



# Ellex Medical Lasers Limited (ASX:ELX)

FY2019  
Investor Presentation

Maria Maieli, CEO

29 AUGUST 2019  
ADELAIDE, AUSTRALIA





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# FY19 Key Summary Information

KEY FINANCIAL INFORMATION – 30 JUNE 2019	
Revenue	\$81.6 million
EBITDA (reported)	(\$1.0 million)
EBITDA (underlying) <sup>1</sup>	(\$0.7 million)
NPAT (Loss)	(\$5.8 million)
Cash at Bank	\$15.4 million
Borrowings	\$15.1 million
Operating cash flow	(\$4.2 million)

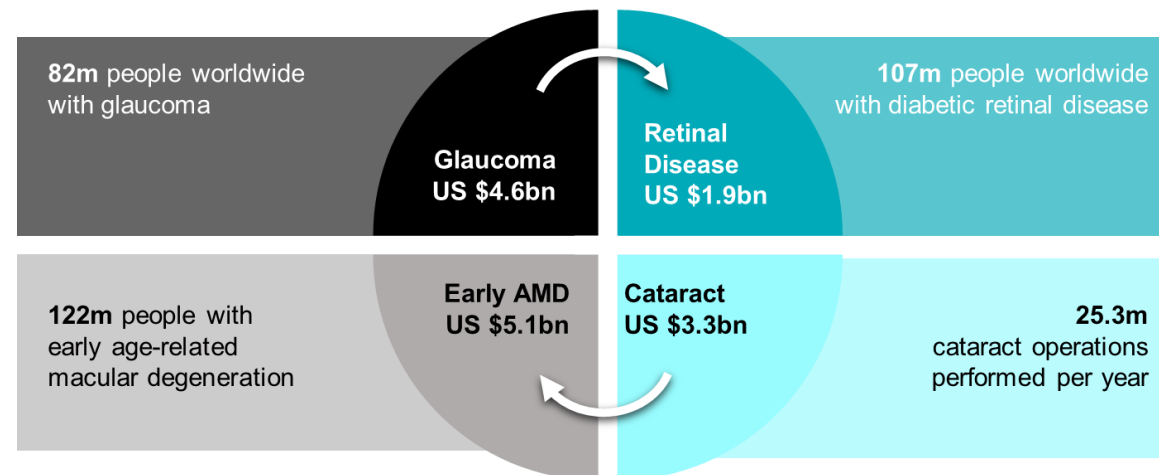
KEY MARKET INFORMATION	
Ticker ASX / OTCQX	ELX / ELXMY, ELXMF
Shares on issue	143.6 million
Market Capitalisation (as at 28 Aug)	\$81 million
Top 20 shareholders	52%
Directors and Management	14%

<sup>1</sup> Underlying EBITDA excludes restructuring charges of \$0.3 million incurred during FY19



# Our Business

- Comprehensive range of ophthalmic lasers, consumable device business and diagnostic equipment, targeting multiple eye diseases
- Installed base of over 35,000 Ellex ophthalmic laser and ultrasound systems globally
- To date, more than 108,000 Ellex iTrack™ consumable devices sold worldwide to treat glaucoma
- A direct sales network in the major markets of USA, Japan, France, Germany and Australia; distribution in >100 countries
- Major growth opportunities in glaucoma and age-related macular degeneration





# FY19 Highlights

- Group sales revenue growth up 3% to \$81.6 million
- Ellex iTrack™ revenues up 29% to \$14.3 million
- 292 patient LEAD Clinical Trial released showing a four-fold reduction in the rate of progression to late stage AMD in 76% of patients (RPD negative) who received Ellex 2RT® over the 36 months of the study<sup>1</sup>
- 4<sup>th</sup> year LEAD trial follow up showed sustained, positive 2RT treatment benefits for those RPD negative patients with intermediate AMD enrolled in the trial who exhibited a strong benefit at 36 months<sup>2</sup>
- Commenced trading on OTCQX® Best Market in the US
- Publication of the LiGHT Study in The Lancet<sup>3</sup> highlighting significant benefits of SLT vs. eye drops for first-line glaucoma treatment
- Next generation ultrasound platform Ellex Eye Prime™ launched at the 2019 ASCRS<sup>4</sup> Meeting

<sup>1</sup> Guymer RH, Wu Z, Hodgson LAB, et al. Sub-Threshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial. Ophthalmology. 2018.

<sup>2</sup> RPD – reticular pseudodrusen; a fatty deposit that is associated with later stages of Age-Related Macular Degeneration (AMD)

