



NOVAEYE
MEDICAL®

Nova Eye Medical Limited (ASX:EYE)
Annual General Meeting

24 November 2021

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ASX:EYE BUSINESS SNAPSHOT

Nova Eye Medical Limited (ASX:EYE) comprises two business units, Glaucoma and AMD/2RT® – these segments address **the leading causes of blindness in the developed world.**

Nova Eye Medical, Glaucoma	
Strategy	Develop, market and sell comprehensive portfolio of glaucoma consumable surgical devices
FY22 Objectives	Scale for growth; increase market share
Market	Glaucoma Surgical Devices; fast-growing and competitive
Competitive Advantage	Proprietary iTrack™ microcatheter technology and Molteno3®
Sales	Established infrastructure; direct sales in USA, Germany, Australia; +20 distributors
Manufacturing	California, USA and Dunedin, New Zealand
IP Status	>95 patents issued and pending in major markets
Regulatory	Clearance in all key global markets
Reimbursement	Favorable CPT codes with/without cataract surgery (USA)

AlphaRET, AMD	
Strategy	Progress 2RT® to market-ready status
FY22 Objectives	Design multi-centre study; ideally to secure FDA clearance for such study
Market	Intermediate Age-related Macular Degeneration (iAMD) – market not addressed
Competitive Advantage	Proprietary 2RT® technology – first mover advantage
Sales	N/A
Manufacturing	Adelaide, Australia
IP Status	>10 patents issued and pending in major markets
Regulatory	CE Mark (iAMD) in Europe, Australia, NZ and USA for diabetic eye disease
Reimbursement	Pending

GLAUCOMA MARKET STRONG GROWTH THEME

Glaucoma is the leading cause of irreversible blindness and the second leading cause of blindness worldwide. The aging global population is driving glaucoma prevalence and provides a strong platform for business growth.

134.2 million¹

People Worldwide with Glaucoma

US\$610m²

CAGR 17%²

Glaucoma Surgical Device market size and growth rate per annum

US\$6.1bn¹

Total Glaucoma Treatment Market, including pharma, market size per annum

- Advancements in diagnostic and imaging technologies permit earlier diagnosis, which in turn drives demand for interventions which permit earlier treatment
- Medications are considered standard of care but are associated with significant drawbacks i.e., low patient compliance, side effects, financial costs
- Glaucoma surgical device solutions, including devices like iTrack™ and Molteno3®, are increasingly recognized as a highly viable alternative – and is currently the fastest growing segment of the ophthalmic market

¹ Market Scope 2021 Glaucoma Surgical Devices Report

² Market Scope 2021 Glaucoma Surgical Devices Report based on sum of MIGS, Canal Surgery Devices and Glaucoma Tubes and Shunts Markets

A GLAUCOMA OPERATING RESULT

Material improvement in operating result was underpinned by a 25% increase in global sales compared to the pcp, including the addition of Molteno3[®] sales, and a reduction in operating costs.

	A\$'000s (year ended 30 June)			US\$'000s (year ended 30 June) ¹		
	FY20	FY21	Growth	FY20	FY21	Growth
Sales	11,572	13,088	13.1%	7,753	9,684	24.9%
COGS	(4,125)	(4,473)		(2,764)	(3,310)	
Gross Margin	7,447 64%	8,615 66%		4,989 64%	6,375 66%	
Operating Expenditure	(11,501)	(8,514)	-26.0%	(7,706)	(6,300)	-18.2%
EBITDA (loss)	(4,054)	101		(2,716)	75	

1. AUD/USD 0.74 in FY21 and 0.67 in FY20

Key FY21 glaucoma growth and profitability drivers:

- Improved sales and marketing management in the USA, the major market for the Company's glaucoma surgical devices
- Establishment of a direct sales business in Germany in November 2020
- Integration of the Molteno3[®], revenue of Molteno3[®] \$673K (US\$492K) since 1 August 2020
- Sales composition using US\$: USA 68% (pcp 71%), Germany 13% (pcp 11%), China 7% (pcp 8%), ROW 11% (pcp 9%)

RECENT GLAUCOMA MARKET DEVELOPMENTS

GROWING MARKET WITH INCREASED COMPETITION, FAVOURABLE CHANGES TO REIMBURSEMENT

New market entrants has triggered new surgeon interest in canaloplasty.

Proposed reimbursement changes in 2022 favourable to canaloplasty, compared with stent-based MIGS.

The iTrack™ microcatheter with its patented features is the original canaloplasty device.

- Stent-free, tissue sparing intervention
- Reimbursement in USA without (and with) concurrent cataract surgery; stent-based MIGS must be performed with cataract surgery

Competition has increased, but so too has the size of the opportunity.

- New, well-funded market entrants are looking to this theme for growth and new devices have emerged. Surgeon interest has also grown.
- Between 2018 and 2021 Marketscope estimates¹ that the market for canal-based surgery (including canaloplasty) has grown 219%.
- During the same period Marketscope estimates that the market for stent-based MIGS has grown 17%.

In August 2021 USA Centers for Medicare and Medicaid (CMS) announced proposed reductions for 2022 insurance reimbursement.

- Canaloplasty reimbursement for physicians proposed to reduce from c\$950 to c\$740 per procedure.
- Reimbursement for physicians for stent-based surgery proposed to reduce from c\$300 to c\$134 per procedure

1, Marketscope 2018 and 2021 Glaucoma Surgical Devices Reports

FY22 GLAUCOMA SALES UPDATE AND OUTLOOK

GLAUCOMA GROWTH CONTINGENT ON NEXT GEN ITRACK™

GERMANY

Investment in direct business model and sales team expansion in progress to support German launch in Q1CY2022.

