Addressing the two leading causes of blindness in the developed world

Nova Eye Medical Limited (ASX:EYE)

Managing Director Presentation to Annual General Meeting

17 November 2022

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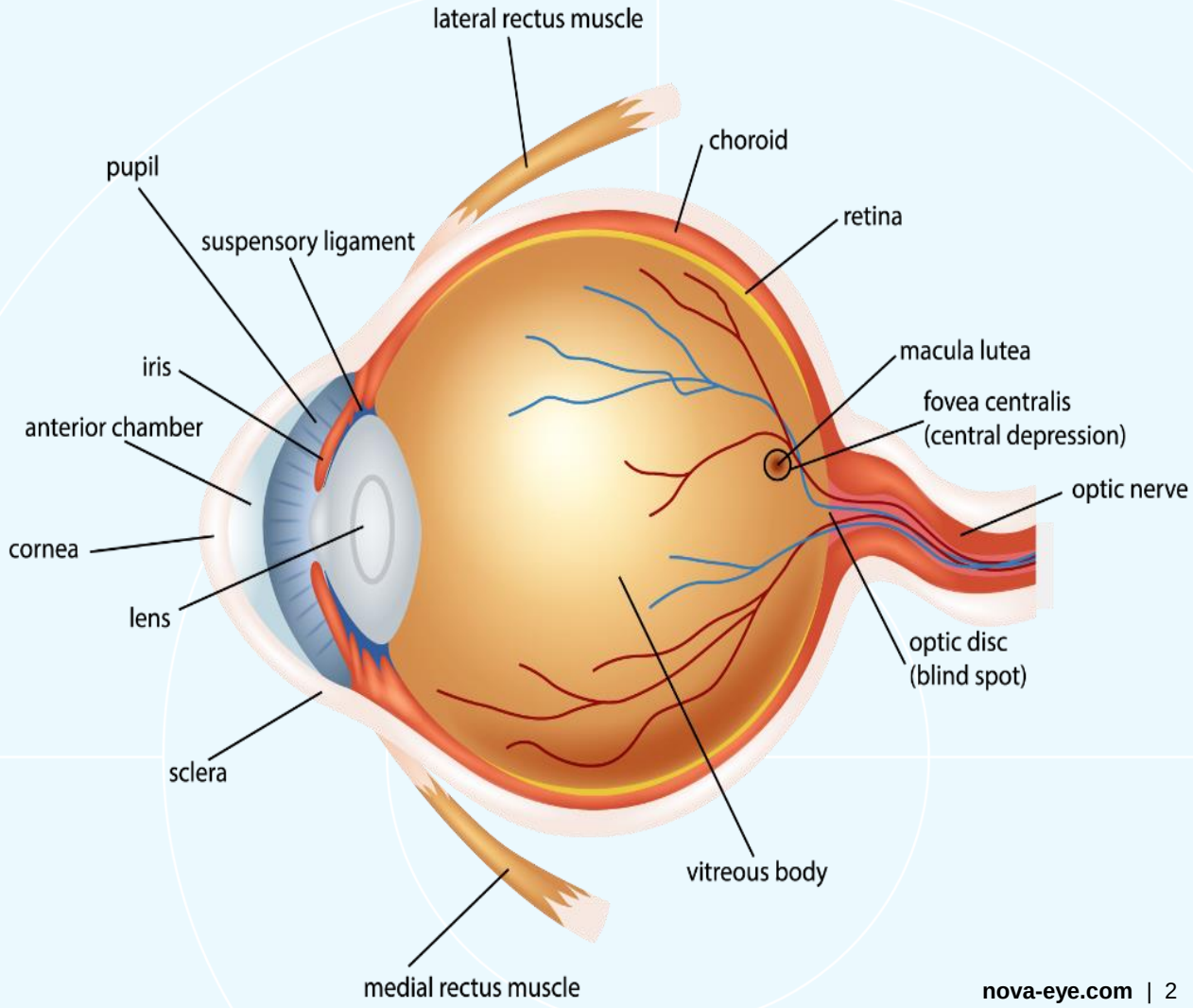


