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The Elusive Search for Funding Continues into 2015

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Leadership guru Peter Drucker is famously quoted as saying, "The best way to predict the future is to create it." This is a powerful statement to the new, or experienced, entrepreneur who strives to change the face of the world, or at least a fragment of reality, through their business vision. Looking specifically at 2015 business trends, it is apparent Americans are beginning to embrace the idea of becoming an "entrepreneur on the side." James D. Price, a self-touted serial entrepreneur and Michigan State faculty member explains that with the low cost of business start-up tools such as mobile payments, logistics and shipping, business mock-up tools, online legal advice and cloud storage, people can start a business in a quarter of the time for a tenth of the costs of what time and costs were in 2005. As Price explains, the access and affordability of vital business tools creates an opportunity for people to keep the safety net of pay and benefits of their day job while launching their start-up. In many lines of business start-ups, this is potentially an exciting time for building a secondary income or a chance building a business from the ground up. Yet, with a wave of uncertainty surrounding the medtech community, the idea of 2015 being a year of the entrepreneur may seem a bit far-fetched. Many within the industry feel like they are constantly dodging proverbial bullets being slung from political mandates and seemingly unattainable demands from investment groups. While the economy might be on the rise in many sectors of the United States, the medical device industry may continue to struggle just to remain afloat.

Perhaps because it aligns with Price's claims that 2015 can be defined by visionaries becoming "entrepreneurs on the side," recognition of an overall decrease in the cost of running a business cannot be overlooked. Although many tools necessary for the development of medical devices is typically expensive, access to technology, programming, parts, tools and even labor is greater than it potentially has ever been. Many of the tools that medical innovators need to run and maintain a business are the same tools used by people who are starting a small retail, resale or service business at home. Adding to the affordability of starting a new business, necessary tools such as cloud based storage, online legal advice and industry forms are often virtually costless. Looking specifically at medtech companies, TecMed CEO Alan Leszinske recently explained, "Today, making prototypes is a quarter of the price as it was when we started nearly 20 years ago. Back then we had to actually design and make each tiny piece of every device we developed which could take dozens upon dozens of man hours. Now, we can log into a website and order, or have made to order, pieces in the exact specifications we need for pennies on the dollar. What was once an extremely costly series of test prototypes is now a reasonable feat." In an open business forum, the costs of starting a business are lower now than they have historically been. In the medical device and technology sector of business, costs might not be as low, but they are decidedly less expensive than ever before, making the medtech industry a bit friendlier to the medically minded entrepreneur.

Making the medical device industry even more inviting is the changing face of the digital health care environment. Technology is transforming the way records are kept to modernizing procedures with bio-medical engineering and research. Medical facilities have turned to electronic self-service check-in processes and many institutions use social media and mobile devices to ensure patients have information and services consistently accessible to patients. The implementation and adoption of these new technologies has enabled doctors and patients to communicate more effectively and make better decisions regarding care. The digital heath care environment has made information more available than it ever has been before. It has also allowed for better training techniques for medical practitioners through the use of video-game based simulations, development of robots to assist patients and facilitate logistics in medical care facilities and in the creation of medical advances to prevent disease and effectively treat them. From a patient care and practitioner perspective, the digital heath care environment is revolutionizing care. However, from the entrepreneurial perspective, digital start-ups align more closely with software start-ups when it comes to the cost of running a business. This again creates great opportunity for growth in the health care sector from a small business view, but also opens up greater participation from visionaries that lack the deep pockets traditional medical device startups have demanded. What remains unchanged, is that although digital participation exists, within the lines of traditional medical devices, the greater the complexity of the device in development, the greater the costs reach in design, research, marketing , manufacturing and regulation. This suggests that the market has opened in some regards, yet remains quite restricted within traditional, yet still vital, industry confines.

The costs, although significantly reduced by currently accessible business tools, are still significant in the medical device industry and often are overwhelmingly high while early start-ups are in research and development stages of business. An argument can be made that in the age of "digital health" where apps and digital health interventions are becoming more accessible and acceptable versions of care, breaking into the medical device industry is financially more along the lines of a software start-up. However, when it comes to developing and introducing Class II and Class III devices, the costs remain prohibitive to start-ups without access to substantial funding that can bring the start-up through research and development stages to follow through to regulatory approval, market and advertising phases. Historically, angel investors and venture capitalists were the financers that drove the medtech industry. Yet, like many entrepreneurial projects in the middle to late 2000s, investment dropped down a cliff. A 2009 report published in PWC Moneytree notes that in 2009, investment dollars dropped 61% and the number of deals plummeted 45% compared the final quarter of 2008. In fact, 2009 saw double digit declines in every major industry sector in both number of deals funded and dollars amounted invested by venture capitalists since 1997. As funding dried up, venture backed IPOs slowly disappeared and organizational merger and acquisition deals became rare. For the medtech entrepreneur, it would be accurate, perhaps overly simple, to say it was not the best of times. The outcome of the withered funding resulted in venture capitalists stopping funding to portfolio companies, a notable increase in layoffs and cost cutting, which increased the U.S. unemployment rate. It also meant a 'new deal' had to be flawless. This resulted in lots of down rounds, fewer deals, all which still required higher reserves and start-up concerns about venture capital, or limited partner defaults on funding. The added increase in government regulation only increased funding challenges making fundraising through traditional means problematic.

