

## ASX RELEASE

Ellex Medical Lasers Limited (ASX:ELX)

Adelaide, Australia

Date: 26 February 2016

Release: Immediate

Topic: Ellex Financial Report for Half-Year ended 31 December 2015



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### Highlights:

- Revenues up by 13% on pcp to \$34.8m
- Profit before tax up by 36% on pcp to \$1.8m
- Fourth consecutive increase in first half profits and margins
- Growth expected to continue in second half and beyond

**Adelaide, Australia, 26 February 2016** – Ellex Medical Lasers Limited (ASX:ELX), a world leader in medical technologies for the diagnosis and treatment of eye disease, today released its financial results for the half year ended 31 December 2015. Ellex reported a profit before tax of \$1.8m compared with \$1.3m in the prior corresponding period. The result was struck on revenue of \$34.8m which was 13% higher (\$4.1m) than the prior corresponding period.

The revenue increase has 3 separate components:

- Positive impact of organic growth in sales of Ellex-branded product in USA, Europe and Japan of 11% (A\$3.4m)
- Positive impact of lower Australian dollar against US\$, Euro and YEN 13% (A\$4.1m)
- Discontinuation of contract manufacturing and lower margin third party product sales along with reduction in other third party product sales that has reduced revenue by 11% (A\$3.4m)

Commenting on the improved sales CEO Mr Tom Spurling said “It is very pleasing that our growth has been driven by contributions from our in-house developed Ellex branded products not just the lowering of the value of the Australian dollar.”

### **Profit before tax**

The increase of 36% in profit before tax has been driven by the increased brand equity of the latest generation of Ellex-branded products. The profit before tax of A\$1.8m has been negatively impacted by the following new operating expenses, which will benefit the second half of FY16 and beyond:

- Investment in iTrack growth initiatives and start-up of a dedicated sales force in USA (approximately A\$0.3m)
- Investment in additional regulatory resources to support the rollout of Integre Pro Scan™ in the USA (FDA approval achieved August 2015) and Japan (Japan FDA approval achieved December 2015) and to renew registrations for certain products in China (approximately A\$0.3m)

Mr Spurling added “This is the fourth consecutive increase in first half profits and margins. We are achieving this in 3 ways; geographical expansion, producing new products with features that allow doctors to upgrade with our products and developing new customers and markets with innovative products that treat disease and conditions hitherto untreated with devices.”

### **Outlook for FY16**

Finally, commenting on the outlook for the remainder of the 2016 fiscal year Mr Spurling stated, “Revenue and earnings have grown nicely in the first half of FY16 and, subject to FX rates and global economic conditions, we expect that the growth achieved will be sustained through to the end of FY16 after allowing for prudent investment in sales and marketing for FY17 growth opportunities, particularly of iTrack in the USA.”

See attached Trading Update Presentation for additional information on regional and product trends.

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## **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](http://www.ellex.com)

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# Ellex Medical Lasers

## Investor Presentation

for the six months ended 31 December 2015  
(prepared 26 February 2016)



Ellex makes and sells innovative products that help eye surgeons around the world to effectively and efficiently treat eye disease; this is one powerful vision



One Powerful Vision

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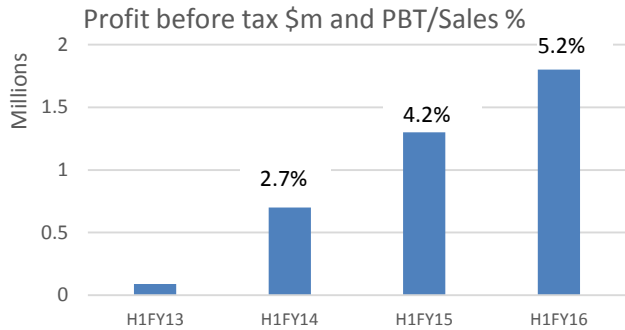


# Overview - 1H FY16 Result

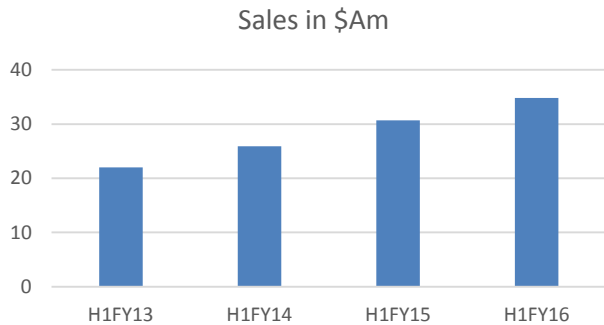
- Ellex delivers record result - 4<sup>th</sup> consecutive increase in 1H profits and margins
- Adjusted\* PBT of \$2.4 million - up 71% on 1H FY15  
(\* Adjusted PBT – Adjusted for new operating expenses that will benefit future periods)
- 1H FY16 Sales of A\$34.8m - up 13% on 1H FY15
- 1H FY16 Profit Before Tax (PBT) of A\$1.8 million – up 36% on 1H FY15
- Current Result driven by new product development & growth around core business
  - Ultra Q Reflex™ & Integre Pro Scan™
- Positioned for Growth – already cash generative & with low gearing
  - contributions from Ellex’s transformational opportunities (iTrack™, 2RT™ and SLT Glaucoma treatment in China and USA) are just starting - they will each make their mark on future periods
  - Move to larger, company-owned manufacturing site in late CY16 is strategically important and delivers required capacity increase (circa 50% immediate & with expansion options at site for more)



