# Ellex Medical Lasers

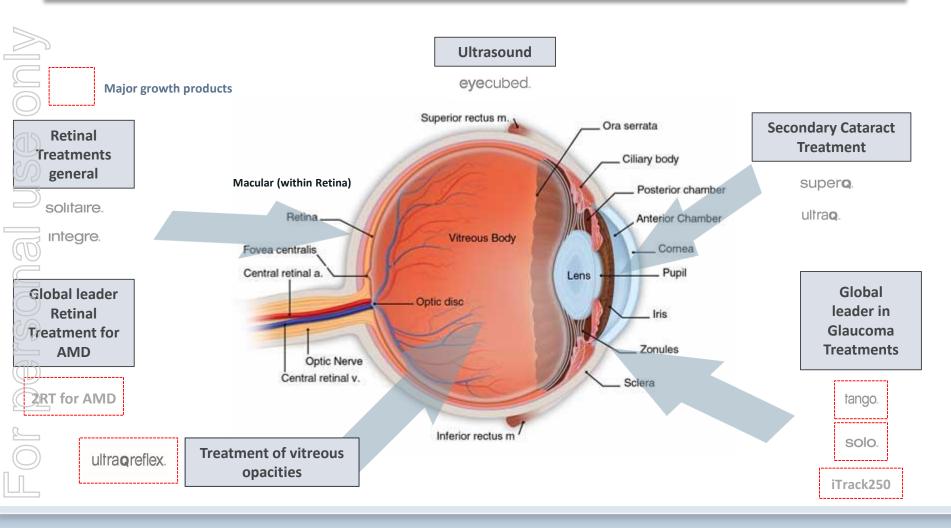
Investor Presentation for six months ended 31 December 2013

(prepared 17 March 2014)

Tom Spurling, CEO



# Ellex develops, manufactures and markets lasers, ophthalmic implants and diagnostic equipment for the treatment of eye disease to a growing global market





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ASX-listed medical device company generating significant global revenues from an increasingly diversified portfolio of medical lasers, diagnostic and implantable devices targeting eye disease

- Globally competitive, innovative player that in February 2014 emerged as a global leader in non-pharma treatment of glaucoma and macular degeneration
- Fully integrated, leading supplier in a large growing global market with a direct presence in major markets
- Ophthalmic laser market expected to grow at a CAGR of 3.3% from 2013-2018, drivers being
  - Ageing population in the developed world
  - Advancing medical treatments in the developing world
  - New technology innovation
  - Cost-effectiveness of device treatments compared with drug treatments
- Acquisition of glaucoma surgical device business on 31 December 2013 provides increasing revenues and access to rapidly growing market (CAGR of 23.5% from 2013-2018) drivers being movement from treatment of glaucoma with drugs to treatment with devices



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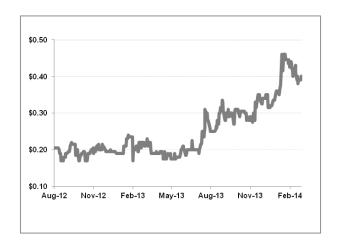
## **Market and Financial Summary**

Summary Financials			
Period	1HFY13	1HFY14	Change (%)
Revenue (\$m)	22.0	25.9	+18%
EBITDA (\$m)	0.9	1.4	+55%
EBIT (\$m)	0.2	1.2	>100%
Reported NPAT (\$m)	0.1	0.4	>100%
EPS (c)	0.04	0.36	>100%
PER (x)	n/a	n/a	-
EV/Sales (x)	n/a	n/a	-
EV/EBITDA (x)	n/a	n/a	-
OCF (\$m)	1.8	1.4	-22%
NTA Per Share (c)	19.0	20.0	-
ROE (%)	n/a	n/a	-

Share Register	
Top 20	47.3%
Directors	19.2%
Ave. Mthly Volume rolling 12 months(m)	1.7

