Perspective

What Medical Device Companies Look for in Pre-Revenue Start-Ups

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CEOs of pre-revenue, technology-based start-ups may be able to enhance value for their product/ technology by better understanding early-on what's important to large, global companies.

Medical device companies seeking transactions are moving away from a shot-gun to a strategic approach. Any proposed acquisition or licensing opportunity for a product and/or technology must support the overall corporate strategy, benefit the corporation in achieving its short and long term goals, drive revenue growth and bottom-line performance and secure buy-in from the leadership team (and possibly the corporation's Board of Directors).

Revenue-generating acquisitions will continue to be preferred by medical device companies as they seek to grow sales, diversify product portfolios and protect margins in a very challenging health care environment. However, 61% of companies acquired in 2010 had no revenues – and the percentage of pre-revenue start-up's acquired actually dropped in each of the previous three years (2009, 2008 and 2007). Corporations have clearly raised the bar and become more highly selective in their pursuit of pre-revenue companies/technologies.

What specifically are medical device acquirers or licensors "looking for" in pre-revenue companies? Aside from advancing their own growth strategy, three "must haves" are typically at the top of a prospective partner's list of requirements — innovation, market access, and a knowledgeable and passionate leadership team. Listed below is some specific information on each as well as takeaways for CEOs of medical device start-ups.

1. **Innovation**

a) A novel product and/or technology that solves an unmet need or clinical issue

> Corporations are looking for opportunities to secure a sustainable competitive advantage and become a top player in a specific category.
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> Technologies/products that have the potential to improve patient outcomes cost effectively (or reduce costs), or improve hospital processes and efficiencies, or minimize or reduce error rates will most likely achieve commercial success. The more traditional innovation model — incremental

product improvements driven by physician collaboration, higher cost-of-goods, an expected higher end market price, and minimal to no clinical data — will have less chance of commercial success.

Platform technologies are more desirable than single products — but a start-up with a platform technology should focus initially on a specific indication/application to avoid diluting efforts and being all-things-to-all-proposed-partners.

An addressable market large enough to be meaningful to a prospective partner is desirable.

Products/technologies that "provide a solution in search of a problem" are likely to be undesirable to prospective partners.

Takeaways for CEOs: Spend the majority of your time in the field with potential physician customers and regularly stress-test your product/technology and validate the clinical need and potential market size.

Listen carefully and critically to physician (and other medical professional) feedback. Refrain from falling in love with your product/technology.

b) Strong IP is a necessity

Prospective partners will need to withstand a potential challenge from a major competitor once the new product/technology hits the radar screen.

Patents, trademarks and licenses that are in order, well-documented, applicable to the product/technology and secured with clear ownership of the IP by the start-up are desirable.

Securing a freedom-to-operate opinion, especially in a crowded space, is desirable as well.

Takeaways for CEOs: Have your "basic" IP in order. An "accelerated" IP strategy is nice-to-have, but may be premature and costly.

Refrain from borrowing money that requires IP securitization.

c) Evidence that the product and/or technology works

Prospective partners will expect to see an operational prototype and clinical proof-of-concept. At a minimum, a start-up will need to provide substantial evidence that the risk of failure of the product/technology will be low.

Positive laboratory and animal test results (and any early economic justifications) are desirable.

Takeaways for CEOs: Eliminate technical risk wherever and whenever possible. Invest in prototypes and/or necessary lab or animal testing to demonstrate that your product/technology either works or can work.

2. **Market Access**

a) Known regulatory pathway and/or global regulatory strategy

A more stringent regulatory landscape in the US has extended timelines and increased the costs to innovate for all medical device companies. Although the US FDA is promising greater transparency regarding 510(k)s and pre-market approval products (PMAs), corporations seeking transactions remain cautious.

Pre-revenue companies will be required to secure "strong signals" from regulatory bodies (in and outside the US) regarding the pathway for their products/technologies.

Having a specific indication for a technology/product is desirable to one that is agnostic. A global regulatory strategy is more desirable than a US only or an OUS only strategy.

Takeaways for CEOs: Eliminate regulatory risk wherever and whenever possible. First, know what you want – then, plan for the unexpected. Communication with the FDA is key -- if possible, get you know your reviewer, Branch Chief and/or Division Head at the FDA (either directly or through your regulatory expert/consultant).

b) Clinical outcomes at least as good as — and preferably better than — the current product or technology in market

All medical device start-ups will need to demonstrate — more than ever — the clinical value of products/technologies. Comparative effectiveness will increase the scrutiny on existing and potential future treatments and products.