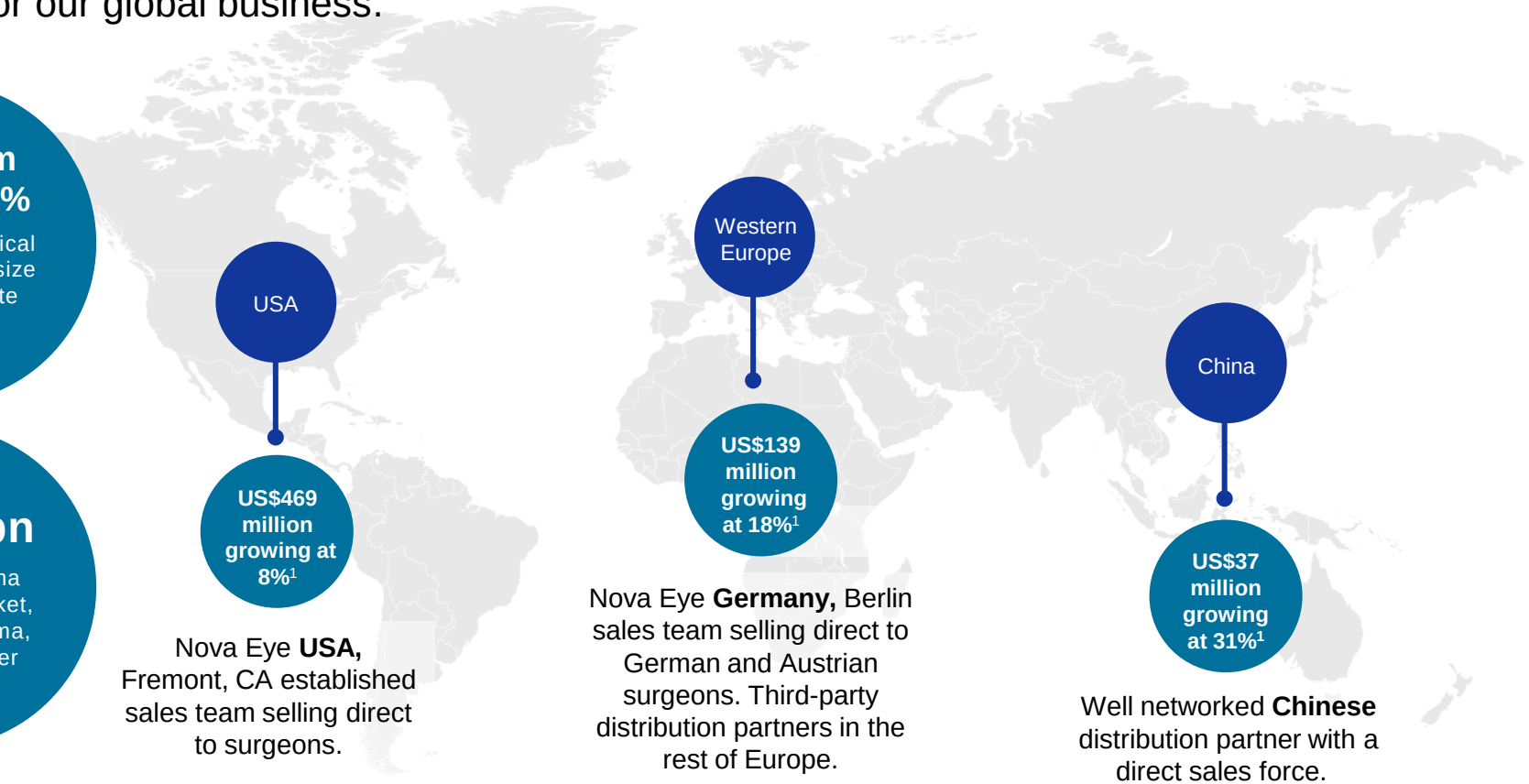
Glaucoma Market Strong Global Growth Theme

Glaucoma is the leading cause of irreversible blindness. The aging global population drives prevalence, representing a significant opportunity for our global business.

144.2 million
people worldwide with Glaucoma

US$667m CAGR 15%
Glaucoma Surgical Device market size and growth rate per annum[1]

US$6.1bn
Total Glaucoma Treatment Market, including pharma, market size per annum



