



# Ellex Medical Lasers Limited (ASX:ELX)

First Half FY2019  
Investor Presentation

22 FEBRUARY 2019  
ADELAIDE, AUSTRALIA





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# 1HFY19 Key Summary Information

## KEY FINANCIAL INFORMATION – 31 DECEMBER 2018

Revenue	\$41.6 million
EBITDA	(\$0.9 million)
NPAT	(\$2.7 million)
Cash at Bank	\$19.2 million
Borrowings	\$15.3 million
Operating cash flow	(\$1.8 million)

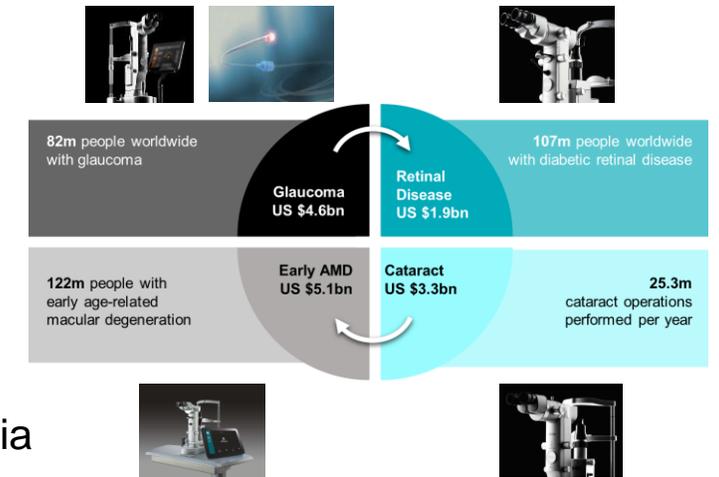
## KEY MARKET INFORMATION

Ticker ASX / OTCQX	ELX / ELXMY, ELXMF
Shares on issue	143.6 million
Market Capitalisation (as at 20 Feb)	\$86.2 million
Top 20 shareholders	53%
Directors and Management	14%



# Our Business

- Comprehensive range of ophthalmic lasers, evolving consumable device business and diagnostic equipment, targeting:
  - Glaucoma
  - Diabetic eye disease
  - Secondary cataracts
  - Age-related macular degeneration (AMD)
  - Vitreous opacities
- Installed base of over 35,000 Ellex ophthalmic laser and ultrasound systems globally
- To date more than 100,000 Ellex iTrack™ consumable devices sold to treat glaucoma
- A direct sales network in the major markets of USA, Japan, France, Germany and Australia
- Additionally, 50 distributors in over 100 countries
- Major growth opportunities the Company is investing financial resources into:
  - **Glaucoma** – shift to minimally invasive glaucoma surgery (MIGS) devices vs surgery; shift to laser-based intervention as first-line therapy
  - **AMD** – Ellex has the only clinically validated laser shown to significantly decrease the rate of progression in intermediate AMD patients





# Our Strategies

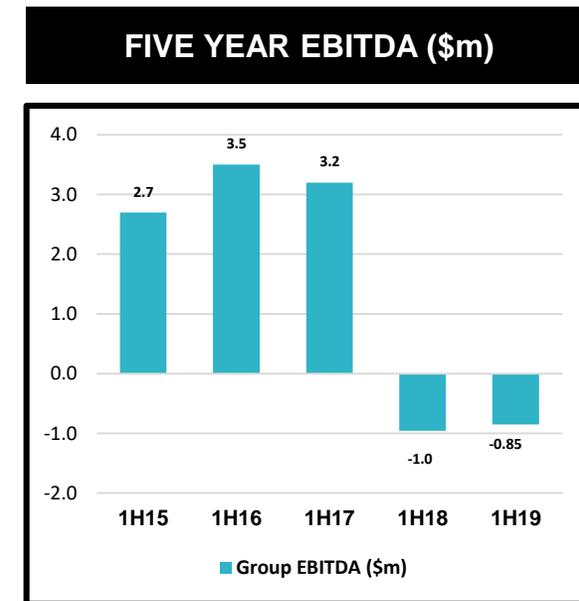
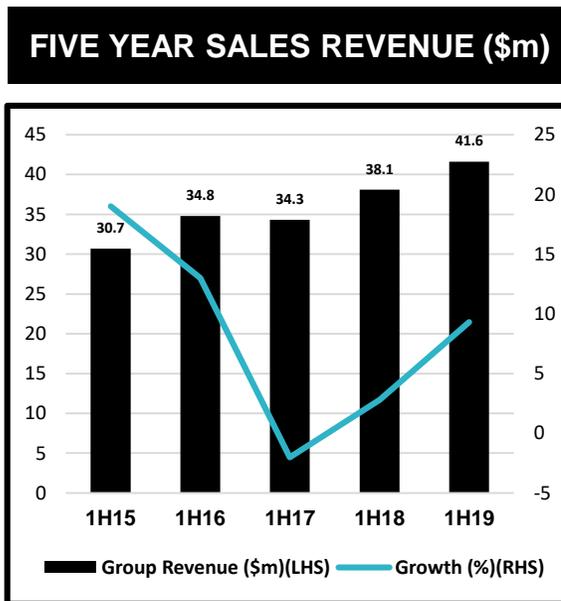
1. **Ellex Laser & Ultrasound:** we will continue to provide a strong base for our business using our well-known industry heritage and dominant market position through a combination of technological innovation, new product releases, marketing and cost management to drive growth in both sales and earnings.
2. **Ellex iTrack™:** we will leverage the Ellex Laser & Ultrasound base to exploit the unique, comprehensive and rejuvenative method of action of the Ellex iTrack™ surgical system to deliver rapid sales growth and ultimately earnings in the very fast-growing MIGS market.
3. **Ellex 2RT® for iAMD:** using the trusted Ellex ophthalmic laser brand, we will aim to make Ellex 2RT® nanopulse laser therapy the standard of care for the +25 million people worldwide with intermediate AMD (iAMD).

