



# *Addressing the two leading causes of blindness in the developed world*

Nova Eye Medical Limited (ASX:EYE)  
Managing Director Presentation to Annual General Meeting

November 2023

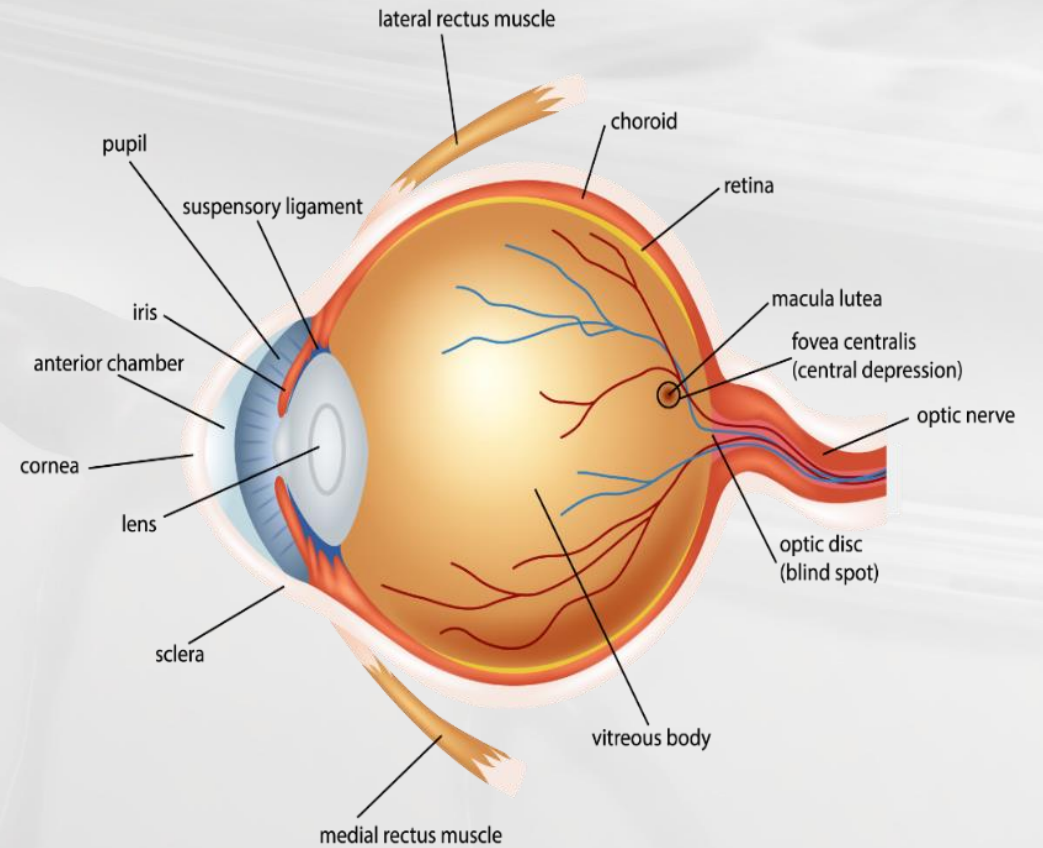
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# Nova Eye is addressing large unmet needs



## Glaucoma Opportunity

- 156 million <sup>(1)</sup> people with glaucoma worldwide US\$6.1m<sup>(1)</sup> annual expenditure on topical drugs US\$607m <sup>(1)</sup> annual expenditure on surgical devices
- The aging global population drives prevalence
- Significant medication drawbacks drive demand for minimally invasive glaucoma surgical (MIG's) devices
- Consumable surgical devices market projected market at 14% CAGR <sup>(1)</sup>