Market Summary		
Shares on Issue	107.6	
Share Price @ 17 March	0.35	
12 month Range	\$0.17 - \$0.47	
Market Cap	\$37.7m	
Net Debt @ 31/12/13	\$2.5m	
Gearing (D/D+E)	13%	
EV (\$million)	\$35.2	

#### Share Price - 12 month





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Major Developments Achieved for Proprietary Retinal Rejuvenation Therapy (Ellex 2RT™)

- Publication of 50 patient early AMD pilot study
- CE mark for Aged Related Macular Degeneration (AMD) the most common diabetic eye disease
- Acceleration of multi-centre, double-blind, placebo controlled clinical trial of 2RT in up to 300 early stage age-related macular degeneration (AMD) patients "LEAD" study

Acquisition of Canaloplasty business from iScience Interventional, Inc. for US\$1.5m cash upfront 120% growth (\$5.3m) in USA sales following introduction of SLT for glaucoma

Ellex emerges as a global leader in non-pharmaceutical treatment of glaucoma and aged-related macular degeneration, the two leading causes of blindness in the developed world



### **Key Financial Highlights 1HFY14**

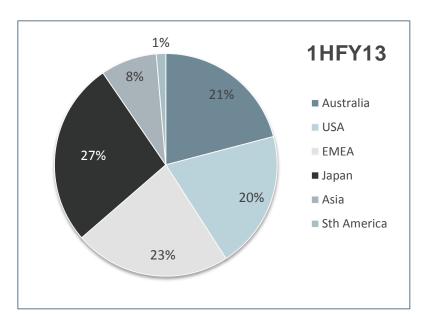
- Sales revenue of \$25.9m, up 18% on pcp
  - Led by 120% improvement in the US
- Gross Margins of 51% up 2 percentage points on the pcp
  - Sales mix benefits from higher margin products
- Capitalised Product Development Expenditure down on pcp
  - High product development in pcp associated with new products
  - Current half focus of engineering team on operations engineering for new products and RoHS compliance costs
- Reported EBITDA of \$1.4m, up 51% on pcp
  - EBITDA Margins of 5.4% up 120 bps
- Underlying EBITDA<sup>1</sup> of approx. \$1.9m, up 110% on pcp
- NPAT of \$0.4m up 171% on pcp

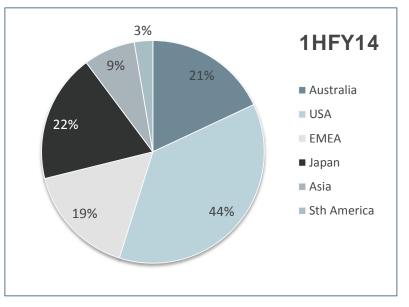
1 Adjustments included for non-recurring; legal costs, RoHS compliance and FX movement



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### **Geographic Sales Split**



