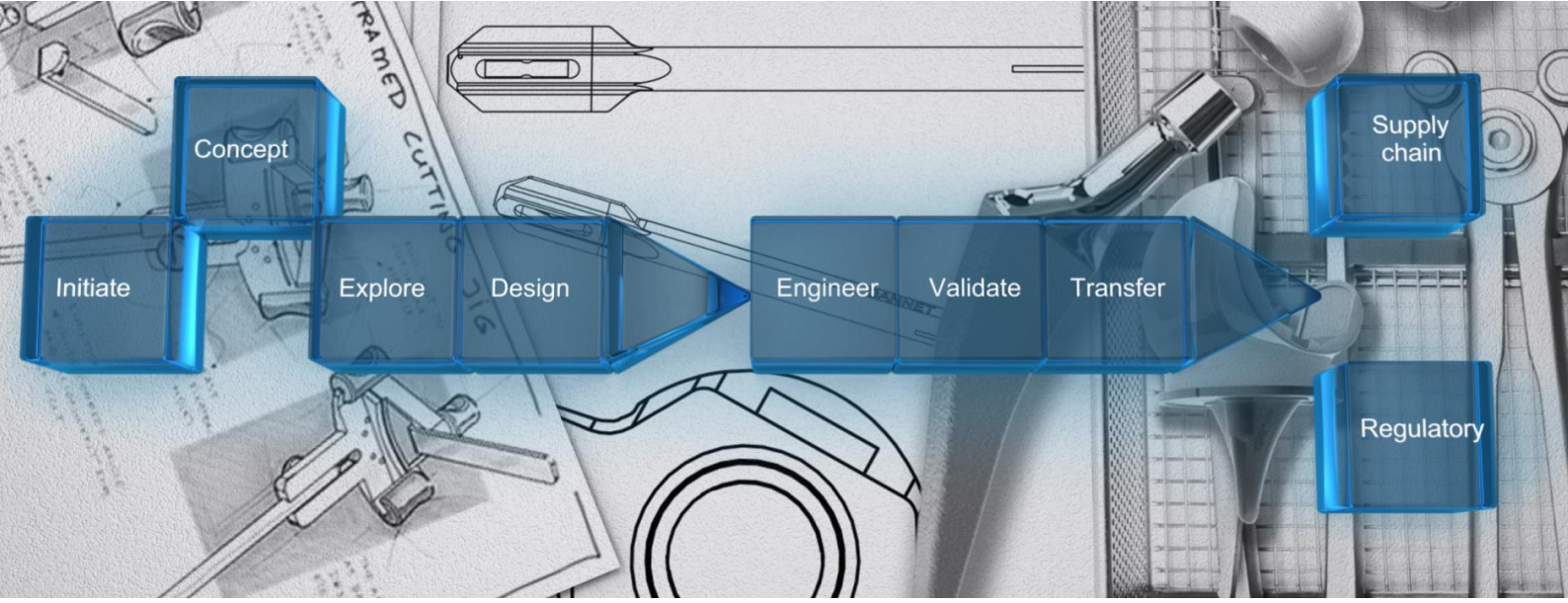

White paper

Creating orthopaedic start-ups efficiently

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Introduction

Most startups in the field of orthopedic medical devices want to bring their new product to market to become an attractive partner for a multinational. In this paper we want to explain what we believe is the best approach to develop a startup and ultimately reach an exit that is profitable for the original founders.

The world market of orthopedic medical devices is currently about $45 billion and expected to rise towards $55 billion in 2025. Now the market is dominated by 5 multinationals (DePuySynthes, ZimmerBiomet, Stryker, Smith & Nephew and Medtronic) which together have about 60 % of the market in their hands. And most companies acting on the orthopedic market have their headquarters based in the United States.

The market in which those medical device companies operate has changed due to scandals, explosion of health care costs and the role of the internet. Startups in this field should understand how the orthopedic market currently works and how they can set up their businesses efficiently to maximize the change of realizing a profitable exit.

Trends in the orthopaedic market

For a startup to become successful it should be aware of the important trends that can be observed in the orthopedic market.

