

Nova Eye Medical Limited (ASX:EYE)

Results Presentation for the Six Months Ended 31 December 2021

17 February 2022

nova-eye.com

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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.**

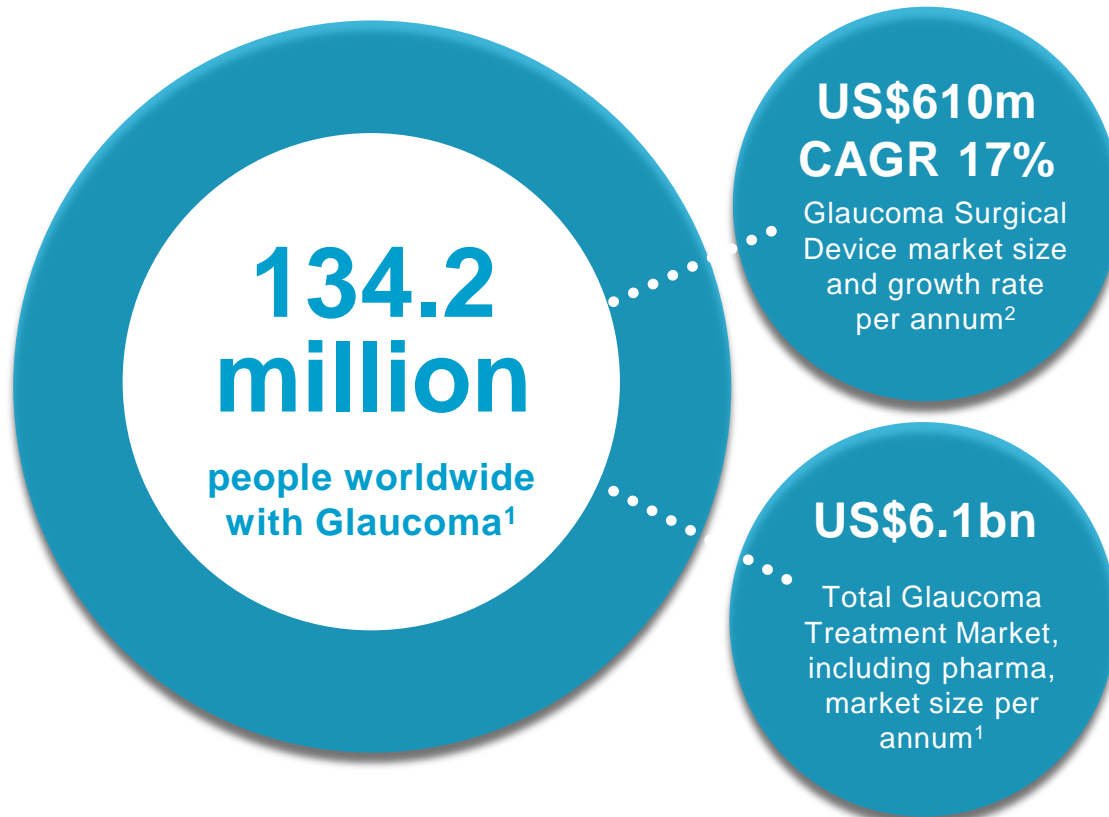
| Nova Eye Medical, Glaucoma | |
|----------------------------|--|
| Strategy | Develop, market and sell comprehensive portfolio of glaucoma consumable surgical devices |
| FY22 Objectives | Investment in initiatives for sales growth |
| Market | Glaucoma Surgical Devices; fast-growing and competitive |
| Competitive Advantage | Proprietary iTrack™ microcatheter technology |
| Sales | Established infrastructure; direct sales in USA, Germany, Australia; +20 distributors |
| Manufacturing | California, USA and Dunedin, New Zealand |
| IP Status | >100 patents issued and pending in major markets |
| 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 Objectives | Major clinical study; preference to secure FDA clearance via IDE-approved study |
| Market | Intermediate Age-related Macular Degeneration (iAMD) – market not addressed |
| Competitive Advantage | Proprietary 2RT® technology – first mover advantage |
| Sales | No sales program at present |
| Manufacturing | Adelaide, Australia |
| IP Status | >10 patents issued and pending in major markets |
| Regulatory | CE Mark (iAMD) in Europe, Australia, NZ and USA for diabetic eye disease |
| Reimbursement | Pending |

