

# Investor Presentation

Nova Eye Medical Limited (ASX:EYE)

March 2023

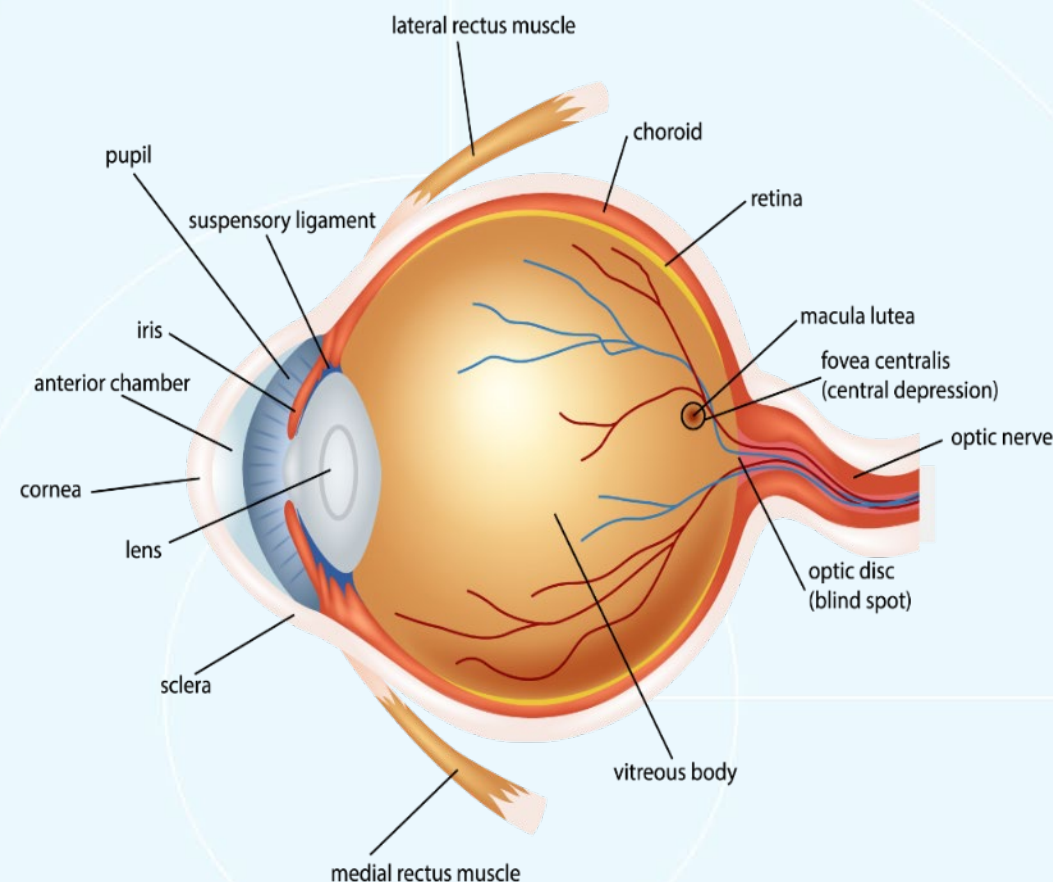
Addressing the two leading causes of blindness in the developed world



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# ASX: EYE Financials and Corporate Snapshot



Nova Eye Medical Limited

**Australian Securities  
Exchange**

ASX

**EYE**

Ticker

**9%<sup>1</sup>**

Management + Board  
Ownership (fully diluted)

**146M<sup>1</sup>**

Shares on Issue

**A\$15.2M<sup>2</sup>**

Revenues  
(based on 12 months)

**A\$24.9M<sup>2</sup>**

Net Assets

**A\$34M<sup>1</sup>**

Market Capitalisation

**A\$3.6M<sup>2</sup>**

Cash  
(Including tax refund of \$1.1m  
received on 6 January 2023)



