



Addressing the leading causes of blindness in the developed world

Nova Eye Medical Limited (ASX:EYE)
Capital Raising Presentation

February 2024

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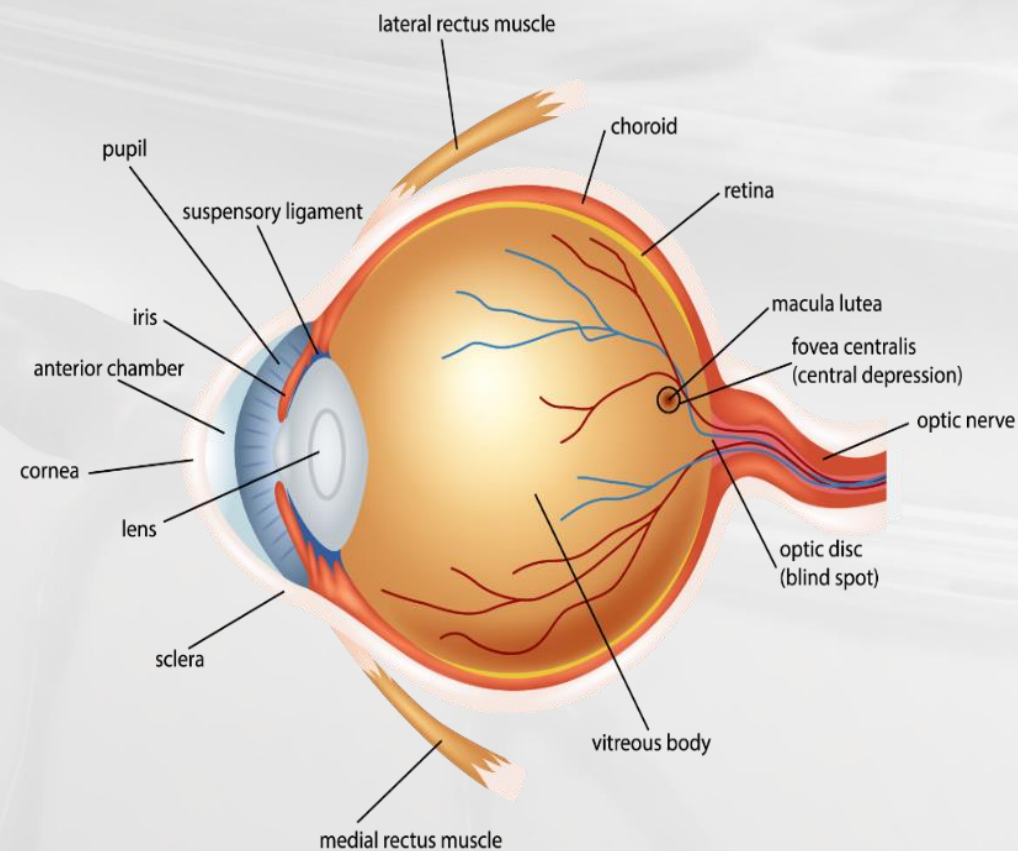
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Executive Summary



- 01** Following FDA clearance on March 30, 2023, and subsequent USA launch of the iTrack™ Advance in May 2023, Nova Eye Medical Limited (Nova Eye) has driven USA glaucoma sales revenue to US\$5.1m for 1H FY24, up 65% on pcp, selling through its own sales team direct to US eye surgeons
- 02** Glaucoma products sales growth in the first half of FY24 was achieved despite market uncertainty during November and December arising from proposed changes to reimbursement tabled by Medicare Administrative Contractors (MACs) to restrict reimbursement coverage. The proposed changes were withdrawn on 29 December 2023 enabling future sales growth
- 03** Nova Eye sees significant near and medium-term opportunities to expand our glaucoma geographic sales footprint across the USA, alongside strategic international markets. Focused product development and clinical evidence collation across the Glaucoma portfolio will de-risk the Company from reimbursement changes
- 04** Announcement of capital raising of \$8.0 million to capitalise on identified near-term growth opportunities in Glaucoma



Nova Eye Medical

Company Overview



Glaucoma Opportunity

- 126 million⁽¹⁾ people with glaucoma worldwide with US\$5.6 billion⁽¹⁾ annual expenditure of which 78%⁽¹⁾ is spent on medications and devices. Market for surgical devices is US\$743 million⁽²⁾ and forecast to reach US\$1,341⁽²⁾ million by 2028
- Significant medication drawbacks drive demand for surgical device alternatives
- Consumable surgical devices market projected market at 15% CAGR⁽²⁾

(1) Marketscope 2023 Glaucoma Surgical Device Market Report and Marketscope 2022 Glaucoma Surgical Device Market Report

(2) Marketscope 2023 Glaucoma Surgical Device Market Report, 2024 estimate and 2028 estimate incorporating stents, canal surgery and glaucoma drainage devices, growth through to 2028

Business Segment Overview

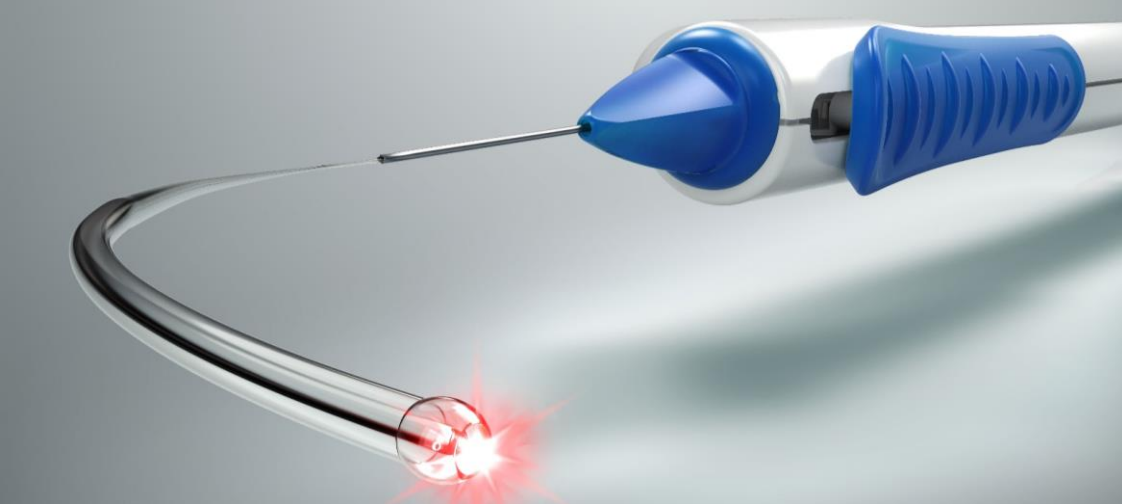


Nova Eye Medical, Glaucoma	
Strategy	Develop, market and sell comprehensive portfolio of glaucoma consumable surgical devices
Key products	iTrack™ Advance, iTrack™, Molteno3,
Total Addressable Market	US\$743m ⁽¹⁾ with the glaucoma surgical devices market growing at 15% CAGR over 2022-28 ⁽¹⁾ displacing medication
Sales	Established infrastructure; direct sales in USA, Germany, Australia; distributors in key markets
Manufacturing	California, USA and Dunedin, New Zealand
IP Status	Patents issued and pending in major markets
Regulatory	Europe and Mutual Recognition Jurisdiction and USA (FDA)
Reimbursement	Reimbursed by USA Medicare

AlphaRET, AMD	
Strategy	Commercialise unique and proprietary technology that addresses AMD with funding from a partner
Key products	2RT®
Total Addressable Market	62 million ⁽²⁾ people worldwide with Intermediate Age-related Macular Degeneration treatment (iAMD) – market not addressed.
Sales	Sales program to coincide with funding
Manufacturing	Adelaide, Australia based contract manufacturing
IP Status	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
Structure	AlphaRET is a wholly-owned subsidiary of Nova Eye Medical Limited.

(1) Marketscope 2023 Glaucoma Surgical Device Market Report, 2024 estimate incorporating stents, canal surgery and glaucoma drainage devices, growth through to 2028

(2) Estimate made by Nova Eye based on the results of clinical studies and Marketscope 2022 Ophthalmic Lasers Market Report, 2024 estimate

