

# Ellex Medical Lasers

Investor Presentation - Australia  
for 12 months ended 30 June 2014

(23 September 2014)



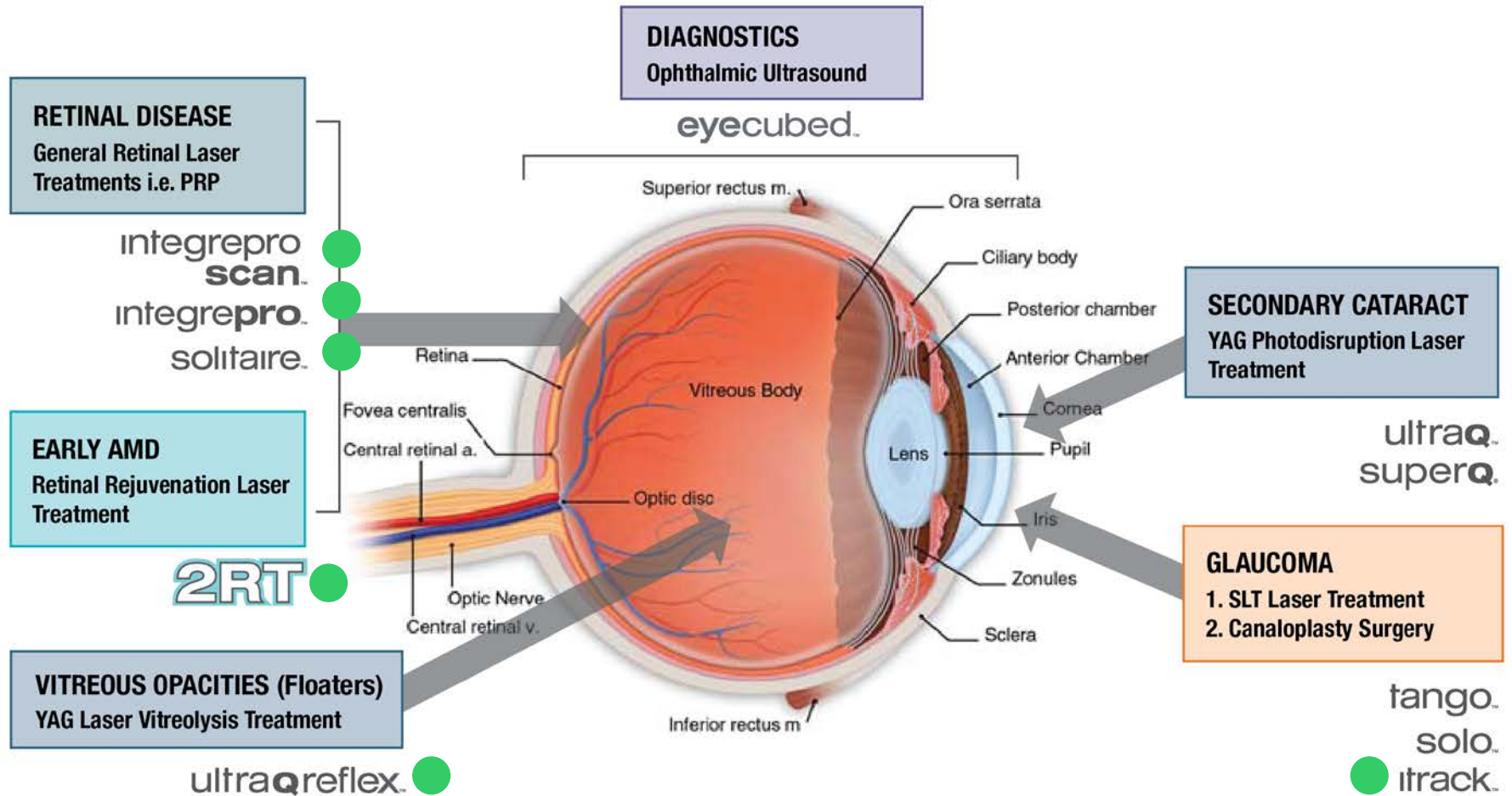
# Ellex Highlights

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

- **Global leadership achieved** in non-pharma treatment of glaucoma and macular degeneration
- Strong revenue growth in FY14 of 27% driven by **US sales increase of 124%** in 2014 on the strength of laser for glaucoma treatment
- Improving recurring component of revenue from 4.9% in FY13 to 8.6% in FY14
- Continued progress in commercialisation strategy of **proprietary 2RT™ technology with first unit sales during FY14** and further sales in early FY15
- **Prospects for growth in both revenue and profitability in FY15** driven by acceleration of 2RT sales, continued adoption of SLT for glaucoma in the US, release of the new Integre Pro photocoagulator range, sales of unique laser for vitreolysis and a full year contribution from canaloplasty business