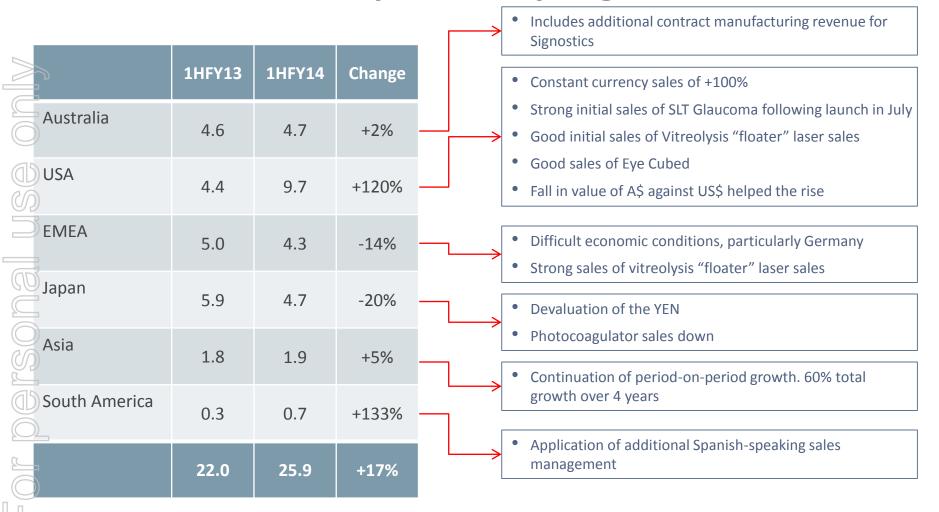


- USA now Ellex's largest market, representing 44% of group sales, up from 20% in 1H13
- USA to continue as dominant market given 2HFY14 SLT, Vitreolysis and canaloplasty sales & FX
- Japan anticipated to improve as production of new multi-wavelength photocoagulator (IntegrePro)
  ramps up which fulfils forward orders and demand is brought forward due Japanese government
  announcement that the VAT rate on general goods and services will increase on 1 April 2014 and again in
  November 2014
- European business will also benefit from ramp up of IntegrePro production
- Asia (mainly China) continues to grow with favourable market demographics



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### Financial Summary – Sales by Region





### Financial Summary – Balance Sheet

ASSETS	30 Jun 13	31 Dec 13
Cash	0.8	3.0
rade receivables	10.5	11.3
Inventories	16.1	16.6
Product development capitalised	8.3	8.8
Deferred tax asset	7.1	6.8
PPE and other assets	4.6	5.0
Total Assets	47.3	51.5

- Cash on hand benefited from \$6m in new equity raised during period
- Increase in receivables due to higher-than-pcp last month sales and acquisition of Canaloplasty business on 31
   December 2013
- Inventory increase in support of new products and acquisition of Canaloplasty business on 31 December 2013
- Increased capitalised product development costs reflect new product investment

LIABILITIES	30 Jun 13	31 Dec 13
Trade creditors	6.5	6.3
Borrowings current	6.4	3.4
Borrowings non current	1.0	2.1
Provisions + Other	2.7	2.9
Total Liabilities	16.5	14.7

- Gross Debt reduced by \$1.9m
- On-covenant performance has meant reclassification of some current debt to non-current
- Well within banking covenants during the 1H
- D/D+E reduced to 13% v 19% at FY13
- Net debt/EBITDA 1.8x v 5.6x at 1HFY13



### Financial Summary – Cash Flow

CASH FLOWS	Half year to	
	31 Dec 2012	31 Dec 2013
Operating Cash Flows	1.8	1.4
Acquisition of canaloplasty business	-	(1.7)
Investing - PP&E	(0.3)	(0.1)
Product Development Costs	(1.2)	(0.8)
Proceeds of share issues	-	6.0
Repayment of borrowings	(0.3)	(1.2)
Net Cash Flow	-	3.6

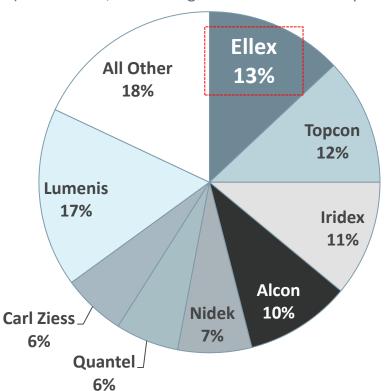
- During FY13 effort in place to reduce inventory to fund product development. In 2014 inventory levels have been constant to support increased sales
- Inventory turns have increased compared with last year following the increase in sales and control of inventory levels



#### **Market Share**

#### Ophthalmic lasers

(includes SLT, Photocoagulators & Photodisruptors)

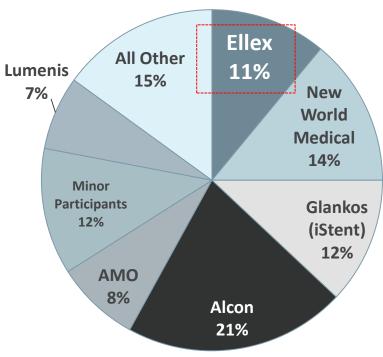


Market size estimate \$380m growing at CAGR of 3.3% to \$450m

Source: Market Scope 2013 Comprehensive Report of the Global Ophthalmic Laser Market

