

Nova Eye Medical Limited (ASX:EYE)

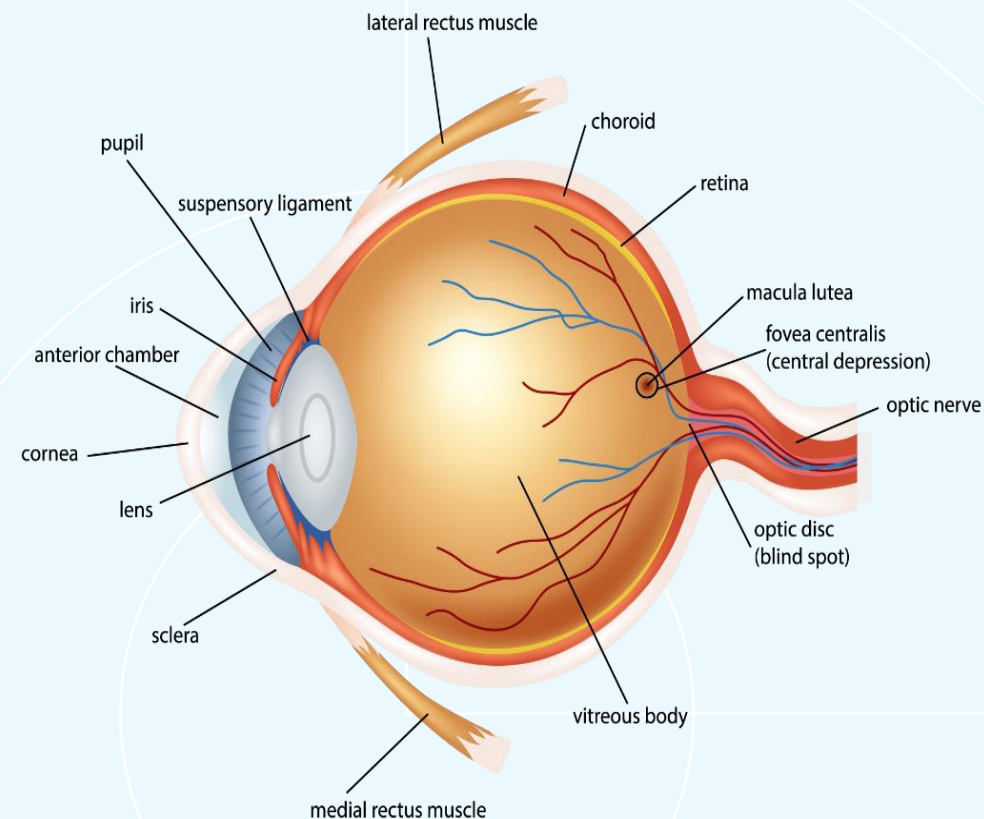
**FY22 Full-Year Results Presentation**

25 August 2022

[nova-eye.com](http://nova-eye.com)

## DISCLAIMER

This presentation has been prepared by Nova Eye Medical Limited (ASX: EYE). While the information in this presentation has been prepared in good faith and with reasonable care, no representation or warranty, express or implied, is made as to the accuracy, adequacy or reliability of any statement, estimates, opinions or other information contained in the presentation. This presentation may contain forward looking statements. These forward-looking statements have been made based upon Nova Eye Medical's expectations and beliefs concerning future developments and their potential effect on Nova Eye Medical (and its controlled entities) and are subject to risks and uncertainty which are, in many instances, beyond Nova Eye Medical's control. No assurance is given that future developments will be in accordance with Nova Eye Medical's expectations. Actual results could differ materially from those expected by Nova Eye Medical. This presentation does not constitute an offer to sell or a solicitation or an offer to purchase any security or financial product or service. Any such offer or solicitation shall be made only pursuant to a Product Disclosure Statement, Information Memorandum, Prospectus or other offer document relating to a financial product or service. Past performance is not necessarily indicative of future results and no person guarantees the performance of any financial product or service or the amount or timing of any return from it. There can be no assurance that the financial product or service will achieve any targeted return, that asset allocations will be met or that the financial product or service will be able to implement its investment strategy and investment approach or achieve its investment objective. The information contained in this presentation is not intended to be relied upon as advice to investors or potential investors, who should consider seeking independent professional advice depending upon their specific investment objectives, financial situation or particular needs.