# FY15 GROWTH OPPORTUNITIES



One Powerful Vision

# Market and Financial Summary

Summary Financials			
Period	FY13A	FY14A	Change (%)
Revenue (\$m)	42.8	54.4	27%
EBITDA (\$m)	1.7	3.0	76%
EBIT (\$m)	0.4	1.5	275%
<b>Reported PBT</b>	<b>0.1</b>	<b>1.3</b>	<b>836%</b>
<b>Underlying PBT</b>	<b>0.1</b>	<b>2.3</b>	<b>n/a</b>
<b>Reported NPAT (\$m)</b>	<b>(0.8)</b>	<b>0.8</b>	<b>n/a</b>
EPS (c)	(1.0)	0.73	n/a
<b>PER (x)</b>	<b>n/a</b>	<b>44.4</b>	
<b>EV/Sales (x)</b>	<b>0.8</b>	<b>0.7</b>	
<b>EV/EBITDA (x)</b>	<b>17.6</b>	<b>11.5</b>	
OCF (\$m)	1.9	2.7	42.1%
NTA Per Share (c)	17.3	21.8	26%
<b>ROE (%)</b>	<b>(2.6)</b>	<b>2.3</b>	<b>n/a</b>

\* Multiples based on an ELX share price of \$0.325

Market Summary	
Shares on Issue	107.6 million
Share Price @ 17 Sept 14	A\$0.325
<b>Market Cap</b>	<b>A\$35.0m</b>
Net Debt @ 30/6/14	A\$3.9m
<b>Gearing (D/D+E)</b>	<b>9.5%</b>
<b>EV</b>	<b>\$38.9m</b>

Share Register	
Top 20	49.5%
Directors	19.1%
Ave. Mthly Volume (m)	1.4



# Ellex Milestones – FY14

- Major Developments Achieved for Proprietary Retinal Rejuvenation Therapy (Ellex 2RT™)
  - Publication of 50 patient early AMD pilot study
  - CE mark for treatment of early stage Aged Related Macular Degeneration (AMD)
  - Sales to early adapters in Europe and Australia to advance clinical understanding of the product
  - Acceleration of multi-centre, double-blind, placebo controlled clinical trial of 2RT early stage age-related macular degeneration (AMD) patients “LEAD” study
- 124% growth (\$11.1m) in USA sales following introduction of SLT for glaucoma and acquisition of the canaloplasty business
- Revenue from Ellex-manufactured ophthalmic consumables and service increased from \$2.1m (5% of sales) in FY13 to \$4.7m (9% of sales) following acquisition of canaloplasty business and emphasis on service contract sales
- 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
- Strong take up of UltraQ Reflex vitreolysis “floater” laser including publication of paper at September 2014 “Euretna” conference in London



# Financial Summary – P&L

	FY13	FY14	Change
Sales (A\$m)	42.8	54.3	+27%
Reported EBITDA (A\$m)	1.7	3.0	+76%
Reported EBITDA Margin (%)	4.0	5.5	
Underlying EBITDA (A\$m)	1.7	4.0	+135%
Reported Earnings before tax (A\$m)	0.14	1.3	
Underlying earnings before tax (A\$m)	0.10	2.3	

## Drivers of change against pcp :

- Significant improvement in sales in USA of SLT and improved sales in Asia
- Flow-through of sales increase into profits negatively impacted by concentration of sales growth in these markets
- Lower A\$ v's Euro and US\$
- Improved gross margins due to improved product mix
- Improvement in recurring revenue from Ellex-manufactured consumables and equipment service from \$2.1m to \$4.7m
- Operating expenditure increase due to higher selling costs in the USA, incorporation of the canaloplasty business and increased clinic support for the roll out of 2RT
- Approximately \$0.6m of non-recurring costs related to intellectual property management and restructuring costs in Germany. In addition, approximately \$0.4m of unresolved foreign exchange losses on inventory held in USA and Japan