Glaucoma Market Strong Global Growth Theme



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



Advancements in diagnostic and imaging technologies permit earlier diagnosis, which in turn drives demand for interventions which permit earlier treatment

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Medications are considered standard of care but are associated with significant drawbacks i.e., low patient compliance, side effects, financial costs

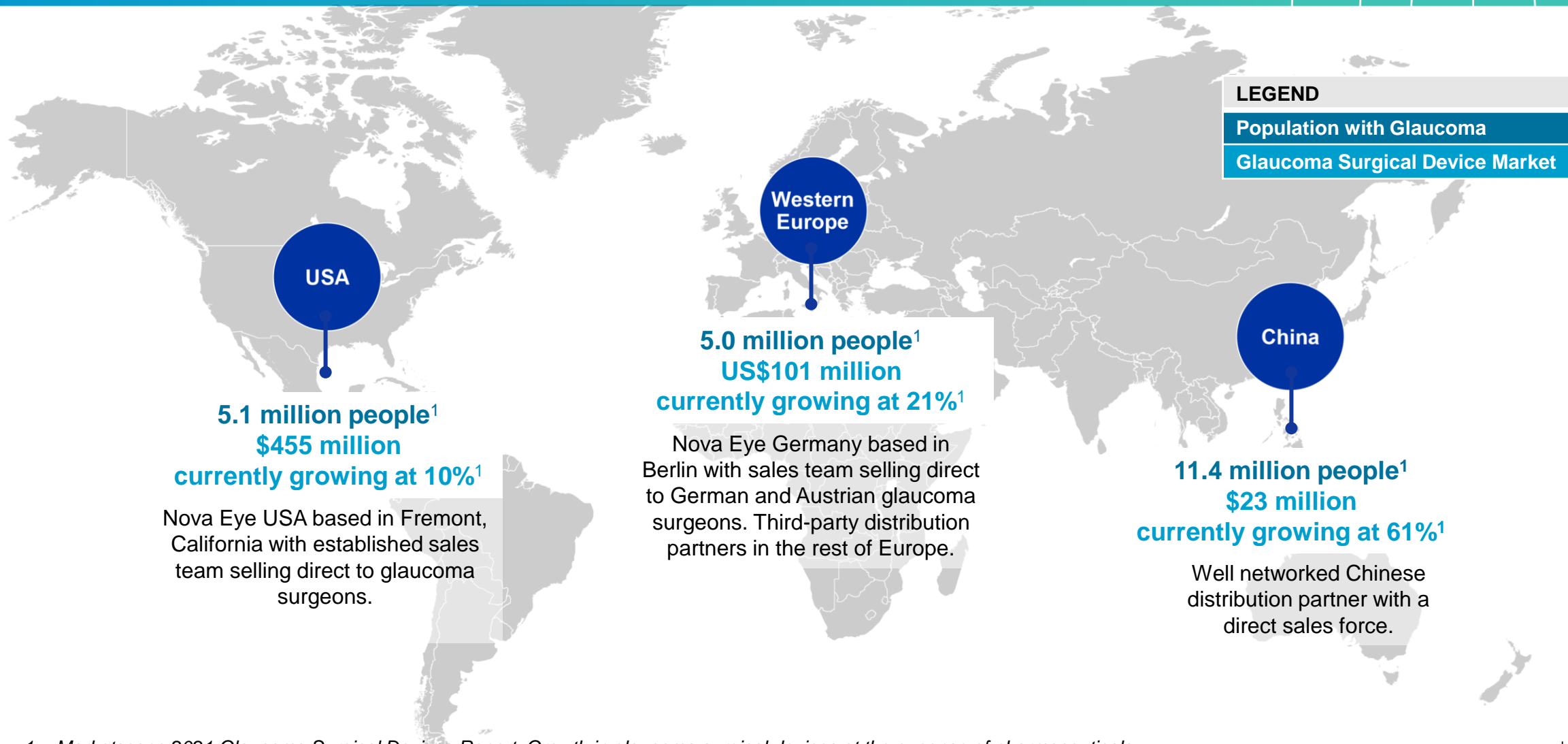
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Glaucoma surgical device solutions, including devices such as iTrack™, are increasingly recognized as a highly viable alternative to medications – and is currently the fastest growing segment of the ophthalmic market

1. Market Scope 2021 Glaucoma Surgical Devices Report

2. Market Scope 2021 Glaucoma Surgical Devices Report based on sum of MIGS, Canal Surgery Devices and Glaucoma Tubes and Shunts Markets

Nova Eye's Market Presence



1. Marketscope 2021 Glaucoma Surgical Devices Report. Growth in glaucoma surgical devices at the expense of pharmaceuticals.

