



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Nova Eye Medical

By TIM BOREHAM

ASX code: EYE

Market cap: \$54.2 million

Share price: 28.5 cents

Shares on issue: 190,327,893

Chief executive officer: Tom Spurling

Board: Victor Previn (chair), Mr Spurling, Rahmon Coupe, Mike Southard

Financials (December half 2022): revenue \$8.39 million (up 28%), net loss of \$6.6 million (\$3 million deficit previously).

Identifiable major holders: Australian Ethical 19%, Jancay Capital 7%, Sedico Pty Ltd (Victor Previn) 5%.

On his second CEO stint at the Adelaide-based eye diseases devices house, Tom Spurling sums up his mission statement in simple terms: "We are preserving the most valuable asset in the world - eyesight".

Having just raised \$8 million in a placement, Nova Eye is in a more financially secure position to save glaucoma sufferers from blindness - one eyeball at a time.

Nova Eye is also about to mount a concerted push into the US market, having won US Food and Drug Administration (FDA) assent for Itrack Advance, a tweaked version of its Itrack catheter device for flushing out the eye.

Commercialized in 2008, Itrack was the pioneering device canaloplasty, a non-penetrating eye canal procedure to reduce the intraocular eye pressure that causes glaucoma.

Indeed, Mr Spurling describes glaucoma as “failure of the plumbing in the eye” (see below).

Itrack has been used in 120,000 surgeries to date.

Nova Eye also has a second string to its bow, a device in development to tackle the equally debilitating age-related macular oedema.

Both conditions are leading causes of blindness.

Eye see they've changed their name

Nova Eye was formed from the ‘remains’ of the ASX-listed Ellex Medical Lasers, which sold off most of its business (lasers and ultrasounds) to French multinational and laser specialist Lumibird for \$100 million.

In April 2020, Ellex shareholders voted overwhelmingly in favor of the deal, which resulted in Ellex distributing \$60 million to shareholders.

The Australian Competition and Consumer Commission launched a public review, but in the end waved the acquisition through.

The sale also includes three of the group’s biggest earning products - lasers used in the treatments of glaucoma, cataracts and diabetic eye disease.

These products accounted for about 80 percent of Ellex’s sales, but the offer of a \$100 million for the subdivision “was bigger than then market cap for the whole company”.

On completion of the deal, Ellex then changed its name to the downsized Nova Eye.

At the time, chair Victor Previn said Nova Eye would focus on the Itrack business and developing the 2RT (retinal rejuvenation therapy) age-related macular degeneration tool.

Mr Spurling joined (or effectively re-joined) the company in April 2021 as an executive, having previously headed Ellex between 2011 and 2019.

He was anointed to the top job in August 2021. Mr Spurling was also a director of the Adelaide-based green energy innovator Sparc Technologies but resigned in March 2022.

Nova Eye retains a research and development and manufacturing base in Adelaide. But most of company's business is in the US, where it has a direct sales team and a manufacturing facility in Fremont, San Francisco.

In Germany, the company sells directly to eye doctors, while elsewhere in Europe the company avails of distributors.

In China - an attractive market because of the expansive and ageing population - the company uses a well-established distributor. "There, we are relatively small but growing fast," Mr Spurling says.

What's the problem?

The ocular irrigation system at the front of the eye circulates nutrients, but with time and age - typically 40 years and over - blockages occur.

The optic nerve is crushed, the pressure builds and eventually patients lose their sight.

"It's painless and asymptomatic and the first sign is the loss of peripheral vision," Mr Spurling says.

In case you're wondering, that's why optometrists do the mildly uncomfortable 'air puff' eye-pressure test.

Mr Spurling says glaucoma typically has been treated with daily drops, which doesn't sound too arduous a task in return for the gift of sight.

Or does it? In reality, adherence is poor with 15 to 25 percent of patients not even renewing a second prescription.

"For someone aged 40 to 50 with a lifespan of another 30 years it's actually quite hard," Mr Spurling says, adding that older patients can have trouble self-administering the drops.

The poor adherence has sparked interest in earlier, minimally invasive surgical intervention and that's where Nova Eye comes into sight.

Just like clearing the gutters

Nova Eye report renewed interest in canaloplasty as part of the "glaucoma treatment armamentarium".

Itrack is used to perform a 360-degree clean-out of Schlemm's canal, the eye's natural ocular drainage system.

The FDA approved Itrack Advance on April 1, 2023.

Looking somewhat like a portable reading light, the devices are a catheter consisting of a light, a pipe and a wire.

The pencil-like handpiece enables surgeons to use their fingers to move the catheter through the canal.

This optical waterway is then flushed out with bio-compatible fluid.

“It’s like clearing the leaves from you gutter and then flushing with a hose,” Mr Spurling says.

“Nothing is left behind.”

Better dr-eye-vability

The key difference between the devices is ‘driveability’.

The original Itrack required the surgeon to navigate the micro-catheter around the canal with forceps, which Mr Spurling likens to pushing a “wet slippery noodle”.

Itrack Advance incorporates a handpiece, enabling surgeons to guide the catheter with a thumb or forefinger.

