

# Ellex Medical Lasers

Investor Presentation  
for 12 months ended 30 June 2013

(prepared 10 September 2013)



# Ellex in a Snapshot

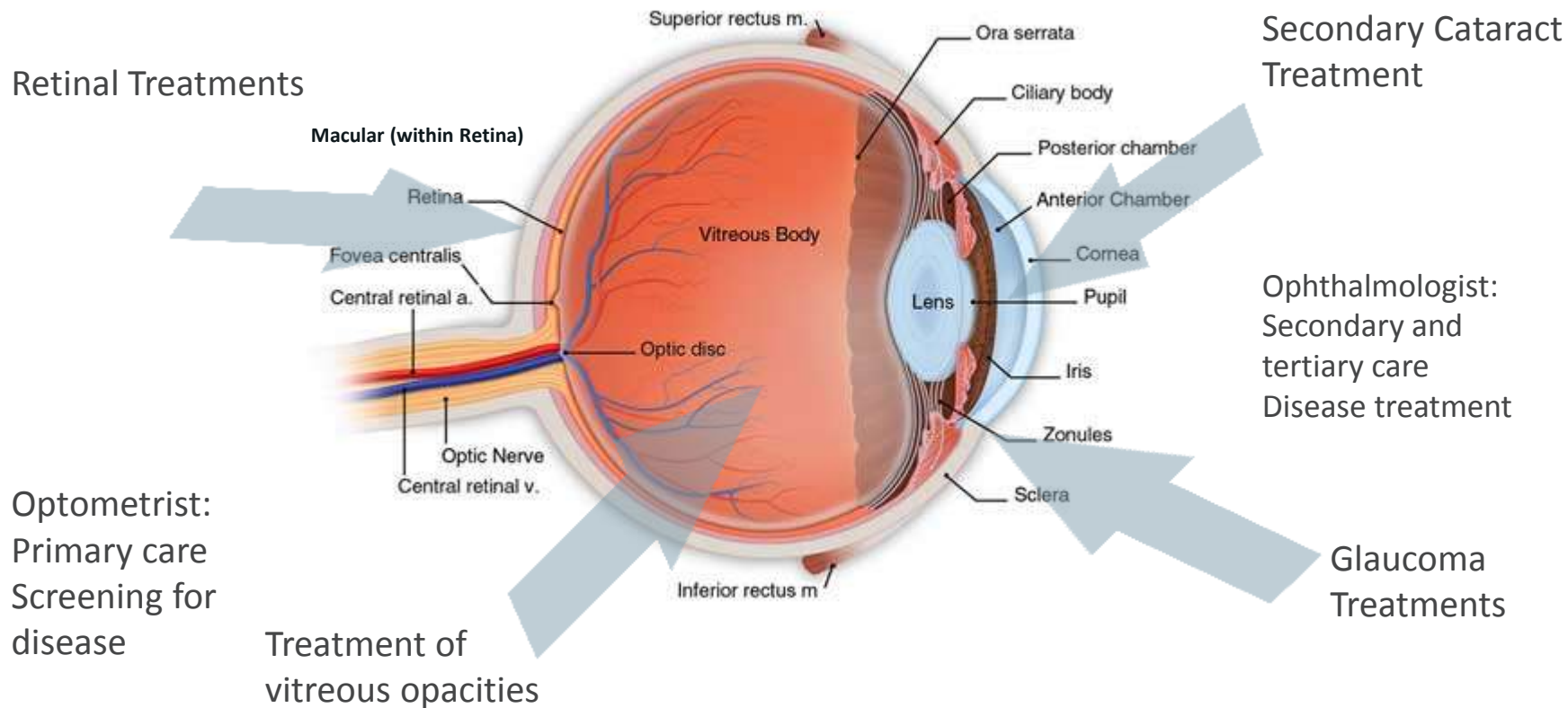
ASX-listed medical device company generating significant global revenues from ophthalmic products coupled with blue-sky potential from new products

- Globally competitive, innovative player
- Leading supplier in a large growing global market
- Ophthalmic laser market expected to grow at a **CAGR of 3.3%** from 2012-2017, 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
- Potential for growth beyond FY14 from new products offering new treatments for eye disease, geographic expansion and exploitation of device service and manufacturing capabilities and FX tailwinds YTD



