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)

Results Presentation for the Year Ended 30 June 2021
19 August 2021

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Shamil Patel, MD, MBA performs iTrack ab-interno canaloplasty (Spectra Eye, Arizona, USA)

FY21 FOCUS

We undertook a concerted effort to reset Nova Eye Medical's global glaucoma sales, marketing, clinical and IP infrastructure to support the scale and growth of our glaucoma consumable surgical device business.

We also invested in the USA regulatory pathway for 2RT®, completing an application for an Investigational Device Exemption (IDE) for the Food and Drug Administration (FDA).

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	+90 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$13.4 million	US$ 9.9 million[1]
Net Tangible Assets (at 30 June 2021)	A$35.3 million	US$26.12 million[1]
Market Capitalization (as at 16 August 2021)	A$62.5 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 16 August 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 >26%*
Minimally Invasive Glaucoma Surgery (MIGS) Market, market size and growth rate per annum

US$5.9bn*
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.

**MarketScope 2020 Report*

NOVA EYE MEDICAL IS SET FOR ADDITIONAL GLAUCOMA GROWTH

With COVID-19 lockdowns we focused our efforts internally, resetting our global sales infrastructure to an operating room (OR) based model, strengthening our IP portfolio, and reinforcing our clinical and marketing effort for growth of our flagship iTrack™ portfolio.

100% Glaucoma-Focus, OR-Based Sales Team

- Following the divesture of the capital equipment business we transformed our sales model to focus exclusively on operating room (OR)-based sales – 100% focused on glaucoma.
- Extensive recruitment and training program implemented during FY21 with intent to scale as market conditions improve.

Robust, Future-Ready IP Portfolio

- Global program to leverage existing IP and to develop new IP for expanded indications and/or new product introductions.
- Established in-house, dedicated team of IP analysts to actively defend and grow IP portfolio.

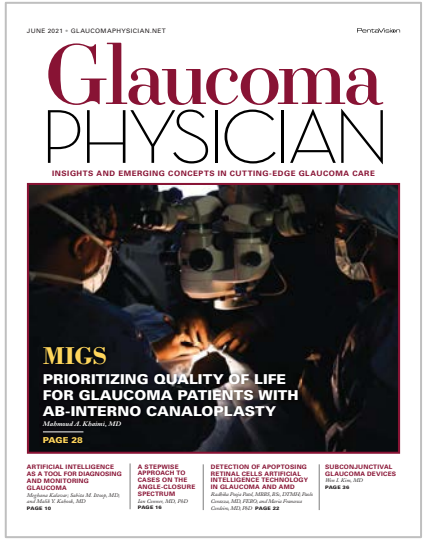
iTrack™ Platform for Future Growth

- iTrack™ represents a unique approach to MIGS and offers a number of clinical and product advantages.
- Over the past 12 months, iTrack™ has garnered increasing attention from industry and physicians; we have disrupted the paradigm of stents as the “go to” MIGS procedure.

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
- Sales growth of 25% (US$ dollars); positive EBITDA
- Development of USA sales and marketing team
- Establishment of direct sales business in Germany



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

iTrack™

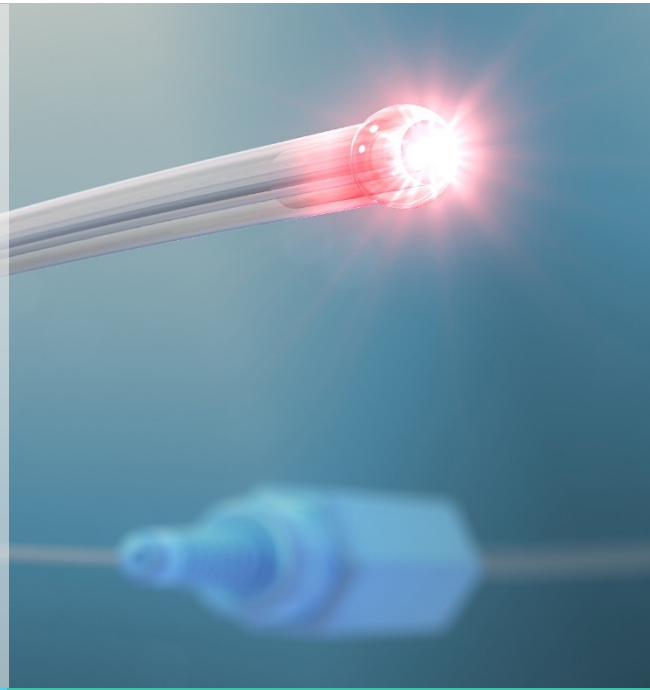
Our proprietary iTrack™ microcatheter technology offers a number of clinical advantages over other glaucoma treatments and MIGS devices and underpins our glaucoma growth strategy.