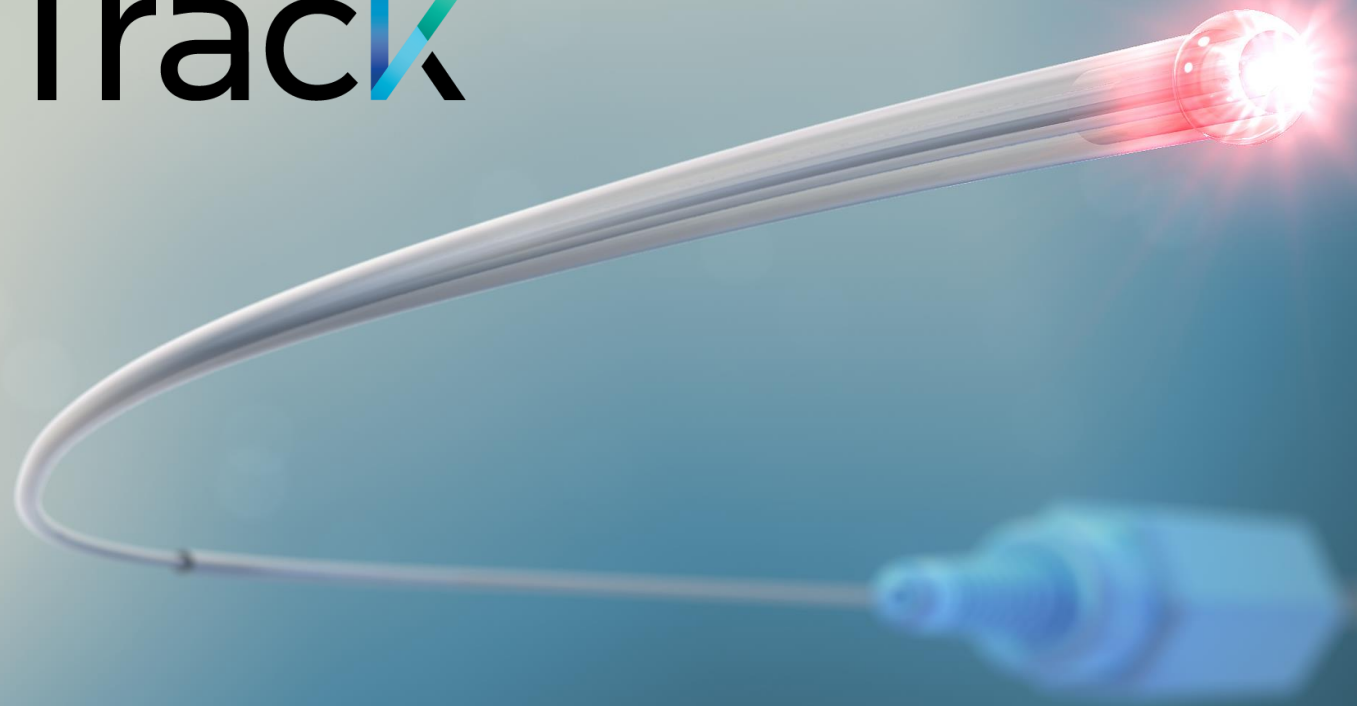
Nova Eye **USA,** Fremont, CA established sales team selling direct to surgeons.

Nova Eye **Germany,** Berlin sales team selling direct to German and Austrian surgeons. Third-party distribution partners in the rest of Europe.

Well networked **Chinese** distribution partner with a direct sales force.

1. *Marketscope 2022 Glaucoma Surgical Devices Reports. Growth in glaucoma surgical devices.*

iTrack™



- Introduced in 2008
- Microcatheter designed for canaloplasty
- Strong body of clinical evidence but technically challenging– requires use of forceps, cutting instruments
- Used predominantly by glaucoma surgeons

iTrack™ ADVANCE

- Launched in markets outside of USA and China in June 2022.
- Combines microcatheter with an easy-to-use handheld injector.
- Designed for all ophthalmic surgery and specialists settings.

