



First iTrack™ surgical case performed in MAGIC Study.
David Lubeck, MD (left) and Shamil Patel, MD, MBA (right).



NOVAEYE
MEDICAL®

Nova Eye Medical Limited (ASX:EYE)

ASX Small & Mid-Cap Conference 14 September 2021

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ASX:EYE BUSINESS SNAPSHOT

Nova Eye Medical Limited (ASX:EYE) comprises two business units, glaucoma and AMD/2RT® – these segments address **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
FY22 Objective	Scale for growth; increase market share
Market	Glaucoma Surgical Devices; fast-growing and competitive
Competitive Advantage	Proprietary iTrack™ microcatheter technology and Molteno3®
Sales	Established infrastructure; direct sales in USA, Germany, Australia; +50 distributors
Manufacturing	California, USA and Dunedin, New Zealand
IP Status	+95 global patents
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
FY22 Objective	Conduct pivotal multi-center trial; secure FDA clearance
Market	Intermediate Age-related Macular Degeneration (iAMD) – market not addressed
Competitive Advantage	Proprietary 2RT® technology – first mover advantage
Sales	N/A
Manufacturing	Adelaide, Australia
IP Status	+10 global patents
Regulatory	CE Mark (iAMD) in Europe, Australia, NZ
Reimbursement	Pending

ASX:EYE CORPORATE SNAPSHOT

Nova Eye Medical Limited		
Exchange	Australian Securities Exchange	
Ticker	EYE	
Management + Board Ownership	12%	
Shares on Issue	143.6 million	
Revenues (12 months to June 2021)	A\$13.4 million	US\$ 9.7 million ¹
Net Tangible Assets (at 30 June 2021)	A\$35.3 million	US\$26.12 million ¹
Market Capitalization (as at 2 Sept 2021)	A\$68.5 million	US\$45.6 million ²
Cash (at 30 June 2021)	A\$17.8 million	US\$13.2 million ¹
Enterprise Value (as at 16 August 2021)	A\$44.7 million	US\$32.4 million ²

1. AUD/USD 0.74 at 30 June 2021

2. AUD/USD 0.73 at 2 Sept 2021

GLAUCOMA

GLAUCOMA MARKET

Glaucoma is the leading cause of irreversible blindness and the second leading cause of blindness worldwide. The aging global population is driving glaucoma prevalence and provides a strong platform for business growth.

131.9 million*

People Worldwide with Glaucoma

US\$600m*

CAGR 25%*

Minimally Invasive Glaucoma Surgery (MIGS) market size and growth rate per annum

US\$6.1bn*

Glaucoma Treatment Market, market size per annum

- Advancements in diagnostic and imaging technologies permit earlier diagnosis, which in turn drives demand for interventions which permit earlier treatment.
- Medications are considered standard of care but are associated with significant drawbacks i.e., low patient compliance, side effects, financial costs.
- Glaucoma surgical device (MIGS) solutions are increasingly recognized as a highly viable alternative – and is currently the fastest growing segment of the ophthalmic market.

**Market Scope 2021 Report*




THE GLAUCOMA TREATMENT SPECTRUM

The treatment paradigm for glaucoma has been transformed over the past 5 years with the introduction of minimally invasive glaucoma surgery (MIGS) which, combined with ageing demographics, provides a strong platform for future market growth.

	MILD	MODERATE	SEVERE
VISION LOSS	Optic nerve abnormalities consistent with glaucoma but no visual field loss	Optic nerve abnormalities and visual field loss in one hemifield	Optic nerve abnormalities and visual field loss in both hemifields
TREATMENT	<ol style="list-style-type: none"> 1-2 medications SLT MIGS 	<ol style="list-style-type: none"> 1-4 medications MIGS 	<ol style="list-style-type: none"> Surgery i.e., trabeculectomy, drainage devices
<p>US\$600m MIGS market size (excl. pharma), 25% CAGR</p>			<p>US\$100m market size, 6% CAGR</p>

NOVA EYE MEDICAL ACROSS THE GLAUCOMA TREATMENT SPECTRUM

We are expanding our glaucoma treatment portfolio to address the full spectrum of the disease process, adding new products and indications to better meet the treatment needs of comprehensive ophthalmologists and glaucoma specialists.