# 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.

Acquired seminal patents expand iTrack™ intellectual property coverage

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



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

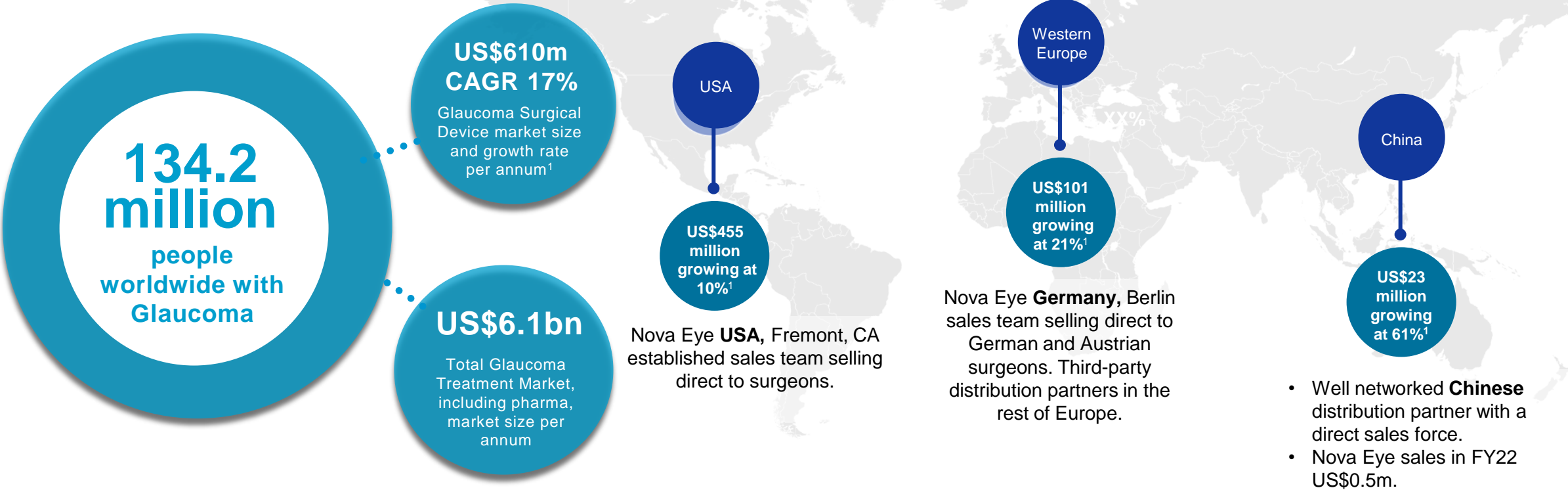


- Launched global data Registry to support real-world clinical evidence.
- Currently 238 patients which demonstrates surgeon support of iTrack™/canaloplasty.

# 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.








1. Marketscope 2021 Glaucoma Surgical Devices Reports. Growth in glaucoma surgical devices.

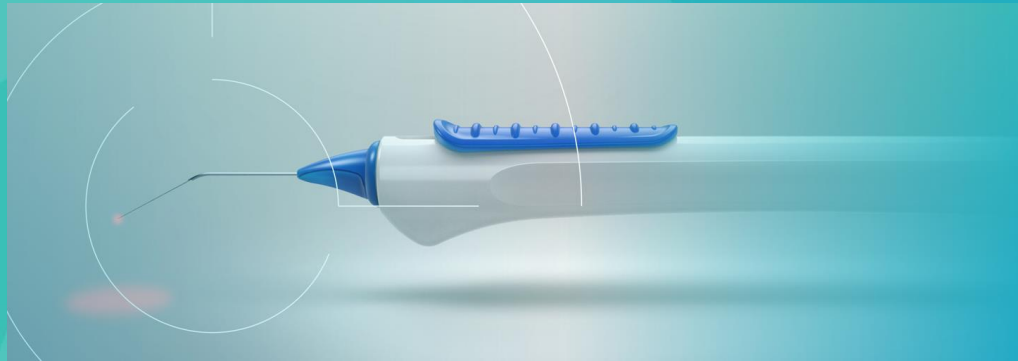
# Glaucoma Technology Portfolio and Pipeline



We continue to invest in a comprehensive portfolio of glaucoma technologies that span the entire glaucoma treatment algorithm, underpinned by our robust R&D and IP pipeline.