USA

Sales team expansion to commence to support USA launch in mid 2022.

- Global sales for the four months ended 31 October 2021 are A\$4.1m. This is growth of 4% compared with PCP in constant currency.
- Sales outside the USA have grown 75% due to investment in German market.
- Sales in the USA have fallen 14% due to increased competition.
- Next generation iTrack™ and is expected to improve growth trajectory in USA and support further accelerated growth in Germany.
 - a. Designed for improved ease of use and improve the competitive position
 - b. Launch delayed due to COVID-19 related global supply chain issues, limited operating room (OR) access and travel restrictions.

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2RT[®], INTERMEDIATE AMD

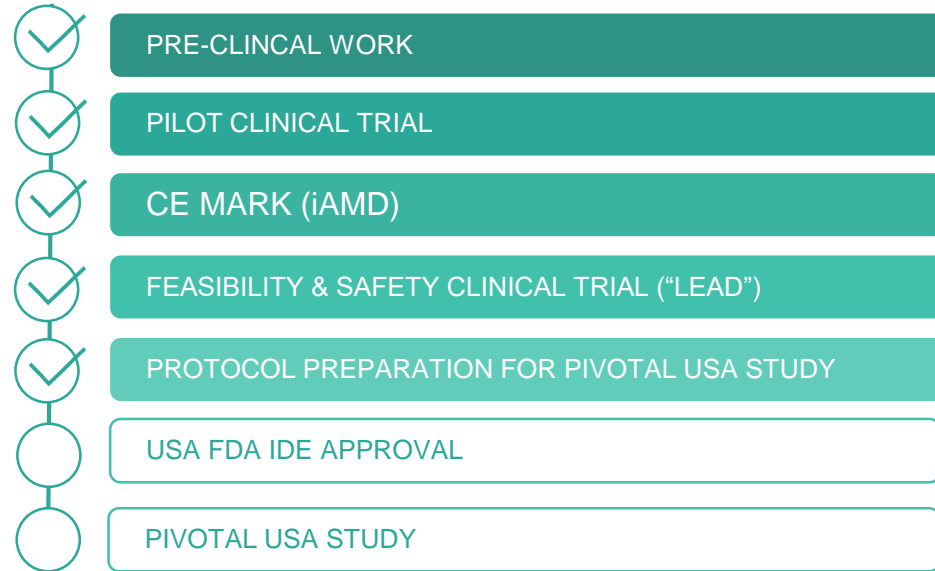
2RT[®] (AlphaRET) is a proprietary, world-first nanosecond laser therapy to treat intermediate AMD (iAMD). While there have been major advances in the treatment of AMD in its late stages (referred to as Wet AMD), there has been little progress in the treatment of AMD in its early stages, such as iAMD.

AlphaRET

2RT® is a subthreshold nano-pulse non-thermal laser and has a method of action unlike any ophthalmic laser in use today

- Investigational Device Exemption (IDE) application with the US Food and Drug Administration (FDA) lodged in early July 2021 to commence a pivotal study
- Response received from FDA requesting further information indicates that they are seeking clarification on our novel method of action. This is a complex area. So far there have been encouraging discussions with FDA but we do not yet have approval. FDA is also interested in procedures for exclusion of patients with reticular pseudodrusen. In addition we are of the view that this may be the first time that the FDA has considered a device for treating intermediate AMD.
- Partnering discussions for the pivotal study and commercialisation work are progressing

ROADMAP PIVOTAL STUDY



AlphaRET

Our proprietary 2RT[®] nanosecond laser therapy is a world-first intervention designed to treat intermediate AMD (iAMD). There is currently no treatment (drugs or devices) for the treatment of iAMD.

2RT[®] MARKET ASSESSMENT

	Population with Early/Intermediate AMD ¹ (millions of people)	Patients who do not meet 2RT [®] treatment criteria ² (millions of people)	Estimated population with Intermediate AMD treatable with 2RT [®] (millions of people)
USA	13.9	-8.6	5.3
Europe	21.6	-13.4	8.2
Other developed nations	8.0	-5.0	3.0
Japan	5.7	-3.5	2.2
China	34.3	-21.3	13.0
LATAM and ROW	61.1	-37.9	23.2
Estimated total addressable market per year	144.6 million		54.9 million

1. *Marketscope 2018 Ophthalmic Laser Report.*

2. *Company estimate based on clinical recommendations from LEAD study.*

AlphaRET

ESTIMATED REVENUE OPPORTUNITY FOR 2RT[®]

Opportunity has corollary with laser vision correction market in early 2000s

Global annual revenues circa US\$600m

- Subject to the completion of a pivotal study or similar to confirm results of the LEAD study (77% reduction in rate of progression to late-stage AMD in select patients with iAMD) the opportunity is very large.
- Business model comprising 1. capital equipment sale and, 2. procedure fee has corollary with laser vision correction technology, which was launched in the US in the early 2000s by start-up companies.
- Estimate of US\$600m⁴ annual revenues based on:
 1. Number of people worldwide with iAMD¹
 2. LEAD protocol: 2x treatments per year²
 3. Procedure fee-based revenue model³
 4. Conservative 10% adoption rate by surgeons globally³

¹Marketscore 2018 Ophthalmic Laser Report. ² Guymer et al "Subthreshold Nano Second Laser Intervention in Age Related Macular Degeneration – The LEAD Randomised Controlled Clinical Trial". ³ AlphaRET estimate. ⁴ Estimate for Europe and other developed nations by Company.

Q&A

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