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

For personal use only



One Powerful Vision

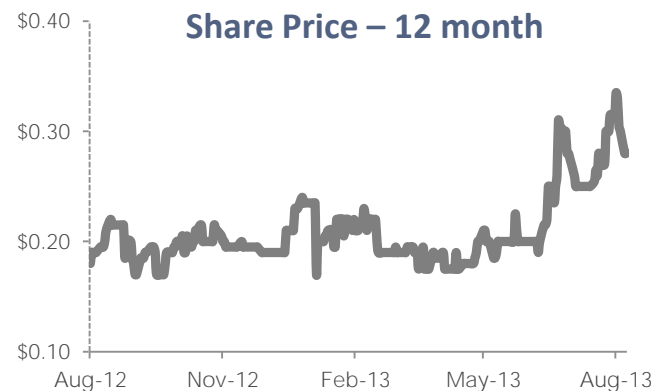
# Market and Financial Summary

For personal use only

Summary Financials			
Period	FY12A	FY13A	Change (%)
Revenue (\$m)	47.5	42.8	-9.9%
EBITDA (\$m)	3.1	1.7	-45.2%
EBIT (\$m)	1.5	0.4	-73.3%
<b>Reported NPAT (\$m)</b>	<b>0.9</b>	<b>(0.8)</b>	n/a
EPS (c)	1.1	(1.0)	n/a
<b>PER (x)</b>	<b>28.1</b>	<b>n/a</b>	
<b>EV/Sales (x)</b>	<b>0.7</b>	<b>0.8</b>	
<b>EV/EBITDA (x)</b>	<b>9.5</b>	<b>17.6</b>	
OCF (\$m)	1.8	1.9	5.6%
NTA Per Share (c)	19.8	17.3	-12.6%
<b>ROE (%)</b>	<b>2.9</b>	<b>(2.6)</b>	

Share Register	
Top 20	44.6%
Directors	24.3%
Ave. Mthly Volume (m)	1.0

Market Summary	
Shares on Issue	84.9m
Share Price @ 9 Sept 13	\$0.30
12 month Range	\$0.17-\$0.34
<b>Market Cap</b>	<b>\$25.5m</b>
Net Debt @ 30/6/13	\$6.6m
<b>Gearing (D/D+E)</b>	<b>19%</b>
<b>EV</b>	<b>\$30.4m</b>



# Diversified Products, Targeting Multiple Eye Diseases – Global Leader

For personal use only

MAJOR PRODUCTS	supera. ultraq.	ultraqreflex.	solitaire. integre.	tango. solo.	2RT	eyecubed.
Laser Type	Photodisruptor	Photodisruptor for vitreous	Photocoagulator	Selective Laser Trabeculoplasty (SLT)	Retinal Rejuvenation Therapy	Diagnostic ocular Ultrasound
Market	Secondary Cataracts	Laser Vitreolysis	Diabetic Macular Edema (DME), Diabetic Retinopathy (DR)	Glaucoma	DME, Age-related Macular Degeneration (AMD)	Imaging
Market Size (\$USm, p/a)^	50.3	new	249.1	46.2	249.1 (DME), AMD - n/a	~26 (2006 data)
5 Year CAGR (2017)^	-1.2% (refer further details)	new	4.0%	2.9%	n/a	n/a
Sales	Global	Global	Global	Global (US launched July 13)	Approved in US, EU (DME only)	Global
Reimbursement	Yes	Yes – well established	Yes – well established	Yes – well established	No (AMD) YES (DME)	Yes – well established

^ “2012 Comprehensive Report on the Global Ophthalmic Laser Market (excluding Excimer and Femtosecond lasers)” - Market Scope LLC



One Powerful Vision

# Ellex Milestones - FY13

- Major Developments Achieved for Proprietary Retinal Rejuvenation Therapy (Ellex 2RT™)
  - CE mark for Diabetic Macular Edema (DME) – the most common diabetic eye disease
  - “Early adopter” sales of 2RT
  - FDA 510(k) filed for DME in the US: cleared by the FDA early July
  - Commencement 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
  - Submission of 50 patient early AMD pilot study data to 12 months
- Manufacture agreement for portable handheld ultrasound devices with Signostics
- Launched 2 new product upgrades: The Ellex UltraQ Reflex™ for the underserved market of laser vitreolysis and a feature upgrade to the global best selling SLT laser the Ellex Tango™
- Launched 2 new products in the retinal business segment to keep step with evolving market trends: the Ellex Rapide™ pattern scanning photocoagulator & the Ellex Integre Pro™ multi-wavelength photocoagulator