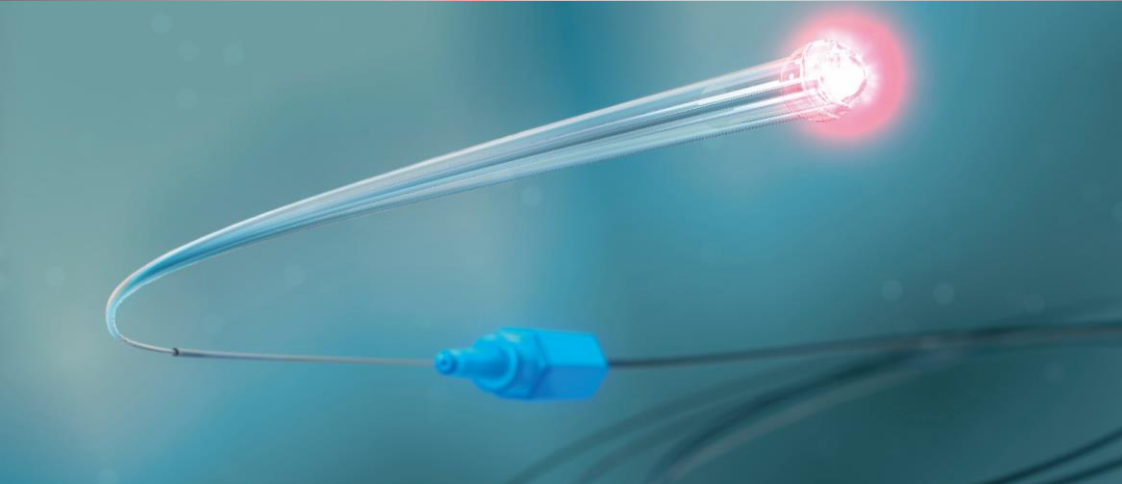


Addressing disease
progression



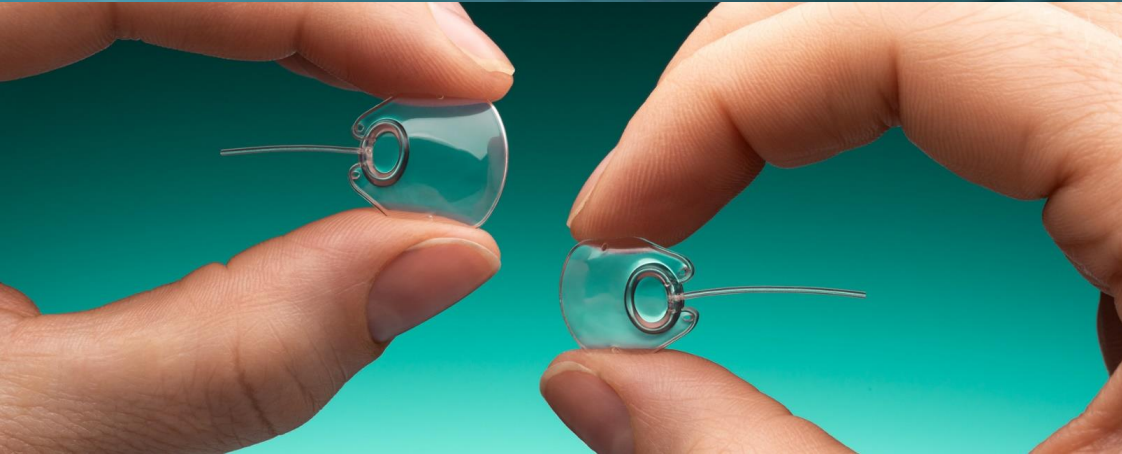
iTrack™
Advance
(mild to moderate)

.....



iTrack™
(mid stage)

.....



Molteno3
(Severe and Complex)

.....

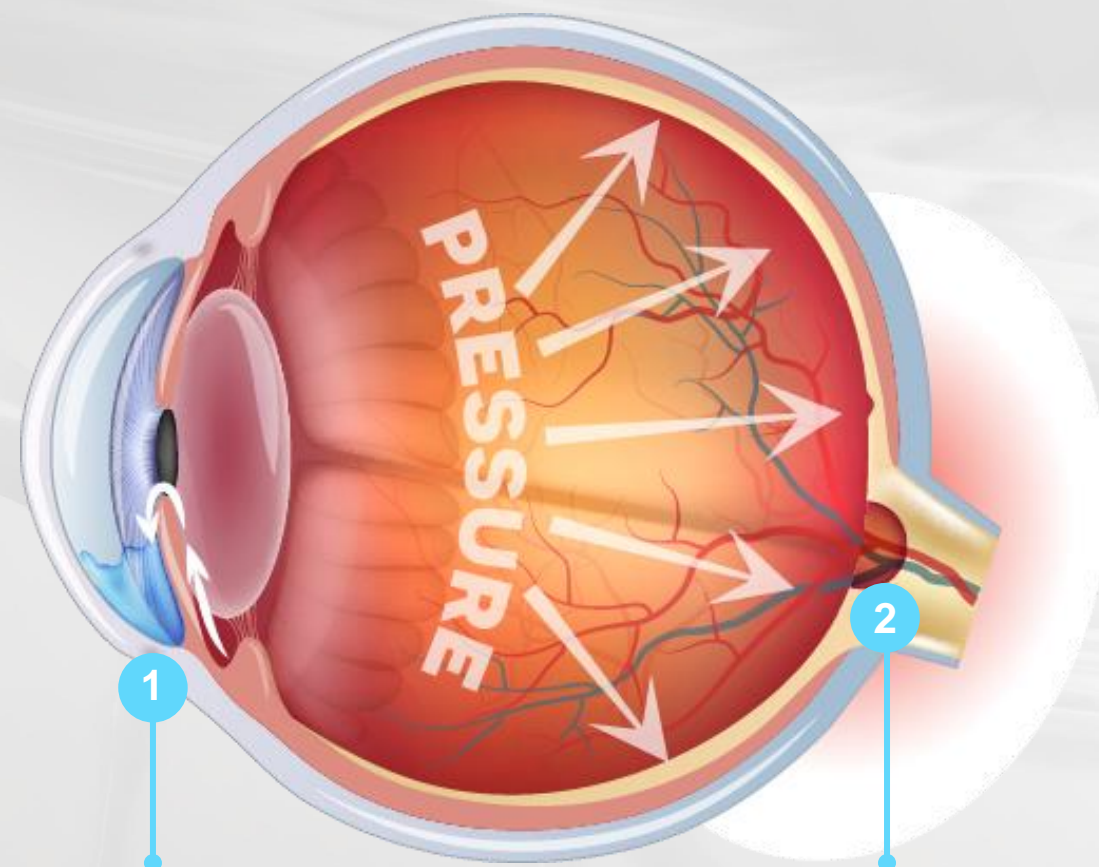
Glaucoma

Nova Eye Current
Product Portfolio

Glaucoma Disease Overview



- Glaucoma is the second leading cause of blindness in the developed world (behind cataracts)⁽¹⁾
- Progressive, irreversible eye disease that causes vision loss due to optic nerve damage from elevated intraocular pressure (IOP).
- There is no cure for glaucoma.
- Topical medications are standard of care but nonadherence is ubiquitous
- Nova Eye's products reduce IOP via surgical procedures



1. Drainage canal becomes blocked; too much fluid stays in the eye and IOP rises.

2. High IOP damages optic nerve, leading to blindness

Glaucoma Treatment Overview

- Traditional medication treatment paradigm is chronic medication use causes eye damage limiting future treatment options.
- Patients and surgeons are transitioning⁽¹⁾ from medications in favour of 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⁽¹⁾.
- Advancements in diagnostic technologies support earlier intervention.
- **Nova Eye is a key player in the global MIGS market with its canaloplasty device, *iTrack*TM Advance.**

(1) Marketscope 2023 Glaucoma Surgical Device Market Report and Marketscope 2022 Glaucoma Surgical Device Market Report



Patient adherence to glaucoma medications is poor

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

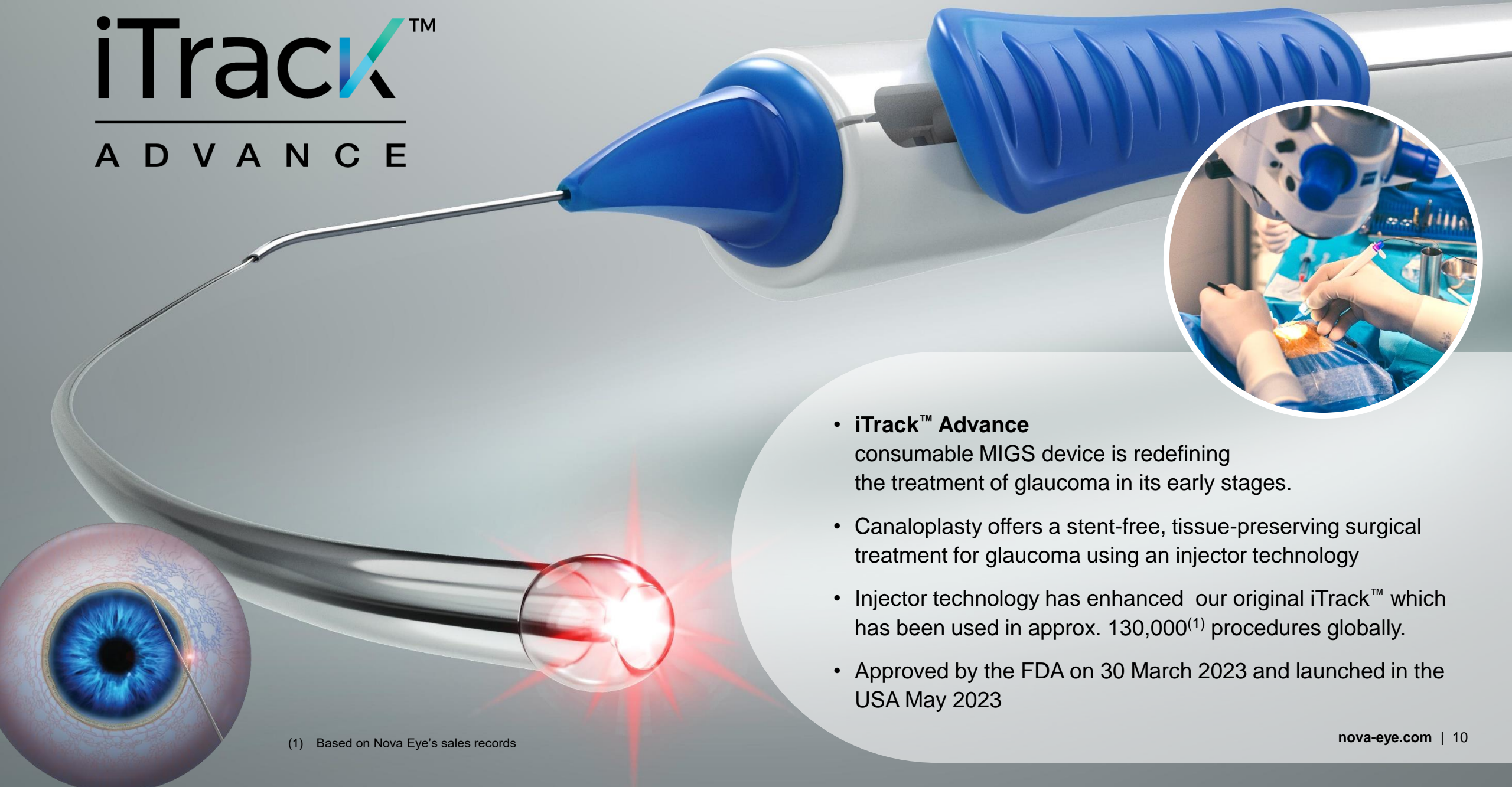
Approx 50% purposely discontinue their medication(s) within 6 months

