



GETTING DOWN TO BRASS TACKS

Dermatology World unlocks the basics of physician entrepreneurship



By Ruth Carol, contributing writer

Inspired by your entrepreneurial colleagues who were featured in the August issue of *Dermatology World*? Do you have an idea for a drug, device, diagnostic test, skin care product, or digital health platform you want to start working on? Not sure where to begin? Keep reading.

MINDSET OF AN ENTREPRENEUR

Physician entrepreneurs are health care professionals who pursue an opportunity under volatile, uncertain, complex, and ambiguous conditions with the goal of creating user-defined value through the deployment of innovation using a business model, according to Arlen Meyers, MD, MBA, president and chief executive officer of the Society of Physician Entrepreneurs.

It begins with a certain mindset. That mindset involves seeing the glass half full, believing that life is about the journey not the destination, being willing to accept challenges, not stopping at no, and being driven by a pursuit, Dr. Meyers said.

It is also important to “know what you don’t know, see your blind spots, and find people who can help,” he added. In many cases, the physician entrepreneur may be the inventor of a product, but may not be the person who builds it and leads the team. >>

A physician entrepreneur must have certain skills and knowledge to accomplish the numerous tasks needed to bring their idea to fruition, Dr. Meyers explained. Those tasks may include protecting intellectual property, obtaining regulatory approval, building a team and leading it, and raising capital. They must be able to deal with uncertainty and know how to solve complex problems that pop up along the way.

A BUSINESS MODEL

But first you need a plan, said Dr. Meyers. “A business model describes how you build, grow, and harvest value out of the business you’re creating,” he said. “You have to figure out how to grow revenue and get a handle on costs so that you make more money than you spend.”

The key to creating a business model is validating the underlying assumptions as quickly and as inexpensively as possible, said Dr. Meyers. He recommends utilizing a ‘VAST’ business model, which can be accomplished by applying the following criteria:

- **Validity:** “If you hypothesize that it will cost two cents to acquire each customer on the internet, but it really costs 20 cents, your model is not valid,” he said. Change the model and test the new one until you find one that works.
- **Automaticity:** Outsourcing, automating, or using technologies to ramp up operations, sourcing, and distribution are a critical part of scaling up.
- **Scalability:** The model creates a business that can produce an infinite number of products at an ever-increasing pace.
- **Time and traction:** The model must create as much profit as quickly as possible with a growing customer base that is loyal to your brand.

Brandon Kirsch, MD, co-founder of ClearifRx.com, echoed the importance of changing the business model as needed and using the least amount of investment possible to test the model’s hypotheses in the real world. If investors are not interested, consider another route, such as the direct-to-consumer dermatologist. That is how he and three colleagues started ClearifRx, an online platform where board-certified dermatologists provide personalized prescription-strength treatments for common skin conditions. A primary reason why businesses fail is that the business model is not viable, Dr. Meyers said. The second reason is that they do not understand the customer, and therefore make products customers are unwilling to buy.

BUSINESS FINANCING

Developing a medical device costs between \$31-\$94 million, depending on the type of FDA approval that it requires. Taking a new drug to market costs approximately \$1 billion. Dermatologists are almost always going to have to take money from investors to take a device or drug forward because of the nature of the cost of doing business, stated Raymond A. Miller, JD, partner and registered patent attorney with Troutman Pepper Hamilton Sanders LLP in Pittsburgh.

Funding sources include investors, venture capitalists, other companies, and grants. Jon Speer, the Greenlight Guru, offers the following tips for obtaining funding to take a medical device to market on his website.

1. **Build a business case for your medical device.** This can be done by conducting thorough market research (see questions in sidebar to get started), and by building a prototype to show proof of concept. Seeing a prototype enables investors to gain a better understanding of the long-term goals and vision of your product, advised Speer.
2. **Establish a solid regulatory strategy:** A regulatory strategy aligns the regulatory activities associated with bringing a medical device to market with the business strategy for that product. A solid regulatory strategy involves proactive planning with clearly documented and sound rationale for the decisions that are ultimately made, which investors will appreciate, he noted.
3. **Document design controls and risk management with a right-sized quality management system (QMS):** Key QMS processes needed for product development are design controls, risk management, and document management, Speer explained. Design controls demonstrate that the product is safe. Risk controls show safety and efficacy. Effective document management is essential because of the large number of documents and records that are generated during product development. Without these elements, investors are taking on a greater risk, which they will not want to do.
4. **Know investor types and what they want:** Typically, investors are concerned with three types of risk, he said. Technical risk focuses on whether the idea works, business risk questions whether there is a market for the product, and people risk focuses on whether the company has the right people to do the job. Knowing the different types of investors can help you more effectively address their concerns.