# Financial Summary – Sales by Region

	FY13	FY14	Change
Australia	9.5	9.4	-1%
USA	8.5	19.0	+124%
EMEA	10.0	10.3	+3%
Japan	10.7	10.4	-3%
Asia	3.2	3.9	+22%
South America	0.9	1.4	+55%
<b>TOTAL</b>	<b>42.8</b>	<b>54.4</b>	<b>+27%</b>
<b>Recurring consumable &amp; service component</b>	<b>2.1</b>	<b>4.7</b>	<b>+124%</b>

- Includes additional contract manufacturing revenue for Signostics (and improved service revenue offset by delays in third party product sales)

- Strong sales of SLT Glaucoma following launch in July
- Solid initial sales of Vitreolysis “floater” laser sales
- Increased sales of Eye Cubed
- Fall in value of A\$ against US\$
- Recurring/Consumables revenue growth due to canaloplasty acquisition and focus on service contracts

- Difficult economic conditions, particularly Germany
- Strong sales of vitreolysis “floater” laser sales & 2RT early adopter sales
- Fall in value of A\$ against Euro and US\$

- Increase in value of A\$ against YEN
- Photocoagulator sales down due to transition of production to new Integre Pro model

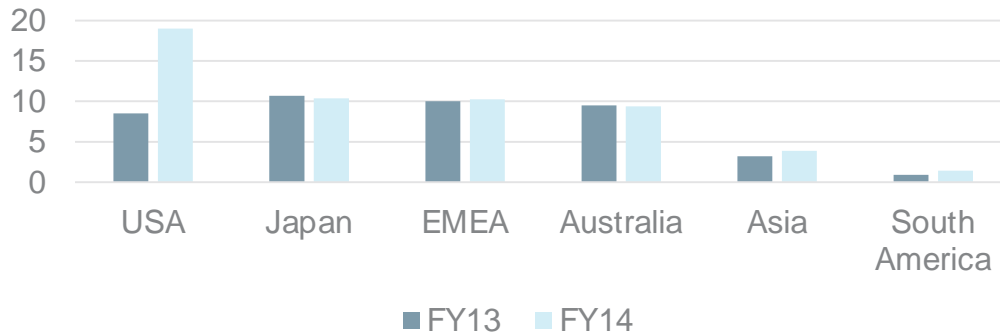
- Continuation of period-on-period growth 50% total growth over 3 years

- Application of additional Spanish-speaking sales management and fall in value of A\$ against US\$



# Constant Currency Review

Revenue by region in constant currency



	% received/ incurred in US\$	
	FY13	FY14
Revenue	30%	45%
Production costs	29%	32%
Operating costs	16%	47%

% change in revenue in constant currency	
USA	101%
Japan	2%
EMEA	-6%
Australia	-1%
Asia	15%
South America	44%
<b>Group</b>	<b>21%</b>

- Solid revenue increase even excluding FX tailwinds
- Material change in exposure to US\$ during the year impacted flow through