<sup>1</sup> As at 24 February 2023

<sup>2</sup> As at 31 December 2022

# Executive Summary



- Nova Eye pioneered the fastest growing segment in the burgeoning ophthalmic market; canal surgery for glaucoma, and holds over 100 patents in this domain
- Nova Eye is one of three principal participants in the canal surgery segment with a forecast segment CAGR of 19% over the five years to 2027
- Nova Eye has invested in developing a next generation product (iTrack™ *Advance*) that has been applauded in trials with leading KOLs
- FDA market clearance for iTrack™ *Advance* is expected in the coming weeks and Nova Eye expects to win significant market share
- Proceeds from the share placement will be used for
  - expansion of the glaucoma surgical device business in the USA, Europe and China through additional sales representatives, marketing and surgeon training.
  - investment in production processes to reduce production costs.
  - corporate costs and general working capital including the AlphaRET business



# ASX: EYE Business Snapshot



Focused on vision and fighting blindness, Nova Eye Medical leads the way in glaucoma and age-related macular degeneration, **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
Market	Canal Surgery segment of the glaucoma surgical devices market scheduled to grow rapidly over 2022 to 2027
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
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 with partner for confirmatory study
Market	Intermediate Age-related Macular Degeneration treatment (iAMD) – market not addressed
Sales	Sales program to coincide with partnering
Manufacturing	Adelaide, Australia based contract manufacturing
IP Status	First mover advantage, >10 patents issued and pending in major markets
Regulatory	CE Mark (iAMD and diabetic eye disease) in Europe, Australia, NZ and FDA (diabetic eye disease only) in USA
Reimbursement	Pending

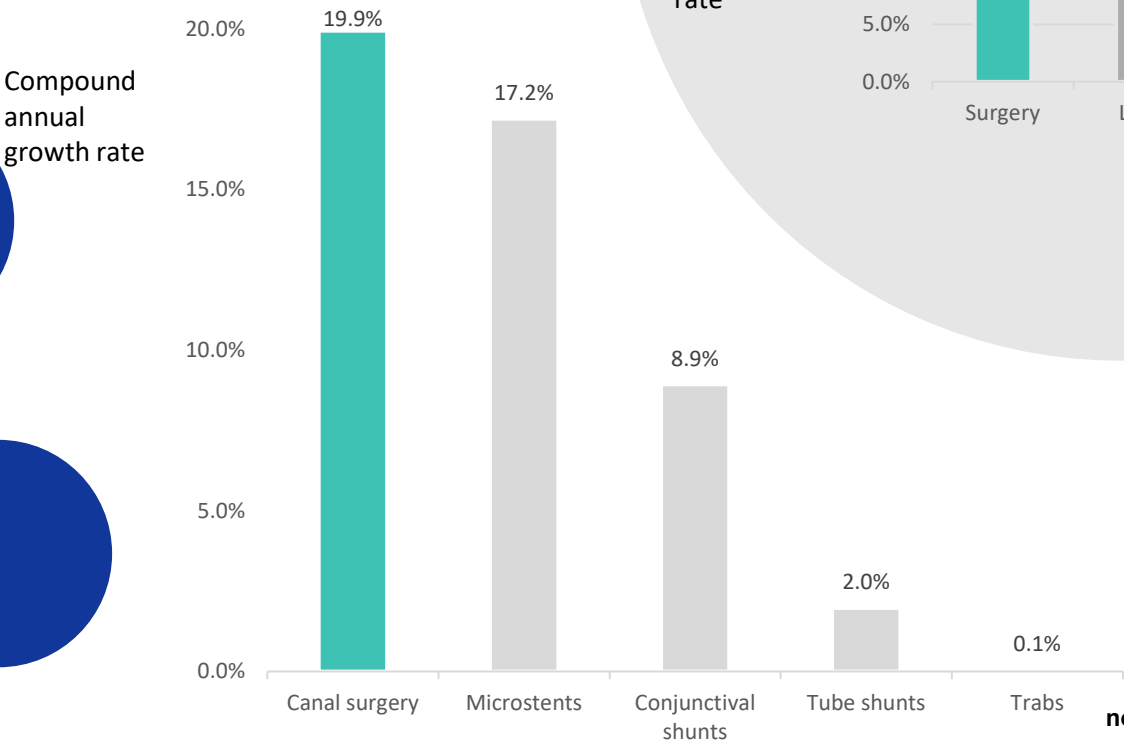
# Glaucoma Market – accessing fast growing segment

