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Techniques in Vascular and Interventional Radiology

An investor perspective on forming and funding your medical device start-up

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Novel and transformative medical technologies of all forms have the potential to make a significant positive impact on the lives of patients and on the health care system, and one common pathway for guiding such innovations from concept through commercialization is via the formation of a company. For entrepreneurs looking to build a medical technology company, several common challenges await, including questions around how and where to raise funding. Here, we review key considerations for the formation of medical technology companies as viewed through the lens of an investor. We survey common sources of capital for early-stage companies, including grants, angel investors, and venture capital, and offer insights into how to differentiate among them to select the best partners for your start-up's needs. Finally, we discuss the critical components of pitching your ideas to potential investors, and offer guidance on best practices and common mistakes. We hope this primer on fundamental concepts and the various health care funding alternatives will prepare entrepreneurs to achieve their mission to improve patients' lives through commercialization of their medical innovations.
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Introduction

From balloon catheters to drug-eluting stents to embolizing microspheres, interventionalists have had a long history of redefining medicine through innovation, and working with industry to bring new interventions to patients around the world. Although there are numerous ways that a medical invention can have a broad effect on patient care, oftentimes this effect is best realized through an entrepreneurial initiative. Typically, this involves persistence down the road of research and development, preclinical and clinical studies, manufacturing, regulatory approvals, sales and marketing, company operations, and other hurdles that separate the great ideas from the therapies and devices ultimately renowned for redefining medicine. In a startup journey, often the most effective and expeditious path forward includes partnership with outside investors who can provide the capital and—in many cases—the expertise to get the company off the ground and the product successfully onto market.

Investments into medical device companies are robust, with approximately $4 billion invested into 400-600 companies in the United States each year (Fig. 1).[1] As medical device investors, we frequently see ideas and companies of all stages, many with physician founders. Some are developing a product for the first time, whereas others are building on their success as serial entrepreneurs. Regardless of which describes you, here we summarize, from the point of view of an investor, fundamental principles to consider when forming a company and fundraising in today's early-stage medical device start-up environment. We are hopeful these best practices will help you and your team succeed in finding high-quality investors, and more importantly, in bringing your innovations to patients while redefining the standard-of-care.

Before Embarking

Before founding a medical device company and raising money, an endeavor which will undoubtedly require heavy investment of your own resources, relationships,

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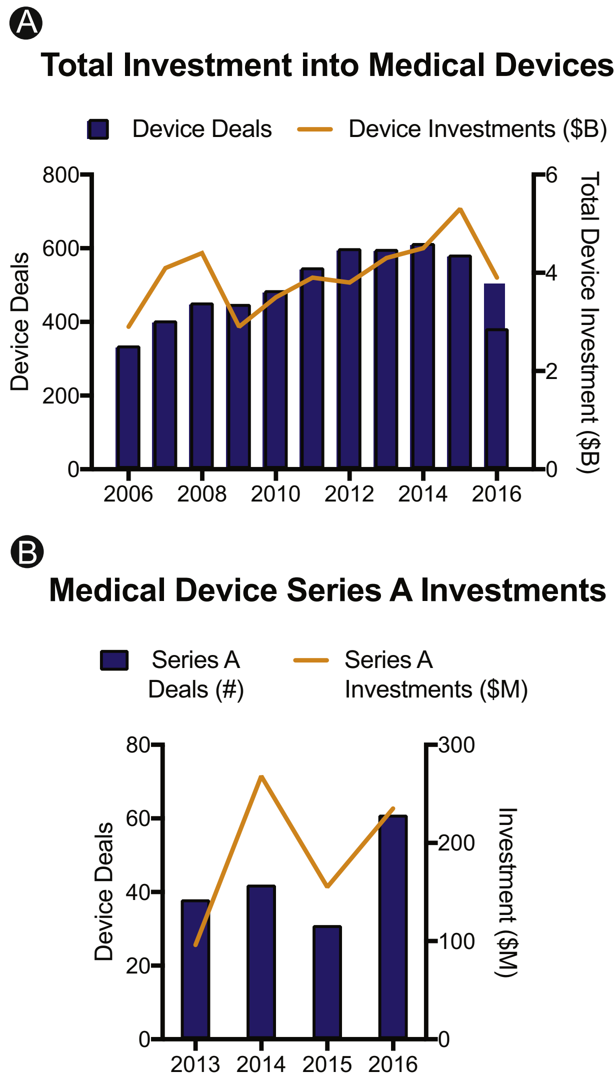

