ASX RELEASE
12 December 2022

Status of Marketing Clearance for *iTrack™ Advance* Canaloplasty Device in the USA

Highlights

- **Feedback received from US Food & Drug Administration (FDA)**
- **Expectations of receipt of marketing clearance now pushed back**
- **The opportunity in the USA remains strong**
- **Recent growth driven by the launch of the iTrack™ Advance outside of the USA**

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 advises that it has received feedback from the US Food & Drug Administration (FDA) in relation to its 510(k) submission for marketing clearance of the Company's new *iTrack™ Advance* canaloplasty device in the USA.

Nova Eye Medical advises that, with the receipt of the feedback from the FDA, it does not expect to receive marketing clearance prior to December 31, 2022, as previously stated. The Company will continue to actively engage with the FDA in support of a marketing clearance.

Nova Eye Medical Managing Director, Tom Spurling, commented:

"The regulatory pathway for marketing clearance for canaloplasty in the USA is extremely rigorous and complex. Our current product, the original iTrack™ canaloplasty microcatheter, remains the only device in the USA with an indication for canaloplasty. We will continue to progress our submission for the iTrack™ Advance and will provide a further update in due course.*

We continue to have an excellent opportunity in the USA with the original iTrack™ canaloplasty microcatheter, because of growing surgeon interest in canaloplasty and a favourable reimbursement environment. Outside of the USA, we will pursue sales of the iTrack™ Advance in the key markets of Germany, the UK, Italy, and Canada. We will also look to introduce iTrack™ Advance into additional markets, with several regulatory evaluations currently in progress."

On November 16, 2022 the Company reported strong sales performance for the four months ended October 21, 2022, with sales revenue of US$3.82 million (A$5.66 million in reporting currency), which materially exceeded the forecast guidance of US$3.4 million.

This growth was driven by the launch of the *iTrack™ Advance* in markets outside of the USA, as well as rebound sales of the Company's iTrack™ in the USA.

The *iTrack™ Advance* has been designed based on the success of the original iTrack™. Both the original iTrack™ and the *iTrack™ Advance* are manufactured by Nova Eye Medical in its state-of-the art manufacturing facility in the USA.

The original iTrack™ was cleared by the FDA in 2008 and has been used in nearly 120,000 canaloplasty procedures globally. It is currently the only device in the USA with an indication for canaloplasty*.

The *iTrack™ Advance* leverages the same design and function of the original iTrack™ but is designed for improved surgical efficiency. A key feature of the *iTrack™ Advance* is an ergonomic handpiece, which enhances the advancement/withdrawal of the microcatheter through Schlemm's canal (part of the eye's drainage channel) and eliminates the need for forceps, as compared to the original iTrack™.

Based on the enhanced ease-of-use and ergonomic design, the *iTrack™ Advance* is expected to drive increased surgeon uptake of the canaloplasty procedure. A description of the opportunity in the USA is attached to this release. Positive surgeon feedback from early clinical use in Germany, the UK, Italy, Canada and Australia further supports the global market opportunity for the *iTrack™ Advance*.

**Other devices currently in use in the USA market do not have an indication for canaloplasty or must be performed in combination with other procedures i.e., trabeculotomy (cutting of trabecular meshwork tissue), because the clinical evidence does not support a standalone indication for canaloplasty.*

– ENDS –

This release dated 12 December 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. For additional information about Nova Eye Medical and its technologies, please visit: www.nova-eye.com

Company
Tom Spurling
Managing Director
+61 417 818 658
tspurling@nova-eye.com

Company
Kate Hunt
Chief Commercial Officer
+61 404 080 679
khunt@nova-eye.com

Investors
Mark Flynn
Investor Relations
+61 416 068 733
mflynn@nova-eye.com

ABOUT NOVA EYE MEDICAL LIMITED

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 longterm 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.

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. Canaloplasty is typically performed using either of the following two surgical techniques.

- Performed via an ab-interno surgical technique, canaloplasty is a highly effective treatment option for cases of mild-moderate glaucoma. It typically reduces intraocular pressure (IOP) to the low teens. It has also been observed to reduce patient dependence on medications. Importantly, the ab-interno surgical 5 technique is an implant-free, tissue-sparing procedure that preserves future treatment options.
- Performed via an ab-externo surgical technique, canaloplasty is a highly effective treatment option for patients with severe glaucoma that overcomes the risks and discomfort associated with traditional glaucoma surgery. With over 100,000 procedures performed to date, 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 (through the acquisition of the business of iScience Interventional Inc) pioneered the canaloplasty market with the launch of the world's first canaloplasty microcatheter, iTrack™, in 2008. Since then, nearly 120,000 canaloplasty procedures have been performed with the iTrack™ microcatheter, cementing its role in the treatment of glaucoma both as a standalone procedure and in combination with cataract surgery. Launched in 2022 in certain markets, the iTrack™ Advance leverages the proprietary features of the original iTrack™ microcatheter but incorporates a new handheld injector and cannula, which improves the overall surgical efficiency of the canaloplasty procedure.

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

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™ 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™ Advance is not available for use or sale in the USA.

