

Nova Eye Medical Limited (ASX:EYE)

Results Presentation for the Six Months Ended 31 December 2021

17 February 2022

nova-eye.com

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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.**

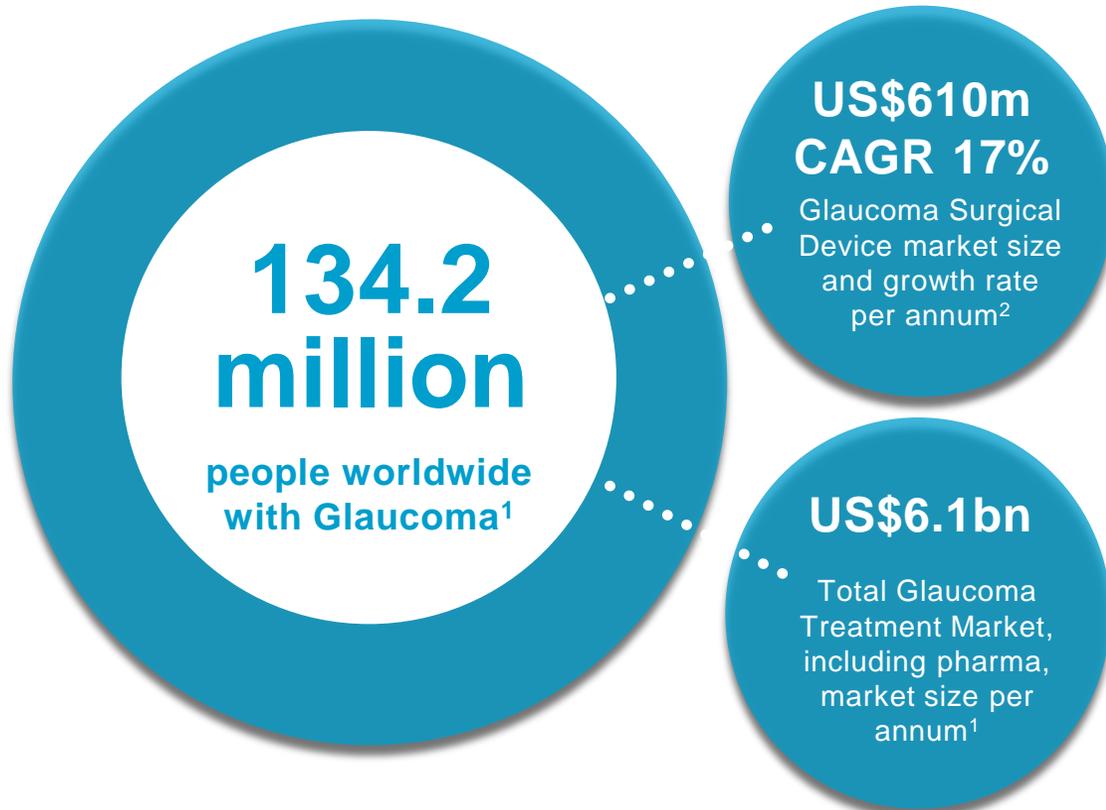
Nova Eye Medical, Glaucoma	
Strategy	Develop, market and sell comprehensive portfolio of glaucoma consumable surgical devices
FY22 Objectives	Investment in initiatives for sales growth
Market	Glaucoma Surgical Devices; fast-growing and competitive
Competitive Advantage	Proprietary iTrack™ microcatheter 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
FY22 Objectives	Major clinical study; preference to secure FDA clearance via IDE-approved 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

Glaucoma Market Strong Global Growth Theme



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



Advancements in diagnostic and imaging technologies permit earlier diagnosis, which in turn drives demand for interventions which permit earlier treatment

