



# Results for the Year ended 30 June 2023

Nova Eye Medical Limited (ASX:EYE)

Strong Financial Results with Record Global Sales

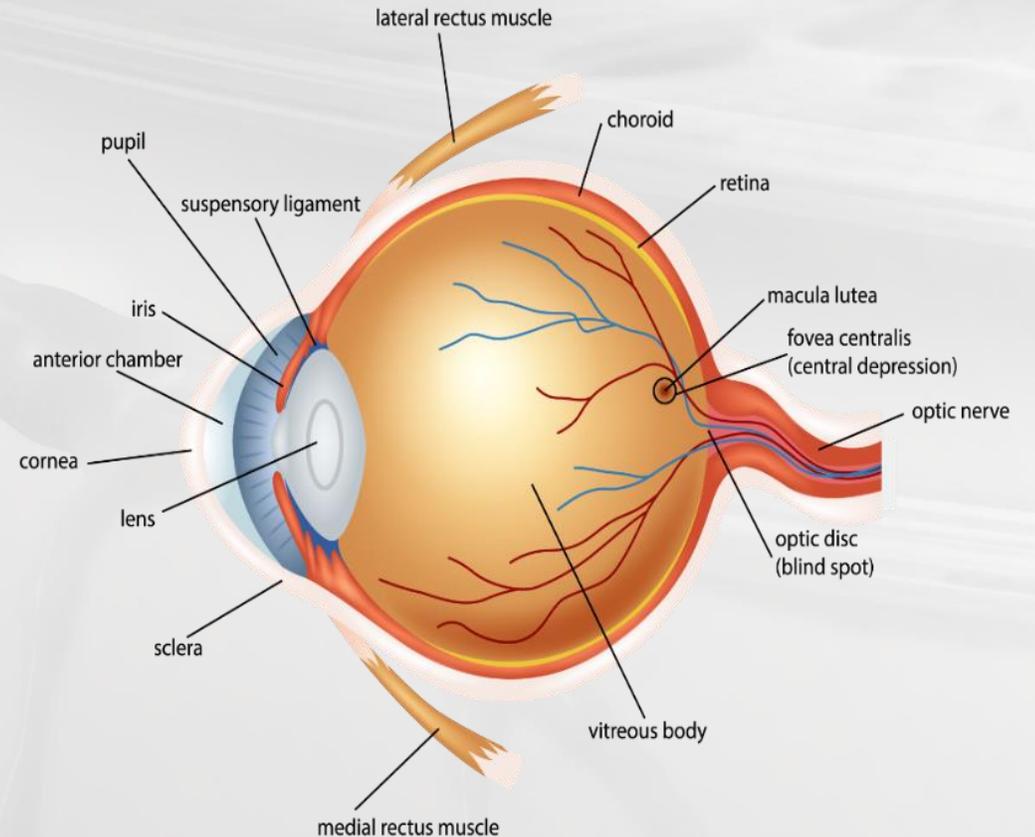
**August 2023**



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# FY23 Achievements

Strong Financial Results with Record Global Sales

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



Substantial lift in  
gross margin to  
**73%**  
compared to 60%  
in the first half FY23



Cash on hand  
**A\$7.4m**  
at 30 June 2023 to  
support growth



Sales in the USA  
3 months to 31 July 2023  
**US\$2.2m**  
up 32% on pcp, driven by  
the new iTrack™ Advance



# iTrack™

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A D V A N C E



- **New iTrack™ Advance** consumable MIGS device is redefining the treatment of glaucoma in its early stages.
- Canaloplasty offers a stent-free, tissue-preserving surgical treatment for glaucoma.
- Enhanced version of our original iTrack™ microcatheter, which was first brought to market in 2008 and has been used in more than 120,000 procedures globally.

# USA Sales Growth Plan, iTrack™ Advance

- A Active Accounts, Glaucoma | x200 surgeons**  
Successfully transitioned existing iTrack™ customer accounts to iTrack™ Advance during May-June 2023.
- B Inactive Accounts, Glaucoma | x300 surgeons**  
Reactivation of inactive customer accounts commenced July 2023 and will continue through FY24.
- C New Accounts, Glaucoma | x900<sup>1</sup> surgeons**  
Sales growth via new glaucoma surgeon accounts to commence later in CY23.
- D New Accounts, Cataract and Comprehensive | x10,000<sup>1</sup> surgeons**  
Sales growth via new cataract and comprehensive surgeon accounts to commence late in CY23.

