



28 November 2019

CEO Address at 2019 AGM

Adelaide, Australia, 28 November 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 announces the Chief Executive Officer address to accompany the investor presentation and Chairman’s address at today’s Annual General Meeting of Ellex shareholders to be held at Ellex’s corporate headquarters at Mawson Lakes, Adelaide at 2:00 pm.

Slide 1: Title

Good afternoon everybody and welcome to the 2019 Ellex Medical Lasers Annual General Meeting here at Ellex’s corporate headquarters and manufacturing facility at Mawson Lakes. My name is Maria Maieli and I am the interim CEO of the Company. At today’s meeting, I will provide an overview of our financial results for the 12 months ended 30 June 2019, along with some commentary on our activities during the year. I will also provide a business update for the first four months of the current financial year, our expectations for the full year and the recent non-binding conditional offer for the Ellex Lasers and Ultrasound business.

Slide 2: Disclaimer

Our shareholders should be aware that today’s presentation will contain forward looking statements regarding Ellex’s expected financial performance for the 2020 financial year.

Slide 3: Our Business

Ellex is a world leader in the design, manufacture and sale of a comprehensive range of ophthalmic lasers, evolving consumable devices and diagnostic equipment. These products serve multi-billion dollar markets namely glaucoma, diabetic eye disease, secondary cataracts, age-related macular degeneration or AMD and vitreous opacities.

Our installed base of lasers and diagnostic equipment globally is in excess of 35,000 units and to date more than 108,000 Ellex iTrack consumable devices have been sold to treat glaucoma. Ellex has a direct sales force in our major markets including the USA, Japan, Germany, France and Australia and a presence in over 100 countries across the globe.

We continue to target our two high growth market segments of glaucoma and age-related macular degeneration, with our innovative range of products having made excellent progress throughout the year in achieving solid growth within both disease indications.

Slide 4: Our Core Competencies

Our shareholders often ask how Ellex has been able to build a global ophthalmology business with a dominant market share in several key segments from Adelaide. The key ingredients to Ellex's success over the long term are product innovation, brand recognition, being vertically integrated and controlling our sales distribution.

We believe this affords us a sustainable competitive advantage relative to our peers and ensures that ophthalmologists continue to use and purchase our high quality, precision manufactured range of ophthalmic lasers, ultrasounds and iTrack devices. It also creates a high barrier to entry for new entrants seeking to gain market share in this space. It has taken us many years to develop this valuable expertise.

Slide 5: Ellex Presence at Major Industry Conferences in 2019

As a brand leader in its ophthalmology segment, Ellex attends major industry conferences, which provides us with an opportunity to liaise directly with our clinician customers, generate sales leads and launch new products.

I would like to recognise our investment at the World Glaucoma Congress in Melbourne where we hosted a symposium on iTrack which was well attended by clinicians, but also several of our institutional investors were in attendance. We were also able to offer clinicians a benchtop simulation model of the iTrack procedure to understand the surgical procedure in more detail.

The next generation of our Ellex Eye Prime ultrasound platform was launched at the American Society of Cataract and Refractive Surgery, also known as ASCRS, meeting.

Slide 6: FY19 Group Financial Summary

I would now like to provide a recap of our FY19 financial performance.

Ellex reported global sales revenue of \$81.6 million, up 3% on the prior corresponding period or pcp.

Our gross margin, excluding production labour was up 410 basis points to 62.2% versus the prior corresponding period or pcp, which reflects currency benefits coupled with improved mix dynamics through a higher proportion of higher margin products in glaucoma.

Our operating expenditures grew 10% to \$52.4 million. We continue to invest into our high growth glaucoma segment to drive future growth.

At the EBITDA level, the group recorded an underlying loss of \$0.7 million, which excludes \$0.3 million in restructuring charges. Our reported EBITDA loss was \$1.0 million which improved slightly over the pcp.

Slide 7: Ellex iTrack Canal-Based Glaucoma Surgery

I wanted to spend a couple of minutes reviewing our performance for the Ellex iTrack segment.

