

## ASX RELEASE

Ellex Medical Lasers Limited (ASX:ELX)

Adelaide, Australia

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Release: Immediate

Topic: Ellex Trading Update for the Six Months Ended 31 December 2016

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**Adelaide, Australia, 2 February 2017** – Ellex Medical Lasers Limited (ASX:ELX), a global leader in medical devices for the diagnosis and treatment of eye disease, today announced that its sales revenue for the six months ended 31 December 2016 will be similar to the prior corresponding period (PCP). The primary cause of the lack of sales growth during the last half year period was the shift of management focus to the establishment of Ellex's new manufacturing facility at Mawson Lakes, Adelaide at the expense of meeting production challenges resulting in production capacity limitations and a consequent inability to deliver core Laser and Ultrasound product against targets. This resulted in a significant customer order backlog as at 31 December 2016, which we expect to deliver against in the half year ending 30 June 2017 as production at Mawson Lakes ramps up.

The iTrack product, which is manufactured at Ellex's Fremont California facility, was unaffected and iTrack sales increased significantly over PCP in the half year to 31 December 2016.

### **Recap on Strategy**

Ellex is a participant in the global market for devices that treat the 4 major causes of blindness. Annual spend on pharmaceuticals and devices in this market is greater than US\$10bn and growing with an aging population, obesity and improving health care in developing countries. Ellex has a strong brand and global distribution channel for its core ophthalmic treatment lasers and diagnostic ultrasounds. Ellex is currently investing in leveraging that brand into the fast growing minimally invasive glaucoma surgery (MIGS) device market with its iTrack product, and the emerging market for early age related macular degeneration (AMD) treatment with its 2RT laser product.

### **Summary of Results for Half Year to 31 December 2016**

- Total revenue of \$34.3m (H1 FY16, \$34.8m);
- Ellex iTrack sales of \$3.6m, being growth of 37% on PCP in constant currency;
- Core laser and ultrasound sales of \$30.4m, being growth of 1% on PCP after adjustment for foreign currency movements and sales order backlog caused by production capacity limitations described above;
- Sales to early adopters of 2RT of \$0.2m (H1 FY16, \$0.6m), our emerging treatment for early stage age related macular degeneration expected to grow materially followed conclusion of ongoing clinical trial in 2018.

- EBITDA of \$3.1m (H1 FY16, \$3.5m), with the decrease over PCP due to planned Ellex iTrack sales expansion investment.

## **Revenue**

Total group revenue across the different market segments for the six months ended 31 December 2016 is expected to be approximately \$34.3m (H1 FY16, \$34.8m). Revenue for the half year period was impacted by the following:

- Positive impact from a \$1m increase (37% in constant currency) in revenue from the Ellex iTrack minimally invasive glaucoma surgery (MIGS) device. The increase was driven by sales in the USA, China and Europe. The appointment late in the period of new USA sales representatives, the impact of the doubling of insurance reimbursement effective 1 January 2017 in the USA and the continued roll out in China is expected to drive an acceleration of sales in the second half.
- Strong sales late in the period in the USA for new Tango Reflex following release in November. Tango Reflex allows doctors to treat glaucoma **and** vitreous floaters. This lifted our glaucoma treatment revenues.
- Production limitations during the half year to 31 December 2016 meant that a sales order backlog was on hand for this product as of 31 December 2016. Sales in the second half are expected to be strong as this backlog is cleared and will be supported by the expanded production capacity associated with the move of production facilities from Gilbert Street, Adelaide to Mawson Lakes.

## **Estimated EBITDA**

The estimated EBITDA of \$3.1m for the half year to 31<sup>st</sup> December 2016 (H1 FY16, \$3.5m) was reduced compared with the prior corresponding period by planned continued investment in iTrack growth initiatives including appointment of a senior sales manager and additional sales representatives (\$0.4m).

## **Production capacity expansion update**

The fit out of our new corporate headquarters and manufacturing plant located at Second Avenue, Mawson Lakes, South Australia (about 14km north of the existing manufacturing site) has taken considerable management effort during the last half year. Completed in December 2016, trial production runs and an audit by the Therapeutic Goods Administration were successfully conducted. The new facility is expected to be progressively commissioned from mid-February 2017 significantly increasing Ellex's production capacity.