Figure 1 Trends in investment into early-stage medical device companies. (A) Over the past decade, the total amount of capital invested and number of deals transacted in medical device companies has steadily increased. (B) The number of Series A investments in medical device companies has significantly increased in recent years. Data from 2016 is extrapolated from data as of September 2016. (All data adapted with permission from Norris et al.[1]) (Color version of the figure available online.)

and time, it is imperative to convince yourself and your team that the opportunity is worthwhile by answering the following basic but ultimately key questions. These are the same questions that prospective investors will ask themselves as they evaluate you and your business:

Are You Ready For This? Is a Venture-Backed Company the Right Path?

The reality is, even in the best of circumstances, most startup companies fail.[2-4] The path to revenue generation and profitability can be long, and as is true with any startup, the financial rewards may not prove to be proportional to the time and effort expended. Taking capital from investors puts responsibility on the company to achieve a liquidity event (also known as an "exit"), but hopefully allows founders and employees to achieve a larger and earlier financial reward, and their investors the opportunity to receive their money back (hopefully many times over, as is their objective). Although businesses that do not take on outside equity investment can organically grow to be successful, venture-backed businesses in particular are often driven toward exits, such as an acquisition or initial public offering of the corporate entity. The timelines to

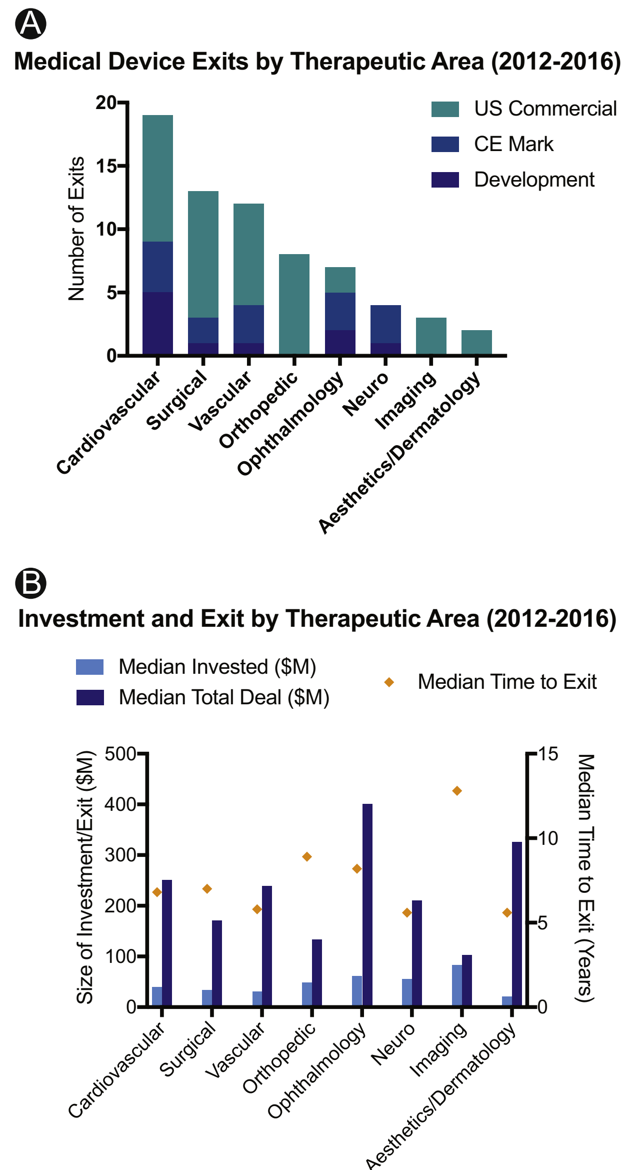

Figure 2 Liquidity events of medical device companies by therapeutic area. (A) In recent years, most acquisitions have been of companies in the cardiovascular, surgical, or vascular areas, and have overwhelmingly been of companies already commercialized in the US market. (B) With some variation across therapeutic areas, companies exiting for $100 million or more (here including both upfront and milestone-based earn-outs) have required $30-$50 million in total invested capital. The median time to exit for companies in most therapeutic areas is approximately 8 years. (All data adapted with permission from Norris et al.[1]) (Color version of the figure available online.)

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