A first trend is that when compared to the market size, there are actually not many customers to sell the orthopedic medical devices to and therefore each customer is very important. They not only bring turnover to the company but also help to develop and test new devices. After all, the orthopedic surgeon is the only person that is allowed to test the device in real life and therefore a cooperation with this profession is essential for all medical device companies to be able to innovate. In the past this often evolved in tight financial connections between the surgeon and the medical device company which has led to excessive situations. New rules made these relations transparent and medical device companies are very strict in following those rules to prevent possible lawsuits.

A second trend following recent scandals like the leaking PIP breast prosthesis and the metal-on-metal hip prosthesis which initiated more and tighter regulations. The EU introduced the medical device regulations (MDR) which makes it much more complex to bring a medical device on the market even if the device is only a copy of an existing one. Also, the FDA is currently taking measures to advance the review of safety and effectiveness of medical devices. Moreover, especially in the US there are specialized law firms actively looking for possible faulty devices and advertisements to attract patients to initiate class action lawsuits.

A third trend is the attempt of governments to get grip on the explosion of health care costs to keep healthcare available for everyone. Too often a startup is focusing only on developing the product and getting CE/FDA approval, however, having market access does not automatically mean that there is a reimbursement for it. All developed countries have their own unique reimbursement system and there are large differences between them. Often clinical data is required to prove efficacy and cost effectiveness before the reimbursement system opens the doors for your product. Even if you get a reimbursement the price you will get for it may be too low to become economically feasible in the long term. Therefore, it is essential for a startup to develop the reimbursement strategy together with the development of the product right from the beginning.

Due to those trends, multinationals became very risk avoiding regarding their mercer and acquisition processes. Where about 10 years ago a multinational bought a startup easily after a short evaluation of the product, such takeover will not happen anymore without a very strict due diligence process that covers all aspects that may possibly affect the multinational in a negative way. Therefore, the goal of a startup should not only be to develop the product but also take care that all potential risks for a multinational are addressed properly.

Startup development in 3 stages

In general, a startup passes 3 stages. In the first stage it begins with an idea from an individual, usually a surgeon or a student who passed university, who is willing to put energy, time and money to create enthusiasm for their idea and raise funding. Once the founder has succeeded in getting funding, he enters the second stage where he develops the product, the manufacturing process and works towards FDA and/or CE approval to be able to place the product on the market. Once the product is on the market usually it does not sell from itself. By then the startups reaches the third stage where it must create real sales by convincing users, distributors, insurance companies and governments about the benefit of the new product. This third stage requires a big investment and to get funding for that stage the startup should have generated solid proof in the previous stages to create confidence for investors.

Many startups fail to reach the third stage and even when a startup succeeds in getting funding for this stage it may lead to such a dilution for the original founders that they will hardly see any return on their investment.

Therefore, we believe that from start on the original founders should work on a smart exit strategy. Timing is essential and we believe that the best option today would be to generate an exit and sell the product to a multinational just before entering the third stage. In this way the product will land in one of the widespread distribution networks controlled by those multinationals and has the highest chances of becoming successful. It also maximizes the chance that the original founders are awarded properly for their efforts.

Revolutionary versus evolutionary technology

Products that are based on revolutionary technology are usually developed within institutes and universities, for example the development of new materials and tissue engineering. There are a lot of technical issues to be solved before such a new technology can be implemented on an industrial scale. For a revolutionary product there is usually a lot of inhouse know how involved that is vested not only in documentation but also in people. For a multinational to start a distribution relationship or to take over a startup with having a revolutionary technology it is important that the employees within the startup stay committed to be sure no knowledge leaks away. Therefore, it is very important to develop the organization of the startup properly with inhouse facilities and resources committed to stay on board, even in case of a takeover.

Most inventions made in the orthopedic market can be classified as an evolution of an already existing product or treatment. Development of those products is hard work and may take a lot of time, but it is not an extremely risky process. In case of an evolutionary technology the asset is the product itself and the manufacturing chain associated with it. This can all be managed well by the multinational without taking over the startup. Therefore, the multinational is usually not so much interested in taking over a complete company but only in taking over the product.