## **Global market trends in glaucoma treatment**

The global market for the diagnosis and treatment of glaucoma is currently valued at approximately US\$4.7bn per annum of which approximately 84% is attributable to

pharmaceuticals. Pharmaceuticals are an effective treatment for glaucoma but rely on patients to systematically self-administer. This is problematic and with technology improvements device treatments that remove the problems of patient compliance are gaining favour with physicians. Such devices for glaucoma treatment (of which Ellex SLT and Ellex iTrack are two) currently account for approximately US\$0.2bn per year of the global glaucoma spend. Marketscope estimates that the global market for device treatment will grow to US\$1bn by 2021, an average CAGR of 39%. Ellex revenues in glaucoma are growing commensurate with this trend. Accordingly, management and the directors continue to actively focus and invest in maximising shareholder value in this area.

### **Commentary**

“We are very pleased with the continued strong growth in our iTrack business and expect sales to accelerate in the second half. We are also pleased with sales late in the period of our new Tango Reflex product. Demand for the product after release late in November 2016, exceeded our production capacity which dampened the half year sales. We are looking forward to having the unencumbered ability to meet demand at the new manufacturing plant.

“Ellex is entering an exciting phase of its evolution with a suite of world class products, strong demand from our customers and the commissioning of an enlarged and state-of-the-art manufacturing facility that will allow us to capitalise on the growing recognition of our brand around the world,” commented Mr Tom Spurling CEO.

### **Outlook**

Based on current global economic environment, trading conditions, foreign exchange rates and sales pipeline data, Ellex advises that it has a reasonable basis to expect the following results for the balance of the 2017 financial year:

- Total revenue in the second half of FY17 to be substantially higher than the first half of FY17 and the PCP, which would result in total revenue for FY17 being materially higher than FY16.
- EBITDA in the second half of FY17 will leverage off higher sales. However, due to the planned investments in the iTrack business, growth of EBITDA relative to H1FY17 and the PCP is expected to be modest.
- iTrack sales to accelerate as a result of the recently announced doubling of the insurance reimbursement in the USA for iTrack surgery, effective 1 January 2017 and continued penetration of MIGS devices as a treatment for glaucoma in all major markets.

The results disclosed herein are a preliminary estimate and subject to finalisation of the half year review by the Company’s auditors. Ellex expects to release its half-year results for the year ended 31 December 2016 during the week beginning 20 February, 2017.

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## ABOUT ELLEX

Ellex designs, develops, manufactures and sells innovative products 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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# **ELLEX MEDICAL LASERS LTD (ASX:ELX)**

**Trading Update for the six months ended 31 December 2016  
2 February 2017**

A detailed presentation on the result will accompany the release of the financial statements during the week commencing 20 February 2017

# ABOUT ELLEX

**Ellex makes and sells innovative products that help eye surgeons around the world to effectively and efficiently treat eye disease; this is one powerful vision**



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# Trading Update – Sales by market segment

	H1FY16 \$Am	H1FY17 Reported A\$m	H1FY17 constant currency \$Am	H1FY17 sales backlog <sup>(1)</sup> \$Am	H1FY17 with year end sales backlog & constant currency <sup>(1)</sup> \$Am	Growth on pcp
Core ophthalmic laser and ultrasound	31.5	30.4	31.0	0.8	31.8	1%
Ellex iTrack in fast growing MIGS market	2.7	3.6	3.7		3.7	37%
2RT for AMD (emerging market)	0.6	0.2	0.3		0.3	-57%
	<b>34.8</b>	<b>34.2</b>	<b>35.0</b>		<b>35.8</b>	

(1) Demand exceeded supply for new product and this represents orders from customers that could not be filled until after 31 December 2016.

## Core Ophthalmic Lasers and Ultrasound

- 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

## Glaucoma MIGS market with Ellex iTrack

- Fast growing market segment circa US\$100m growing at 44% CAGR to \$700m by 2020
- Patent-protected, unique treatment device with high clinical efficacy
- FDA approved, CE marked for Europe, approved in China
- No. 2 in US market
- Approved for Insurance Reimbursement in USA
- Consumable recurring revenue business model

## Ellex 2RT treatment for Macular Degeneration (AMD)

- Emerging market for early AMD treatment – clinical trial to read out in Mid 2018
- \$5bn currently spent annually on pharma for late stage disease management
- Ellex 2RT treatment, patent-protected with significant lead on competition
- Ellex 2RT may defer need for expensive, invasive pharma
- Per-use recurring fee business model