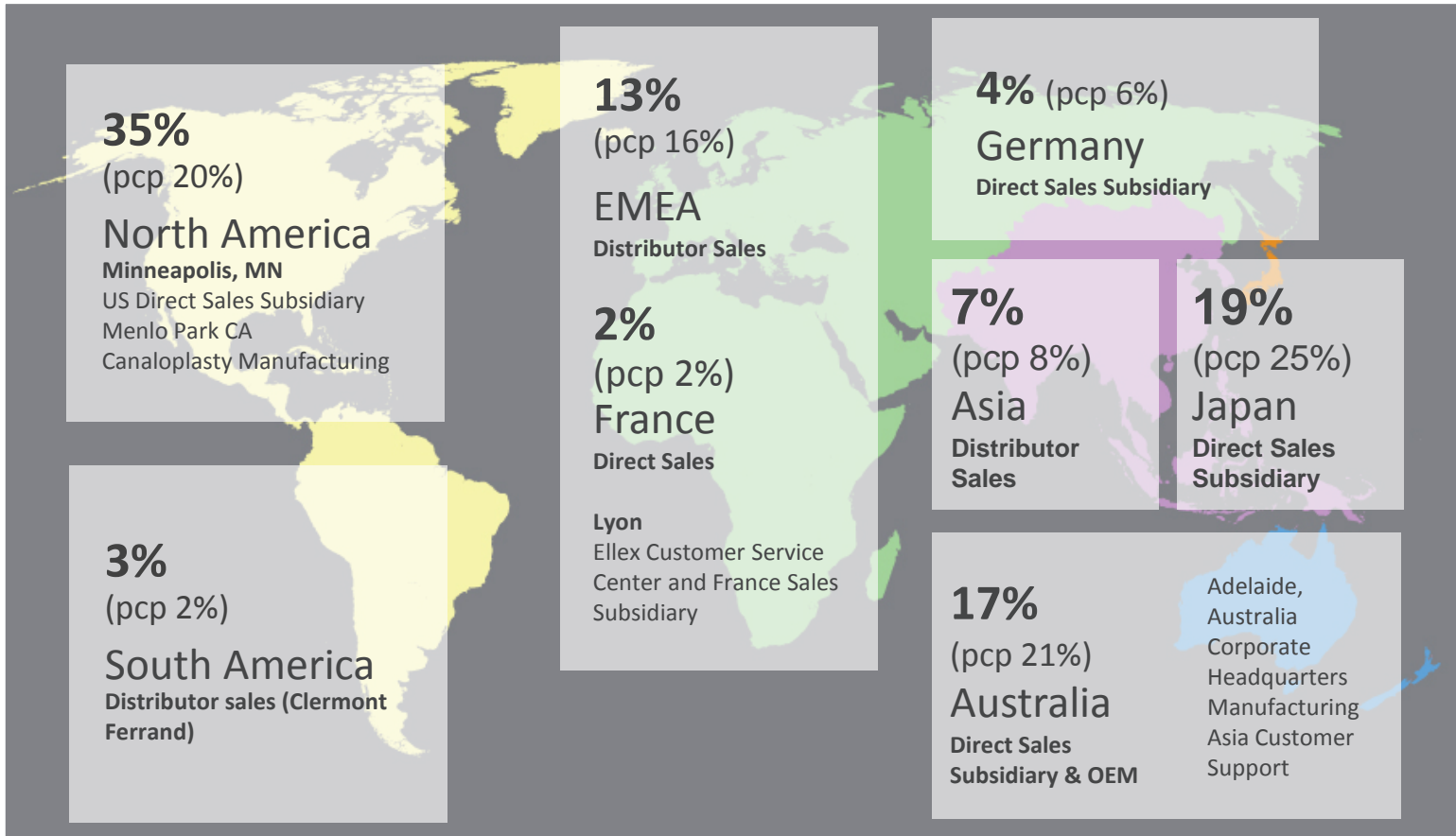
# Financial Summary – P&L Constant Currency

	FY14 Reported (A\$m)	FY13 (A\$m)	FY14 – Constant Currency FY14 (at FY13 FX rates) A\$m Constant Currency	Change in constant currency amounts
Sales	54.4	42.8	51.7	21%
Reported EBITDA	3.0	1.7	2.1	24%
Remove: unrealised FX loss on inventory on hand	0.4	-	0.4	
Remove: non recurring costs	0.6	-	0.5	
Underlying EBITDA	4.0	1.7	3.0	77%

	Average FX rate v's A\$		Net position for year v's A\$
	FY13	FY14	
USD	1.02	0.92	Devaluation 9.8%
YEN	89.9	92.7	Appreciation 3.1%
EURO	0.79	0.68	Devaluation 13.9%



# Global Revenue – Review



# Financial Summary – Balance Sheet

ASSETS	30 Jun 13	30 June 14
Cash	0.8	1.8
Trade receivables	10.5	11.8
Inventories	16.1	15.7
Product development capitalised	8.3	9.7
Deferred tax asset	7.1	6.8
PPE and other assets	4.6	8.4
<b>Total Assets</b>	<b>47.3</b>	<b>54.2</b>

- Cash on hand benefited from \$6m in new equity raised during period
- Increase in receivables due to higher-than-pcp last month sales in June 2013
- Inventory reduction of \$0.8m affect by additional canaloplasty inventory on hand of \$0.4m
- Increased capitalised product development costs reflect new product investment
- PPE & other assets increased due to capitalisation of deferred consideration on canaloplasty acquisition

LIABILITIES	30 Jun 13	30 June 14
Trade creditors	6.5	5.9
Borrowings	7.4	5.7
Deferred consideration	-	2.6
Provisions + Other	2.7	3.1
<b>Total Liabilities</b>	<b>16.5</b>	<b>17.3</b>

- Gross Debt reduced by \$1.7m
- Deferred consideration due to vendors of canaloplasty business
- Within banking covenants
- Trade creditors reduced due to better operating cash



