

Addressing the Leading Causes of Blindness

Nova Eye Medical Limited (ASX:EYE)

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Business Snapshot



Nova Eye Medical leads the way in interventional treatment solutions for glaucoma and age-related macular degeneration (AMD), **the leading causes of blindness in the developed world.**

Nova Eye Medical, Glaucoma			AlphaRET, AMD	
Strategy	Develop, market and sell comprehensive portfolio of glaucoma consumable surgical devices		Strategy	Commercialise 2RT [®] to technology with partner
Market	Canaloplasty segment of the glaucoma surgical devices market scheduled to grow rapidly 2022-27		Market	Intermediate Age-related Macular Degeneration treatment (iAMD) – market not addressed. Underserved market for retinal disease therapy
Sales	Established infrastructure; direct sales in USA, Germany, Australia; +20 distributors		Sales	Sales program to coincide with partnering
Manufacturing	California, USA and Dunedin, New Zealand		Manufacturing	Adelaide, Australia based contract manufacturing
IP Status	>100 patents issued and pending		IP Status	First mover advantage, >10 patents issued and pending in major markets
Regulatory	Clearance in all key global markets, including USA (FDA)		Regulatory	CE Mark (iAMD and diabetic eye disease) in Europe, Australia, NZ. FDA USA clearance for diabetic eye disease
Reimbursement	Favorable CPT codes (USA)			

Company Overview



Capital Structure	
ASX Code	EYE
Share Price (at 7 September 2023)	\$0.195
Shares on Issue	190 M
Unlisted Options	3.35 M
Market Capitalisation	\$37.16 M
Cash	\$7.54M
Top 20 Shareholders	51%

Shareholders







Others







FY23 Achievements

Strong Financial Results with Record Global Sales



GLAUCOMA, DISEASE OVERVIEW

- Glaucoma is the leading cause of blindness in the developed world.
- Progressive, irreversible eye disease that causes vision loss due to optic nerve damage.
- Elevated intraocular pressure (IOP) is the most significant risk factor for the development of glaucoma.
- There is no cure for glaucoma.
- Topical medications are standard of care but nonadherence is ubiquitous.



iTrack[™]

A D V A N C E

- New iTrack[™] Advance consumable MIGS device is redefining the treatment of glaucoma in its early stages.
- Canaloplasty offers a stent-free, tissue-preserving surgical treatment for glaucoma.
- Enhanced version of our original iTrack[™] microcatheter, which was first brought to market in 2008 and has been used in more than 120,000 procedures globally.

Our Glaucoma opportunity

- The glaucoma consumable surgical devices market is the fastest growing segment of the ophthalmic market.
- The aging global population drives prevalence, representing a significant opportunity for our global business.
- Significant drawbacks associated with medications drives preferential growth of our proprietary consumable surgical devices.



USA Sales Growth Plan, iTrack[™] Advance



Active Accounts, Glaucoma | x200 surgeons Successfully transitioned existing iTrack[™] customer accounts to iTrack[™] Advance during May-June 2023.

Inactive Accounts, Glaucoma | x300 surgeons Reactivation of inactive customer accounts commenced July 2023 and will continue through FY24.



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New Accounts, Glaucoma | **x900**¹ **surgeons** Sales growth via new glaucoma surgeon accounts to commence later in CY23.

New Accounts, Cataract and Comprehensive | x10,000¹ surgeons

Sales growth via new cataract and comprehensive surgeon accounts to commence late in CY23.

"iTrack[™] usage has been primarily by glaucoma specialists. The iTrack[™] Advance will make canaloplasty more accessible to the much broader market of cataract and anterior segment surgeons." **David Lubeck, MD (Chicago, USA)**



USA SALES UPDATE

Following the USA launch of *iTrack*TM *Advance* at the ASCRS meeting in May 2023, total USA sales in the three (3) months to 31 July 2023 were approx. US\$2.2 million, up 32% on the pcp and sales growth since then is on target.

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Solid sales growth in the USA is being experienced and expected to continue, with our targeted program of new customer account acquisition.