Glaucoma Technology Portfolio and Pipeline



Comprehensive portfolio of glaucoma technologies spanning the entire glaucoma treatment algorithm, underpinned by a robust R&D and IP pipeline.

| PROGRAM STATUS | STAGE OF GLAUCOMA | | | |
|--------------------|---|--|--|---|
| | MILD GLAUCOMA | MODERATE GLAUCOMA | SEVERE GLAUCOMA | COMPLEX GLAUCOMA |
| COMMERCIAL | | iTrack™ Canaloplasty device manually deployed by glaucoma specialist <i>(Available all global markets)</i> | iTrack™ Canaloplasty device manually deployed in major eye surgery by glaucoma specialist <i>(Available all global markets)</i> | Molteno3® Glaucoma drainage device <i>(Available all global markets)</i> |
| COMMERCIAL IN 2022 | iTrack™ ADVANCE Canaloplasty device injector deployed by comprehensive ophthalmologist | iTrack™ ADVANCE Canaloplasty device injector deployed by glaucoma specialist | | |
| PIPELINE | | <ul style="list-style-type: none"> • August 2021 patent acquisition • Engineering program to introduce new Minimally Invasive Glaucoma Surgery (MIGS) device | | |

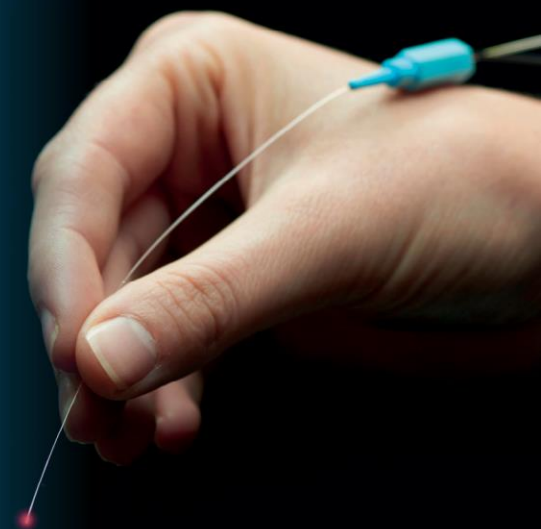
The proprietary ***iTrack***™ is a manually deployed microcatheter used to perform canaloplasty, a breakthrough surgical procedure that can be performed via either an ab-interno surgical technique (akin to “keyhole” surgery) i.e., MIGS, or via an ab-externo surgical technique (major eye surgery), depending on disease severity and/or surgeon preference.

iTrack™ offers a number of technical advantages over other glaucoma and MIGS devices and underpins our glaucoma growth strategy.

| | |
|---------------|---|
| Indication | Canaloplasty |
| Approval | All global approvals in place, including FDA and CE Mark |
| Reimbursement | Favourable CPT codes with/without cataract surgery in the USA |
| Patient | Mild, Moderate and Severe Glaucoma |
| Surgeon Type | Glaucoma surgeon |

10+ years
of surgical
use

100,000+
procedures
performed
globally



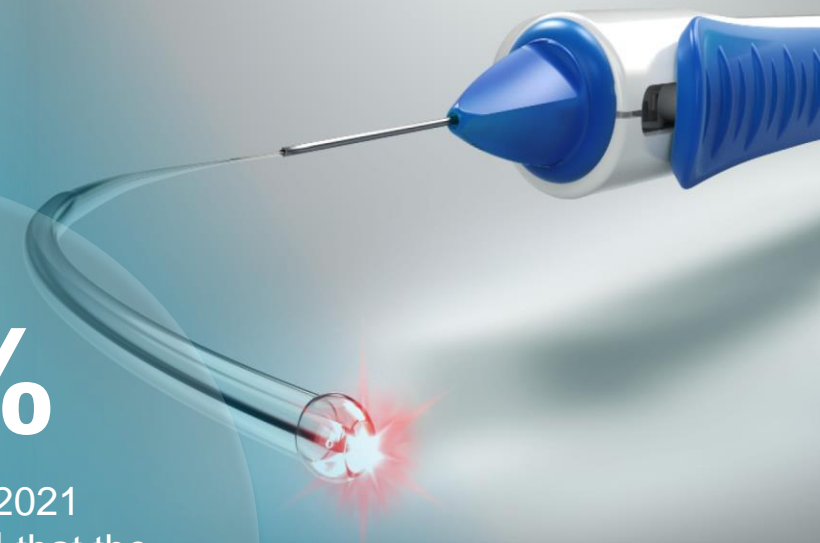
The next generation ***iTrack*TM Advance** is an injector deployed microcatheter. It takes the established effectiveness, accuracy and reliability of the original iTrackTM microcatheter and combines it with an ergonomic, easy-to-use handheld injector designed for all ophthalmic surgery and specialist settings.