**In the long term, these strategies will provide our shareholders with material returns.**



# 1HFY19 Group Financial Summary

- Sales revenue of \$41.6 million, up 9% on the prior corresponding period (pcp) and up 3% on a constant currency (cc)<sup>1</sup> basis
  - Four year CAGR of 8%, ahead of typical overall industry growth rates
- Operating expenditures were up 21% (up 14% in cc terms) to \$27 million versus pcp reflecting continued investment into high growth glaucoma and iAMD segments to drive future growth
- Gross margin (ex-labour) was up 678 bps to 62.4% versus pcp
- EBITDA loss of \$0.85 million, improved 12% versus pcp
- Operating cash flow of -\$1.8 million reflected an increase in working cap associated with higher inventory build on sales expectations, particularly for Ellex iTrack in 2019



<sup>1</sup> Constant Currency (cc) derived by converting 1HFY19 at 1HFY18 average A\$ exchange rates for USD, EUR, YEN



# 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>5</sup> growth in glaucoma markets
  - Both high margin products for Ellex and beneficial to margin at the cc level
- EMEA consists of direct markets (France, Germany – Lasers & Ultrasound only) with the balance via distributors.
  - Growth declined, resulting from the takeover of German distributor for Ellex iTrack & general decline in purchasing sentiment
  - Partially offset by significant contribution from 2RT sales in AMD post LEAD clinical study results and improved SLT laser sales
- Japanese revenues declined marginally by 8% on pcp
  - Focus on higher margin product sales
  - Improved gross margins despite lower sales
- Asian growth of 90% was solid across the entire product segment
  - Continued growth in Chinese market for Ellex iTrack
  - Solid regional demand for other Ellex products
- ANZ was up 17% versus the pcp
  - Momentum in SLT and initial sales of Ellex 2RT<sup>®</sup> post LEAD

Region	1H18 (\$m) & sales mix %	1H19 (\$m) & sales mix %	growth pcp	cc <sup>1</sup> growth pcp
North America	15.7 (41%)	18.2 (44%)	15%	8%
EMEA <sup>2</sup>	9.9 (26%)	9.1 (22%)	(7%)	(12%)
Japan	6.0 (16%)	5.6 (13%)	(8%)	(7%)
Asia (ex-Japan)	2.0 (5%)	3.7 (9%)	90%	78%
ANZ <sup>3</sup>	3.9 (10%)	4.6 (11%)	17%	17%
LATAM <sup>4</sup>	0.6 (2%)	0.4 (1%)	(40%)	(43%)
<b>TOTAL</b>	<b>38.1 (100%)</b>	<b>41.6 (100%)</b>	<b>9%</b>	<b>3%</b>

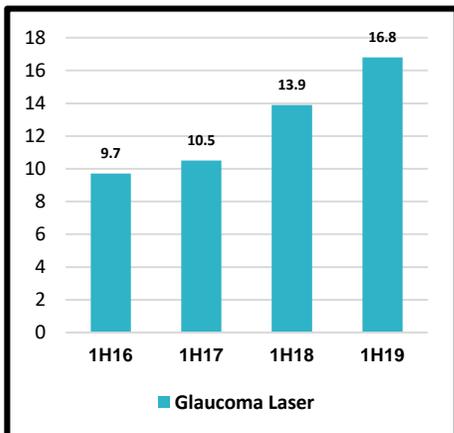
<sup>1</sup> Constant Currency (cc) derived by converting 1HFY19 at 1HFY18 average A\$ exchange rates for USD, EUR, YEN; <sup>2</sup> EMEA – Europe, the Middle East and Africa; <sup>3</sup> ANZ - Australia and New Zealand; <sup>4</sup> LATAM - Latin America; <sup>5</sup> SLT – Selective Laser Trabeculoplasty



# Revenue by Eye Disease (Capital Equipment)

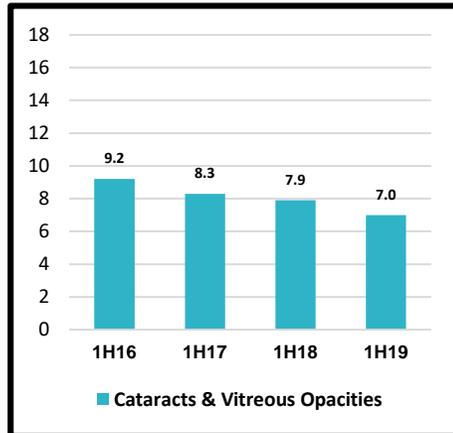
- Glaucoma lasers, notably the world-leading Ellex SLT lasers grew 21% on pcp (up 18% in cc terms) and has now delivered a three year CAGR of 20%. The market remains underpenetrated, and SLT is now a standard of care first-line therapy
- Cataracts and Vitreous Opacity lasers declined 11% over the pcp (13% in cc terms) - focus on higher margin Reflex™ range for floater treatment
- Retina disease lasers grew 5% over the pcp (4% in cc terms), which was pleasing given competition and a shift to drug therapy
- 2RT® recorded a 532% increase in sales over pcp with strong initial sales post LEAD trial data recorded
- Diagnostic ultrasound revenue was down 32% on pcp (down 39% in cc terms), users awaiting product launch

**GLAUCOMA LASER**  
FOUR YEAR SALES REVENUE (\$m)



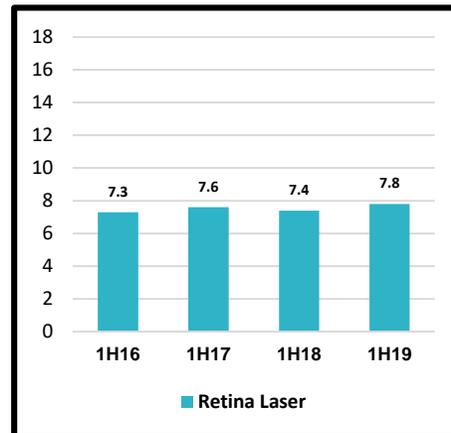
3 Year CAGR – 20%

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



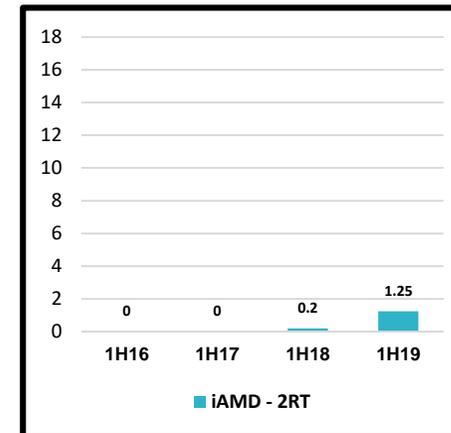
3 Year CAGR – (9%)