The bottom line for attracting investors is the ability to demonstrate that your technology is worth funding and that your team has the knowledge and skills to deliver what is promised, Speer concluded.

On a much smaller scale, Dr. Kirsch initially funded his company with \$3,000 from each partner. They did much of the work themselves: building a turnkey store-and-forward telehealth platform, creating the website, blog, and marketing materials, and developing novel, highly specialized prescription-strength compounds. The ClearifRx team raised additional money mostly from dermatologist colleagues and angel investors. The team considered getting a business loan but decided against it because of unfavorable recourse provisions and onerous reporting requirements.

Another funding option is to obtain a grant. Advancing Innovation in Dermatology, a not-for-profit organization committed to catalyzing the development of new products for skin conditions, has financial resources available and gives grants to help promote innovations, noted Dr. Kirsch who is on the Education Committee for Advancing Innovation in Dermatology. Since the Society of Physician Entrepreneurs is an open innovation network, anyone with an interest in getting an idea to patients can join, not just physicians, including investors, said Dr. Meyers.

LEGAL CONSIDERATIONS

The biggest legal considerations depend on whether you are developing a device, drug, or cosmetic/cosmeceutical product, because that has implications for FDA approval, and how you are advertising your product as that has implications for the Federal Trade Commission (FTC), Miller explained. “It all depends on what you include in the product, whether it has been approved or not, and what you say about it,” he said.

FDA approval for new drugs requires pre-clinical studies on non-human subjects and three phases of clinical trials in humans. New drug approvals take, on average, 12 years, compared with new device approvals, which take an average of seven years. Medical devices can be “FDA registered,” “FDA cleared,” or “FDA approved.” Most medical devices are “FDA cleared” through the 510(k) pathway compared with the pre-market approval pathway, the latter of which is significantly more expensive and time-consuming. The FDA offers information about its approval process on the agency’s website, which can help determine what type of approval will be needed for the product.

Patents and trademarks, which protect different types of intellectual property, are a must when developing a product.

To qualify for a patent, the product must be novel and non-obvious, meaning that it does not already exist in some form or fashion in the prior art and would not be obvious from the prior art, Miller also said. “A product using ingredients not found in the dietary stream needs FDA approval unless you can establish that these ingredients are generally regarded as safe,” he added.

Another option is to launch a product with known ingredients and use the monograph as a basis of the claim for the product, provided you can show that you satisfy the monograph, Miller said. Launching an existing compounded product for a new indication, for example, may not require FDA clearance or additional clinical trials.

Resources for conducting a search for filed and existing patents include Google Patent Search and the U.S. Patent and Trademark Office’s (USPTO) Public Patent Application Information Retrieval system. After conducting your own search initially, hiring a patent attorney to conduct a comprehensive search is recommended. “That will protect you to make sure that your idea or product is novel non-obvious and you’re not infringing on somebody else’s patent or trademark,” Miller added.

Applying to register a trademark protects the brand name and logo used on a product. Searching the USPTO’s trademark database will help determine if any trademark has already been registered or applied, which would prevent you from registering your trademark. A common mistake people make is to pursue a trademark and spend less time on protecting their idea with a patent, Miller said.

While the FDA has some jurisdiction over cosmetics to ensure their safety, Miller said, the agency does not require as rigorous an approval process for cosmetics as it does for devices and drugs. Cosmeceutical is a term coined by the cosmetic industry referring to cosmetic products that have medicinal or drug-like benefits, but it is not recognized by the Federal Food, Drug, and Cosmetic Act. Cosmetics are products intended for cleaning the human body, making a person more attractive, or changing a person’s appearance. In contrast, products intended to affect the way a person’s body works, or to treat or prevent disease are considered drugs. A product can be both a drug and cosmetic.

The FTC requires claims in advertisements to be truthful and evidence-based, and they cannot be deceptive or unfair. For advertising, you need to be sure you’re not making false or misleading statements. “Saying that a cosmetic product will make you look 30 years younger could get you in trouble if you can’t provide objective evidence to demonstrate that the product is going to fulfill those claims,” Miller said. If the product “enhances the appearance of fine lines and wrinkles,” it’s not a drug. If it “reduces wrinkles,” it may be a drug. The FTC provides information, resources, and advice about advertising and marketing for small businesses on its website.

