

## **iTrack™ Advance Commercial Roll-Out Commenced - Next Generation Canaloplasty Device for Glaucoma**

### **Highlights**

- ***iTrack™ Advance* cleared for sale in Europe and the Asia Pacific**
- **Commenced commercial roll-out in Europe, with focus on the German market**
- **Initial orders received, first shipments made and first commercial, in-human cases completed**
- **Launch to drive increased surgeon uptake of the canaloplasty procedure by cataract surgeons and comprehensive ophthalmologists**
- **Early sales and encouraging surgeon feedback providing solid momentum for sales growth in 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, is pleased to announce the commencement of the commercial roll-out of its next generation canaloplasty device, *iTrack™ Advance*, in select markets in Europe and the Asia Pacific.

The *iTrack™ Advance* is a consumable surgical device for glaucoma, which builds on Nova Eye's proprietary iTrack™ technology. Initial orders for *iTrack™ Advance* have been received and the first shipments have been made to surgeons. Early sales numbers and encouraging surgeon feedback provide solid momentum for future sales growth in FY23.

Nova Eye Medical Managing Director, Tom Spurling commented:

*"We are very excited that the roll-out of the iTrack™ Advance has begun. With a number of industry-leading features and backed by a strong IP portfolio, we expect iTrack™ Advance to drive improved sales performance for the group during the 2023 fiscal year."*

*"Across most of our global markets, we have noted a marked increase in surgeon interest in canaloplasty<sup>1</sup>. As an implant-free procedure that preserves the trabecular meshwork for subsequent procedures, canaloplasty offers significant utility to surgeons and their patients. The introduction of the iTrack™ Advance underscores our commitment to grow the canaloplasty field."*

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<sup>1</sup> Market Scope 2018 and 2021 Glaucoma Surgical Devices Reports

Melbourne ophthalmic surgeon Dr. Nathan Kerr, a leading authority in minimally invasive glaucoma surgery (MIGS) and the head of glaucoma surgical trials at the Centre for Eye Research Australia (CERA), recently performed the world's first surgical case with the *iTrack™ Advance* and commented:

*"The iTrack™ Advance is a revolutionary device, combining the proven efficacy of the iTrack™ microcatheter canaloplasty in an ergonomic and easy-to-use preloaded handheld injector.*

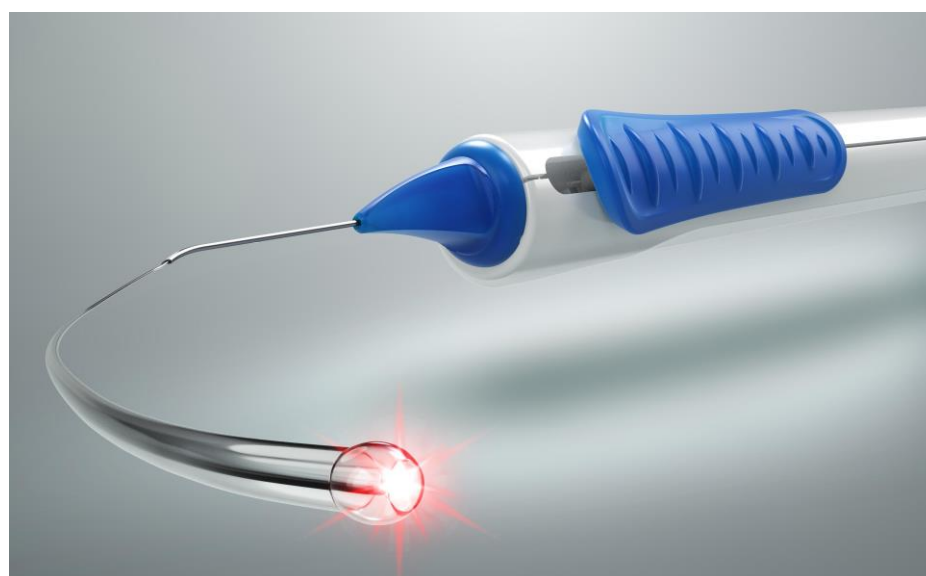
*The iTrack™ Advance can be performed with cataract surgery or as a standalone procedure. Without the need for an implant or surgeons, the iTrack™ Advance is designed to lower eye pressure and may reduce or eliminate the need for glaucoma eye drops."*



## **iTrack™ Advance**

The new *iTrack™ Advance* device is designed to improve the overall efficiency of the canaloplasty procedure. It combines the company's industry-leading iTrack™ microcatheter technology with a custom-designed cannula and handheld injector. It features a proprietary illuminated fibre optic tip, which allows the surgeon to continuously monitor the location of the microcatheter in Schlemm's canal. The *iTrack™ Advance* also features a proprietary guide-wire mechanism that enables the microcatheter to catheterise up to 360 degrees of the canal in a single intubation.