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 abinterno technique in the United States.

Recap of growth opportunity with iTrack™ Advance

Nova Eye Medical Limited (ASX:EYE)

12 December 2022

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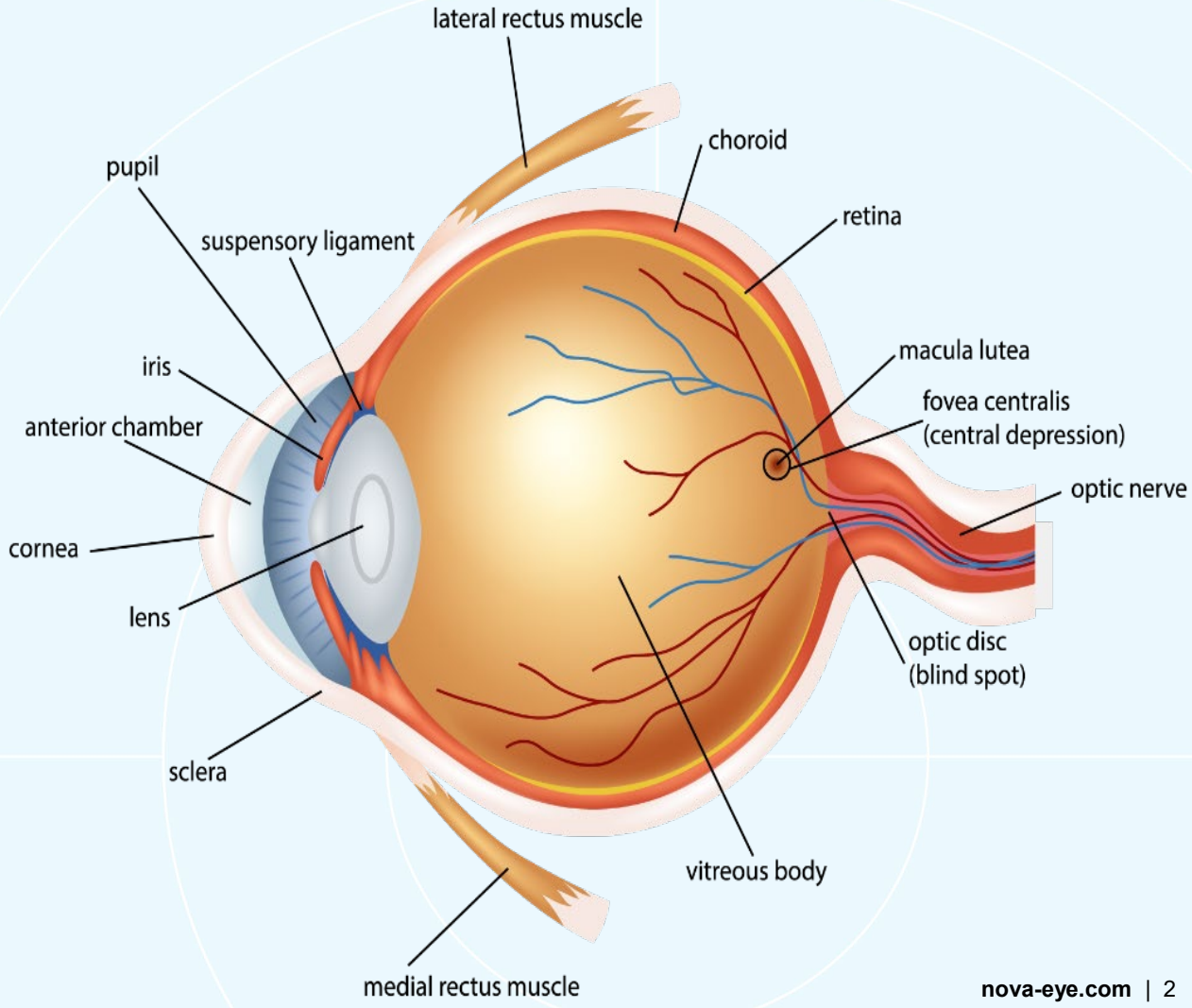


