

## ASX RELEASE

**Ellex Medical Lasers Limited (ASX:ELX)**

**Adelaide, Australia**

**Date: 4 December 2015**

**Release: Immediate**

**Topic: Ellex provides a Summary of ABiC iTrack™ Opportunity**



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**Adelaide, Australia, 4 December 2015** – Ellex Medical Lasers Limited (ASX:ELX), a global leader in medical devices for the diagnosis and treatment of eye disease, outlines the significant market opportunity and growth strategy for its ABiC iTrack™ device.

### Highlights of the ABiC iTrack™ opportunity to ELX

- Rapid growth medical device market
- Consumable business model with recurring revenue
- Market validated and ready for material sales expansion
- Revenue and customer reference base
- Patents in place
- FDA approvals in place
- Insurance reimbursement in place
- Market comparables show very high business valuation prospect
- All manufacturing facilities in place and scalable

### Background

Ellex iTrack Inc. is a San Francisco Bay Area-based company and a wholly-owned subsidiary of Ellex Medical Lasers Limited. Ellex iTrack manufactures and sells a clinically proven, single-use, patented, minimally invasive device used by eye surgeons in glaucoma surgery (MIGS). Glaucoma is a degenerative disease that is characterised by a failure of ocular drainage systems. The device, known as the iTrack™, has been approved for use by eye surgeons in the USA by the Federal Food and Drug Administration (FDA) and is reimbursed by all major health insurance companies.

The iTrack™ MIGS device has, until recently, been exclusively used by a dedicated group of specialist glaucoma surgeons in the USA and Germany, in a relatively complex, 40-minute surgical procedure. The outcomes, as measured by the lowering of patients' intraocular pressure (IOP) and in the reduction of anti-glaucoma medications required, are considered to be "best in class".

Ellex iTrack Inc. has now developed and launched a simple, 5-minute surgical procedure known as ab interno canaloplasty (ABiC) that has broadened the appeal and utility of the iTrack™ device to the wider eye surgeon community, including cataract surgeons, while maintaining clinical efficacy. Known as the ABiC iTrack™, initial USA test marketing of the device commenced in 2015 and has resulted in a 17% increase in sales during the 5 months to 30 November 2015 compared with the same period in 2014.

### Market Opportunity for MIGS devices

The relatively new MIGS market is forecast to grow from approximately US\$90 million per annum in 2015 to nearly US\$700 million per annum in 2020. The MIGS market has emerged because existing glaucoma treatments, on which the annual global spend is US\$4.6 billion, require patients to comply with daily topical medication regimes and, in later stage disease, invasive eye surgery. These treatments are characterised by poor patient compliance and high post-operative complication rates. The ABiC iTrack™ obviates these problems.

The table below outlines the independent market size assessment for the MIGS market over the coming five years.

| YEAR                                   | 2015     | 2016      | 2017      | 2018      | 2019      | 2020                  |
|--|----------|-----------|-----------|-----------|-----------|-----------------------|
| Market size for MIGS and BAGS in US\$m | US\$90.2 | US\$159.1 | US\$257.5 | US\$366.8 | US\$500.9 | US\$686.7<br>CAGR 44% |

Data from Market Scope Report "2015 Report on the Global Glaucoma Surgical Device Market" (BAGS: Blebless Ab externo Glaucoma Surgery the surgery for which the iTrack was originally released)

### An analogy with cardio-vascular treatment

Historically the standard treatment approach for a patient with a blocked artery was open heart/ chest surgery. With improvements in technology and surgical technique, the use of cardiac stents, inserted via a minimally invasive procedure to expand blocked arteries, is now considered to be the standard first-line treatment for blocked arteries. In the same way, it is expected that MIGS devices will replace many invasive glaucoma surgery treatments.

### Competition and Competitive Advantage

In the USA the dominant participant in the MIGS market is Glaukos Inc. (GKOS:NYSE, market capitalisation 3 December 2015 of US\$790 million) which currently has a market share of approximately 90%. Glaukos has pioneered the establishment of the MIGS market in the USA over the last 2 to 3 years with the iStent™ product. It is important to note that, outside of the USA, Ellex iTrack Inc. also has good market traction. In September 2015, Allergan plc (NYSE:AGN) acquired privately held Aquesys Inc for US\$300 million. Aquesys has developed a device for the MIGS market. The Aquesys device does not yet have FDA approval.