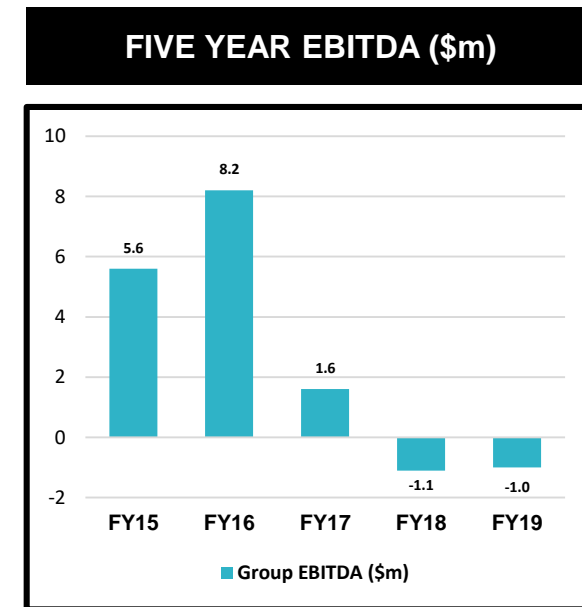
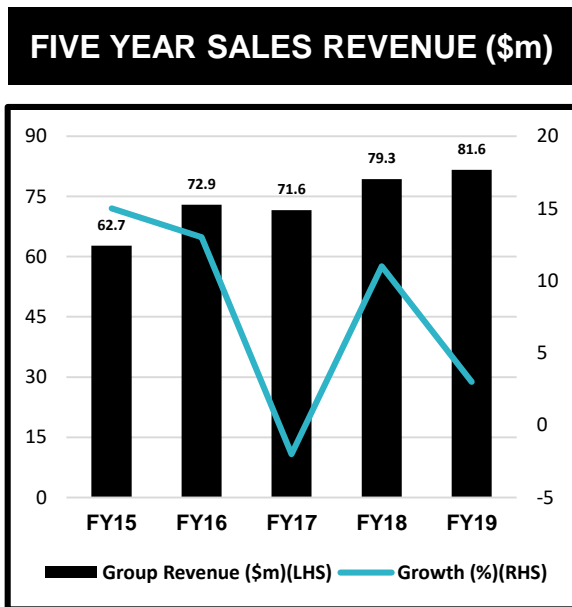
<sup>3</sup> Gazzard, G. et al . 2019. Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled trial. The Lancet. 393:10175.

<sup>4</sup> ASCRS - American Society of Cataract and Refractive Surgery



# FY19 Group Financial Summary

- Sales revenue of \$81.6 million, up 3% on the prior corresponding period (pcp) and down 6% on a constant currency (cc)<sup>1</sup> basis
  - Four year CAGR of 9%, ahead of typical overall industry growth rates
- Operating expenditures were up 10% (down 4% in cc terms) to \$52.4 million versus pcp reflecting continued investment into the high growth glaucoma segment
- Gross margin (ex-labour) was up 410 bps to 62.2% versus pcp
- Underlying EBITDA<sup>2</sup> loss of \$0.7 million, reported EBITDA loss of \$1.0 million, improved 3% on pcp
- Negative operating cash flow of \$4.2 million reflected increased working capital of \$3.4 million



<sup>1</sup> Constant Currency (cc) derived by converting FY19 at FY18 average A\$ exchange rates for USD, EUR, YEN;

<sup>2</sup> Underlying EBITDA excludes restructuring expenditure of \$0.3 million



# Revenue by Geography

- North America (USA) continues to be the strongest Ellex market by absolute growth and by sales mix
  - Driven by Ellex iTrack and SLT<sup>4</sup> growth in glaucoma markets
- EMEA consists of direct markets (France, Germany – Lasers & Ultrasound only) with the balance via distributors
  - Solid growth for 2RT sales in AMD post LEAD clinical study results, improved SLT laser sales, flat iTrack performance
- Japanese revenues increased 4% on pcp
  - Continued focus on higher margin product sales
- Asian growth of 14% was solid across the entire product segment
  - iTrack growth in China, regional demand for other products continued
- ANZ was up 7% versus the pcp
  - Continued momentum in SLT and initial sales of Ellex 2RT<sup>®</sup> post LEAD

Region	FY18 (\$m) & sales mix %	FY19 (\$m) & sales mix %	growth pcp
North America	36.5 (46%)	38.3 (47%)	4%
EMEA <sup>1</sup>	15.8 (20%)	15.8 (19%)	(0.2%)
Japan	11.7 (15%)	12.1 (15%)	4%
Asia (ex-Japan)	4.3 (5%)	4.9 (6%)	14%
ANZ <sup>2</sup>	9.1 (11%)	9.7 (12%)	7%
LATAM <sup>3</sup>	1.7 (2%)	0.8 (1%)	(50%)
<b>TOTAL</b>	<b>79.1 (100%)</b>	<b>81.6 (100%)</b>	<b>3%</b>

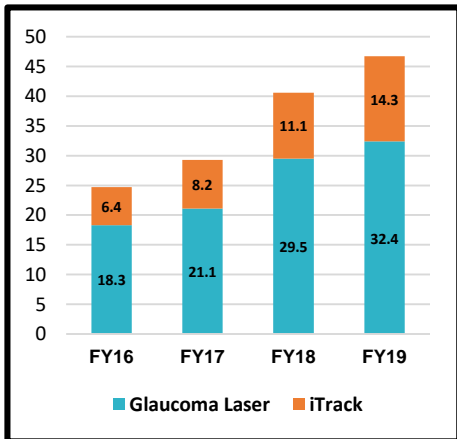
<sup>1</sup> EMEA – Europe, the Middle East and Africa; <sup>2</sup> ANZ - Australia and New Zealand; <sup>3</sup> LATAM - Latin America; <sup>4</sup> SLT – Selective Laser Trabeculoplasty



# Revenue by Eye Disease

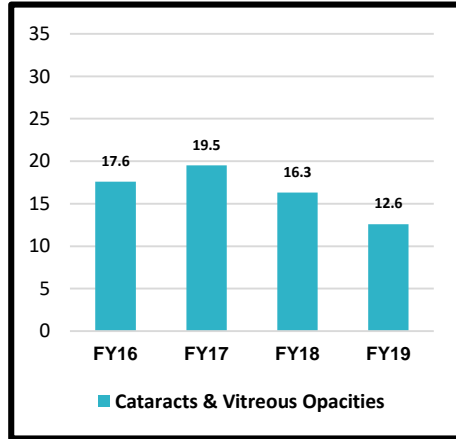
- Glaucoma therapy sales grew +15% on pcp, comprising SLT lasers +10% on pcp and iTrack consumable devices +29% on pcp with a significant increase in glaucoma product mix, from 36% in FY16 to 57% of group revenues in FY19, justifying investment and focus into this high growth, underpenetrated market. SLT expected to become a first-line standard of care post LiGHT Study
- Cataracts and Vitreous Opacity lasers declined 23% over the pcp; competitive pricing pressures continue
- Retina disease lasers declined 2% over the pcp; continued pressure from pharmaceutical interventions
- 2RT<sup>®</sup> recorded a 260% increase in sales over pcp with strong initial sales post LEAD trial in 1H, moderated in 2H
- Diagnostic ultrasound revenue was down 37% on pcp; awaiting release of new product Eye Prime™ subsequently launched in May