## AMD Opportunity

- 200million <sup>(2)</sup> people with Age Related Macular Degeneration (AMD) worldwide with only 29 million with the disease in its very late stage being treated
- 54 million<sup>(3)</sup> people have intermediate stage (iAMD) without any established treatment
- Like glaucoma, aging global population and increased screening drives prevalence of AMD.
- Randomized clinical study demonstrated potential of proprietary 2RT<sup>®</sup> to delay progression of AMD
- Nova Eye has structured AlphaRET as an SPV to pursue commercialization with an equity partner

(1) Marketscope 2023 Glaucoma Surgical Device Market Report

(2) Marketscope 2022 Ophthalmic Lasers Market Report

(3) Estimate made by Nova Eye based on the results of clinical studies

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# RECAP

Strong Sales in FY23 and strong growth in USA during FY24

FY 23 Record  
global sales  
**US\$11.3m**  
for the glaucoma  
surgical devices  
segment



US sales for  
4 months ended  
31 October 2023  
US\$3.34 million,  
up 74% from  
PCP



MACs sudden  
decision to re-  
classify canaloplasty  
as an investigational  
procedure expected  
to temporarily  
interrupt USA sales  
growth



Despite temporary  
interruption, we see  
a strong future for  
iTrack and a return  
to sales growth

# Proposed USA Medicare Changes



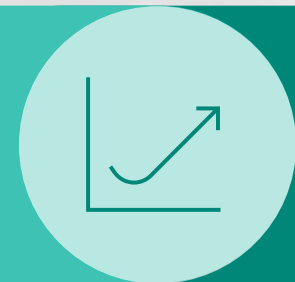
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Local coverage determination (LCD) proposed changes for Medicare reimbursement of (MIGS) in the USA, affecting six companies directly, have been proposed by 5 Medicare Administrative Contractors (MACs).



There are 7 MACs in the USA and the remaining 2 have so far not participated and new changes require 12 months' notice.

The changes have designated canaloplasty as “investigational”. If implemented, surgeries conducted after 23 December 2023 will not be covered.



The Company intends lodge a formal LCD Reconsideration Request on the basis that the MACs have overlooked data, CPT 1 Code and FDA Clearance. This will be our platform for MAC engagement in the future

The MACs have also imposed new criteria for clinical data inconsistent with both FDA approval standards and Medicare CMS guidelines<sup>(1)</sup>



250+ published scientific papers and 400+ patients being followed in a registry will be presented to reestablish reimbursement in the long term.

(1) Centre for Medicare Services allocation of CPT 1 code

# Molteno3<sup>®</sup>

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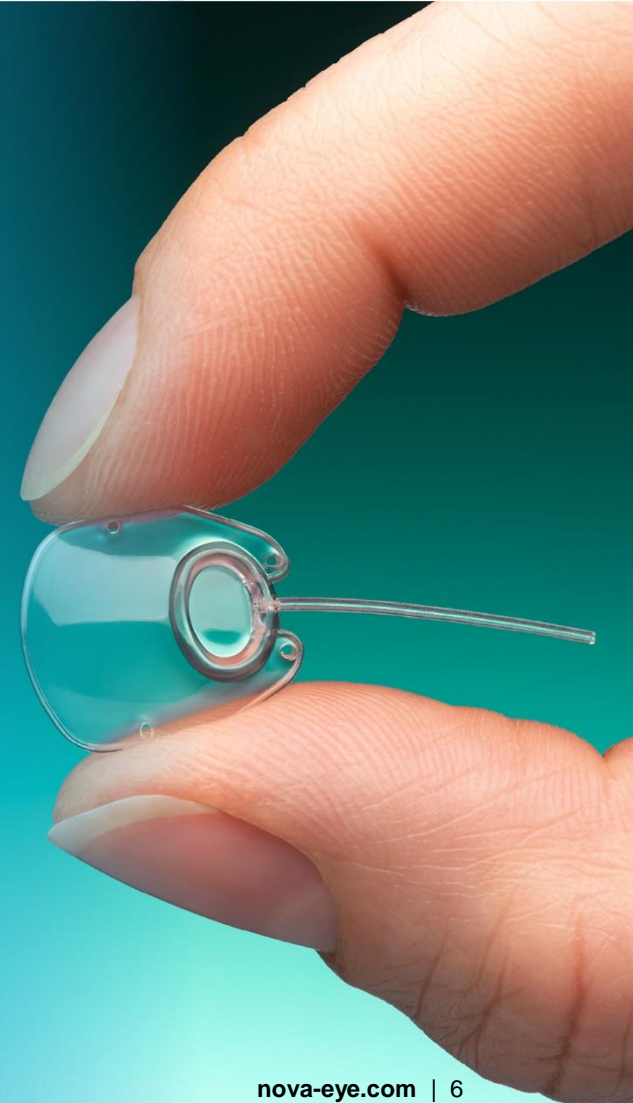
Implanted in thousands of patients worldwide for more than 30 years, the ***Molteno3<sup>®</sup>*** Glaucoma Drainage Device has been clinically validated to deliver consistent, long-term reduction in intraocular pressure (IOP) in cases of severe or complex glaucoma.