	MILD		MODERATE		SEVERE	
PRODUCT BRAND		iTRACK™			iTRACK™	MOLTENO3®
TREATMENT CATEGORY		Minimally Invasive Glaucoma Surgery (MIGS)		Minimally Invasive Glaucoma Surgery (MIGS)	Non-penetrating Glaucoma Surgery	Glaucoma Surgery
TREATMENT DESCRIPTION		Ab-interno canaloplasty 		Ab-interno trabeculotomy Future product introduction based on patents acquired Aug 2021	Ab-externo canaloplasty 	Glaucoma drainage device (GDD) 

FY21 GLAUCOMA HIGHLIGHTS

In FY21 we executed several initiatives to drive market awareness of the iTrack™ MIGS device, which resulted in sales growth but, more importantly, set the foundation for further growth in FY22 and beyond.

New data reinforced superior safety profile of iTrack™

Initiated new multi-center MAGIC study, iTrack™

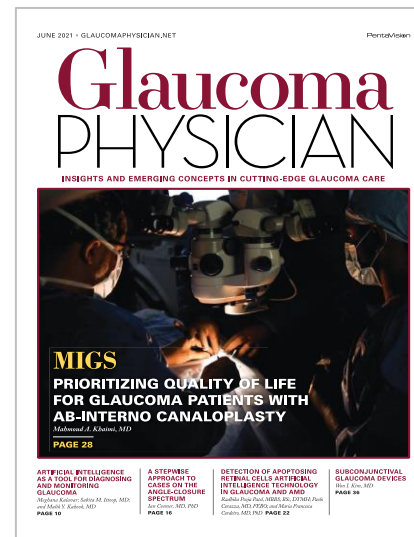
Acquisition of Molteno3® and integration into US sales channel

Development of USA sales and marketing team

Establishment of direct sales business in Germany

Acquisition of patents to drive product line expansion (Aug 2021)

Sales growth of 25% (US\$ dollars); positive EBITDA



The US publication “Glaucoma Physician” (circulation +20,000 ophthalmologists) featured iTrack™ on its June cover, signaling strong industry interest in canaloplasty.

iTrack™

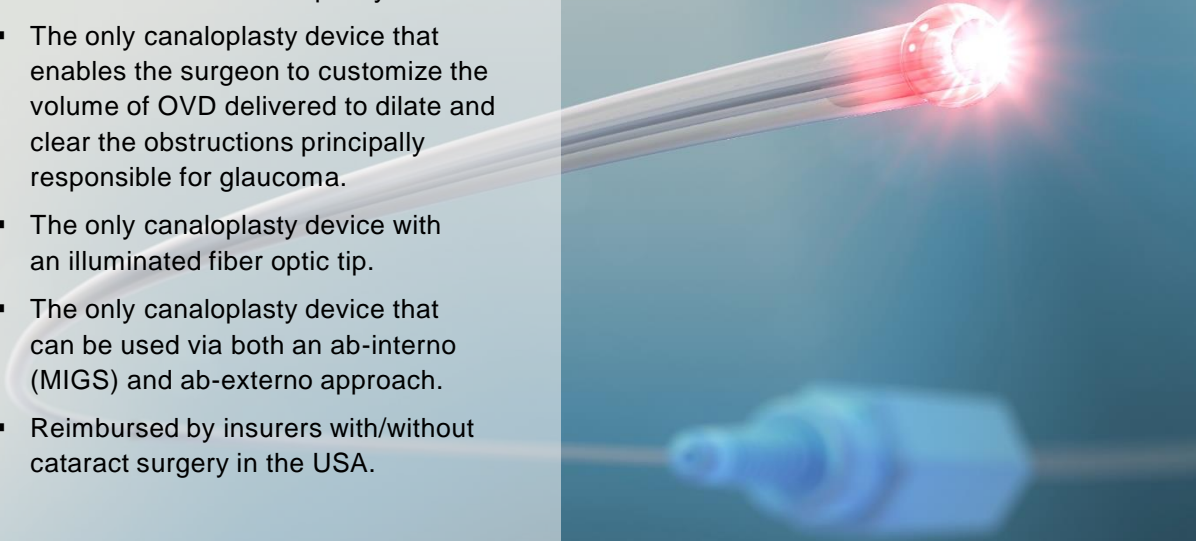
Our proprietary iTrack™ microcatheter technology offers a number of clinical advantages over other glaucoma treatments and MIGS devices for mild to moderate glaucoma.

Today, iTrack™ is recognized as a key player in the MIGS market and is positioned for strong growth following a post-COVID recovery.