**GLAUCOMA (SLT + iTrack)**  
FOUR YEAR SALES REVENUE (\$m)



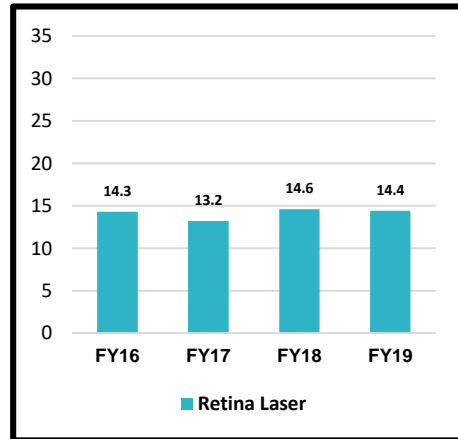
3 Year CAGR – 24%

**CATARACTS & VITREOUS OP.**  
FOUR YEAR SALES REVENUE (\$m)



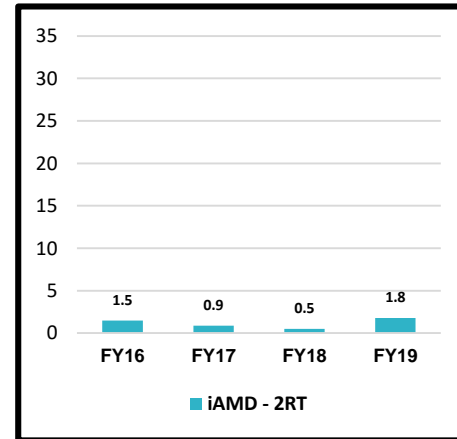
3 Year CAGR – (10%)

**RETINA LASERS**  
FOUR YEAR SALES REVENUE (\$m)



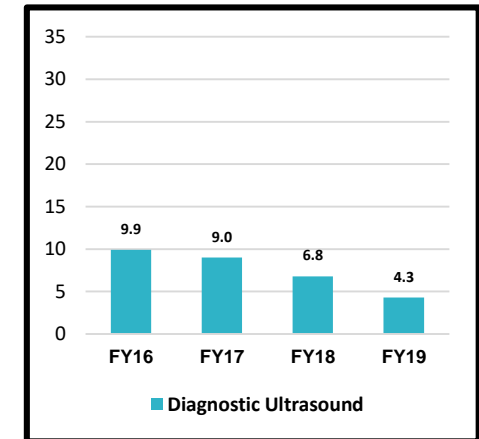
3 Year CAGR – 0.2%

**INTERMEDIATE AMD – 2RT<sup>®</sup>**  
FOUR YEAR SALES REVENUE (\$m)



3 Year CAGR – 7%

**DIAGNOSTIC ULTRASOUND**  
FOUR YEAR SALES REVENUE (\$m)



3 Year CAGR – (24%)

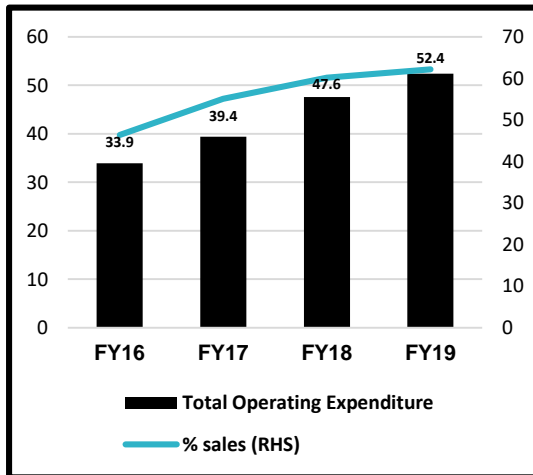




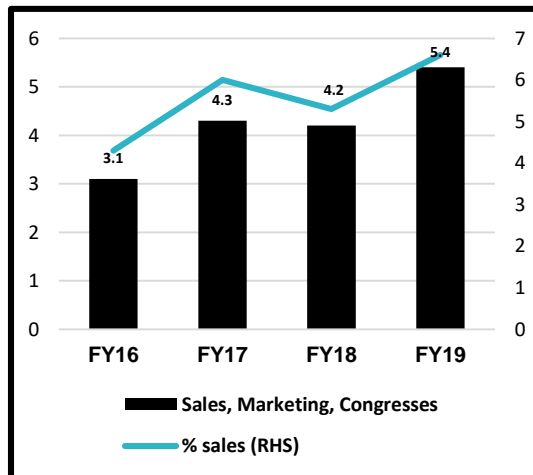
# Operating Expenditure

- Total operating expenditure was up 10.2% to \$52.4m (64% of sales versus 60% in pcp)
- Employee expenses were up 10% on pcp principally due to headcount expansion across field sales and management capability, commissions paid on sales growth and FX effects
- Our sales and marketing spend of \$5.4m (up 29% on pcp) was a result of increased efforts for Ellex iTrack in the key US market, SLT and the marketing of 2RT post LEAD, along with currency impacts (highly USD denominated)

