

## ANNUAL GENERAL MEETING 23 NOVEMBER 2016

ELLEX MEDICAL LASERS LTD (ASX:ELX)

## **ABOUT ELLEX**

Ellex designs, manufactures and sells world-leading medical devices for the treatment of eye disease.



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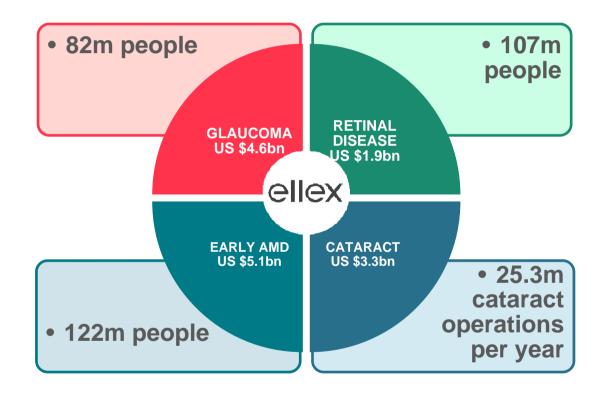


## **ELLEX SUMMARY**

- Fourth consecutive year of improvement in sales and profit.
- Ellex is a leading global brand that is trusted in the traditional laser and ultrasound market.
- We are leveraging Ellex brand into two new market segments:
  - the fast growing market for minimally invasive glaucoma surgery (MIGS) and;
  - the emerging market for treating early stage age related macular degeneration (AMD).
- Each of these markets is substantially larger than the traditional ophthalmic laser and ultrasound market.



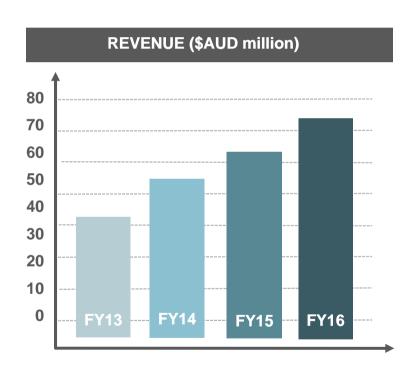
## GLOBAL MARKET FOR TREATING THE FOUR LEADING CAUSES OF BLINDNESS

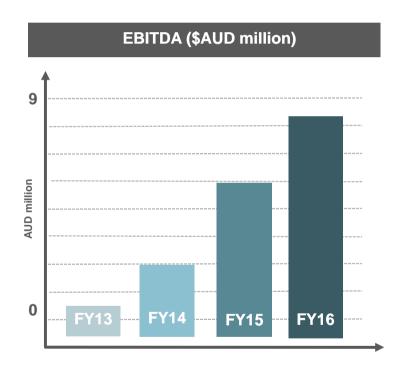




## **ELLEX – INCREASING REVENUE & PROFIT**

- Sales have grown at a CAGR of 15% over 4 years
- Profit has grown both in absolute and percentage terms





