

Nova Eye Medical Reports Global Revenue of A\$6.54m for 6 Months Ended 31 December 2021

Highlights

- **Glaucoma segment sales growth in Europe and China**
- **Pre-launch activities underway for new canaloplasty device *iTrack™ Advance***
- **Progress continues on clinical program for AlphaRET, 2RT®**

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 half-year financial results for the six months ended 31 December 2022.

Glaucoma Surgical Devices Segment

Nova Eye Medical reported group revenues of \$6.54 million, attributable almost entirely to the sale of its portfolio of proprietary glaucoma surgical devices. This represents a 1.6% increase in glaucoma surgical device revenue in constant currency terms, compared with the prior comparative period (pcp). EBITDA-level loss from the glaucoma surgical devices segment was \$0.67 million, an improvement from \$0.97 million in the pcp after allowing for \$1.4 million of US Government COVID 19 stimulus received during this current reporting period.

The global market value for glaucoma surgical devices is currently estimated at US\$610 million¹ per year with 17% annual growth¹. Nova Eye Medical is a founding participant in this market with a product portfolio that is well known and trusted globally by leading glaucoma surgeons. Despite modest sales growth during the half year ended 31 December 2021, the Company is confident that progress on its next generation canaloplasty device, *iTrack™ Advance*, including the commencement of pre-launch activities in Europe, provides an outlook for strong sales growth.

The new *iTrack™ Advance* offers improved ease of use and will drive procedural adoption by a new, larger demographic of surgeons comprising comprehensive ophthalmologists.

“During the period we commenced a series of pre-launch activities for the new *iTrack™ Advance*, including a surgical training program. This program has initially centred on our existing base of glaucoma professors in Germany and will be followed by outreach to new customers, cataract surgeons and comprehensive ophthalmologists. This will be an exciting milestone in our efforts to drive greater procedural adoption of canaloplasty and thus to

¹ Market Scope 2021 Glaucoma Surgical Devices Report based on sum of MIGS, Canal Surgery Devices and Glaucoma Tubes and Shunts Markets

generate sales growth,” commented Tom Spurling, Managing Director of Nova Eye Medical.

Glaucoma surgical device sales in Europe grew by 26% during the period (in constant currency compared with pcp) to US\$1.22 million. Sales also grew in China by 44% (in constant currency compared with the pcp) to US\$0.49 million. Sales in the USA, however, fell by 10% during the period (in constant currency compared with the pcp) to US\$3.04 million.

The solid revenue growth in Europe was primarily due to investments in commercial infrastructure in Germany, including the establishment of a direct sales team. In China, a sustained marketing and sales effort by the Company’s local distribution partner resulted in improved sales performance.

In the USA sales fell due to intensified levels of competition. Despite this challenge, favourable reimbursement changes from January 1, 2022, have triggered new surgeon interest in canaloplasty, which, combined with the Company’s new *iTrack™ Advance* canaloplasty device is expected to drive sales growth and regain market share.

“Following its successful introduction into key territories in Europe over the coming months, a major priority for the business in 2022 will be the USA market launch of the *iTrack™ Advance*. This device takes the established effectiveness, accuracy and reliability of the original *iTrack™* and combines it with an ergonomic, easy-to-use handheld injector that’s optimised for all ophthalmic surgery and specialist settings. As a result of its improved ease of use, we expect uptake by comprehensive surgeons to be strong. This will facilitate greater patient access to canaloplasty during the earlier stages of the disease process,” said Mr. Spurling.

