

Supplement to

Cataract & Refractive Surgery TODAY

February 2012

THE NEXT BIG THING

Perspectives on the innovation cycle
for ophthalmic medical devices,
products, and services.

Adapted from presentations given at the
2011 ACOS Summit Orlando, October 21, 2011.

ACOS

The Next Big Thing

Perspectives on the innovation cycle for ophthalmic medical devices, products, and services.

INTRODUCTION BY ROBERT K. MALONEY, MD



The relationship between physicians and industry has become one of the most charged political issues in health care.

The benefits that derive from a close partnership between physicians and industry have been forgotten in the rush to limit the possibility of conflicts of interest. Some of our most successful technologies have arisen from industry-physician partnerships: phacoemulsification, vitrectomy, and excimer lasers, to name just a few. Our patients see better and live better every day because of innovations that were conceived, designed, and developed by ophthalmologists in partnership with industry. We are in a unique position to identify the needs of our patients and to dream up the innovative concepts that change their world, and ours.

The American-European Congress of Ophthalmic Surgery (ACOS) is founded on the idea that partnership between physicians and industry is good for our patients. At the 2011 ACOS Orlando Summit, physicians and industry thought leaders gathered for a free exchange of ideas about innovations that affect the entire ophthalmic community. This supplement summarizes four of the meeting's presentations that focus on the innovation cycle in medicine. We hope it inspires you to get involved in ophthalmic innovation. We hope it challenges you to invent the next phacoemulsification, or vitrectomy, or excimer laser, and develop the concept in partnership with the companies that have the resources and experience to guide it into clinical use. ■

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What Does it Take to Be an Innovator?

Participating in the innovation cycle is daunting but potentially rewarding.

BY J. ANDY CORLEY



Developing a new product is by no means an easy task, nor is there a formula for how it is done. Physicians are scientists by nature and are used to linear, cause-and-effect relationships. But the world of medical innovation is anything but predictable. Product development is fraught with uncertainty, risk, and adversity. Despite those hardships—and perhaps because of them—success can be extremely rewarding.

It is not enough to have good intentions or a novel idea; being able to execute on that idea takes a certain wherewithal and patience that few possess. During the course of my career, I have recognized a few important concepts that all innovators should be aware of as they attempt to move an idea from the back of a napkin to the marketplace.

Mental Preparation. The most important thing for the potential innovator is to prepare himself or herself for the long road ahead. In today's regulatory climate, the typical lifecycle from idea through pipeline is 8 to 10 years and about \$70 to \$100 million of investment. Innovators must ask themselves whether they are ready to shoulder that tremendous responsibility. Are they prepared for rejection, failure, condescension, doubt, and negativity? Innovators are answerable to stakeholders with unique and particular demands; a thick skin is a definite requirement.

Ideas. New ideas do not arise from sudden epiphanies. Rather, ideas take time. They percolate inside the innovator's head, and as that person communicates with others, the concept grows and matures.

Confirmation. Innovation requires the utmost belief in the importance of an idea. Although it is desirable that others want to join the team and help grow the idea, it is impossible to build unilateral support among peers and colleagues, let alone among financiers. Cynicism and skepticism are different forms of feedback; the former wants you to fail, and the latter pushes you to make your idea better.

EIGHT STEPS TO INNOVATION

- Mental preparation: be ready to endure a long, challenging, and demanding process.
- Ideation: unmet need; preferably a big market.
- Confirmation: peer, professional, industry, and management support.
- Capitalization: you, seed money, and series A funding.
- Regulation: can it be approved, and in which markets?
- Clinical confirmation: does it work? Iteration.
- Commercial confirmation: will it sell?
- Realization: sell to the highest bidder. This requires a collaborative effort.

Capitalization. Simply put, ideas take money. Finding funding sources is paramount to actualizing ideas, especially in the medical field, where regulatory scrutiny and oversight is a part of life. Venture capital has become an important component in the innovation cycle in health care, and often venture capitalists want to know that the innovator has his or her own personal stake in the game.

Regulation. Some form of regulatory approval is necessary for all products introduced to the health care market, but getting there has become increasingly difficult. The innovator must be prepared for an open and frank discussion about risk. As onerous as the process is, there is no way around regulatory requirements.

Clinical Confirmation. Testing a novel product is both exciting and angst-inducing. Introducing the product to human subjects generates a whole host of new anxieties. My experience has shown that the probability of getting a product right the first time is extremely low. Be prepared for failure, be prepared to

keep trying, and be prepared for the process to take years to accomplish.

There is no easy answer for how to make ideas happen, but that should not discourage physicians from being involved in the innovation cycle. Rather, physicians are in the unique position of using products on a daily basis; they talk with patients and understand their individual hardships and the dilemmas they face; they see the unmet needs. Who is better equipped than physicians

and practitioners in the health care field to generate the next great idea that will have an impact on patients' lives? ■

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Financing New Companies: A Venture Capital Perspective

Investors seek smart ideas and strong teams of people who inspire confidence.