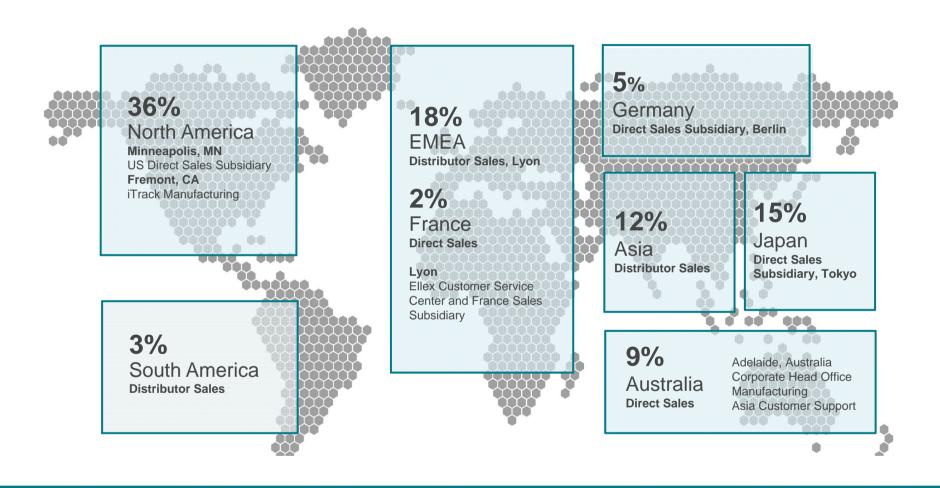


## FINANCIAL SUMMARY - SALES BY REGION

	FY13	FY14	FY15	FY16	Change	<ul> <li>Growth of iTrack<sup>™</sup> (29% constant currency growt</li> </ul>
USA	8.5	17.9	20.5	25.9	+26%	Improved sales of new products
Asia	3.2	3.9	4.4	8.7	+98%	Growth in China
Japan	10.7	10.4	8.4	10.8	+29%	New products, new sales management structure
EMEA	10.0	11.4	15.4	17.1	+11%	• Improved sales of new products
South America	0.9	1.4	2.2	2.0	-10%	Some iTrack <sup>™</sup> growth
Australia	9.5	9.4	11.8	8.4	-28%	Low world oil prices have impacted demand
TOTAL	42.8	54.4	62.7	72.9	+16%	Primarily includes discontinued low-margin contra manufacturing
Recurring Ellex- branded consumables & service component (% of total)	4.7 (9%)	8.3 (13%)	9.9 (14%)	10.7 (15%)		CAGR of revenue FY13 to FY16 is 15%



## **ELLEX REVENUE BY TERRITORY**





## FINANCIAL SUMMARY – BALANCE SHEET

ASSETS	30 June 15	<b>30 June</b> 16	
Cash	4.6	7.3	
Trade receivables	12.5	15.7	
Inventories	16.3	19.2	
Product development capitalised	10.7	11.6	
Deferred tax asset	5.8	5.3	
PPE, Ellex iTrack <sup>™</sup> deferred consideration and other assets	9.1	9.4	
Land and buildings	-	4.0	
Total Assets	59.0	72.5	

LIABILITIES	30 June 15	30 June 16	
Trade creditors	5.8	8.3	
Borrowings – mortgage	-	2.1	
Borrowings – trade	6.8	6.1	
Deferred consideration	3.4	3.3	
Provisions + Other	3.2	4.0	
Total Liabilities	19.2	23.8	

- Net debt (all trade and mortgage borrowings less cash) of \$0.9m compared with \$2.2m at 30 June 2015.
- Net cash (cash less trade borrowings) of \$1.1m at 30 June 2016.
- Inventory growth to support higher sales evidenced by constant stock turn ratio.
- Deferred US\$ consideration on Ellex iTrack<sup>™</sup> falls as payments made but rises as A\$ depreciates.
- Purchase of land and buildings at Mawson Lakes, South Australia and fitout in progress. Being funded with mortgage debt and cash reserves.