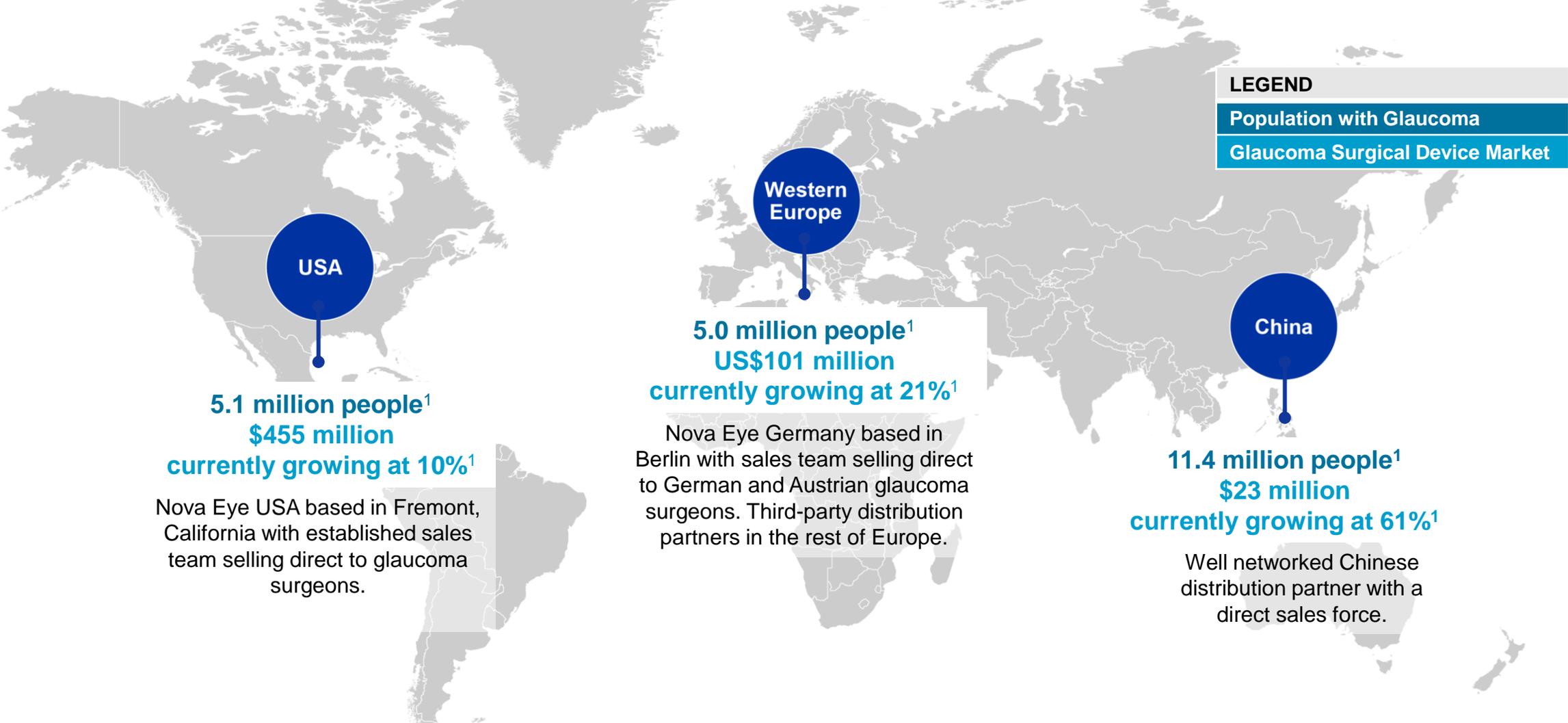
Medications are considered standard of care but are associated with significant drawbacks i.e., low patient compliance, side effects, financial costs

Glaucoma surgical device solutions, including devices such as iTrack™, are increasingly recognized as a highly viable alternative to medications – 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

Nova Eye's Market Presence



1. Marketscope 2021 Glaucoma Surgical Devices Report. Growth in glaucoma surgical devices at the expense of pharmaceuticals.

Glaucoma Technology Portfolio and Pipeline



Comprehensive portfolio of glaucoma technologies spanning the entire glaucoma treatment algorithm, underpinned by a robust R&D and IP pipeline.

