacturers. In fact, these companies are responding to a generalized and global manufacturing trend where the major OEMs [original equipment manufacturers] are pushing for more and more outsourcing of production.

IMPLANTS: Yet at the same time the major OEMs continue to expand their in-house production.

Madani: Because they have no choice! Because they do not see enough robust solutions coming from the CMOs to meet their needs. The players in the CMO space today are not structured enough to meet the real opportunity coming from the OEMs. Yes, we have seen Tecomet, Orchid or Greatbatch, now called Integer, growing year after year through acquisitions, and we can expect this trend to continue, not only for the major players but among the medium-sizes CMOs as well.

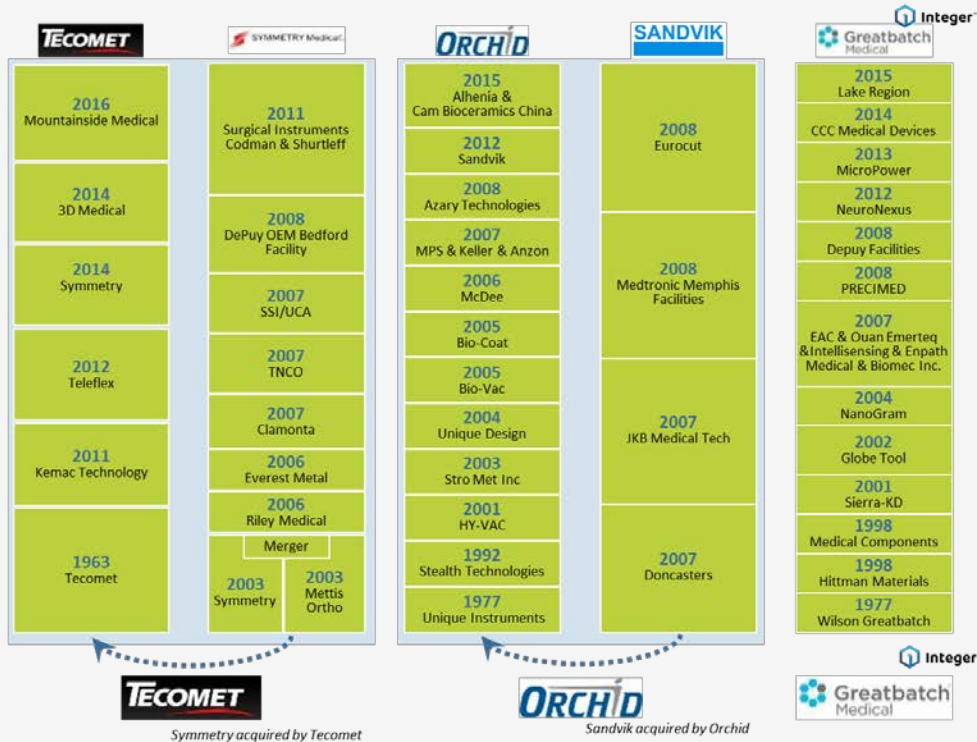
Outsourcing rate of the Major OEMs increases continuously: 2000-2020



Source: Avicenne analysis 2016

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Orthopaedic Contract Manufacturing concentration by acquisition



Source: Avicenne analysis 2016

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This should not be surprising in such a young industry. We have seen this development trend in the aerospace industry and among outsourcing companies in the automotive industry. In fact, companies like Symmetry, Tecomet and Orchid actually came from these industries! They entered the orthopedic space a little at a time as they saw the market opening and then growing rapidly, continually expanding. To that point the major orthopedic OEMs had no choice but to manufacture their products internally. Progressively they began shifting a portion of manufacturing to these external companies.

We can expect this trend to continue, even accelerate as orthopedics follows the same road as automotive and aerospace. We believe the outsourcing rate of different orthopaedic companies will increase continuously.

IMPLANTS : What do you mean when you say the CMO space today is not structured to meet the real opportunity?

Madani: Look at it from the desk at Stryker, Zimmer-Biomet, DePuy or any major OEM: They don't want to contract out their production piece-by-piece to many different manufacturers. They would prefer to have a limited number of suppliers, a one-stop shop if possible, the way it works in the automotive industry, or in the aeronautics industry. There, a major like Renault or Boeing can turn to several suppliers certified to be Tier One companies capable of handling the volume and quality. In turn these suppliers can turn to companies certified as Tier Two. This is what we can call a structured industry. And it is not what we see in the orthopedics industry. Zimmer Biomet, DePuy and Stryker do not have this kind of resources among their suppliers. It remains an unstructured sector.

IMPLANTS: And this is where we need to go in orthopedics?