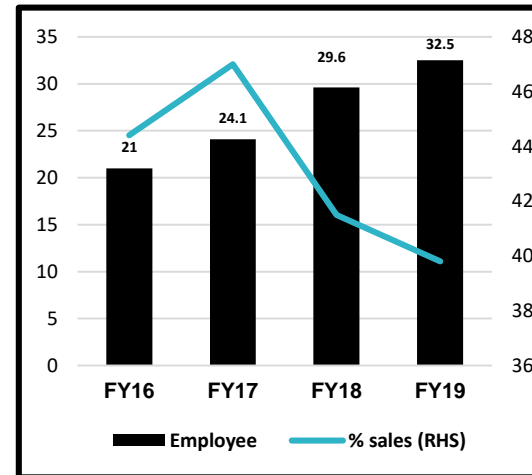
**TOTAL OPERATING EXPENSES (\$m)**



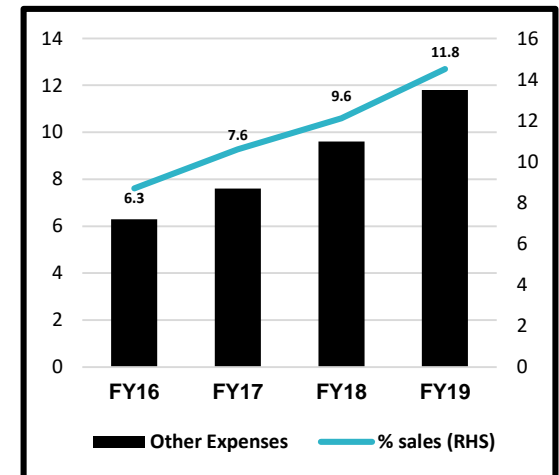
**SALES, MARKETING EXPENSES (\$m)**



**EMPLOYEE EXPENSES (\$m)**



**OTHER EXPENSES\* (\$m)**



\* Other: Includes professional consultants, travel, other

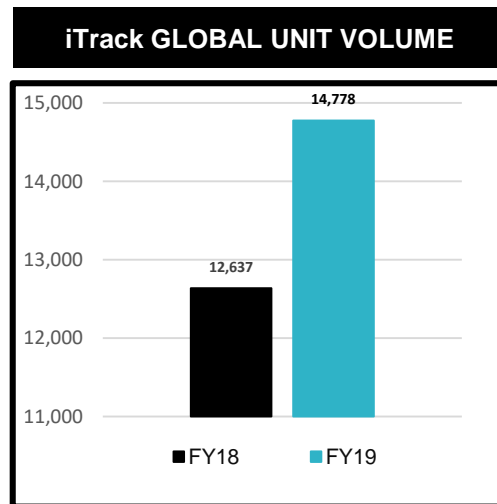


Ellex iTrack™ MIGS

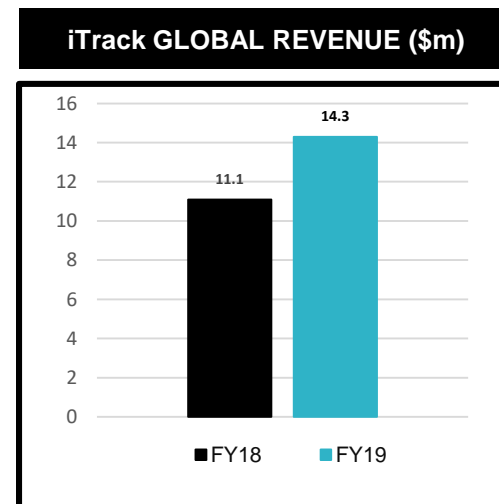


# FY19 Financial Results – Ellex iTrack

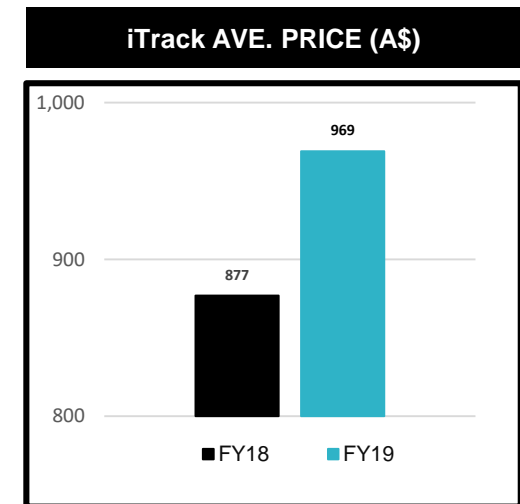
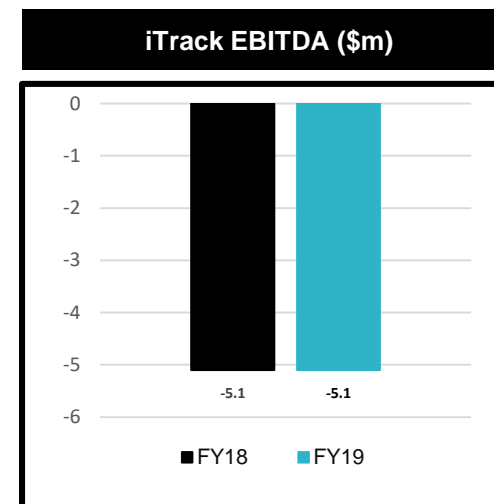
- Unit volumes increased 17% on pcp and revenues were up 29% to \$14.3m
- Low **double-digit price rise** implemented in 4QFY2019, reimbursement remains very strong in key US market
- Higher Average AUD price attributable to US price increase, FX benefits and mix effects from higher US volumes
- Gross margin (ex-labour) was 79% (down from 84% in pcp), reflecting manufacturing rework
- Demonstrated strong cost base leverage with iTrack segment in 2H, recording \$1.1m EBITDA loss (vs. \$4m loss in 1H)