BY CHARLES M. WARDEN, MBA



Finding the “next big thing” to the benefit of large numbers of patients is the ultimate goal of the venture investor. The idea alone is not enough, however. A team of inventors, managers, investors, collaborators, and clinicians must come together over time to advance an idea to success. It is not enough to have a good idea. To be durable, a successful commercial enterprise must be built around the idea to deliver it to the market sustainably. Ultimately, though, venture capital firms have to answer to investors, and so the end result of a financial investment (the eventual return on that investment) is undeniably important.

IDEAS AND PEOPLE

In the health care arena, investors need to see a clear path to how an idea can be transformed into a stand-alone company that produces a product or service that is beneficial enough to patients to warrant payment for that product. Venture capital firms in particular are purchasing a stake in a young company with the idea that once the product is developed and the company matured, its stake, if not the entire company, will be sold.

The breakthrough potential of an idea is certainly important, but it is not the only criterion considered. There must be a sizable enough market to warrant investment; ideas that may change the world for a few people are relevant, but ideas that can have an impact on large numbers of patients have greater impact and likely make

“In the health care arena, investors need to see a clear path to how an idea can be transformed into a stand-alone company.”

for more attractive investment opportunities. Inherent to that consideration, of course, is whether there is a customer pool waiting for an idea to come to market.

The end-user potential of a concept is one thing, but if there is not a team of people in place who can actualize an idea, it is unlikely to advance. Ideas and companies move through phases where different functional capability may be necessary at one phase versus another.

In the early days, developing a product and putting it through initial testing requires one set of expertise, much of which might be available through consultants and advisors. Later on, when a final version of the product is undergoing clinical trials, a more formal team structure is likely necessary. The good news is that all the forces that make a successful business thrive—managerial leadership, clinical insight, engineering, marketing, finance, and capital, to name a few—do not have to all be in place from the onset. Rather, components can be added along the way as needed. Assembling a good team, just like growing an idea, takes time, careful thought, and patience.

WORKING TOGETHER

From the venture capital perspective, investing in a company is kind of like buying a new house, except that the new house is not designed for single occupancy. Venture money is often just one component of the overall financial health of a company, and so venture capitalists represent just one stakeholder in the entire process. There really should be a sense of teamwork, where all the stakeholders are working together to make a company successful. It is important for the entrepreneur to think carefully about the mix of stakeholders he or she assembles, as they will need to be highly functional as a team over the long term.

CONCLUSION

Investment in early-stage concepts is risky and intimidating. Many worthwhile ideas do not turn out to be viable later on. Yet, venture investors are under pressure to deliver returns to their investors regardless. At the

same time, venture capitalists have a vested interest in ensuring that a company thrives, and so the close working relationship with innovators is ultimately a means to an end where everybody wins. ■

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Financing An Idea: An Innovator's perspective

So you have a good idea. Now what?

BY AMAR SAWHNEY, PhD



In many ways, the move into the role of being an innovator or a leader of a company takes a tremendous leap of faith in both your idea and in yourself. In that regard, it is a move that should not be taken lightly, nor without careful consideration and planning. The innovator would do himself or herself a tremendous service by getting educated about the process before making the leap.

Becoming a successful innovator is by no means easy, and there is no single path or formula. It is a complex topic, and it can take years of study and experience to get it right. Nevertheless, I would like to share some thoughts about things to consider in getting your idea financed, once you have decided to pursue your entrepreneurial dream.

THE TERM SHEET

Assuming that a marketable idea has been established, the most important thing for the innovator to think about is financing, which can come in several forms. Not all ideas need millions of dollars to actualize. Some goods and services

INVESTOR CONSIDERATIONS

- Find out if investors you approach have the capital to make new deals.
- Find out where their target sweet spot is:
 - In what stage(s) of financing are they active?
 - How much are they willing to invest per deal/stage?
 - Are they funding leaders or followers?
- Focus on funds that:
 - Lead the deal
 - Have expertise in ophthalmology
 - Have deep pockets for the future
 - Can pull together a syndicate of investors
- Talk to other entrepreneurs to evaluate the reputation of potential investors:
 - What is their decision-making process?
 - Which partners to approach

can be funded through personal means, money from friends and/or family, and grants from the government and charitable foundations.

If the idea for a product or service and the company surrounding it continue to grow or need significant capital investment, venture capital firms represent a potentially lucrative source of funding dollars. Venture capital firms are a burgeoning source of investment capital in health care and especially in ophthalmic research. As a general principle, they like to know that the innovator has sunk his or her own money into the company, but the innovator should be careful so as not to lose everything if the venture does not pan out.

Not all venture capital firms are created equal, and it is worth doing some intensive due diligence to select the right financing partner. Some important questions to consider: Do they have money in their fund, and how much? What is their specialty? Do they have a track record of success? It may be wise to talk with other entrepreneurs to find out the reputation of a venture firm; it is foolhardy to simply take the first offer presented.

The agreement between the entrepreneur and a venture capital firm is called a *term sheet*. There are many complex variables of a term sheet, and the entrepreneur would be wise to engage a corporate attorney with relevant experience to help navigate the process. Regardless, there are some common elements to a term sheet:

Valuation. How is the company valued, and what is the potential future value of the company? In some ways, the entity with the money has the upper hand, but egregious terms set a precedent for a usurious relationship.