The clinical method of action of ABiC iTrack™ is more comprehensive than both the iStent™ and the Aquesys device, as shown in the table below:

|                 | Method of action impact on ocular outflow systems |                         |                             |                       |                    |
|-----------------|---|-------------------------|-----------------------------|-----------------------|--------------------|
|                 | Collector channels cleared                        | Schlemm's canal cleared | Trabecular meshwork cleared | Subconjunctival space | Allows retreatment |
| ABiC iTrack™    | Yes   | Yes                     | Yes                         |                       | Yes                |
| Glaukos iStent™ |   |                         | Yes                         |                       |                    |
| Aquesys         |   |                         |                             | Yes                   |                    |

The insurance reimbursement status of ABiC iTrack™ is also superior to both the iStent™ and the Aquesys device, as shown in the table below:

|                 | Approvals and Insurance |                                      |
|-----------------|-------------------------|--------------------------------------|
|                 | FDA Approval            | Insurance reimbursements in place    |
| ABiC iTrack™    | Yes                     | Yes                                  |
| Glaukos iStent™ | Yes                     | Yes (but only with cataract surgery) |
| Aquesys         |                         |                                      |

## Growth Strategy

Ellex iTrack Inc. is a profitable business unit, currently generating US\$4.0 million per annum in sales, of which 65% are in the USA. This equates to approximately 5% of the total MIGS market. Ellex iTrack Inc. expects to capture additional market share by investing funds in marketing and sales initiatives and in the iTrack™ R&D pipeline. Specifically, Ellex iTrack Inc will drive market share improvement of the ABiC iTrack™ by promoting the following differentiating marketing and sales messages:

- Superior clinical outcomes as a stand-alone procedure, in addition to a combined procedure performed in conjunction with cataract surgery
- Comprehensive method of action that targets multiple potential blockage sites in the eye and impacts 360 degrees of the ocular drainage system rather than a single site
- The ability to delay or eliminate more invasive surgical options with a restorative procedure; a fundamental tenet of glaucoma management
- Superior insurance reimbursement status in the USA
- Proven clinical heritage with circa US\$40 million of development, FDA approval and 40,000 procedures completed.

Commenting on this growth strategy, Ellex CEO, Mr Tom Spurling, stated, “The ABiC iTrack™ product is well positioned within the fastest growing segment of the ophthalmic device market and is a clinically superior product to our main competitor. With the right investment in marketing, we expect to materially increase our share of this market and grow sales and earnings in the years to come”.

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## **ABOUT ELLEX**

Ellex designs, develops, manufactures and sells innovative product that help eye surgeons around the world to effectively and efficiently treat eye disease. Ellex is a world leader in this field. Headquartered in Adelaide, Australia, Ellex has ophthalmic lasers and devices that treat glaucoma, retinal disease primarily caused by diabetes, secondary cataract and vitreous opacities, as well as age-related macular degeneration. Manufacturing is carried out in Adelaide, Australia and Fremont, California. Sales and service directly to eye surgeons is conducted via subsidiary offices in Minneapolis, Lyon, Berlin and Tokyo. A network of more than 50 distribution partners around the world services other markets.

For additional information about Ellex and its products, please visit [www.ellex.com](http://www.ellex.com)

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### **For further information on Ellex, please contact:**

Tom Spurling, CEO

Ellex Medical Lasers Limited

82 Gilbert Street, Adelaide, SA, 5000

W +61 8 8104 5293 | M +61 417 818 658

tspurling@ellex.com

Victor Previn, Chairman

Ellex Medical Lasers Limited

82 Gilbert Street, Adelaide, SA, 5000

W +61 8 8104 5200 | M +61 414 661 994

vprevin@ellex.com

Maria Maieli, CFO & Company Secretary

Ellex Medical Lasers Limited

82 Gilbert Street, Adelaide, SA, 5000

W +61 8 8104 5200

mmaieli@ellex.com