3 Year CAGR – 29%



3 Year CAGR – 31%

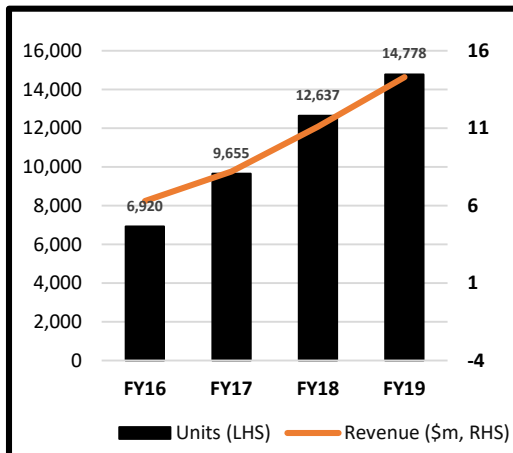




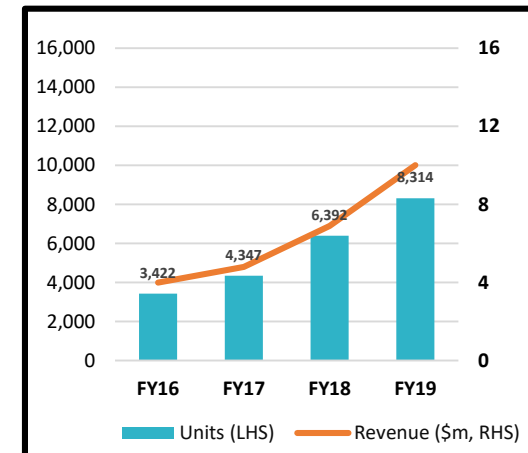
# Ellex iTrack Performance by Region

- USA unit sales were up 30% versus the pcp (revenues +45% to \$10m, +33% in cc terms) reflecting continued expansion of accounts, users and deeper penetration within accounts
- OUS unit sales were down 9% (revenues +2% to \$3.3m), some improvement in German sales via Hoya Corporation
- Chinese unit sales were up 42% versus the pcp (revenues +7% to \$1.1m), impact of tariffs impacted net pricing despite strong volumes. Ellex iTrack continues to be the only MIGS device approved in the Chinese market

