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How to Take a Retina Product Idea From Concept to Market

Do you have the entrepreneurial spirit? Are you eager to develop a product that solves a problem for you and your patients? The 2019 Winning Pitch Challenge first-place winner Jeffrey Gross, MD, offers a roadmap for developing your innovation.

Create your concept—My product idea was sparked after many of my patients complained about the speculum, saying “It hurts worse than the shot!”

Find a problem. What do your patients and staff complain about? Find a common problem that needs a solution.

Team up—Find a partner or paid consultant to help develop your plan. Get a non-disclosure agreement (NDA) to protect your idea.

If your project is a device, a mechanical or biomedical engineer will be very helpful and speed the process along, *if* that individual has the same energy and work ethic as you. If you have adult children, include them on your team if they have appropriate talents.

Sketch your idea—Create a drawing or sketch and date it. Describe whether this is a completely original idea or if it was created in tandem with another inventor. Remember how the concept went from idea to sketch, as it will be important when people ask how you came up with the idea.

Create a digital image—Develop or commission a digital or computer-aided design (CAD) image of the device. This could get expensive if you need to outsource the job. If you, your partner, or a member of your team has this expertise, your project will move along quickly.

Develop a prototype—Use the CAD image to create a 3-D printed prototype of the device. Make appropriate modifications through CAD and additional printing until the device can be tested.

I am fortunate to have a partner who is a mechanical engineer and can create CAD, has a 3-D printer, is experienced in developing medical tools, and can tool injection molds. This alliance was an enormous benefit in developing my idea.

Test your product—If possible, test the device on friends, family and volunteer patients. Take many photos, videos, and testimonials. Get written releases to use images.

Find out if you need any further testing for product safety: Is your product a Food and Drug Administration (FDA) significant- or insignificant-risk device? Schedule time and set aside money for this step.

Know your market—Understand your product’s potential market, both in the United States and worldwide. Describe that market. Include all applicable age groups (infants) and even veterinary applications.

Incorporate—Form a limited liability company (LLC), name it, and wordmark the company name. Secure your domain name or uniform resource locator (URL) early. If someone else gets it based on seeing your trademark, it may cost \$1,000 or more to acquire the URL. There’s a whole industry of folks who spend their days searching trademarks and wordmarks and buying them, knowing that the inventors will want those URLs—and be willing to pay dearly for them.

Protect your intellectual property (IP)—Find a qualified IP attorney, preferably one at an IP-only firm, with experience in medical and biomedical areas. This person should have the necessary energy, work ethic, and interest, so your product won’t be put on the back burner. Negotiate a fixed fee for services, calls, emails, etc.

Name the product—Choose a descriptive product name that does not include words like *EZ* or *simple*. The name should be one that anyone with basic knowledge of medical devices can identify with the product. Again, wordmark the name and get a URL with that name.

Conduct a patent search—Look for any prior art and patents. You may find something similar or something to help you modify your idea. Searches cost about \$500 each.

Submit a provisional patent application—Working with your IP attorney, provide images or drawings of your device as well as descriptors. Think way outside the box for all potential applications, insertion techniques, materials, sizes, accessories, or attachments. A provisional patent application is highly recommended to participate in the Winning Pitch Challenge or other competitions.

Devise a strategic plan—Lay out a 5-year plan for your product’s development, manufacturing, and distribution. Try to estimate the cost of production, volume of sales, profit, and obstacles to overcome. List players, potential employees, the inventors and owners, and the facility.

Define the business opportunity—Decide on a product price that is a significant multiple of production costs and still reasonable, especially if a disposable device. Remember to include packaging and sterilizing costs, if applicable, for devices. Describe potential sales revenue, retail pricing, and comparisons to existing products.

Develop a marketing strategy—List avenues for marketing. Will it be separate sales, part of a kit, an alliance with strategic partner for distribution? Will your product be sold wholesale or through retail direct sales?

Fund allocation of first-year costs—Identify design, testing, regulatory, marketing, IP, and other first-year costs and who will pay for them.

Develop the pitch deck—A *pitch deck* is a succinct, compelling slide presentation that

Continued on page 47

8% of sham-controlled subjects underwent cataract surgery, generally between Month 18 and Month 39 (Median Month 21 for OZURDEX® group and 20 for Sham) of the studies.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies with OZURDEX® in pregnant women. Topical ocular administration of dexamethasone in mice and rabbits during the period of organogenesis produced cleft palate and embryofetal death in mice, and malformations of the abdominal wall/intestines and kidneys in rabbits at doses 5 and 4 times higher than the recommended human ophthalmic dose (RHOD) of OZURDEX® (0.7 milligrams dexamethasone), respectively.