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



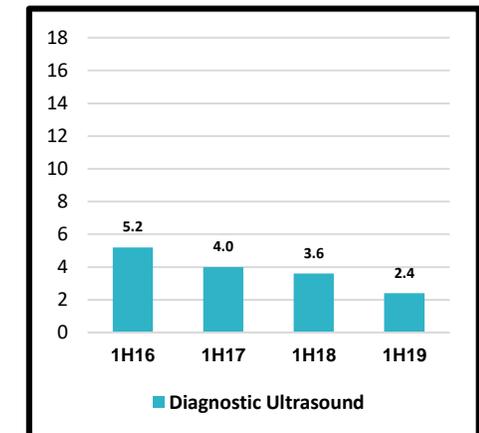
3 Year CAGR – 2%

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



3 Year CAGR – n/a

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

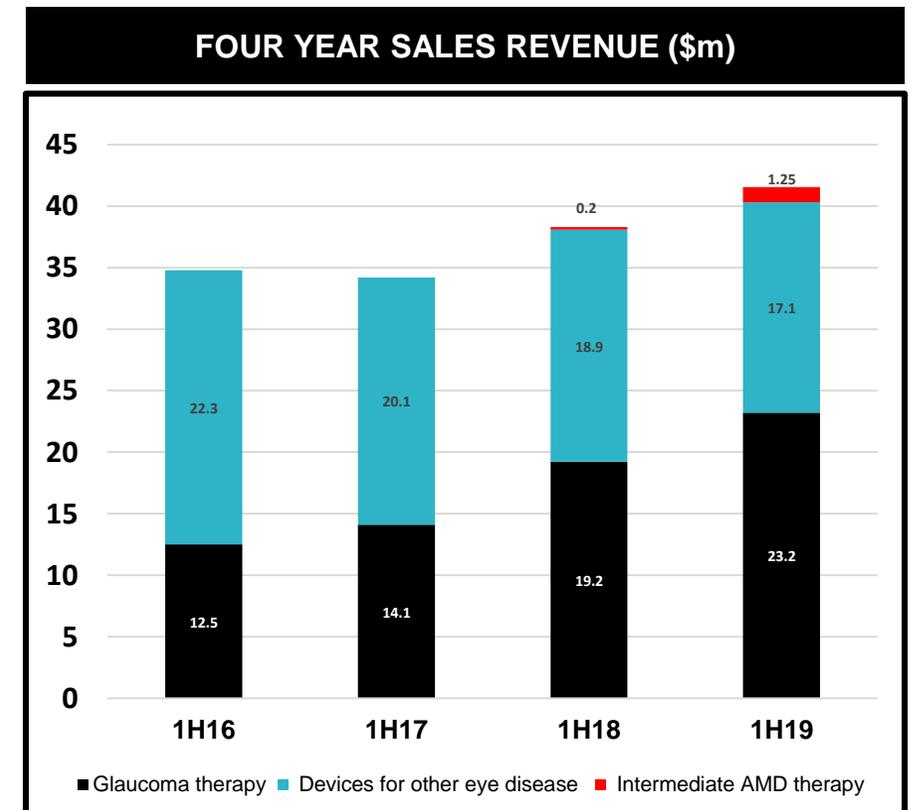


3 Year CAGR – (23%)



# Revenue Composition (Capital Equipment & Consumable Devices by Eye Disease)

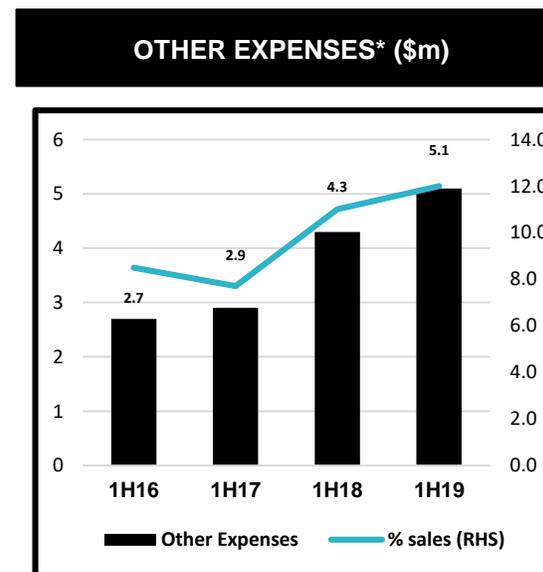
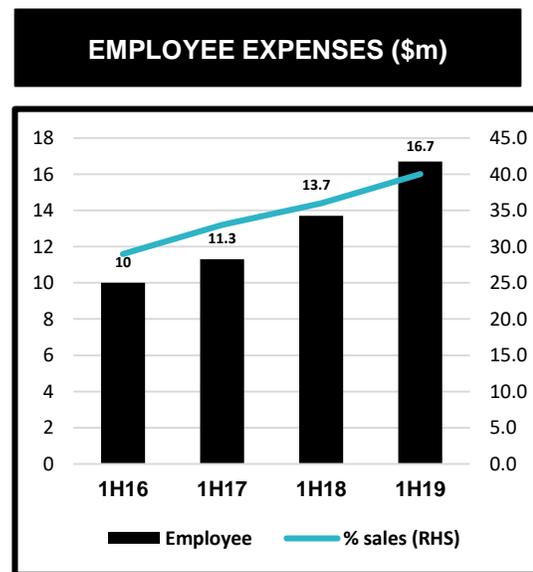
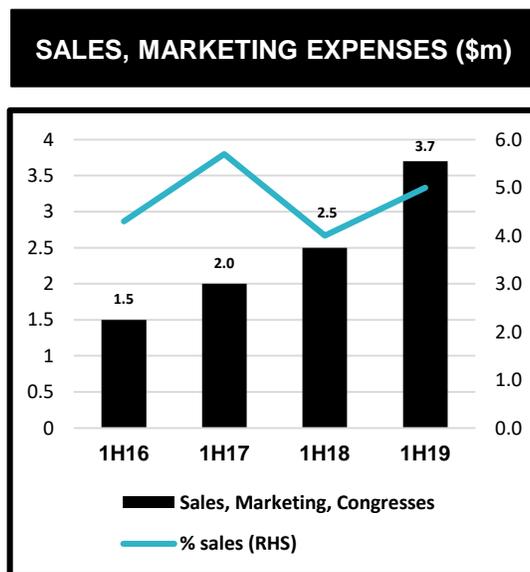
- Glaucoma therapy sales comprising SLT and Ellex iTrack were up 18% (15% in cc terms) versus pcp
- Glaucoma therapy revenue three year CAGR of 23%
  - SLT – 20%
  - Ellex iTrack – 33%
- Significant increase in glaucoma product mix, from 50% in 1H16 to 56% in 1H19, justifying investment and focus in this high growth market
  - Glaucoma device market CAGR to 2023 of 23% (MIGS 34%)\*
  - SLT market CAGR to 2023 of 1.3%\* (Ellex sig. ahead on growth)
- Revenues from other eye disease\*\* devices were down 21% versus pcp, with declining three year revenue CAGR of 17% reflecting overall market maturity and Ellex strategy to focus on higher margin products, with less pricing pressure





# Operating Expenditure

- Total operating expenditure was up 21% (14% in cc) to \$26.9m (65% sales versus 59% in pcp), which is consistent with Ellex group strategy to provide an enhanced capability to generate solid growth in the glaucoma and iAMD markets, globally
- Employee expenses were up 22% 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 \$3.7m (up 49% 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)