	STAGE OF GLAUCOMA			
	Mild Glaucoma	Moderate Glaucoma	Severe Glaucoma	Complex Glaucoma
Commercial in Europe, USA and China		 Canaloplasty device manually deployed by glaucoma specialist	 Canaloplasty device manually deployed in major eye surgery by glaucoma specialist	 Glaucoma drainage device
Commercial in Europe since June 2022	 Canaloplasty device injector used by comprehensive ophthalmologist	 Canaloplasty device injector used by glaucoma specialist		
<b>PIPELINE</b>		<ul style="list-style-type: none"> <li>• August 2021 key technology patent acquisition</li> <li>• Engineering program to introduce new Minimally Invasive Glaucoma Surgery (MIGS) device</li> </ul>		

- The new *iTrack*<sup>™</sup> **Advance** is an injector deployed microcatheter, leveraging the effectiveness, accuracy and reliability of the original *iTrack*<sup>™</sup>.



- *iTrack*<sup>™</sup> **Advance** combines a microcatheter with an ergonomic, easy-to-use handheld injector designed for all ophthalmic surgery and specialists settings.

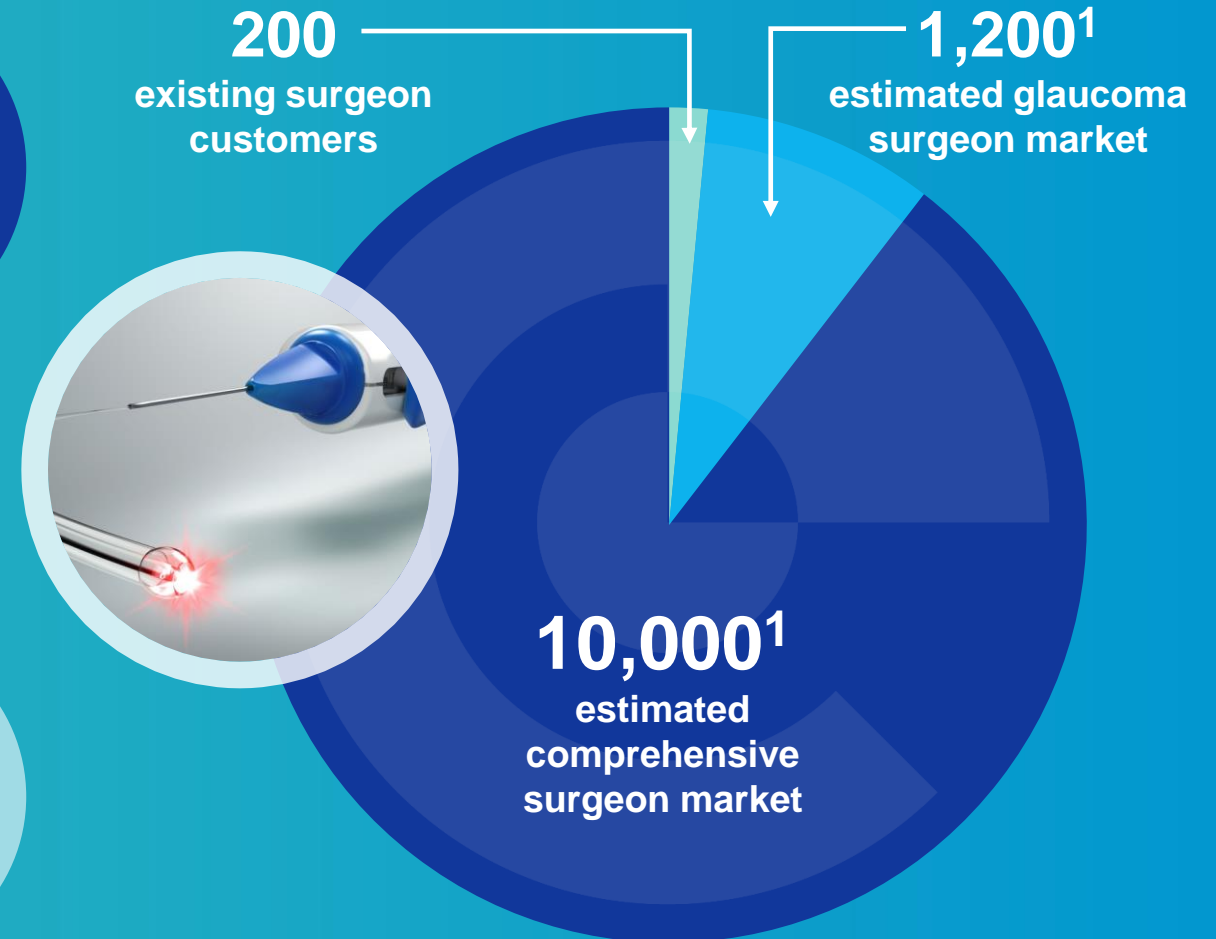
- From regulatory submissions through to clinical and commercial programs, *iTrack*<sup>™</sup> **Advance** was the primary focus for our global business in FY22.