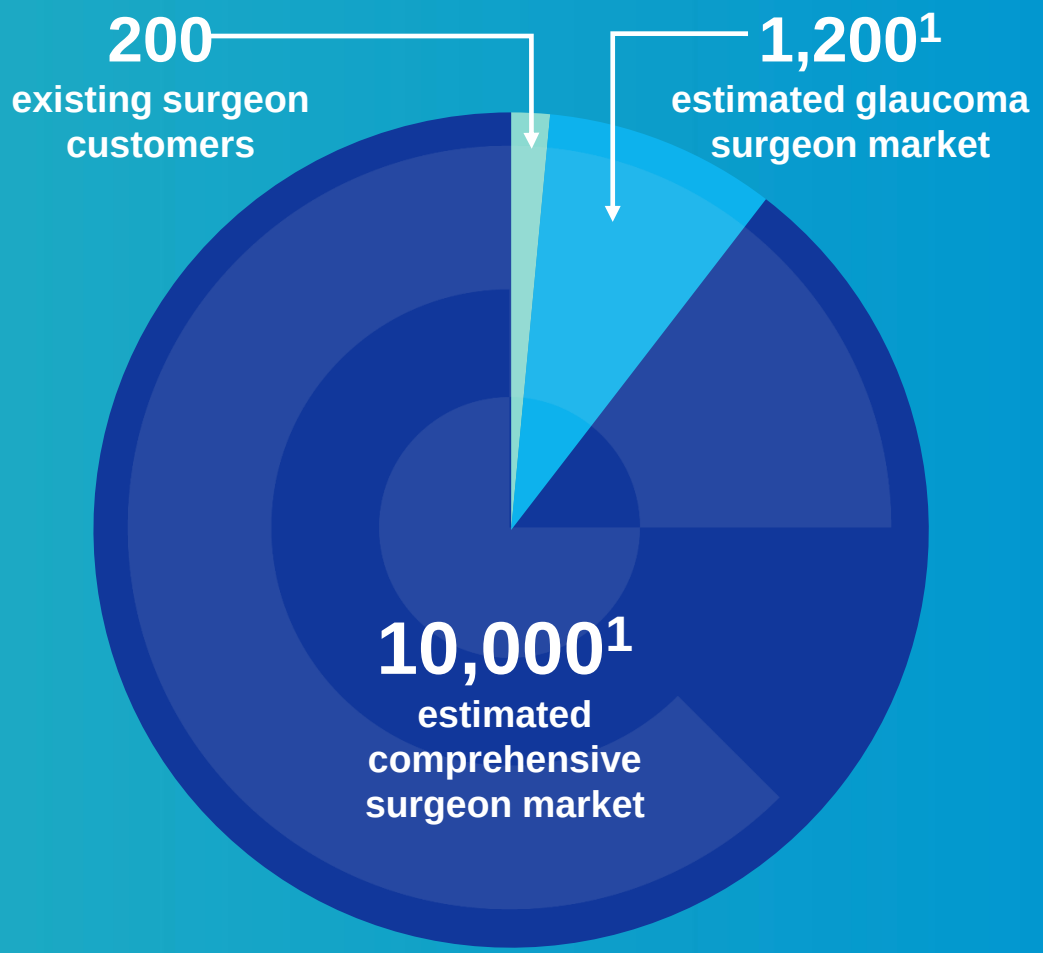
iTrack™ ADVANCE

The new ***iTrack™ Advance*** will appeal to cataract surgeons as well as glaucoma surgeons, expanding the total addressable market by c.10x.

In the USA, iTrack™ is regularly used by approximately 200 specialist glaucoma surgeons. The new *iTrack™ Advance* will appeal to the additional 1,200 glaucoma surgeons and the additional 10,000 comprehensive and cataract surgeons.

"Up to this point in time, iTrack™ usage has been primarily by glaucoma specialists. The recent introduction of iTrack™ Advance will make the canaloplasty procedure more accessible to the much broader market of cataract and anterior segment surgeons. They will now be able to efficiently utilize canaloplasty for the treatment of their patients with glaucoma, in combination with cataract surgery or as a standalone procedure."

David Lubeck. MD (Arbor Centers for EyeCare, Chicago, USA)



1. Nova Eye estimate

FY22 ACHIEVEMENTS

The 2022 financial year saw us expand the depth of our operations in the Glaucoma Surgical Consumable Device segment, achieving a series of commercial, market access, product development and clinical goals.

Achieved production-ready status for the new iTrack™ Advance canaloplasty device despite COVID related engineering and supply chain challenges.

Successfully navigated global regulatory landscape to secure clearance for the iTrack™ Advance in Europe, Canada and Australia.

- Secured European CE Mark
- Lodgement of 510(k) submission to the USA Food and Drug Administration (FDA) (Note: clearance expected in FY23 Q2)

Acquired seminal patents to expand iTrack™ intellectual property coverage

Continued to invest in our peer-to-peer marketing strategy and the accumulation of clinical evidence.

- Launched global data Registry to support real-world clinical evidence.
- Currently 238 patients which demonstrates surgeon support of iTrack™/canaloplasty.

European Market FY22

<u>Financial Performance:</u> Strong German sales during the period, up 24% on the prior period. Today, Germany accounts for 17% of total global sales.

- Positive sales momentum underscored by the launch of *iTrack™ Advance*.
- Comprehensive clinical and surgical training program launched in January 2022, targeting the German glaucoma faculty.
- Endorsement of the glaucoma community is supporting the clinical and commercial roll-out to cataract/comprehensive surgeons, underway since June 2022.

Revenue	**Full year to June 2021** (US$)	**Full year to June 22** (US$)	**Growth**
Germany & Austria	$1,288,019	$1,597,944	24.1%
Rest of Europe (Distributors)	$1,067,666	$1,063,110	-0.4%
Total	**$2,355,686**	**$2,661,054**	

USA Market FY22

<u>Financial Performance</u>: Sales revenue was down 3% on the prior period. This followed a strong rebound during the 6 months to 30 June 2022 in which sales grew 10%, compared with sales in the 6 months to 31 December 2021.

Positive turnaround in sales of our legacy iTrack™ microcatheter is attributed to the return of previous customers after trialling competitor devices, and due to renewed interest in the role of canaloplasty in the glaucoma treatment armamentarium.

	Full year to June 2021 (US $)	Full year to June 22 (US $)	Growth
Revenue	**$6,607,860**	**$6,382,833**	**-3.4%**

	Six months to Dec 21 (US $)	Six months to June 22 (US $)	Growth
Revenue	**$3,037,820**	**$3,345,013**	**10%**

FY22 Glaucoma Operating Result

	A $'000's[1]		US $'000's[1]	
	FY21	FY22	FY21	FY22
Sales	13,088	13,137	9,684	9,534
COGS[2]	(4,473)	(5,123)	(3,310)	(3,703)
Gross Margin	8,615	8,014	6,374	5,791
Gross Margin	**66%**	**61%**	**66%**	**61%**
Operating expenditure[3]	(8,514)	(11,106)[4]	(6,300)	(8,026)
EBITDA/(loss)	**101**	**(3,092)**	**74**	**(2,235)**
Additional investment in new product development and patent acquisition	(2,836)	(5,104)[5]		