\* Other: Includes professional consultants, travel, other

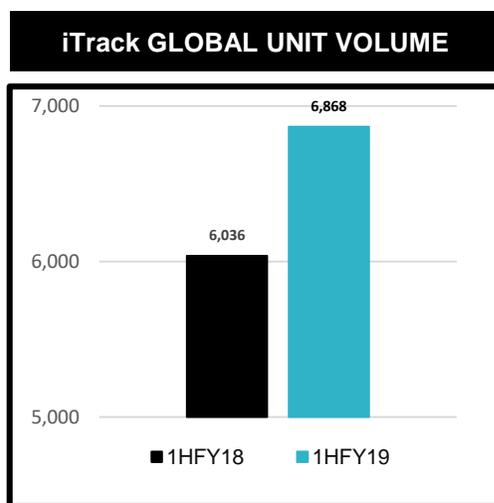


Ellex iTrack™ MIGS

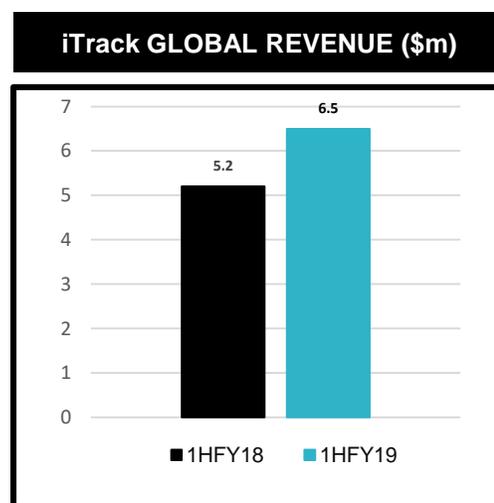


# 1H FY19 Financial Results – Ellex iTrack

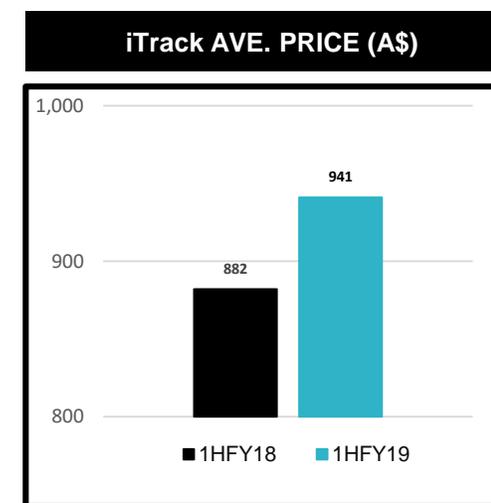
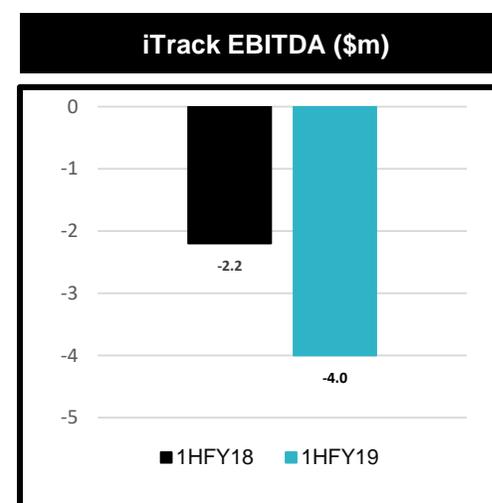
- Unit volumes increased 14% on pcp and revenues were up 24% (up 16% on a cc basis) to \$6.5m
- Pricing remained stable in USD terms, reimbursement remains very strong in key US market
- Higher Average AUD price attributable to FX benefits and mix effects from higher US volumes
- Gross margin (ex-labour) was 82% (up significantly from 73% in pcp), reflecting higher volumes and positive mix effects
- Increase in EBITDA loss reflects increased sales and marketing investment, coupled with negative impact of USD denominated cost base (cc EBITDA loss was \$3.7m)



3 Year CAGR – 33%



3 Year CAGR – 28%

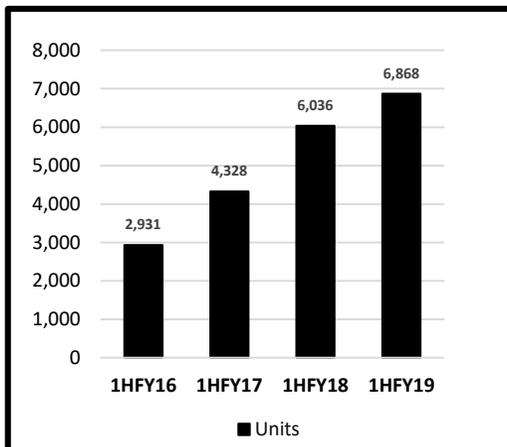




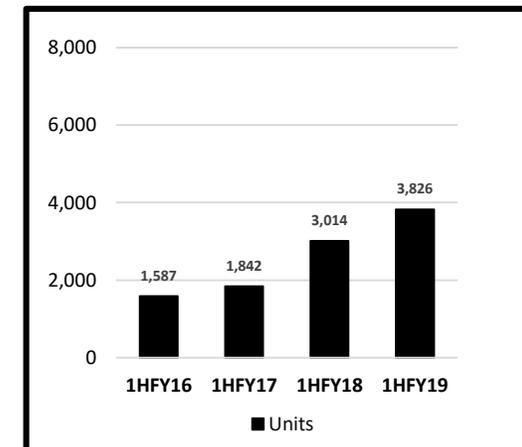
# Ellex iTrack Units by Region

- US unit sales were up 27% versus the pcp reflecting continued expansion of accounts and users and higher re-order rates
  - Approximately 75% of Ellex iTrack procedures are undertaken in the Ambulatory Surgical Setting (ASC), the balance within hospitals
- OUS unit sales were down 12% reflecting a slowdown in ordering from our German distributor, Fritz Ruck into a takeover bid by Hoya Corporation in October (TYO:7741) and increased competition from MIGS competitors
- Chinese unit sales were up 43% versus the pcp, a strong result as Ellex iTrack continues to be the only MIGS device approved in the Chinese market