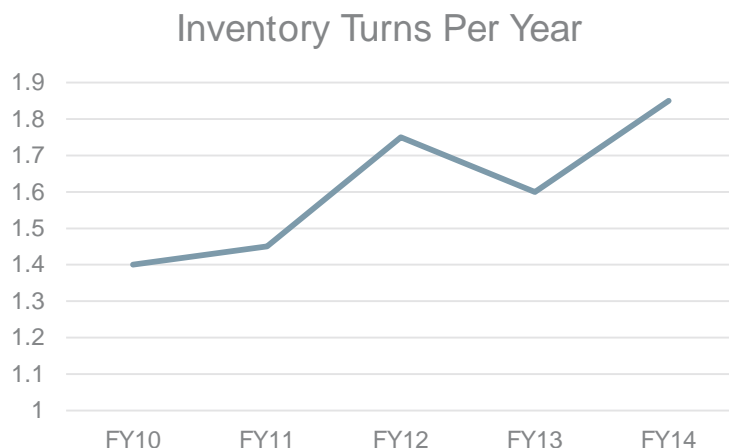
# Financial Summary – Cash Flow

Improved operating cash flow and reduced trade creditors

Continuation of long term trend to increase inventory turns

Capital raising to support acquisition of canaloplasty business and debt repayments

PPE investment focussed on production facilities for new Integre Pro photocoagulator



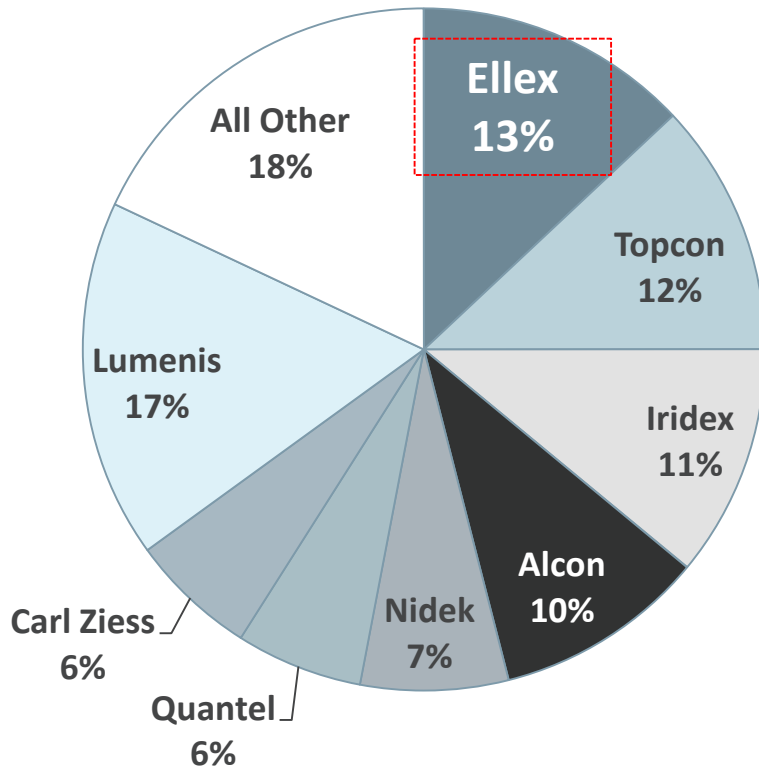
CASH FLOWS	FY13 A\$m	FY14 A\$m
Operating Cash Flows	1.9	2.2
Investing - PP&E	(0.6)	(0.6)
Cap. Development Costs	<u>(2.2)</u>	<u>(2.1)</u>
<b>Net Operations</b>	<b>(0.9)</b>	<b>(0.5)</b>
Acquisition of business	-	(1.6)
Debt repayments	(0.8)	(1.4)
Proceeds of share issue	-	5.9
<b>Net Cash Flow</b>	<b>(1.8)</b>	<b>2.4</b>