- **360° treatment** – overcomes limitations of focal-based treatments
- **Stent-free treatment** – re-establishes natural aqueous flow, rather than mechanically changing aqueous flow
- **Tissue-sparing treatment** – does not limit future treatments

canaloplasty.com

- The world's first canaloplasty device.
- The only canaloplasty device that enables the surgeon to customize the volume of OVD delivered to dilate and clear the obstructions principally responsible for glaucoma.
- The only canaloplasty device with an illuminated fiber optic tip.
- The only canaloplasty device that can be used via both an ab-interno (MIGS) and ab-externo approach.
- Reimbursed by insurers with/without cataract surgery in the USA.



iTRACK™ SAFETY COMPARED WITH iSTENT® (GKOS)

The unique stent-free, tissue sparing mechanism of iTrack™ re-establishes natural aqueous flow to effectively reduce IOP while also preserving the health of the corneal endothelium.

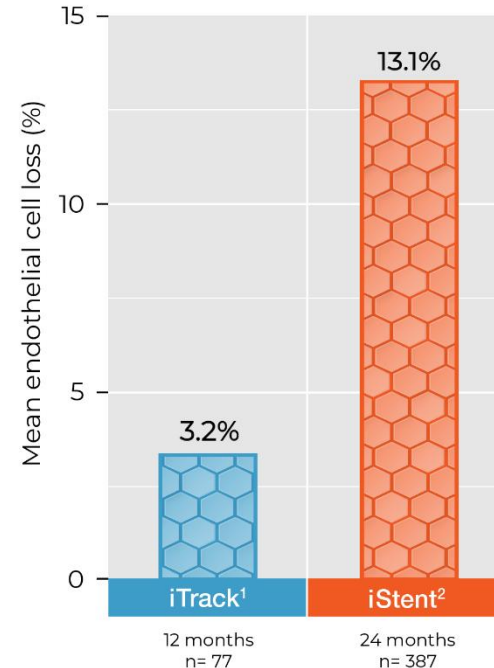
At American Society of Cataract and Refractive Surgeons Congress 2021 doctors Lubeck and Noecker presented 12-month data from a 5-year prospective multi-center study evaluating endothelial cell density (ECD) in eyes undergoing iTrack™ ab-interno canaloplasty in combination with cataract surgery.

Mean change in ECD was **-3.2% (SD ±9.0%)** – and represents one of the lowest reported rates of ECL of all MIGS procedures.

The presentation was awarded ASCRS best paper of the session (MIGS II).

1. Lubeck DM., Noecker RJ. Evaluation of Endothelial Cell Density and Loss Following iTrack Ab-Interno Canal Based Surgery. ASCRS 2021 (Paper Presentation).
2. Samuelson, T et al, Prospective, Randomized, Controlled Pivotal Trial of an Ab Interno Implanted Trabecular Micro-Bypass in Primary Open-Angle Glaucoma and Cataract, Ophthalmology June 2019, pages 811-821 2.
3. Samuelson, T et al, A Schlemm Canal Microstent for Intraocular Pressure Reduction in Primary Open-Angle Glaucoma and Cataract, Ophthalmology, Jan 2019, pages 29-37.

glaucoma-iTrack.com/ECL



FY21 GLAUCOMA OPERATING RESULT

Material improvement in operating result was underpinned by a 25% increase in global sales compared to the pcp, including the addition of Molteno3[®] sales, and a reduction in operating costs.

	A\$'000s (year ended 30 June)			US\$'000s (year ended 30 June) ¹		
	FY20	FY21	Growth	FY20	FY21	Growth
Sales	11,572	13,088	13.1%	7,753	9,684	24.9%
COGS	(4,125)	(4,473)		(2,764)	(3,310)	
Gross Margin	7,447 64%	8,615 66%		4,989 64%	6,375 66%	
Operating Expenditure	(11,501)	(8,514)	-26.0%	(7,706)	(6,300)	-18.2%
EBITDA (loss)	(4,054)	101		(2,716)	75	

1. AUD/USD 0.74 in FY21 and 0.67 in FY20

Key FY21 glaucoma growth and profitability drivers:

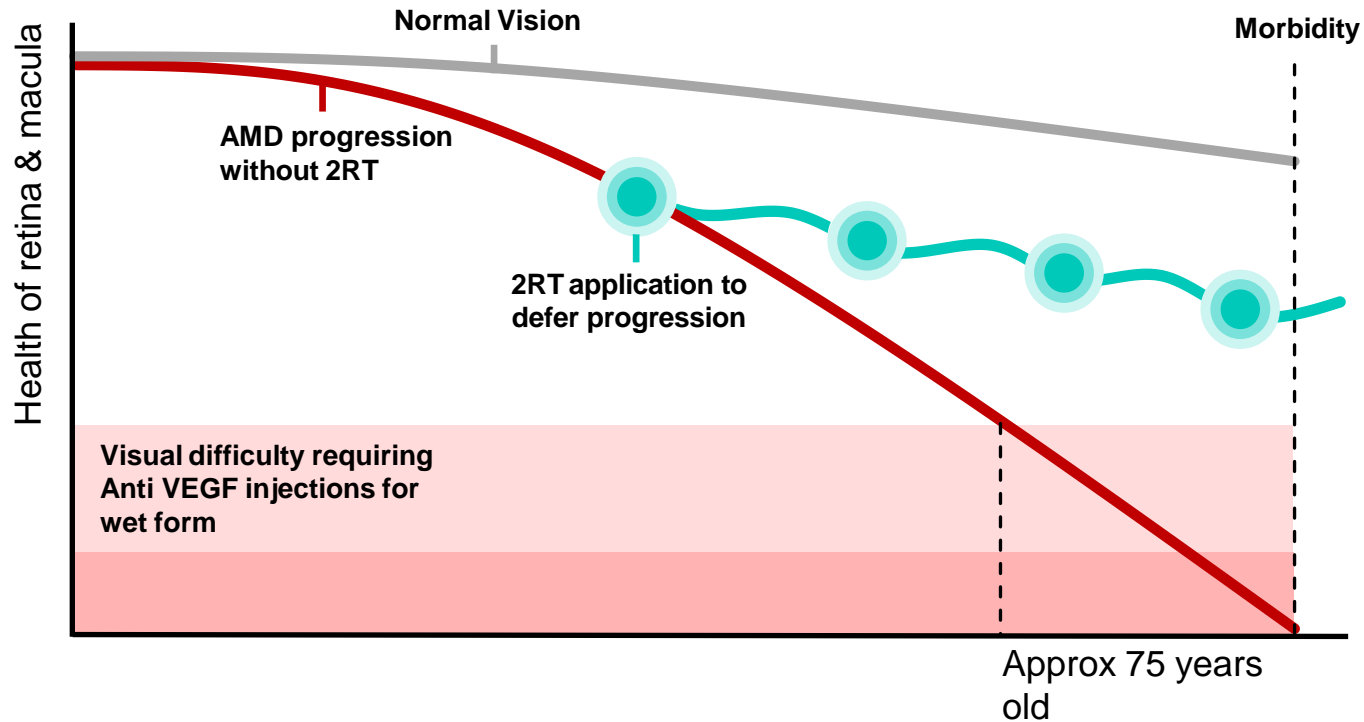
- Improved sales and marketing management in the USA, the major market for the Company's glaucoma surgical devices
- Establishment of a direct sales business in Germany in November 2020
- Integration of the Molteno3[®] (and synergies with the iTrack™ portfolio); revenue of Molteno3[®] \$673K (US\$492K) since 1 August 2020
- Sales composition using US\$: USA 68% (pcp 71%), Germany 13% (pcp 11%), China 7% (pcp 8%), ROW 11% (pcp 9%)

2RT[®], INTERMEDIATE AMD

2RT[®] (AlphaRET) is a proprietary, world-first nanosecond laser therapy to treat intermediate AMD (iAMD)