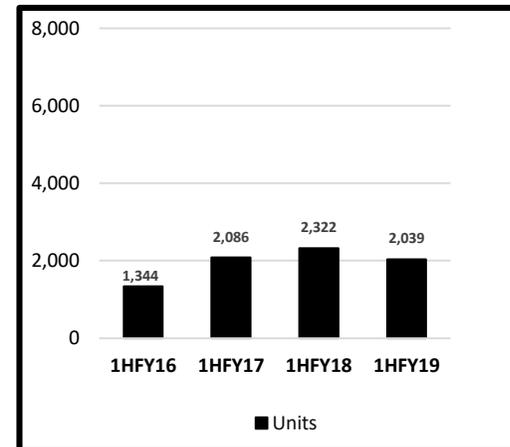
4 YEAR iTrack GLOBAL UNIT VOLUME



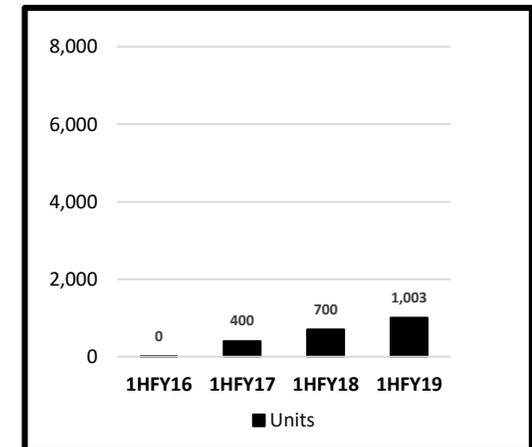
4 YEAR iTrack USA UNIT VOLUME



4 YEAR iTrack OUS (Ex. CHINA) UNIT VOLUME



4 YEAR iTrack CHINA UNIT VOLUME

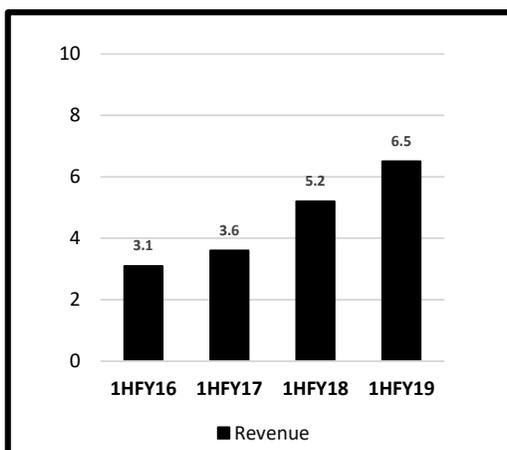




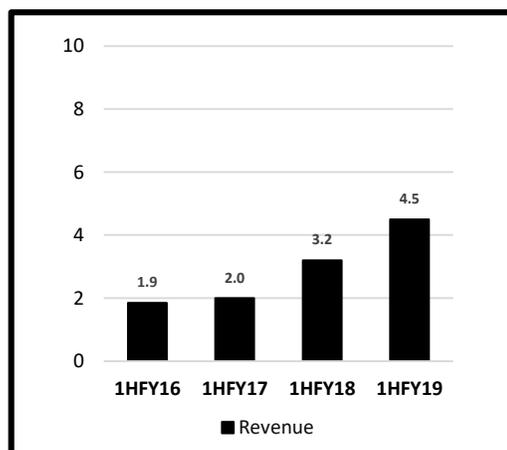
# Ellex iTrack Revenue by Region

- During the period, Ellex iTrack revenues benefited from higher volumes, stable pricing and FX tailwinds
- US revenues were up 39% on the pcp (up 30% in cc terms)
- OUS (Ex. China) revenues were down 10% on the pcp (down 16% in cc terms)
- Chinese revenues were up 27% on the pcp (up 18% in cc terms)

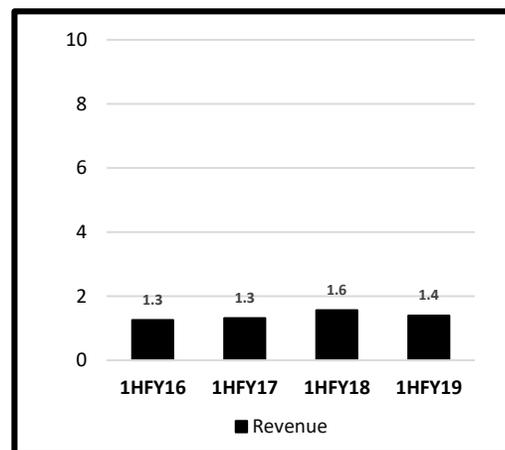
4 YEAR iTrack GLOBAL REVENUE (\$m)



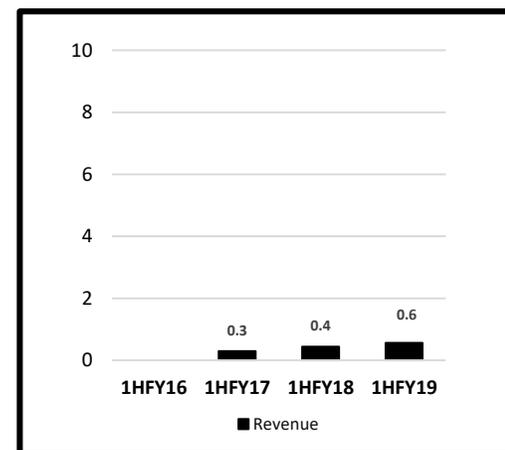
4 YEAR iTrack USA REVENUE (\$m)



4 YEAR iTrack OUS REVENUE (\$m)



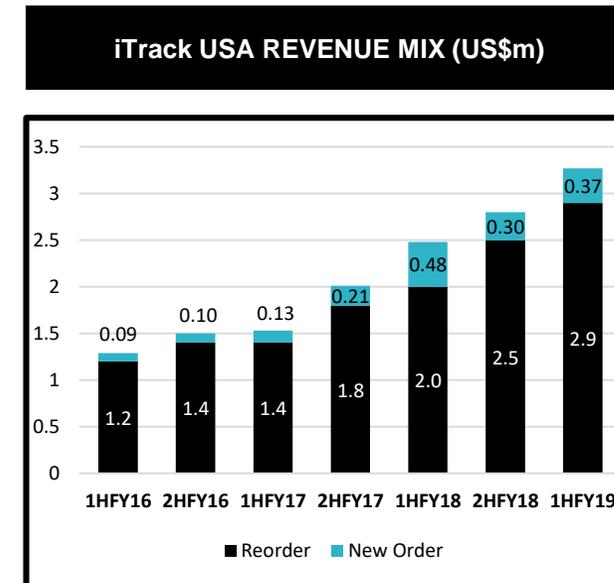
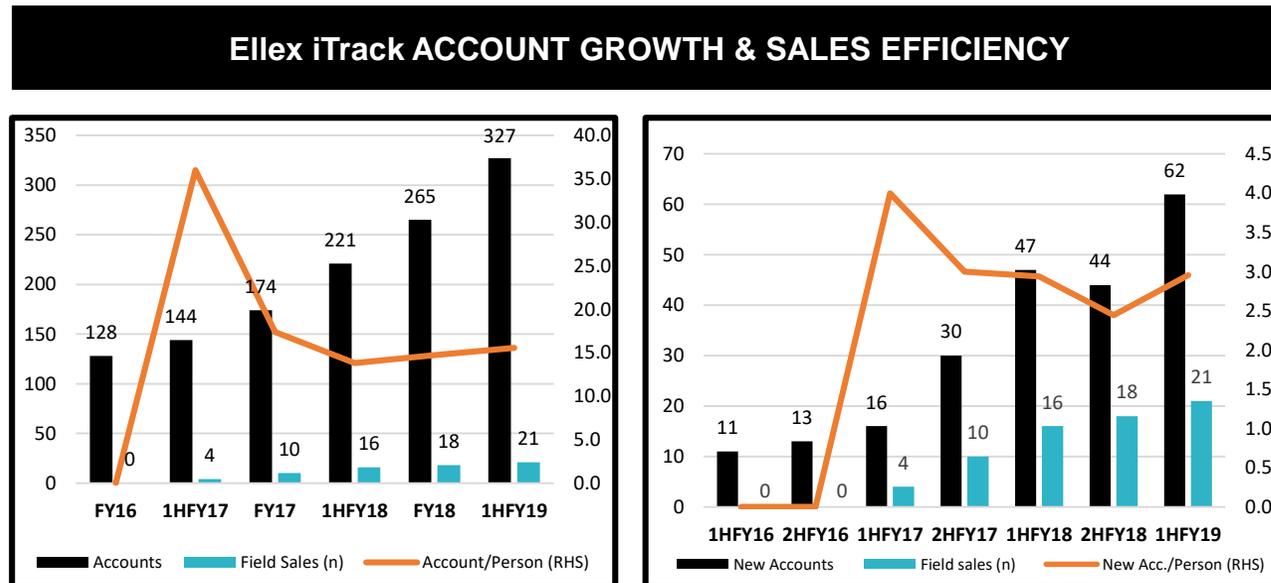
4 YEAR iTrack CHINA REVENUE (\$m)





