

dren naturally gaze at even a distant visual target. Based on these two advantages, it is thought that this screening visual acuity test for children could be carried out over a short period of time without difficulty, so that this test may be widely applicable for use in the visual acuity tests of children.

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Qualitative factors underlying the successful investment in new ophthalmic pharmaceutical products in the United States

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Editor,

Because of the recent economic downturn and reduced investment return during the last decade, the risks involved in developing a new pharmaceutical company have grown (Wheatcroft 2010; Fisher 2011). A greater understanding of such factors might provide lessons to the ophthalmic community, which lessen the risk to both investors and the start-ups, and advance the successful development of new medicines to the ultimate benefit of patients.

The purpose of this study was to evaluate factors related to a successful investment exit in start-up pharmaceutical companies in ophthalmology.

The study design was a retrospective, nonpatient-based, observational comparison of start-up companies with new ophthalmic pharmaceutical products. Companies included in this analysis were founded between 1990 and 2005 and located their primary development operations in the United States. The p-value was set at 0.025 because of multiple comparisons in the study. Only publically available data were included. Therefore, financial data were not consistently available for this analysis.

Of the 25 companies included, 5 (20%) were considered sold (exited company or product) and 20 (80%) remained unsold. There was a greater chance of a successful exit in companies doing so before 5 years ($p = 0.0004$). There were four companies that were sold before 5 years: 1 each at 1, 2, 3 and 4 years after being founded, and one company after 5 years (sold after 8 years). Twenty companies remained unsold at the time of our analysis.

Sold companies were at a later stage of development upon exit than unsold companies ($p = 0.02$). Sold companies were at a development phase of Phase II ($n = 2$) and with approval to commercialize ($n = 3$) while unsold companies were at in preclinical ($n = 6$), in Phase II ($n = 10$), Phase III ($n = 3$) and 1 with a licence to commercialize.

However, no significant differences were noted between sold and unsold companies as to product indications ($p = 0.48$); geographic location ($p = 0.46$); whether the chief executive officer (CEO) held this position before in another company ($p = 1.0$), specifically in ophthalmology ($p = 1.0$) or as

an executive/director position within an ophthalmic company ($p = 0.04$); whether the chief scientific officer held this position in a prior company ($p = 1.0$) or specifically in ophthalmology ($p = 0.62$); whether the company created a scientific advisory board ($p = 1.0$); whether the board of directors (BOD) contained at least one member who served on a board with a prior company ($p = 1.0$), or specifically on an ophthalmic BOD ($p = 0.61$); and the number of BOD members ($p = 0.78$), the number of venture capital partners ($p = 0.93$) or the number of BOD members associated with a venture capital partner ($p = 0.25$) (Table 1).

The reason for this low rate of success of exiting was not clear by our results. We speculate that the recent lack of investment capital because of the weaker economy may have contributed to the chance of financial failure (Kaitin & DiMasi 2011; Benjamin & Margulis 2005). Other reasons for not exiting potentially might have resulted from inadequate assessment of the marketplace; poor management; or a miscalculation of the funding required to bring the product to a later phase of development when larger investment groups might provide capital (Gladstone & Gladstone 2004; Collins & Lazier 1992; The Chubby Team 2011). Further, scientific or regulatory-based development issues conceivably might have hindered product development (Stewart et al. 2013).

Our data also may indicate that if a start-up company does not exit within 5 years, the likelihood of success may be diminished. The reasons for this finding are not completely known; however, our data are consistent from the biotech community in general for which most start-up sales are between 1.5 and 7.5 years (Eldon 2012). Further, exited companies were in a later phase of research than unsold companies. In these cases, exited companies may have had more available data giving a purchasing company greater confidence to buy.

This study suggests that capital outlays for start-up ophthalmic pharmaceutical companies may involve financial risk and may tie up investment dollars for an extended time. Factors suggesting a successful exit are few, but a later stage of develop-

Table 1. Personnel and corporate information.

	Companies missing info	Sold* N = 5	Unsold* N = 20	p-value
CEOs that were prior CEOs		2/3	7/13	1.0
CEOs that were prior CEOs in ophthalmology		0/5	2/18	1.0
CEOs that were prior executive/director in ophthalmology		4/1	5/15	0.04
Scientific advisory board	1	3/2	13/6	1.0
CSO/R + Ds that were prior CSO/R + Ds	1	2/3	9/10	1.0
CSO/R + Ds that were prior CSO/R + Ds in ophthalmology	2	1/4	7/11	0.62
BOD members that were prior BOD members	3	4/1	15/2	1.0
BOD members that were prior BOD members in ophthalmology	3	2/3	11/6	0.61
Average number of BODs	3	7.0	7.6	0.78
Average number of BODs in VC	4	3.8	2.6	0.25
Average number of VC partners/company	5	3.4	3.3	0.93

CEO = chief executive officer; CSO = chief scientific officer; R + D = research and development; BOD = board of directors; VC = venture capital.

If any BOD member had prior ophthalmic experience, it reflected a positive result for the company as a whole.

* Positive responses/negative responses.

ment and a product sale before 5 years may be important.

As an initial evaluation of start-ups in ophthalmology, this study is limited in several ways. Our study was not prospective, and it could not provide financial data. Further, our study could not address drivers governing a sale on an individual company basis. These factors might include among others: the results of Phase II data and the market issues surrounding individual indications (i.e. the availability of generics, brand competition and FDA requirements). Future research should provide greater clarity on the issues confronting start-ups and ways the ophthalmic community might assist them.

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Editor,

We would like to present a new technique of preparation of donor for endothelial keratoplasty (EK), the femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK). The challenge today is to find a technique of EK reproducible, automatized, giving the smoothest stromal interface of donor to obtain the best visual post-operative recovery (Price & Price 2006).

We used scanning electron microscopy (SEM) to compare the smoothness