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.
.....

iTrackTM

A D V A N C E



- **iTrackTM 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 using an injector technology
- Injector technology has enhanced our original iTrackTM which has been used in approx. 130,000⁽¹⁾ procedures globally.
- Approved by the FDA on 30 March 2023 and launched in the USA May 2023

(1) Based on Nova Eye's sales records

Clinically Significant Features iTrack™ Advance vs Other MIGS

Designed to reduce the elevated IOP associated with glaucoma by improving trabecular flow through the natural outflow pathway.

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	✓	✓	✓	✓	✓
KDB⁽¹⁾	New World Medical	Goniotomy i.e. cutting of tissue	Mild-moderate glaucoma	✓	✗	✗	✓	✗
OMNI⁽¹⁾	Sight Sciences	Canaloplasty followed by goniotomy i.e. cutting of tissue	Mild-moderate glaucoma	✓	✓	✓	✓	✗
iStent⁽¹⁾	Glaukos	Micro-trabecular bypass stent	Mild-moderate glaucoma	✓	✗	✗	✗	✓
Hydrus⁽¹⁾	Alcon	Micro-trabecular bypass stent	Mild-moderate glaucoma	✓	✓	✗	✗	✓

(1) Based on collation of information in Marketscope 2023 Glaucoma Surgical Device Market Report and company information on websites

USA Sales Growth Opportunity, iTrack™ Advance

- Nova Eye's direct-to-surgeon sales channel is driving growth of iTrack™ Advance, Nova Eye's flagship product.
- Recruitment of additional sales representatives drives new account acquisition through improved geographical coverage
- Additional marketing and clinical support drives surgeon re-order rates and enhances product introduction

A

Active Accounts, Glaucoma | approx. 200 accounts

Successfully transitioned existing iTrack™ customer accounts to iTrack™ Advance during May-June 2023.

B

Inactive Accounts, Glaucoma | approx. 300 accounts

Reactivation of inactive customer accounts commenced in July 2023 is continuing through FY24.

C

New Accounts, Glaucoma

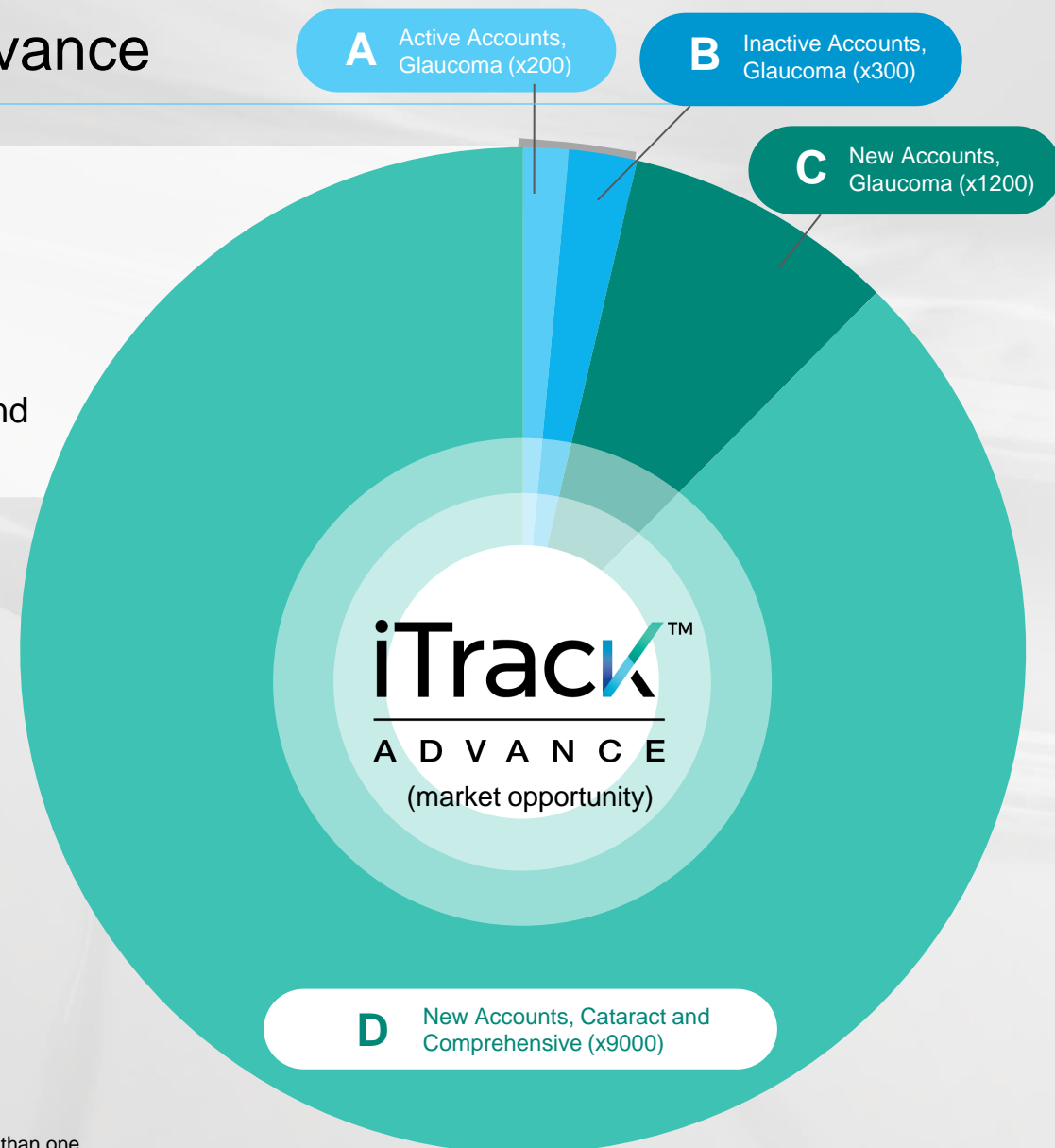
Potentially 1200⁽¹⁾ accounts available for sales growth via new glaucoma surgeon accounts

D

New Accounts, Cataract and Comprehensive

Potentially 9000⁽²⁾ accounts available for sales growth via new cataract and comprehensive surgeon accounts

- 1) 2,364 glaucoma specialists per Marketscope 2023 Glaucoma Surgical Device Market Report. An account can have more than one glaucoma surgeon. Management estimates that this equates to between 900 and 2000 accounts. An estimate of 1200 has been made based on a ratio of two per account
- 2) 11,238 cataract surgeons per Marketscope 2023 Glaucoma Surgical Device Market Report. An account can have more than one cataract surgeon. Management estimates that this equates to between 6000 and 11000 accounts. An estimate of 9000 has been made.