# Detailed Ellex iTrack USA Update

- New account set up has been strong, without significant headcount expansion creating greater efficiencies and lower cost
- Increase in new orders of 23% versus pcp, while new order/reorder mix was stable versus the 2HFY18 – reorders expected to improve in 2HFY19 given 32% increase in 1HFY19 new A/Cs versus pcp
- Significant runway of opportunity remains: 1HFY19 Accounts imply ASC penetration rate of ~13%, user penetration of ~5%
- Planned CAPEX for Stage 3 production expansion to >100,000 units per annum delayed, as internal capacity exceeds 50,000 units, implying <25% utilisation at FY18 unit production volume



\* Field sales includes territory sales representatives and clinical trainers



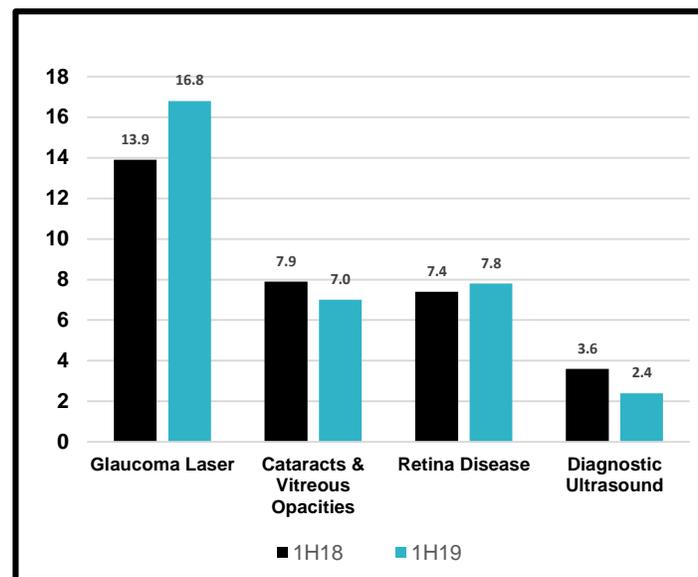
Lasers & Ultrasound



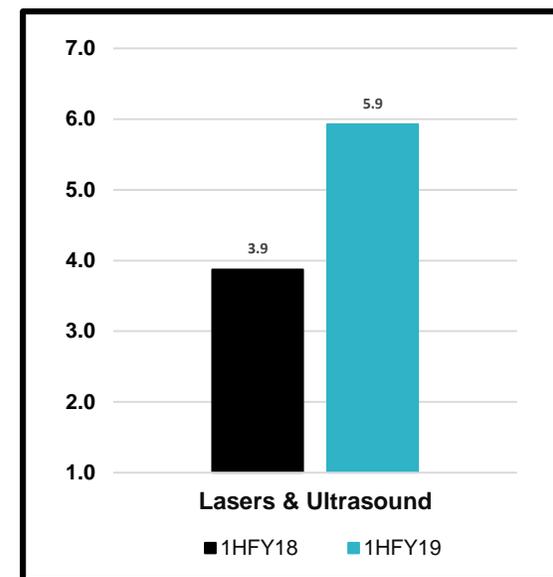
# 1HFY19 Financial Results – Lasers & Ultrasound

- Lasers and ultrasound revenue up 4% to \$33.9m (up 2% in constant currency terms), gross margin up 620 bps to 58.9%
  - Sales focus on higher margin products, particularly in the US and Japan
- Segment EBITDA surged 53% to \$5.9m
  - Combination of cost base leverage, product mix effects and favourable FX effects
  - Flat OPEX (\$1m in OPEX reduction in cc terms)
- Glaucoma SLT laser sales were up 21% to \$16.8m (up 18% in cc)
  - Concerted marketing effort, growth in combined SLT/vitreous opacity laser (Tango Reflex™)
  - Shift away from pharmaceutical (eyedrop) interventions to SLT as a first-line standard of care
- Retina disease lasers were up 5% to \$7.8m
  - Doctor acceptance of Ellex retina lasers as best in class devices
  - Partially offset by shift to pharmaceutical interventions
- Cataract and vitreous opacities lasers down 11% to \$7.0m
  - Pricing pressures from conventional photodisruptors
  - Purchasing decision delays in Europe
- Diagnostic ultrasound down 32% to \$2.4m
  - Delayed customer orders as awaiting for new product launch
  - Two product introductions planned 2HFY19

LASERS & ULTRASOUND REVENUE BY DISEASE (\$m)



LASERS & ULTRASOUND EBITDA (\$m)