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)**



*“There is enough data to support the use of canaloplasty for early glaucoma. What’s more, this device can truly pressurize the canal. The new iTrack™ Advance does not have the overhead of requiring a second instrument to feed the catheter into Schlemm’s canal. And since no device is left behind, there is potentially a lower risk of long-term complications. Based on my initial experience with iTrack™ Advance, I plan to teach canaloplasty to my residents.”*

**Arsham Sheybani, MD**  
**Washington University, St. Louis, USA**



*“iTrack™ Advance is my go-to MIGS procedure. The handpiece offers improved efficiency, which will appeal to a broad group of surgeons. Importantly, the new device maintains the integrity of the original iTrack™ microcatheter, delivering pressurized viscodilation over the full circumference of the canal – this is what sets it apart from the competition.”*

**Mahmoud A. Khaimi, MD**  
**Dean McGee Eye Institute**  
**University of Oklahoma, Oklahoma, USA**



## Important FY22 Activities

- Global Clinical Team (outside the USA) training surgeons in Germany, the UK, Italy, Spain, Poland, Canada and Australia.
- Surgical training roll-out to top tier glaucoma surgeons and key MIGS advocates; will drive adoption by rest of market.
- Early engagement on ergonomics and usability in the operating room created early interest.
- Enhanced and increased our commercial infrastructure in Germany, in recognition of its growing contribution to our global business.
- Reimbursement strategy in place to support sales to cataract surgeons and comprehensive ophthalmologists.
- Representation at key regional and national tradeshows.
- Commenced post-market, multi-center, prospective, randomized “CATALYST” Study across five German study sites.
- Continued recruitment for post-market, multi-center prospective, randomized “MAGIC” Study.

# European Market Update

**Financial Performance:** 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.



German surgeon and iTrack™ Advance

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%
<b>Total</b>	<b>\$2,355,686</b>	<b>\$2,661,054</b>	

# USA Market Update

**Financial Performance:** 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™ device 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		Six months to Dec 21 (US \$)	Six months to June 22 (US \$)	Growth
Revenue	\$6,607,860	\$6,382,833	-3.4%	Revenue	\$3,037,820	\$3,345,013	10%

