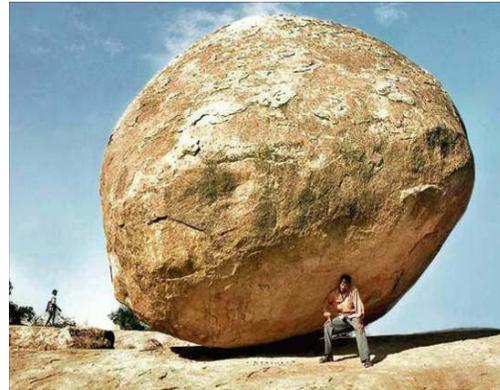


David Barone, the principal of Boston Medtech Advisors, was in Israel in early January and presented "Business Development in the U.S.: Expectations and a Bit of Experience" to a group of incubator company entrepreneurs at the [Misgav Technology Center \(MTC\)](#).

David Barone started off with good news: The medical device industry is alive and well. It is strong and expected to continue to grow as new technologies are introduced. He pointed out, however, that many smaller medical device and medtech companies have difficulty securing venture capital financing, but went on to explain that momentum in the industry will continue as larger medical manufacturers put products in their pipelines that are based on technologies from early-stage companies.



David Barone claims the person in this picture is the entrepreneur of a start-up company!

In fact, Barone commented that "major corporations have increasingly invested in early-stage medical device companies ... through venture development funds" or through a number of pharmaceutical companies. There is a growing trend "towards outright purchase of private companies as one of the primary exit scenarios." He noted that "between 2002 and 2004, the 10 largest U.S. medical device companies have acquired between 20 and 25 companies per year." Boston Scientific alone made six acquisitions and 19 equity investments during that time period.

Focus on Financing

According to Barone, entrepreneurs usually ask him two standard questions: 'How much money should I raise?' and 'How quickly can I get it?'

Golden Rule of Financing

Each plan will take twice as long to execute and three times the amount of money, or vice versa.

Their most typical question, Barone went on to say, is, 'Can you introduce me (us) to investors?' He remarked that actually the **right** question entrepreneurs should be asking is, "What should I do to **attract** investors?" As for the answer, Barone said it lies in three key areas:

1. Identifying the problem or the need — and only then identifying the solution;
2. understanding what you **really** sell, which isn't always so obvious, and;
3. defining the business model and establishing a thorough understanding of the market.

Barone enumerated 10 common pitfalls in medical device development (see box). How to avoid them? "It's fairly easy. It all comes back to these three key areas."

Strategic Moves

David Barone's Top 10 Pitfalls in Medical Device Development

"Early on," Barone remarked, "you need to know the direct and indirect competitors, the key opinion leaders, decision-makers (always more than one who is obvious) and influencers, the reimbursement environment and coverage guidelines, and the economic impact on the providers/users." Baron reminded the audience, too, that on average a medical product or technology takes nearly 17 years to reach the market from the idea stage to commercially accepted product! So, be prepared to ... persevere.

As for the reimbursement environment, Barone stated unequivocally, "**In the United States these days, medical technology won't go anywhere unless it meets the criteria used by health insurers for evaluating new technologies.**"

Barone shared the following criteria, which are used by the [Technology Evaluation Center \(TEC\)](#) of Blue Cross

and Blue Shield Association, the largest health insurer in the United States.

1. Failure to identify all future competitors
2. Clinical trials consider only FDA requirements (limited consideration for long-term marketing and reimbursement efforts)
3. Inadequate account targeting; not optimizing initial design for primary market segment
4. Going after too broad of a market
5. Failure to identify and secure support of product champions
6. Failure to consider the entire financial impact on decision makers (usually a physician)
7. Failure to gain support of managed care (for procedures, amounts reimbursed, and utilization guidelines)
8. Heavy reliance on distributors
9. Attempt to change practice patterns and protocols
10. Overestimating disposable utilization per installed system

1. The technology must have final approval from appropriate government regulatory bodies.
2. Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

Perspectives on Partnership

If looking for a U.S. partner to assist with R&D, product development, access to market, and capital, Barone chuckled before saying, "there's no free lunch."

"A pre-nuptial agreement is a must. And like any other relationship, make you sure are going into it for the right reason, and that you see the strengths and weaknesses of the partners." You must, he stressed, weigh the "long-term worries vs. short-term benefits" of a partnership relationship. For example, "exclusivity may mean losing access to other industry players; loss of interest by the U.S. partner or change in direction may cause the company to have to restart in a new direction."

For those companies that have decided to establish a U.S. presence, Barone advised to move forward during the very early stages of development. While it is not always "practical," some companies can consider the "U.S. bridge option," which maintains a part-time presence in the States through a contractual arrangement with a third party that "is affordable, trustful, understands the industry, can bridge the business-culture

gap, and is based on the East Coast." He cautioned the entrepreneurs not to "open an office in El Al business class," which will definitely help their mileage but not their business.

During a career that spans more than 25 years, [David Barone](#) has founded a number of health care companies, served as an advisory to start-ups and young companies, and worked with and for a number of entrepreneurs and VC investors. He has held senior management positions in a number of medical device companies, overseeing product development, marketing, pilot manufacturing, clinical evaluations, regulatory affairs, and intellectual properties. He is a member of the boards of directors of several companies. He has a bachelor's degree in electrical engineering from the Technion-Israel Institute of Technology. He received a master's degree in biomedical engineering and an MBA from the Rensselaer Polytechnic Institute in New York.

[Boston MedTech Advisors](#) is a Boston-based consulting and professional services company focused on medtech and health care. The company provides market analysis, business development, reimbursement strategies, and financing support. They work with companies to achieve important milestones, enhance competitive position, lower operating expenses, raise financing, and improve market and business strategies.