Pre-revenue companies who work with their clinical team and/or a reputable CRO early on to identify clinical endpoints and a study design meaningful to regulators and payers will have an advantage. Collecting economic data to validate procedural costs will be deemed desirable.

The ideal study may be randomized, double-blinded and go head-to-head against a competitor. Prospective studies will trump retrospective studies. A superiority claim (over competitive therapies and not necessarily a placebo) will trump product equivalence.

Be vigilant with your clinicians and ensure they remain within the agreed clinical protocol.

Takeaways for CEOs: Eliminate clinical risk wherever and whenever possible. Consider remaining in "beta phase" (versus a national launch) to remain capital efficient and demonstrate continued fundamental progress with product/technology/clinical results.

c) An existing or clear path to reimbursement

Companies remain under pressure to satisfy not only the regulatory needs of the FDA but the requirements from the Centers For Medicare and Medicaid (CMS) to ensure that products are adequately reimbursed. In addition, the bar for private insurance has been raised. For virtually all

therapeutic 510(k) and PMA products at higher price points, reimbursement is critical. Lack of reimbursement can limit market acceptance to innovative technologies despite clinical value.

A well-designed reimbursement strategy, integrated early in the development process with key disciplines — development, marketing, clinical/regulatory, reimbursement, operation's — is desirable. Reaching out to experts early on to help formulate a strategy is equally desirable. Either way, defining a targeted patient population for a clinical trial is an integral part of the process and will eliminate unpleasant surprises in the future.

Become knowledgeable about the reimbursement landscape before investing heavily in product development. At a minimum, have a reimbursement plan in-hand and be comfortable discussing existing coverage, codes and payment.

Determine the economic impact the procedure will have on the hospital, physician, patient and payer — and consider developing a value proposition for each.

Takeaways for CEOs: FDA approval does not mean payer approval. If there is no reimbursement for your product/technology, it will simply not sell. Staying under-the-radar is not a long-term reimbursement strategy.

d) Sound quality systems and design controls in place; manufacturing scalability

Over the past several years, the US FDA has issued warning letters to numerous medical device companies for having "less-than-robust" quality systems. In turn, medical device companies have invested millions of dollars in upgrading their own quality systems — and demanded that their vendors follow suit.

Developing and maintaining quality systems and processes for manufactured and vended products is not only desirable — it is mandatory. Stress-test your quality system by having an independent third party audit your facility (or your primary vendor's facility) — preferably before a potential corporate partner does so.

Consider using vendor's who are already on the "approved list" of large medical device companies. Consider outsourcing versus investing in captive manufacturing.

Challenge your ability (or your vendor's ability) to scale-up and know the resultant costs. Ensure your projected cost savings — based on anticipated higher volumes – are well grounded and defensible.

Takeaways for CEOs: Don't cut corners on your quality system. At a minimum, poor design controls may de-value your product/technology. If you don't have a quality system in place, show a prospective partner that one can easily be put into place.

Screen potential vendors and select one based on multiple criteria including demonstration of a robust quality system — not just best price.

3. **Knowledgeable and Passionate Leadership Team**

Ensure select senior positions are staffed with proven, passionate professionals. A knowledgeable team can navigate its way around a technology issue.

Use your money wisely — every dollar should have a purpose, and that purpose is to return a minimum of $10 for each $1 invested.

Determine who you need on the payroll and who can be replaced by an outside consultant.

Ensure potential acquirers or licensors know who you are — and what you're up to — early in the game.

Refrain from staffing-up in a rush to commercialize. However, once regulatory clearance is secured anywhere in the world, gain market traction in a narrow and deep way.

Takeaways for CEOs: Make an exit part of your company's ongoing planning process — but don't expect to sell or license your product/technology before it's ready.

As corporations become more highly selective in their pursuit of pre-revenue opportunities, start-ups will need to better distinguish their products/technologies. Being prepared and having your house in order before approaching prospective partners is highly recommended. By knowing what prospective partners are looking for, identifying and addressing negative surprises early on, CEO's will be better able to define and defend their product/technology, tell a more compelling story and maximize value.

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