Glaucoma Device Sales in USA and outlook



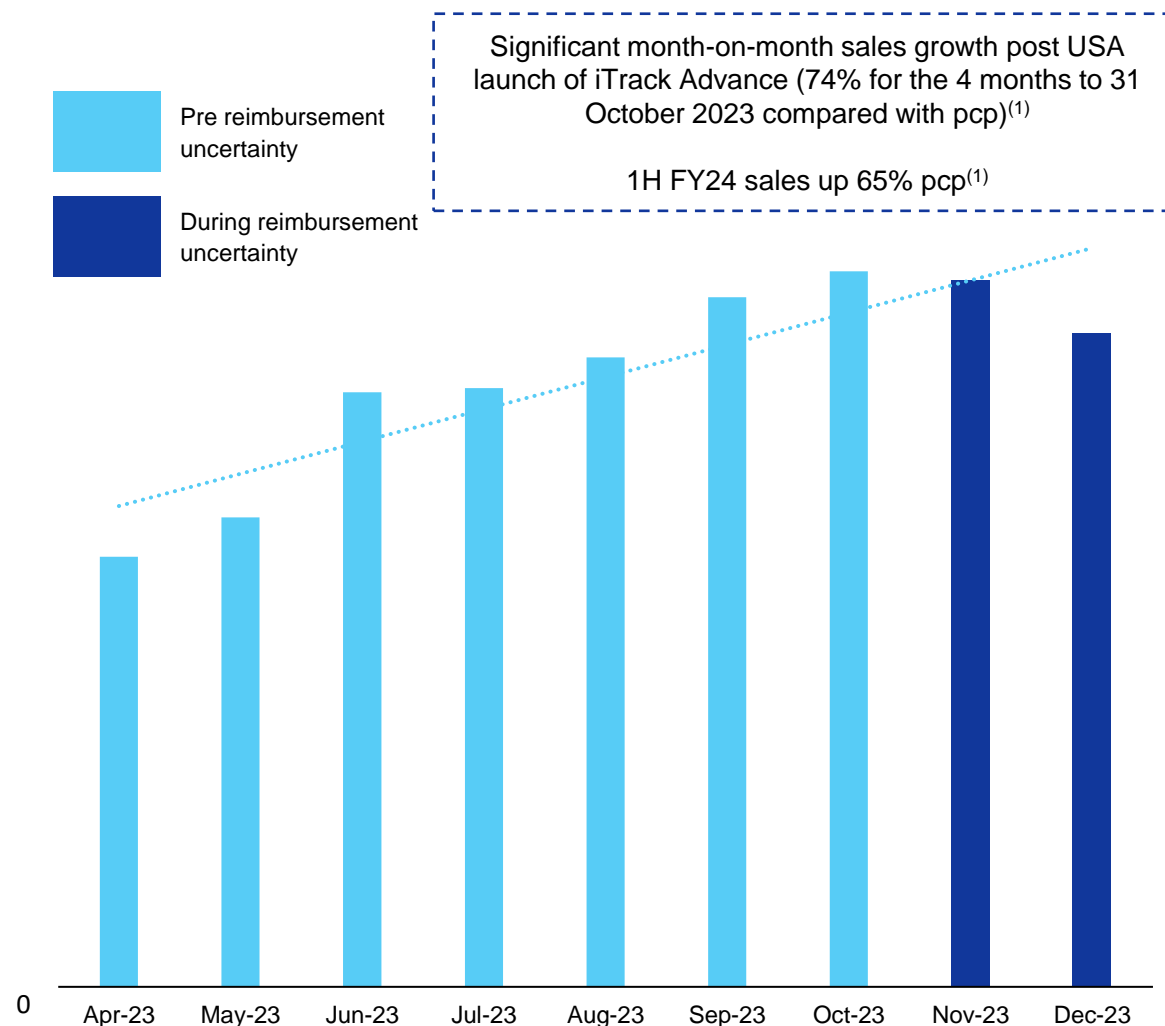
- US\$5.1m⁽¹⁾ sales for the 6 months to 31 December 2023 (65% growth) despite sales in November and December 2023 negatively impacted by the uncertainty of proposed reimbursement changes that were announced on 31 October 2023. Uncertainty resolved on 29 December 2023 restoring surgeon purchasing confidence.

- Since its USA launch in May 2023 the *iTrack™ Advance* has demonstrated a steady increase in demand from ophthalmologist customers.

- With reimbursement uncertainty resolved, Nova Eye expects USA sales growth to accelerate.

- January 2024 sales are up approximately 54% against January 2023 and in line with December 2023 as customers are educated on the resolution of the proposed reimbursement changes and Christmas and New Year holidays impact purchasing cycles.

USA sales since launch of iTrack™ Advance



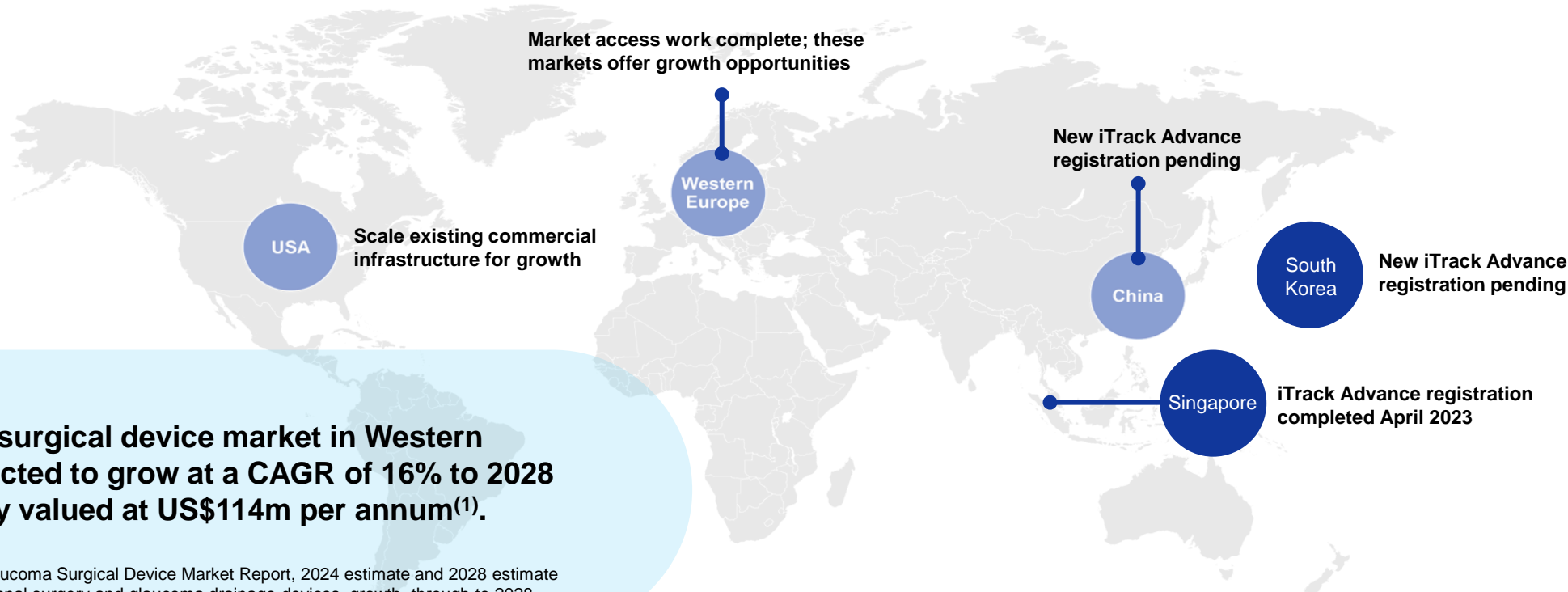
(1) Unaudited sales based on Company financial records

(2) Refer to details in Appendix A

Growth Opportunities Outside of the USA



- During H1FY24 Nova Eye has invested in market access in key territories outside the USA. New investment in sales infrastructure offers growth opportunities.
- Western Europe and Canada markets with product registrations, reimbursement and sales channel in place: Germany (via hybrid direct and distributor channel), UK (iTrack™ Advance NHS and NICE approved), Spain, Italy, Poland, Switzerland, UAE and Canada (via hybrid direct and distributor channel)
- China – approvals in place, approval iTrack™ Advance pending. Established distributor with early market penetration temporarily disrupted in 2023 by medical industry-wide government review of marketing methods.
- South Korea – sales channel in place and registration for iTrack™ Advance pending.
- Singapore – Hybrid direct and distributor sales channel. Singapore is an important reference market in driving procedural adoption throughout South-East Asia.



Growth Market

The glaucoma surgical device market in Western Europe is expected to grow at a CAGR of 16% to 2028 and is currently valued at US\$114m per annum⁽¹⁾.

(1) Marketscope 2023 Glaucoma Surgical Device Market Report, 2024 estimate and 2028 estimate incorporating stents, canal surgery and glaucoma drainage devices, growth through to 2028

H1 FY24 Global Sales



	H1 FY23 (Audited)	H2 FY23	FY23 (Audited)	H1 FY24 (unaudited)	Growth on PCP
US Dollars '000's					
USA	3,060	3,587	6,647	5,050	65%
Western Europe	1,331	1,252	2,583	1,255	-6%
Western Europe OEM sale of equipment ⁽¹⁾	256	-	256	-	N/A
China	1,050	736	1,786	315	-70%
Total	5,697	5,575	11,272	6,620	16%

Focus of sales and marketing investment in USA following launch of iTrack™ Advance in May 2023 with demonstrated growth results. Investments in marketing outside the USA have been limited.

Western European iTrack™ sales have fallen 6% in 1H FY24 compared to the PCP reflecting the limited sales and marketing investment in this region (focus on USA).





Sales to China temporarily disrupted in 2023 by medical industry-wide government review of marketing methods. PCP was impacted by a delivery of previous order scheduled for 30 June 2022 delivery delayed export documentation until 5 July 2022.

(1) Sales in Germany and Europe in the PCP included a OEM sale of a package of iLumin light sources

Glaucoma Product Portfolio and Disease State



Portfolio of glaucoma technologies addressing different stages of the disease

PROGRAM STATUS	STAGE OF GLAUCOMA			
	MILD GLAUCOMA	MODERATE GLAUCOMA	SEVERE GLAUCOMA	COMPLEX GLAUCOMA
COMMERCIAL	 Canaloplasty device injector deployed by comprehensive ophthalmologist in conjunction with cataract surgery.	 Canaloplasty device injector deployed by glaucoma specialist as standalone procedure - restores trabecular flow.	 Canaloplasty manually deployed by glaucoma specialist with scleral surgery and/or suture - restores trabecular flow.	 Glaucoma drainage device deployed by glaucoma specialist - drainage device bypassing trabecular flow.
	Product development opportunities			• Severe and complex glaucoma is an underserved segment.
		• Product range to cater to the preferences of eye surgeons treating broader range of patients with expansion of reimbursement codes.		

