



Nova Eye Medical Limited (ASX:EYE)

**Annual General Meeting** 

21 November 2024

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# **Company Overview**

Capital Structure	
ASX Code	EYE
Share Price (at 20 November 2024)	\$0.16
Shares on Issue	229M
Unlisted Options	~3.35M
Market Capitalisation	\$36.65M
Cash at 30 September 2024	\$3.70M
Top 20 Shareholders	45%

#### Shareholders

Significant shareholders in top 20 shareholders

- Australian Ethical Investments 18.21%
- Various Australian Funds 4.16%
- Victor Previn (Chair) 5%

#### Directors<sup>(1)</sup>

- Rahmon Coupe ~1,300,000 ordinary shares
- Tom Spurling ~1,000,000 ordinary shares and 700,000 options
- Dan Webb 550,000 ordinary shares
- Mike Southard 20,000 ordinary shares

(1) All ordinary shares purchased on market or via subscribing to new share issues

(2) 99% of revenue and 75% of costs n USD or Euro



#### Global Sales and Group EBITDA US\$ (2)





\$0.35

\$0.30

\$0.25

\$0.20

\$0.15

\$0.10

# Highlights



#### • Strong U.S. Sales Growth

• Sales increased 35% during the four months to October 31, 2024, compared to the prior corresponding period (pcp), reflecting strong market penetration by our direct sales force.

#### Robust Global Performance

• Global sales rose 44% (including 55% in the USA) over the trailing 12 months. Achieving early returns on commercial investments in international markets.

#### Supply Chain Resilience

- Temporary supply chain challenges in the first quarter impacted growth but were effectively resolved.
- Sales rebounded in October, meeting growth targets and solidifying operational stability.
- Progress Toward Profitability in Glaucoma Division
  - U.S. glaucoma operations are approaching breakeven, with a significantly improved with EBITDA loss of A\$0.4 million for the six months to June 30, 2024, down from A\$2.5m in H1FY24.
  - The division is on track to achieve breakeven in FY25.

## What is Glaucoma?

- Glaucoma is the second leading cause of blindness in the developed world (behind cataracts)<sup>(1)</sup> with no cure.
- The body produces a protein rich liquid that circulates through the ocular structures to keep it healthy.
- Glaucoma is a failure of the eye's natural outflow system through which that liquid flows. Pressure builds.
- Progressive, irreversible eye disease that causes vision loss due to optic nerve damage from elevated intraocular pressure (IOP).



too much fluid stays in

the eye and IOP rises.

<sup>(1)</sup> Marketscope 2024 Glaucoma Surgical Device Market Report

nerve, leading to blindness.

# **Glaucoma Treatment Overview**

- Traditional medication treatment paradigm is chronic medication use which causes eye damage limiting future treatment options.
- Patients and surgeons are favouring<sup>(1)</sup> minimally invasive glaucoma surgery (MIGS) earlier in the disease state.
- MIGS are a solution to nonadherence and can offer improved safety profile and better certainty of outcome<sup>(1)</sup>.
- 131 million<sup>(1)</sup> people with glaucoma worldwide with US\$5.7 billion<sup>(1)</sup> annual expenditure of which 92%<sup>(1)</sup> is spent on medications and devices. Market for surgical devices is US\$772 million<sup>(2)</sup> and forecast to reach US\$1,560<sup>(2)</sup> million by 2029.
- Nova Eye is a key player in the global MIGS market with its canaloplasty device, *iTrack*<sup>™</sup> *Advance*.



# Patient adherence to glaucoma medications is poor

Approx 50% of patients are non-compliant with their medications

Approx 50% purposely discontinue their medication(s) within 6 months

Nordstrom BL, Friedman DS, Mozaffari E, Quigley H, Walker AM. Persistence and adherence with topical glaucoma therapy. Am J Ophthalmol. 2005;140(4): 598-606

Glaucoma surgical devices are increasingly recognised as a viable alternative to medications – and this is the highest area of focus and return for the patient, the physician and the supplier.