“This design makes it more appealing and available to a wider range of surgeons,” Mr Spurling says.

Currently, the company sells Itrack to around 200 US surgeons but the tweaked device opens up access to about 1,200.

In effect, the extra 1,000 are the surgeons lacking the finesse to chase the “wet slippery noodles”.

In the US, the company has started converting its existing Itrack customers and in April made the first sale among the wider surgeon cohort.

“We have direct evidence of good support for this product,” Mr Spurling says.

Management expects Itrack Advance sales in the US to drive “significant sales during the current and future fiscal years”.

The company is also developing Molteno3, for late stage severe and complex glaucoma.

At 0.4 millimetres wide, Molteno3 is a plate that slides between the tissue planes and adjacent extraocular muscles.

While no part of the Itrack is left in the eye, Molteno3 stays in the peepers.

Targeting cataract surgeons

Beyond glaucoma, there's a broader market of 9,800 cataract surgeons.

Cataract removals are commonplace and Itracks are not directly relevant for the procedure.

But about 20 percent of patients who present for cataract operations also have glaucoma.

"The idea of Itrack is it provides patients with the option of a minimally-invasive surgery at the same time as cataracts to solve their glaucoma," Mr Spurling says.

"This reduces or eliminates the need to take drops every day."

... and AMD

The second string to Nova Eye's bow relates to treating aged-related macular degeneration – AMD - which is more prevalent than glaucoma.

The company is developing Alpha RET, a novel proprietary ophthalmic laser based on so-called 2RT (retinal rejuvenation therapy) platform and the world's first AMD laser therapy.

2RT stabilises the degeneration if caught early enough, but may have to be repeated after five years.

While the device has Conformité Européenne (CE) mark approval, it essentially is in development and subject to a vaunted pivotal trial pitched at US approval.

The company's stated intention is not to use the proceeds from the Itracks to fund a trial, but to tap money from "global participants" interested in backing the trial.

Mr Spurling says the laser has the potential to delay progression of disease from intermediate to late stage and "materially disrupt the AMD treatment paradigm."

In other words: it could be bigger than the Itracks.

Finances and performance

With \$2.63 million of cash in the bank at the end of December 2022, Nova Eye needed to raise some cash.

Announced on March 2, the placement was struck at 18 cents - a 22 percent discount to the prevailing 'undisturbed' price - with sophisticated and professional investors participating.

Already the company's biggest shareholder, Australian Ethical boosted its stake to just below the allowable 19.9 percent.

The directors also chipped in \$270,000.

The funds are earmarked for expanding the rollout of the Itracks in the US, Europe and China.

In the six months to December 31, 2022, the company generated revenue of \$8.39 million, 28 percent higher than the previous corresponding period and mainly from the Itracks.

The loss of \$6.6 million compared to the previous \$3 million deficit.

In the pandemic-affected year to June 2022, the company posted revenue of just under \$13.4 million and lost \$7.5 million.

The company reported a bounce in US Itrack revenues, as surgeons trialing rival devices returned to the fold.

The company is coy about pricing but Mr Spurling says there is a "healthy reimbursement structure" for physicians, hospitals and insurers.

The eye facilities buy the devices and Nova Eye also takes a per-procedure cut of reimbursement.

Over the last year Nova Eye shares have varied between 19 cents (March 7 2023) and 32 cents (December 21 2022). The shares hit a record high of 85 cents in January 2020.

Sizing the rivals

While many healthcare device companies claim to have the market to themselves, Mr Spurling describes the glaucoma landscape as "very competitive".

Naturally, Itrack is superior to its peers.

"Our tech goes around 360 degrees of the canal; our competitors only do 180 degrees in a single pass," Mr Spurling says.

"Our catheter has a light, which gives the doctor a better understanding of where the catheter is in the canal; a surgeon using our competitor products is guessing where it is."

The owner of the Omni device, the Nasdaq-listed Sight Science trades on a market capitalisation of \$US450 million and last year generated \$US45 million in revenue.

"They are only four times bigger than us in revenue but ten times bigger than us in terms of market capitalization," Mr Spurling says.

The private New World Medical markets a device called KDB Glide.

Dr Boreham's diagnosis:

Over time, the age-related macular degeneration business could prove to be bigger and more lucrative than the glaucoma segment.

But it's best to showcase the toys one already has and Mr Spurling notes there are 140 million people with glaucoma in the world. The surgical intervention market is valued at \$US600 million now and growing at 15 percent a year.

Including the drugs, the total glaucoma market is worth \$US6 billion.

"We see a very strong landscape and as one of the top three companies in this space we have a very good opportunity," Mr Spurling says.

"We have a good product in the consumable surgical device market, one of the fastest in ophthalmology and in an absolute sense."

With Itrack advance only just starting to be sold in the US, the company should have a good bead on sales by the end of December.

Early indications are promising, although we're a little wary of the level of competition and the risk of pricing being eroded.

Otherwise, there's potential with this one as far as the eye can see.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort ... that he can find. Hang on, where are my glasses?