Glaucoma Device Product development



Expanding product portfolio leveraging existing IP to expand range of device surgeries covered by reimbursement codes

Extend product range to cater to the preferences of eye surgeons treating broader range of patients.

- iTrack™ Advance product enhancements for “Next Gen” trabeculotomy product.
- Low risk regulatory pathway in USA determined
- Stable need for trabeculotomy with well-established reimbursement code.

Severe and complex glaucoma is an underserved segment.

- Molteno3® product enhancements for Molteno “Next Gen” glaucoma drainage device (GDD) segment.
 - Low risk regulatory pathway in USA determined
 - Stable need for GDD’s with well-established reimbursement code
- (Progress on Molteno “Next Gen” is subject to cash generated from sales growth)

Glaucoma surgical devices segment	Global market size 2024 (US\$ m) ⁽¹⁾	Nova Eye Product
Canal surgery devices and stents	\$634m	iTrack™ product suite
GDD segment (aka “Tube Shunts”) ⁽¹⁾	\$108m	Molteno® product suite
Total	\$742m	

(1) Marketscope 2023 Glaucoma Surgical Device Market Report

Strong Existing Clinical Data Set Underpins Surgeon Adoption



Recent Peer Review Data

Publication	Authors	Journal	Data Overview
Consistency in Standalone Canaloplasty Outcomes Using the iTrack Microcatheter	Khaimi, M (USA), Gallardo M (USA) and Korber N (Germany).	Clinical Ophthalmology, 2024.	<ul style="list-style-type: none">• Multicenter, multi-surgeon, retrospective review of a consecutive case series• At 12 months, IOP (mmHg) was reduced in 57 of the 58 (98%) remaining eyes; one eye had the same IOP with a reduced number of medications.
Clinical outcomes of canaloplasty via an ab-interno surgical technique using the iTrack device: a narrative review	Koerber N (Germany), Ondrejka S (Germany).	International Ophthalmology, 2023.	<ul style="list-style-type: none">• Nine studies which totalled 365 eyes.• At 12 and 24 months, IOP (mmHg) decreased from 20.0±2.5 preoperatively to 13.8±0.6 and 14.0±0.9.
6-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Primary Open-Angle and Pseudoexfoliative Glaucoma	Koerber N (Germany), Ondrejka S (Germany).	Journal of Ophthalmology, 2023.	<ul style="list-style-type: none">• Single-center retrospective case series of patients (n=27 eyes) followed for up to 6 years.• The mean IOP was reduced significantly from 19.9±5.2 mmHg (n=27) at baseline (no washout) to 14.6±3.3 mmHg at the 6-year follow-up (n=18; p<0.001).
Long-Term Clinical and Safety Outcomes of Canaloplasty Performed across All Grades of Glaucoma Severity	Patel S (USA), Reiss G (USA).	Journal of Ophthalmology, 2023.	<ul style="list-style-type: none">• Single-center, retrospective case series study of glaucoma eyes (n=72) with mild-moderate glaucoma as compared to severe glaucoma.• The mean preoperative IOP for the 72 eyes was 18.6±5.8 mmHg, which showed a 25% reduction to 13.5±4.7 mmHg at 36 months (p<0.001).
Surgical Management of Intraocular Pressure With Ab-interno Canaloplasty in Postkeratoplasty Patients: 12-Month Results	Riaz KM et al (USA).	Cornea, 2023.	<ul style="list-style-type: none">• Single-center, retrospective case series of postkeratoplasty eyes(n=17) undergoing ab-interno canaloplasty (ABiC).• ABiC effectively reduced IOP and maintained graft survivability in postkeratoplasty eyes for at least 12 months.

Program of Data Collection Continuing



Clinical Study Program – additional data collation de-risks exposure to future reimbursement changes

Study Name	Study Type	Study Sites	Study Details	Study Synopsis
iTrack™ Global Data Registry WCG IRB (approval number) 20200728	Prospective, multicenter, real-world registry study	20+ sites in the USA, UK, Canada, Australia, Singapore and Germany.	<ul style="list-style-type: none">350+ patient data entries completed since mid 2022All glaucoma severities i.e., mild, moderate and severe	<ul style="list-style-type: none">Independent cloud-based platform that collates efficacy and safety data for the canaloplasty procedure (iTrack™ and iTrack™ Advance)Hosted in collaboration with the International Glaucoma Surgery Registry (IGSR), the official registry partner of the European Glaucoma Society (EGS).
CATALYST Study NCT05564091	Prospective, multicenter randomised control trial.	5+ sites in Germany, the Netherlands and Australia	<ul style="list-style-type: none">140 patients in total (recruitment ongoing)Mild-moderate glaucomaCanaloplasty performed in combination with cataract surgery	<ul style="list-style-type: none">“Cataract Surgery in Conjunction with Canaloplasty via an Ab-Interno Approach in Patients with Mild to Moderate Primary Open-Angle Glaucoma”Comparison of iTrack™ Advance performed in combination with cataract surgery, compared to cataract surgery alone.
MAGIC Study (Europe) NCT05786196	Prospective, multicenter randomised control trial.	5+ sites in the UK, Italy, Spain and Germany.	<ul style="list-style-type: none">78 patients in total (recruitment ongoing)Mild-moderate glaucomaCanaloplasty performed as a standalone procedure	<ul style="list-style-type: none">Multicenter Glaucoma Study Investigating Standalone CanaloplastyComparison of the iTrack™ Advance as compared to the OMNI® Surgical System (Sight Sciences).



Offer Details



Offer Summary



Offer structure and size	<p>Nova Eye is seeking to raise approximately A\$[8.0] million via the issue of approximately [38.1] million new fully paid ordinary shares (“New Shares”)</p> <ul style="list-style-type: none"> • An institutional Placement to raise up to approximately A\$[3.0] million (“Placement”) • A 1 for [8.0] pro-rata accelerated non-renounceable entitlement offer (“ANREO”) to raise approximately A\$[5.0] million (“Entitlement Offer”) (together, the “Equity Raising” or “Offer”)
Offer Price	<p>The Equity Raising will be conducted at A\$[0.210] per New Share representing a:</p> <ul style="list-style-type: none"> • [23.6]% discount to the last traded price of \$[0.275] on [09 February 2024] • [24.2]% discount to the 10-day VWAP price of \$[0.277] • [20.5]% discount to TERP of \$[0.264]
Use of Proceeds	<p>Proceeds from the Equity Raising will be used to advance near-term growth opportunities across Nova Eye’s Glaucoma business, including expanding the geographical presence of iTrack™ Advance sales in the US and Europe, and to broaden the product portfolio in Glaucoma surgical devices.</p>
Placement and Institutional Entitlement Offer	<p>The Placement and the Institutional component of the Entitlement Offer (Institutional Entitlement Offer) will be conducted by way of a bookbuild process from [9am] [Monday, 12 February 2024] to [12pm] [Tuesday, 13 February 2024].</p> <p>Entitlements under the Institutional Entitlement Offer that are not taken-up, entitlements of ineligible institutional shareholders and ineligible retail shareholders under the Entitlement Offer will also be sold in the bookbuild process.</p>
Retail Entitlement Offer	<p>The Record date for the Retail component of the Entitlement Offer (“Retail Entitlement Offer”) is 7.00pm [Wednesday, 14 February 2024].</p> <p>The Retail Entitlement Offer will open on [Monday, 19 February 2024] and close on [Friday, 08 March 2024]</p>
Ranking	<p>Each New Share issued under the Equity Raising will rank equally with existing fully paid ordinary shares on issue</p>
Bookrunner	<p>E&P Corporate Advisory</p>
Joint Lead Managers	<p>E&P Corporate Advisory, MST Financial, Taylor Collison</p>

Use of Proceeds

Glaucoma Surgical Devices:\$7.0m

\$3.7m USA sales growth - USA sales representative expansion, marketing and clinical data program enhancement

\$1.6m Outside USA sales growth - Expand commercial infrastructure in prospective markets to leverage investment in market access

\$1.7m Broaden product portfolio and regulatory approvals to de-risk reimbursement changes⁽¹⁾