Geographic sales composition:

Sales composition using US$: USA 67% (pcp 68%), Western Europe 28% (pcp 24%), China 5% (pcp 7%)

1. *AUD to USD FX rate FY21 = 0.74, AUD to USD FX rate = 0.72*
2. *Cost of good sold negatively impacted by manufacturing set up for iTrack™ Advance. Improvements expected over time.*
3. *FY22 includes reimbursement of costs by US government of A$1.4m for COVID 19 incurred costs (stimulus).*
4. *Investments made in FY22 to support iTrack™ Advance market launch in clinical evidence, Germany sales team, expansion of clinical training, marketing promotions and surgeon engagement. FX impact additional A$0.3m compared with pcp.*
5. *Non recurring costs for development of iTrack™ Advance and for acquisition of seminal patents. Cash at bank at 30 June 2022 of A$8m.*

Sales Update to 31 October 2022

- Following the commercial launch of the new *iTrack™ Advance* in select markets in Europe and Canada in June 2022, revenue up **28% (in constant currency)** to **US$3.82 million** during the 4 months to 31 October 2022 period, compared with the PCP.
- In Australian dollars, sales were A$5.66 million, growth of 38%.
- The result materially exceeded the forecast guidance of US$3.4 million provided earlier this year.
- After adjusting for a delayed shipment of iTrack™ canaloplasty microcatheters to China in July 2022, originally slated to ship in June 2022, the underlying sales increase during the period was **18% in constant currency** at **US$3.51 million** (A$5.22 million, growth of 27%).

Four months ended 31 October 2022:

28% increase in sales (cc) to US$3.82 million

Note: 18% sales increase (cc) to US$3.51 million when adjusted for delayed FY22 Chinese shipment.

AlphaRET

2RT® is a proprietary, world-first nanosecond laser therapy to treat 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.

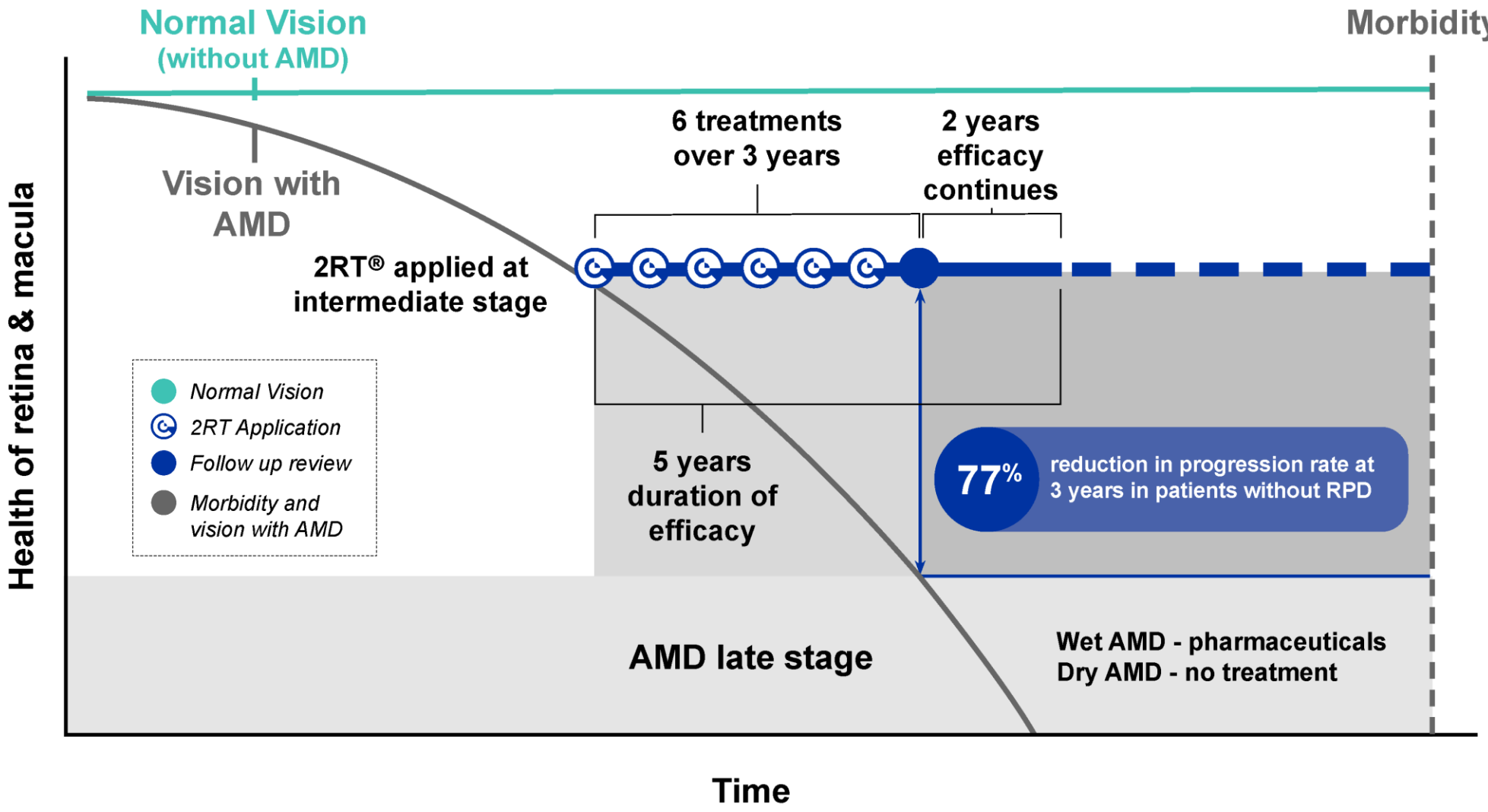
- **Age-related macular degeneration (AMD) is the leading cause of blindness in industrialized countries in people over the age of 50 years.**
- While there have been major advances in the treatment of AMD in its late stages (referred to as Wet AMD), there has been little progress in the treatment of AMD in its early and intermediate stages (intermediate AMD, iAMD).
- The Wet AMD market is currently the only AMD market served by a therapy (namely anti-VEGF injections). This market is valued at US$5.1bn annually. AlphaRET™ intends to provide a therapy for the hitherto unserved iAMD market.
- 2RT® is a leading candidate therapy in the world to meet a major unmet medical need. 2RT® has the potential to transform the global treatment of AMD by treating patients earlier in the disease state. This represents a revolutionary change from the status quo and thereby provides enormous clinical and commercial potential.
- Supported by a strong body of existing scientific, pre-clinical and clinical evidence that we have so far in place, commercialisation of 2RT® requires conducting a follow-up confirmatory pivotal clinical study.
- Estimated addressable market is 54 million people per year which is estimated to be a US$600m/year revenue opportunity.