# Financial Summary – P&L

	FY12	FY13
Sales (A\$m)	47.5	42.8
EBITDA (A\$m)	3.2	1.7
EBITDA Margin (%)	6.6	4.0
Earnings before tax (A\$m)	1.1	0.14

## Drivers of change against pcp:

- 45% increase in revenues (\$1m) from Asia in FY13 compared with pcp due to enhanced marketing efforts and stronger distributor management
- 75% improvement to \$2.8m in service and contract manufacturing revenue
- Gross margin % improvement associated with higher mix of Ellex-manufactured product sales vs third party product sales compared with pcp
- Culture of cost containment: lower operating costs (down 2%) , including reduction in employee costs, despite new investment in US business in support of SLT launch for FY14
- Depreciation of YEN against AUD reduced revenues by approximately \$1.2m
- High sales in Australia of retinal cameras to optometry sector in pcp (approx. 300 optometry store installations in FY12 – non recurring – impact \$3.5m)



# Geographic Segments – 1H, 2H Sales

For personal use only

	1H12	1H13	Change
Australia	7.7	4.6	-40%
USA	6.0	4.4	-35%
EMEA	5.7	5.0	-12.2%
Japan	6.7	5.9	-12.0%
Asia	1.3	1.8	38%
South America	0.3	0.3	-
	<b>27.7</b>	<b>22.0</b>	<b>-21%</b>

- Retinal camera sales in Australia and USA not repeated in FY13
- In USA, high December 2012 quarter sales prior to Jan 2013 reimbursement changes
- Sales down in EMEA with economic uncertainty

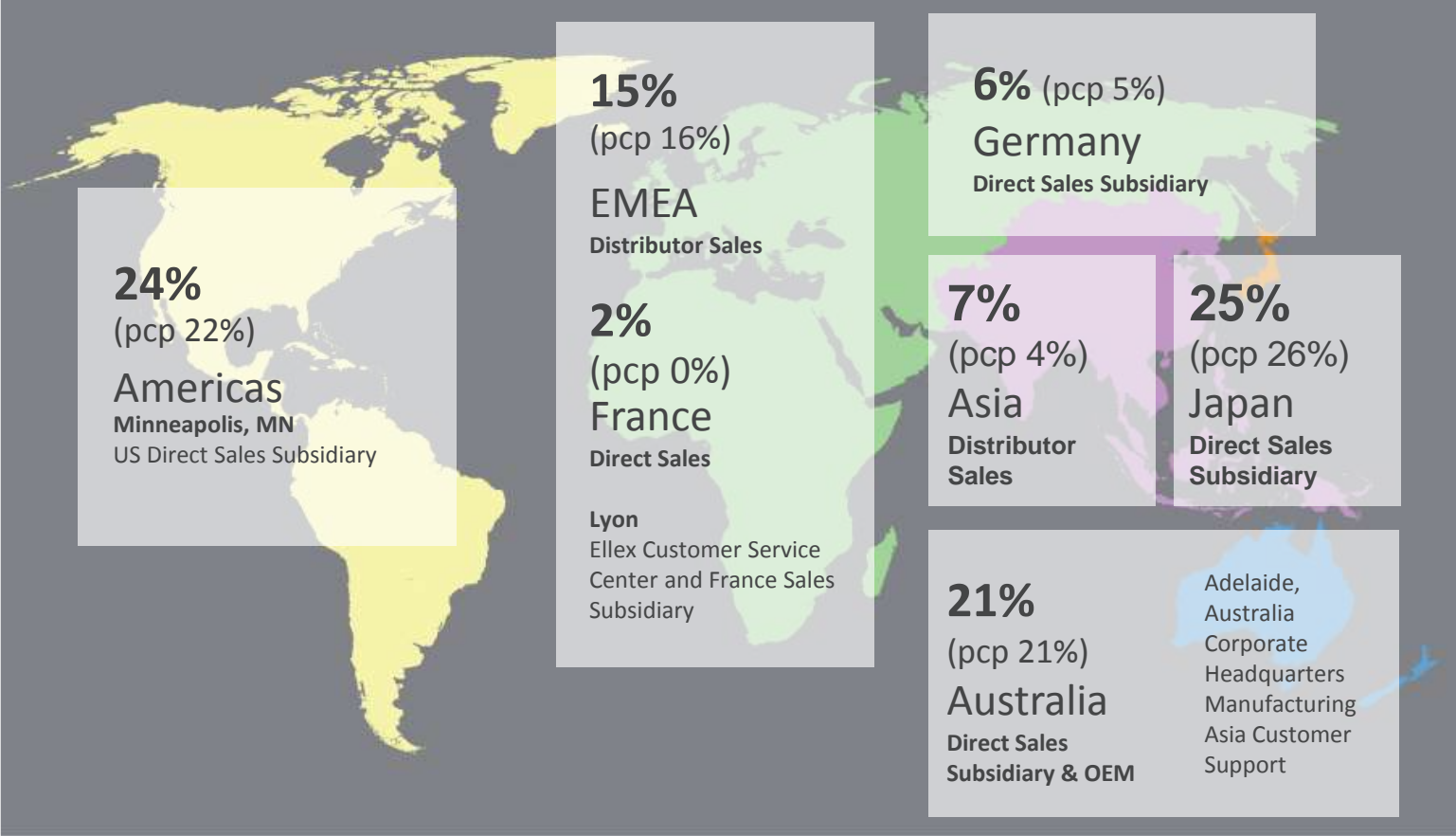
	2H12	2H13	Change
Australia	4.9	5.0	2%
USA	3.9	4.1	6%
EMEA	4.0	4.9	19%
Japan	5.5	4.8	-15%
Asia	1.0	1.5	31%
South America	0.7	0.5	-
	<b>19.8</b>	<b>20.8</b>	<b>5%</b>

