Planning a Non-American Exit

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For nearly all medical device companies, there will come a time when it is in the leadership's best interest to consider their exit strategy. But while many founders and start-up executives may limit their search within the United States, more and more smart executives are looking overseas for their exit from the business. This can sometimes be an intimidating process for those not familiar with international regulations but it's a consideration more medical device companies should look into.

Of course the main question these owners may be asking is: Where do I start? And the fact is, you should start thinking about your exit as soon as the company is formed. If a non-American exit may be in your plans, it's essential you have an international strategy in place from the very beginning. This will include filing necessary patent applications to protect your IP early and generally designing a product that will be suitable for international markets, as well as seeking international contacts early on.

If you have successfully laid the groundwork, the next big concern is knowing what type of exit will be most beneficial for you. There are, of course, many factors that go into this decision but the main options are fairly straightforward. In many, if not most, cases, a non-American exit will mean a complete purchase. This usually includes a larger international company buying their way into the U.S. through a smaller, yet successful, American firm. Even publically traded companies can be targets for foreign buyers. A good example occurred in 2010, when India-based Opto Circuits purchased American company Cardiac Science.

Of course another option is to seek a division sale, where perhaps only one product or sector of your medical device company would be acquired. This might be ideal if you are shifting the focus of your company away from a certain industry or looking for an international partner yourself. German manufacturer Drager's purchase of the Air Shields division of U.S.'s Hill-Rom was a well-publicized example of this in 2004.

A final option could be to charter an IPO, however this is often a much more difficult proposition. Medical device IPOs are somewhat successful in foreign countries but less so in the United States. Australia, China and Israel are good examples of where this option might work best but an American company would need to greatly build up their international presence if they were to be successful in this route.

Of course, all founders looking to sell are trying to receive the best price. But how do you know when that time of peak value arrives? In my experience, the biggest medical device acquisitions occur when the company being bought has a firm infrastructure in place. This should be a key consideration before attempting an exit. Distributors, vendors, a sales force, etc. should all be developed and financials

should be heading in the right direction. Buyers will investigate your cash flow and sales records thoroughly before signing on the dotted line.

The main reason this infrastructure is so essential is that while you are planning an exit outside the U.S., the purchasing companies are usually using you to enter the U.S. market. So in general, international buyers need to be confident that your company can provide them sound footing in the American market. This tactic is becoming increasingly popular because foreign regulations are often less strict and more cost-effective. Many young medical device companies first test the non-American markets in order to limit startup costs and work through any early problems. Once cash flow is no longer an issue, these companies can then apply for FDA approval and begin finding partners in the U.S. market.

Examining these less strict regulatory markets may also be smart for the American companies eyeing a foreign exit. The main reason is marketing. The bottom line is that the more prospective buyers that know about your company, the more likely you are to receive multiple bids. When you are seeking international bidders, showing that your product has the ability to sell both in and out of the United States is a powerful asset. The key is choosing to enter markets you know the product will sell in.

International networking is also important and should be a priority from the time your company is founded. The easiest way to establish recognition in foreign markets is to simply make friends. Make sure to network with leaders at other medical device companies as well as with local international business and trade organizations. Most states even offer government funded programs for businesses looking to make connections abroad. Use resources within the company as well. Find investors, strategic partners and board members with good international experience. It’s very likely they already have some strong contacts in each market you are targeting.

Finally, as a last pointer to an international exit, don’t forget to investigate each country’s own intellectual property and regulatory rules. This will be key to identifying where the best fit for your device is and where you are likely to get the best purchase offers. For example, you wouldn’t want to attempt an entrance that requires you to repeat all or some of the clinical trials when a more lenient country might allow your previously performed trials to transfer. The way to make sure this doesn’t happen is to bring in an expert. Find intellectual property agents and regulatory consultants that have experience overseas and they can guide you to where your best targets should be.

Overall there are certainly many considerations to take into account when planning a non-American exit. But this is a growingly popular option for medical device companies and one that could result in a much return on investment than thinking only within the States. Start thinking globally early and it could pay off well when the time comes to sell.

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