*“iTrack™ usage has been primarily by glaucoma specialists. The iTrack™ Advance will make canaloplasty more accessible to the much broader market of cataract and anterior segment surgeons.”*  
**David Lubeck, MD (Chicago, USA)**

Current Sales Growth

32% FY23

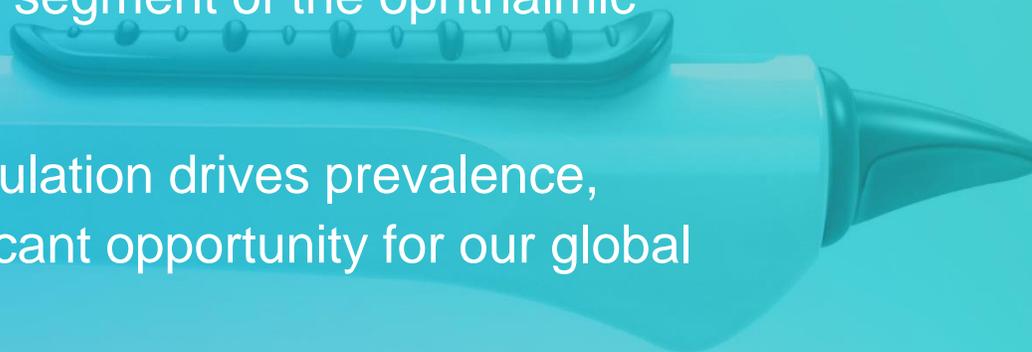


<sup>1</sup> Nova Eye estimate

# Our Glaucoma opportunity



- The glaucoma consumable surgical devices market is the fastest growing segment of the ophthalmic market.
- The aging global population drives prevalence, representing a significant opportunity for our global business.
- Significant drawbacks associated with medications drives preferential growth of our proprietary consumable surgical devices.



1. Marketscope 2023 Glaucoma Surgical Devices Reports. Growth in glaucoma surgical devices.

# Important FY23 Activities



Record global sales revenue of US\$11.3 million for the glaucoma surgical device segment during the period, up 18% on the prior comparable period.



Equates to sales revenue of A\$16.7million, up 26% on the prior comparable period.

In the USA, sales were achieved late in the second half of the year, following marketing clearance of the Company's new iTrack™ Advance.



Total sales in the USA for FY23 was US\$6.6 million, a modest increase from US\$6.4 million in the prior year.

Momentum in the USA continued through July 2023, with the three-month period ending July 2023 achieving a 32% uplift in sales compared to previous corresponding period.



Acceleration of sales occurred during this three-month period (May-July 23).

Outside of the USA, FY23 sales were US\$4.6 million, an increase of 46% on the pcp.



Strong result was principally driven by sales of original iTrack™ into China, now 16% of total global sales revenue. Sales in Europe were flat.

# Clinical Data Update

Continued to invest in clinical data program to support market development and market access initiatives, including:

**iTrack™ Global Data Registry**, hosted in collaboration with the International Glaucoma Surgery Registry (IGSR) and initiated in 2022, currently comprises 20 sites in the USA, Canada, Europe, Asia and Australia and incorporates more than 350 iTrack™ /iTrack™ Advance procedures. WCG IRB (approval number) 20200728. See data inset.

**MAGIC Europe** multi-center, randomized trial comprises six sites in the UK, Italy, Spain and Germany. Patient recruitment targeted for completion in early 2024 calendar year. NCT05786196.

**CATALYST** multi-center, randomized control trial comprises four sites in Germany. Patient recruitment targeted for completion in early-mid 2024 calendar year. NCT05564091.

# Real-World Registry Data

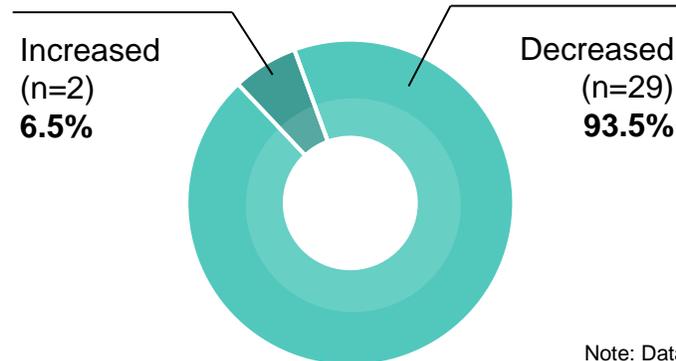
Reinforces Safety and Efficacy of iTrack™

## Summary of the Real-World Registry so far:

- 367 patients of a broad range of ethnicities.
- 265 patients with primary open-angle glaucoma, 45 patients with angle-closure glaucoma, 62 patients with other forms of glaucoma.
- 226 patients classified as mild to moderate, the balance having advance or severe glaucoma.
- 12 month follow up completed on part of this population.