Other Costs: \$0.5m

\$0.5m MDR⁽²⁾ compliance and working capital

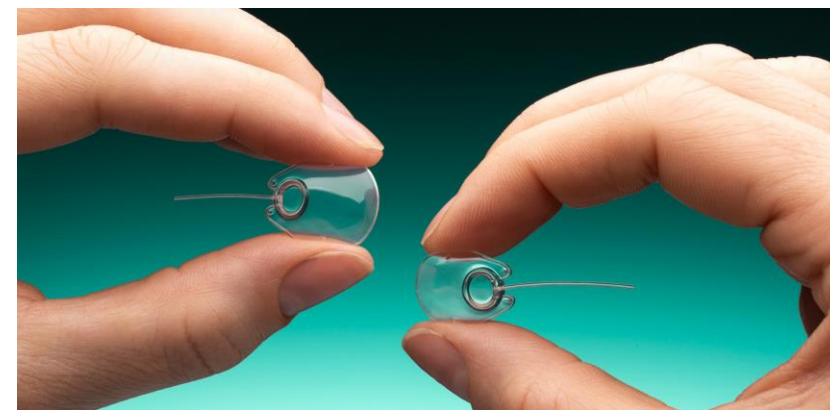
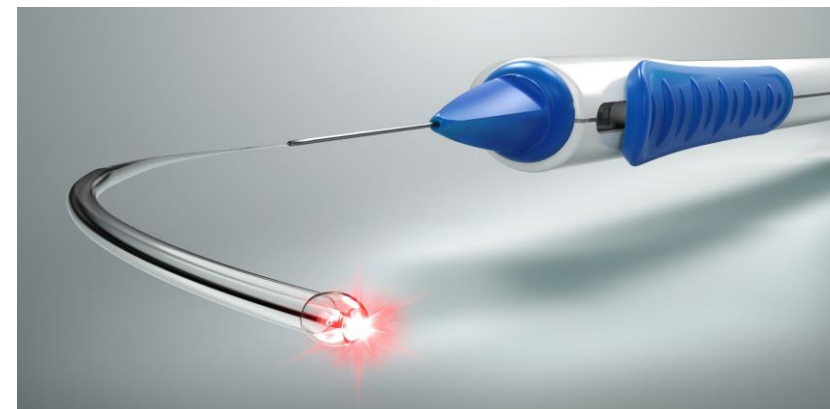
Offer Costs: \$0.5m

\$0.5m Costs of the Offer

Total: \$8.0m

1) iTrack Next Gen only. Molteno Next Gen investment subject to cash generated from operations

2) Medical Device Regulation in Europe



Indicative Offer Timetable



Item	Date
Trading Halt and announcement of the Equity Raising, lodgement of Offer Documents	[Monday, 12 February 2024]
Institutional Placement and Institutional Entitlement Offer opens	[9am, Monday, 12 February 2024]
Institutional Placement and Institutional Entitlement Offer closes	[12pm, Tuesday, 13 February 2024]
Announcement of completion of the Institutional Entitlement offer, trading halt lifted, existing securities recommence trading	[Wednesday, 14 February 2024]
Record Date for Retail Entitlement Offer (7pm)	[Wednesday, 14 February 2024]
Retail Entitlement Offer opens	[Monday, 19 February 2024]
Allotment of New Shares issued under the Institutional Entitlement Offer and Placement	[Thursday, 22 February 2024]
Retail Entitlement Offer closes	[Friday, 08 March 2024]
Announcement of results of the Retail Entitlement Offer and notification of any shortfall	[Friday, 15 March 2024]
Allotment and issue of New Shares under the Retail Entitlement Offer	[Friday, 15 March 2024]
Trading commences on a normal basis for New Shares issued under the Retail Entitlement Offer	[Monday, 18 March 2024]

Operating Results for H1FY24



		FY23 (Audited)				H1 FY24 (unaudited)			
		Australian dollars ('000'S)							
Group	Glaucoma	AlphaRET	Corporate	Group	Glaucoma	AlphaRET	Corporate	Group	
Revenue	16,661	364		17,025	10,062	77		10,139	
GM	11,392	323		11,715	6,900	40		6,940	
	68%				69%				
Operating expenditure	(17,676)	(1,364)	(2,225)	(21,265)	(9,433)	(473)	(1,213)	(11,119)	
EBITDA (loss)	(6,284)	(1,041)	(2,225)	(9,550)	(2,533)	(433)	(1,213)	(4,179)	

Commentary on H1FY24 compared with FY23

- Improved gross margin
- Improved ratio of operating expenditure to revenue shows leverage

Glaucoma only	FY23 (Audited)	H1 FY24 (unaudited)
	USA dollars ('000's)	
Revenue	11,273	6,619
GM	7,548	4,539
	67%	69%
Operating expenditure	(11,548)	(6,128)
EBITDA	(4,000)	(1,589)

Balance Sheet at 31 December 2023



	31 December 2023 (unaudited) \$'000's	30 June 2023 (audited) \$'000's
Current assets		
Cash and cash equivalents	2,612	7,419
Trade and other receivables	2,204	2,221
Income tax refund receivable	0	884
Inventories	4,131	3,806
Prepayments	284	270
Total current assets	9,231	14,600
Non-current assets		
Trade and other receivables	70	71
Property, plant and equipment	932	965
Lease right-of-use asset	1,097	1,397
Intangible assets	7,986	8,454
Capitalised development expenditure	4,558	4,870
Total non-current assets	14,642	15,757
Total assets	23,873	30,357

	31 December 2023 (unaudited) \$'000's	30 June 2023 (audited) \$'000's
Current liabilities		
Trade and other payables	4,149	4,311
Borrowings and lease obligations	714	639
Provisions	1,458	1,324
Total current liabilities	6,328	6,274
Non-current liabilities		
Borrowings and lease obligations	500	892
Deferred tax liability		-
Total non-current liabilities	500	892
Total liabilities	6,821	7,166
Net assets	17,052	23,191
Equity		
Issued capital	45,294	45,175
Reserves	(215)	(87)
Accumulated (losses) / profits	(28,028)	(21,897)
Total equity	17,052	23,191

Nova Eye
is addressing large
unmet needs and
has a plan in place
to grow
the glaucoma business



Glaucoma Segment

- USA sales growth acceleration
- Sales growth in markets outside the USA
- Targeting cash flow break even by FY25
- New product introduction



Appendix A

Additional materials



Nova Eye Glaucoma Surgical Device Reimbursement Transaction in USA



Eye surgeon selects
Nova Eye product



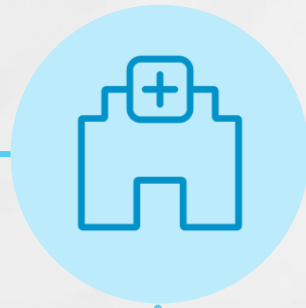
Nova Eye delivers the
product to the Facility and
invoices the Facility.



The operating notes are submitted to
Medicare Administrative Contractor
(MAC) responsible for that
geographic area ⁽¹⁾



Eye surgeon operates in a facility
which is either a Hospital (HOPD) or
an Ambulatory Surgery Centre
(ASC) and advises purchasing
department to issue an order to
Nova Eye for the product



Eye surgeon conducts the
surgery. CMS⁽²⁾ reimbursement
code specified in surgery
operating notes.



The MAC will pay the claim on
behalf of CMS in two parts; a
payment to the Facility (fee to
either HOPD or ASC) and a
payment to the eye surgeon
(Physician Fee)



(1) Medicare for patients older than 65-years, certain private payors for other patients
(2) Center for Medicare and Medicaid Services

Reimbursement for Nova Eye Products in the USA



Product	Facility Fee for applicable surgery for 2024 (US\$)		Physician Fee for applicable surgery for 2024 (US\$)
	HOPD	ASC	
iTrack Advance for canaloplasty surgery	\$3,877	\$2,045	\$607
Molteno3 Glaucoma Drainage device	\$2,222	\$1,183	\$828

- Fees set and reviewed annually by CMS
- Differential product pricing to HOPD and ASC
- Nova Eye invoices the Facility and the product price is paid from the Facility fee
- Payments against a particular CMS code by MACs can change from time to time with the issue of a new “Local Coverage Determination (LCD)”

Recent Developments in USA Reimbursement



Five MACs table draft local coverage determinations¹ (LCD) proposing changes to reimbursement for minimally invasive glaucoma surgeries (MIGS).

On 31 October 2023 WPS issued a “final” LCD and on 9 November the other 4 MACs did the same. They are required to give 45 days’ notice, making the effective date 23 December 2023.

On 8 December 2023 the effective date of the LCDs was shifted to 29 January 2024.

July 2023

Aug 2023

Sep 2023

Oct 2023

Nov 2023

Dec 2023

Jan 2024

An LCD is a determination made on coverage made that applies to the region for which the MAC is responsible.

Among other changes, the final LCDs designated canaloplasty as “investigational” and would not be reimbursed.

Nova Eye immediately activated near-term initiatives designed to overcome the challenges imposed by the proposed LCD changes to reduce the expected impact on sales revenue and provided support to doctors and professional bodies to lobby against the changes.

