Ophthalmology MANAGEMENT
Article

Partnering for innovation

The entrepreneurial ophthalmologist must consider key factors when partnering with VC firms.

By Jeffry Weinhuff October 1, 2018

"**S**trategic acquirers" in the ophthalmic industry have a long history of purchasing or licensing innovative companies that often result from the partnership of ophthalmologists and venture capitalists (VCs). These ophthalmic "Strategics" — which include companies like Alcon, Allergan, Bausch + Lomb, Johnson & Johnson Vision and Zeiss — have almost $1 trillion in market value and have acquired over $17 billion of later-stage ophthalmology companies in the last five years, according to investment research website YCharts. Nearly two-thirds of these acquired companies were backed by venture investors.

This article is intended to help ophthalmologists and inventors learn about the vital roles innovators, VCs and Strategics each play in this system of innovation as well as the critical factors for an entrepreneurial company's success.

WHY OPHTHALMOLOGY?

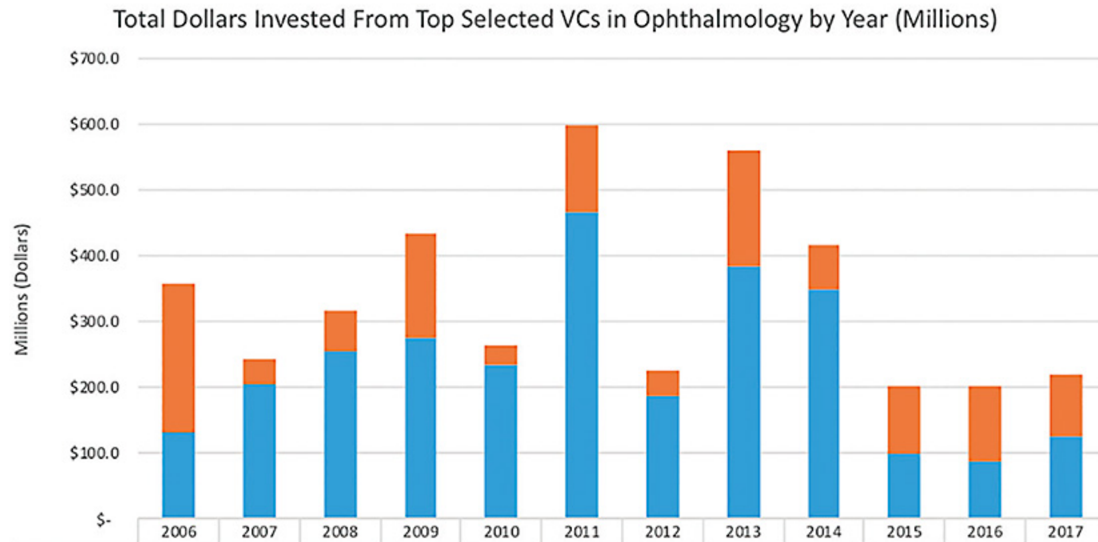
Our industry is a walled garden, uniquely attractive for investment. The global ophthalmology industry is estimated by *MarketScope* at about $42 billion and is growing at a relatively fast clip, about 11% annually. Innovation is highly prized by Strategics, which are always looking to improve their services and gain a competitive edge in the market. Major innovations in ophthalmology have usually been created by independent entrepreneurial companies. The ophthalmology community works together to foster innovation, as highlighted by Brent Saunders, CEO of Allergan, during an Ophthalmology Innovation Summit interview in November, 2017: "The use of technologies, the innovators … the venture capital guys … the big company guys, the small company folks … everyone is trying to work together to solve problems to figure out where is the next innovation, where should we invest to help patients, what new promising treatments, products, diagnostics and technologies ... are going to help people."

Ophthalmology investing is not for the faint of heart. Major hurdles include FDA approval pathways, clinical trials, intellectual property issues, reimbursement issues, market assessments, strategic fit and commercial launch. In addition, an entrepreneurial company team must address all of these aspects while advancing their technology. Most non-life science investors find the skill set quite challenging compared to tech investing, which features more wide-open access and lack of regulatory risk. It is no wonder that Strategics are interested in acquiring companies that have de-risked their products at attractive prices. In the last five years, more than 22 companies have been acquired at aggregate values in excess of $250 million each. However, even with a handsome prize for success, the challenge is daunting.

CHANGING INVESTOR LANDSCAPE

In 2006, more than 20 life science venture firms were investing in devices and drugs for ophthalmology. By 2011, annual investment in ophthalmology peaked at $600 million, according to CB Insights data. Many were investing in competing early-stage startups, all addressing the same perceived indication. Valuations increased, timeframes for approval seemed to extend forever and the resultant returns were unappealing, particularly in device investing. Intelligent investors concluded they might have better risk/reward propositions elsewhere.

Now, fewer VC firms are active in the industry; those remaining include Clarus, Delphi, Flying L, InterWest and Visionary. Certain larger, broadly focused health care funds also participate in ophthalmology pharma or very late-stage device investing, including Deerfield, HIG, Longitude and Versant. In 2017, total funding levels shrunk to $220 million, according to data from CB Insights, a company that analyzes corporate financial information (**Figure 1**).



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Pharma Deals	$226.6	$36.0	$61.0	$160.3	$30.0	$133.1	$36.6	$176.4	$67.0	$101.0	$116.0	$95.7
Device Deals	$130.6	$206.0	$255.2	$274.1	$235.1	$464.8	$187.6	$384.5	$350.0	$100.0	$86.2	$125.2

Figure 1. Data gathered from CB Insights for select leading VC firms investing in ophthalmology.