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™ AND CORNEAL HEALTH

Endothelial cell loss or ECL is now recognized as an indicator of MIGS safety. Data presented during FY21 demonstrates that iTrack™ is associated with less ECL than other MIGS option.

12-month data suggests that iTrack™ may preserve the health of the corneal endothelium – offering a considerable advantage over competitor MIGS.

- Corneal endothelial cells line the posterior, innermost aspect of the cornea.
- Corneal endothelial cells cannot regenerate; therefore, preservation of endothelial cells is paramount for corneal health.
- There is an increased awareness of the impact of MIGS on corneal health following the 2018 market withdrawal of the CyPass® stent (Alcon) due to excessive endothelial cell loss or ECL.

"With focal-based MIGS procedures, where we are redirecting aqueous flow to a specific point such as a stent, it is possible that we cause more endothelial trauma by directing aqueous currents toward a single point of exit only – versus a procedure such as iTrack™, which increases outflow through the entire system evenly."

David Lubeck, MD
Arbor Eye Care, Chicago

iTRACK™ SAFETY COMPARED WITH OTHER MIGS

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.

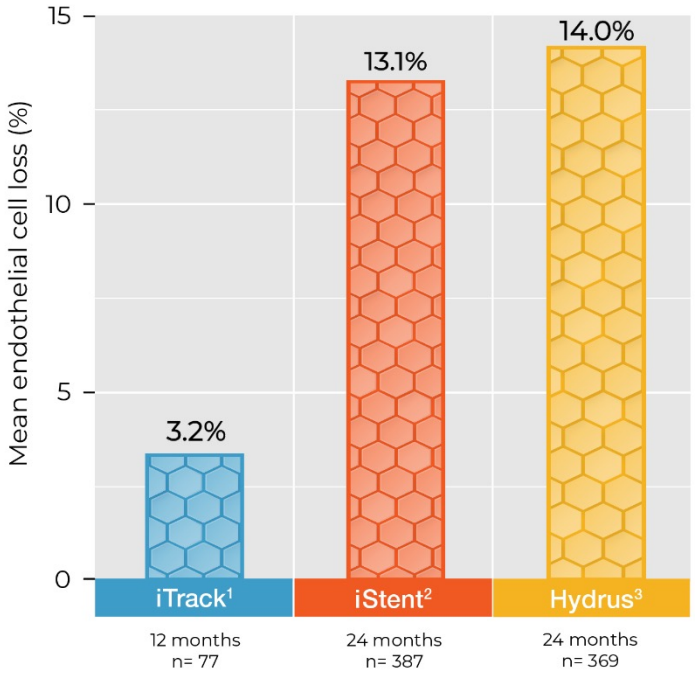
At American Society of Cataract and Refractive Surgeons Congress 2021 doctors Lubeck and Noecker presented 12-month data from a 5-year prospective multi-center study evaluating endothelial cell density (ECD) in eyes undergoing iTrack™ ab-interno canaloplasty in combination with cataract surgery.

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



iTRACK™ PEER REVIEW

A series of prospective and retrospective data sets from the USA, Switzerland, Poland and the UK were published during the FY21 period, helping drive physician uptake of iTrack™.

[24-Month Efficacy of Viscodilation of Schlemm's Canal and the Distal Outflow System with iTrack Ab-Interno Canaloplasty for the Treatment of Primary Open-Angle Glaucoma]

Gallardo, MJ. 24-Month Efficacy of Viscodilation of Schlemm's Canal and the Distal Outflow System with iTrack Ab-Interno Canaloplasty for the Treatment of Primary Open-Angle Glaucoma. Clinical Ophthalmology 2021:15 1591–1599.

[Canaloplasty ab interno (ABiC) – 2 Year Results of a Novel Minimally Invasive Glaucoma Surgery (MIGS) Technique]

Gallardo, MJ. 24-Month Efficacy of Viscodilation of Schlemm's Canal and the Distal Outflow System with iTrack Ab-Interno Canaloplasty for the Treatment of Primary Open-Angle Glaucoma. Clinical Ophthalmology 2021:15 1591–1599.