3 Year Revenue CAGR of 3%



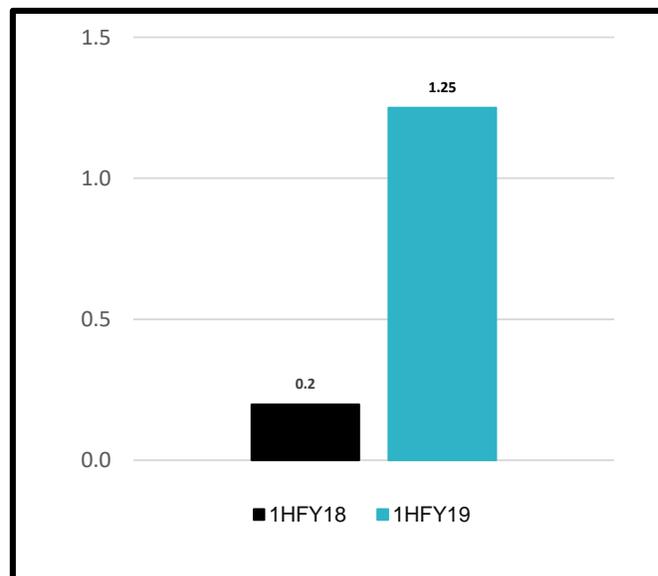
Ellex 2RT<sup>®</sup> for Intermediate AMD



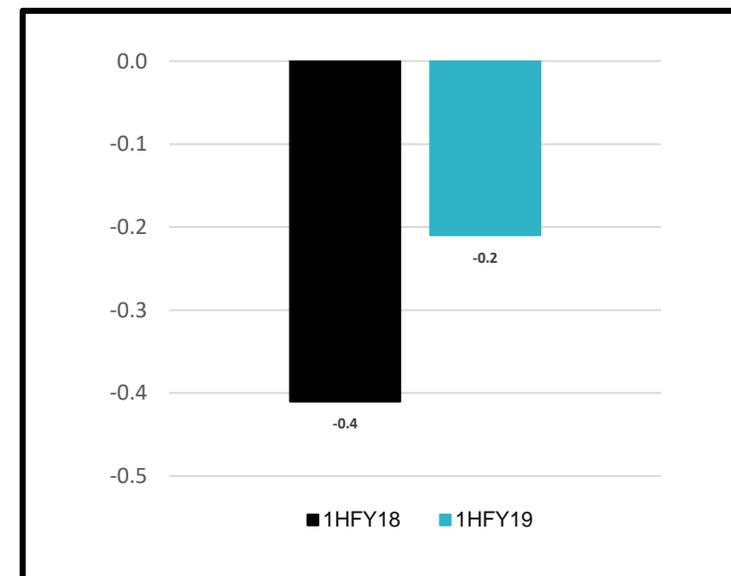
# 1H19 Financial Results – 2RT

- 532% increase in revenue to \$1.2m
- Gross margin declined 300 bps to 57% versus pcp as unit sales mix initially skewed to distributor markets
- Segment EBITDA loss decreased \$0.2m, despite significant sales & marketing post LEAD results
- >80% 1H19 sales in 2Q19, post LEAD results
- EU sales driven by iAMD<sup>1</sup> indication post LEAD
- First sale recorded in the USA<sup>2</sup>
- Purchase price & per procedure fee stable
- Procedural fee revenue +100% to \$0.2m versus pcp

ELLEX 2RT REVENUE (\$m)



ELLEX 2RT EBITDA (\$m)

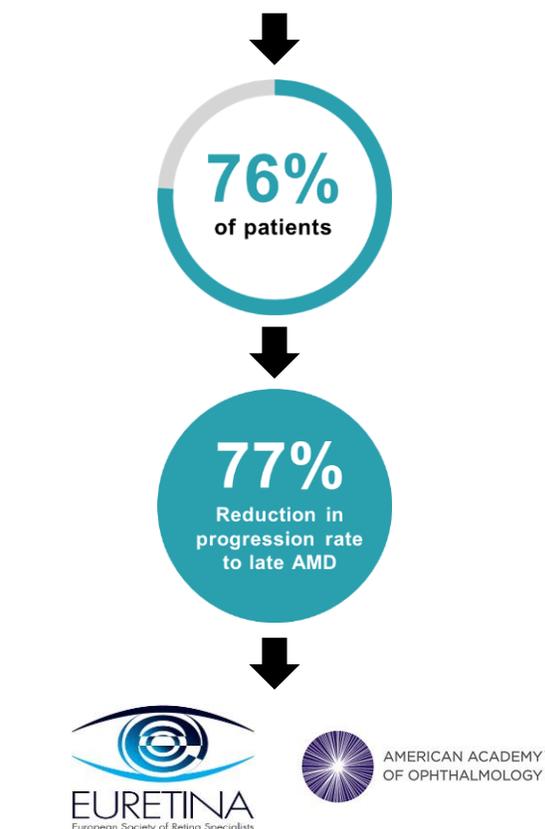


# 2RT Update on Initiatives

- Focus on the education and marketing of the LEAD clinical study results (Sept) showing a clinically meaningful 77% reduction in the progression rate to late AMD in 76% of patients in the study
- Sales and marketing campaign across EURETINA and AAO\* with 30,000 clinicians + associates in attendance – generated a number of future sales prospects
- LEAD was the first ever study to show a significant efficacy effect in an iAMD population
- Currently establishing two important reference sites: Stanford University (Byers Eye Institute) for CSME and a second site in Germany
- On track to establish US regulatory pathway for 2RT in iAMD with the FDA during CY19
  - Commenced pre-submission dialogue with the FDA
  - Ellex notes recent FDA acceptance of novel registrable primary endpoints in advanced 'dry AMD' unrelated to visual acuity and measured by imaging assessment in 2x Phase 3 pivotal studies (Apellis Pharmaceuticals; NASDAQ:APLS)

TIMELINE	STRATEGY	ACHIEVED?
Short	Increase EU, AU and NZ footprint	Yes (+531% sales post LEAD)
Medium	Secure pathway from FDA for registration	Pending – 2019
Long	FDA clearance & SOC^ therapy in iAMD	2020 & beyond

## LEAD 2RT





# Outlook

**Ellex reaffirms it remains on track to grow group sales and deliver an improved EBITDA result in FY19 subject to global economic conditions and foreign exchange rates**

- While Ellex iTrack and 2RT performed strongly for the 1H, there was an unexpected slow down in equipment sales in the US and EMEA in the 2QFY19, which saw group revenue growth moderate for the 1H v AGM update on sales through October
- Ellex iTrack will continue its trajectory of growth in FY19, with EBITDA now expected to be similar to FY18 levels
- Ellex Laser & Ultrasound segment FY19 EBITDA growth on FY18, due to continued clinical adoption of Ellex Tango™ / Ellex Tango Reflex™ in glaucoma disease and diligent cost management
- Momentum in Ellex 2RT sales observed in 1HFY19 expected to continue into FY19, albeit off a low base



# Contacts

## TOM SPURLING

## MARIA MAIELI

## DR. TOM DUTHY

## JULIA MAGUIRE

### CEO

M (USA) : +1 510 504 1267

M (AUS) : +61 417 818 658

E: [tspurling@ellex.com](mailto:tspurling@ellex.com)

### CFO & Company Secretary

W: +61 8 7074 8200

E: [mmaieli@ellex.com](mailto:mmaieli@ellex.com)