PROGRAM STATUS	STAGE OF GLAUCOMA			
	MILD GLAUCOMA	MODERATE GLAUCOMA	SEVERE GLAUCOMA	COMPLEX GLAUCOMA
COMMERCIAL		iTrack™ Canaloplasty device manually deployed by glaucoma specialist <i>(Available all global markets)</i>	iTrack™ Canaloplasty device manually deployed in major eye surgery by glaucoma specialist <i>(Available all global markets)</i>	Molteno3® Glaucoma drainage device <i>(Available all global markets)</i>
COMMERCIAL IN 2022	iTrack™ ADVANCE Canaloplasty device injector deployed by comprehensive ophthalmologist	iTrack™ ADVANCE Canaloplasty device injector deployed by glaucoma specialist		
PIPELINE		<ul style="list-style-type: none"> • August 2021 patent acquisition • Engineering program to introduce new Minimally Invasive Glaucoma Surgery (MIGS) device 		

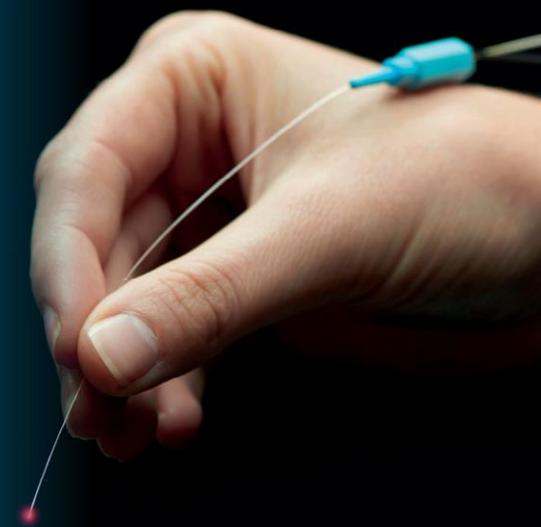
The proprietary *iTrack*™ is a manually deployed microcatheter used to perform canaloplasty, a breakthrough surgical procedure that can be performed via either an ab-interno surgical technique (akin to “keyhole” surgery) i.e., MIGS, or via an ab-externo surgical technique (major eye surgery), depending on disease severity and/or surgeon preference.

iTrack™ offers a number of technical advantages over other glaucoma and MIGS devices and underpins our glaucoma growth strategy.

Indication	Canaloplasty
Approval	All global approvals in place, including FDA and CE Mark
Reimbursement	Favourable CPT codes with/without cataract surgery in the USA
Patient	Mild, Moderate and Severe Glaucoma
Surgeon Type	Glaucoma surgeon

10+ years
of surgical
use

100,000+
procedures
performed
globally



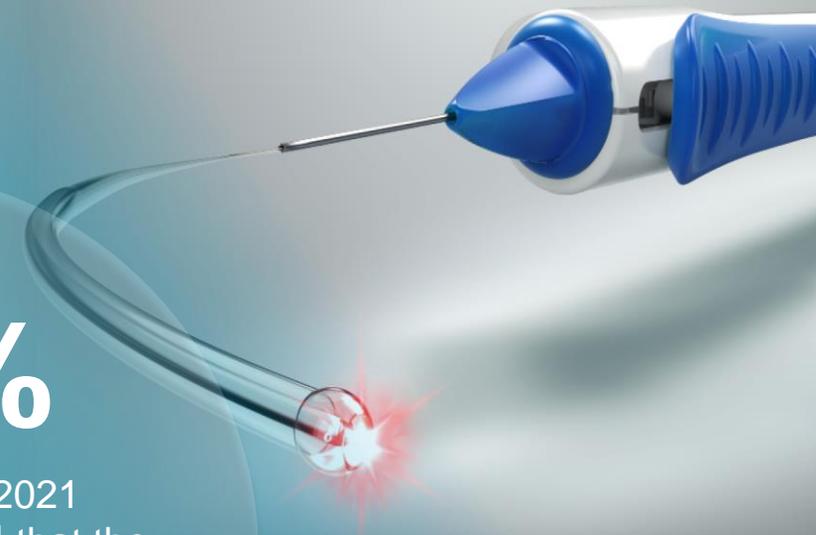
The next generation ***iTrack™ Advance*** is an injector deployed microcatheter. It takes the established effectiveness, accuracy and reliability of the original iTrack™ microcatheter and combines it with an ergonomic, easy-to-use handheld injector designed for all ophthalmic surgery and specialist settings.

Over the past 12 months canaloplasty has garnered increasing attention from surgeons in the USA, due to favourable reimbursement changes. *iTrack™ Advance* is well positioned to capitalise on the growing interest in the canaloplasty field.