Due diligence

When a multinational is interested in your product it will start an extensive due diligence process first before starting serious negotiations. The startup must prove that many requirements are met by delivering the right documents like patents, approvals and contracts that are generated by a validated process. Those requirements not only consider the product itself but also all other aspects of your startup. The main requirements that will pass such a process are listed below.

- All contracts, including the shareholder contracts and NDA's should meet the standards of a multinational and clearly define the liabilities.

- Detailed technical file and Device Manufacturing Record conform the quality standard of the multinational, who have usually much higher demands then a European notified body or the FDA.

- Documented proof that the product is developed according to the appropriate MDR/ CFR regulated processes and that those processes will withstand an extensive audit of a multinational.

- Clear contracts with surgeons that are involved in the design and evaluation of the products. Those contracts should show health care compliance for every surgeon involvement, even the smallest involvement should be documented.

- Granted patents for the products that at least show freedom to operate to minimize the risk that a competitor will sue the multinational for infringement once the product is rolled out through the distribution network. For a multinational a granted patent is not enough, preferably there should be a legal opinion available from a recognized patent attorney.

- A certified manufacturing line for the products involved that has the ability to quickly scale up the manufacturing numbers without losing quality.

- CE mark and FDA approval for the products held either by the startup or a strategic partner of the startup that is contractual bounded to cooperate with the multinational in case of entering a distribution agreement with the startup or a takeover.

- The product should fit in the reimbursement systems of the main countries where the multinational wants to introduce the product.

- Published clinical data collected under Good Clinical Practice conditions that show the efficacy for the patient and efficiency for the reimbursement system.

- An international surgeon group that includes key opinion leaders located in some of the important countries should support the product, e.g. by holding lectures and provide training.

Value creation

As already discussed, every startup starts with an individual having an idea and a drive to realize it. Lot of the effort of a startup will be to meet all requirements to pass the due diligence process of a multinational. However, all this work does not really drive the value of your startup. A multinational will only discuss seriously about a takeover if your product starts (or potentially) start to impact their current business. This is a process that takes several years and will only happen when the startup is able to create the right story around the product. In contrary to a due diligence process, the value determination of a startup is less based on real facts. The main driver here is the perception which benefit your product could have for the multinational when distributing the product through their own distribution chain.

Beside meeting all requirements to pass the due diligence process the most important goal when developing a startup is to build the story around your product. The better you create your story the more potential pain you can cause to the multinational for not having this product. It is this story that brings the multinational to your table in the first place. The startup should increase the value perception by developing evidence like clinical results, involvement of key opinion users and show initial sales in important target markets. Creation of that story is a mixture of marketing activities, being present on the right congresses, creating attention in news bulletins, making surgeons talk about your product and in the end have decent clinical data in your hands.

Multidisciplinary process

The creation of this story and the fulfillment of all requirements to pass the due diligence, requires cooperation of several disciplines and a significant investment to bring it to an exit successfully. For an average startup in the orthopedic field, about $10 to $15 Million of investment is needed to reach an exit. Considering the trends in the current orthopedic market and its increased complexity of regulations it is almost impossible for a startup to build up from scratch in house all the expertise needed. For that reason, there is a tendency under startups to outsource critical aspects to specialized companies and develop strategic partnerships.

This tendency is relatively new although outsourcing the manufacturing part is well accepted in the medical device market for several decades. The reason for sourcing out manufacturing has always been that it is not economically feasible for startup companies to invest in own machines. However, due to the increased complexity to generate and sell new orthopedic products, this becomes now also true for other disciplines like development work, regulatory, market access and reimbursement. Outsourcing those aspects will be inevitable to meet reasonable timelines and spend the investment budget efficiently. Moreover, a cooperation with strategic partnerships will make an acquisition by a multinational more likely because multinationals usually already have established relations with those partners and know the quality they deliver.

Conclusion

Every new medical device in the current orthopedic market should land in one of the fine-mazed distribution networks of a multinational to become successful. A startup that wants to bring a new product to the orthopedic market should be very aware of this and base its strategy to reach that goal. Outsourcing within strong partnerships is a good alternative to reach this goal in an efficient way.