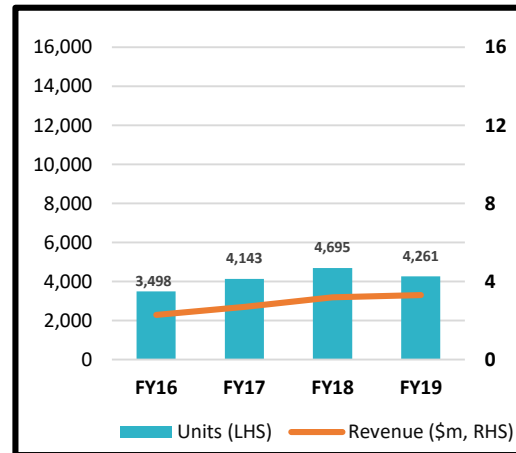
4 YEAR iTrack GLOBAL PERFORMANCE



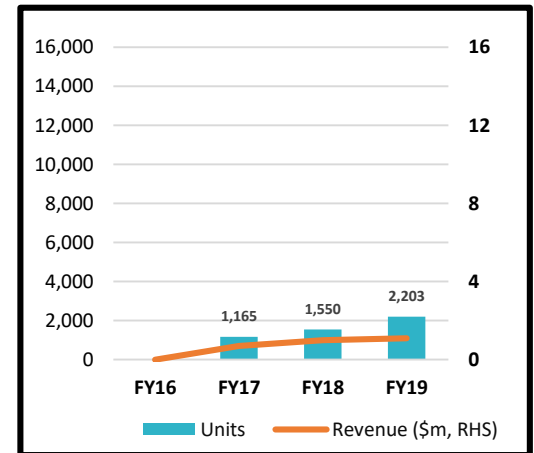
4 YEAR iTrack USA PERFORMANCE



4 YEAR iTrack OUS (Ex. CHINA) PERFORMANCE



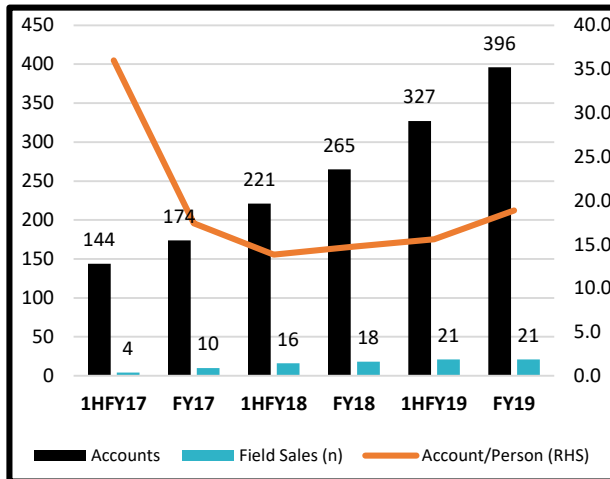
4 YEAR iTrack CHINA PERFORMANCE



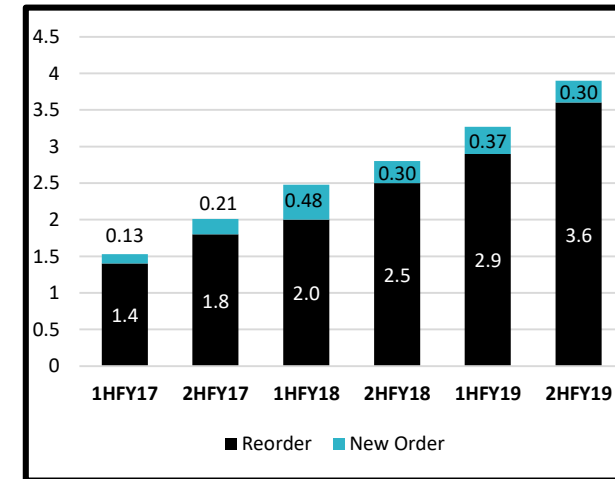
# Detailed Ellex iTrack USA Update

- New account growth of 49% has been strong, with field sales representation in the 2H identical to 1HFY19
- Increase in FY19 re-orders of 46% versus pcp, while new order/reorder mix of 91% / 9% reflected a focus on higher volume customers
- Significant runway of opportunity remains: FY19 Accounts imply ASC penetration rate of ~17%, user penetration of ~6%
- <30% utilisation of current manufacturing capacity at FY19 unit production volume

**Ellex iTrack ACCOUNT GROWTH & SALES EFFICIENCY**



**iTrack USA REVENUE MIX (US\$m)**



\* Field sales includes territory sales representatives and clinical trainers



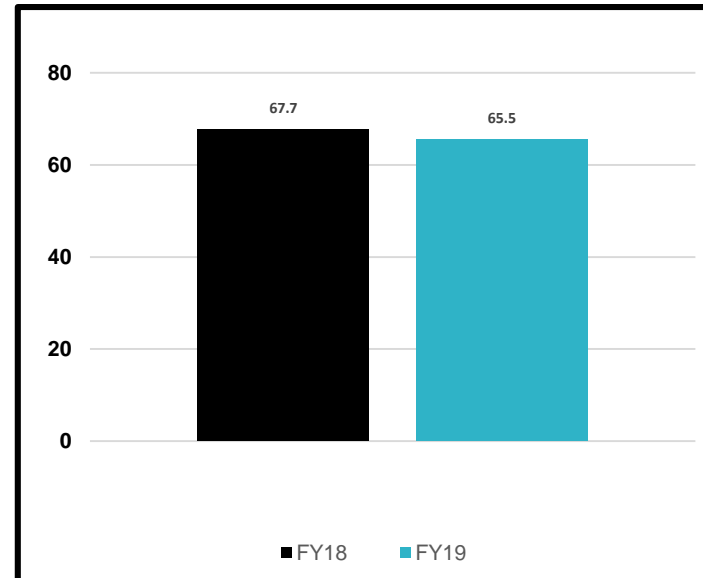
# Lasers & Ultrasound



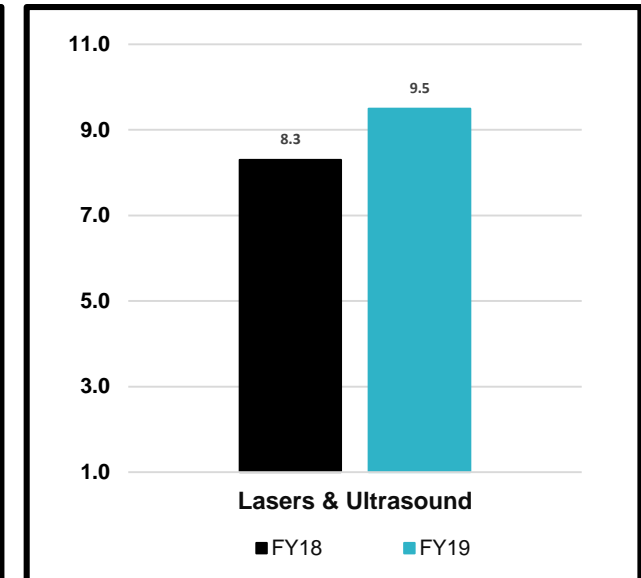
# FY19 Financial Results – Lasers & Ultrasound

- Lasers and ultrasound revenue were down 3% to \$65.5m
- Gross margins up 5% to 59% ex labour
- Segment EBITDA increased 6% to \$9.5m

LASERS & ULTRASOUND REVENUE BY DISEASE (\$m)



LASERS & ULTRASOUND EBITDA (\$m)