- Strong marketing and selling effort in Europe in emerging economies
- Improvement in service and contract manufacturing revenues in Australia and USA
- Application of additional marketing and selling support in Asia
- Early impact of new product laser vitreolysis
- These positives were offset by fall of Japanese YEN against the A\$





# Global Revenue – Geographic Diversity



# Financial Summary – Balance Sheet

ASSETS	FY12 (A\$m)	FY13 (A\$m)
Cash	1.8	0.8
Trade receivables	9.4	10.5
Inventories	14.9	16.1
Product development	6.6	8.3
Deferred tax asset	7.9	7.1
PPE and other assets	4.4	4.6
<b>Total Assets</b>	<b>44.9</b>	<b>47.3</b>

- Inventory increase in support of new products
- Increase in receivables due to higher-than-pcp June sales
- Product development up with new product spend

# Financial Summary – Balance Sheet (cont.)

LIABILITIES	FY12 A\$m	FY13 A\$m
Trade creditors	2.5	6.5
Borrowings current	3.8	6.4
Borrowings non current	4.1	1.0
Employee provisions and other liabilities	2.6	2.7
<b>Total Liabilities</b>	<b>12.9</b>	<b>16.5</b>

- Scheduled debt repayments made
- Creditors up with inventory build
- Support from Bankers

# Financial Summary – Cash Flow

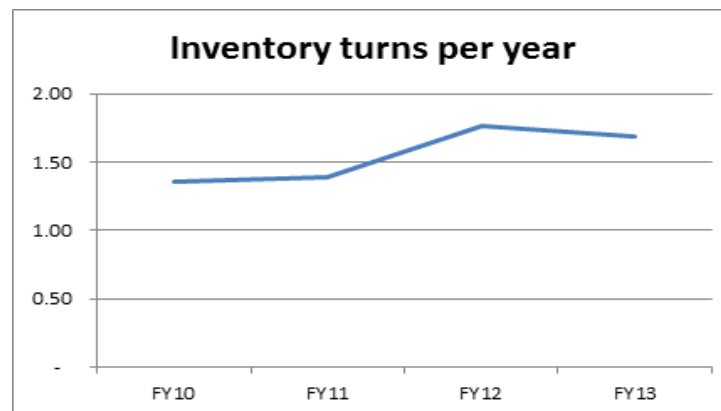
During FY13 \$1.9m of cash from operations (up from \$1.8m pcp) to fund:

- Capitalised development (new products)
- Build up of inventory for new product launch and SLT in USA and contract manufacturing
- Scheduled debt repayments
- PPE to support new production equipment for contract manufacturing and new products
- Working capital continues to fall (\$17.3m v \$19.1m in pcp) – releasing cash

Culture of cost control provided operating cost reduction

Inventory turns have fallen compared with last year in support of new products = usage of \$0.8m of cash