Indication	Canaloplasty
Approval	CE Mark
Patient	Mild-Moderate Glaucoma
Surgeon Type	Comprehensive ophthalmologist, cataract surgeon, glaucoma surgeon

219%

Between 2018 and 2021 Marketscope estimates¹ that the market for canal-based surgery (including canaloplasty) has grown 219%.¹ This compares to growth of only 17% in the stent-based MIGS market i.e., iStent.¹



Molteno3[®]

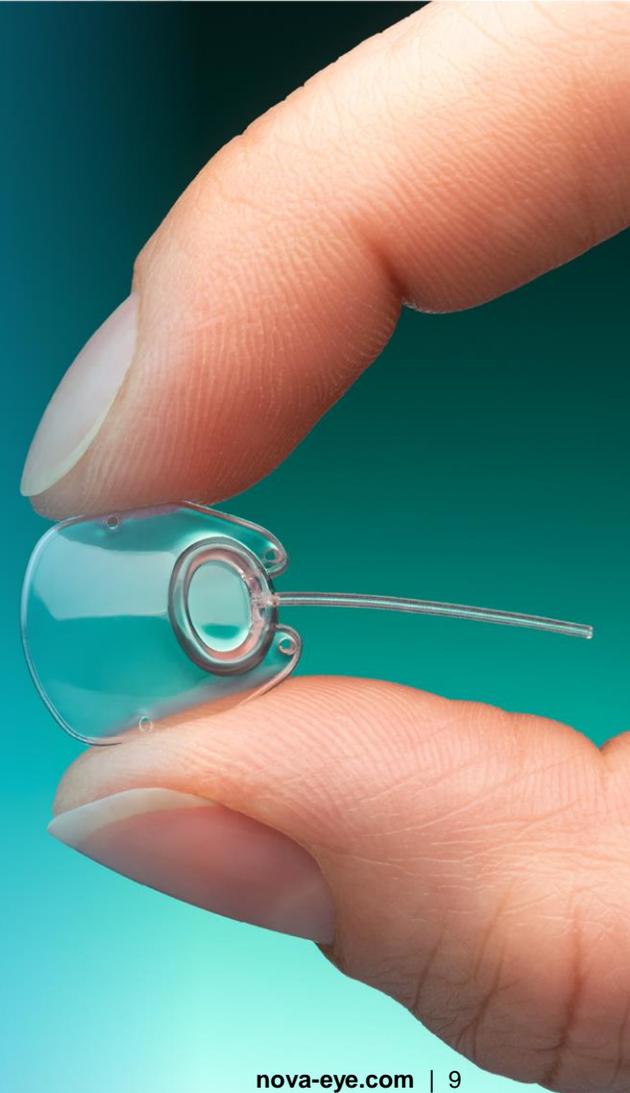
Implanted in thousands of patients worldwide for more than 30 years, the ***Molteno3[®]*** Glaucoma Drainage Device has been clinically validated to deliver consistent, long-term reduction in intraocular pressure (IOP) in cases of severe or complex glaucoma.

Indication	Glaucoma Drainage Surgery
Approval	All global approvals in place, including FDA and CE Mark
Reimbursement	Favourable CPT code
Patient	Complex/Advanced Glaucoma
Surgeon Type	Glaucoma surgeon

30+ years
of surgical use

0.4mm

At just 0.4mm, Molteno3[®] is the slimmest plate on the market, which simplifies surgical insertion and reduces OR time.



iTrack™ Advance Development Milestones



PRODUCTION UNITS

CE MARK

EUROPEAN PRE-LAUNCH ACTIVITIES

EUROPEAN LAUNCH

US FDA (510K) MARKETING CLEARANCE

USA LAUNCH

MAGIC STUDY

TO SUPPORT EDUCATIONAL EFFORTS – NOT REQUIRED FOR USA LAUNCH

iTrack™ Advance Sales Growth Strategy



1

The new *iTrack™ Advance* device has broad market appeal.

2

The current *iTrack™* device is principally sold to glaucoma surgeons only. In the USA there are approximately **1,200¹ glaucoma surgeons**.

3

The *iTrack™ Advance* will allow access to comprehensive ophthalmologists. In the USA there are approximately **10,000² comprehensive ophthalmologists**.