A disclaimer helps protect you against liability risks, Miller added. There are rules for how prominent the disclaimer should be, what typeface, and where it is displayed.

Miller encourages people to file for a patent application before discussing their idea in print or in public. “If you talk to people about it, they should sign a confidentiality agreement,” he said, adding, “People love to talk about their ideas, but it’s not necessary to say everything to get the advice you’re seeking.”

If all this work seems overwhelming, consider licensing the product instead, Miller said. “You can get around all these requirements by entering into a licensing agreement with another company that will develop, sell, and market the product while you get a royalty. It minimizes your legal risk as well because it is the company that makes the product that is responsible, not you.”

MARKETING PLAN

If you’re still onboard with getting involved in product commercialization, you will need a marketing plan.

A critical first step is defining the customer(s) who would want to purchase the product, stated Yi Yang, PhD, professor and chair of the Marketing, Entrepreneurship and Innovation Department at the University of Massachusetts, Lowell. She recommended creating a persona, who is a fictional representation of an actual user. Websites, such as HubSpot, offer tools to help create a persona. The persona should have a name, age, race, religion, gender, family situation, income, education, job/profession, living situation, shopping habits, hobbies, and values. If the product can be used by both males and females, then create both a male and female persona. It is important to segment the market for your product to include all customers, she noted.

Once the persona(s) is defined, it is time to develop a marketing plan using the 4 Ps: **product**, **price**, **place**, and **promotion**.

Product: Design the product to meet the customer’s needs. Be sure to address all the customers’ needs. “If a dermatologist develops a cream or medication, not everyone will use it,” Dr. Yang said. “Who has the problem it will address? Does it have to be gentle enough for a baby’s skin? Does it have to provide extra moisture for an elderly person?”

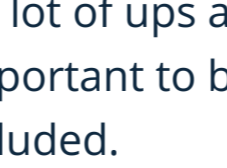
Price: Consider how much it costs to make the product and what competitors charge for similar products. When it comes to pricing, there is a product’s real value and its perceived value. A higher price connotes that the product is a luxury item, whereas a lower price may appeal to more consumers. “People are willing to pay a lot for skin care products that are effective,” she said. Use market research and the persona information to determine how much the customer will pay.

Place: Determine where to sell the product by using the persona information about shopping habits. Where does the customer hang out in-person and online? For example, the Etsy platform offers unique, handmade products whereas Amazon and eBay sell practically everything, Dr. Yang said. If a customer can afford to pay more for a premium product, then Etsy may be the better fit as it is more in line with the perceived value of the product, she noted.

Promotion: Develop a promotional strategy that includes advertising and public relations. A website is essential because it’s where customers can learn more about the product and read reviews, but it’s not necessarily effective for promoting the product, Dr. Yang said. The persona information will help choose which social media platforms will be most effective in steering customers to your website. Both younger and older generations are on social media, but they are not in the same space. Consider word-of-mouth for selling a product to more mature customers and physicians. If the product is for elderly patients, promoting it among peers can be very effective because older generations tend to trust physicians more than the younger generations, she said. Consider advertising through professional societies, conferences, and meetings to reach physicians.

“We need doctors who are guided by their sense of responsibility for their patients to take risks to become entrepreneurs,” Dr. Kirsch said. “If dermatologists don’t become more entrepreneurial, they’re just going to become employees who can be replaced by mid-levels, and the care of our patients will become highly dependent on prevailing corporate interests.”

Being a physician entrepreneur can be a very rewarding journey, but there are a lot of ups and downs, Dr. Yang said. There can be a lot of failed attempts before they become successful. It’s important to be willing to take some risks and not be afraid of failure. “Don’t just think about it. Do it,” she concluded.



QUESTIONS FOR GUIDING MARKET RESEARCH

Conducting market research when developing a medical device is an essential component of a business model. To help get started, Jon Speer, the Greenlight Guru, suggests on his website that the entrepreneur ask themselves the following questions:

- Why is my medical device necessary?
- Is there a proven clinical need for my medical device?
- Are there existing medical devices on the market similar to mine?
- Who will be the end-user(s) of my medical device?
- Who will purchase my medical device?
- What is the market size for my medical device?

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