CASH FLOWS	FY13 A\$m	FY12 A\$m
Operating Cash Flows	1.9	1.8
Investing - PP&E	(0.6)	(0.2)
Cap. Development Costs	(2.2)	(1.4)
Financing Cash Flows	(0.8)	(0.05)
<b>Net Cash Flow</b>	<b>(1.8)</b>	<b>0.3</b>



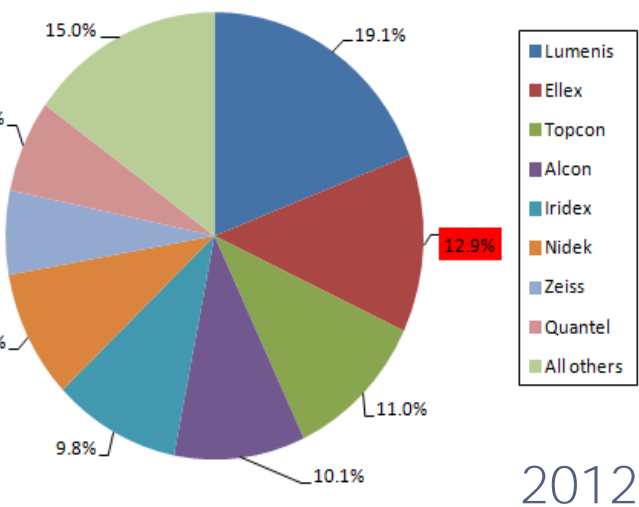
# Interest in Ophthalmic Lasers Growing

- Abbot (NYSE: ABT) acquisition of Optimedica Corporation for US\$250m upfront and further US\$150m in earn out
  - Femtosecond cataract surgery market (ELX does not compete in this market)
  - FDA approved 3Q 2012, CE Mark 1Q 2012
  - Limited Sales
  - Recognition of rapid growth in laser cataract surgery market
- Bausch and Lomb acquires Technolas Perfect Vision in 4Q CY12
  - Undisclosed buy-out of JV
  - Femtosecond cataract surgery platform
  - Bausch and Lomb acquired by Valeant (NYSE:VRX) in 3Q CY13 for US\$8.7b
- Solid 12 month performance of listed ophthalmic companies, multiple expansion
  - Ellex, Iridex, Topcon



# Ellex Estimated Market Position & Comp

Share of global ophthalmic laser market



2012

Glaucoma Laser	Secondary Cataracts Laser	Laser vitreolysis	Diabetic Retinopathy Laser	Diagnostic Ultrasound	AMD laser
Ellex	Ellex	Ellex	Ellex	Ellex	Ellex
Lumenis	Lumenis		Lumenis		
Quantel	Quantel		Quantel	Quantel	
	Zeiss		Iridex		
	Nidek		Nidek	Nidek	
			Valon		
			Topcon		
Lightmed	Lightmed		Lightmed		

**Good Opportunity in USA**

**Good Opportunity**

**Major Opportunity**

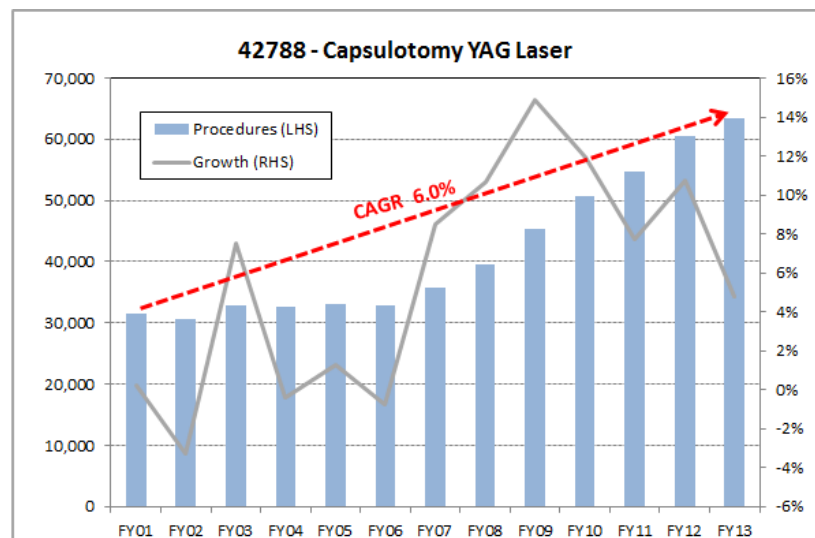
- Ellex and two other players entered the US Glaucoma Market in July following Lumenis patent expiry
- Different levels of competition in different markets
- New laser vitreolysis treatment product shows good potential



