The eyes have it, or at least that is what NicOx now believes with its recently announced migration into the world of ophthalmology. Within the last eight days NicOx has announced positive phase II results from its glaucoma drug BOL-303259 and the acquisition of private UK eye care group Altacor, two events that have firmly repositioned the French group and helped double its share price, to €4.16.

They have also helped distance NicOx from the failure of its vaunted pain drug naproxcinod (NicOx gets the bad news on naproxcinod, July 22, 2010). Speaking to EP Vantage Michele Garufi, NicOx chief executive, says the acquisition is the “the first step” of many in building a medium sized ophthalmology company from scratch with reach in both Europe and the US.

“The aging population providing an increased focus on vision, the underdiagnosis of ophthalmology diseases, and the possibility of repurposing drugs not used in ophthalmology in eye care, are all reasons that make this a very attractive market,” Mr Garufi explains.

Market opportunity

The increasing attractiveness of the eye care market can be seen in recent acquisitions in the space, including Sanofi’s takeout of Fovea for $128m upfront and more recently Merck & Co’s $430m purchase of Inspire Pharmaceuticals.

While Mr Garufi says NicOx would have moved into eye care regardless of the success or failure of BOL-303259, it would have been a much harder sell to investors. Additionally, the clinical win from BOL-303259, which showed very strong efficacy, was probably the last chance for NicOx’s nitric-oxide donating platform to deliver the goods before being written off by the markets.

Some observers had speculated that the technology was more likely to be more effective in a closed system like the eye rather than being used systemically as in the case of naproxcinod.

Proceeding with caution

Certainly Altacor looks like a low-risk starting point to exercise the new strategy. The company already has five products on the market dealing with mild to severe dry eye. All are housed under the group’s Clinitas franchise and include both over-the-counter and prescription drugs. Last year, Altacor had sales of about £660,000 ($1.04m).

The UK company also has ALT 005, a phase III pre-operative antiseptic, which is partnered with an undisclosed US speciality pharma company. A second phase III study is planned for later this year and filings in both the US and Europe are expected by the end of 2012.

Despite having more than €93m ($123m) in cash, which is about to be topped up by a €10m payment from BOL-303259 licensing partners Bausch + Lomb, NicOx is initially only paying £2m ($3.2m) for Altacor. This gives it an 11.8% stake and an option to acquire the rest of the company for £9m either in cash or shares. The decision must be made by May 31 and the deal includes a time sensitive earn-out of up to £8.5m based a number of factors including the filing and US approval of ALT-005.

The next steps

NicOx will be needing as much of its cash as possible if it is to achieve its goal of positioning itself in the global eye care market, which is forecast to have sales of $17.4bn by 2016, according to EvaluatePharma.

“In eye care you don’t have too many medium sized players in Europe and the US. Apart from the big players like Allergan and Alcon you have only ISTA in the US, a $250m revenue stage company, and nothing else from a commercial point of view. So there is an opportunity to create another mid-sized company attracting all the opportunities that cannot be picked up by the big five because they have their own individual projects,” says
Ramping up to be a mid-sized player will involve buying late-stage and marketed products and potentially whole companies in Europe and US, with the emphasis being on product deals in the US, he says. The group is hoping to build enough critical mass with these products to market them in both Europe and the US.

Mr Garufi says there have already been a number of products offered to NicOx. “When we decided to do this and tested the market for opportunity we realised that there were plenty of deals and it reassured us of our decision to move into this area.”

NicOx also has a small family of in-house eye products, including a pre-clinical macular oedema drug that had been put on hold following the failure of naproxcinod, that are now heading back into the clinic.

Integration issues

While the strategy sounds simple enough, the challenge for NicOx is almost certainly going to making progress in a fiercely competitive market in which it has little experience. The company also needs to choose its assets carefully if it is to keep investors, who have vigorously pushed the shares to their highest level in almost two years, on its side.

NicOx has bought in US regulatory and commercialisation expertise in the form of Jerry St Peter, who helped develop the commercial unit of Inspire Pharmaceuticals ahead of its sale to Merck last summer.

The challenge that Mr St Peter and Mr Garufi now have is maintaining the momentum that NicOx has built.