4

Nova Eye will grow sales by accessing a market approximately 10x the current market size.



1. Nova Eye estimate based on various industry data points
2. Based on article in February 19, 2021 edition of *Ocular Surgery News*

European Market Update

Financial Performance: solid growth in German market as a result of establishment of sales team and its expansion, with sales revenue up 26% during the period compared to the PCP.

	Half year to December 2020 (US \$'000's)	Half year to December 2021 (US \$'000's)	Growth
Revenue	974	1,224	26%

Activities: pre-launch activities for iTrack™ Advance commenced ahead of planned launch in Q2 CY2022

- Training program for existing and new canaloplasty surgeons.
- Market preview at the DGII Congress (German Society of Cataract and Refractive Surgery), including official dry lab program of the DGII hosted by leading glaucoma surgeon Prof. Norbert Koerber.



Norbert Koerber, MD, PhD (Augenentrum Köln-Porz, Germany), a leading authority in glaucoma surgery, takes part in dry lab training for the new iTrack™ Advance ahead of its official launch in Q2 CY2022. Also pictured is Lisa Majeski, Director of Surgical Training – Global, Nova Eye.

USA Market Update



Financial Performance: sales revenue down 10% compared to the PCP, due to increased levels of competition. Despite these challenges, new surgeon interest in canaloplasty provides a strong platform for growth for the new *iTrack™ Advance* canaloplasty device.

	Half year to December 2020 (US \$'000's)	Half year to December 2021 (US \$'000's)	Growth
Revenue	3,363	3,037	-10%

Comments: favourable reimbursement changes in 2022, compared with stent-based MIGS, driving increased surgeon interest in canaloplasty:

- Canaloplasty reimbursement for physicians proposed to reduce from US\$950 to US\$770 per procedure.
- Reimbursement for physicians for stent-based surgery proposed to reduce from US\$300 to US\$134 per procedure

H1FY22 Glaucoma Operating Result

Improved EBITDA-level operating result.

	A \$'000's			US \$'000's ¹		
	H1FY21	H1FY22	GROWTH	H1FY21	H1FY22	GROWTH
Sales	6,423	6,488	1.0%	4,677	4,752	1.6%
COGS	(2,425)	(2,660)		(1,766)	(1,948)	
Gross Margin	3,998	3,828		2,911	2,804	
Gross Margin	62%	59%				
Operating expenditure	(4,971)	(5,934)		(3,620)	(4,346)	
US Govt COVID19 Stimulus	–	1,449		–	1,061	
EBITDA/(loss)	(973)	(673)		(709)	(481)	

Key H1FY22 information:

- Sales composition using US\$: USA 64% (pcp 72%), Western Europe 26% (pcp 21%), China 10% (pcp 7%)
(Note: China growth was 44% on PCP.)
- Increase in opex for German business expansion, clinical development and *iTrack™ Advance* pre-launch activity.