# Market Size and Growth – Photodisruption

For personal use only

- 10% to 35% of all cataract procedures give rise to photodisruptor procedures. These procedures require Ellex's photodisruptor lasers – SuperQ™ (standard), UltraQ™ (premium)
- Ellex Photodisruptors are the global leading brand of lasers for secondary cataract treatments
  - Fast, painless
  - Well established reimbursement across all major markets
  - No threat from drug based approaches
- Australian Medicare trend indicative of global trend
  - CAGR 5.1%
  - Ellex SuperQ™ has been the leading photodisruptor since 1996
  - Cataract will continue to show strong increase due to the ageing of the global population



Source: Medicare Australia



One Powerful Vision

# Market Size and Growth – Laser Vitreolysis

- UltraQ Reflex™ also known as the Ellex Floater Buster - floaters are collagen fibre clumps causing spots, strings or cobwebs over the retina.

Common age-related problem – v. limited treatment options

- Vitreous detachment: **25%** of 60 year olds, **60%** of 80 year olds
- Disability considered worse by patients than diabetic retinopathy, Glaucoma and = to AMD
- Size and growth directly related to other Ellex markets

Laser vitreolysis is the application of nanosecond pulses of light to disrupt the collagen causing the floaters – With the UltraQ Reflex™, Ellex has overcome equipment limitations that have hindered treatment options

Reimbursement, efficacy and solid economics:

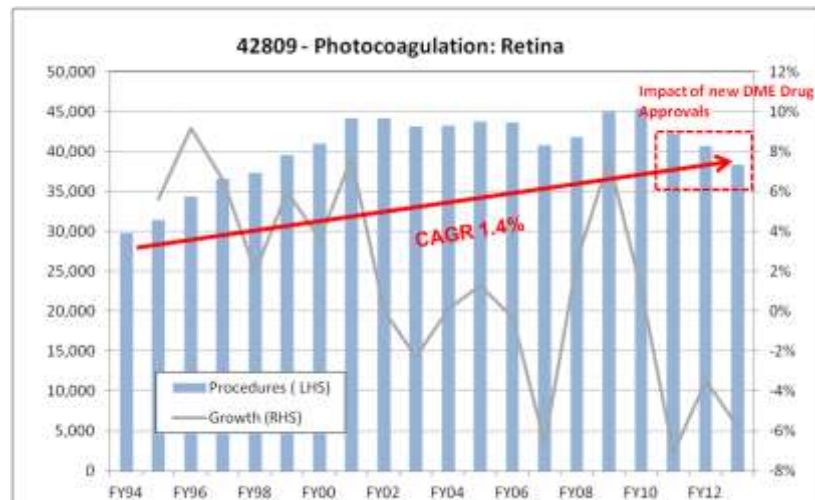
- Code in place in most jurisdictions though it has not often been used (628 times in Australia in 2012) . US CPT 1 Code 67031 in place .
- Peer reviewed clinical publications have shown 80-90% improvement with YAG laser.
- Preliminary market research suggest using UQ Reflex™ for 5 to 7 procedures per week could achieve an investment payback of 20 weeks.





# Market Size and Growth – Photocoagulation

- Ellex Integre™ and Solitaire™ key products
- Photocoagulator lasers are an **gold standard** treatment for diabetes-related eye disease
  - Well established reimbursement across major markets
- Recent new drug approvals have caused a decline in photocoagulation procedures in Australia, based on Medicare data
- Australian Medicare trend of CAGR 1.4% below global trend expectations of 4.0% CAGR to 2017
  - Driven by growing rates of diabetes in developed and the developing world
- Ellex developed two new products during FY13, the Integre Pro™ and Rapide™ platform to keep step with evolving market trends. Sales commenced during July/August FY14.