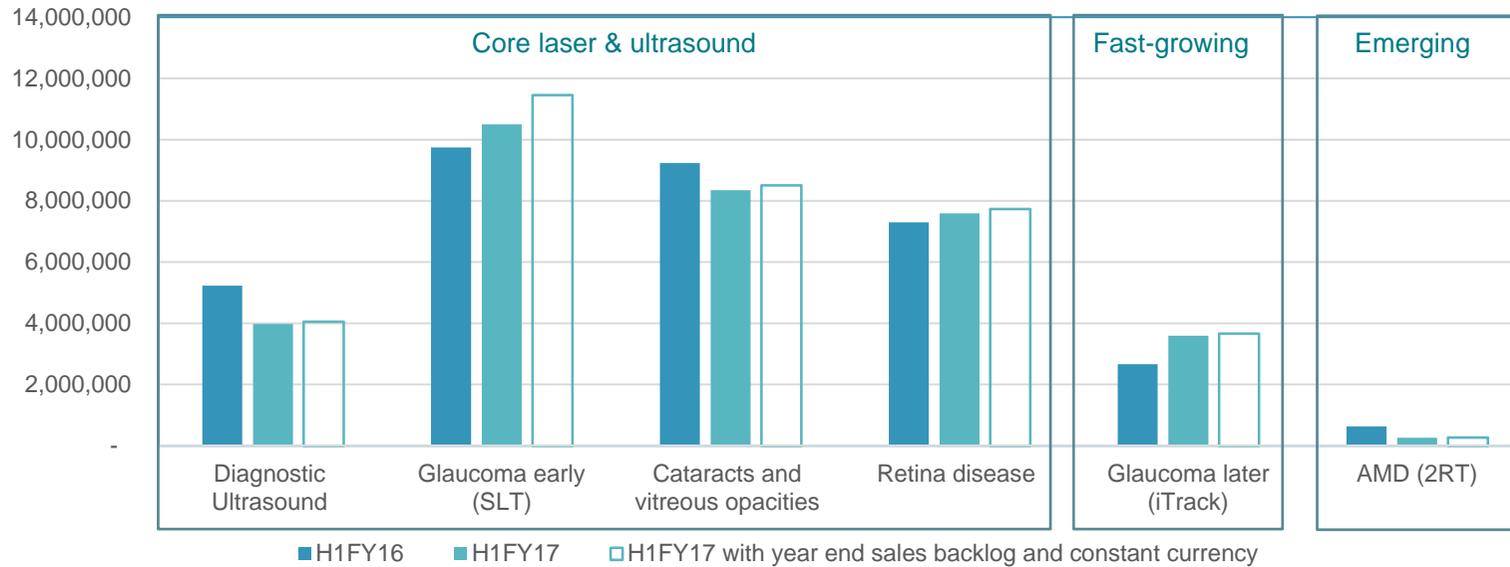


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# Trading Update – Sales by category of eye disease

Revenue by eye disease H1FY16 vs H1FY17 (A\$) adjusted



- Diagnostic ultrasound down due to technical delays in new product that have stalled sales into second half
- Glaucoma SLT up with release of dual action SLT and vitreous opacities laser
- Cataracts and vitreous opacities slightly down due to impact of new dual action laser and slightly lower demand in Asia
- Retina up with increasing take up of Integre Pro Scan range.



# Trading Update - Sales by region all products

	1H FY15 A\$m	1H FY16 A\$m	1H FY17 A\$m	1H FY17 A\$m (constant currency)	Change on PCP
Australia	5.9	4.0	3.4	3.4	-14%
USA	10.0	14.1	12.8	13.4	-5%
EMEA	7.4	8.2	9.3	9.6	18%
Japan	3.9	4.2	4.4	4.0	-5%
Asia	2.3	3.5	3.2	3.3	-6%
South America	1.3	0.8	1.2	1.3	51%
<b>TOTAL</b>	<b>30.8</b>	<b>34.8</b>	<b>34.3</b>	<b>35.0</b>	<b>0.4%</b>

- Production & supply chain delays resulted in sales order backlog at 31 December 2016 in Australia

- Fall due to technical delays in new ultrasound product
- Good sales of new dual action glaucoma lasers with floater treatment capability

- Good demand sales across all lines

- 1HFY16 included high revenue low-margin demonstration/used product sales
- 1HFY17 lower revenue but net higher margin