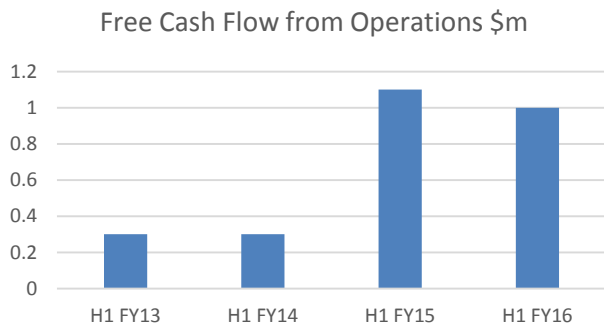
# Highlights for first half of FY16



- Third year of PBT increase and percentage margin increase, PBT CAGR >100% over 4 years
- Absolute profit improvement from increase in sales revenue
- Expanded percentage margin from improved sales of higher margin Ellex product and discontinuation of less profitable contract manufacturing and third party lines
- Profit before tax negatively impacted by investment in sales growth for iTrack™ and new regulatory expenses



- CAGR of 12% is well above independent assessment of market growth of 4.5%
- The components; growth in revenue from Ellex branded products of \$3.4m (11% on PCP), positive impact of lower A\$ of \$4.1m (14% on PCP) and lowered revenue from discontinuation of contract manufacturing and lower-margin third part product sales along with reduction in other third party product sales
- Good growth from lasers for treating vitreous floaters and diabetic retinal disease



- Free cash flow from operations equals cash flow from operation less property plant and equipment spend and less product development spend.
- Slight reduction in FCF from operations due to relatively higher December 2015 sales.
- Free cash used to repay debt. Net debt at 31 December 2015 is now \$1.0m (\$2.2m at 30 June 2015)
- Inventory turns rise again for the fourth year in a row and has released \$1.2m of cash in the last 18 months



# Market and Financial Summary

Summary Financials			
Period	1H FY15	1H FY16	Change (%) FY15 to FY16
Revenue (\$m)	30.7	34.8	+13%
EBITDA (\$m)	2.7	3.5	+30%
Amortisation and Depreciation, interest and implied interest	1.3	1.7	+31%
PBT (\$m)	1.3	1.8	+36%
Reported NPAT (\$m)	0.8	1.2	+50%
EPS (cents per share)	0.75	1.08	+44%
OCF (\$m)	2.6	2.8	+8%
FCF from operations (\$m)	1.1	1.0	-9%
NTA Per Share (c)	17.0	20.0	+18%

Market Summary	
Shares on Issue	107.6m
Share Price @ 24 Feb 2016	\$0.73
Market Cap	\$78.6m
Net Debt @ 31/12/15	1.0
Gearing (D/D+E)	11%
EV (\$million)	\$79.6m

Share Register as at February 2016	
Top 20	47%
Directors and Management	20%





# Balance Sheet

ASSETS	31 Dec 14	30 June 15	31 Dec 15
Cash	3.9	4.6	4.2
Trade receivables	11.2	12.5	12.9
Inventories	18.4	16.3	16.0
Product development capitalised	10.2	10.7	11.2
Deferred tax asset	6.3	5.8	5.3
PPE, iTrack™ deferred consideration and other assets	8.0	9.1	9.7
<b>Total Assets</b>	<b>58.0</b>	<b>59.0</b>	<b>59.3</b>

LIABILITIES	31 Dec 14	30 June 15	31 Dec 15
Trade creditors	6.6	5.8	5.8
Borrowings	6.4	6.8	5.2
Deferred consideration	3.2	3.4	3.2
Provisions + Other	3.5	3.2	3.7
<b>Total Liabilities</b>	<b>19.9</b>	<b>19.2</b>	<b>17.9</b>

- Increase in receivables due to very high December 2015 sales compared with December 2014
- Inventory reduction from better management
- Increased capitalised product development costs reflects new product investment, net of amortisation
- Net debt reduced from \$2.2m at 30 June 2015 to \$1.0m
- Value in \$A of deferred consideration due to vendors of iTrack™ business has increased with lower \$A against US\$