Indication	Glaucoma Drainage Surgery
Approval	All global approvals in place, including FDA and CE Mark
Reimbursement	Favorable CPT code
Patient	Complex Advanced Glaucoma
Surgeon Type	Glaucoma surgeon
Innovation	New improved version in progress

**30+ years**  
of surgical use

**0.4mm**

At just 0.4mm, Molteno3<sup>®</sup> is the slimmest plate on the market, which simplifies surgical insertion and reduces OR time.



# Overcoming the USA Reimbursement Challenges



- The changes by the MACs, if implemented are expected to cause a temporary reduction in sales growth in the USA in the coming months.
- Nova Eye has invested in an expansive IP portfolio that provides us with options to release of new devices and to expand indications for use for existing devices.
- Reimbursement coverage for glaucoma drainage devices, including our Molteno product, remain strong.
- Our IP portfolio allows us to pivot our product range to rectify the temporary sales reduction.

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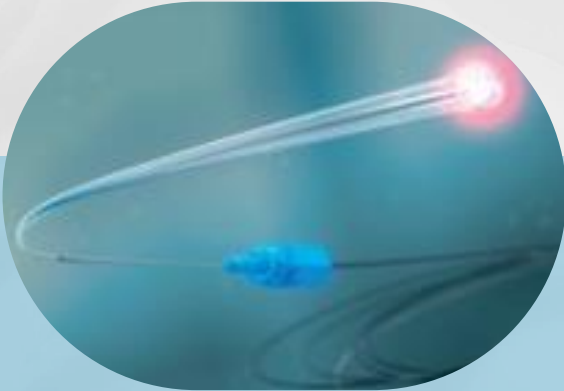
# Nova Eye Current Glaucoma Product Portfolio



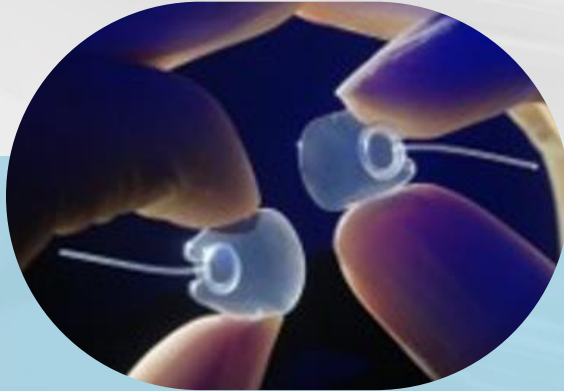
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iTrack Advance



iTrack



Molteno 3



iLumin





# Sales update for the four months to 31 October 2023



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	US\$ millions (unaudited sales)		Growth on PCP
	4 months ended 31 October 2022	4 months ended 31 October 2023	
<b>USA</b>	1.92	3.34	74% (1)
<b>Germany and Europe</b>	1.07	0.81	-24% (2)
<b>Global excluding China</b>	<b>2.99</b>	<b>4.15</b>	<b>39%</b>
<b>China</b>	0.78	-	Timing (3)
<b>Global including China</b>	3.77	4.15	

1) Major focus of sales and marketing investment has been in USA following launch of iTrack Advance in May 2023 with promising sales results. Investments in marketing outside the USA have been limited.