3 Year Revenue CAGR of 0.2%



Ellex 2RT<sup>®</sup> for Intermediate AMD

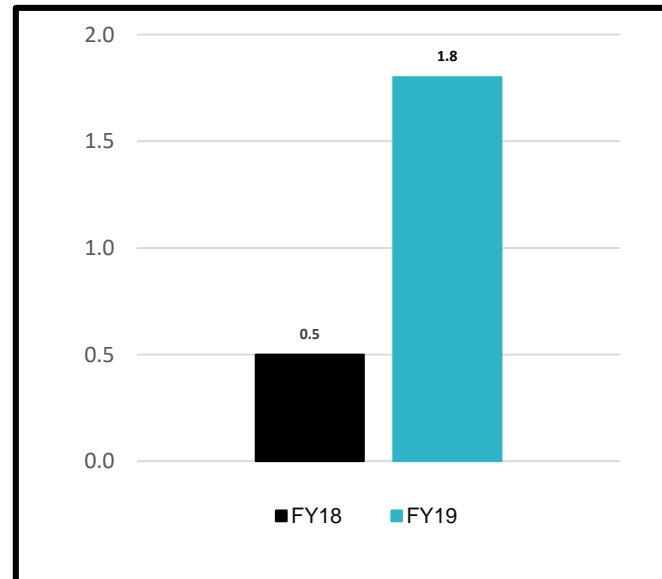




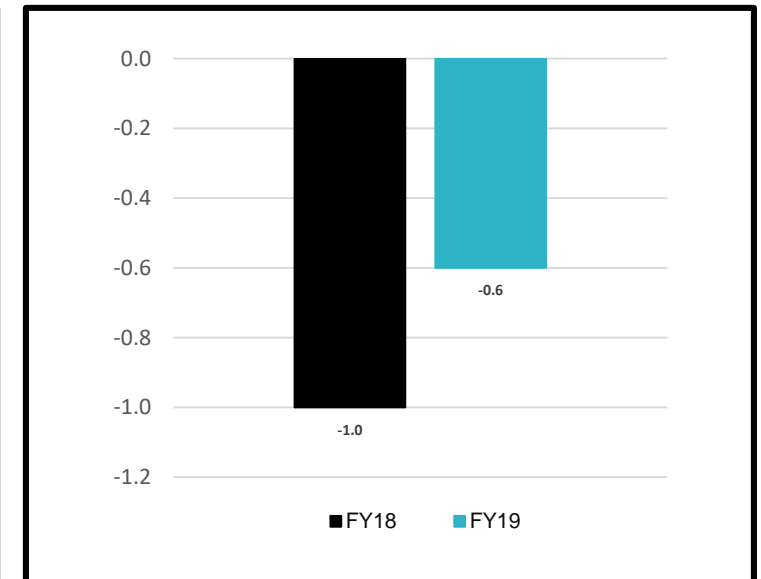
# FY19 Financial Results – 2RT

- 260% increase in revenue to \$1.8m
- Sales moderated in the 2H
- Gross margin increased 15% to 57% versus pcp as unit sales mix initially skewed to distributor markets
- Segment EBITDA loss decreased to \$0.6m
- EU sales driven by iAMD<sup>1</sup> indication post LEAD
- Several new sales recorded in the USA<sup>2</sup>
- Purchase price & per procedure fee stable
- Procedural fee revenue of \$0.2m versus pcp

ELLEX 2RT REVENUE (\$m)



ELLEX 2RT EBITDA (\$m)

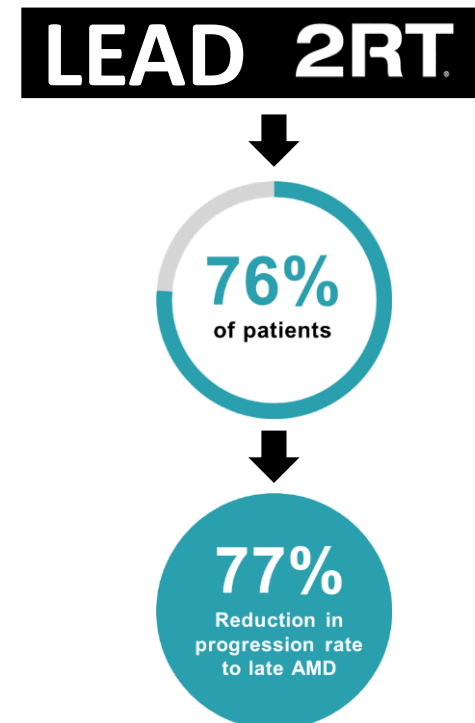


<sup>1</sup> intermediate Age-Related Macular Degeneration; <sup>2</sup> 2RT has a 510(k) clearance by the FDA for clinically significant macular edema (CSME)



# 2RT FDA Update

- LEAD was the first ever study to show a significant efficacy effect in an iAMD population
- Establish the US regulatory pathway for 2RT in iAMD with the FDA; expected during CY19
- Submission to the FDA anticipated in current Quarter
- FDA meeting / outcome in 4Q CY19





# Outlook

- FY20 EBITDA expected to show an improvement versus FY19, subject to global economic conditions and foreign exchange rates
- iTrack revenue growth to continue, positive EBITDA contribution in the 2H FY20
- Focus on OPEX control as investing phase moves to sales execution
- Focus on reduction in working capital requirement, particularly inventory
- Promote LiGHT Study findings to underpin market leadership position in SLT for glaucoma
- Leverage specialist glaucoma sales force capability to promote **both** iTrack and SLT to increase global footprint and emergence of Ellex as a glaucoma player



# Contacts

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## QUESTIONS/DISCUSSION



# Appendices



# Average FX Rates

Average FX		
	FY18	FY19
AUD:USD	0.77	0.72
AUD:EUR	0.65	0.63
AUD:YEN	85.4	79.6



# FY19 EBITDA by Segment

	A\$'000's				
	CLU	iTrack	2RT	Corporate	Total
<b>Revenue</b>	<b>65,522</b>	<b>14,324</b>	<b>1,791</b>	<b>-</b>	<b>81,637</b>
Other Income	-	-	-	592	592
Changes in inventories of finished goods and work in progress	1,007	54	(8)	-	1,053
Raw materials and consumables used	(28,132)	(2,998)	(762)	-	(31,892)
	<b>38,397</b>	<b>11,380</b>	<b>1,021</b>	<b>592</b>	<b>51,390</b>
Gross margin related % <sup>(1)</sup>	59%	79%	57%		
Employee benefits expense	(18,095)	(10,967)	(313)	(3,097)	(32,472)
Legal expenses	-	-	-	(78)	(78)
Advertising, marketing and congress expense	(3,621)	(1,380)	(377)	-	(5,378)
Product development raw materials and consumables used	(1,638)	-	(45)	-	(1,683)
Realised foreign exchange (loss)/gain	730	(24)	20	-	726
Facility & Other expenses	(6,307)	(4,154)	(864)	(2,207)	(13,532)
<b>EBITDA</b>	<b>9,466</b>	<b>(5,145)</b>	<b>(558)</b>	<b>(4,790)</b>	<b>(1,027)</b>