# Free Cash Flow from operations

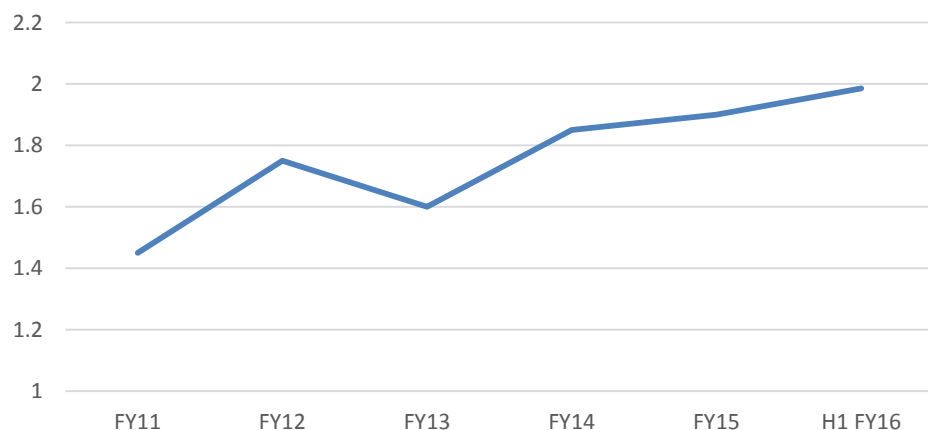
Net free cash flow (FCF) from operations only in line with PCP due to high December 2015 sales.

Cap'd development costs in line with PCP and include 2RT "LEAD" clinical trial of \$0.4m per year

Inventory turns improvement continues into 4<sup>th</sup> consecutive year.

PPE investment in additional production facilities to meet growing demand.

Inventory Turns Per Year



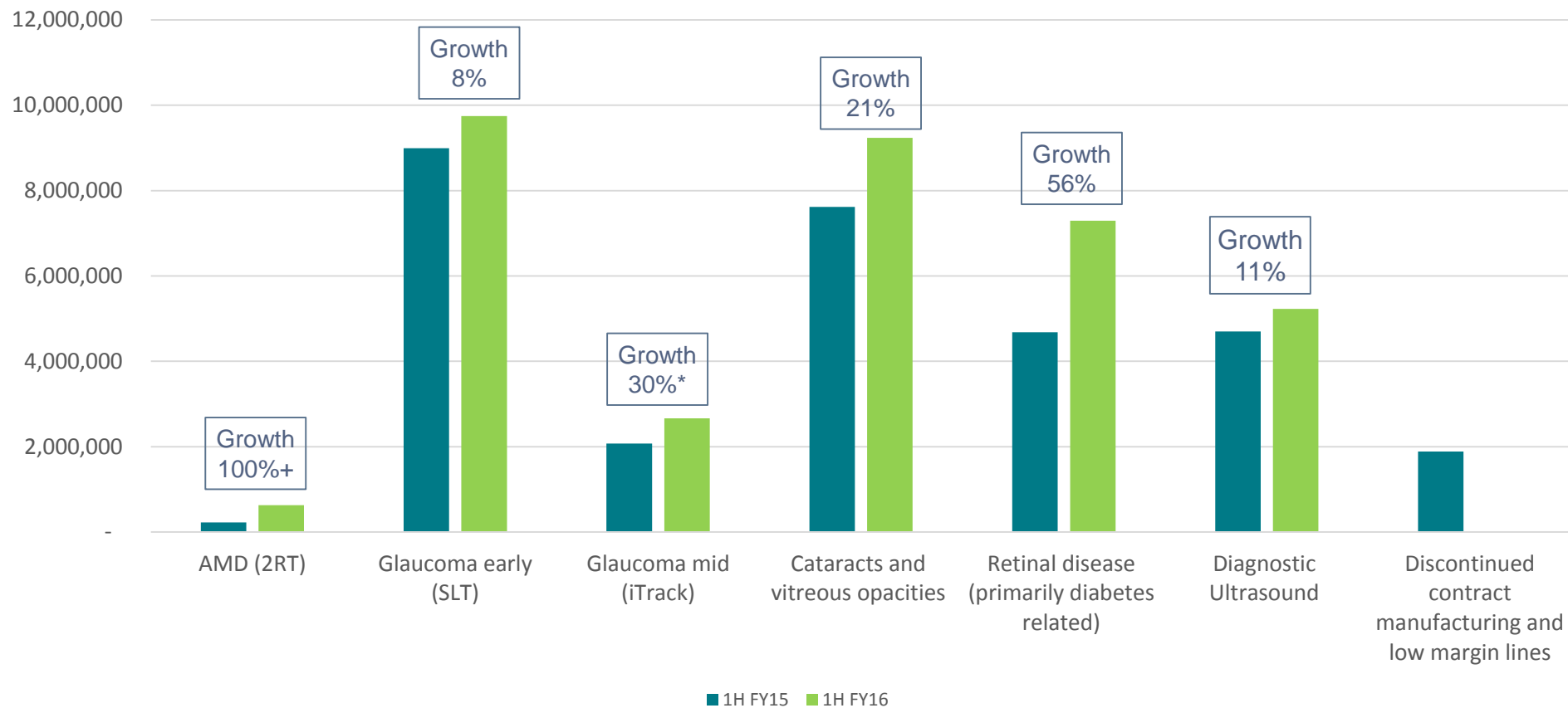
Improvement in stock turns has released approximately \$1.2m of cash over the last 18 months