1. AUD/USD 0.73 in H1FY22 and 0.72 in H1FY21

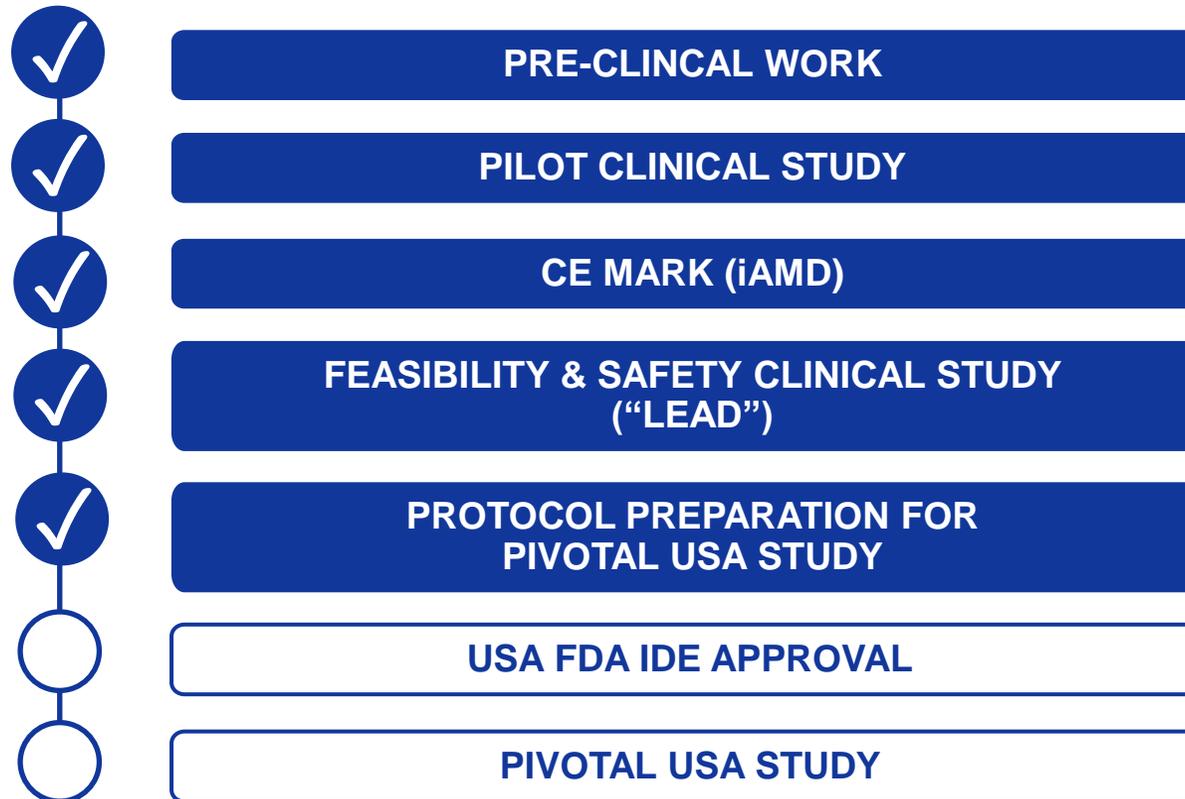
2RT[®] is a proprietary, world-first nanosecond laser therapy to treat intermediate AMD (iAMD).

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.**
- 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.
- 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 cleared for sale in Europe and Australia (for iAMD) (Note: There are approximately 30 2RT[®] users in Europe and Australia.)
- Commercialisation of 2RT[®] requires the conduct of a follow-up clinical study.
- Estimated addressable market is 54 million people per year which is estimated to be a US\$600m/year revenue opportunity.

2RT[®] Development Milestones

Our current strategy for 2RT[®] is to undertake a multi-center study, preferably in the USA, to gain FDA clearance for the treatment of intermediate AMD.



- Successfully completed Investigational Device Exemption (IDE) application with the US Food and Drug Administration (FDA) in early July 2021 to commence a pivotal clinical study for 2RT[®] and have been in discussion with FDA since.
- The study may also be conducted outside the USA.
- The plan is to partner the investment in the 2RT[®] clinical program.
- Expenditure of \$0.6m in H1FY22 compared with \$0.5m in PCP for the development of the study package.

ASX: EYE Financials and Corporate Snapshot



Nova Eye Medical Limited		
Exchange	Australian Securities Exchange	
Ticker	EYE	
Management + Board Ownership	7%	
Shares on Issue	146 million	
Revenues (6 months 31 December 2021)	A\$6.5 million	US\$4.8 million ¹
Net Tangible Assets (at 31 December 2021)	A\$34.1 million	US\$25.2 million ¹
Market Capitalization (as at 11 February 2021)	A\$39 million	US\$27.9 million ²
Cash (at 31 December 2021)	A\$13.4 million	US\$10.0 million ¹
EBITDA/(loss) (6months to 31 December 2021)	A\$(2.2 million)*	US\$(1.6 million) ¹

*Note: EBITDA/(loss) \$(0.8) million in PCP

1. AUD/USD 0.74 at 31 December 2022
2. AUD/USD 0.73 at 11 February 2022

Nova Eye Group Outlook



1

Europe: execute European launch of new *iTrack™ Advance* canaloplasty device, commencing Q3 FY2022

2

USA: complete *iTrack™ Advance* 510(k) regulatory submission to the USA Food and Drug Administration (FDA) to facilitate product launch later in 2022.

3

China: support distribution partner to improve market penetration of *iTrack™* canaloplasty device

4

2RT®: partner the 2RT® clinical program to support major multi-center study.



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