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## **Nova Eye Medical reports 25% growth in Glaucoma Device Sales for the 2021 Fiscal Year**

- **Glaucoma Consumable Surgical Device sales revenue of A\$13.1 million, up 13% (25% in constant currency) on pcip**
- **Glaucoma Consumable Surgical Device EBITDA of A\$0.1 million, compared to A\$4.1 million loss in pcip**
- **Submission of 2RT® Investigational Device Exemption (IDE) application to FDA**
- **Group sales revenue of A\$13.4 million, compared to A\$12.8 million in pcip**
- **Group EBITDA loss of A\$3.7 million, compared to A\$5.9 million loss in pcip**

**Adelaide, Australia, 19 August 2021** – 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 2021 (FY21).

In general there was a reduction glaucoma surgical procedures in the USA and other key markets during the period due to COVID restrictions. Notwithstanding this the Company recorded solid sales revenue growth of 13.1% to A\$13.1 million for its glaucoma consumable surgical devices (iTrack™ and Molteno3®). This compares with sales revenue of A\$11.6 million for the year ended 30 June 2020. After allowing for the appreciation of the Australian dollar (A\$) against the US dollar (US\$), sales revenue growth was 24.9% measured in constant currency terms. Most of this sales growth was driven by improved market penetration of the Company's proprietary iTrack™ minimally invasive glaucoma surgery (MIGS) device.

Improved operating efficiencies during the period resulted in a material 26% reduction in operating costs from A\$11.5 million to A\$8.5 million. As a result the glaucoma device business reported an EBITDA of A\$0.1 million (A\$4.1 million loss).

Commenting on the positive operating result, Executive Director, Tom Spurling, noted the Company's strong sales performance in the USA, in addition to the establishment of a wholly owned subsidiary in Germany in November 2020 to sell its glaucoma treatment technologies direct to eye surgeons in Germany.

"Several initiatives were executed during the period to drive improved market penetration of the Company's iTrack™ MIGS device, which resulted in strong sales growth. More importantly, however, these initiatives have set the foundation for further growth in the coming years."

"While the USA remains our most important market, our direct sales presence in Germany represents an important milestone in our stated growth strategy. We have a rich history in Germany, and it represents one of the most important markets for our glaucoma treatment products. In 2014,

canaloplasty was formally recognized as the new 'gold standard' in the surgical treatment of glaucoma by the patient advocacy group German Federate Eye Association."

#### Nova Eye Medical, Glaucoma

The Company made a concerted effort to reset its global glaucoma sales, marketing, clinical and IP infrastructure during the period, with much of this effort focused on the Company's proprietary iTrack™ MIGS device, which offers substantial opportunity for growth in the burgeoning MIGS market.

Significant investments were also made in the Company's clinical program for iTrack™ during the period, including the initiation of a new multi-center clinical study ("MAGIC", NCT04769453) to provide prospective clinical evidence in support of the superior effectiveness of iTrack™.

A further highlight was the presentation of new safety data from a 5-year prospective multi-center study evaluating endothelial cell loss (ECL) in eyes undergoing iTrack™ ab-interno canaloplasty in combination with cataract surgery. Presented by Dr. David Lubeck (Arbor Eye Care, Chicago) and Dr. Robert Noecker (Ophthalmic Consultants of Connecticut, Connecticut) the data demonstrated mean ECL of 3.2% (SD ±9.0%) – and represents the lowest reported rate of ECL of all MIGS procedures.

"Endothelial cell loss is today recognized as a key indicator of MIGS safety. This follows the 2018 market withdrawal of the CyPass stent (Alcon) due to excessive ECL. The new safety data from doctors Lubeck and Noecker suggests that iTrack™ may preserve the health of the corneal endothelium and thereby offers a considerable advantage over other MIGS. It also validates the stent-free, tissue-sparing mechanism of the iTrack™ ab-interno canaloplasty procedure," commented Tom Spurling.

#### AlphaRET, 2RT®

The Company established a special purpose company in October 2020, AlphaRET, to better focus the 2RT® project. This focus included the completion of an application for an Investigational Device Exemption (IDE) to the USA Food and Drug Administration (FDA) in July 2021, to support the regulatory pathway for 2RT®.

"2RT® is an important technology and filing the IDE was a significant undertaking. An investment of approximately A\$1.1 million over the past 12 months has been made to achieve this milestone and we are currently in discussions with the FDA to progress approval of the pivotal study for the Company's 2RT® treatment for intermediate age-related macular degeneration," said Tom Spurling.

#### Group Result

Driven by the improved result from the glaucoma business, the Company's overall EBITDA loss was A\$3.7 million, compared to A\$5.8 million in the pcp. The Company held cash and cash equivalents of A\$17.8 million as at 30 June 2021.

#### Outlook

Nova Eye Medical 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. In the USA, a planned ramp up in sales, marketing and clinical investment will support market

penetration, sales growth and improved market share. In Germany, a targeted sales program will be implemented to grow overall market share. The Company will also invest in an expansive intellectual property (IP) and product development activities, including the launch the next generation iTrack™ device,

For 2RT®, AlphaRET will continue to prioritize the regulatory pathway for the USA market via approval to commence the pivotal study. The Company is intending to seek a partner to fund the study.

***This release dated 19 August 2021 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 –**

**Company**

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**ABOUT 2RT®**

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).

## 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<sup>®</sup> and clearly delineates the 2RT<sup>®</sup> project from the Company's core glaucoma business. In the immediate term AlphaRET will prioritize the USA regulatory pathway for 2RT<sup>®</sup>, which includes the filing of an Investigational Device Exemption (IDE) with the US Food and Drug Administration (FDA) for a pivotal clinical study. The aim of the pivotal study will be to obtain regulatory clearance from the FDA to treat iAMD patients with 2RT<sup>®</sup>.

For additional information about AlphaRET, please visit: [www.alpha-ret.com](http://www.alpha-ret.com)

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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<sup>™</sup> 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<sup>®</sup> 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](http://www.nova-eye.com)