Surgical glaucoma interventions are forecast to grow at 14.7% per annum globally over the next 5 years. The fastest growing form of glaucoma surgery

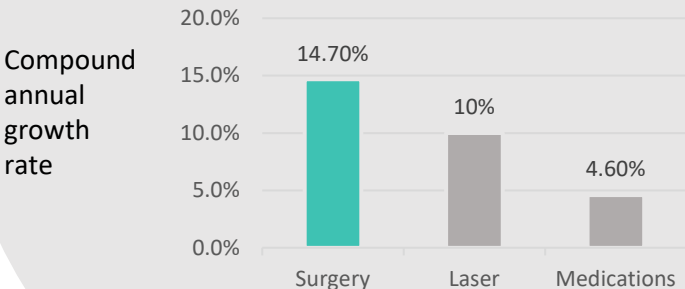
Canal surgery procedures are forecast to grow at 20% per annum over the next 5 years, faster than any other surgical device intervention option.

Nova Eye Medical is well positioned to meet the growing demand for innovative glaucoma treatments.

Glaucoma surgical device intervention<sup>1</sup> (2022 to 2027)

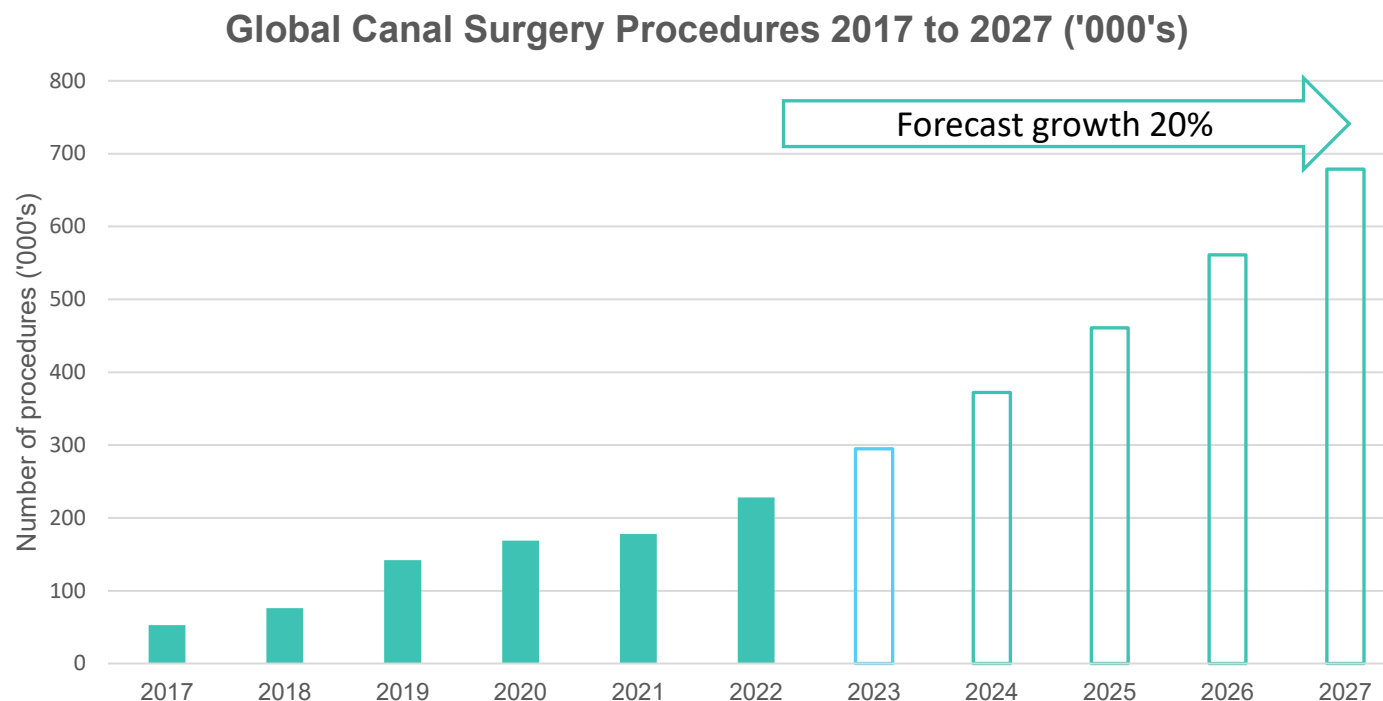


Glaucoma interventions<sup>1</sup> (2022 to 2027)



<sup>1</sup> All data from Marketscope 2022 glaucoma surgical devices report

# Canal Surgery Segment Market Growth




- Canal Surgery Segment Procedures growth rate of 20% forecast between 2022 and 2027
- Canal Surgery Segment Revenue is expected to grow at a CAGR of 19% to US\$440m in 2027
- Major current participants in the Canal Surgery Segment: Nova Eye Medical, Sight Sciences, New World Medical

# iTrack<sup>TM</sup>

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A D V A N C E

The image shows a surgical device with a blue handle and a long, thin, curved metal shaft. The handle has a blue grip with a series of ridges. The shaft is silver and ends in a small, rounded tip. A red laser light is visible at the tip of the shaft, creating a starburst effect.