Over the past 12 months canaloplasty has garnered increasing attention from surgeons in the USA, due to favourable reimbursement changes. *iTrack*TM Advance is well positioned to capitalise on the growing interest in the canaloplasty field.

| | |
|--------------|---|
| Indication | Canaloplasty |
| Approval | CE Mark |
| Patient | Mild-Moderate Glaucoma |
| Surgeon Type | Comprehensive ophthalmologist, cataract surgeon, glaucoma surgeon |

219%

Between 2018 and 2021 Marketscope estimates¹ that the market for canal-based surgery (including canaloplasty) has grown 219%.¹ This compares to growth of only 17% in the stent-based MIGS market i.e., iStent.¹



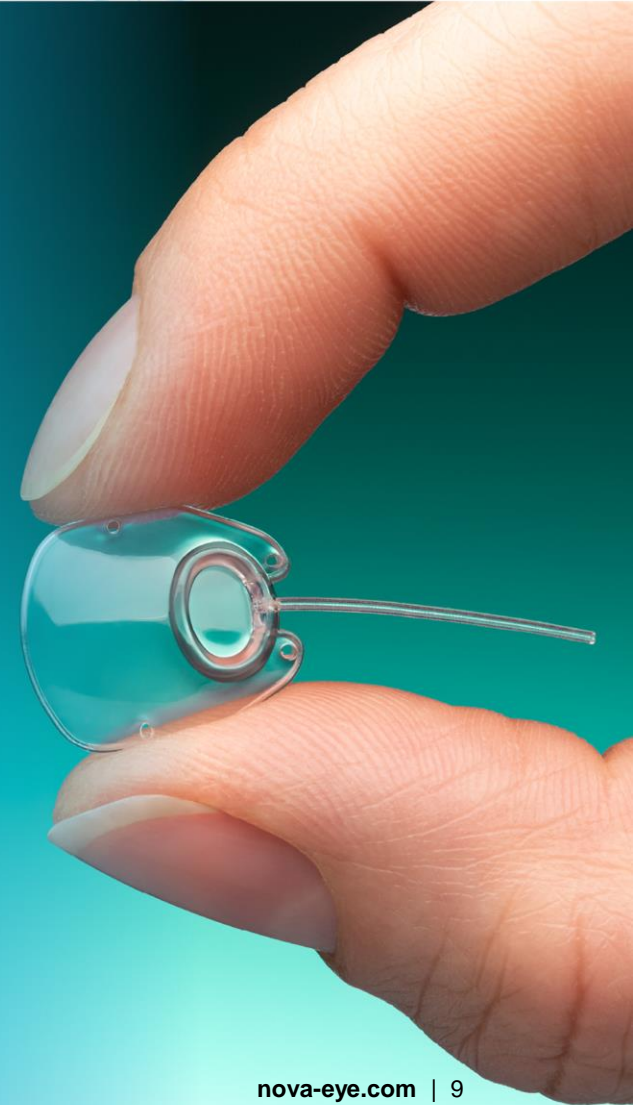
Implanted in thousands of patients worldwide for more than 30 years, the **Molteno3[®]** Glaucoma Drainage Device has been clinically validated to deliver consistent, long-term reduction in intraocular pressure (IOP) in cases of severe or complex glaucoma.

| | |
|---------------|--|
| Indication | Glaucoma Drainage Surgery |
| Approval | All global approvals in place, including FDA and CE Mark |
| Reimbursement | Favourable CPT code |
| Patient | ComplexAdvanced Glaucoma |
| Surgeon Type | Glaucoma surgeon |

