



29 August 2019

## Group Sales Revenue Increase of 3% to \$81.6 million

### Highlights:

- **Ellex iTrack™ revenues were up 29% to \$14.3 million, with 2HFY19 EBITDA loss narrowing to \$1.1 million driven by a 35% cc revenue increase in the US**
- **Ellex 2RT® revenue increased 260% to \$1.8 million following the release of the LEAD clinical trial data in intermediate age-related macular degeneration (iAMD) in Sept**
- **Underlying EBITDA<sup>1</sup> loss of \$0.7 million, driven by a 6% increase in Lasers & Ultrasound EBITDA to \$9.5 million, offset by EBITDA loss of \$5.1 million for iTrack segment and \$0.6 million EBITDA loss for 2RT®**
- **Reported Net Loss After Tax of \$5.8 million**

**Adelaide, Australia, 29 August 2019** – Ellex Medical Lasers Limited (ASX:ELX; OTCQX: ELXMY, ELXMF), a world leader in medical technologies for the diagnosis and treatment of eye disease, today announced its full year fiscal results for the period ended 30 June 2019 (FY19).

Ms Maria Maieli, CEO of Ellex Medical Lasers commented: “I am pleased with the overall performance of Ellex in FY19, particularly in meeting our market guidance despite some difficult trading conditions encountered late in the fiscal year for our Lasers & Ultrasound segment. Our iTrack business in the key US market showed an acceleration in growth in the second half, and given the solid reimbursement available in this market, Ellex was able to increase the list price for iTrack in the fourth quarter by a low double-digit amount, which will be beneficial for our iTrack margins in FY20.”

Ms Maieli further commented “Since the Board appointed me as Interim CEO from my CFO role, I have been focused on leveraging the strength in our glaucoma franchise to drive continued growth in iTrack and SLT by integrating some elements of our sales process to generate a higher proportion of leads and thereafter, conversion. As the Company exits a period of significant investment in our glaucoma franchise particularly, a focus on costs and working capital improvements remain an objective for the current financial year. We expect group EBITDA to show an improvement in FY20.”

<sup>1</sup> Excludes restructuring charges of \$0.3 million

## **Ellex iTrack performance**

The Ellex iTrack surgical system global unit volumes were up 17% versus the pcp and revenues were up 29%. The segment EBITDA recorded a loss of \$5.1 million, which was similar to FY18. Second half EBITDA loss was just \$1.1 million, reflecting the significant increase in sales within the US market and a moderation in operating expenditures as the benefits of iTrack education and awareness programs (such as the Company's major presence at the World Glaucoma Congress in Melbourne in March). Ellex iTrack has exhibited a three year compound annual growth rate (CAGR) in global revenues of 32%.

In the US, Ellex iTrack recorded an increase in unit volumes of 30% to 8,314 units reflecting continued adoption by ophthalmologists, strong reimbursement and an expanded footprint. OUS sales were down 9% to 4,261 units reflecting a slowdown in ordering from our German distributor that underwent corporate ownership change during this period. Chinese unit sales were up 42% versus the pcp to over 2,203 units and represents a strong result as Ellex iTrack continues to be the only MIGS device approved in the Chinese market.

Ellex was able to implement a low double digit price increase for iTrack in the fourth quarter of FY19, reflecting the solid overall reimbursement for the ophthalmologist undertaking the procedure and the ASC/hospital payment rates. The benefits of this price increase will flow more directly in FY20.

The awareness of iTrack in the surgical glaucoma market continues to grow, with two additional publications released highlighting the benefits of Ab Interno Canaloplasty (ABiC™) surgical approach with iTrack late in the first half.<sup>2</sup>

The current capacity at our manufacturing site in Fremont, California exceeds 50,000 units, implying <30% utilisation at FY19 unit production volume.

## **Laser & Ultrasound performance**

The core Laser & Ultrasound revenue of \$65.5 million declined 3% in FY19, principally due to a weaker than expected second half sales performance. Segment gross margins (ex-labour) expanded by 500 basis points to 59% driven by a favourable mix of FX effects and stronger sales of higher margin Selective Laser Trabeculoplasty (SLT) lasers to treat glaucoma. The Company was also prudent on expenditures to ensure they were directed to support higher margin and growth laser products, which despite a reduction in overall Laser & Ultrasound sales, saw a 6% increase in EBITDA to \$9.5 million.