As funding mandates and trends changed, the flexible entrepreneur in the early 2000s quickly understood that to access pivotal funding, survival meant having a product on the table, ready to bring to market with a revenue model in place proving profitability, a strong cash reserve, a clear understanding of competitors and market uptake. The start-up also had to be able to prove that customers had the ability to pay for the product, or device, they were fighting to bring to market. To get to this necessary level of preparedness, medical device companies soon realized that survival meant learning how to become fundraisers for themselves before they could approach a venture capitalist. This is the trend that holds firm today.

In speaking with TecMed, Inc. president Alan Leszinske, he explains, “If you aren’t willing to get on the phone and tell people about what you are creating and why you are doing it and ask them for financial support, you aren’t passionate enough about your work to bring it to fruition.” This mindset aligns with current funding trends. Investors, whether they are angel investors or venture capitalists, expect start-ups to raise between $200,000 and $500,000 from family and friends before seeking more formal investment. This lowers the risk for the investor, as early funding is typically the most risky, but it also shows that the people who know you best trust you. This creates credibility within the eyes of the investor. Leszinske also emphasizes that “doing your own fundraising for your own causes gives you more ownership over your business. You remain in control and can really build your business so it aligns with your goals and mission.” Although cold calling friends and family and asking for support is potentially challenging, it is also the first step for the modern medtech entrepreneur to get off the ground.

Another funnel of funding stems from grants offered through the federally funded Small Business Innovative Research program which is aimed at supporting research and development in US owned small businesses. The grants offer start-ups with less than 500 employees funding in the realm of $100k to a million dollars and tend to fund startups that are focused on research and development in well-defined scientific areas or high priority programs. Angel funding continues to occur on levels much lower than before with3% of all startups getting funded after being processed through increasingly difficult angel group processes. Venture Capital groups are also still visible within startups, yet no longer are at the forefront of funding. Recent reports shows that Venture Capital only fund less than 2% of the companies they review, making their funding dollars elusive. This begs the question of where funding should be sought.

Today, news feeds buzz about finding “strategic partners” for funding and emphasize the need for entrepreneurs to grab the reigns and drive internal fundraising efforts through the use of crowdfunding sites and grant applications. Although Angel Investors and Venture Capitalists are still lurking quietly in the corners, they are no longer considered the bread and butter driving the industry. Strategic partners are considered non-traditional sources of income. One such category is the use of divergent corporate venturing where the entrepreneur seeks capital from established corporations. In these deals, large medical device companies will make debt and equity investments in small, private companies in return for an option to sell and/or manufacture the device at a later date. Interestingly, these types of relationships are being formed across market lines, meaning that large corporations outside of the medical device industry are seeking medtech startups where technology might be used within the medical industry, but also adapted to meet the needs of the funding group in a divergent manner. Synergetic energy in harnessing technologies and their use drives divergent corporate venturing.

Another trend in funding is partnering with non-profits. This type of relationship tends to focus on the research and development stages of a medtech startup, yet are beginning to help with the transition into marketing and commercialization. Innovators and non-profit organizations collaborate to achieve financial and mission-driven goals. The programs allow groups focused on various patient or care advocacy to find, and support, startups that are developing the tools or devices they are fighting to have access to. The next approach, even more direct than working with non-profits, is connecting directly with potential future customers. Engaging directly with customers is currently recognized as an astute strategy for accessing funds because people are becoming more and more willing to pay in advance for future services. Working with non-profits and directly with customers may have once seemed far-fetched, even an unreasonable strategy, for accessing funding. Now, medtech entrepreneurs view it as an open opportunity of fundraising and recognize that accessing the immediate population who will benefit from their technology is a fairly straight forward path to accessing funding.

The last, seemingly obvious, strategy for medical technology companies to harness funding is, in fact, to turn to technology. Crowdfunding is a celebrated strategy that permits businesses across industries access to vetted investors representing millions of investment dollars. Crowdfunding portals allow businesses to set up profiles for investors to explore. Some experts have compared crowdfunding sites to online dating, where people might not engage with you if your profile does not fit the ‘ideal’ start-up they envision, regardless of how realistic their ‘ideal’ investment partner is. Additionally, others have noted that making public declarations about business plans, products and needs for money opens up a potential Pandora’s Box of criticism from a peanut gallery that just might damage the credibility of the start-up. On the other hand, credible investments have been invested in medtech start-ups. This turns crowdfunding into a weights and balances game for the medtech entrepreneur and investor, questioning whether the benefits outweigh the risks, which is always an appropriate consideration for all concerned.

There is little doubt that bringing new, innovative, potentially life-altering technology to market today is overwhelmingly challenging. The process of accessing necessary funding is complex and perhaps more competitive now than it has even been in the medtech industry. Venture capital, once the life blood of medtech, has virtually dried up, demanding entrepreneurs explore non-traditional avenues to access the funding necessary to bring medical devices from concept to market. Today, success for the medical device and technology entrepreneur is no longer bound within the realm of creativity and innovation of the science supporting their devices, but balanced precariously on the creativity and innovation of successful fundraising initiatives and strategic business planning.

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