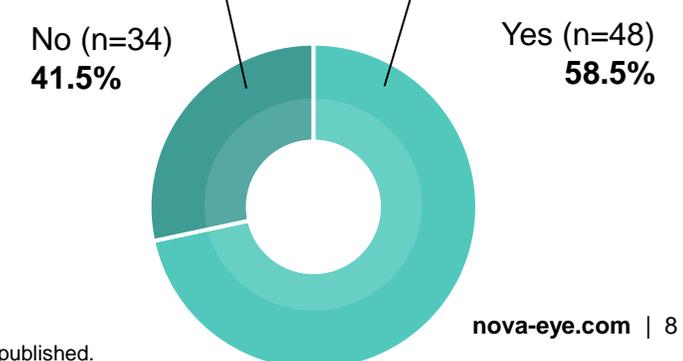
## IOP Reduction

(Preop IOP >18 mmHg, 12 months)



## Medication-Free

(All Eyes, 12 months)



Note: Data not yet published.

# FY23 Glaucoma Operating Result



US \$'000's <sup>1</sup>		US \$'000's <sup>1</sup>		
		H1FY23 (July 2022 to Dec 2022)	H2FY23 (Jan 2023 to June 2023)	FY23
6,359	Sales USA	3,084	3,564	6,648
3,175	Sales OUS	2,496	2,129	4,625
<b>9,534</b>	<b>Total Sales</b>	<b>5,580</b>	<b>5,693</b>	<b>11,273</b>
(3,703)	COGS <sup>2</sup>	(2,203)	(1,522)	(3,725)
5,791	Gross Margin	3,376	4,171	7,548
<b>61%</b>	<b>Gross Margin %</b>	<b>61%</b>	<b>73%</b>	<b>67%</b>
(8,026)	Operating expenditure <sup>2</sup>	(5,900)	(5,748)	(11,548)
<b>(2,235)</b>	<b>EBITDA/(loss)</b>	<b>(2,524)</b>	<b>(1,577)</b>	<b>(4,100)</b>

## Geographic Sales Composition:

- Sales composition US\$:
  - USA 59% (pcp 67%)
  - W Europe 25% (pcp 28%)
  - China 16% (pcp 5%)
- Large contribution from China
- Sales in Europe were flat

## Gross Margin improvement in H2:

- Higher average selling prices
- Production efficiencies in Fremont for iTrack™ Advance

1. AUD to USD FX rate FY22 = 0.74, AUD to USD FX rate = 0.66, average

2. FY22 excludes reimbursement of costs by US government of US\$1.1m for COVID 19 incurred costs (stimulus).

# AlphaRET for RETINAL DISEASE



2RT<sup>®</sup> is a proprietary, world-first nanosecond laser therapy to treat retinal disease including 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 and other retinal diseases.

- **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.
- Estimated addressable market is 54 million people equating to US\$600m/year<sup>1</sup> revenue opportunity.
- Commercialisation of 2RT<sup>®</sup> requires funding that exceeds the financial resources currently available to the Company.
- In discussion with potential partners to take a direct equity interest in AlphaRET in exchange for funding.

## AlphaRET

<sup>1</sup> Nova Eye estimate

# FY23 Group Cash



	A\$'000's		
	H1FY23 (July 2022 to Dec 2022)	H2FY23 (Jan 2023 to June 2023)	FY23
Receipts from customers	8,613	8,968	17,581
Payments to suppliers	(13,268)	(12,609)	(26,237)
Income tax refund and R&D rebate	429	968	1,397
Other/ Grants	(29)	464	435
<b>Cash (out) flow from group operations</b>	<b>(4,615)</b>	<b>(2,209)</b>	<b>(6,824)</b>

- Material improvement in cash out flow from operations in the second half due to
  - Increased selling prices
  - Production improvements in Fremont
  - Reduction in expenditure on AlphaRET
- Income tax refund receivable of \$0.9m at 30 June 2023

Group cash on hand  
at 30 June 2023  
**\$7.4 million**

# Nova Eye Group Outlook



Sales of new iTrack™ Advance in the USA are expected to drive significant sales growth for the Company's glaucoma surgical device segment in the 2024 financial year and beyond.



Operating expenditure will increase to support the expansion of global sales in the glaucoma surgical device segment, with the improvement in the underlying operating results for the glaucoma surgical segment evident in the second half of 2023 financial year expected to continue during the year ending 30 June 2024.