The superior features of iTrack<sup>TM</sup> Advance position us for significant sales growth from the fast-growing canal surgery segment.

- Launched in markets outside of USA and China in June 2022.
- USA launch pending finalisation of FDA clearance





# iTrack<sup>TM</sup>



- 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



# Clinically Significant Features iTrack™ Advance vs Other Canal Surgery Devices

Canal Surgery Device	Ocular Pressure Reduction @ 12 months	Medication reduction @ 12 months	Adverse Event Rate	Treatment of Canal	Method of Action	Delivery Capacity	Navigation
iTrack™ (original requiring forceps)	47% reduction <sup>1</sup>	68% <sup>1</sup>	16% <sup>1</sup>	360° Patented <sup>4</sup>	Visco delivery	>100µl	Light beacon at tip Patented <sup>4</sup>
iTrack™ Advance (incorporating handheld injector instead of forceps)	47% reduction <sup>1</sup>	68% <sup>1</sup>	16% <sup>1</sup>	360° Patented <sup>4</sup>	Visco delivery	>100µl	Light beacon at tip Patented <sup>4</sup>
OMNI <sup>5</sup> (Sight Sciences)	28% reduction <sup>2</sup>	32% <sup>2</sup>	31% <sup>2</sup>	≤180° Up to twice	Visco delivery and tears tissue	≤11µl <sup>7</sup>	No navigation indication
KDB Glide <sup>6</sup> (New World Medical)	13% reduction <sup>3</sup>	35% <sup>3</sup>	23% <sup>3</sup>	As determined by surgeon	Excises tissue	Nil	No navigation indication

<sup>1</sup> Lewis et al. ASCRS 2007 (iTrack Device)