[Combined Ab interno viscocanaloplasty (ABiC) in open angle glaucoma: 12-month outcomes]

Gillmann, K., Aref, A., Niegowski, L.J. et al. Combined Ab interno viscocanaloplasty (ABiC) in open-angle glaucoma: 12-month outcomes. Int Ophthalmol (2021).

[Mini-canaloplasty as a modified technique for the surgical treatment of open-angle glaucoma]

Rękas, M., Konopińska, J., Byszewska, A. et al. Mini-canaloplasty as a modified technique for the surgical treatment of open-angle glaucoma. Sci Rep 10, 12801 (2020).

iTRACK™ PODIUM

With increased interest in ab-interno canaloplasty, a number of surgeons provided their iTrack™ clinical experience via the podium during FY21, adding significant credibility and momentum to the marketing and sales effort for iTrack™.

European Society of Cataract & Refractive Surgery (ESCRS) 2020
Paper: Long-term (48-month) results of Ab-interno Canaloplasty (ABiC) Combined with Phacoemulsification
Norbert Koerber, MD, PhD (Germany)

European Society of Cataract & Refractive Surgery (ESCRS) 2020
Paper: Evaluation of endothelial cell density and loss following I track ab-interno canal based surgery
David Lubeck, MD (USA)

American Glaucoma Society (AGS) 2021
Poster: iTrack Efficacy Across the Disease Spectrum
Mark Gallardo, MD (USA)

American Glaucoma Society (AGS) 2021
Poster: iTrack™ Efficacy in Cases of Steroid-Induced Glaucoma and Avastin-Induced Glaucoma
Logan Vincent, MD (USA)

European Glaucoma Society (EGS) 2021
Paper: Mini-canaloplasty as a modified technique for the surgical treatment of open-angle glaucoma
Marek Rekas, MD, PhD (Poland)

MAGIC MULTI-CENTER STUDY

The prospective, multi-center MAGIC Study was initiated in April 2021 to provide clinical evidence in support of the superior clinical effectiveness of iTrack™.

glaucoma-iTrack.com/MAGIC

- There are a number of technical and surgical considerations of the iTrack™ canaloplasty microcatheter which translate to superior clinical outcomes.
- A lack of head-to-head comparative data enabled the competition (Sight Sciences, SGHT) to gain market share during FY19-20.
- Nine USA sites will enroll 156 patients, randomized to treatment with iTrack™ and OMNI® (Sight Sciences) over 12-month follow-up.

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

AlphaRET

In FY21 we established a special purpose company, AlphaRET to focus on the 2RT® opportunity, while continuing to foster growth of our glaucoma treatment technologies under the Nova Eye Medical brand.

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

2RT® works by stimulating the rejuvenation of cells in the retina to initiate a healing response that targets the underlying causes of AMD.

- Age-related macular degeneration (AMD) remains the leading cause of blindness in industrialized countries.
- 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 i.e., early and intermediate AMD
- 2RT® is cleared for sale in Europe and Australia (for (iAMD) and is on a pathway to secure FDA clearance in the USA. (Note: There are currently 50 2RT® clinical reference sites in Europe and Australia.)
- The Wet AMD market is currently the only AMD market served by a therapy (namely anti-VEGF injections). This market is valued at US$5.1bn annually. AlphaRET intends to provide a therapy for the hitherto unserved iAMD market.

2RT® MARKET ASSESSMENT

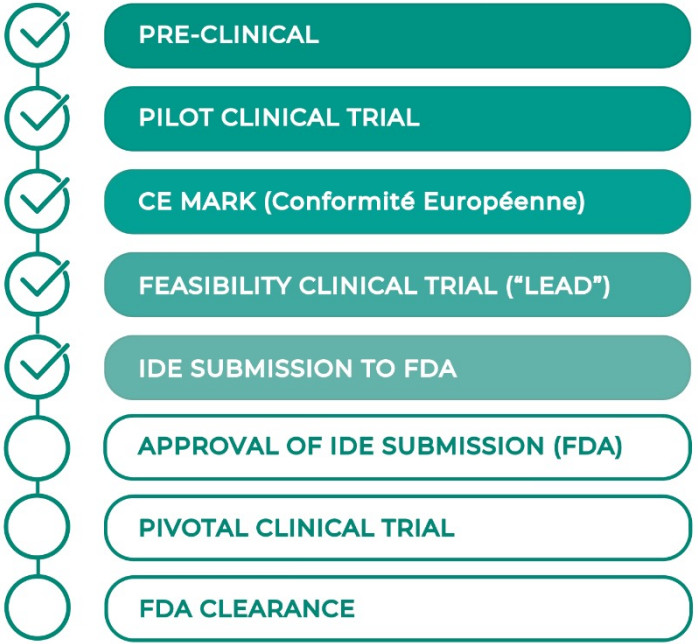
Our proprietary 2RT® nanosecond laser therapy is a world-first intervention designed to treat intermediate AMD. There is currently no treatment (drugs or devices) for the treatment of intermediate AMD.