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



**Mahmoud A. Khaimi, MD**  
Clinical Professor and James P. Luton, MD  
Endowed Chair in Ophthalmology  
Glaucoma Fellowship Director  
Dean McGee Eye Institute, University of Oklahoma

# Business Snapshot



Nova Eye Medical leads the way in interventional treatment solutions for glaucoma and age-related macular degeneration (AMD), **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	Canaloplasty segment of the glaucoma surgical devices market scheduled to grow rapidly 2022-27
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, including USA (FDA)
Reimbursement	Favorable CPT codes (USA)

AlphaRET, AMD	
Strategy	Commercialise 2RT® to technology with partner
Market	Intermediate Age-related Macular Degeneration treatment (iAMD) – market not addressed. Underserved market for retinal disease therapy
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. FDA USA clearance for diabetic eye disease

# Company Overview

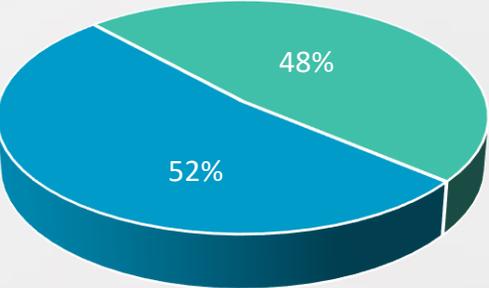


## Capital Structure

ASX Code	<b>EYE</b>
<b>Share Price</b> (at 21 August 2023)	<b>\$0.25</b>
Shares on Issue	190 M
Unlisted Options	3.35 M
<b>Market Capitalisation</b>	<b>\$49.5 M</b>
Cash	\$7.54M
Top 20 Shareholders	55%

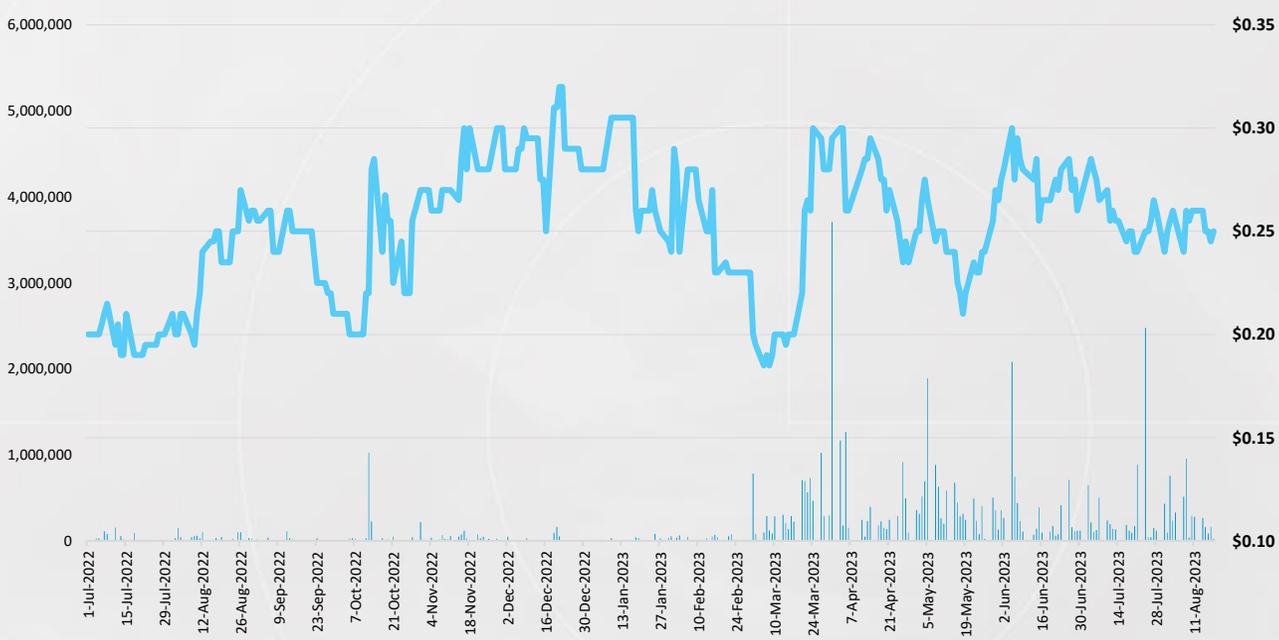
## Shareholders

Significant shareholder support from the top 20 shareholders



- Top 20 Shareholders
- Others

## Share Price Chart



■ Volume — Share Price





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MEDICAL®

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