Improvement in net operations cash

# Market Share

## Ophthalmic lasers

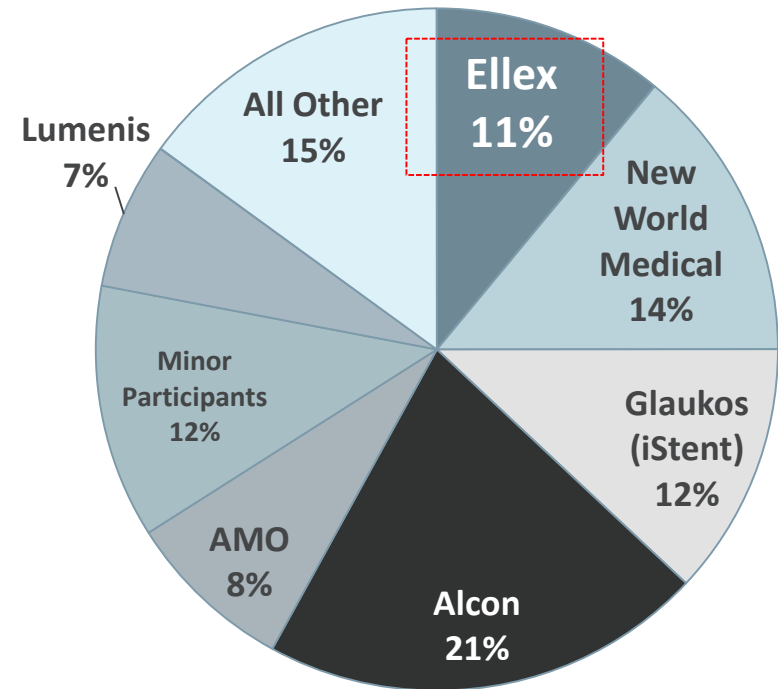
(includes SLT, Photocoagulators & Photodisruptors)



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

## Glaucoma Surgical Devices

(includes SLT and canaloplasty)



Market size estimate \$275m growing CAGR of 24% to \$870m by 2019

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

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



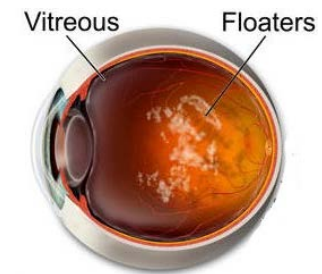
# US SLT Glaucoma Update

- Majority of US sales growth directly attributable to launch of SLT in July 2013
- In USA, SLT continues to grow in acceptance as a first-line standard of care in primary open angle glaucoma, driving clinician uptake. This trend was evident outside the USA in previous years.
- Market Scope now assesses that following the launch of SLT in the USA Ellex as the global leader
- Success of Ellex in SLT has seen recent entry of a competitor product in the USA. This has potential to grow the total market as has been evident from the entry of Ellex into the market
- **Outlook** : Continued growth in market for SLT in the USA is evident as doctor education, marketing effort, excellent product and motivated direct sales team takes share of glaucoma drug therapy spend



# UltraQ™ Reflex™ Vitreolysis Laser Update

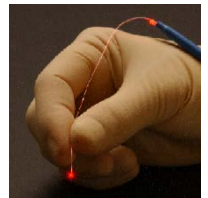
- Launched progressively late in 2013 financial year: represents first marketed vitreolysis laser that is accurate, pain-free and non-invasive
- Common age-related problem – v. limited treatment options
  - Vitreous “Floaters” though benign do considerably affect patient QoL
  - Very common in ageing population
  - Size and growth directly related to other Ellex markets, in particular cataract operations, particularly using advanced multi-focal IOLs
- During FY14 sales have exceeded expectations. Sales in 2H were approx. 20% higher than 1H of FY14 so growth is evident
- Unlike other Ellex laser products, the UltraQ Reflex generates a “wow factor” with patients who receive the treatment due to immediate relief from the daily annoyance of floaters
- 168 patient study completed by Dr Paul Singh, an early adopter clinician in the USA, showed 92% of patients reported improved quality of life after treatment with the UltraQ Reflex
- **Outlook** : Growth expected from continued and growing interest from doctors evidenced by overwhelming responses to Ellex webinars and tradeshow symposia in all territories (ESCRS symposium Oct 2103 = 100 attendees, ESCRS symposium Sept 2014 = 200 attendees)



# Canaloplasty Update



- Canaloplasty sales in 2H FY14 were higher than the corresponding period when the business was owned by iScience
- Change of ownership did not result in fall in sales
- European sales, particularly Germany, continue to steadily grow
- Loyal support from USA doctors but effort has been to educate the market in the USA of the reinvigoration of the canaloplasty procedure under Ellex ownership
- Major cost reduction initiative underway in 1Q FY15 to move manufacturing facility from large space in Menlo Park to alternative site in nearby Fremont with material annual rent savings expected
- **Outlook :**
  - Recurring revenue from disposable provides diversification from capital equipment sales
  - Growth in revenue and profitability expected from full year ownership, cost reductions and gradual USA and Europe sales growth