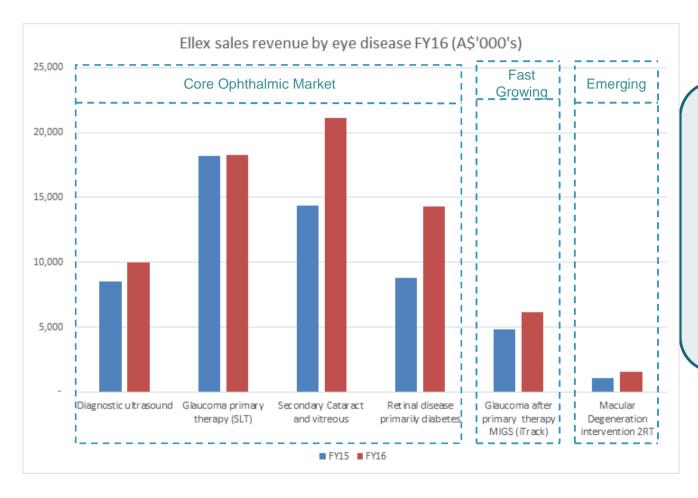
# FINANCIAL SUMMARY – FREE CASH FLOW FROM OPERATIONS

CASH FLOWS	FY13 A\$m	FY14 A\$m	FY15 A\$m	FY16 A\$m
Operating Cash Flows	1.9	2.7	6.9	5.2
Investing - PP&E	(0.6)	(0.6)	(1.9)	(1.5)
Cap. Development Costs	(2.2)	(2.1)	(2.3)	(2.8)
Net free cash flow (FCF) from operations	(0.9)	(0.5)	2.7	0.9
Acquisition of iTrack <sup>™</sup> business and earn out payments	-	(1.6)	(0.6)	(0.7)
Purchase of land & buildings for increased production	-	-	-	(3.8)
Debt (repayments) /proceeds	(8.0)	(1.4)	1.0	1.5
Proceeds of share issue	-	5.9	-	4.7
Net Cash Flow	(1.7)	2.4	3.1	2.6

- Reduction in operating cash flow compared with pcp reflects high sales in June 2016 compared with June 2015 and the need to increase raw materials to support increase in production.
- Production levels from the Adelaide facility in the three months ended 30 June 2016 were 75% higher than production levels during the same time in 2015 (50% higher in H2 FY16, compared with H2 FY15).



## REVENUE BY DISEASE HIGHLIGHTS GROWTH OPPORTUNITIES



### **FY16 Highlights**

- New retinal products registered in USA, Japan.
- New cataract and vitreous opacities product launched in China & Japan.
- Continued growth of Ellex iTrack<sup>™</sup>
- Increase in SLT competition in all markets limited growth



## CORE OPHTHALMIC MARKET

## Ophthalmic Lasers and Ultrasound Generated 90% of FY16 revenue

- Market segment is approx. US\$350m/annum
- Growing with aging population and new emerging markets (like China)
- Ellex is a global leader in this segment with increasing market share
- Ellex growing at higher than market rate because of continued investment in innovation and marketing of new treatments (like floaters)
- Business model is capital equipment sales



## GROWTH BY LEVERAGING ELLEX BRAND INTO FAST GROWING & EMERGING MARKETS

### Glaucoma MIGS Market with Ellex iTrack™

Ellex iTrack generated 8% of FY16 revenue

- Fast moving market segment circa US\$100m growing at 44% CAGR to \$700m by 2020
- Patent-protected, unique treatment device with high clinical efficacy
- Ellex iTrack<sup>™</sup> relaunched during FY16 and 29% sales growth achieved in USA
- FDA approved, CE marked for Europe, approved in China
- No 2 in US market
- Consumable recurring revenue business model

## Ellex 2RT™ treatment for Macular Degeneration (AMD) 2RT™ generated 2% of FY16 revenues

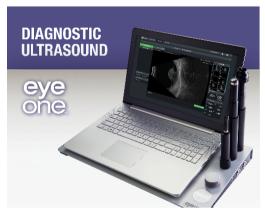
- Emerging market for early AMD treatment
- \$5bn currently spent annually on pharma for late stage disease management
- Ellex 2RT<sup>™</sup> treatment, patent-protected with significant lead on competition
- Ellex 2RT<sup>™</sup> may defer need for expensive, invasive pharma
- Per-use recurring fee business model



# LEADING PRODUCTS IN CORE OPHTHLAMIC LASER & ULTRASOUND MARKET



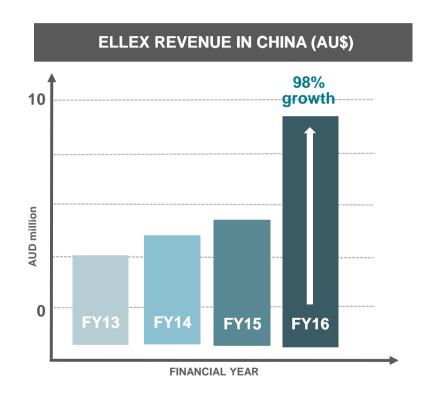








# OPHTHALMIC LASER & ULTRASOUND - GROWTH IN CHINA



- The current spend in China for the treatment of eye disease is US\$2.7 billion per annum – and this is expected to grow to US\$5.3 billion by 2021 (CAGR 15%) (1).
- Demand in China primarily relates to new hospital fit-out and can be unpredictable
- Ellex is undertaking investment in FY17 to improve in-country presence.