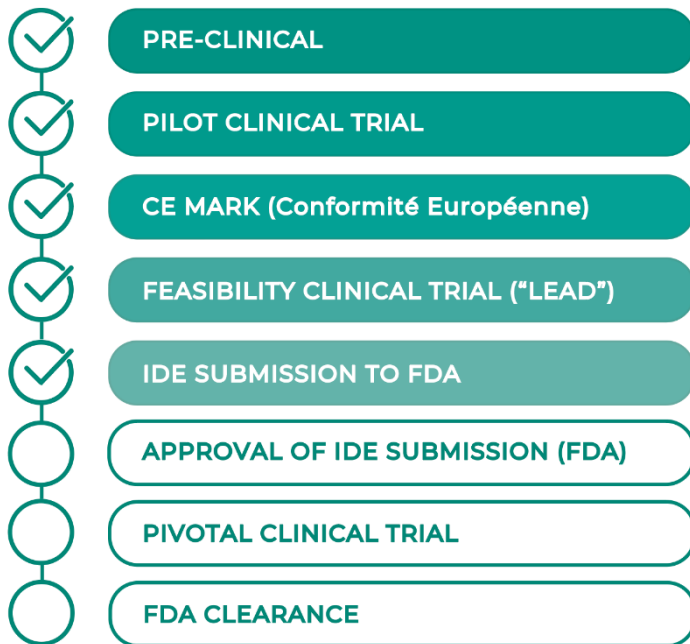
While there have been major advances in the treatment of AMD in its late stages (referred to as Wet AMD), there has been little progress in the treatment of AMD in its early stages

2RT[®] FOR PATIENTS BEFORE LATE STAGE DISEASE



AlphaRET

While there have been major advances in the treatment of AMD in its late stages (referred to as Wet AMD), there has been little progress in the treatment of AMD in its early stages



- 300 person clinical study conducted in Australia and Europe demonstrated that 2RT[®] reduced the rate of disease progression by 77% in patients with intermediate AMD.
- Investigational Device Exemption (IDE) application with the US Food and Drug Administration (FDA) lodged in early July 2021 to commence a pivotal clinical study for 2RT[®]
- Currently in discussions with the FDA to progress approval of pivotal study.
- Subject to final design acceptance and costings for study, the plan is to partner the 2RT[®] clinical and commercial development program.
- **There is no FDA cleared drug or device-based treatments for intermediate AMD.**

2RT[®] MARKET ASSESSMENT

Our proprietary 2RT[®] nanosecond laser therapy is a world-first intervention designed to treat intermediate AMD. There is currently no treatment (drugs or devices) for the treatment of intermediate AMD.

	Population with Early/Intermediate AMD ¹ (millions of people)	Patients who do not meet 2RT [®] treatment criteria ² (millions of people)	Estimated population with Intermediate AMD treatable with 2RT [®] (millions of people)
USA	13.9	-8.6	5.3
Europe	21.6	-13.4	8.2
Other developed nations	8.0	-5.0	3.0
Japan	5.7	-3.5	2.2
China	34.3	-21.3	13.0
LATAM and ROW	61.1	-37.9	23.2
Estimated total addressable market per year	144.6 million		54.9 million

1. Marketscope 2020 Report.
2. Company estimate based on clinical recommendations from LEAD study.

FY21 GROUP CASH FLOW

	A\$ million (year ended 30 June 2021)	US\$ million ¹ (year ended 30 June 2021)
Cash generated/ (used) from operations	(4.1)	(3.0)
(Deduct):		
Expenditure on 2RT (IDE)	(1.1)	(0.8)
Repayment of leases	(0.4)	(0.3)
New product development	(0.7)	(0.5)
Plant and equipment acquired	(0.6)	(0.4)
Free cash flow	(6.9)	(5.1)
Add/(deduct):		
Income tax paid	(8.9)	(6.6)
Acquisition of Molteno3	(1.0)	(0.7)
Payment of dividend	(61.0)	(45.1)
Cash balance at year end	17.8	13.2

1. AUD/USD 0.74

NOVA EYE GROUP OUTLOOK

Subject to change due to COVID, Nova Eye Medical Limited is well positioned to propel growth of its glaucoma consumable surgical devices through FY2022

- 1** | **USA Sales Focus:** significant investment in glaucoma consumable surgical device sales, marketing and clinical development to support aggressive market penetration, sales growth and improved market share.
- 2** | **German Sales Focus:** leverage recently established direct German business to target significant sales growth.
- 3** | **Investment in Glaucoma Technology Pipeline:** expansive IP and product development, including launch of the next generation iTrack™ (pending COVID-19 market recovery).
- 4** | **2RT® Pivotal Study:** obtain approval for pivotal study and partner the 2RT® clinical program to support regulatory pathway in USA.

CONTACT

Tom Spurling

Managing Director

W: +61 8 8362 0193

E: tspurling@nova-eye.com

Tom Duthy, PhD

Investor Relations and
Corporate Development

M: +61 402 493 727

E: tduthy@nova-eye.com

Kate Hunt

Head of Marketing

M: +61 404 080 679

E: khunt@nova-eye.com