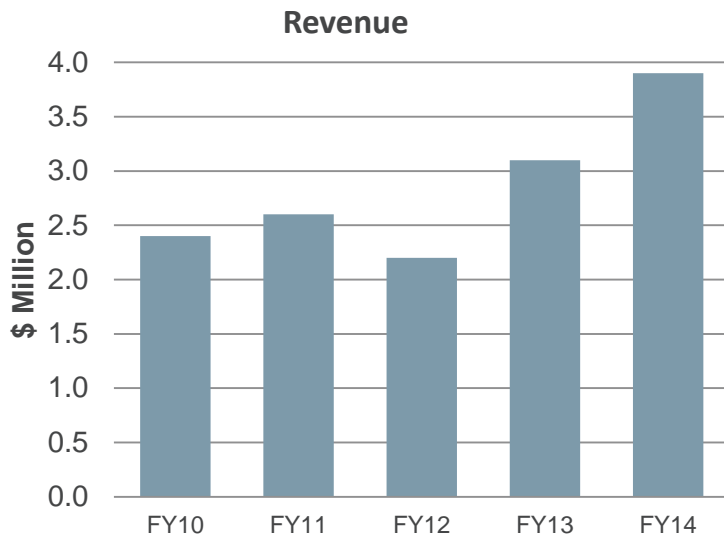


# Integre Pro Photocoagulator Product Release

- “Integre Pro” photocoagulator production commencement in March 2014, replacing the “Integre” family phased out in mid FY14. Laser for treatment of macular edema (retina)
- Integre Pro offers doctors better power, more wavelength treatment options and better optics than competitive products
- Integre PRO SCAN will provide Integre Pro functionality with a multisport scan pattern. Pattern laser photocoagulation provides faster treatment with more patient comfort



# Asia Growth Opportunity



- Good total growth over 4 years
- New distributor in China appointed late 2013
- China opportunity strong given current low level per-capita of cataract operation
- Regulatory issues require careful management

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%
<b>Total</b>	<b>22,218,120</b>	<b>100.0%</b>	

**Estimated 2013 Cataract Surgeries by Country**

*Source: Market Scope*



# Ellex 2RT™ Update

- Ellex 2RT™ 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.
- 2RT has shown good potential as a treatment for early stage AMD
- Age-Related Macular Degeneration (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 **112m** patients globally with no drug or device treatments currently approved for use.
- Ellex achieved a CE Mark for 2RT in early AMD in February 2014, allowing the device to be sold across EMEA, Australia, NZ and several SE Asian / South American countries that recognise the mark. Since then sales have been made to doctors in Europe and interest level is growing rapidly
- Established small in-house clinical support to gather data from early adopters and feed into case studies to aid commercial roll out
- 2RT presented for sale for the first time at Ellex booth at European Society of Cataract and Refractive Surgeons (ESCRS) and EURETINA Conference over 12 to 16 September 2014. Symposium talk by Dr Wilson Heriot attended by 200 doctors.
- **Outlook:**
  - Sales of 2RT expected to add to sales growth for the group in FY15



# 2RT™ – Clinical Program

## **LEAD trial being conducted CERA in Australia**

- Major clinical study called LEAD launched in Nov 2012. Multi-centre, double-blind, 1:1 randomised controlled study of high-risk bi-lateral intermediate AMD patients
- As of end August 2014: Recruitment at 171 patients across 6 sites.
- Interim outcomes on 18 month data available in H1 2016
- Final assessment of outcomes will be available 3 years after completion of recruitment

## **Other International Clinical trials**

Interest in 2RT has given rise to two new trials being planned/promoted at sites outside of Australia. Announcements on progress expected during FY15



# Outlook for FY15

## Important factors influencing outlook:

- Demand for SLT in the USA is expected to remain strong
- Interest in UltraQ Reflex for Vitreolysis is very strong as will contribute to year-on-year growth
- Production ramp up of Integre Pro
- Operating cost management
- Full year contribution from canaloplasty
- Sales of 2RT

## Outlook:

Subject to these important factors, growth in revenue is expected in FY15 compared with FY14 with improved profitability rates



END