CASH FLOWS	1H FY13 A\$m	1H FY14 A\$m	1H FY15 A\$m	1H FY16 A\$m
Operating Cash Flows	1.8	1.3	2.6	2.8
Investing - PP&E	(0.3)	(0.1)	(0.3)	(0.5)
Cap. Development Costs	(1.2)	(0.9)	(1.2)	(1.3)
<b>Net free cash flow (FCF) from operations</b>	<b>0.3</b>	<b>0.3</b>	<b>1.1</b>	<b>1.0</b>
Acquisition of business	-	(1.6)	-	-
Debt (repayments)/proceeds	(0.3)	(1.2)	0.5	(2.4)
Proceeds of share issue	-	5.9	-	-
<b>Net Cash Inflow/(Outflow)</b>	<b>-</b>	<b>3.4</b>	<b>1.1</b>	<b>(1.4)</b>



# Sales by category of Eye Disease

Revenue by Eye Disease H1FY15 vs 1H FY16 (A\$)\*\*



\* iTrack™ USA sales 69% (pcp 60%) of total and are 47% up on pcp

\*\* Approximately half of the growth for each eye disease category relates to the lower A\$ against all major currencies compared with pcp



# Sales by Region over time

	1H FY13 A\$m	1H FY14 A\$m	1H FY15 A\$m	1H FY16 A\$m	Change on PCP
Australia	4.5	4.7	5.9	4.0	-32%
USA	4.4	9.6	10.0	14.1	+41%
EMEA*	5.1	4.3	7.4	8.2	+11%
Japan	6.0	4.7	3.9	4.2	+8%
Asia	1.7	1.9	2.3	3.5	+52%
South America	0.3	0.7	1.3	0.8	-38%
TOTAL	22.0	25.9	30.7	34.8	+13%
<b>Recurring Ellex-branded consumables &amp; service component</b>	<b>1.1</b>	<b>1.9</b>	<b>4.0</b>	<b>5.0</b>	<b>+20%</b>

- Primarily includes discontinued contract manufacturing and lower margin third party product sales

- Improved sales of Ellex brand SLT, Ultra Q Reflex™ and ultrasound
- Growth in iTrack™
- Lower A\$ against US\$

- Better sales of Ellex brand Integre Pro Scan™ Ultra Q Reflex™ and ultrasound
- Small positive impact of lower A\$ against EURO

- Better sales of Ellex brand SLT laser and ultrasound
- Small positive impact of lower A\$ against YEN

- Continued growth in demand particularly Ultra Q Reflex™, some positive FX impact

- Health care spending in this market is particularly sensitive to Government revenue from oil sales

CAGR of revenue FY13 to FY16 is 12%

\* Europe, Middle East and Africa



# Japan Business Update

	1H FY13	1H FY14	1H FY15	1H FY16
Sales in Japan in A\$	\$6.0m	\$4.7m	\$3.9m	\$4.2m
Percentage of Sales Complementary Third Party Product	21%	30%	46%	15%
Percentage of Sales Ellex Brand	79%	70%	54%	85%

- Rectification of this underperforming territory has made progress but is not yet complete.
- Efforts in Japan have resulted in strong increase in sales of higher-margin Ellex-branded product.
- Efforts now focussed on optimisation of sales structure vs cost. Includes closure of regional sales office in Osaka and territory redistribution.
- Japan result was a "drag" on the bottom line result for 1H FY16 by an amount equivalent to 1H FY15.
- Approval to sell Integre Pro Scan™ received from Japanese authorities on 18 December 2015 will provide a sales boost in H2.



# Impact on PBT of new operating expenses

	1H FY15 \$m	1H FY16 \$m
Estimated profit before tax (reported)	1.3	1.8
<ul style="list-style-type: none"> <li>Investment in iTrack™ sales force in USA over October to December 2015</li> </ul>	-	0.3
<ul style="list-style-type: none"> <li>Investment in additional regulatory work for new products in USA (September 2015 FDA approval Integre Pro Scan™), Japan (December 2015 approval Integre Pro Scan™) and China</li> </ul>	0.1	0.3
<b>Estimated PBT adjusted for new operating expenses</b>	<b>1.4</b>	<b>2.4</b>
<b>% of sales</b>	<b>4.7%</b>	<b>6.9%</b>
<b>Growth</b>		<b>71%</b>



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# Ellex - An important participant in a global market greater than US\$10bn per annum

- 80 million people in the world with **glaucoma** (global spend on pharma and devices per year US\$4.6 billion)
- 105 million people in the world with **retinal disease related primarily to diabetes** (global spend on pharma and devices per year US\$1.5 billion)
- **24.4 million cataract** operations per year in the world (global spend on pharma and devices per year US\$3.3 billion)
- 118 million with **early stage age-related macular degeneration** (global spend at least US\$5.1 billion almost exclusively pharma).