- Rapid growth in 1HFY16 of lasers & ultrasound associated with specific new hospital builds was not repeated in 1HFY17. Long term Asian outlook is very good
- Good sales of iTrack, as only approved MIGS device in China

- Good demand and sales across all lines



## Trading Update – Ellex iTrack sales by region

	\$Am			
	H1FY16	H1FY17	H1FY17 CC <sup>(3)</sup>	Growth %
USA	1.8	2.0	2.1	+15% <sup>(1),(2)</sup>
Asia	0.1	0.5	0.5	+33% <sup>(2)</sup>
Rest of World	0.8	1.1	1.1	+49%
	<b>2.7</b>	<b>3.6</b>	<b>3.7</b>	<b>+37%</b>

(1) Sales of iTrack in H2FY17 expected to improve with doubling of reimbursement effective 1 January 2017

(2) Sales management, distribution management, USA sales representatives and clinical trainers employed as of 29 January 2017 of 11 (6 at start of H1FY17)

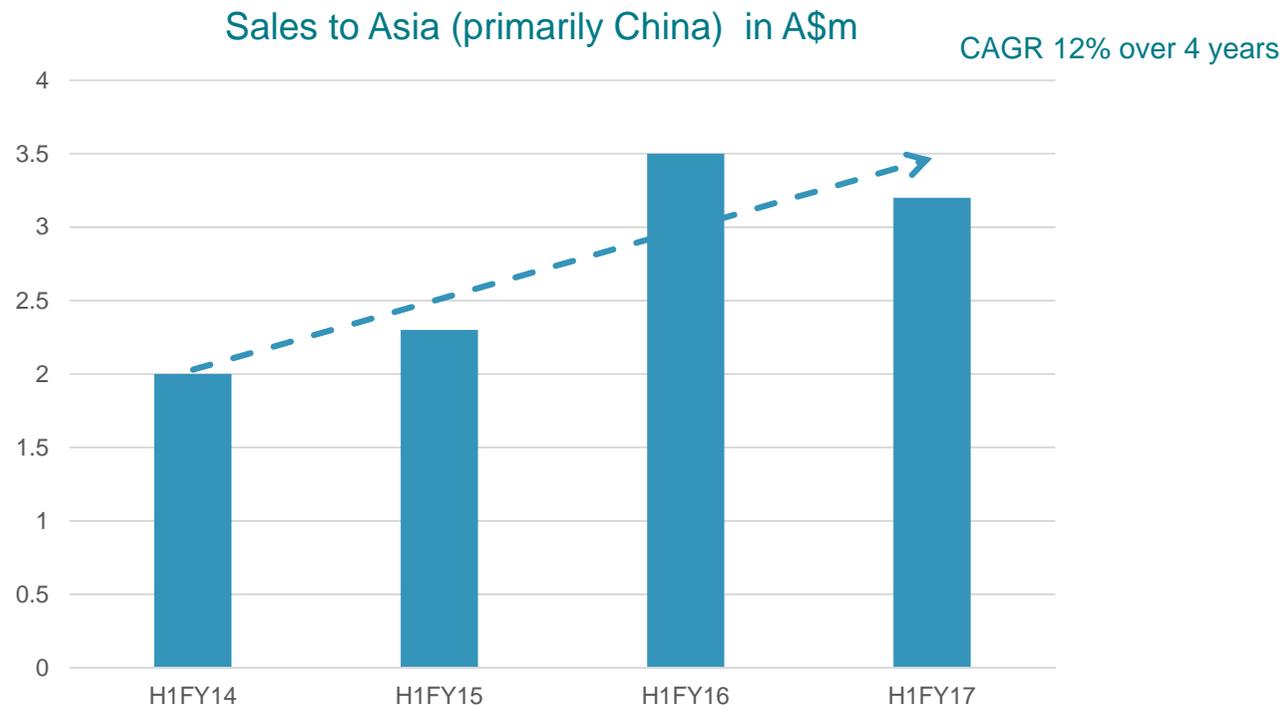
(3) Constant currency US\$ and Euro revenues



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# Trading Update - Sales to Asia



- Rapid growth in 1HFY16 of lasers & ultrasound associated with specific new hospital build was not repeated in 1HFY17. Long term Asian outlook is very good.
- Good sales of iTrack, as only approved MIGS device in China



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# END

Detailed Investor Presentation to be released with the  
financial statements during the week commencing 20 February 2017

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