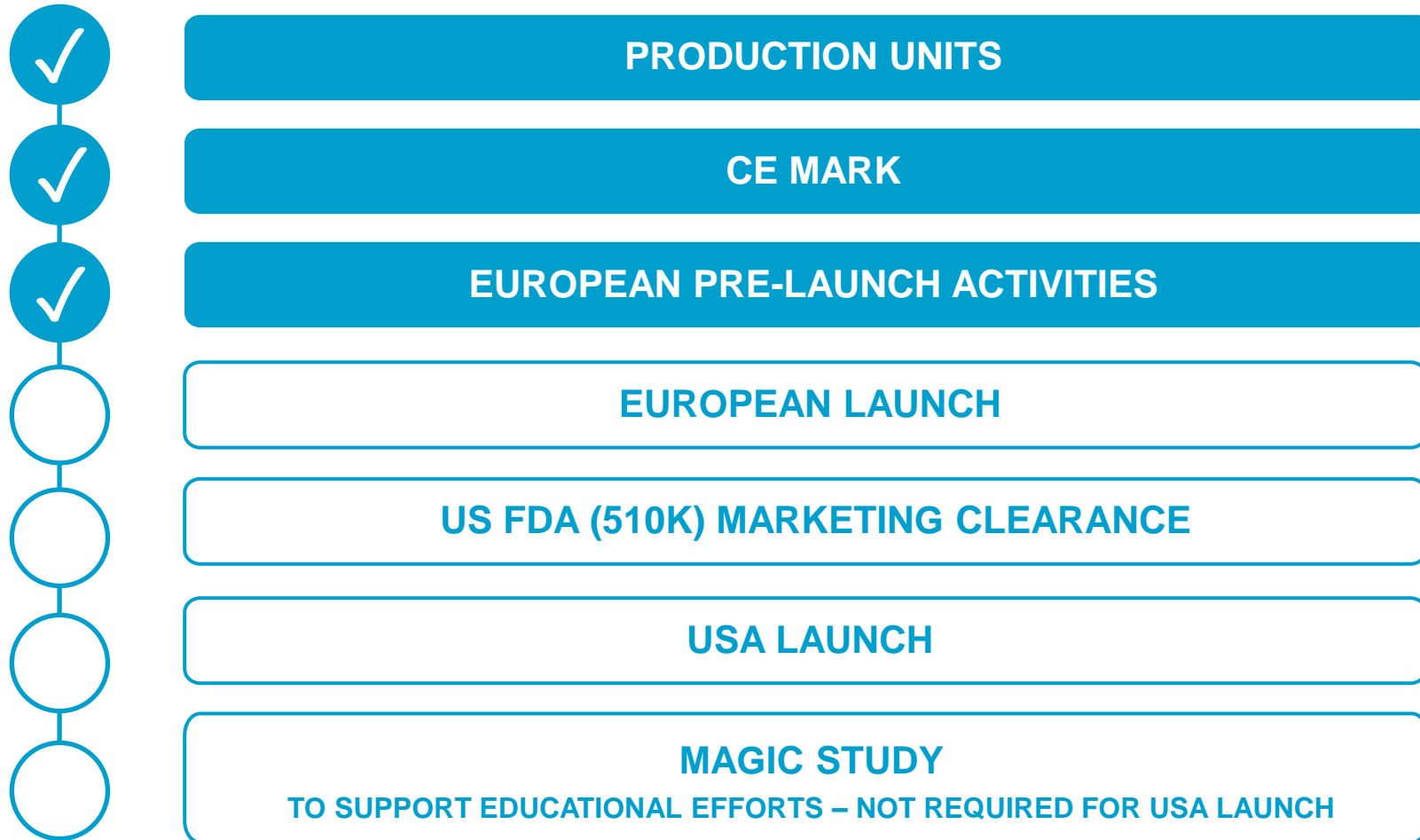
30+ years
of surgical use

0.4mm

At just 0.4mm, Molteno3[®] is the slimmest plate on the market, which simplifies surgical insertion and reduces OR time.



iTrack™ Advance Development Milestones



iTrack™ Advance Sales Growth Strategy

1

The new *iTrack™ Advance* device has broad market appeal.

2

The current iTrack™ device is principally sold to glaucoma surgeons only. In the USA there are approximately 1,200¹ glaucoma surgeons.

3

The *iTrack™ Advance* will allow access to comprehensive ophthalmologists. In the USA there are approximately 10,000² comprehensive ophthalmologists.

4

Nova Eye will grow sales by accessing a market approximately 10x the current market size.