(i) Marketscope: "2016 China Ophthalmic Market Report" March 2016



## PRODUCTION CAPACITY EXPANSION UPDATE

### Work completed:

- New site at Mawson Lakes 15km north of Adelaide CBD acquired in March 2016
- Building of approx. 5,500sqm doubles production floor area
- Site area of 22,000sqm will provide future expansion potential
- Production process validation and verification in progress

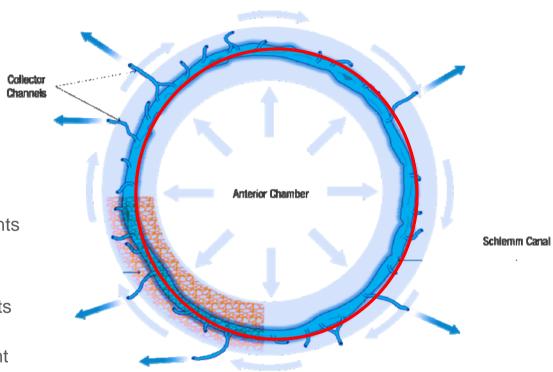
### Work to complete:

- Finalisation of validation of production processes at new site
- Audit and qualification of Mawson Lakes by Therapeutic Goods Administration (TGA)
- Completion of move expected by end of March 2017



### FAST-GROWING MIGS MARKET – ELLEX ITRACK™

- Acquired in January 2014 and relaunched in FY16 as MIGS procedure as new surgical procedure "ab-interno canaloplasty" (ABiC™)
- ABiC<sup>™</sup> is a fast, simple surgical procedure using Ellex iTrack<sup>™</sup> single use catheter device for "angioplasty" of the eye on patients with glaucoma
- Ellex iTrack<sup>™</sup> differs from competitor MIGS because it treats 360° of Schlemm's canal, rather than the insertion of a single point stent (canal bypass)





# **ELLEX ITRACK™ IN FAST-GROWING MIGS MARKET**

### **Key activities and milestones:**

#### **JANUARY 2014**

Acquired from Menlo Park based company iScience. The patented iTrack<sup>™</sup> catheter for angioplasty for the eye, known as canaloplasty

#### **JULY 2014**

Ellex introduced a simple surgical procedure, named ab interno Canaloplasty (ABiC<sup>™</sup>), with Ellex iTrack<sup>™</sup> and commenced trials

#### **OCTOBER 2015**

Promising 6 month clinical results of ABiC™ presented at US conference triggered limited commercial roll-out in US market with dedicated sales team

#### **MAY 2016**

Excellent 12 month clinical results confirm clinical efficacy and confidence to invest in market development

#### **JUNE 2016**

Growth in US market revenue of 29% reported directly attributable to new ABiC<sup>™</sup> procedure. Total sales of A\$6.1m

#### **SEPTEMBER 2016**

Appointment of Senior Ophthalmic sales manager to lead global expansion of ABiC™ with Ellex iTrack™.

### **OCTOBER 2016**

Successfully obtained lift in US reimbursement effective 1 Jan 2017.

### **JANUARY 2017**

Strong growth expected in USA market following reimbursement uplift and sales team expansion



## **ELLEX ITRACK™ VALUATION POTENTIAL**

- Measured by revenue the Ellex iTrack<sup>™</sup> is currently the number 2 MIGS device in the world
- Dominant participant in the MIGS market is Glaukos (GKOS:NYSE) with its iStent <sup>™</sup> product
- GKOS has current revenues from iStent<sup>™</sup> of approximately US\$100m per annum and has a market capitalisation on the NYSE of approximately US\$1.0 billion
- Allergan also purchased (in 2015) a MIGS device for glaucoma treatment from Aquesys for approximately US\$300m. This device does not yet have FDA approval.
- Alcon recently purchased a MIGS device for glaucoma treatment from Transcend Medical for approximately US\$200m. Obtained FDA approval in August 2016.