3

Sales team expansion has improved geographical coverage and surgeon access since the product launch in the USA.



Material increase in production capacity underway to meet strong sales demand.

Clinical Data Update

Continued to invest in clinical data program to support market development and market access initiatives, including:

iTrack[™] Global Data Registry, hosted in collaboration with the International Glaucoma Surgery Registry (IGSR) and initiated in 2022, currently comprises 20 sites in the USA, Canada, Europe, Asia and Australia and incorporates more than 350 iTrack[™] /iTrack[™] Advance procedures. WCG IRB (approval number) 20200728. See data inset.

MAGIC Europe multi-center, randomized trial comprises six sites in the UK, Italy, Spain and Germany. Patient recruitment targeted for completion in early 2024 calendar year. NCT05786196.

CATALYST multi-center, randomized control trial comprises four sites in Germany. Patient recruitment targeted for completion in early-mid 2024 calendar year. NCT05564091.

Real-World Registry Data

Reinforces Safety and Efficacy of iTrack[™]

Summary of the Real-World Registry so far:

- 367 patients of a broad range of ethnicities.
- 265 patients with primary open-angle glaucoma, 45 patients with angle-closure glaucoma, 62 patients with other forms of glaucoma.
- 226 patients classified as mild to moderate, the balance having advance or severe glaucoma.
- 12 month follow up completed on part of this population.



AlphaRET for RETINAL DISEASE

2RT[®] is a proprietary, world-first nanosecond laser therapy to treat retinal disease including intermediate AMD (iAMD).

2RT[®] works by stimulating the rejuvenation of cells in the retina to initiate a healing response that targets the underlying causes of AMD and other retinal diseases.

- Age-related macular degeneration (AMD) is the leading cause of blindness in industrialised countries in people over the age of 50 years.
- Late-stage Wet AMD market is currently the only market served (drug therapy anti-VEGF injections). Nova Eye estimates that this market is valued at US\$13.6bn annually.
- AlphaRET 2RT[®] is a leading candidate therapy to treat patients with iAMD, earlier in the disease state, preventing late-stage progression. This represents a revolutionary change from the status quo and provides enormous clinical and commercial potential.
- Estimated addressable market is 54 million people equating to US\$600m/year¹ revenue opportunity.
- Commercialisation of 2RT[®] requires funding that exceeds the financial resources currently available to the Company.
- In discussion with potential partners to take a direct equity interest in AlphaRET in exchange for funding.



Overview of AMD Market



Late stage macular degeneration



 Apellis, US\$5.1 bn (NASDAQ: APLS) FDA approval with labelling conditions received 17 Feb 2023. Injections every 6 to 8 weeks. C. US\$20,000 per year for treatment^{(3).}

DISEASE PROGRESSION

- 1) AlphaRET estimate based on LEAD study and MarketScope 2022 Ophthalmic Lasers Report including allowance for 24% of iAMD patients (based in LEAD study) cannot be treated because they have RPD
- 2) Macular Degeneration Foundation Australia recommendation pamphlet "Nutrition for AMD".USA National Eye Institute AREDS/AREDS 2 study concluded that supplements reduces the rate of progression from intermediate AMD to advanced AMD by 17% for cohort 3 3). Australian June 2022 PBS data
- 3) Apellis press release 17 February 2023
- 4) Expenditure on Eylea, Avastin and Lucentis USA Medicare Report Aug 2021

Nova Eye Group Outlook



Sales of new iTrack[™] Advance in the USA are driving and are expected to drive, significant sales growth for the Company's glaucoma surgical device segment in the 2024 financial year and beyond.



Operating expenditure will increase to support the expansion of global sales in the glaucoma surgical device segment, with the improvement in the underlying operating results for the glaucoma surgical segment evident in the second half of 2023 financial year expected to continue during the year ending 30 June 2024.

Continue work towards a transaction with a partner to fund AlphaRET 2RT[®] commercialisation.



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nova-eye.com | 14



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