# Ellex Medical Lasers Limited Annual General Meeting

28 November 2013



## Ellex: Strategically positioned for growth

- Ellex is now a leading international supplier of ophthalmic products to a growing global market, albeit a very competitive market.
- Within this market your company has a unique combination of strong engineering, manufacturing and technical capacity and, most importantly, established global distribution.
- These elements are augmented by a portfolio of intellectual property that provides the business with long-term growth opportunities.



#### FY13 – Operational Performance

- Fiscal year 2013 profitability continued to be impacted by the high value of the AUD against the USD and the EURO.
- In the second half of the year the devaluation of the YEN against the AUD caused further deterioration in our operational performance.
- As a result, and combined with other factors, your business reported an operating profit before tax of only \$140,000 for the year, down from \$1.1million in the prior year.



### Sales Composition FY13 and trends

	AUD 000's		
	FY13	FY12	
Australia (direct sales)	9,464	12,614	Major sale to Specsavers in 2012 not repeated in 2013
USA (direct sales)	8,511	9,872	Uncertainty with USA health system direction
EMEA (80% distributors & 20% direct)	9,963	9,651	Growth from establishment of direct sales business in France
Japan (direct sales)	10,738	12,186	YEN devaluation
ASIA (distributors)	3,185	2,206	Continued growth in this market
South America (distributors)	943	984	
	42,804	47,503	



#### Key Recent Achievements

- Release of more new products in the last 12 months than at any time in the last 5 years. Growth is expected to flow through from this in FY14.
- Demonstrated commitment to, and culture of, cost control and raw material inventory reduction to fund product development.
- Successful placement of shares to raise \$3.3m in September 2013 to fund working capital, acceleration of 2RT LEAD trial recruitment, debt reduction and growth.
- Commencement of sales of SLT (glaucoma laser) in the USA in July 2013.



#### Intellectual Property Protection Update

- During the 2013 fiscal year, we commenced a program to more aggressively protect our intellectual property, particularly related to our world-leading SLT/YAG combination laser (Tango<sup>™</sup>).
- Commencing in Europe and then moving into the USA, our program triggered a response from the USA arm of Lightmed Corporation of Taiwan and a claim was lodged in the Northern District California Court in August 2013.



#### Intellectual Property Protection cont'd

- This claim alleges that our IP protection program breached certain trade practice laws.
- While we are rigorously defending the claim through the court process, recently Lightmed and Ellex opened discussions with a view to settling this claim. These discussions are progressing.



#### FY14 Progress

- Since May 2013 the lower AUD against both the USD and Euro is beneficial. YEN remains devalued compared with PCP.
- Sales in USA for the 4 months to 30 October 2013 are 80% above the same time last year.
- The release of our leading Tango and Solo SLT glaucoma lasers to the USA market has been well received and has driven the increase.
- The considerable ophthalmologist interest in our SLT products at the AAO meeting in New Orleans on 20 to 23 November suggests that the trend will continue.



#### FY14 Progress cont'd

- Tempering these excellent results, the sales performance in Japan (hitherto our largest market), Europe and Middle East have been down on the PCP.
- November and December is an important selling season for your business (particularly in USA where it is the end of the tax year). Orders appear to be strong and production is now the focus.
- Provided demand trends continue, and production and delivery occurs on schedule, an increase in revenue for the first half of approximately 10% is expected along with a meaningful increase in earnings compared with PCP.



#### Ellex 2RT™ – Recap

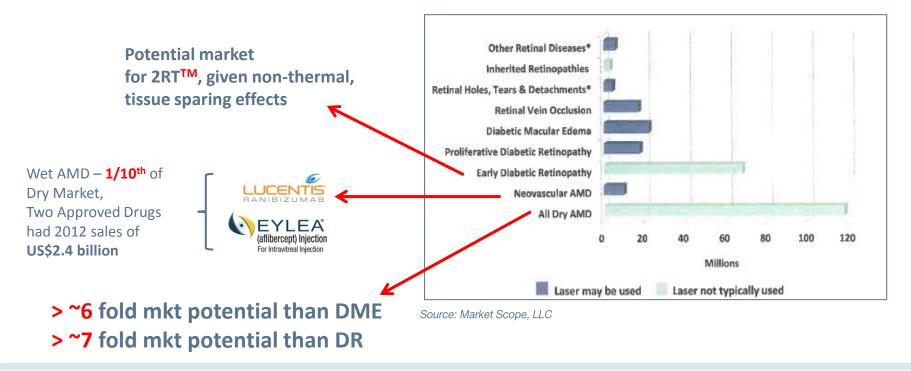
- Ellex 2RT<sup>TM</sup> is a proprietary breakthrough therapy that triggers tissue rejuvenation, a process that removes ailing cells and repopulates with healthy new cells without causing damage to crucial photoreceptors
- Ellex 2RT<sup>TM</sup> has thus far been trialled for retinal diseases including AMD and diabetic retinopathy with promising results that show edema reduction, drusen reduction and improvements in patient visual acuity
- Regulatory Status DME: CE Mark (Europe) July 2012, FDA 510(k) cleared July 2013
- Regulatory Status AMD: CE Mark pending completion of technical file
- Ellex 2RT<sup>TM</sup> technology is protected by multiple international patent.
- EU commenced limited commercial roll out during FY13
  - Early adopter sales achieved
  - Pain free alternative to traditional photocoagulation in DME
  - Tissue sparing (unlike P/C) potential for earlier intervention
  - Leverage off DME reimbursement codes
  - Ellex photocoagulator products remain the company's primary DME treatment offering
- US Clearance in July 2013
  - Early adopter sales can now be targeted
  - Leverage off existing US direct sales force and support team (20) & indirect
  - Leverage for AMD trials pathway





#### Ellex 2RT™ for Early AMD – Game Changing Potential

- 2RT™ represents a substantial First-to-Market Opportunity in early AMD treatment
- Long track record of laser-based approaches treating eye disease reduces risk
- Lasers are Standard of Care across major eye diseases (glaucoma, DR, DME etc)
- 2RT™ is a logical extension of tissue sparing and cell regenerative SLT
- ~112m patients early AMD, for which no laser (or other treatment) currently approved
- 2RT™ could be the first CE Mark Laser for treating Early AMD





### 2RT update

- Publication of seminal paper by Prof Robyn Guymer MB, BS, PHD, "Nano-second laser application in intermediate Aged Related Macula Degeneration (AMD) – 12 month results of fundus appearance and macular function". This paper demonstrated the effectiveness of our 2RT laser in improving fundus appearance and macular function in 50 patients
- Acceleration of recruitment for LEAD (Laser intervention in Early Aged-related macular Degeneration) clinical trial.
  Recruitment is now at 110 patients at sites in Melbourne, Perth and Sydney.



#### 2RT update continued

- First International trial site progressing: two out of three approvals in place and final approval due imminently.
- An additional European site being planned and negotiated.
- 2RT trial sites are also being negotiated at prominent institutions in the USA.



### Summary

- Your business achieved a small, \$140,000 profit in FY13, essentially this is breakeven.
- Due to good results in USA, management is projecting a meaningful improvement in earnings for the six months to 31 December 2013, though lower-than-pcp sales in Japan and EMEA are tempering the size of the increase.
- Game-changing 2RT project is making progress and further early adopter sales for FY14 may be possible.



# Thank you