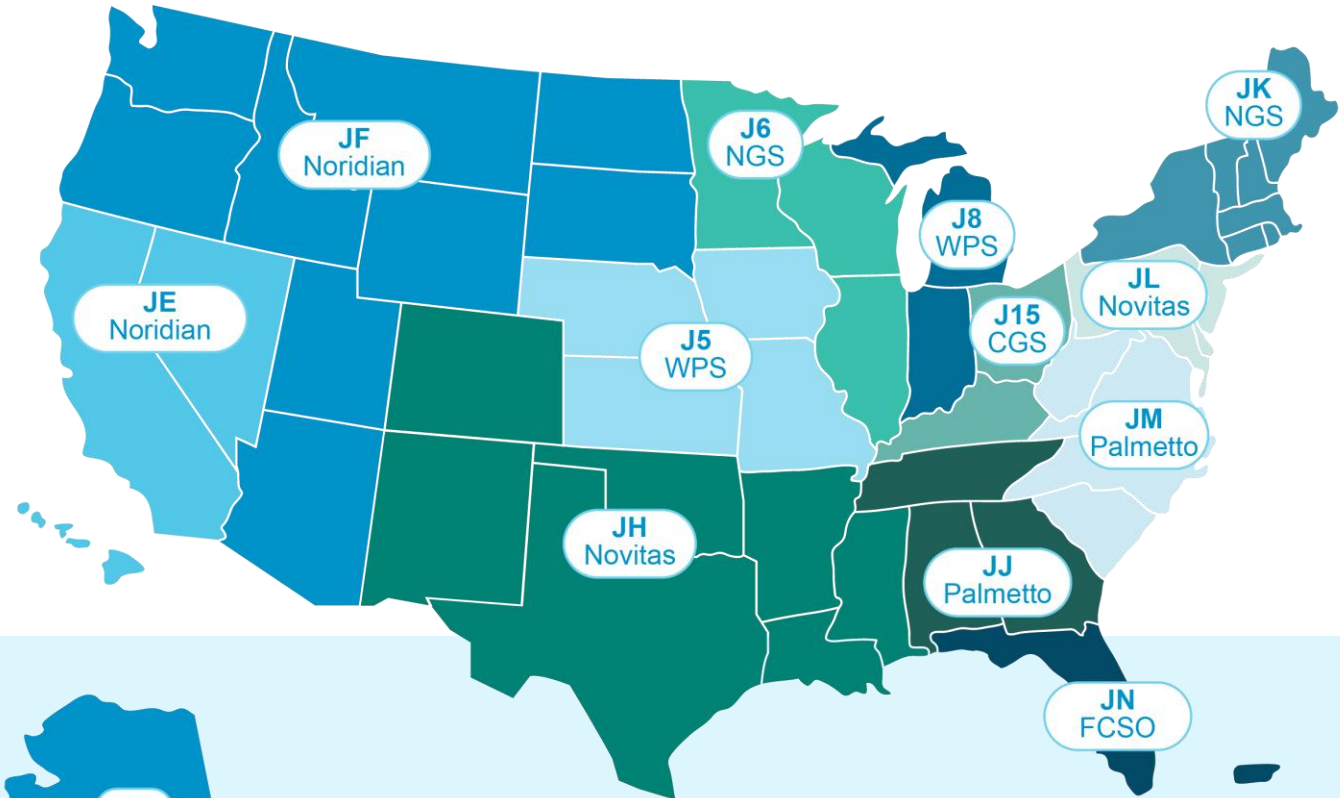
On 29 December 2023, the LCDs were withdrawn and reimbursement for canaloplasty to continue unchanged.

1. In 2020, by Palmetto, issued a draft LCD and it was eventually withdrawn without making it the “final”.

Who are the Medicare Administrative Contractors?



- The MACs are private insurance contractors granted responsibility by the US Government Center for Medicare and Medicaid Services (CMS) to administer the health care funding allocated by Congress
- MACs administer claims, review doctors' operating notes, consider whether the surgery was medically necessary and pay the claims based on allowances (codes) provided by CMS



MACs that proposed changes to Local Coverage Determinations (LCDs):

- National Government Services (NGS)
- WPS Government Health Administrators (WPS)
- Palmetto GBA (Palmetto)
- Celerian Group Company (CGS)
- Noridian Healthcare Solutions (Noridian)

MACs that DID NOT propose changes to LCDs:

- First Coast Service Options (FSCO)
- Novitas Solutions (Novitas)



Appendix B

Key Risks



Key Risks – Specific



As with any share investment, there are risks associated with an investment in the Company. The numerous risk factors are both of a specific and general nature. Some risks can be mitigated by the use of safeguards and appropriate systems and controls, but some are outside the control of the Company and cannot be mitigated.

Section 1 identifies and highlights some of the specific risks that potential investors should consider prior to acquiring shares in the Company. However, the following is not, and does not purport to be, a comprehensive statement of all relevant risks and is not listed in order of importance. Potential investors should seek their own financial or other professional advice in relation to the risks and must make their own assessment regarding an investment in the Company.

1 Specific Risks

Business Strategy Execution	<p>Nova Eye’s success will depend on its ability to successfully execute its business strategy. Nova Eye’s future growth, profitability and cash flows depend on the ability of the Company’s management to successfully execute its business strategy, which is dependent on a number of factors, including but not limited to its ability to:</p> <ul style="list-style-type: none">– develop its portfolio through new product development and market execution;– innovate and develop new products that address consumer needs;– build and maintain sufficient supply to maintain service demand;– continue to expand its distribution channels to increase market presence, brand recognition and sales;– successfully expand into targeted international markets;– expand margins through sales growth and supply chain integration and efficiency initiatives; and– maintain disciplined capital management and working capital to improve the generation of cash flow. <p>There is no guarantee that Nova Eye can successfully achieve any or all of the above initiatives or anticipated time frames. The failure of Nova Eye to execute its business strategy could have a material adverse effect on the Company’s business, financial condition and results of operations.</p>
Competition Risk	<p>The innovative medical devices market is highly competitive. If Nova Eye can not compete effectively and competitors begin to produce comparable products and patient outcomes the Company’s results could be negatively affected. Nova Eye competes on an international scale with companies around the world. Some competitors may have greater resources in comparison with Nova Eye and thus have the ability to respond more effectively to shifting business and economic conditions. Competition in the innovative medical devices market is based on functionality compared with existing treatments, pricing of products, quality of products and packaging, perceived value and quality of brands, innovation, promotional activities, advertising, editorials, and other activities. The actions of Nova Eye’s competitors can not be predicted across the aforementioned areas or whether new competitors will emerge in the medical devices market, including competitors who offer comparable products at more attractive prices. In addition, further technological breakthroughs, new product offerings by competitors, and the strength and success of competitors’ marketing programs may impede Nova Eye’s growth and the implementation of its business strategy. In addition Nova Eye is dependent on the following factors to compete in its market:</p> <ul style="list-style-type: none">– the continued strength of its products and brands;– ongoing growth and innovation in Nova Eye’s market segments;– the success of Nova Eye’s branding, execution and integration strategies;– the successful management of new products;– successfully entering new markets and increasing penetration in existing geographies; and– its ability to protect the Company’s intellectual property and utilise it to create value and support its business strategy.

Key Risks – Specific



Specific Risks (cont.)

Product Safety and Liability	Product safety or quality failures, actual or perceived, or allegations of product contamination, even when false or unfounded, may negatively impact Nova Eye's brands and could cause consumers to choose competing products. Allegations or adverse commentary on product safety or suitability for use by a particular consumer, even if untrue, may require Nova Eye to recall a product from all of the markets in which the affected product was distributed. Such issues or recalls could negatively affect Nova Eye's reputation and growth. If Nova Eye's products are perceived to be defective or unsafe, or if they otherwise fail to meet customer or regulators' expectations, the Company's relationships with customers could suffer, the appeal of one or more of its brands could be diminished, and the Company could lose sales or become subject to liability claims. In addition, safety or other defects in Nova Eye's competitors' products could reduce consumer demand for Nova Eye's products if consumers view them to be similar. Any of these outcomes could result in a material adverse effect on Nova Eye's business, financial condition and results of operations.
Counterparty Risk	Nova Eye is reliant on its main customers and suppliers. Inputs for Nova Eye's products consist of raw materials and packaging components and are purchased from various third party suppliers. The loss of multiple suppliers or a significant disruption or interruption in the supply chain could have a material adverse effect on Nova Eye's products. Increases in the costs of raw materials or other commodities may adversely affect the Company's profit margins if higher costs cannot be offset by price increases or lowering distribution costs. Nova Eye's third party suppliers pose risks to the Company if they do not comply with ethical, social, product, labour and environmental laws, regulations or standards, or their engage in politically or socially controversial conduct, such as animal testing, could negatively impact their reputations. Any of these failures or behaviours could lead to various adverse consequences, including damage to Nova Eye's reputation, decreased sales and consumer boycotts.
Reliance on Key Customers	There is a general risk that Nova Eye may fail to retain customers for a number of reasons, including pricing, competition or a failure to meet consumer expectations of its products.
Reputational Risk	Nova Eye's failure to protect its reputation, or the failure of the Company's partners to protect their reputations, could have a material adverse effect on the image of Nova Eye's brands. Nova Eye's ability to maintain its reputation is critical to the image and consumer perception of its various products. Nova Eye's reputation could be jeopardised if it fails to maintain high standards for product quality and integrity or if the Company, or the third parties with whom it does business, do not comply with regulations or accepted practices. Any consequential negative publicity may reduce demand for Nova Eye's products. Failure to comply with local laws and regulations, to maintain an effective system of internal controls or to provide accurate and timely financial information could damage Nova Eye's reputation. Nova Eye depends on the reputations of its third party clients, which can be affected by matters outside of the Company's control. Damage to Nova Eye's reputation or the reputations of its third-party clients could have a material adverse effect on Nova Eye's results of operations, financial condition and cash flows, as well as require additional resources to rebuild the Company's reputation.

Key Risks – Specific



Specific Risks (cont.)

