ASX RELEASE
26 AUGUST 2022

Nova Eye Medical Reports 2022 Financial Results

- **Glaucoma Consumable Surgical Device sales revenue of A$13.1 million and group sales revenue of A$13.4 million.**
- **The June 2022 launch of the Company's new canaloplasty device, iTrack™ Advance, contributing to 24% sales revenue growth in Germany compared to the prior period.**
- **Maintained sales in the USA of the Company's legacy product iTrack™ in the face of strong competition.**
- **Cash balance of A$8.0 million which will support sales growth of the Glaucoma Consumable Surgical Device segment in FY23.**
- **Projected sales growth of at least 15% forecast for the first four months of FY23**

Nova Eye Medical Limited (ASX: EYE) (**Nova Eye Medical** or the **Company**), a medical technology company committed to advanced ophthalmic treatment technologies and devices, today announces the full year audited financial results for the period ended 30 June 2022 (FY22).

During FY22 Nova Eye Medical completed several strategic initiatives and investments, including:

- Successfully completed the product development, clinical validation and production engineering of the iTrack™ Advance, the Company's new generation canaloplasty device.
- Secured key regulatory and product registration clearances for the new iTrack™ Advance in Europe, Canada and Australia with USA FDA approval application lodged and pending clearance in the last quarter of calendar year 2022.
- Commenced commercial launch of the new iTrack™ Advance in Europe, comprising comprehensive surgical training program and increased representation at regional tradeshows and events.
- Expanded and enhanced the Company's direct sales infrastructure in Germany.
- Continued investment in clinical development programs to support market access and reimbursement requirements, including Global iTrack Data Registry.
- Secured rights to seminal patents to expand glaucoma product portfolio.
- AlphaRET™ completed planning for the 2RT® confirmatory pivotal study based on USA FDA feedback.

The Company recorded sales revenue of A$13.4 million during the period, of which A$13.1 million was generated by the Glaucoma Consumable Surgical Devices segment (iTrack™ Advance, iTrack™ and Molteno3®). This compares with group sales revenue of A$13.4 million and Glaucoma Consumable Surgical Device revenue of A$13.1 million for the year ended 30 June 2021. Sales were maintained in the face of COVID-19 - driven delays and strong competition. After allowing for changes in foreign currency a reduction in sales revenue of 1.5% was recorded for the Glaucoma Consumable Surgical Device segment.

The EBITDA-level loss for the group was A$6.4 million, compared with A$3.7 million in the prior comparative period. This result was driven primarily by investments in the Glaucoma Consumable Surgical Devices segment to bring the iTrack™ Advance to production-ready status. It also included lodgement of the 510(k) submission with the USA Food & Drug Administration (FDA), and various commercial initiatives to support growth of the new iTrack™ Advance in the 2023 financial year.

While sales were the same year on year, two important outcomes were achieved in the Company's direct sales markets of the USA and Germany. In the USA, renewed interest in the role of canaloplasty in the glaucoma treatment armamentarium, as compared to stent-based MIGS procedures, and the return of previous customers after trialling competitor devices, contributed to 10% growth in sales revenue in the second half of the 2022 financial year from the legacy iTrack™ product. In Germany, sales revenue grew 24% compared with the prior year following ongoing investments in the Company's direct sales infrastructure in the region.

Nova Eye Medical Managing Director, Tom Spurling commented:

> *"During the year there was a $5.1 million investment in completing the design and production engineering of our new device iTrack™ Advance, and in securing seminal patent rights to expand iTrack™ patent coverage. We expect the new iTrack™ Advance to materially improve the surgical efficiency and user experience of the well-regarded iTrack™ and will lead to strong sales, particularly in the USA, following the necessary regulatory clearance. The Company lodged a 510(k) application with the USA FDA and expects to receive the necessary clearance in FY23. Outside of the USA we successfully secured regulatory clearance in key markets in Europe, as well as Australia and Canada. Feedback and early clinical assessments from key opinion leaders provides positive reinforcement that we are well-positioned to exploit the burgeoning glaucoma market. Glaucoma remains the leading cause of irreversible blindness in the world, affecting 134 million people worldwide. This number is expected to rise to 153 million by 2026[1.]."*

AlphaRET™, 2RT®

2RT® is an important technology to the Nova Eye Medical Group and is managed by the Company's AlphaRET™ division. It is a leading candidate therapy to meet a major global, unmet ophthalmic and medical need. 2RT® has the potential to transform the global treatment of age-related macular degeneration (AMD) by treating patients earlier in the disease state. This represents a revolutionary change from the status quo and thereby provides enormous clinical and commercial potential.

The Company estimates the global revenue opportunity for 2RT® to be US$600 million per year.

To support the commercial pathway for this opportunity, the Company is planning to conduct a follow-up confirmatory pivotal clinical study. This study will aim to confirm the results of a *post hoc* analysis reported in "Subthreshold Nanosecond Laser Intervention in Age-Related Macular Degeneration - The LEAD Randomized Controlled Clinical Trial" (Robyn H. Guymer, MBBS, PhD, et al, *Ophthalmology)*[1]. LEAD reported a 77% reduction in the rate of disease progression in 76% of patients who did not have a pre-existing eye condition at enrolment.

