Choosing and Planning Your Exit Strategy

Across our prior columns, we have been exploring business and product development-related issues specifically revolving around entrepreneurs and start-up initiatives. In this installment, we will review considerations surrounding exit strategy for new entrepreneurs.

Your exit strategy impacts many aspects of your business plan and approach, and not taking this important fact into consideration will certainly impact your future options. It is not a matter of whether you will exit, but of when and how.

The exit strategy needs the consensus of partners and investors as well, which could be a rate-limiting step. You need everyone to agree on the best way forward—whether a sale, an acquisition, a license, partnerships or going it alone—and that it is in the interest of everyone who has put either money or sweat equity in the company. We have all big hopes and, in some cases, we have to make a realistic assessment of any exit opportunities being presented, balanced with the actual chances for a larger, but less likely, future potential exit.

Different People, Different Strategies

For example, if you suggest to your key partners or employees that you have no plans to exit the company in the near term, but then sell within two years of founding it, they are likely to be dissatisfied and could disrupt the sale. Or if you want to sell the business in five years but your operating partners want to own and manage it for the next 10, then you will have a problem. The sooner you start planning your scenarios, the more rewarding the eventual exit is likely to be. Alas that is not a one-size-fits-all formula. The range of exit scenarios includes taking the company public through an initial public offering; selling the company to a strategic partner; licensing of individual products; or another transaction like private equity. Acquisition is an attractive strategy to many entrepreneurs since another company purchases the business for either cash or stock, or a combination of both. The only issues are whether the acquiring company will retain the old management team and/or make substantial changes in the acquired company’s operations and staff.

Different people start companies for different reasons, and that can influence their exit strategy. Initially everything looks great as the founder(s) own a 100 percent of the business. If they take on investment over time from VCs, angels or individuals, they usually give up a portion of the company or shares. Of course, those shareholders will have a say in any potential exit strategy. A word of caution: Choose them carefully, and ensure partners you will be taking on share overall strategic view for the company and timing of exit. As

Eric Young, general partner of Canaan Partners, a global venture capital firm that has invested in more than 250 companies in the past two decades said: “Some people want to change the world and that’s why they start a company, and some people just don’t want to work for anyone else.”

Nonetheless, a time will come when you have to make a decision to exit either because you need operating cash or because you have reached a point where you will have created enough value and enough buzz to be acquired. Or you may be faced with a situation to exit to return the invested capital, or a positive respectable double return, versus going the distance for larger returns however with higher risk.

Part of your decision will depend on whether or not you want to continue to manage your business. In an IPO this may not be an issue as you and your team generally play much the same roles before and after the transaction; however, in an acquisition, the acquiring company may replace you and your team with their own team or you may be playing the same roles but within a new structure. In such a case the old adage of having too many cooks in the kitchen may apply.

As a founder and business owner, I (MJR) can only testify that it is not an easy decision but one that has to be made when it is necessary. It is an excellent solution for companies like mine who were struggling with the fact that the funds that were necessary to move the programs forward were not raised in due time, or due to a lack of interest, or a bad market. So we all want a planned exit but it is not always planned ahead.

Common Scenarios

As we work with early-stage entrepreneurs and companies, we see a few common scenarios that arise in which the full amount of needed funding is not raised, or some other consideration alters the originally planned exit pathway:

1. The story was too long. Having a tight story is the key. Addressing this mainly to new entrepreneurs, we see many companies that have a slide deck that surpasses 30 or 40 slides and they get into too much detail for an introductory meeting. Have a different level of presentations for the introductory (many times non-confidential) versus the follow-up discussions held under a confidentiality agreement. Advice to readers: Ultimately, the point of your first meeting is not to close a deal but to get a second meeting.

2. The story is incomplete. Make sure the slide deck hits the key areas: product profile; how it fills an unmet need; market and product landscape; differentiating factors of the product; development plan; regulatory plan; budget; risks and how they’re being addressed; operational plan (internal and leveraging external resources like contract research organizations); and a model to project sales.

On the clinical side you’ll need: FDA-acceptable endpoints; what builds value and informs Phase III designs; competing trials (e.g., with orphan indications, how many trials of the same indication across competing products can the field take at once?); whether the proof of concept will be with non-FDA-acceptable endpoints, such as structural endpoints in some retinal diseases; how you’ll build the story that informs decision making; and to make sure to accurately represent in your plan what is acceptable for Phase III. We frequently see initial slide decks talk about proof-of-concept endpoints that can be accepted for Phase III, when in fact they can’t from a regulatory perspective. Have your facts straight and be direct about the proof-of-concept approach. Otherwise it may lose credibility. Of course,
and because they’re not attached to a mini-retinas swim around in the dish, sizes similar to uncut organoids. These surviving organoids to grow to reach protocols. A trisection also spurs the increasing the yield of retinal organoids which look like little half moons, three pieces at an early stage of eye organoid grown from stem cells into retina protocol involves cutting a retina-minded to just go and study what they are not developmentally or stem cell-els,” says Dr. Karl. “By working out the barness that we need for people with-yet reached that tipping point of ro-sisting organoid systems, we have not (continued from page 5)

“Even with our new additions to existing organoid systems, we have not yet reached that tipping point of robustness that we need for people without the expertise to grow these models,” says Dr. Karl. “By working out the details, we also hope to help those who are not developmentally or stem cell-minded to just go and study what they want.”

The Karl Lab’s change to the mini-retina protocol involves cutting a retina organoid grown from stem cells into three pieces at an early stage of eye development. Each of these pieces, which look like little half moons, eventually grows into the full suite of cells found in the retina, thereby increasing the yield of retinal organoids up to fourfold compared to previous protocols. A trisection also spurs the surviving organoids to grow to reach sizes similar to uncut organoids. These mini-retinas swim around in the dish and because they’re not attached to a surface, better reflect the structure of retinal tissue during development.

The next objective is to make his 3-D “mini-retinas” even more complex, perhaps by bringing in blood vessels, as well as to use the organoids to study regeneration and the function of different neural cell types—specifically, from the human retina.

Preventing Neuropathy in KPro Cases

Researchers from Massachusetts Eye and Ear/Harvard Medical School have identified inflammatory factors that cause optic neuropathy following implantation of a keratoprosthesis—similar to what glaucoma patients experience, without the rise of pressure in the eye—and have shown that blocking one of those factors, tumor necrosis factor alpha, successfully halts the development of optic nerve damage in a mouse model. Their findings, published online in Investigative Ophthalmology and Visual Science, shed light on the underlying process responsible for optic neuropathy in KPro patients and also suggest a new pathway for preventing optic nerve damage in patients who receive the KPro implant.

“We used a mouse model of the KPro to, first of all, identify the inflammatory factors that cause damage to the eye, and then we also quantified the amount of nerve cell death in the back of the eye that mediates the optic neuropathy; and, lastly, we looked at blocking these factors with antibodies,” said Reza Dana, MD, MSc, MPH, director of the Cornea and Refractive Surgery Service at Massachusetts Eye and Ear and the Claes H. Dohlman Professor of Ophthalmology at Harvard Medical School. “We found that the KPro leads to high levels of TNFα, and that by blocking TNFα, we can prevent the nerve damage.”