The Ellex mission is to make and sell innovative devices that help eye surgeons around the world to effectively and efficiently treat these eye diseases.

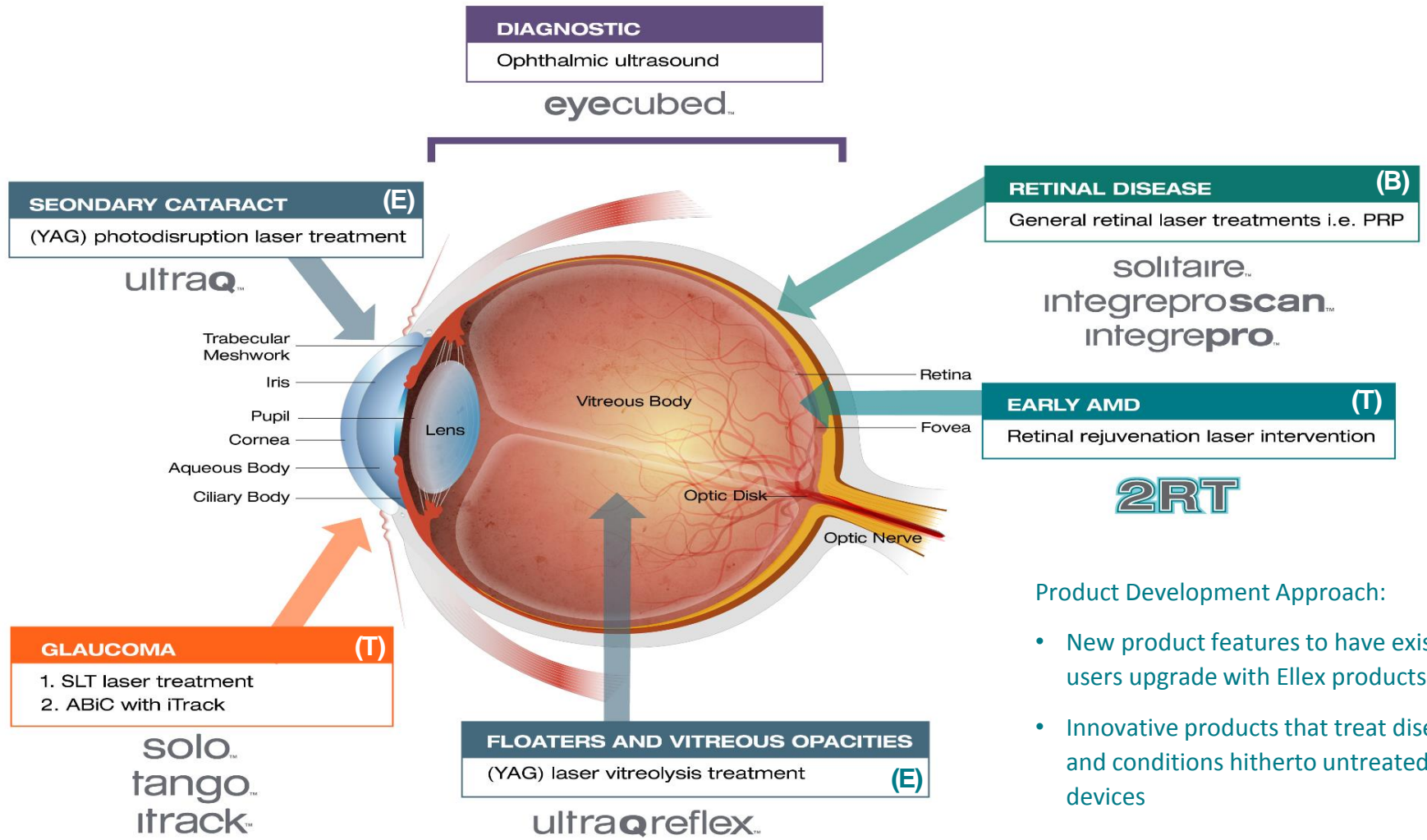


- We grow our business and increase our margins by:
- geographical expansion
  - producing new products with features that allow existing doctors to upgrade with our products
  - developing new customers and markets with innovative products that treat disease and conditions hitherto untreated with devices





# ELLEX – OPHTHALMIC PRODUCTS



## Product Development Approach:

- New product features to have existing users upgrade with Ellex products
- Innovative products that treat disease and conditions hitherto untreated with devices