SLT laser revenue grew 10% to \$32.4 million and constituted 49% of the segment by revenue (FY18: 44%). During the second half, the results of a large clinical trial called LiGHT were reported in the prestigious The Lancet journal, which sought to understand the benefits of SLT as a first-line treatment option for untreated, newly diagnosed patients with ocular hypertension and glaucoma

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<sup>2</sup> Gallardo et al., 2018. Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. *Clinical Ophthalmology* 2018;12 2149–2155.  
Gallardo et al., 2018. Circumferential viscodilation of Schlemm's canal for open-angle glaucoma: ab-interno vs ab-externo canaloplasty with tensioning suture. *Clinical Ophthalmology* 2018;12 2493–2498

versus pharmaceutical eye drops. Not only did patients who received SLT exhibit better control of their disease at three years, none of the SLT patients' disease progressed to a stage that required surgical intervention and overall the procedure was more cost effective than eye drops. When coupled with compliance, toxicity issues and the increased rate of cataract surgery versus SLT observed in the LiGHT trial, Ellex believes it will materially enhance clinician interest for SLT in markets such as the UK and the US, where eye drops are recommended as a first-line therapy. Ellex's SLT laser business has exhibited a compound annual growth rate (CAGR) of 21% by revenues over the last three years. The majority of Ellex SLT sales are primary placements, not replenishments.

Our retinal disease franchise lasers declined modestly by 2% to \$14.4 million as the shift from photocoagulator lasers to treat diabetic retinopathy and diabetic macular edema towards approved pharmaceutical treatments continued.

Sales of Ellex's cataract and vitreous opacities lasers were down 23% to \$12.6 million. Sales were negatively impacted by some product cannibalisation from Ellex's dual glaucoma and cataract laser Tango Reflex™, pricing pressures from conventional photodisruptor lasers and purchasing decision delays experienced in Europe.

Sales of diagnostic ultrasound equipment was down 37% to \$4.3 million with customers awaiting the release of the launch of our next generation ultrasound offering, Ellex Eye Prime™ in May 2019, which offers significant performance advantages to increased resolution and image quality.

### **Ellex 2RT performance**

Sales of Ellex's proprietary Retinal Rejuvenation Therapy laser, 2RT increased 260% to \$1.8 million, following the release of the Company's LEAD clinical study which showed that treatment with 2RT achieved a clinically meaningful 77% reduction in the rate of progression of 76% of patients with intermediate age-related macular degeneration (iAMD) to advanced forms of the disease over the 36 months of the study. 4<sup>th</sup> year LEAD trial follow up showed sustained, positive 2RT treatment benefits for the 76% of RPD<sup>(-)</sup> patients with intermediate AMD enrolled in the trial.

2RT segment EBITDA loss improved to \$0.6 million during the 2019 financial year. Ellex remains committed to establishing a regulatory pathway with the FDA for 2RT in iAMD during 2019, with FDA submissions for a US clinical trial and a meeting planned.

### **Cash Flow and Balance Sheet**

Operating cash outflows of \$4.2 million reflected an increase in working capital associated with higher inventory build on sales expectations, particularly for Ellex iTrack in 2019. Capital expenditure of \$0.7 million was down 41% on the pcp following the completion of the manufacturing expansion of Ellex's Mawson lakes facility in Adelaide and Ellex iTrack™ manufacturing in Fremont, California. The installed capacity at both sites provides Ellex with the flexibility and

capability to meet the expected increase in demand for its innovative ophthalmology products over the long term.

The Company maintains a conservative level of debt, with gearing (D/D+E) of 19% and net cash of \$0.3 million (gross debt: \$15.1 million, cash \$15.4 million). Balance sheet capitalised development costs of \$15.3 million increased 3% over the pcp. Product development capitalised during the period was down 25% to \$2.4 million and total product development expenditure (expensed and capitalised) was down 2% to \$4.1 million versus the pcp.

## **Outlook**

Ellex FY20 EBITDA is expected to show an improvement versus FY19, subject to global economic conditions and foreign exchange rates. Our high growth iTrack segment is expected to continue revenue growth and generate positive EBITDA in the 2H of FY20. Ellex will focus on OPEX control as investing phase moves to sales execution and reducing our working capital requirement, particularly inventory.

**- ENDS -**

## **Investor Conference Call Details**

As a reminder, Ellex will be hosting an investor conference call this morning at 9:00 am Australian Eastern Standard Time, with the details below.

<b>DATE:</b>	<b>Thursday, 29 August 2019</b>
<b>TIME:</b>	<b>9:00 am (Australian Eastern Standard Time)</b>
<b>CONFERENCE ID:</b>	<b>10001676</b>
<b>TOLL FREE DIAL-IN DETAILS:</b>	
Australia toll-free:	<b>1800 558 698</b>
Australia local dial:	<b>+61 2 9007 3187</b>
USA:	<b>1855 8811 339</b>
UK:	<b>0800 051 8245</b>
Hong Kong:	<b>800 966 806</b>
Singapore:	<b>800 101 2785</b>
Japan:	<b>0053 116 1281</b>
China:	<b>4001 200 659</b>

## **Pre-registration Link**

Investors who wish to pre-register for the conference may do so by following the link below. You will be given a unique pin number to enter when you call, which provides immediate access to the event.

<https://s1.c-conf.com/diamondpass/ellexmedical-10001676-invite.html>

## **Webcast Link**

The slide presentation and audio can also be viewed live at the following link:

<https://webcast.openbriefing.com/5471/>

A recording of the call and slide presentation will be made available within the Investors section of the Company website at: <https://www.ellex.com/investors/presentations/>

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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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