# **iTrack**<sup>™</sup>

#### A D V A N C E

- iTrack<sup>™</sup> Advance
  Single-use MIGS device is redefining the treatment of glaucoma in its early stages.
- Canaloplasty offers a stent-free, tissue-preserving surgical treatment for glaucoma using an injector technology.
- Injector technology has enhanced our original iTrack<sup>™</sup> which has now been used in approx. 150,000<sup>(1)</sup> procedures globally.
- iTrack<sup>™</sup> Advance was approved by the FDA in April 2023 and has driven substantial sales growth since then.

# *iTrack*<sup>(TM)</sup> Advance - Angioplasty of the Ocular System







 Clearing blockages and rejuvenating the eye's natural outflow pathways that have been compromised by glaucoma disease.

## Clinically Significant Features *iTrack<sup>™</sup> Advance* vs Other MIGS

Device	Company	Procedure	Patient Population	Natural Outflow Pathway		Implant- free	Preserves Tissue	
				Trabecular Meshwork	Schlemm's Canal	Collector Channels		
iTrack™ Advance	Nova Eye Medical	Canaloplasty	Mild-moderate glaucoma	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
KDB <sup>(1)</sup>	New World Medical	Goniotomy i.e. cutting of tissue	Mild-moderate glaucoma	$\checkmark$	×	×	✓	×
OMNI <sup>(1)</sup>	Sight Sciences	Canaloplasty followed by goniotomy i.e. cutting of tissue	Mild-moderate glaucoma	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	×
iStent <sup>(1)</sup>	Glaukos	Micro-trabecular bypass stent	Mild-moderate glaucoma	$\checkmark$	×	×	×	$\checkmark$
Hydrus <sup>(1)</sup>	Alcon	Micro-trabecular bypass stent	Mild-moderate glaucoma	$\checkmark$	$\checkmark$	×	×	$\checkmark$



Canaloplasty surgery has a well-established CPT1 code authorised by the USA CMS<sup>2</sup>



(2) Centers for Medicare and Medicaid Services

(3) 2024 Approved Rates. Rates approved for 2025 are US\$2,094 to the facility and US\$600 for the surgeon

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## Revenue by Geographic Region



US \$000's	4 months to 31 Oct 23 <sup>(1)</sup>	4 months to 31 Oct 24 <sup>(1)</sup>	Growth on PCP	Trailing 12 months to 31 Oct 23 <sup>(1)</sup>	Trailing 12 months to 31 Oct 24 <sup>(1)</sup>	Growth on PCP
USA	3,338	4,385	31%	8,033	12,419	55%
Germany	435	563	29%	1,490	1,759	18%
China	-	360		957	1,356	42%
ROW	382	318	-17%	1,083	1,111	3%
Total sales in US\$	4,155	5,627	35%	11,563	16,645	44%
Total sales in A\$		8,525			25,219	

- Robust growth continues, with a 44% increase year-on-year driven primarily by ongoing USA demand.
- October sales realigned to growth targets underscoring the strong surgeon appetite for the Company's *iTrack*™ Advance.
- Sales growth in all global territories achieved for the first time.

#### [1] Based on management accounts

# USA Sales 2 Years to 30 June 2024 and First 4 Months FY25

- Four consecutive half-year periods of growth in USA. Introduction of *iTrack™ Advance* in April 2023 (H2FY23).
- Growth continues into the first four months of FY25.
- Revenue growth in H2FY24 compared with H2FY23, demonstrates surgeon take up and satisfaction with *iTrack*<sup>™</sup> *Advance*.
- Marketing investment, surgeon engagement and expanded podium presence, augmented by sales specialists' recruitment, has driven sales increase.