# Large Market Potential

Disease	Current Ellex Devices	Total annual spend on disease treatment with pharma and devices	Current device-market accessible to Ellex <sup>(2)</sup>	Assessed device-market position against listed peers <sup>(1)</sup>
Glaucoma – early stage	SLT with Tango™, Solo™	US\$4.6 billion <sup>(1)</sup>	US\$60 million (CAGR 4.5% plus more with pharma replacement)	1. Ellex 2. Lumenis (LMNS:NASDAQ)
Glaucoma – later stage	iTrack™ (approx. US\$50m invested prior to acquisition by Ellex)		US\$90 million growing to circa US\$700m by 2020 (CAGR 44%)	1. Glaukos (GKOS:NYSE) 2. Ellex
Cataracts and Vitreous Floaters	Ultra Q™ and Ultra Q Reflex™	US\$3.3 billion plus 24 million cataract operations per year <sup>(1)</sup>	US\$65 million (CAGR 4.5% plus more with vitreous floater treatment)	1. Ellex 2. Lumenis
Diabetic Disease of Retina	Integre Pro™ and Integre Pro Scan™	US\$1.5 billion <sup>(3)</sup>	US\$305 million (CAGR 4.5% plus more with pharma replacement )	1. Iridex (IRIX:NASDAQ) 4 or higher. Ellex (probably lifted in 1H FY16)
Early-Stage AMD and Clinically Significant Macula Edema	2RT™	US\$5.1 billion <sup>(4)</sup> (CAGR 7%) in just 7 major economies	<u>Emerging</u> - market will be a function of the current annual spend of US\$5.1b	1. Ellex (assessed by ELX)

(1) MarketScope LLC Reports, (2) Combination of Ellex estimate and MarketScope LLC Reports (3) “Global Diabetic Retinopathy Market 2015 to 2019” Technavio Insights (4)PharmaPoint: Macular Edema and Macular Degeneration- Global Drug Forecast and Market analysis to 2023” published in Dec 2014



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# Growth Strategy by category of eye disease

Growth Strategy	AMD (2RT)	Glaucoma SLT (Tango and Solo)	Glaucoma (iTrack™)	Retinal disease mainly diabetes (Integre Pro™ and Pro Scan™)	Cataracts and vitreous opacities (Ultra Q™ and Ultra Q Reflex™)	High resolution Diagnostic Ultrasound (Eyecubed™)	Critical success factor for each growth strategy
Geographical expansion	✓	✓	✓				Investment in, and management of, new “feet on the ground” in new domains
New product features for existing users			✓	✓	✓	✓	Strong new product pipeline to allow release of one or two new products per year
New devices for diseases and conditions hitherto untreated with devices	✓	✓			✓		Regulatory approvals, clinical trial investment and/or investment in doctor training
Market size (device and pharma)	US\$5.1bn	US\$4.6bn	US\$90m growing to US\$700m by 2020	US\$1.5bn	US\$3.3m	US\$140m	



# Estimated timing of growth opportunities impact on earnings

(based on date of expected material impact compared with 1H FY16 earnings)

	<u>FY16</u>	<u>FY17</u>	<u>Beyond</u>	Comments
AMD – 2RT™		Improving	✓	Subject to LEAD trial interim outcome (interim report in May 2016 and final report in May 2018)
Glaucoma – SLT growth	USA ✓	USA ✓	USA ✓	Marketing and training driven
	Asia	Asia ✓	Asia ✓	Marketing and training driven
Glaucoma – iTrack™		✓	✓	Marketing and training driven and investment required at rate greater than historical rate for sales growth
Retinal disease – Integre Pro Scan™	✓	✓	✓	
Cataracts and Vitreous – Ultra Q Reflex™	✓	✓	✓	Marketing and training driven
Diagnostic Ultrasound		✓	✓	New product launch in FY17



# AMD 2RT™ - Clinical Update Treatment of early-stage age-related macular degeneration

## LEAD trial being conducted Centre for Eye Research 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
- Recruitment of 240 patients completed in March 2015
- Interim outcomes on 18 month patient data available in 2H 2016. Final assessment of outcomes will be available 3 years after 31 March 2015