Slide 8: FY19 Financial Results – Ellex iTrack

The regional contribution of iTrack unit sales, showed our strongest market, the USA continued, to perform with unit sales up 30% on the prior corresponding period or pcp. iTrack outside the US, or OUS, unit sales excluding China were down 9%, although revenues were up slightly. We noted some improvement in German sales via Hoya Corporation, which acquired our previous distributor in the first half.

Chinese unit sales were up 42% versus the pcp. Unfortunately, the impact of tariffs impacted net pricing despite these solid volumes. Ellex iTrack continues to be the only MIGS device approved in the Chinese market.

Collectively, our global iTrack unit volumes increased 17% on pcp and revenues were up 29% to \$14.3 million.

During the fourth quarter of the financial year, Ellex implemented a low double-digit price rise for iTrack in the US market, noting this was the first price increase in a number of years and reimbursement continues to remain very strong in that market. Although there were some benefits that accrued during that quarter at the new price, clearly the full effects of the increase will be in the 2020 financial year and beyond.

Segment Gross margin (ex-labour) was 79% (down from 84% in pcp), reflecting some manufacturing rework during the period at our facility in Fremont, California.

Our iTrack business highlighted strong cost base leverage during the second half, which recorded \$1.1m EBITDA loss versus a \$4 million loss in the first half to give a full year EBITDA loss of \$5.1 million.

The higher than Average AUD price for iTrack was mostly attributable due to FX benefits and mix effects from a higher US volume component.

Slide 9: Lasers and Ultrasound and Ellex 2RT for Intermediate AMD

I will now provide a snapshot of the overall financial performance during FY19 of our remaining two business segments, namely Lasers and Ultrasound and Ellex 2RT.

Slide 10: FY19 Financial Results Lasers and Ultrasound, 2RT

As flagged at the commencement of the presentation today, shareholders will note that despite negative revenue growth of 3% to \$65.5 million, our Lasers and Ultrasound gross margin expanded by over 500 basis points to 59% and segment EBITDA increased 6% to \$9.5 million versus the pcp. While the second half performance lagged that of the first half in terms of top line growth, it was pleasing to see the growth in EBITDA from this segment overall.

As with previous financial years, our Lasers and Ultrasound EBITDA was invested into growth opportunities for iTrack and 2RT. Hence, the group reported an EBITDA loss of \$1 million, slightly better than last financial year, while the underlying EBITDA loss of \$0.7 million excluded approximately \$0.3 million in one-time restructuring charges.

Looking at the 2RT segment in more detail, we saw solid growth in sales of our 2RT laser, up 260% to \$1.8 million. Investors will recall the 532% growth in the first half to \$1.2 million, following the LEAD results, indicating that sales volumes and revenues moderated in the second half.

Segment EBITDA loss narrowed to a loss of \$0.6 million, an improvement from the \$1.0 million loss in the pcp. We have recorded several unit sales into the United States, where 2RT is FDA cleared for clinically significant macular edema or CSME, but not iAMD. Purchase prices and per procedure fees were stable and fees collected were \$0.2 million for the year.

Slide 11: 2RT FDA Update

I now just wanted to provide an update on our corporate activities as they relate to 2RT, particularly with the FDA process which is ongoing.

Shareholders will recall from our announcements since first reporting the LEAD clinical data in September 2018 that we have been resolutely focused on the education and marketing of the results, which showed a clinically meaningful 77% reduction in the rate of progression to late AMD in 76% of patients enrolled in the study at three years. LEAD was the first ever study to show a significant efficacy effect in an iAMD population.

This effect was maintained at four years, despite these patients receiving no further 2RT treatment post the clinical study.

We are strong believers in the meaningfulness of these clinical results, despite the study not meeting the primary endpoint, across the entire study population.

Ellex Remains on track to establish US regulatory pathway for 2RT in iAMD with the FDA prior to the end of calendar year 2019 with submission to the FDA of regulatory documents having been completed and the meeting which was to be held prior to the end of 2019 has now been re-scheduled by the FDA to early first quarter 2020.

iAMD is an attractive, growing market where patients are currently untreatable as there are no regulatory cleared products that have specifically demonstrated a benefit in these patients. Accordingly, Ellex has focused some considerable time in trying to unlock the inherent value of this market by engaging with the regulators who 'set the bar' on registrations of new devices and drugs.