#### Glaucoma Surgical Devices

(includes SLT and canaloplasty)



Market size estimate \$275m growing CAGR of 23.5% to \$790m by 2018

Minor Participants = EndoOptiks, Lightmed, Maltemo, Neomedix & Mobius



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#### **US SLT Glaucoma Update**

- Majority of US sales growth directly attributable to launch of SLT in July
  - Prior to the launch of SLT in the USA, Ellex ex-US market share was 42%. Market Scope now assessed that following the launch of SLT Ellex has a <u>global</u> market share of 41% vs 39.4% held by Lumenis.
  - Expectation that we could replicate our ex-US market share in the US has been met.
  - Growth in market for SLT lasers evident as doctor education, marketing effort, excellent product and motivated direct sales team takes share of glaucoma drug therapy spend

#### Outlook:

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- Continued growth anticipated in the 2H
- SLT continues to grow in acceptance as a first-line standard of care in primary open angle glaucoma, driving clinician uptake



### **Canaloplasty Acquisition Update**











Combining SLT with the acquisition of iScience canaloplasty, Ellex now has a 11% share of the Glaucoma surgical products and as such, is a global leader in non-drug treatment of glaucoma

Ellex US direct sales force fully trained in 1Q CY14, 2 clinical training staff recruited to train doctors; positioning strategy three fold:

- (1) Major benefits on efficacy (SAE rate <1% versus trabeculectomy, tube shunts >20%)
- (2) Identical Pressure Lowering Effects as existing Standard of Care (SOC) and can be used in intermediate stage patients
- (3) Fully reimbursed by Medicare and most major payors
- (4) Lower costs and management time for doctors using canaloplasty vs trabeculectomy

First orders received from European distributor sales\$0.3m for the 2 months since acquisition

#### **Outlook** remains favourable:

- Change of ownership has not impacted sales, positive growth anticipated from 2Q CY14 onwards
- Jan/Feb sales in-line in US\$ terms with 2013 (despite no effective sales force), in A\$ terms sales +10%
- Shaping as a major expansionary opportunity for Ellex over next few years



### **UltraQ™** Reflex™ Vitreolysis Laser Update

Launched progressively late in 2013 financial year: represents first marketed vitreolysis that is accurate, pain-free and non-invasive

1HFY14 sales of \$1m, market response is therefore strong

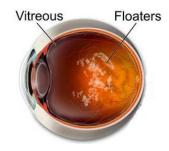
Common age-related problem – v. limited treatment options

- Vitreous "Floaters" though benign do considerably affect patient QoL
- Very common in ageing population
- Size and growth directly related to other Ellex markets, in particular cataract operations



- Favourable coding: US CPT 1 Code 67031
- Clinical Feedback Positive
- Rapid pay back period for clinicians

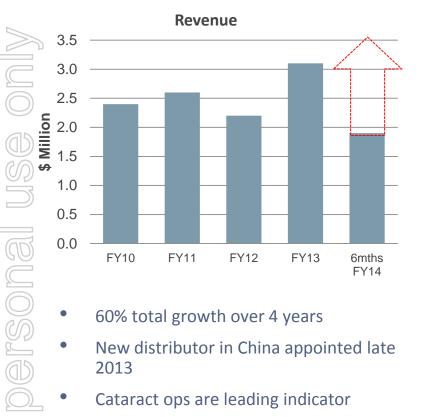






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### Asia Growth Update



- 60% total growth over 4 years
- New distributor in China appointed late 2013
- Cataract ops are leading indicator
- China opportunity strong given current low level per-capita of cataract operation