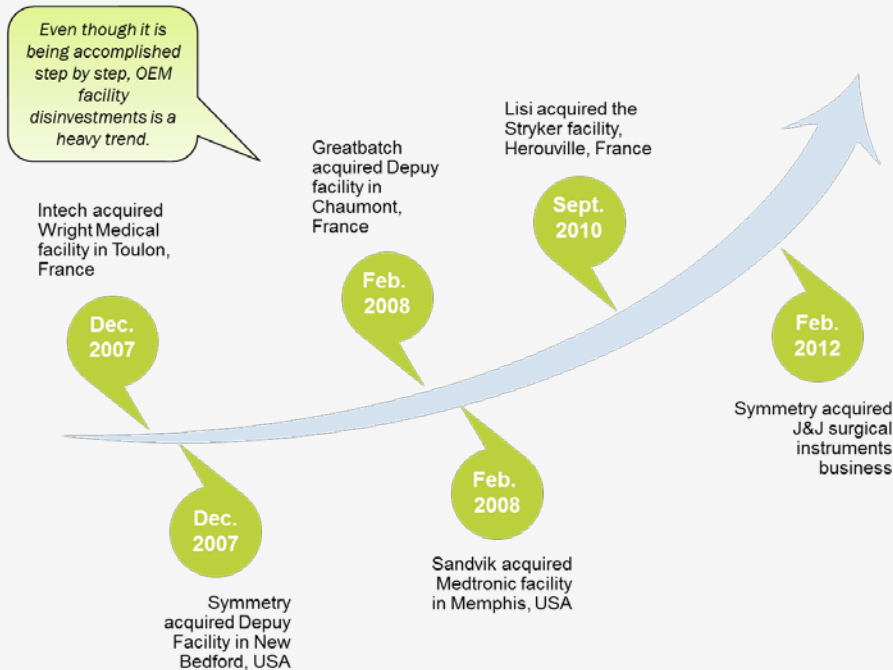
Madani: We believe this is the opportunity. We believe the acquisitions, expansion and consolidation among suppliers and CMOs will continue in the future to give birth to a new era for CMOs in orthopedics. When the CMO market becomes structured enough, it will create a vast number of new opportunities for the major OEMs. We are already hearing the first signs of this structure with CMOs being called Preferred Suppliers or Strategic Partners by the OEMs.

Manufacturing is not the core business for major OEM companies. In the long term, the OEM players would like to be focused only on the design and development of new products and then the sale and distribution of those products. But not on the manufacturing of products. This is what we see today in the automotive industry where up to 70% of production is external. This is where we should be moving in orthopedics.

IMPLANTS: How "vast" are the opportunities for CMOs?

Madani: This depends on how "organized" a CMO wants to be, its vision for playing a role in the industry. For example, it is not hard to imagine a major OEM divesting itself of certain manufacturing operations. The moment that a major manufacturer is able to divest itself of a facility, to someone capable of managing it, they will do it. We have already seen steps in this direction taken by DePuy, Stryker and Medtronic. It can become a heavy trend, especially for the segment like the casting.

Heavy trend: The OEM facility disinvestments



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There are other things that a CMO can do to be a strategic supplier. Today, the major automotive companies work with auto part makers who offer very strong R&D departments that can bring forward innovations to propose. The supplier brings new technologies, novel capabilities that can improve product design and share some regulatory and quality issues.

To reach this level of structure, CMOs need to expand, to grow. Yet restructuring the CMO sector does not always mean a company needs to be bigger. CMOs can also expand their offering to OEMs by acquiring and enhancing their skills and expertise. The best example would be in partnering on the regulatory burden, to be able to say to major clients that they can also take a share of the regulatory issues, demonstrate to major customers that they can handle these matters. There is also the potential for CMOs to share a portion of product risk with OEM customers.

In other words, to be a strategic partner, the CMO needs to help bring a product to market, to participate in the project, to even completely manage aspects of the project.

Constant growth in tough market conditions through 2020

The good-old-days of the double digits growth are behind us as the major players shift their focus to younger product segments and emerging markets. Meanwhile nimble challengers are chewing into market share with

innovative technologies. Can CMOs keep up with the changes? In the second part of this interview, Ali Madani from Avicenne Medical shares insights from recent completed studies.

- **What is the real potential in emerging markets?**
- **What role will niche products play in the next five years?**
- **What is the impact of regulatory changes?**

For CMOs, the best is yet to come

You might want to catch your breath. While it's true that expansion of contract manufacturing organisations (CMOs) in the orthopedic industry has been breath-taking with new acquisitions, the trend is not going to stop anytime soon. And according to Ali Madani, founder and managing partner of Avicenne Medical, the biggest and the best is yet to come.

Ahead of the IMPLANTS 2017 conference on June 8 in Paris, Madani shared insights from his study of trends product manufacturing by major orthopedic companies and how he believes the CMO market can further expand and evolve.

In the **first part of the interview**, Madani described the need for greater structure in the CMO sector, and detailed the opportunities to be realized. In this second part of the interview he sharpens the focus with a comparison of the trends driving expansion for OEMs and the factors shaping growth among CMOs.

IMPLANTS: Why are you convinced we will see further expansion of major CMOs?

Ali Madani: Purely in terms of size we can see even the largest CMOs today are too small for the opportunities tomorrow. Today we are looking at a sector where the largest supplier generates some \$500 million per year, compared to a major OEM with sales of \$10 billion that spends something on the order of \$2 billion to produce its products. Our studies at Avicenne show the average among the top 15 CMOs is \$142 million in annual revenue. Right off we can see why the major OEMs do not have any alternative but to manufacture their products themselves. There is simply not an alternative solution available! Even the biggest CMOs are not capable of providing a full offer to the majors. These companies are too small to absorb the volume of production from the majors.