1. Nova Eye estimate based on various industry data points
2. Based on article in February 19, 2021 edition of *Ocular Surgery News*

European Market Update

Financial Performance: solid growth in German market as a result of establishment of sales team and its expansion, with sales revenue up 26% during the period compared to the PCP.

| | Half year to December 2020 (US \$'000's) | Half year to December 2021 (US \$'000's) | Growth |
|---------|--|--|--------|
| Revenue | 974 | 1,224 | 26% |



Activities: pre-launch activities for iTrack™ Advance commenced ahead of planned launch in Q2 CY2022

- Training program for existing and new canaloplasty surgeons.
- Market preview at the DGII Congress (German Society of Cataract and Refractive Surgery), including official dry lab program of the DGII hosted by leading glaucoma surgeon Prof. Norbert Koerber.

Norbert Koerber, MD, PhD (Augencentrum Köln-Porz, Germany), a leading authority in glaucoma surgery, takes part in dry lab training for the new iTrack™ Advance ahead of its official launch in Q2 CY2022. Also pictured is Lisa Majeski, Director of Surgical Training – Global, Nova Eye.

USA Market Update

Financial Performance: sales revenue down 10% compared to the PCP, due to increased levels of competition. Despite these challenges, new surgeon interest in canaloplasty provides a strong platform for growth for the new *iTrack™ Advance* canaloplasty device.

| | Half year to December 2020 (US \$'000's) | Half year to December 2021 (US \$'000's) | Growth |
|---------|--|--|--------|
| Revenue | 3,363 | 3,037 | -10% |

Comments: favourable reimbursement changes in 2022, compared with stent-based MIGS, driving increased surgeon interest in canaloplasty:

- Canaloplasty reimbursement for physicians proposed to reduce from US\$950 to US\$770 per procedure.
- Reimbursement for physicians for stent-based surgery proposed to reduce from US\$300 to US\$134 per procedure

H1FY22 Glaucoma Operating Result



Improved EBITDA-level operating result.

| | A \$'000's | | | US \$'000's ¹ | | |
|--------------------------|--------------|--------------|--------|--------------------------|--------------|--------|
| | H1FY21 | H1FY22 | GROWTH | H1FY21 | H1FY22 | GROWTH |
| Sales | 6,423 | 6,488 | 1.0% | 4,677 | 4,752 | 1.6% |
| COGS | (2,425) | (2,660) | | (1,766) | (1,948) | |
| Gross Margin | 3,998 | 3,828 | | 2,911 | 2,804 | |
| Gross Margin | 62% | 59% | | | | |
| Operating expenditure | (4,971) | (5,934) | | (3,620) | (4,346) | |
| US Govt COVID19 Stimulus | – | 1,449 | | – | 1,061 | |
| EBITDA/(loss) | (973) | (673) | | (709) | (481) | |

Key H1FY22 information:

- Sales composition using US\$: USA 64% (pcp 72%), Western Europe 26% (pcp 21%), China 10% (pcp 7%)
(Note: China growth was 44% on PCP.)
- Increase in opex for German business expansion, clinical development and *iTrack™ Advance* pre-launch activity.