Clinical Evidence Supports Plan for Successful Confirmatory Pivotal Study

1. Gunawan, JR., et al., Effect of subthreshold nanosecond laser on retinal structure and function in intermediate age-related macular degeneration. Clin Exp Ophthalmol. 2022 Jan;50(1):31-39
2. Guymer, RH., et al., Subthreshold Nanosecond Laser in Age-Related Macular Degeneration: Observational Extension Study of the LEAD Clinical Trial. Ophthalmol Retina. 2021 Dec;5(12):1196-1203.
3. Cohn, AC., et al., Dose Response in the Subthreshold Nanosecond Laser Trial in Early Stages of AMD: A LEAD Study Report. Ophthalmic Surg Lasers Imaging Retina. 2021 Jul;52(7):380-386
4. Nanosecond Laser Treatment in Chorioretinopathia Centralis Serosa without RPE Defects: A Retrospective case Series. Klin Monbl Augenheilkd. 2021 Jan;238(1):60-66
5. McGuiness, MB., et al., Association between Patient-Reported Outcomes and Time to Late Age-Related Macular Degeneration in the Laser Intervention in Early Stages of Age-Related Macular Degeneration Study. Ophthalmol Retina. 2020 Sep;4(9):881-888
6. Luu, CD., et al., Multi-focal electro-retinogram responses following sub-threshold nano-second laser intervention in age-related macular degeneration. Clin Exp Ophthalmol. 2020 Sep;48(7):938-945
7. Kaymak, H., et al., Efficacy of nanosecond laser treatment in central serous chorioretinopathy with and without atrophy or retinal pigment epithelium. Int J Retina Vitreous. 2020 Jun 4;6:11
8. Guymer, RH., et al., Sub-threshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomised Controlled Clinical Trial. Ophthalmology. 2019 jun;126(6):828-838
9. Wu, Z., et al., Secondary and Exploratory Outcomes of the Subthreshold Nanosecond Laser Intervention Randomized Trial in Age-Related Macular Degeneration: A LEAD Study Report. Ophthalmology Retina. 2019 Dec;3(12):1026-1034
10. Cusumano, A., et al., Doyne honeycomb retinal dystrophy- functional improvement following subthreshold nanopulse laser treatment: a case report. J Med Case Rep. 2019 Jan 10;13(1):5
11. Vessey, KA., Ho, T., Jobling, AI., Nanosecond Laser Treatment for Age-Related Macular Degeneration Does Not Induce Focal Vision Loss or New Vessel Growth in the Retina. Ophthalmol Vis Sci. 2018;59:731-745
12. Lek, JJ., et al., Subthreshold Nanosecond Laser Intervention in Intermediate Age-Related Macular Degeneration Study Design and Baseline Characteristics of the Laser in Early Stages of Age -Related Macular Degeneration Study (Report Number 1). Ophthalmology Retina. 2017 May-Jun;1(3):227-239
13. Guymer, R.H., et al., Nanosecond-laser application in intermediate AMD: 12-month results of fundus appearance and macular function. Clin Experiment Ophthalmol. 2014 July;42(5):466-479
14. Pelosini, L., et al., Retinal Rejuvenation Therapy for Diabetic Macular Edema – a pilot study. Retina 2013 Mar; 33(3) :548-58
15. Casson, R.J., et al., Pilot randomized trial of a nanopulse retinal laser versus conventional photocoagulation for the treatment of diabetic macular Edema. Clin Experiment Ophthalmol. 2012 Aug;40(6):604-10
16. Wood, JPM., et al., Physiological response of the retinal pigmented epithelium to 3-ns pulse laser application, in vitro and in vivo. Clin Exp Ophthalmol. 2021 Jul;49(5):454-469
17. Chidlow, G., et al., Investigations into localized re-treatment of the retina with a 3-nanosecond laser. Lasers Surg Med. 2016 Aug;48(6):602-615
18. Jobling, A.I., et al., Nanosecond laser therapy reverses pathologic and molecular changes in age-related macular degeneration without retinal damage. FASEB J, 2015. 29,696-710.
19. Wood, J.P., et al., Retinal damage profiles and neuronal effects of laser treatment: Comparison of conventional Photocoagulator and a Novel 3-Nanosecond Pulse laser. Invest Ophthalmol Vis Sci. 2013;54:2305-2318
20. Chidlow, G. et al., Glial cell and inflammatory responses to retinal laser treatment: comparison of a conventional photocoagulator and a novel, 3-nanosecond pulse laser. Invest Ophthalmol Vis Sci. 2013 Mar 28;54(3):2319-32
21. Zhang, JJ., et al.,Laser-mediated activation of human retinal pigment epithelial cells and concomitant release of matrix metalloproetinases. Invest Ophthalmol Vis Sci, 2012
22. Cohn, AC., et al., Subthreshold Nano-Second Laser Treatment and Age-Related Macular Degeneration. J Clin Med. 2021 Jan 28;10(3):484
23. Chhablani, J., et al., RESTORATIVE RETINAL LASER THERAPY: Present state and future directions. Surv Ophthalmol. 2018 May-Jun;63(3):307-328
24. Chehade, L., et al., Short-pulse duration lasers: a review. Clin Exp Ophthalmol. 2016 Nov;44(8):714-721