The reduction of funding for devices has been particularly acute, with 2017 ophthalmology device funding declining to about $125 million from the 2011 peak of about $464 million. Pharma funding has remained fairly stable in the neighborhood of $100 million annually. Funding is still available for deals with attractive technology and teams, but investors are very selective and innovators need to ensure they have a comprehensive approach to building a business and sharing their vision with investors.

VC'S ROLE AND APPROACH

VC firms enable entrepreneur and inventor team efforts. VC firms provide capital, advice and industry resources to help the team execute its business plan and strategy. VCs remain in close touch with the portfolio needs of the strategic community.

Rarely do VCs create an idea from whole cloth and build a company on their own. Most successful, innovative companies are comprised of teams, including an inventor/ophthalmologist, proven business executives and engineers and scientists collectively capable of carrying out a sophisticated plan of creating and proving a new product. VC investors typically assist in this effort as active investors, but day-to-day responsibility for conceiving and executing the plan business plan rests with the team.

IMPACT OF OPHTHALMOLOGISTS ON VC

Key Opinion Leaders (KOLs) are important and influential in our industry. These ophthalmologists play an active role in helping emerging companies establish and refine their approach. A number of them drive their own companies as inventors and executives, including Ron Kurtz, MD, Richard Lindstrom, MD, Eugene de Juan, MD, and Kerry Solomon, MD

More typically, company teams and VCs recruit KOLs with relevant experience to serve on medical and scientific advisory boards. The board members provide advice on how a potential product will integrate into a practice, including factors such as clinical utility, regulatory strategy, scientific issues, market approach and pricing. If the companies are successful in achieving FDA approval, KOLs are found on podiums at meetings explaining to MDs how the new product may fit into clinical practice.

In ophthalmology, it is impossible to overstate how important it is to have the right KOL advisors for a new technology. Not only do they influence the right approach to build a drug or device, but their opinions are also valued by VC investors and Strategics when considering an investment or company purchase. For instance, 100% of the recent Visionary Ventures portfolio companies were referred by members of its 43-member KOL investor group, and more than 20% of those companies were created by those KOLs. Such a well-informed approach makes investment less risky for emerging companies and their VC partners.

HOW TO APPROACH BUILDING A COMPANY

To be successful and attract the needed capital, the ophthalmologist/inventor should address the following:

1. **Large unmet market need.** With our regulatory environment, it takes years of effort to successfully create a product that will make a meaningful impact. Make sure that the new approach is a significant improvement over the standard of care or addresses a completely unmet need. Think about where the product fits into existing strategic product portfolios.
2. **Create a team capable of executing the strategy.** Strong companies typically pair inventors, technical professionals and experienced business executives for successful outcomes. Look for executives with a proven track record in a related field, and take a hard look at the chemistry of the team. If your gut tells you it is wrong, keep looking for partners with whom you can spend years.
3. **Know your IP.** Intellectual property is an important factor in considering whether to spend time on a project. Find a reliable IP law firm and have it review the field. If you decide to go forward, you will need your law firm to provide a Freedom to Operate opinion to potential investors and acquirers. Without strong IP, you cannot protect your idea.
4. **Know your regulatory pathway.** Your approval pathway will determine how much time and capital you will need. Proper planning is important, and several well-known, ophthalmology-focused organizations, such as Camargo, ClinReg and ORA, can help. A good regulatory consultant speaks the FDA language and can smooth your route.
5. **Consider reimbursement or cash pay early.** A good idea only becomes a company if it can successfully commercialize. Work with reimbursement consultants early in development to see where you fit in existing codes or how to develop a cash-pay strategy. Trying to get a new code is a very long-term pathway. Understanding reimbursement makes you much more valuable to a potential partner.

6. **Understand your timeline.** Planning your objectives on a timeline makes your approach concrete and financeable. Take responsibility for setting goals, and understand fallbacks.
7. **Find your KOL team early.** Many KOLs are excited to help create a useful drug or device. Identify appropriate KOL partners by reviewing articles or podium presentations in related fields. They will typically receive a small amount of options and cash reimbursement for time spent on company business. This can be your most productive use of capital and equity. Experienced KOLs guide you through the development process, introduce you to VC investors and help you position your company in the eyes of the ophthalmic community.
8. **Find your early money from existing relationships.** Most initial capital will come from your team, family and friends. Non-institutional investors or affluent individual “angel investors” are also useful for early rounds. Often, a convertible note structure allows you to raise money without having to debate valuation with these investors. When a professional venture round is put in place, the early investors convert their notes at a discount to the VC round. In ophthalmology, the VC community now typically focuses on later-stage clinical projects in devices and a bit earlier in pharma projects. This often results in Strategic partnerships before Phase 3 clinical trials.
9. **Look for venture money among VC investors knowledgeable in your space.** All VC firms are not created equal. It seems obvious, but technology VCs will not be comfortable investing in a regulated industry they don’t understand. Focus on VC investors who know ophthalmology and can help you with strategy and required resources, as well as capital. Attend the OIS meetings at AAO, ASCRS and ASRS. The network and support provided by the OIS organizers is uniquely valuable.
10. **Build your company to run for the long term.** Most ophthalmology companies partner with the major Strategics at some point. Simply put, the costs of global marketing and customer support are difficult to bear for a single-product company. The best run companies, especially with medical device products, plan to support themselves independently and prove their technology in the market through a controlled and targeted market launch. Independent companies can also be successful via an IPO with a focused strategy. Examples of this include Glaukos or Aerie.

CONCLUSION

Ophthalmologists drive innovation in our industry. The field is supportive of new companies and approaches, as Strategics are highly interested in innovation from external research and development sources and companies. Now is a great time for ophthalmologists and entrepreneurs to partner with VCs and Strategics to drive innovation. **OM**

About the Author

Jeffry Weinhuff is the managing partner of Visionary, a venture capital firm that invests in promising emerging ophthalmology companies.

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