<sup>2</sup> Vold et al. AAO 2020

<sup>3</sup> Pratte et al. Journal of American Ophthalmology 2020

<sup>4</sup> Covered by Nova Eye international patents

<sup>5</sup> Covered by Sight Sciences international patents

<sup>6</sup> Covered by New World Medical international patents

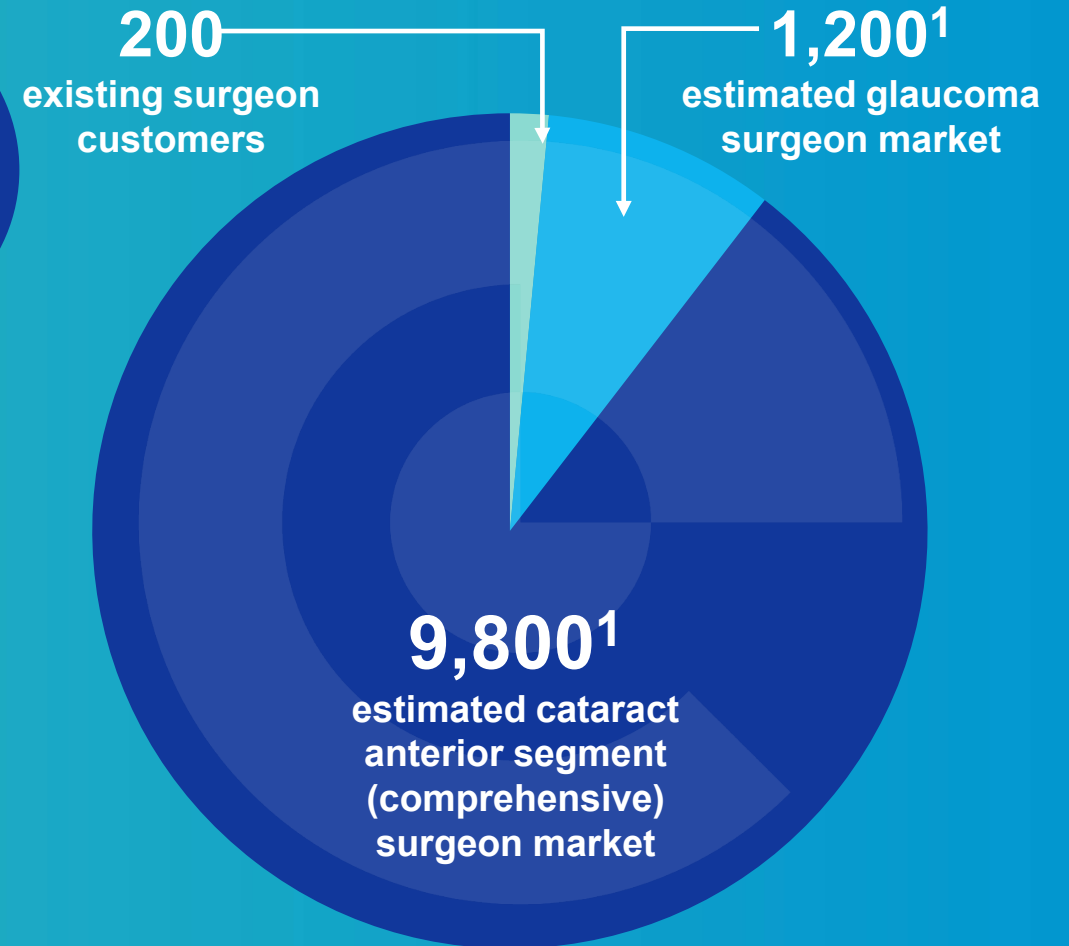
<sup>7</sup> As cleared for sale in USA

iTrack™ Advance significantly improves surgical ease of use without changing method of action.

The new ***iTrack™ Advance*** is expected to broaden Nova Eye Medicals customer base significantly in the USA. The device will not only appeal to glaucoma surgeons but also anterior segment surgeons / comprehensive surgeons, expanding the total addressable market in the USA by c.50x compared to current customers and c.8x1. compared with glaucoma surgeons alone

*“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.*

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



# H1FY23 Glaucoma Operating Result



GLAUCOMA SEGMENT				
	A \$'000's <sup>1</sup>		US \$'000's	
	H1FY22	H1FY23	H1FY22	H1FY23
Sales	6,488	8,316	4,752	5,698
COGS	(2,660)	(3,493)	(1,948)	(2,393)
Gross Margin	3,828	4,823	2,804	3,305
<b>Gross Margin</b>	<b>59%</b>	<b>58%</b>	<b>59%</b>	<b>58%</b>
Operating expenditure	(5,934)	(8,840)	(4,346)	(6,057)
<b>EBITDA/(loss)</b>	<b>(2,122)</b>	<b>(4,017)</b>	<b>(1,542)</b>	<b>(2,753)</b>