Launch of *iTrack*<sup>™</sup> Advance in the USA in April 2023





USA sales growth FY23 to 31 October 2024

## **USA Market Share Estimate - iTrack**





- (1) Nova Eye trailing 12 months revenue to 31 October 2023 and 31 October 2024 for iTrack only, excludes Molteno.
- (2) Based on published data for USA sales 2023 and 9 months to 30 September 2024. and Nova Eye estimate using guidance for 2024 provided in GKOS September 2024 quarterly report
- (3) Balancing item using (1), (2), (3) and (4). There is no data published by the companies to support this. The companies listed sell products in this market.
- (4) Based on published data for 2023 and 9 months to 30 September 2024. and Nova Eye estimate using guidance for 2024 provided in SGHT September 2024 quarterly report
- (5) Based on Market Scope Glaucoma Surgical Devices 2024 report, sum of stents, canaloplasty and goniotomy
- (6) Assumes Alcon Hydrus, New World Medical Kahook Dual Blade, and AbbVie Xen stent. There may be other products.

## **USA Reimbursement Update**

- Surgeries with iTrack continue to attract the established CPT1 reimbursement code from US Medicare (CMS).
- From December 2024 MAC's (Medicare Administrative Contractors) will reduce reimbursement payments of stents used in for combination with MIGS procedures in same patient eye.
- 2025 US Medicare reimbursement for surgeries with iTrack continues at a constant rate, underpinning our growth plans.

### Operating results for glaucoma segment shows positive trends <sup>(1)</sup>



USD '000	H1FY23	H2 FY23	H1FY24	H2FY24
Sales global	5,698	5,575	6,673	8,565
GM	3,305	4,243	4,604	6,262
	58%	76%	69%	73%
Opex	(6,057)	(5,491)	(6,193)	(6,530)
EBITDA(loss)	(2,752)	(1,248)	(1,589)	(268)

#### **Glaucoma Segment Global Sales and EBITDA** 10,000 8,000 6,000 4,000 2,000 (2,000)(4,000)H1FY23 H2 FY23 H1FY24 H2FY24 US\$000's Sales global EBITDA(loss)

#### Commentary

- Improved gross margin with expanded volumes
- Continuing production methods improvement to lower costs
- Improved return on marketing investment with recruitment of new sales reps in the USA has seen sales growth improve the bottom line
- Last 4 half year periods, show progressive improvement in EBITDA

(1) Approximately 99% of glaucoma segment revenues and 90% of the glaucoma segment costs are denominated in US\$ or Euros

#### Positive glaucoma operating results drive group results



AU\$'000's	H1FY23	H2FY23	H1FY24	H2FY24
Sales glaucoma	8,315	8,346	10,062	13,096
Group EBITDA (loss) <sup>(2)</sup>	(6,096)	(3,454)	(4,203)	(1,781)

Sales and Group EBITDA in AUD

AU\$'000's	H2FY24
Glaucoma segment	(451)
AlphaRET segment	(268)
Corporate	(1,062)
Group EBITDA (loss) <sup>(2)</sup>	(1,781)

(1) Approximately 99% of glaucoma segment revenues and 75% of the group costs are denominated in US\$ or Euros
 (2) US government COVID grant income recognised is income in FY23 and R&D grant income in FY24 removed to aid period to period comparison



 Sustained Sales Momentum: Strong sales growth in FY24 extended into FY25, demonstrating resilience and market demand, despite temporary supply chain disruptions (now resolved).

- Operational Recovery: October 2024 sales rebounded to meet growth targets, underpinned by robust adoption of the *iTrack™ Advance* by leading surgeons globally.
- Clear Path to Profitability: The glaucoma segment is nearing breakeven, with FY25 expected to mark a significant milestone in Nova Eye's financial performance.



- 2RT has the potential to change the treatment paradigm for age-related macular degeneration.
- To fully exploit its potential, capital is required, and the Board is seeking nondilutive alternatives
- The company remains committed to pursue sales growth and profitability improvement in our interventional glaucoma business while we continue to seek partnerships to fund 2RT



#### Tom Spurling Managing Director +61 8 8362 0193 tspurling@nova-eye.com

#### Mark Flynn

Investor Relations +61 416 068 733 mflynn@nova-eye.com