	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.

2RT® DEVELOPMENT MILESTONES

Our current strategy for 2RT® is to undertake a multi-center study in the USA to gain FDA clearance for the treatment of intermediate AMD.



- Successfully completed Investigational Device Exemption (IDE) application with the US Food and Drug Administration (FDA) 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.**

FY21 ALPHARET EXPENDITURE

AlphaRET expenditure in FY21 related to the IDE submission for FDA (USA) market clearance.

	A$'000s (year ended 30 June 2021)	US$'000s (year ended 30 June 2021)
Operating Expenditure	1,128	835

- During FY21 2RT® revenue was principally per-procedure revenue from existing clinical reference sites.
- FX rate USD to AUD of 0.74

GROUP FINANCIALS

FY21 GROUP OPERATING RESULT

A$ million (year ended 30 June)	Nova Eye Medical (Glaucoma) and AlphaRET (2RT) Result		Corporate Result		Group Operating Result		Group Operating Result US$m[1]
	FY20	FY21	FY20	FY21	FY20	FY21	FY21
Sales	12.8	13.4			12.8	13.4	9.9
COGS (excl labour)	(4.4)	(4.5)			(4.4)	(4.5)	(3.3)
Gross Margin	8.4 65.6%	8.9 66.4%			8.4	8.9	6.6
Operating Expenditure	(12.2)	(9.7)	(2.0)	(2.9)	(14.2)	(12.6)	(9.3)
EBITDA (loss)	**(3.8)**	**(0.8)**	**(2.0)**	**(2.9)**	**(5.8)**	**(3.7)**	**(2.7)**
Interest Income					-	0.3	
Amortisation & depreciation					(1.4)	(1.4)	
Profit/(loss) before tax					**(7.2)**	**(4.8)**	

- AlphaRET operating costs in FY21 include A$1.1m in development of 2RT® FDA pathway.
- Corporate costs in FY21 included enhanced IP management, establishment of Nova Eye Medical brand, enhanced business and corporate development, establishment of German subsidiary, advanced R&D and residual transaction costs associated with dividend

1. AUD/USD 0.74 as at 30 June

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

GROUP BALANCE SHEET AT 30 JUNE 2021

	A$ million		US$ million[1]
	30 June 2020	30 June 2021	30 June 2021
Cash	95.7	17.8	13.2
Trade and other receivables	3.8	4.0	3.0
Income tax refund receivable	-	1.4	1.0
Inventories	2.9	2.9	2.1
Other current assets	0.6	0.3	0.2
Property and plant	1.2	1.3	1.0
Leased properties	1.7	2.2	1.6
Intangible assets	3.3	3.4	2.5
Capitalized development expenditure	7.5	8.7	6.4
Total Assets	**116.7**	**42.0**	**31.1**
Trade and other payables	(3.8)	(2.0)	(1.5)
Borrowings and lease obligations	(3.3)	(3.7)	(2.7)
Employee benefit provisions	(0.6)	(0.8)	(0.6)
Income tax payable	(8.2)	-	-
Deferred tax liability	(0.3)	(0.1)	(0.1)
Total Liabilities	**(16.2)**	**(6.6)**	**(4.9)**
Net Assets/Equity	**100.5**	**35.4**	**26.2**

1. AUD/USD 0.74 as at 30 June

NOVA EYE GROUP OUTLOOK

Nova Eye Medical Limited is well positioned to propel growth of its glaucoma consumable surgical devices through FY2022 as COVID-19 vaccination rates accelerate and surgical centers re-open to patients. It will also partner the clinical program for 2RT® for the pivotal FDA study.

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.

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