## H1 FY23 Investments iTrack™ Advance

- Training of early adopter U.S. surgeons prior to U.S. launch
- Increased tradeshow attendance and podium presence in Europe
- Establishment of clinical training team in Europe
- Additional sales representatives in Germany
- Original iTrack™ one of only two glaucoma devices approved in China

Sales Composition			
	US\$ (constant currency)		
	Six months to Dec 2021	Six months to Dec 2022	Growth
USA	3,037,820	3,083,566	2%
Germany	789,486	882,648	12%
China	490,000	1,049,718	114%
Rest of World	434,394	681,750	57%
	<b>4,751,700</b>	<b>5,697,681</b>	<b>20%</b>

# AlphaRET for AMD



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 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<sup>®</sup> 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.
- Commercialisation of 2RT<sup>®</sup> requires conducting a follow-up confirmatory pivotal clinical study.
- Estimated addressable market is 54 million people equating to US\$600m/year<sup>1</sup> revenue opportunity.

## AlphaRET



# Overview of AMD Market

## Intermediate stage disease - AlphaRET

(Treats underlying causes of AMD.)

### Intermediate AMD

54 million  
people worldwide<sup>(1)</sup>

Addressable  
by 2RT<sup>®</sup>

There is currently no treatment for patients with iAMD.  
Nutraceuticals are currently recommended<sup>(2)</sup>

## Late stage macular degeneration

### Wet AMD (CNV)

Choroidal Neovascularization

15 million  
people worldwide <sup>(1)</sup>.

- Australian PBS A\$0.6 billion <sup>(3)</sup>
- USA Medicare US\$3.5 billion <sup>(4)</sup>

Highest spends on any ocular drug  
in USA and any drug in Australia.  
Treating symptoms.  
Requires retreatment.

### Dry AMD (GA)

Geographic Atrophy

14 million  
people worldwide <sup>(1)</sup>

New emerging therapies include:

- Iveric Bio, US\$2.9 bn (NASDAQ: ISEE)
- Apellis, US\$6.1 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<sup>3</sup>.

DISEASE PROGRESSION

1) AlphaRET estimate based on LEAD study and MarketScope 2018 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 2021 PBS data<sup>8</sup>  
3) Apellis press release 17 February 2023 .  
4) Expenditure on Eylea, Avastin and Lucentis USA Medicare Report Aug 2021

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



Our 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.



## PRE-CLINICAL WORK



## PILOT CLINICAL STUDY



CE MARK (iAMD) APPROVED FOR SALE IN AUSTRALIA,  
NEW ZEALAND AND EUROPE. FDA APPROVAL FOR DIABETIC EYE  
DISEASE



## FEASIBILITY & SAFETY CLINICAL STUDY ("LEAD")



## PROTOCOL PREPARATION FOR CONFIRMATORY PIVOTAL CLINICAL STUDY



## CONFIRMATORY PIVOTAL STUDY COMMENCEMENT



## FDA: EXPANSION OF INDICATION TO INCLUDE iAMD AS WELL AS DIABETIC EYE DISEASE

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>.

So far expressions of interest to participate in the study received from all 28 invited retinal research institutions and leading retinal specialists.

Continuing to engage and progress discussions with a number of high-calibre potential partners.

# Update on iTrack™ Advance in USA



- As previously announced, iTrack™ Advance is currently progressing through the US FDA 510(k) pathway.
- FDA has recently requested that we file two final administrative changes to our documentation. This documentation has now been submitted.
- We anticipate FDA clearance for iTrack™ Advance in the coming weeks subject to finalisation of the administrative changes.

# Nova Eye Group Outlook




Sales of new *iTrack™ Advance* in the USA are expected to drive significant sales growth during the current and future fiscal years.

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Operating expenditure will increase to support the expansion of USA commercial infrastructure with the underlying operating results for the glaucoma surgical segment expected to improve progressively during the year ending 30 June 2024.

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Maintain AlphaRET strategic position as a world-leading technology with the potential to meet a very large unmet need and finalise transaction with a partner.



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