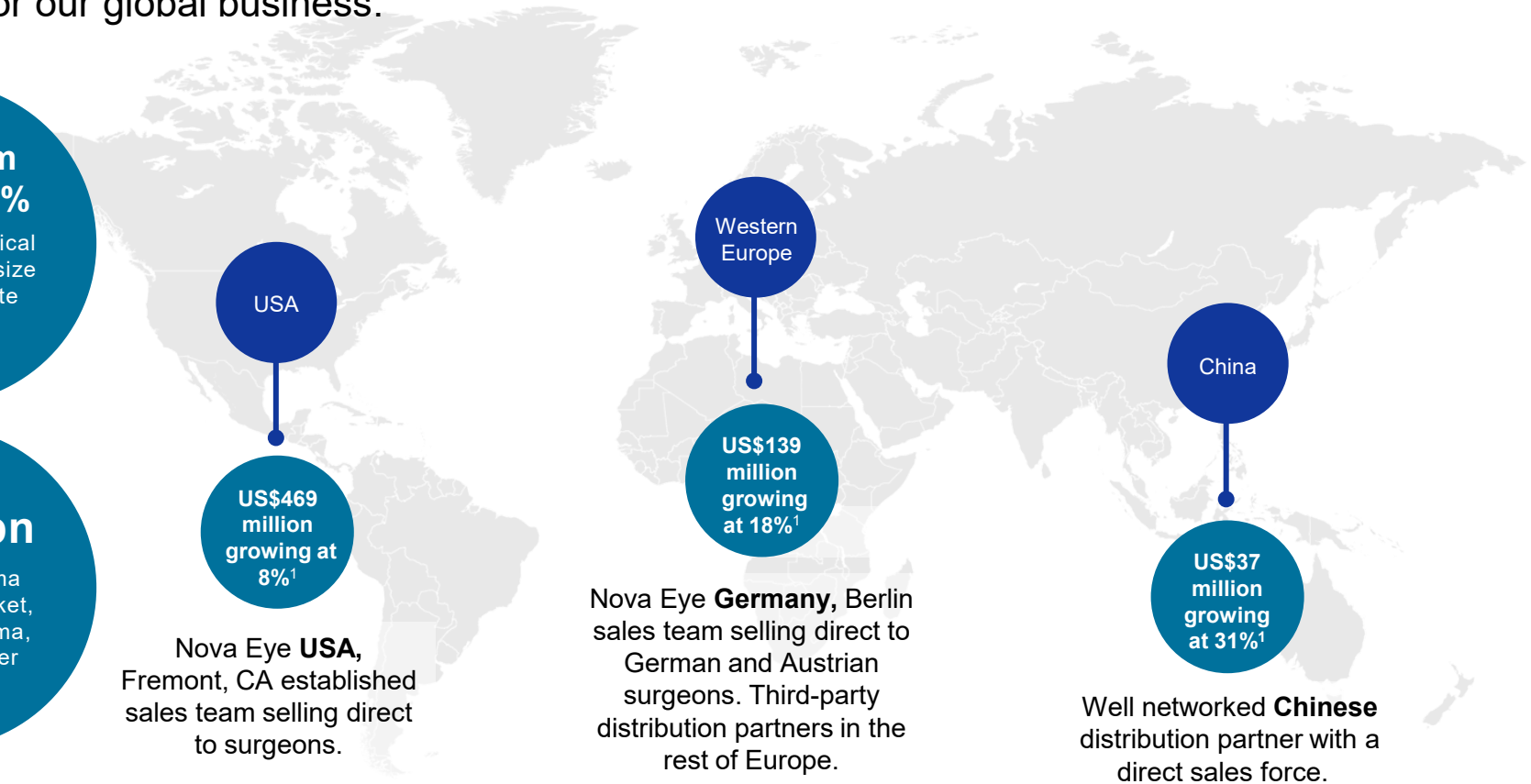
Glaucoma Market Strong Global Growth Theme

Glaucoma is the leading cause of irreversible blindness. The aging global population drives prevalence, representing a significant opportunity for our global business.

144.2 million people worldwide with Glaucoma

US$667m CAGR 15%
Glaucoma Surgical Device market size and growth rate per annum[1]

US$6.1bn
Total Glaucoma Treatment Market, including pharma, market size per annum



Nova Eye **USA,** Fremont, CA established sales team selling direct to surgeons.

Nova Eye **Germany,** Berlin sales team selling direct to German and Austrian surgeons. Third-party distribution partners in the rest of Europe.

Well networked **Chinese** distribution partner with a direct sales force.

1. *Marketscope 2022 Glaucoma Surgical Devices Reports. Growth in glaucoma surgical devices.*

iTrack™

- Introduced in 2008
- Microcatheter designed for canaloplasty
- Strong body of clinical evidence but technically challenging– requires use of forceps, cutting instruments
- Used predominantly by glaucoma surgeons

iTrack™ ADVANCE

- Launched in markets outside of USA and China in June 2022.
- Combines microcatheter with an easy-to-use handheld injector.
- Designed for all ophthalmic surgery and specialists settings.

Sales Update to 31 October 2022

- Following the commercial launch of the new *iTrack™ Advance* in select markets in Europe and Canada in June 2022, revenue up **28% (in constant currency)** to **US$3.82 million** during the 4 months to 31 October 2022 period, compared with the PCP.
- In Australian dollars, sales were A$5.66 million, growth of 38%.
- The result materially exceeded the forecast guidance of US$3.4 million provided earlier this year.
- After adjusting for a delayed shipment of iTrack™ canaloplasty microcatheters to China in July 2022, originally slated to ship in June 2022, the underlying sales increase during the period was **18% in constant currency** at **US$3.51 million** (A$5.22 million, growth of 27%).

Four months ended
31 October 2022:

28% increase in sales (cc) to US$3.82 million

Note: 18% sales increase (cc) to US$3.51 million when adjusted for delayed FY22 Chinese shipment.

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
Chief Commercial Officer
M: +61 404 080 679
E: khunt@nova-eye.com