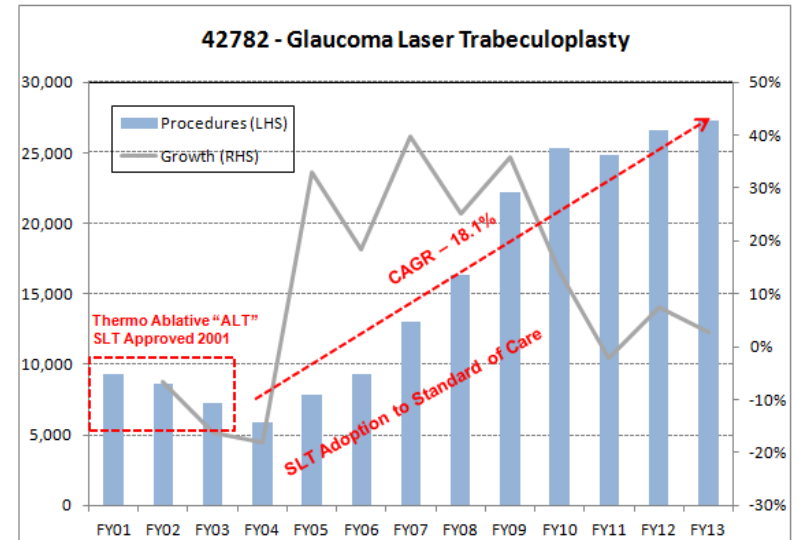
Source: Medicare Australia



# Market Size and Growth – SLT

For personal use only

- Ellex holds a 42% global (ex-US) share in glaucoma laser market – Tango and Solo key products.
- SLT is an emerging **gold standard** treatment for primary open angle glaucoma
  - Very strong evidence of effect, tissue sparing
  - Well established reimbursement across major markets
  - Recommended front-line therapy in the US, parts of EU
  - Equivalent in pressure lowering effects to drug approaches (eye drops, 1-2x daily required) less side effects
  - Low cost, rapid, pain-free, no compliance issues, repeatable = very cost-effective
- Medicare CAGR FY04-FY13 of 18.1%, growth moderated in recent years. Global CAGR to 2017 – 2.9% anticipated.
- Ellex entered USA glaucoma market in July following expiry of Lumenis patent: annual US market size estimated to be growing to US\$13-\$14m



Source: Medicare Australia



One Powerful Vision

# USA SLT Launch – Excellent Progress

- Strong presence at major US ophthalmic conferences – indicative interest v. strong
- Direct US sales force increased and training complete
- Superb channel synergies – ophthalmologists know Ellex brand well, leverage off existing sales force, cross-selling opportunities
- Competitors have also entered the market: Quantel and Lightmed
- July and August 2013 sales have been in line with our plan.
- USA SLT expected to be a strong contributor to FY14 revenue growth and beyond



# Opportunity in China

- Market Scope estimates a CAGR of 9.1% over 2012 to 2017
- Driven by age and improving standards of care
- Statistics on cataract surgery are a leading indicator of subsequent demand for secondary cataracts, glaucoma and vitreous opacities treatments
- Ellex has experienced rising demand in China and the rest of Asia

## Opportunity:

Population of India is slightly smaller than population of China yet 4x more cataract surgeries are being performed in India. This will change as China develops.

**Estimated 2012 Cataract Surgeries by Country**

Country	Cataract Surgeries	Percent of Total Cataracts
1. India	6,045,284	29.2%
2. United States	3,436,080	16.6%
3. Japan	1,314,260	6.4%
4. China	1,260,000	6.1%
5. Germany	884,340	4.3%
6. Brazil	836,000	4.0%
7. France	658,000	3.2%
8. Italy	548,000	2.7%
9. Russia	385,653	1.9%
10. UK	375,000	1.8%
11. Canada	369,421	1.8%
12. Spain	334,273	1.6%
13. South Korea	326,510	1.6%
14. Mexico	274,429	1.3%
15. Australia	200,510	1.0%
16. Vietnam	178,084	0.9%
17. Pakistan	152,548	0.7%
18. The Netherlands	150,985	0.7%
19. Taiwan	150,309	0.7%
20. Indonesia	148,066	0.7%
21. Saudi Arabia	146,722	0.7%
22. Poland	109,128	0.5%
All Other Countries	2,395,561	11.6%
<b>Grand Total</b>	<b>20,679,163</b>	<b>100%</b>

Source: Market Scope



# Ellex 2RT™ – DME and AMD opportunities

Ellex 2RT™ 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™ 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:** CE Mark (Europe) July 2012, FDA 510(k) cleared July 2013

Ellex 2RT™ 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
- Training complete
- Strong interest to date
- Leverage for AMD trials pathway