### Investor Relations & Corporate Development

M: +61 402 493 727

E: [tduthy@ellex.com](mailto:tduthy@ellex.com)

### Media Relations The Capital Network

M: +61 419 815 386

[julia@thecapitalnetwork.com](mailto:julia@thecapitalnetwork.com)

For more information visit [www.ellex.com](http://www.ellex.com)



## QUESTIONS/DISCUSSION



# Appendices



# Average FX Rates

Average FX		
	1HFY18	1HFY19
AUD:USD	0.78	0.725
AUD:EUR	0.66	0.62
AUD:YEN	87.2	81.4



# 1HFY19 EBITDA by Segment

	A\$'000's				
	CLU	iTrack	2RT	Corporate	Total
<b>Revenue</b>	<b>33,912</b>	<b>6,468</b>	<b>1,250</b>	-	<b>41,630</b>
Other Income	-	-	-	250	250
Changes in inventories of finished goods and work in progress	1,252	125	(19)	-	1,358
Raw materials and consumables used	(15,189)	(1,318)	(523)	-	(17,030)
	19,975	5,275	708	250	26,208
Gross margin related % <sup>(1)</sup>	59%	82%	57%		
Employee benefits expense	(9,260)	(5,713)	(156)	(1,605)	(16,734)
Facilities expense	(359)	(250)	(13)	(569)	(1,191)
Legal expenses	-	-	-	(51)	(51)
Advertising, marketing and congress expense	(2,181)	(1,150)	(374)	-	(3,705)
Product development raw materials and consumables used	(687)	-	(25)	-	(712)
Realised foreign exchange (loss)/gain	465	(15)	19	-	469
Other expenses	(2,025)	(2,152)	(371)	(582)	(5,130)
<b>EBITDA</b>	<b>5,928</b>	<b>(4,005)</b>	<b>(212)</b>	<b>(2,557)</b>	<b>(846)</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



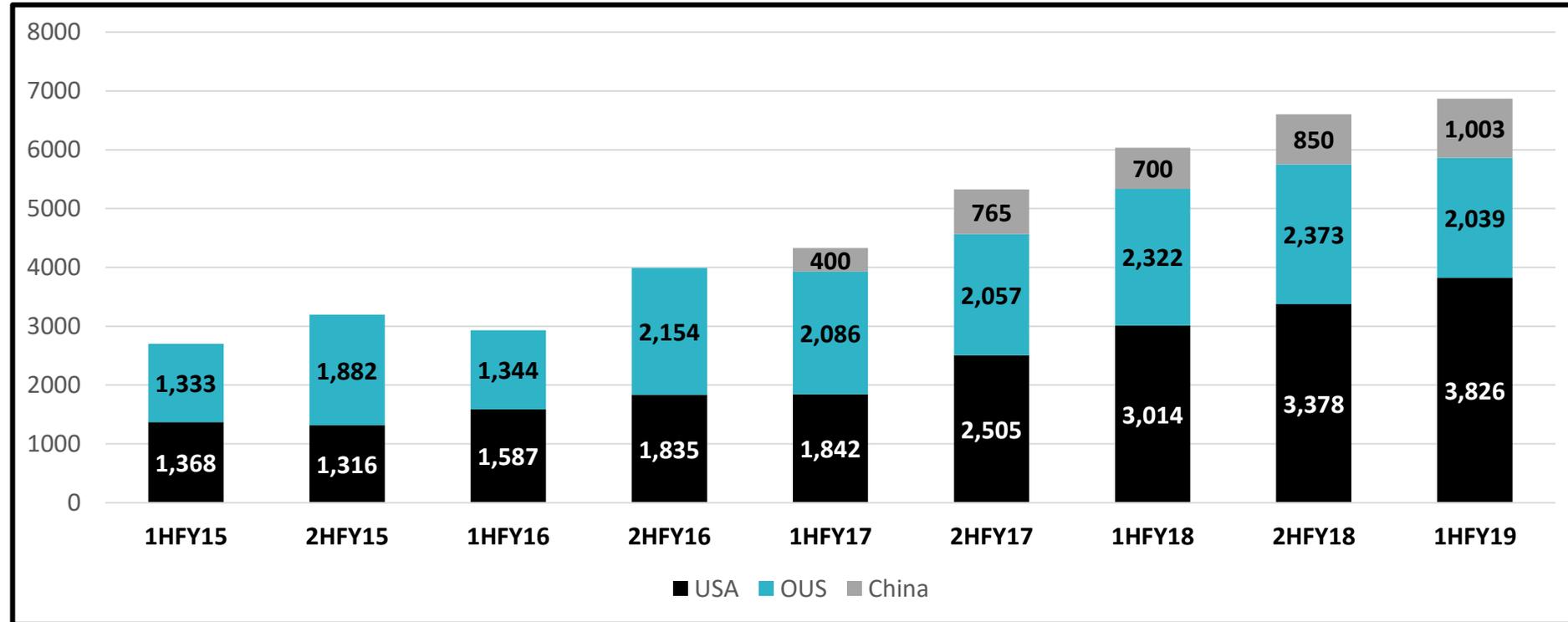
# 1HFY18 EBITDA by Segment

	A\$'000's				
	CLU	iTrack	2RT	Corporate	Total
<b>Revenue</b>	<b>32,685</b>	<b>5,221</b>	<b>197</b>	<b>-</b>	<b>38,103</b>
Other Income	-	-	-	143	143
Changes in inventories of finished goods and work in progress	(1,328)	473	(70)	-	(925)
Raw materials and consumables used	(14,103)	(1,892)	(9)	-	(16,004)
	17,254	3,802	118	143	21,317
Gross margin related % <sup>(1)</sup>	53%	73%	60%		
Employee benefits expense	(9,250)	(3,411)	(55)	(963)	(13,679)
Facilities expense	(380)	(152)	(6)	(548)	(1,086)
Legal expenses	-	-	-	(84)	(84)
Advertising, marketing and congress expense	(1,474)	(749)	(261)	-	(2,484)
Product development raw materials and consumables used	(449)	-	(3)	-	(452)
Realised foreign exchange (loss)/gain	(227)	7	(1)	-	(221)
Other expenses	(1,597)	(1,685)	(206)	(779)	(4,267)
<b>EBITDA</b>	<b>3,877</b>	<b>(2,188)</b>	<b>(414)</b>	<b>(2,231)</b>	<b>(956)</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
<b>TOTAL Units</b>	<b>2,701</b>	<b>3,198</b>	<b>2,931</b>	<b>3,989</b>	<b>4,328</b>	<b>5,327</b>	<b>6,036</b>	<b>6,601</b>	<b>6,868</b>
growth % (pcp)			9%	25%	48%	34%	39%	24%	14%
growth % (HoH)		18%	-8%	36%	8%	23%	13%	9%	4%