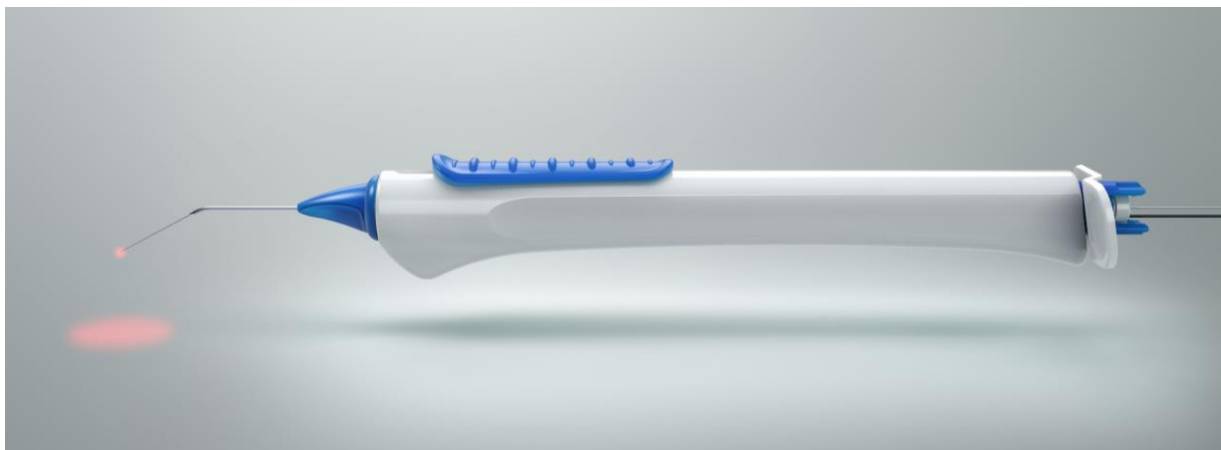


Image: Nova Eye Medical's next generation canaloplasty device, *iTrack™ Advance*.

AlphaRET

The Company's AlphaRET division is responsible for the commercial and clinical development of 2RT[®]; a world-first rejuvenative retinal laser therapy that utilises a nanosecond laser pulse and proprietary pixelated laser beam profile in the treatment of intermediate age-related macular degeneration, the leading cause of blindness in industrialised countries.

During the period the Company invested \$0.6 million in the 2RT[®] clinical program, including key documentation in support of the planned multi-center study, such as the study design and protocol. It also comprised technical and clinical submissions to the United States Food and Drug Administration (FDA).

"On our progress with the FDA and 2RT[®], our efforts are ongoing and the dialogue with the FDA has been constructive. Whilst our preference is to conduct the multi-center study in the USA, we are actively evaluating other study pathways. Further, partnership discussions are also underway to support funding of the study," commented Mr. Spurling.

Outlook

- **Europe:** execute European launch of new *iTrack*[™] *Advance* canaloplasty device, commencing Q3 FY2022
- **USA:** complete and lodge *iTrack*[™] *Advance* 510(k) submission to the FDA to facilitate product launch later in CY2022
- **China:** support distribution partner in improved market penetration of *iTrack*[™] canaloplasty device
- **2RT[®]:** partner the 2RT[®] clinical program to support major multi-center study

This release dated 17 February 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 –

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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 advanced and complex 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 CANALOPLASTY

First introduced in 2008, canaloplasty is a surgical treatment for glaucoma that targets the main sites of outflow resistance in the conventional outflow pathway: the trabecular meshwork, Schlemm's canal, and the distal collector channels. Based on the same principles as angioplasty, a flexible microcatheter is cannulated 360 degrees around Schlemm's canal during the procedure to manually break and remove blockages. Next, viscoelastic fluid is injected into Schlemm's canal as the microcatheter is withdrawn to dilate the distal outflow system and to improve the function of the trabecular meshwork. Importantly, canaloplasty is an implant-free, tissue-sparing procedure.

With over 100,000 canaloplasty procedures performed to date with the iTrack™, clinical studies show that canaloplasty has an excellent safety profile, with minimal post-operative follow-up, fast recovery time, and infrequent intra-operative and postoperative complications

ABOUT THE iTRACK™ PORTFOLIO

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. Introduced 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.

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

The 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.

The iTrack™ has a CE Mark (Conformité Européenne) and 510(k) clearance in the United States 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™ is currently not 510(k) cleared for use with the ab-interno surgical technique in the United States.