While it is too early to communicate to you our preferred strategic approach until after the FDA meeting and outcome, Ellex has three options, which includes partnering 2RT to defray the clinical costs in exchange for sharing of commercial returns, spinning-out 2RT into a separate Company and having it funded independently or to self-fund the clinical trial in the US.

Slide 12: FY20 Trading Update

I will now provide investors with a snap shot of our financial performance in the first four months of the 2020 financial year.

Although we have fallen a little behind on our revenue expectations so far this year, our 2020 cost focus continues, with OPEX down 6% versus pcp delivering an improvement in EBITDA of 18% to a \$2.0 million loss versus the pcp.

Our four-month group sales to 31 October are up 3% on pcp to \$24.8 million. Lasers & Ultrasound sales are up 6% to \$20.5 million, driven by SLT in glaucoma with sales up 16% to \$8.6 million.

Offsetting the lasers and ultrasound performance has been the iTrack performance, with USA sales up 3% to \$3.0 million, and worldwide sales down 2% to \$4.0 million. The remainder of the global iTrack business encompassing ex-USA and China is down 15% to \$1.0 million. Our account level feedback in the USA indicates the sluggish sales momentum is not price-related. As I indicated earlier, Ellex put through a low double-digit price increase in the fourth quarter of FY19 for its hospital and day surgery accounts in the USA.

We have undertaken a Strategic review of iTrack business in light of this performance, with the following initiatives implemented:

The appointment of a VP, Glaucoma Solutions; who commenced on 18 November & has responsibilities for the glaucoma business in the USA.

The appointment of an Asia Pacific specialist for iTrack to support continued China growth profile and new market entries.

We have extended product marketing initiatives to drive clinical awareness and adoption finally we aligned field sales compensation plan to drive adoption at new plus existing Ambulatory Surgical Centres.

Despite these early challenges, shareholders should note that the market for iTrack, as evidenced by its reimbursement remains strong. For instance, the 2020 final payment rule by US Medicare which sets the fees paid for our product showed a circa 4% increase in payment for the ASC/hospital, while the physician procedure fee unchanged. Moreover, we have seen a strong sales performance versus the pcp so far in November with worldwide sales up 27% versus the pcp.

Finally, we continue to innovate on our current iTrack product and expect to introduce new product enhancements to the market

Slide 13: Potential Sale of Ellex Lasers & Ultrasound

Last night, we requested and were granted a voluntary suspension of our securities on the ASX following the receipt of a non-binding conditional offer for the Lasers & Ultrasound business segment. The suspension was requested given the proximity of the offer to the AGM.

The unsolicited approach by this group endorses Ellex's strong brand, market position in the ophthalmic laser segment, globally. The group sees considerable value in Ellex's R&D capability, manufacturing infrastructure and channel to market.

Discussions are well advanced and Ellex has granted the group a 14 day period of exclusivity to conduct detailed due diligence enquiries and negotiate definitive transaction agreements.

Ellex expects the voluntary suspension to end following an announcement to the market that transaction documents have been entered into, or that negotiations have ceased. Shareholders should note there is no guarantee a transaction will be completed at this stage.

Slide 14: Outlook

Looking now at our expectations for the remainder of the 2020 financial year. Subject to changes that would result from a transaction of the Ellex Lasers & Ultrasound business, we expect our group EBITDA for the 2020 financial year to improve on FY19 subject to global economic conditions and foreign exchange rates.

Despite the challenging start to FY20, we continue to expect iTrack will deliver sales growth relative to the pcp and that business to turn EBITDA positive in the second half of FY20.

We will focus on operating expenditure control as investing phase moves to sales execution and focus on reduction in working capital requirement, particularly inventory.

The Board expects to finalise the appointment of a permanent CEO in early calendar year 2020 as well.

Slide 15: Contacts

That now concludes the formal presentation of our 2019 AGM presentation. Thank you for listening.

Slide 16: Questions / Discussion

Are there any questions from the audience?

- ENDS -

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

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