2) Sales in Germany and Europe in the PCP included a OEM sale of the iLumin light source of US\$256,000. After adjusting for this sale, iTrack sales have been steady in 2023 compared to the PCP reflecting the limited sales and marketing investment in this region.

3) Deliveries of product to distributor in China are made twice per year. Recent trading challenges with China have impacted timing. Order for H1FY24 is scheduled for December 2023. PCP was impacted by a delivery of previous order scheduled for 30 June 2022 delivery delayed export documentation till 5 July 2022

# Growth Opportunities Outside of the USA

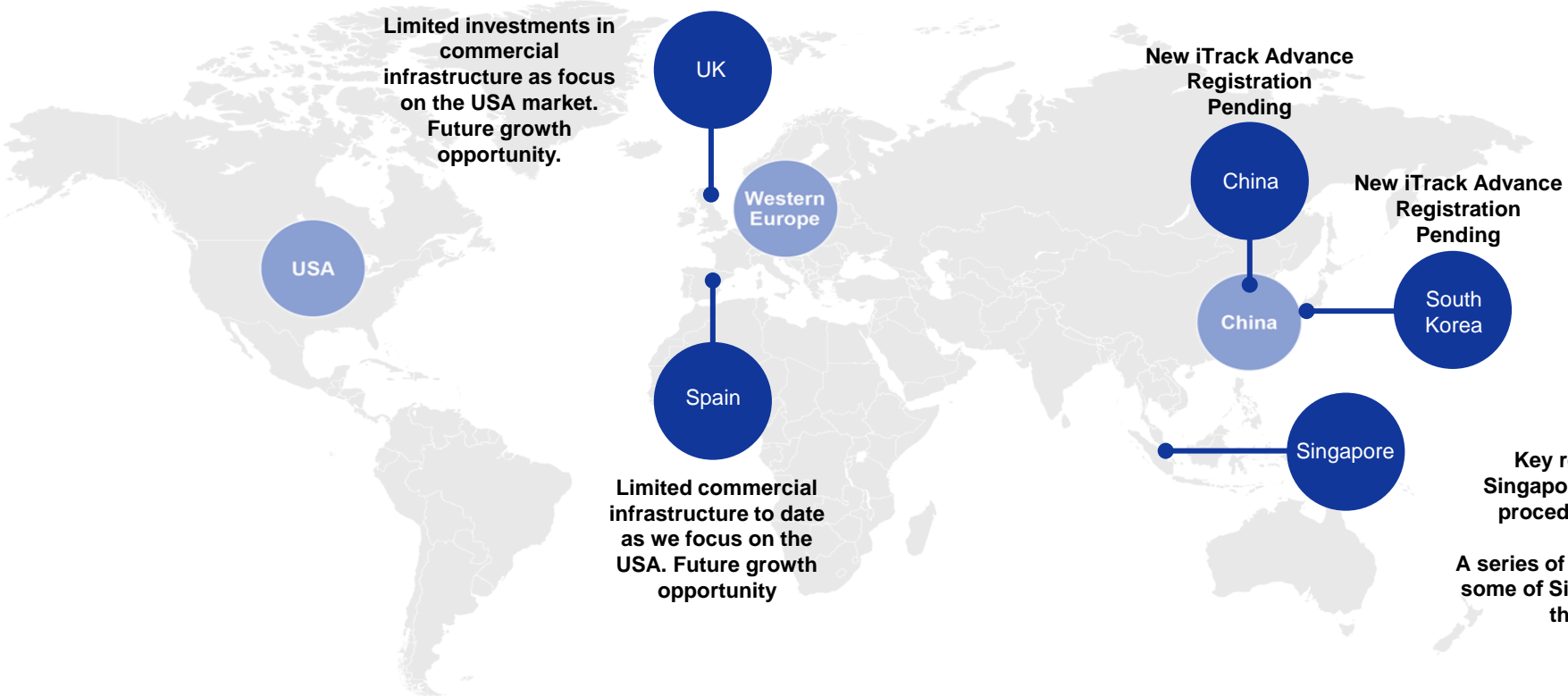


Markets outside of the USA continue to offer potential for Nova Eye's portfolio of proprietary products.

Nova Eye Medical secured several important registrations in key strategic markets outside of the USA during the period.

Registrations for iTrack Advance in China and South Korea are underway.

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Key registration completed in last 12 months- The Singaporean market is an important reference in driving procedural adoption throughout the South East Asia.

A series of surgical trainings have already been conducted at some of Singapore's leading teaching institutions, including the Singapore National Eye Centre (SNEC).

# AMD affects 200m people worldwide causing blindness



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## Intermediate stage disease – AlphaRET 2RT Treatment

**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>

## Preventing onset of Late stage AMD

**Wet AMD (CNV)**  
Choroidal Neovascularization  
15 million people worldwide <sup>(1)</sup>

- Australian PBS A\$0.7 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 only. Requires retreatment.

**Dry AMD (GA)**  
Geographic Atrophy  
14 million people worldwide <sup>(1)</sup>

New emerging therapies include:

- Iveric Bio recently acquired for US\$10 bn
- Apellis, US\$5.1 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>.