# FY22 Glaucoma Operating Result



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

## 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.

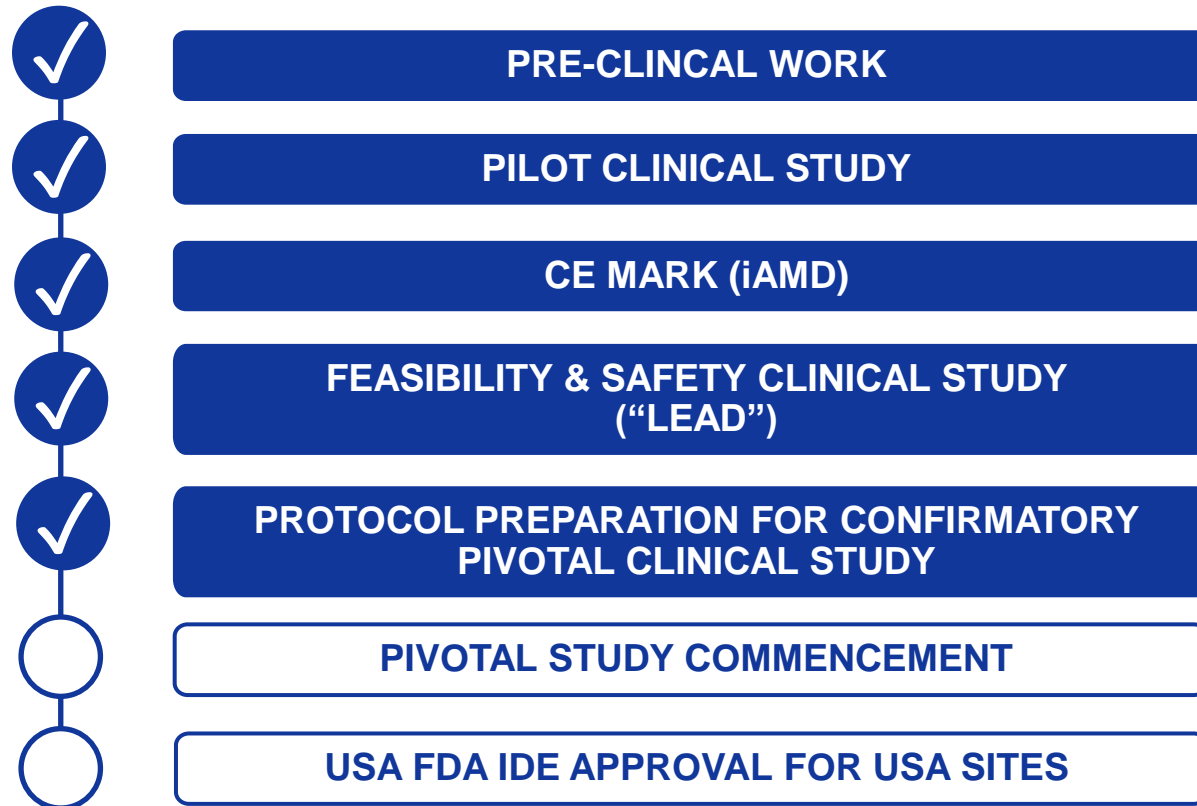
2RT<sup>®</sup> is a proprietary, world-first nanosecond laser therapy to treat intermediate AMD (iAMD).

2RT<sup>®</sup> 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<sup>™</sup> intends to provide a therapy for the hitherto unserved iAMD market.
- 2RT<sup>®</sup> is a leading candidate therapy in the world to meet a major unmet medical need. 2RT<sup>®</sup> 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.
- Commercialisation of 2RT<sup>®</sup> 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.

# 2RT<sup>®</sup> Development Milestones

Our current strategy for 2RT<sup>®</sup> 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.