24 Peer-reviewed papers

2RT® for Intervention in AMD Progression



Intervention concept schematic based on *a post hoc* analysis reported within "Subthreshold Nanosecond Laser Intervention in Age-Related Macular Degeneration - The LEAD Randomized Controlled Clinical Trial" Robyn H. Guymer, MBBS, PhD, et al and published in peer reviewed journal *Ophthalmology* of the American Academy of Ophthalmology

This post hoc analysis found that the 77% reduction in the rate of progression occurred in patients who did not have reticular pseudodrusen (RPD) at enrolment. 24% of the study population had RPD at enrolment.

Initial Recruitment of Investigator Sites, Pivotal Study

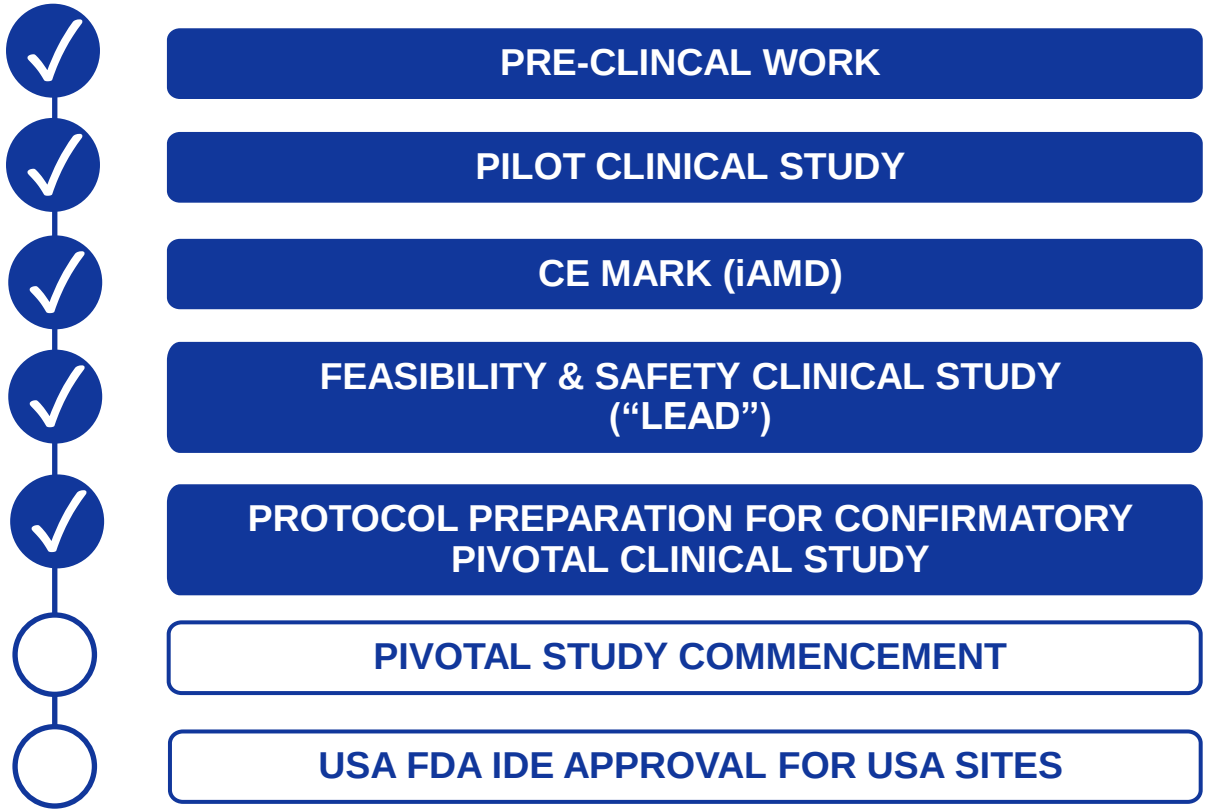
Significant milestone in the Company's plans to conduct the multi-center confirmatory study, intended to validate the results of the 2018 "LEAD" Study: **twenty-eight (28) of the world's leading retinal researchers and clinical experts across Europe, Canada and Australia have confirmed their participation in the study,**