When an orthopedics company with \$10 billion in sales is working with a subcontractor that generates just \$10 million in sales, we can safely say there is not a sufficient structure with levels of sophistication as we see in the automotive or aeronautics industries. There is room to grow.

IMPLANTS: How would you summarize the market drivers affecting CMOs?

Madani: Clearly the heavy trend will be for more outsourcing from all OEMs. Yet the OEMs would like to externalize more than products, and we can expect to see a divestiture of implant manufacturing facilities to those CMOs capable of handling the responsibilities. Finally, the headline trend for CMOs would be opportunities in the growth of the market share for challengers to the major OEMs. These nimble competitors tend to outsource as much

as 80% of their production, a high outsourcing rate comparable to what we see in other industries. As a result, the growth of challengers will also grow the business for CMOs.

IMPLANTS: How does this compare with the market dynamics in the OEM market?

Madani: First I would set a context by saying that over the past decade or more the OEMs have benefited from population growth globally, and the aging of that population as with age the need for orthopaedic product increases. Obesity in the developed countries has also increased the need for implants. Meanwhile the OEMs have been able to diversify their product mix, introducing new products with higher prices and higher margins.

Still, we believe the double digits growth in developing countries over the past 15 years is behind us and we are expecting 4.4% growth through 2020. Looking ahead to those next five years, the major players are already looking for the growth relays such emerging countries, and we can expect this to continue, even intensify.

For example, in our study we show that the hip implants ratio, meaning the number of implants utilized per 10,000 inhabitants, tends towards asymptote in the developed countries, such as the USA, Europe, or Australia. Where that value is 20, we see in the emergent countries that hip implant ratio has only reached 1 or 2! This prefigures a huge growth opportunity for the next decade. For example, China's growth in hip and knee for 2015-2020 is forecast at more than 20% per year!

Yet through 2020 we expect this geographic shift will be the only market driver based on macro population factors. Instead, we believe the market will be driven by new product opportunities. Established products like hip and knee have become mature products and the OEM players, are looking to younger product segments where the potential for growth is faster.

- Orthobiologics growth in developed countries
- Extremities to become a multi-billion market with double-digit growth
- Trauma with historically constant growth
- Niche segments with high growth, such as vertebral disks, etc.

IMPLANTS: It sounds like happy days are here again. Are all the arrows on your chart moving upwards?

Madani: In macro terms, there will be a steady growth globally in the number of implants sold. But that does not translate to revenue growth. Healthcare systems are being squeezed on costs everywhere, which places a powerful price pressure at the end-user market level. This has been amplified by the the rise in certain countries of group purchasing, collective negotiations for products that exercises an increasingly powerful influence on the market. This will continue.

Meanwhile the margins for all companies have been hit hard by increasingly heavy regulatory requirements. To the point that some companies employ more people in regulatory affairs than in research and development! This onerous trend will only continue. The **new legislation coming into force in Europe**, for example, is especially tough on implants.

Finally, there is always the risk of an economic downturn, such as a recession.

IMPLANTS: How does price pressure play out across the industry? Does it hit everyone equally?

Madani: Pricing changes tend to hit the OEM companies hardest, while the impact is felt less directly at the CMO level. The major manufacturers often grant multi-annual contracts wherein they negotiate a “normal & slight” price decrease over several years. As for the OEM challengers, we do not see a significant price decrease for these companies, due to the nature of their products and offering.

IMPLANTS: You mentioned the risk of an economic downturn. How would that play out?

Madani: We have been through recessions in both 2008 and again in 2012. In these periods instruments along with the cases and trays that are linked with them, saw a slight decrease. New instrument projects were postponed by the OEMs. But very quickly, after one year, the instruments along with cases and trays, increased in terms of value and rapidly recovered the loss of growth.

We also note that even in these periods of recession, implants manufacturing, whether at a CMO or internally at OEMs, continued to grow, though at a lower rate of growth than during “normal” periods.

About AVICENNE Medical

Since 1990, AVICENNE Medical team members have been working within the medical device industry for strategic and operational studies. They have advised major players in this industry on development strategy and implementation, technical and economic appraisals as well as mergers and acquisitions. AVICENNE has also advised multiple Private Equity firms on acquisitions (US\$ 50M+ value) and build-up. Additionally, Avicenne have worked as advisors for small & medium-sized companies on entry strategies for new markets, adjacencies or new geographic territories as well as business model improvements and partnership strategies. Globally, AVICENNE has been involved in more than 450 projects for 200+ customers in the Medical Devices Industry. Avicenne has published several annual surveys like “European Orthopaedic Market 2016-2021” or “Worldwide Orthopaedic Contract Manufacturing market 2016-2021 and top 100 supplier profiles”. Ali Madani founded AVICENNE in 1992 and he is the speaker and chair at several medical device conferences worldwide. In 2005, he founded “IMPLANTS”, a medical device industry conference and exhibition, which he has chaired ever since.

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