(1) In accordance with reporting in previous years this ratio is highlighted as a proxy for gross margin as it does not include cost of production labour which is shown in employee benefits





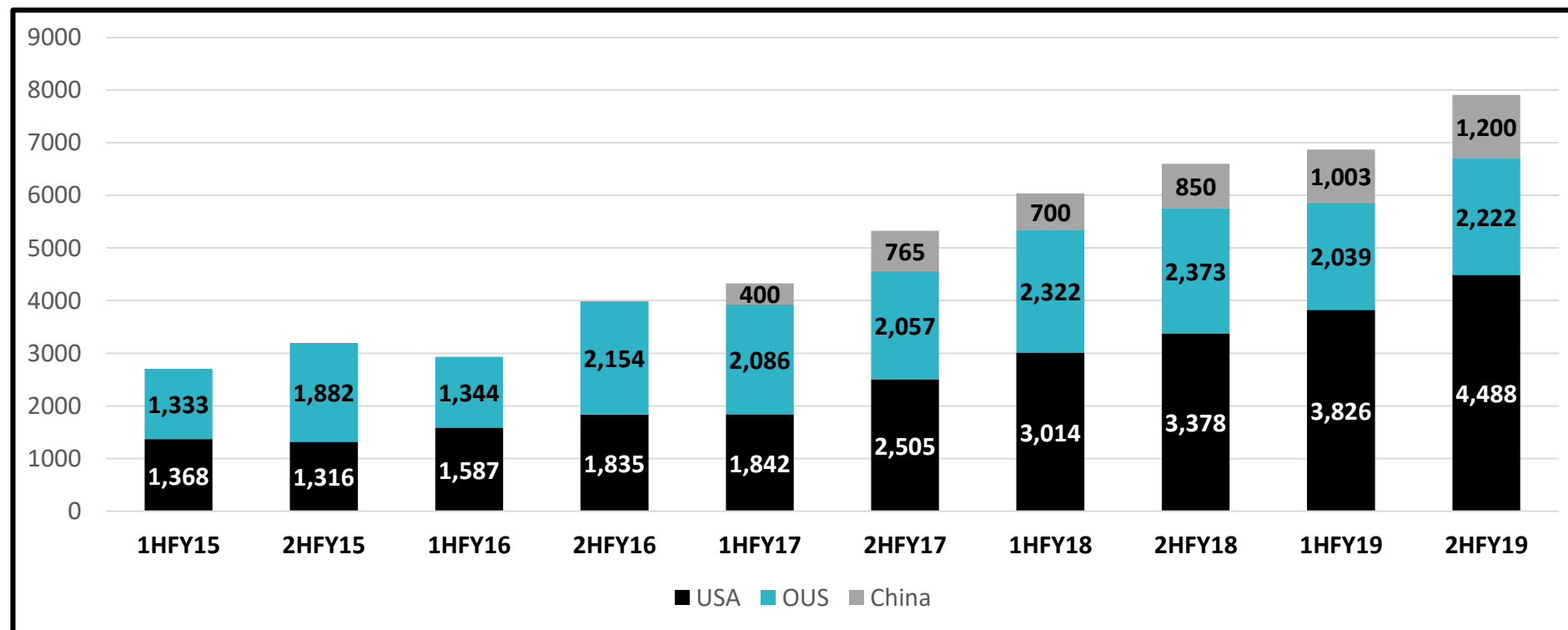
# FY18 EBITDA by Segment

	A\$'000's				
	CLU	iTrack	2RT	Corporate	Total
<b>Revenue</b>	<b>67,668</b>	<b>11,085</b>	<b>497</b>	<b>-</b>	<b>79,250</b>
Other Income	-	-	-	477	477
Changes in inventories of finished goods and work in progress	(646)	282	(28)	-	(392)
Raw materials and consumables used	(30,483)	(2,082)	(261)	-	(32,826)
	36,539	9,285	208	477	46,509
Gross margin related % <sup>(1)</sup>	54%	84%	42%		
Employee benefits expense	(18,659)	(8,648)	(209)	(2,137)	(29,649)
Legal expenses	-	-	-	(253)	(253)
Advertising, marketing and congress expense	(1,808)	(1,760)	(617)	-	(4,184)
Product development raw materials and consumables used	(1,022)	-	(8)	-	(1,030)
Realised foreign exchange (loss)/gain	460	(35)	3	-	428
Facility & Other expenses	(7,056)	(3,905)	(373)	(1,542)	(12,876)
<b>EBITDA</b>	<b>8,454</b>	<b>(5,063)</b>	<b>(996)</b>	<b>(3,450)</b>	<b>(1,055)</b>

(1) In accordance with reporting in previous years this ratio is highlighted as a proxy for gross margin as it does not include cost of production labour which is shown in employee benefits



# iTrack 1H/2H unit sales



	1HFY15	2HFY15	1HFY16	2HFY16	1HFY17	2HFY17	1HFY18	2HFY18	1HFY19	2HFY19
<b>TOTAL Units</b>	2,701	3,198	2,931	3,989	4,328	5,327	6,036	6,601	6,868	7,910
growth % (pcp)			9%	25%	48%	34%	39%	24%	14%	33%
growth % (HoH)		18%	-8%	36%	8%	23%	13%	9%	4%	15%