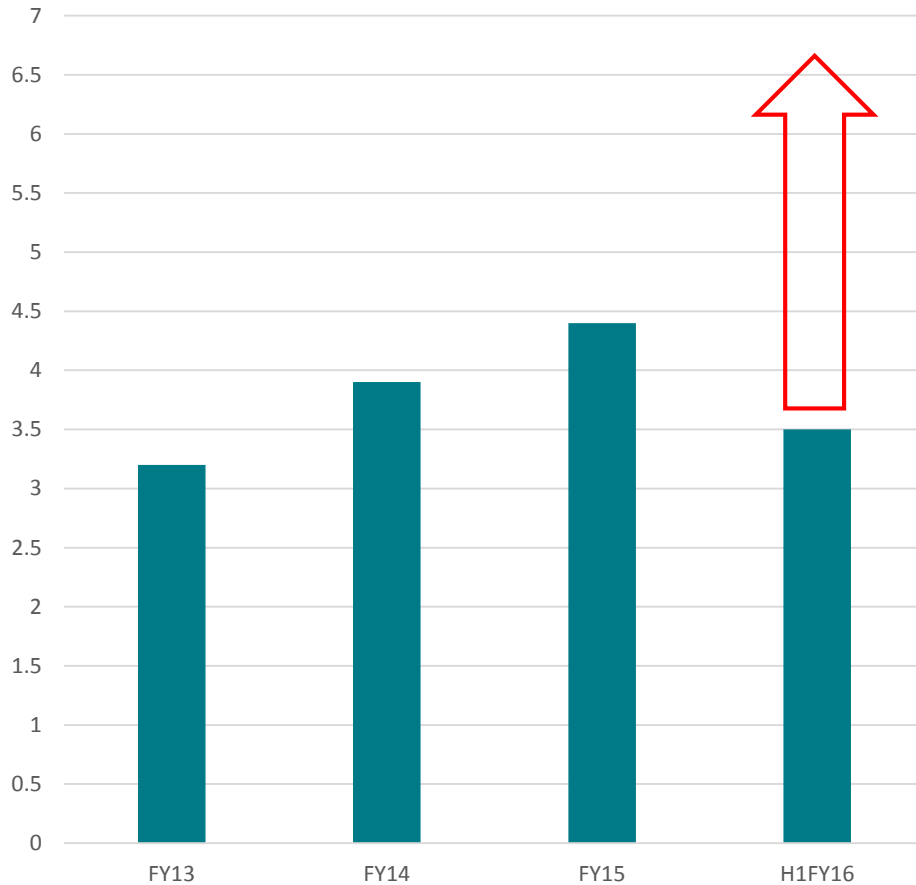
# AMD 2RT™ - Early-Adopter Sales Update

- Approved for sale for treatment of early AMD in countries that following “CE Mark” regulatory regime which include our direct markets in Germany, France, Australia and New Zealand and distributor markets in Asia (excluding China and Japan).
- Sales of 2RT units have been made to doctors in Germany, France, Italy, Belgium, Poland, Austria, Netherlands, Australia and New Zealand. Doctors now treating patients with 2RT for early stage AMD. We estimate approximately 1300 patients have so far been treated in the world.
- Sales will continue to grow as pool of clinical data supporting efficacy grows and experiences of early adopters are discussed amongst clinicians.
- Procedure fee of approximately \$100 per treatment being charged on all customer sales since 15 September 2015.



# Glaucoma - SLT Asia

Sales in Asia \$m (all products)



- Good growth in Asia in 1H FY16 of all product sales is continuation of a strong theme
- China opportunity strong given current low level per-capita of cataract operation low usage of SLT and large investment in new ophthalmology hospitals
- Regulatory issues continue to require careful management but are progressing nicely
- Investments required in expanding SLT usage in China.



# Glaucoma - SLT USA

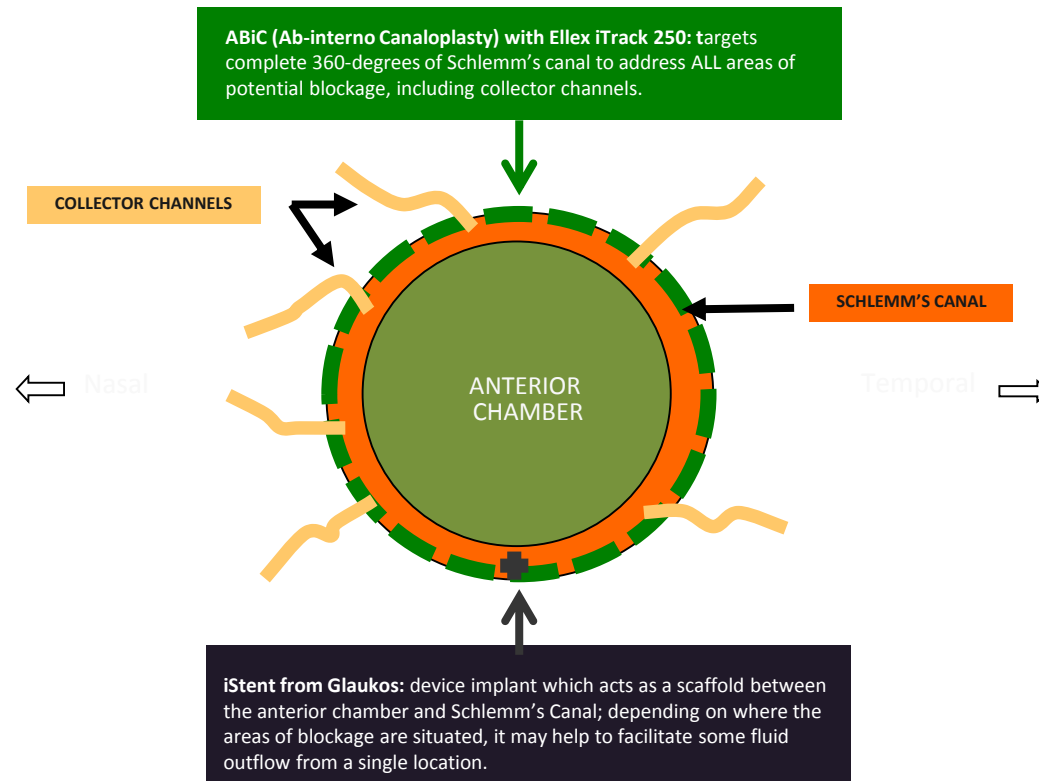
- Market for SLT still growing with more USA doctors accepting SLT as preferable first-line treatment of glaucoma compared with topical drugs. This is evident in 1H FY16.
- Per capita take up of SLT in the USA is still low compared with Europe and Australia. This will improve with additional marketing and training.