During the 2022 financial year the Company's AlphaRET™ division finalised the key study design considerations for the confirmatory pivotal study, based on feedback from the USA FDA of the Company's investigational device exemption submitted in July 2021, and commenced study preparations accordingly. This investment in the 2RT® confirmatory pivotal clinical study during the period was offset by reductions in corporate costs. AlphaRET™ also commenced an outreach program to potential partners to fund the confirmatory pivotal study during the period.

Composition of EBITDA level (loss) and cash

Segment	**FY21 A$ million**	**FY22 A$ million**
Glaucoma	0.1	(3.1)
AlphaRET™ 2RT®	(0.9)	(1.5)
Corporate	(2.9)	(1.9)
Group EBITDA/(loss)	**(3.7)**	**(6.4)**

For the year ended 30 June 2022 group cash outflow from operations was A$4.7million. In addition, A$5.1 million was invested in product development and the acquisition of key glaucoma patents. As of 30 June 2022, the Company has cash at bank of A$8 million.

Outlook

- Investments in the 2022 financial year and European launch of iTrack™ Advance will trigger sales growth in the 2023 financial year.
- Subject to the continuation of current market conditions, sales for the four months to 31 October 2022 are expected to be more than US$3.4m, which is growth of approximately 15% compared to the prior corresponding period.
- USA launch of iTrack™ Advance expected in the last quarter of the 2022 calendar year.
- After the significant non-recurring cash investments made in the 2022 financial year, the business has sufficient cash to meet its plans for the 2023 financial year.
- For 2RT®, AlphaRET™ will progress efforts to partner to fund a confirmatory pivotal study and will continue to make a small, targeted investment in preparatory study-related work.

This release dated 26 August 2022 has been authorised for lodgement to ASX by the Board of Directors of Nova Eye Medical Limited and lodged by Simon Gray, Company Secretary.

– ENDS –

1. Marketscope 2021 Glaucoma Surgical Devices Report

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ABOUT NOVA EYE MEDICAL

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons in more than 100 countries globally, these technologies include iTrack™ minimally invasive glaucoma surgery (MIGS), a consumable surgical device that restores the eye's natural outflow pathway to lower pressure inside the eye and to eliminate patient reliance on anti-glaucoma medications for mild-moderate glaucoma. The Molteno3® glaucoma drainage device platform is designed to enhance surgical utility and optimize clinical outcomes for long-term IOP control in cases of severe glaucoma. It also offers the benefit of a simplified and faster surgical procedure. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by a global network of more than 50 distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

For additional information about Nova Eye Medical and its technologies, please visit:
www.nova-eye.com

ABOUT iTRACK

Nova Eye Medical (formerly iScience Interventional) pioneered the canaloplasty market with the launch of the world's first canaloplasty device, iTrack™, in 2008. Since then, more than 100,000 canaloplasty procedures have been performed with the iTrack™ device, cementing its role in the treatment of glaucoma both as a standalone procedure and in combination with cataract surgery. Launched in 2022, the iTrack™ Advance leverages the proprietary features of the original iTrack™ device but incorporates a new handheld injector design, which improves the overall surgical efficiency of the canaloplasty procedure.

iTrack™ Advance has a CE Mark (Conformité Européenne) for the treatment of open-angle glaucoma and is currently available in selected markets in Europe and the Asia Pacific. iTrack™ Advance is not available for use or sale in the USA. The iTrack™ Advance is indicated for fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open-angle glaucoma.

iTrack™ has a CE Mark (Conformité Européenne) and US Food and Drug Administration (FDA) 510(k) # K080067 for the treatment of open-angle glaucoma. The iTrack™ canaloplasty microcatheter has been cleared for the indication of fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open-angle glaucoma. The iTrack™ canaloplasty microcatheter is currently not 510(k) cleared for use with the ab-interno technique in the United States.

For additional information about the iTrack™ portfolio, including safety information, please visit: www.glaucoma-iTrack.com

For additional information about iTrack™ Advance, including safety information, please visit: https://itrack-advance.com/

ABOUT ALPHARET

Established in October 2020, AlphaRET Pty Ltd (AlphaRET) is a wholly owned subsidiary of Nova Eye Medical Limited. AlphaRET is focussed on executing the commercialization efforts for 2RT® and clearly delineates the 2RT® project from the Company's core glaucoma business.

For additional information about AlphaRET, please visit: www.alpha-ret.com

2RT® Indications of Use

CE MARK:

- *The treatment of Clinically Significant Macular Edema (CSME); and*
- *In patients with early Age-related Macular Degeneration (AMD) where it can produce bilateral improvements in macular appearance and function.*

US 510(k):

- *The treatment of Clinically Significant Macular Edema (CSME).*