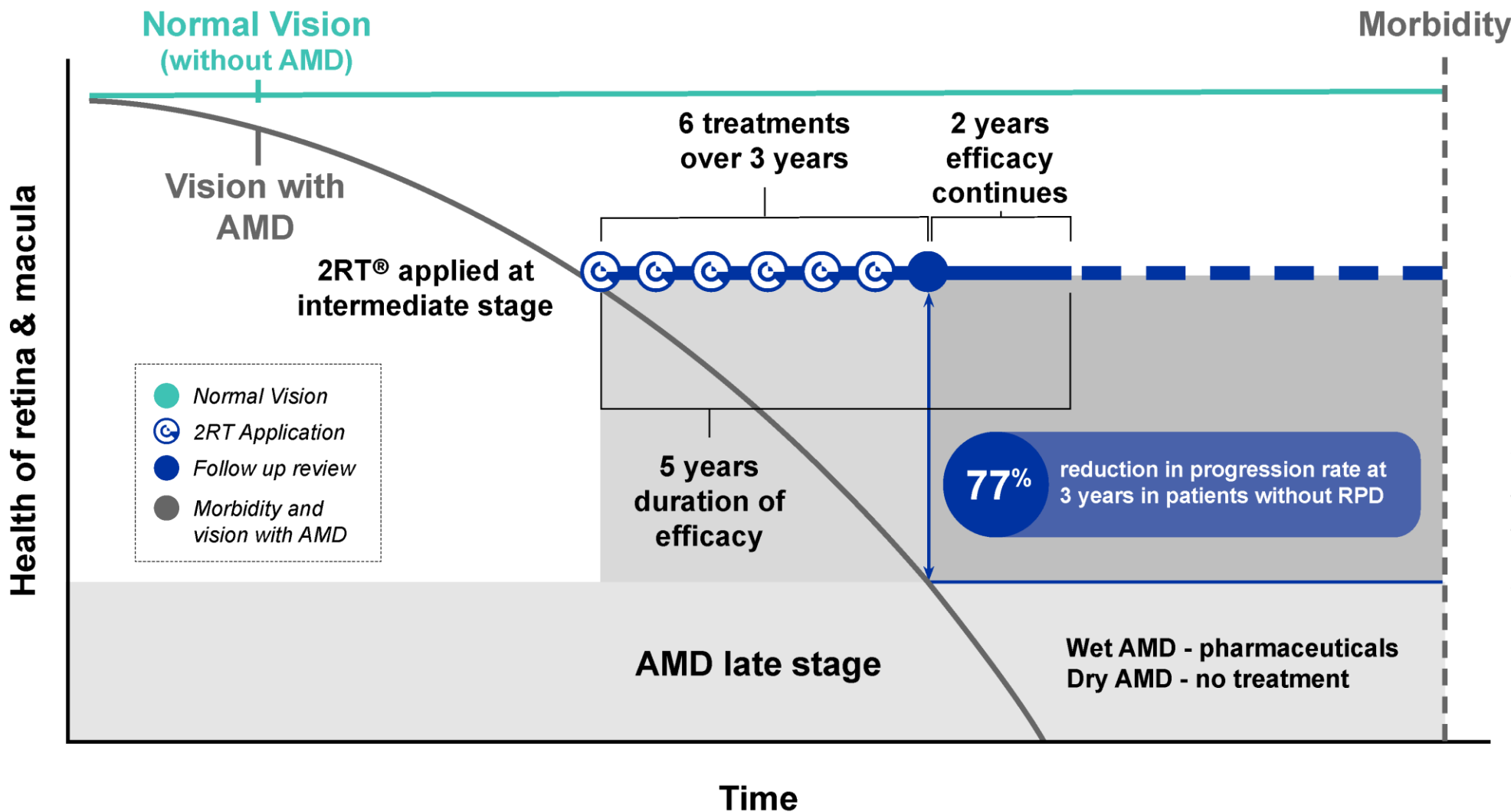
Completed Investigational Device Exemption (IDE) application with the US Food & Drug Administration (FDA) in early July 2021 to commence a pivotal clinical study for 2RT<sup>®</sup>.

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 all 22 retinal research institutions and leading retinal specialists who have been invited.

# 2RT<sup>®</sup> 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.

# Nova Eye Group Outlook

- Investments in the 2022 financial year and the European launch of *iTrack™ Advance* will trigger sales growth of the Glaucoma Surgical Consumable Device segment in the 2023 financial year.
- Subject to the continuation of current market conditions, sales for the four months to 31 October 2022 are expected to be more than US\$3.4m, which is growth of approximately 15% compared to the prior corresponding period.
- 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

**7%**

Management + Board  
Ownership

**146M**

Shares on Issue

**A\$13.1M**

Revenues  
(12 months 30 June 2022)

**A\$30.4M**

Net Assets  
(as at 30 June 2022)

**A\$35M**

Market Capitalisation  
(as at 24 August 2022)

**A\$8.0M**

Cash  
(at 30 June 2022)



# 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



**Tom Spurling**

Managing Director

M: +61 417 818 658

E: [tspurling@nova-eye.com](mailto:tspurling@nova-eye.com)

**Mark Flynn**

Investor Relations

M: +61 416 068 733

E: [mflynn@nova-eye.com](mailto:mflynn@nova-eye.com)

**Kate Hunt**

Chief Commercial Officer

M: +61 404 080 679

E: [khunt@nova-eye.com](mailto:khunt@nova-eye.com)