1. AUD/USD 0.73 in H1FY22 and 0.72 in H1FY21

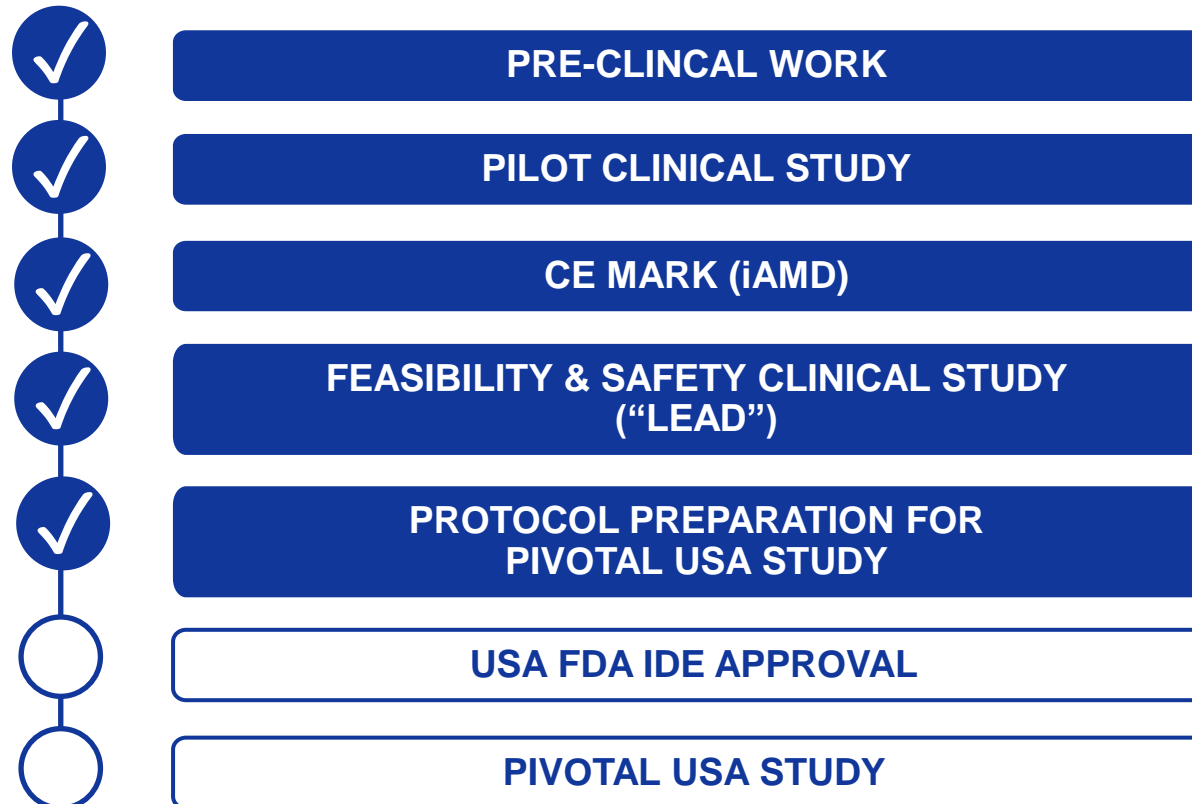
2RT[®] is a proprietary, world-first nanosecond laser therapy to treat intermediate AMD (iAMD).

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) is 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 and intermediate stages.
- 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[®] is cleared for sale in Europe and Australia (for iAMD)
(Note: There are approximately 30 2RT[®] users in Europe and Australia.)
- Commercialisation of 2RT[®] requires the conduct of a follow-up clinical study.
- Estimated addressable market is 54 million people per year which is estimated to be a US\$600m/year revenue opportunity.

2RT[®] Development Milestones

Our current strategy for 2RT[®] is to undertake a multi-center study, preferably 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[®] and have been in discussion with FDA since.
- The study may also be conducted outside the USA.
- The plan is to partner the investment in the 2RT[®] clinical program.
- Expenditure of \$0.6m in H1FY22 compared with \$0.5m in PCP for the development of the study package.

ASX: EYE Financials and Corporate Snapshot



| Nova Eye Medical Limited | | |
|--|--------------------------------|--------------------------------|
| Exchange | Australian Securities Exchange | |
| Ticker | EYE | |
| Management + Board Ownership | 7% | |
| Shares on Issue | 146 million | |
| Revenues (6 months 31 December 2021) | A\$6.5 million | US\$4.8 million ¹ |
| Net Tangible Assets (at 31 December 2021) | A\$34.1 million | US\$25.2 million ¹ |
| Market Capitalization (as at 11 February 2021) | A\$39 million | US\$27.9 million ² |
| Cash (at 31 December 2021) | A\$13.4 million | US\$10.0 million ¹ |
| EBITDA/(loss) (6months to 31 December 2021) | A\$(2.2 million)* | US\$(1.6 million) ¹ |

*Note: EBITDA/(loss) \$(0.8) million in PCP

1. AUD/USD 0.74 at 31 December 2022

2. AUD/USD 0.73 at 11 February 2022

Nova Eye Group Outlook



1

Europe: execute European launch of new *iTrack™ Advance* canaloplasty device, commencing Q3 FY2022

2

USA: complete *iTrack™ Advance* 510(k) regulatory submission to the USA Food and Drug Administration (FDA) to facilitate product launch later in 2022.

3

China: support distribution partner to improve market penetration of *iTrack™* canaloplasty device

4

2RT®: partner the 2RT® clinical program to support major multi-center study.



nova-eye.com

Tom Spurling

Managing Director

M: +61 417 818 658

E: tspurling@nova-eye.com

Mark Flynn

Investor Relations

M: +61 416 068 733

E: mflynn@nova-eye.com

Kate Hunt

Head of Marketing

M: +61 404 080 679

E: khunt@nova-eye.com