# Glaucoma - iTrack™

- iTrack™ is an innovative single-use catheter device for use by ophthalmologists on patients that have glaucoma that is no longer responding to intervention with SLT.
- It is sold by Ellex directly to doctors in the USA and via distributors to doctors in Europe (mainly Germany and Italy). The price of the iTrack™ is approximately \$1,000 each.

- Originally launched in the USA in 2010 it was a pioneer minimally invasive glaucoma surgery (MIGS) device built around a 30 minute procedure that has proven efficacy in lowering IOP with a very low/non-existent complication rate in 40,000 cases.
- Today the MIGS market is currently led by Glaukos.



- Acquired by Ellex in January 2014, the iTrack™ was relaunched in June 2015 based on its use in a shorter 5 minute surgical procedure known as Ab Interno Canaloplasty (ABiC). This has appealed to doctors.
- Since July 2015, and with only a minimal investment in additional marketing, there has been 20% growth in sales in the USA in 1H FY16 compared with pcp.
- We have made some investment in sales representatives in USA and expect to make a prudent manageable investment in 2H FY16 and beyond. We expect the USA sales growth rate to increase materially.



# Retinal disease - Integre Pro Scan™

- Integre Pro Scan™ release in Europe provided good revenue and margin growth
- Integre Pro Scan™ offers doctors better power, more wavelength treatment options and better optics and more user friendly, intuitive control systems than competitive products
- Approval for sale in USA secured in early September 2015 and in Japan on 18 December 2015. This offers a good opportunity for 2H FY16 sales.



# Production Facilities Expansion

- Contract signed to acquire building 15km's to the north of current location in Adelaide CBD.
- 4500sqm of space is 50% more available space than the existing facilities in the Adelaide CBD. Surrounding land offers space for further expansion.
- Planning for fitout for medical device manufacturing and support manufacturing systems is currently underway and this will determine total project cost.
- Debt-funding facility in place.
- Moving will commence around October 2016 and will be completed by late January 2017.
- Efficient and effective management of this activity is an important FY17 project.



# Outlook - Summary

“Revenue and earnings have grown nicely in the first half of FY16 and, subject to FX rates and global economic conditions, we expect that the growth achieved will be sustained through to the end of FY16 after allowing for prudent investment in sales and marketing for FY17 growth opportunities, particularly of iTrack™ in the USA.”



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# Reformatted P&L (from 4D)

	\$A000's		
	Six months ended 31 Dec 2013	Six months ended 31 Dec 2014	Six months ended 31 Dec 2015
<b>Revenue related:</b>			
Revenue	25,883	30,691	34,809
Realised FX	( 475)	521	(586)
Other income	57	32	271
	25,465	31,244	34,494
<b>COGS related items:</b>			
Changes in inventories	240	621	78
Raw materials consumed	( 12,906)	( 14,997)	(15,168)
	( 12,666)	( 14,376)	(15,090)
<b>Gross Margin related</b>	12,799	16,869	19,404
	50.3%	54.0%	56.2%
<b>Operating costs related:</b>			
Employee benefits expense (includes production labour)	( 7,570)	( 8,328)	(9,959)
Legal fees	( 159)	( 237)	(203)
Advertising and marketing	( 814)	( 1,701)	(1,479)
Product development raw materials and consumables	( 199)	( 352)	(541)
Facilities cost	( 819)	( 1,140)	(991)
Other costs	( 1,835)	( 2,408)	(2,708)
<b>Total operating cost related</b>	( 11,396)	( 14,167)	(15,881)
	44.8%	45.3%	46.0%
<b>EBITDA</b>	1,403	2,703	3,523
	6%	9%	10.1%
<b>Interest</b>	( 141)	( 87)	(88)
<b>Amortisation and depreciation</b>	( 608)	( 1,322)	(1,584)
Implied interest on deferred consideration (iTrack™)	-	-	(101)
<b>PBT</b>	<b>654</b>	<b>1,293</b>	<b>1,750</b>

## Changes over PCP

Expanded headcount with growing sales of products. Increasing revenue per FTE.

Timing of expenditure

Lower rent at Fremont, CA facility compared with Menlo Park, CA.

Amortisation up as new products come onto market



# Ellex Medical Lasers (ASX:ELX)

Ellex manufactures and sells innovative products that help eye surgeons around the world to effectively and efficiently treat eye disease; this is one powerful vision



Thankyou.  
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