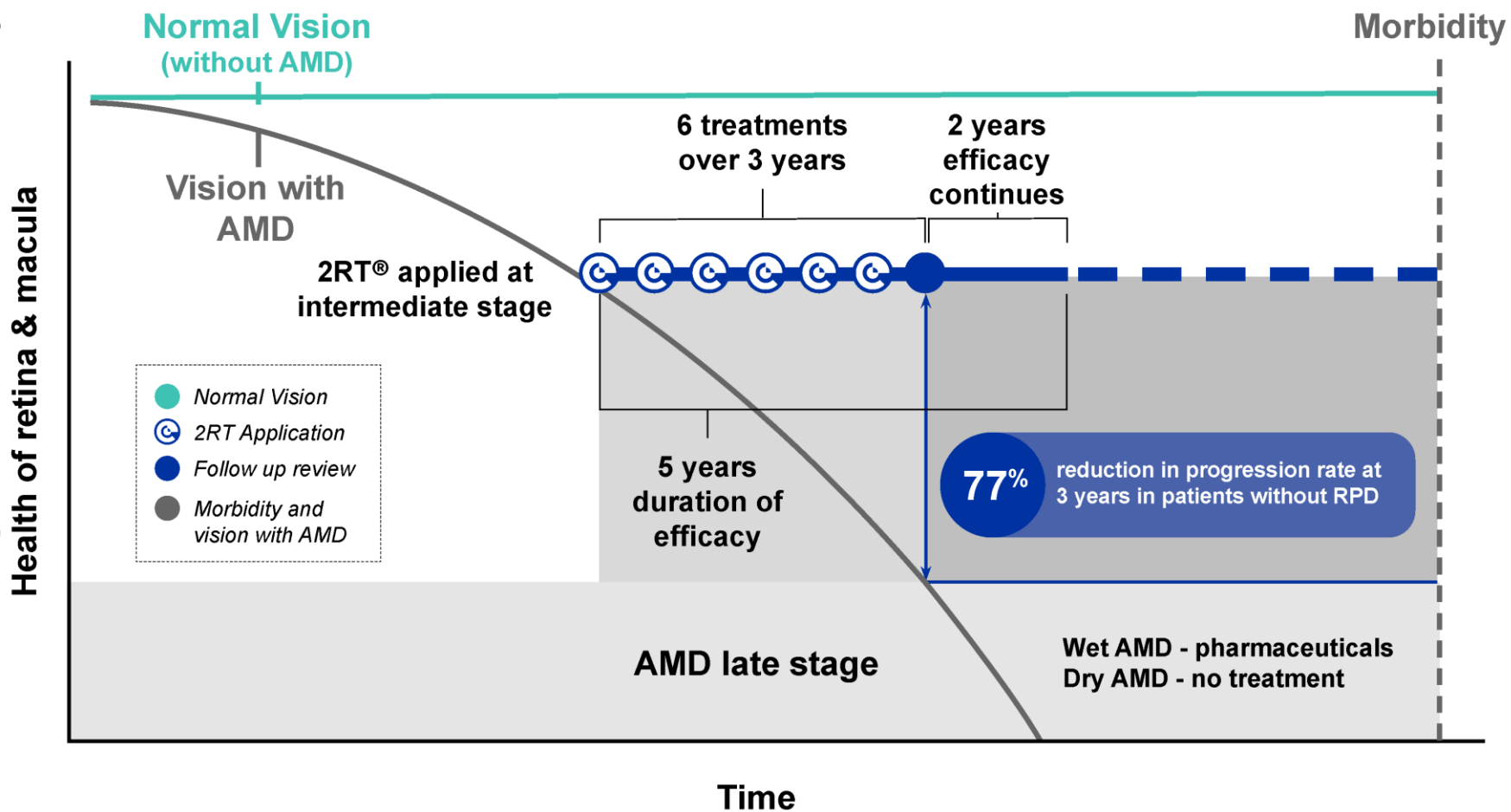


1) AlphaRET estimate based on LEAD study and MarketScope 2022 Ophthalmic Lasers Report including allowance for 24% of iAMD patients (based in LEAD study) cannot be treated because they have RPD  
2) Macular Degeneration Foundation Australia recommendation pamphlet "Nutrition for AMD". USA National Eye 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 2022 PBS data  
3) Apellis press release 17 February 2023 .  
4) Expenditure on Eylea, Avastin and Lucentis USA Medicare Report Aug 2021

# 2RT® for Intervention in AMD Progression



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Intervention schematic based on LEAD\* Clinical Trial demonstrated 77% reduction in the rate of progression in patients without reticular pseudodrusen (RPD) at enrolment.

24% of the study population had RPD at enrolment

New Protocol to exclude RPD patients from treatment

\* Post Hoc Analysis of Randomized Controlled Clinical Trial Robyn H. Guymer, MBBS, PhD, et al and published in peer reviewed journal *Ophthalmology* of the American Academy of Ophthalmology

# Current regulatory approvals for 2RT®



- **Europe and Mutual Recognition Jurisdictions** (including Switzerland, UK, Australia, NZ) where 2RT is approved for the treatment of patients with early AMD where it is approved for bilateral improvement in macular appearance and function.
- **Europe and Mutual Recognition Jurisdictions** (including Switzerland, UK, Australia, NZ, Canada) where 2RT is approved for the treatment of patients with clinically significant macular edema.
- **USA where 2RT has marketing clearance via a 510(k) approval** for treatment of patients with clinically significant macular edema.


Granted approvals provide the opportunity for immediate sales on commercial funding


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# Nova Eye Group Outlook




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 Sales of new iTrack™ Advance in the USA are currently running above plan but recent proposed changes to reimbursement coverage for canaloplasty procedures is expected to negatively impact sales in the coming months

 In the medium to longer term USA sales growth is expected to return and market access work recently undertaken is expected to grow sales OUS

 The company continues to carefully manage its cash resources

 Continue work towards a transaction with a partner to fund AlphaRET 2RT® commercialisation.



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