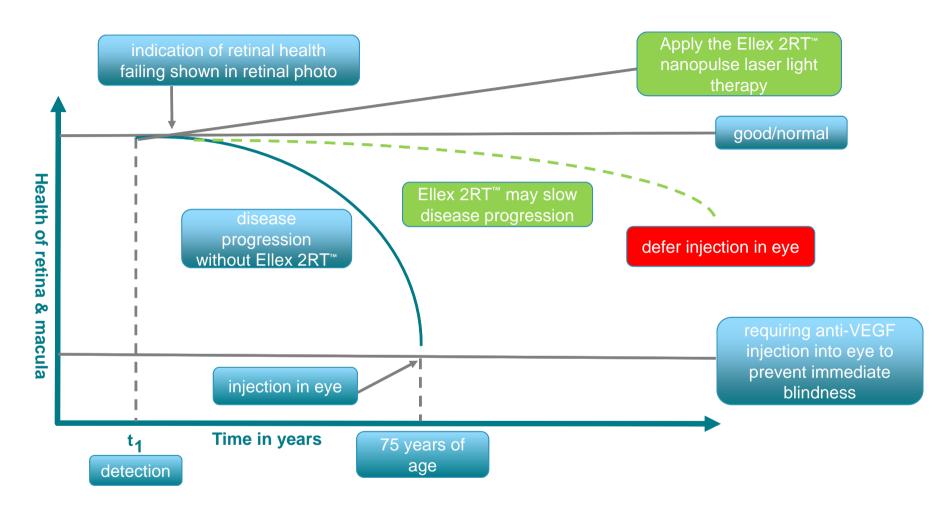
## **ELLEX 2RT™ FOR EARLY AMD**



- AMD ("Age-Related Macular Degeneration"):
  - a. leading cause of blindness in the developed world
  - b. affects one in seven Australians over the age of 50 (Source: Macular Disease Foundation, Access Economics).
- AMD is estimated to directly cost the Australian community more than AU\$2.6 billion annually (Source: CERA Centre for Eye Research Australia).
- UNMET NEED: late stage AMD is treated with 6 weekly injections of drugs directly into a patient's eye. This preserves vision but is:
  - a. onerous on patients and caregivers, and;
  - b. burden for government health schemes to purchase the drugs



### **ELLEX 2RT™ MAY DELAY LATE-STAGE AMD PROGRESSION**





## **ELLEX 2RT™ FOR EARLY AMD**

- Total pharma spend \$5bn per annum globally indicates the importance of disease treatment to health care systems
- Currently there are 122m people with early stage macular degeneration receiving treatment
- Ellex 2RT is patent protected device that is significantly ahead of any other competitor
- Ellex 2RT fits well into existing Ellex distribution channel
- There are presently no alternative therapies
- Ellex 2RT is expected to contribute significantly to growth in FY19 and beyond after completion of clinical trial laser intervention in early age related macular degeneration (LEAD) trial which will report in mid 2018



## **OUTLOOK FOR FY17**

### 1. CORE OPHTHALMIC LASER & ULTRASOUND:

Sales for the first half FY17 will be dependent on our ability to meet demand with finished product from our factory, which is in transition to the new manufacturing site, and timing of significant orders from China. We remain very positive on the demand in the current fiscal year and the long term demand outlook for Ellex ophthalmic lasers and ultrasound.



## **OUTLOOK FOR FY17**

### 2. MIGS/ ELLEX ITRACK™:

The sales growth rate over the FY16 financial year for our iTrack™ device has been accelerating since 1 July 2016 to mid November 2016 and is up on the growth rate over the same period last year. We believe that our additional sales management, the addition of more sales representatives in the USA and the lift in reimbursement will accelerate sales further in FY17.

### 3. ELLEX 2RT™:

The emphasis of Ellex 2RT<sup>™</sup> program this year is one-on-one marketing to early adopters in Europe, Australia & New Zealand. This will generate sales at similar levels to FY15 and FY16. Ellex 2RT<sup>™</sup> sales take up will be ultimately dependent on the clinical trial results expected in mid 2018. Investment in clinical trials, KOL development and marketing this unique potential therapy will continue through FY17 & FY18.



## **THANK YOU**