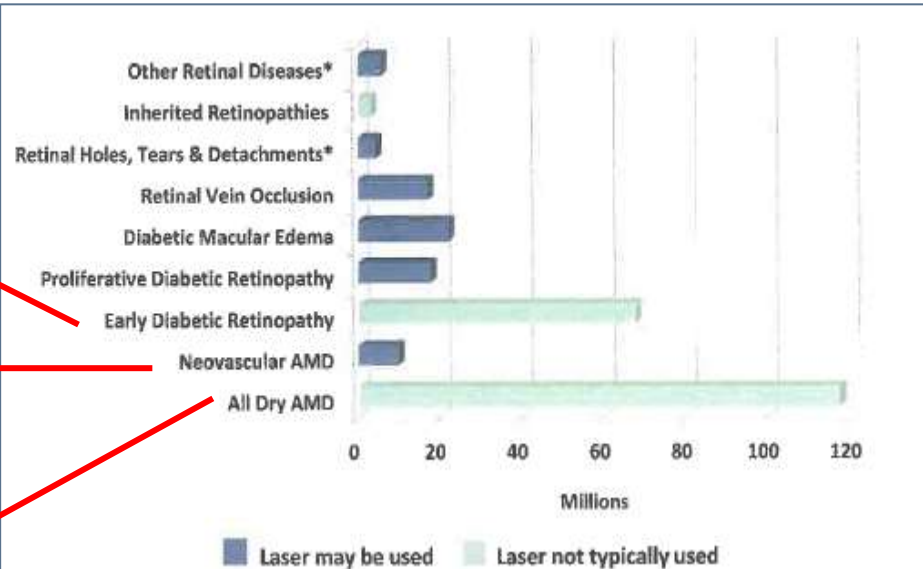


# Ellex 2RT™ for Early AMD – Game Changing Potential

- 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

Potential market for 2RT™, given non-thermal, tissue sparing effects

Wet AMD – 1/10<sup>th</sup> of Dry Market,  
Two Approved Drugs had 2012 sales of US\$2.4 billion



Source: Market Scope, LLC

> ~6 fold mkt potential than DME  
> ~7 fold mkt potential than DR

For personal use only



# Ellex 2RT™ AMD Clinical Program Update

- 50 patient pilot data on early AMD patients showed promising results at 12 months, with majority showing some visual improvement and drusen reduction – no safety issues identified
  - 12 month data has been submitted for publication
  - Forms basis of CE mark in Europe for early AMD
- 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 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
  - 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
- Ellex plans to commit additional resources to the LEAD study
  - Recruitment now past 50 patients
  - Two further Australian clinical sites up and running
  - Additional sites in US and Europe under negotiation
  - **Acceleration in recruitment expected to result**



# Expanded Ellex Product Range FY14

For personal use only

Treatment Area	New for FY14
Photodisruptor for vitreous opacities	Ultra Q Reflex for treatment of vitreous opacities. Hitherto hard-to-treat or difficult-to-treat
SLT for treatment of glaucoma	Tango with enhanced viewing optics and laser power optimisation
Photocoagulator for treatment of retina (mainly diabetes related)	<ul style="list-style-type: none"> <li>Integre Pro – multi wavelength for multiple treatment options on a single platform</li> <li>Rapide – pattern scanning for faster, lower-trauma treatment</li> </ul>
Diagnostic Ultrasound	Improvements to core Eye Cubed technology including interface to electronic medical records
2RT™ treatment of the retina <u>for diabetes-related disease</u>	Limited commercial release of 2RT for photoreceptor-sparing treatment of diabetes related macula oedema

- More new products than at any time over the last 5 years
- Capital equipment focus which is sensitive to economic conditions and cyclical
- Augment capital equipment revenue flows with recurring revenue streams from consumable ophthalmic products using existing distribution channels





# Outlook

- **Key Significant Milestones including**
  - Publication of 12 month AMD data for 2RT™
  - CE Mark (European Approval) for 2RT™ in AMD: **potential world first**
  - Acceleration of recruitment for LEAD AMD RCT
  - Update on SLT progress in US Market
  - Update on 2RT™ progress in USA
- **Meaningful top-line growth anticipated in FY14, driven by**
  - SLT launch in the US
  - New products
  - Enhanced contract manufacturing /technical service revenues – up \$1m in FY13, growth to continue
  - FX – AUD v USD/EUR/JPY/GBP
  - Geographic expansion particularly China
- **Meaningful improvement in EBITDA and NPAT also anticipated**