Country	Cataract + RLE Surgeries	Percent of Total Cataract + RLE	Cumulative Percent
India	6,309,731	28.4%	28.4%
United States	3,637,361	16.4%	44.8%
Japan	1,342,547	6.0%	50.8%
China	1,330,711	6.0%	56.8%
Germany	910,278	4.1%	60.9%
Brazil	871,354	3.9%	64.8%
France	676,090	3.0%	67.9%
Italy	562,925	2.5%	70.4%
Russia	462,214	2.1%	72.5%
Spain	394,577	1.8%	74.3%
United Kingdom	394,178	1.8%	76.0%
Canada	385,646	1.7%	77.8%
Korea, South	346,321	1.6%	79.3%
Mexico	287,143	1.3%	80.6%
All Other	4,307,044	19.4%	100.0%
Total	22,218,120	100.0%	

**Estimated 2013 Cataract Surgeries by Country** 

Source: Market Scope



Ellex 2RT<sup>TM</sup> is a proprietary pain-free, non-invasive breakthrough therapy that triggers tissue rejuvenation, a process that removes ailing cells and repopulates with healthy new cells without causing damage to crucial photoreceptors

<u>Age-Related Macular Degeneration</u> (AMD) is a chronic, progressive eye disease. Currently only late stage "wet forms" which are 10% of cases are treatable with 2012 drug sales of US\$2.4billion and growing. Early stage AMD represents over **110m** patients globally with no drug or device treatments currently approved for use.

50 patient pilot data on early AMD patients showed promising results at 12 months

- 44% reduction in accumulation of drusen, a key risk factor of AMD progression
- 64% of patients at greatest risk of AMD progression were down-staged

#### **Outlook:**

- 2RT represents a substantial, proprietary opportunity for Ellex (patents to 2027)
- Initial orders under limited commercial roll out to early adopters
- 24 month pilot data to report in 2014, answering Q of maintainability of benefit over long term
- US clinicians gain access as 2RT is approved for Diabetic Macular Edema (DME) since July 2013





## **2RT**<sup>TM</sup> – **LEAD** Clinical Trial Update

Of person

Major clinical study called LEAD launched in Nov 2012. Multi-centre, double-blind, 1:1 randomised controlled study in up to 300 high-risk bi-lateral intermediate AMD patients

- Primary endpoint is reduced progression to advanced AMD in those patients treated with 2RT™ v sham laser assessed by ocular examination, colour fundus photography, OCT and fluorescein angiography at 36 months, drusen reduction and improved fundus appearance
- Secondary endpoint is progression to advanced AMD in the non-treated eye
- Protocol allows for single administration of 2RT™ and then 6 monthly repeats in treated group

#### Additional resources committed in 3Q CY13 to the trial:

- 17% recruited (n=51) at mid September 2013
- As at 1 March, recruitment at n = 109 or 36%, representing a 19% increase over 5.5 months
- Number of centres has expanded from 2 in FY13 to 5 as at 1HFY14
- Recruitment benefiting from results of pilot study
- CE Mark anticipated to drive further interest in study
- Anticipate recruitment to complete in 2015, with results anticipated asap after completion



#### Important factors influencing outlook:

- Demand for SLT, UltraQ Reflex for Vitreolysis and new multi-wavelength photocoagulator continues to be strong
- Production ramp up continuing with third shift commenced on some product lines. Supply chain management, production staff training and safety and product quality is the focus
- Continued FX tailwinds compared with same period in 2013
- Canaloplasty revenues for the 6 months ending 30 June 2014 are expected to be in line with \$4m annual rate at the time of acquisition
- Near-term sales in Japan are to benefit as customers bring forward sales decisions as a result of Japanese government announcement to increase the VAT rate on 1 April and 1 November 2014
- Conditions in Europe continue to be uncertain

#### **Outlook:**

Sales continue to accelerate with 8 month YTD sales growth of +21% on pcp vs 1H growth of 17.7%. This trend is expected to continue for the remainder of 2HFY14



**END** 