Business Disruption	Nova Eye is engaged in developing, manufacturing and distributing innovative medical device devices for medical applications, utilising patented technology. As a result, Nova Eye is subject to the risks inherent in such activities, including industrial accidents, environmental events, strikes and other labour disputes, disruptions in supply chain or information systems, securing or maintaining adequate coverage or reimbursement by government or third-party payors for procedures using the iTrack®, the iTrack® Advance, Molteno 3®, loss or impairment Nova Eye's product quality control, safety, licensing requirements and other regulatory issues, as well as natural disasters, pandemics, border disputes, acts of terrorism, and other external factors over which is out of Nova Eye's control.
Growth Risk	Should the Company's growth accelerate at a higher rate than anticipated, the Company may, through lack of availability of materials or packaging, inability to scale production in a timely manner, lack of manufacturing capacity, lack of suitable labour or other unforeseen circumstances, be unable to supply its products in a timely manner to meet the demand of its customers. Should this occur, the Company may risk the loss of either third party manufacturing clients or suffer a reduction in the customer base for its own products. Such events could have an adverse effect on both the reputation of the Company as well as its financial results.
Reliance on Key Management	Nova Eye, and each of its businesses, depend substantially on its key management, the loss of whose services might significantly delay or prevent the achievement of its business strategy. Nova Eye's ability to retain and attract qualified individuals is critical to its success. Nova Eye may not be able to attract, retain or replace suitable individuals currently or in the future on acceptable terms, or at all, and the failure to do so may adversely affect the Company.
Access to Equity and Debt Funding	Volatility in the financial markets could negatively affect Nova Eye's ability to raise capital through debt and equity raisings. Nova Eye's ability to raise additional funds will be subject to, among other things, factors beyond the control of the Company and its Directors, including cyclical factors affecting the economy and share markets generally. The Directors can give no assurance that Nova Eye can raise funds in the future on favourable terms, if at all.
Impairment of Intangibles	Nova Eye has intangible assets on its balance sheet relating intangible assets. Under the relevant accounting standards Nova Eye is required to annually test for impairment all indefinite life intangible assets. If this annual testing revealed that some or all of Nova Eye's intangible assets are impaired to a level below their carrying value, Nova Eye would be required to write down the value of those intangible assets. Such write downs could have a material adverse effect on Nova Eye's financial position.

Key Risks – Specific



Specific Risks (cont.)

Health Insurance Reimbursement risk	<p>The Company derives revenue from sales of our products to physicians and surgery facilities, which typically bill all or a portion of the costs and fees associated with our products to various third-party payors, including Medicare and Medicaid in the USA, private commercial insurance companies, health maintenance organisations, and other healthcare-related organisations. Medical reimbursement systems vary significantly from country to country, with some countries limiting medical centres' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. As a result, access to adequate coverage and reimbursement for procedures in which our products are used by third-party payors is essential to their acceptance and adoption by patients, facilities and physicians. These third-party payors continually review new and existing technologies for possible coverage and can deny or reverse coverage for new or existing products and procedures, and there can be no assurance that third-party payor policies provide coverage, or will continue to provide coverage, for procedures in which the Company's products are used.</p>
Regulatory and Legislative Risk	<p>Nova Eye's business is subject to numerous laws and regulations in Australia and overseas. Changes in these laws and regulations, including their interpretation or enforcement, that affect, or will affect, the Company's business or products, including changes in accounting standards, tax laws and regulations, environmental or climate change laws, restrictions or requirements related to product content, labelling and packaging, regulations or accords, trade rules and customs regulations, could adversely affect Nova Eye's financial results. Failure to adhere to various regulatory requirements and any regulatory action or enforcement may adversely affect Nova Eye's financial position. Obtaining and maintaining approvals from regulatory bodies or other third parties can involve significant time and expense, and delays in obtaining approvals or adapting to changes to laws and regulations may adversely impact Nova Eye's operations.</p>
Intellectual Property Infringement	<p>Nova Eye's commercial success depends at least in part on its ability to operate without infringing, misappropriating or otherwise violating the trade marks, patents, copyrights and other proprietary rights of others. Nova Eye cannot be certain that the conduct of its business does not and will not infringe, misappropriate or otherwise violate such rights. As Nova Eye gains greater visibility and market exposure as a public company, third parties may allege that Nova Eye's products, services or activities infringe, misappropriate or otherwise violate their trade mark, patent, copyright or other proprietary rights in an attempt to gain a competitive advantage. Defending against allegations and litigation could be expensive, take significant time and divert management's attention. Nova Eye may also be required to pay substantial damages or be subject to court orders prohibiting the Company and its customers from selling certain products or engaging in certain activities.</p> <p>If Nova Eye operates its business in a way which infringes, misappropriates or otherwise violates the trade marks, patents, copyrights and proprietary rights of others, this could have a material adverse impact on the Company's business, financial condition and results of operations.</p> <p>Nova Eye's intellectual property is important to its success and any unauthorised use of any of the Company's intellectual property may result in the Company needing to commence litigation to protect those intellectual property rights which may incur significant costs. In addition, a failure to properly protect intellectual property rights may adversely affect the Company's business and reputation. There can be no assurances that the Company will be able to register or protect new intellectual property it develops in the future or prevent the unauthorised use of its intellectual property.</p>

Key Risks – Specific



Specific Risks (cont.)

Insurance Coverage

Nova Eye has adequate levels of insurance to protect Nova Eye from potential losses and liabilities. There is a possibility that events may arise which are not adequately covered by existing insurance policies. In this case the Company may suffer adverse effects to its financial results as well as to the value of its brands. The Company cannot guarantee that its existing insurance will be available or offered in the future. An inability of the Company to secure such cover in the future could restrict the ability of the Company to conduct its business, and this could have a negative impact on the financial results of the Company.

Unforeseen Expenditure Risk

Nova Eye's future growth requires access to capital to fund its business strategy. Nova Eye expects that the proceeds from this Capital Raising will provide sufficient capital resources to enable Nova Eye to achieve its stated business strategy. In the event Nova Eye requires additional funding, there is no assurance that additional funding will be available on acceptable terms, if at all.

Increased Input Costs

Cost blow outs including but not limited to, labour, raw materials, freight, energy and key consumables could have a material impact on Nova Eye's operation and financial performance if these costs cannot offset.

Foreign Exchange Rate Fluctuations

Fluctuations in currency exchange rates may positively or negatively impact Nova Eye's financial position and operating results. Exchange rate fluctuations may affect Nova Eye's the input costs. The main currencies to which Nova Eye is exposed are the US Dollar, the Euro and the Australian Dollar. The exchange rates between these currencies in recent years have fluctuated significantly and may continue to do so in the future. A declining Australian Dollar will negatively affect Nova Eye's ongoing and future capital expenditure programs and may increase the costs of input materials. An appreciating Australian dollar may lead to a lower Australian dollar value for sales denominated in foreign currencies.

Key Risks – General



Section 2 identifies and highlights some of the general risks that potential investors should consider prior to acquiring shares in the Company. However, the following is not, and does not purport to be, a comprehensive statement of all relevant risks and is not listed in order of importance. Potential investors should seek their own financial or other professional advice in relation to the risks and must make their own assessment regarding an investment in the Company

General Risks

Market and an Investment in Shares	The market price of Nova Eye's shares will fluctuate due to various factors, many of which are non-specific to the Company, including the number of potential buyers or sellers of Nova Eye's shares on the ASX at any given time, recommendations by brokers and analysts, Australian and international general economic conditions, inflation rates, interest rates, changes in government, fiscal, monetary and regulatory policies, changes in law, fire, flooding, extreme weather events, natural disasters, global geo-political events and hostilities, acts of terrorism, state of emergency declarations, outbreaks of pandemics, outbreaks of war, and investor perceptions. These factors may cause Nova Eye shares to trade at a lower price than the Issue Price under the Placement.
General Economic Conditions	<p>The trading price of Nova Eye shares may be adversely impacted by various factors, including new or changed governmental measures, business closures, lockdowns, quarantines, travel and other restrictions and resultant impacts on economies and financial markets. The historic share price performance of Nova Eye provides no guidance as to its future share price performance.</p> <p>Any deterioration in the domestic and global economy may have a material adverse effect on the performance of Nova Eye's business and Nova Eye's share price. It is possible that new risks might emerge as a result of Australian or global markets experiencing extreme stress, or existing risks, may manifest themselves in ways that are not currently foreseeable. The equity markets have in the past and may in the future be subject to significant volatility.</p>
Liquidity risk	Nova Eye is an ASX listed entity. Therefore the ability to sell Nova Eye shares will be dictated trading volumes of the Nova Eye shares at the time of sale. Trading volume itself is a function of the size of Nova Eye and the cumulative investment intentions of all current and possible investors in Nova Eye at any one point in time.
Risk of Dilution	<p>Current shareholders in Nova Eye who do not participate in the Offer will have their percentage shareholding in Nova Eye diluted. Investors may also have their investment diluted by future capital raisings or issues of new equity securities by Nova Eye.</p> <p>Nova Eye may issue new equity securities in the future to finance acquisitions or pay down debt which may, under certain circumstances, dilute the value of a shareholder's interest in Nova Eye.</p>
Operational Risk	Operational risk is the risk of loss resulting from inadequate or failed internal processes, people or systems (including information security systems), or from external events. Nova Eye is exposed to a variety of risks including those arising from process error, fraud, technology failure, security and physical protection, staff skills, workplace safety, compliance, business continuity and crisis management.



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