In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

Topical ocular administration of 0.15% dexamethasone (0.75 mg/kg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in mice. A dose of 0.75 mg/kg/day in the mouse is approximately 5 times an OZURDEX® injection in humans (0.7 mg dexamethasone) on a mg/m² basis. In rabbits, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.20 mg/kg/day, on gestational day 6 followed by 0.13 mg/kg/day on gestational days 7-18) produced intestinal anomalies, intestinal aplasia, gastroschisis and hypoplastic kidneys. A dose of 0.13 mg/kg/day in the rabbit is approximately 4 times an OZURDEX® injection in humans (0.7 mg dexamethasone) on a mg/m² basis. A no-observed-adverse-effect-level (NOAEL) was not identified in the mouse or rabbit studies.

Lactation

Risk Summary

Systemically administered corticosteroids are present in human milk and can suppress growth and interfere with endogenous corticosteroid production or cause other unwanted effects. There is no information regarding the presence of dexamethasone in human milk, the effects on the breastfed infants, or the effects on milk production to inform risk of OZURDEX® to an infant during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for OZURDEX® and any potential adverse effects on the breastfed child from OZURDEX®.

Pediatric Use: Safety and effectiveness of OZURDEX® in pediatric patients have not been established.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to determine whether OZURDEX® (dexamethasone intravitreal implant) has the potential for carcinogenesis or mutagenesis. Fertility studies have not been conducted in animals.

PATIENT COUNSELING INFORMATION

Steroid-related Effects

Advise patients that a cataract may occur after repeated treatment with OZURDEX®. If this occurs, advise patients that their vision will decrease, and they will need an operation to remove the cataract and restore their vision.

Advise patients that they may develop increased intraocular pressure with OZURDEX® treatment, and the increased IOP will need to be managed with eye drops, and, rarely, with surgery.

Intravitreal Injection-related Effects

Advise patients that in the days following intravitreal injection of OZURDEX®, patients are at risk for potential complications including in particular, but not limited to, the development of endophthalmitis or elevated intraocular pressure.

When to Seek Physician Advice

Advise patients that if the eye becomes red, sensitive to light, painful, or develops a change in vision, they should seek immediate care from an ophthalmologist.

Driving and Using Machines

Inform patients that they may experience temporary visual blurring after receiving an intravitreal injection. Advise patients not to drive or use machines until this has been resolved.

Rx only

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tells your product's story. First, look online at as many examples as you can find of famous-company pitch decks.

List no more than 3 major items on each slide of your pitch deck. Start with the "hook" to grab attention early. Choose pleasing colors and make your slides easy to read. List the problem, solution, market, innovation, competition, trends, costs, timeline, IP, and examples.

Try to keep your pitch deck under 25 slides for an 8-minute presentation. Use patient testimonials if possible. Create an animated video of the device to explain its use. Describe the IP steps and timing. List the members of your team, along with their credentials and how they can help you succeed.

I chose The Winning Pitch Challenge, but there also are other competitions and opportunities available to you as a medical entrepreneur. The preparations are similar no matter which path you choose.

Get help from a mentor—New-product developers can obtain help from seasoned mentors, such as CEOs of companies with products similar to your device, venture capitalists, and others. Ask for an NDA if possible.

The mentor can help with your pitch deck, design enhancements, colors, distribution ideas, etc. Mentor assistance is often a free benefit of participating in a competition.

Evaluate your competitors—If you choose to enter a competition, research the other finalists' products online to assess them. Consider attending the Ophthalmology Innovation Summit (OIS) to see how companies pitch their products and how presentations are prepared for investors. Review all the videos, blogs, and examples for the competition. You can see examples of this at www.WinningPitchChallenge.net.

Practice, practice, practice your delivery—Stand up as you practice. Consider practicing in front of someone or while looking in the mirror. Look at TED Talks and read TED Talk books.

Be sure to tell a compelling story! This is key to a winning presentation. Memorize your slides and practice the pitch with mental images of the slides.

Ask for investment funding—Develop the "ask"; decide whether you plan to sell a percentage of the company for an up-front investment, or if you will license or sell the rights to manufacturing and/or distribution. Identify potential strategic partners and describe them in the pitch.

Even if you decide to self-fund, be sure to seek something from the judges during the pitch; this is one of the judging criteria in the Winning Pitch Challenge.

Take first place—Be ready for interviews. 🎯

Financial Disclosures

Dr. Gross - ACUCELA INC: Investigator, Grants; BIOGENWARE, LLC: Founder, Speaker, Intellectual Property Rights, No Compensation Received, Other Financial Benefit; COVALENT MEDICAL, LLC: Stockholder, Stock; GENENTECH/ROCHE: Investigator, Grants; HEIDELBERG ENGINEERING: Speaker, Honoraria; JAEB CENTER FOR HEALTH RESEARCH: Investigator, Other, Grants, Salary; OHR PHARMACEUTICAL, INC: Investigator, Grants; REGENERON PHARMACEUTICALS, INC: Investigator, Grants.