Nova Eye expects the introduction of *iTrack™ Advance* to drive increased surgeon uptake of the canaloplasty procedure by cataract surgeons and comprehensive ophthalmologists. This is a materially larger customer base than the glaucoma surgeon segment the Company's original iTrack™ device has targeted.



Canaloplasty is globally recognised as a highly effective, implant-free surgical treatment for glaucoma. The intricacies of the procedure, however, which have included manual intubation of the microcatheter through the canal using forceps, previously limited its adoption by a broad cross section of surgeons.

*“As with most medical professions, the growing pool of glaucoma patients has seen a shift in treatment and management. Patients with glaucoma were once exclusively treated by glaucoma surgeons. Today, comprehensive ophthalmologists and cataract surgeons are*

*increasingly responsible for the treatment of patients with early-stage glaucoma. We have designed the iTrack™ Advance in line with this shift in patient care and expect the iTrack™ Advance to be readily adopted into the glaucoma toolkit of cataract surgeons and comprehensive ophthalmologists. In the USA we estimate that there are 10 times more cataract surgeons and comprehensive ophthalmologists than glaucoma surgeons,”* commented Mr. Spurling.

## **European Launch of iTrack™ Advance**

Commercial roll-out of the new *iTrack™ Advance* is currently underway in the United Kingdom, Italy, Switzerland and, most importantly, Germany.

Canaloplasty is well accepted in the German market and has been used for more than a decade in the surgical treatment of late-stage glaucoma. The Company is now investing in growing market acceptance of canaloplasty for earlier stage intervention in the treatment of mild-moderate glaucoma, underscored by the launch of the new *iTrack™ Advance*. This parallels the Company's continued investment in the expansion of its direct commercial infrastructure in Germany, which was established in late 2020.

*“Our sales force in Germany is now systematically introducing iTrack™ Advance to German surgeons. With the first orders received and the response from surgeons very positive, we will continue to ramp up our local German infrastructure to support the roll-out of the iTrack™ Advance,”* commented Mr. Spurling.

The Company expects to provide an update on sales for the year ending 30 June 2022, including the sales results in Europe, in mid-July 2022.

## **– ENDS –**

This release dated 8 June 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](http://www.nova-eye.com)

### **Company**

Tom Spurling  
Managing Director  
+61 417 818 658  
[tspurling@nova-eye.com](mailto:tspurling@nova-eye.com)

### **Company**

Kate Hunt  
Head of Marketing  
+61 404 080 679  
[khunt@nova-eye.com](mailto:khunt@nova-eye.com)

### **Investors**

Mark Flynn  
Investor Relations  
+61 416 068 733  
[mflynn@nova-eye.com](mailto:mflynn@nova-eye.com)

## ABOUT THE GLOBAL GLAUCOMA MARKET

<sup>2</sup>Glaucoma is the leading cause of irreversible blindness and the second leading cause of blindness worldwide. The aging global population is driving glaucoma prevalence and provides a strong platform for business growth.

**134.2 million<sup>2</sup>**

People Worldwide with Glaucoma

**US\$610m<sup>3</sup>**

**CAGR 17%<sup>3</sup>**

Glaucoma Surgical Device market size and growth rate per annum

**US\$6.1bn<sup>2</sup>**

Total Glaucoma Treatment Market, including pharma, market size per annum

- Advancements in diagnostic and imaging technologies permit earlier diagnosis, which in turn drives demand for interventions which permit earlier treatment
- Medications are considered standard of care but are associated with significant drawbacks i.e., low patient compliance, side effects, financial costs
- Glaucoma surgical device solutions, including devices like iTrack™ and Molteno3®, are increasingly recognised as a highly viable alternative – and is currently the fastest growing segment of the ophthalmic market

## 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 the iTrack™ portfolio of canaloplasty devices for the treatment of glaucoma. The Company also manufactures and sells the proprietary Molteno3® glaucoma drainage device for the treatment of severe or complex glaucoma. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by sales offices in Adelaide, Australia and Berlin, Germany, and a global network of more than 50 distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

<sup>2</sup> Market Scope 2021 Glaucoma Surgical Devices Report

<sup>3</sup> Market Scope 2021 Glaucoma Surgical Devices Report based on sum of MIGS, Canal Surgery Devices and Glaucoma Tubes and Shunts Markets