Board Participation and Structure. A good board is composed of company insiders and outsiders, investors, and founders working together to make the entire enterprise run smoothly and to great profit. Try and avoid an uneven board or one that balloons to include too many members.

Liquidation Preference. How much money will the investors get out of the company after it is sold before the founder(s) get paid?

Anti-dilution Protection. This basically defines what happens to ownership shares in subsequent rounds of revenue generation; specifically, to what degree are shares devalued if future rounds of financing are done at lower levels of valuation.

Other Rights. There are a host and series of rights, privileges, and covenants defined on the term sheet that can make life very uncomfortable for the founder if they are ignored. So, be diligent, do research, and be prepared to negotiate for your rights.

MAKING IT ALL WORK

Hardships are inevitable with any new venture. The ratio of failures to successes in new ventures is shockingly high. Therefore, establishing and maintaining a strong working

DOs AND DON'Ts

Do

- Raise sufficient funds to reach a meaningful milestone.
- Find a good lawyer—one who is versed in venture financings—to read the fine print.
- Soft sell with a few friendly groups before going wide.
- Clean house.
- Secure all intellectual property, contracts, agreements, financials, and references.
- Be prepared for a 6-month process during which you have to speak to 50 to 75 groups.
- Have two investor candidates (better terms and better valuation), and combine them to get the “best of both worlds.”

Do not

- Fixate only on valuation.
- Stop generating leads until you have a signed term sheet.
- Let competing term sheets collude.

relationship with investors is crucial. That rapport can be undermined by failure to meet promised results. Thus, meeting established milestones, be they financial, clinical, or developmental, is the best defense.

During the initial negotiation, investors will likely attempt to establish some safeguards against failure. They may insist upon ‘pay-to-play’ provisions that, when enacted, require initial investors to contribute additional dollars or else lose shares. Or, they may stipulate a “cramdown,” or a dilution of the innovator’s shares, thereby affording greater ownership share and investment return to the investor. The bottom line is that the smart innovator has a plan for success and executes that plan with vigor, but the smart innovator also protects himself or herself in case of failure. This is where good legal counsel proves itself invaluable.

The relationship with the investor is critically important, and that is why it is a good idea to soft sell the idea to a select group before reaching out to a wider pool of investors. That said, the innovator should be prepared to reach out to 50 to 75 potential sources of funding capital, and he or she should not stop generating leads until the term sheet is signed.

Being an innovator is not easy, but it can be extremely rewarding, both financially and personally. There is no singular path to success, but all success stories appear to have some common elements: flexible leadership, hard work, careful planning, and relentless execution. In short, always aim for success, but have a plan to survive failure. ■

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Learning From Failure

How one reacts in hard times often sets the tone for ultimate success.

BY WILLIAM J. LINK, PhD



Conventional wisdom states that we tend to learn our most valuable lessons from our mistakes rather than our successes. I have enjoyed a number of great wins in my career of bringing new ideas and products to market, but I have improved at what I do because of situations that did not work out. Many lessons are learned from failure, the first one being humility.

TEAM BUILDING

I have been involved in the commercialization of close to 70 products throughout my career, as well as a number of products that have failed. Most projects, even those that have ultimately been huge financial wins, have had periods of trials and tribulations.

Often, what makes a project successful is the team that surrounds it. Although a great team can surely make lemonade out of good technology, an average team can also make lemons out of a great technology. What makes a team successful? Or, what are the qualities of a team that can buoy a sinking project? Tenacity is one trait; a “don’t quit, won’t quit” attitude is essential. Perhaps most important, though, is establishing a culture of transparency and open debate that fosters forward progress.

HIGH RISK, HIGH REWARD

Good companies do not rest on their laurels, and they refuse to stop working until the job is done correctly. True success is neither short term nor a one-time occurrence; in terms of commercial health care products, true success is achieved when the product is profitable, doctors and users are satisfied with its performance, and patients are benefitting from it.

Ensuring the long-term viability of an innovation requires time, patience, and money. A company does not necessarily have to be large in size to achieve greatness;

“Good companies do not rest on their laurels, and they refuse to stop working until the job is done correctly.”

small companies sometimes have advantages. Large companies with competing research interests may re-allocate resources at the first hint of trouble, whereas small operations predicated on a single idea have no choice but to stay the course.

Small companies also tend to be more flexible than larger operations. The lack of infrastructural resources can be a detriment, however, especially in today’s regulatory environment that often forces a company to begin its new idea development outside the United States. The average time from concept to market is about 10 years in the United States, longer than a smaller operation may be able to sustain financially.

Good businesses can anticipate risks ahead of time and prepare for the unpredictable. Organizations must be proactive and creative in dealing with hardships, which requires a financial and emotional commitment from individuals. There is a lot at stake in the innovation cycle, and failure to perform has the potential to affect people’s lives. Many people stand to benefit from a new company’s success. ■

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