Robert Finger, PhD, MD. Professor and Consultant Ophthalmologist from the Department of Ophthalmology at the University of Bonn, Germany, Prof. Dr. Finger is a leading authority in age-related macular degeneration (AMD) research.

Professor Guymer AM is the Deputy Director, Centre for Eye Research Australia (CERA) and Professor in the Department of Surgery (Ophthalmology), University of Melbourne, and Senior Medical Retinal Specialist, Royal Victorian Eye and Ear Hospital, East Melbourne, Australia. She is one of the world's leading retinal experts and is well respected in the fields of both early- and late-stage AMD.

2RT® Development Milestones

Our current strategy for 2RT® is to undertake a confirmatory pivotal clinical study at sites in Europe, Australia, Canada and ultimately the USA to gain FDA clearance for the treatment of intermediate AMD funded by partners.



Completed Investigational Device Exemption (IDE) application with the US Food & Drug Administration (FDA) in early July 2021 to commence a pivotal clinical study for 2RT®.

Development of a pivotal confirmatory study plan based on the feedback received from the FDA on the IDE.

Study protocol and supporting statistical plan developed to meet the requirements of global regulatory agencies, including the USA FDA.

So far expressions of interest to participate in the study received from leading retinal specialists to participate in the study

Nova Eye Group Outlook

- Sales of new *iTrack*™ *Advance* canaloplasty device in markets in Europe and Canada are expected to continue to grow; however, the total sales growth for the remainder of the 2023 fiscal year will be largely contingent on the timing of marketing clearance of the iTrack™ Advance in the USA.

- Subject to marketing clearance, USA launch of *iTrack*™ *Advance* planned for last quarter of the 2022 calendar year.

- After the significant non-recurring cash investments made in the 2022 financial year, the business has sufficient cash to meet its plans for the 2023 financial year.

- For 2RT®, AlphaRET will progress efforts to partner to fund a confirmatory pivotal study and will continue to make a small, targeted investment in preparatory study-related work.

ASX: EYE Financials and Corporate Snapshot

Nova Eye Medical Limited

Australian Securities Exchange
Exchange

EYE
Ticker

9%
Management + Board Ownership
(15 November 2022 fully diluted)

146M
Shares on Issue

A$13.1M
Revenues
(12 months 30 June 2022)

A$30.4M
Net Assets
(as at 30 June 2022)

A$43.8M
Market Capitalisation
(as at 16 November 2022)

A$8.0M
Cash
(at 30 June 2022)

NOVAEYE MEDICAL

AlphaRET

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
FY23 Objectives	Grow sales from FY22 investments
Market	Glaucoma Surgical Devices; fast-growing and competitive
Competitive Advantage	Proprietary iTrack™ microcatheter technology
Sales	Established infrastructure; direct sales in USA, Germany, Australia; +20 distributors
Manufacturing	California, USA and Dunedin, New Zealand
IP Status	>100 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
FY23 Objectives	Partner and commence a confirmatory pivotal study
Market	Intermediate Age-related Macular Degeneration (iAMD) – market not addressed
Competitive Advantage	Proprietary 2RT® technology – first mover advantage
Sales	No sales program at present
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

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