

Ellex Medical Lasers
Limited (ASX:ELX)

US Institutional Roadshow
Investor Presentation

8 October 2018





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Ellex Group Key Information

Key Information (ASX:ELX)		
Market Cap (2 Oct)	A\$105million	US\$79million
Revenue	A\$79.1million	US\$60million
Cash at Bank (30 June 2018)	A\$23.1million	US\$17.3million
Borrowings (30 June 2018)	A\$15.0million	US\$11.3million
Operating cash flow during 12 months to 30 June 2018	A\$0.5million	US\$0.4million

* AUD/USD exchange rate 0.75

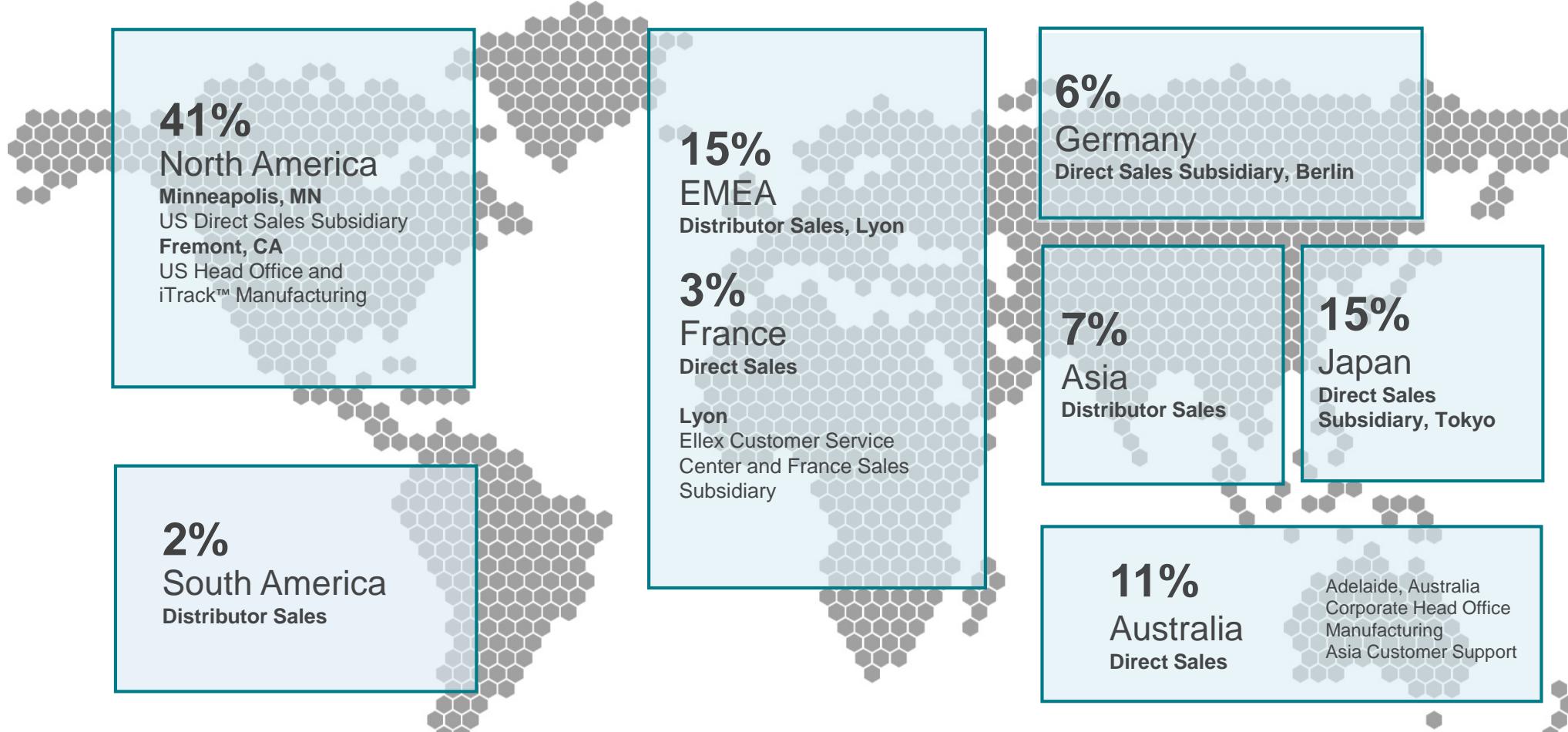
3 Segments:

- Ellex Laser & Ultrasound
- Ellex iTrack™
- Ellex 2RT®

- ✓ Participating in the global market for supply of products that treat the four major causes of blindness; glaucoma, diabetic eye disease, cataracts and age-related macular degeneration
- ✓ Strong base business brand with global distribution channel
- ✓ Growth strategy from unique products that restore and rejuvenate ocular systems
- ✓ Growth strategy self-sustaining from existing cash from operations
- ✓ Recently reported results of major clinical trial for a nano-pulse laser therapy for Age-Related Macular Degeneration (AMD) – LEAD Study
- ✓ Ellex 2RT® slowed progression of intermediate AMD to late AMD by 77% versus sham in a well-defined, clinically significant patient group



Ellex Established Global Sales Channel



- Manufacturing Laser & Ultrasound in Adelaide, Australia
- Manufacturing Ellex iTrack™ in Fremont, CA



Ellex 2RT® and the LEAD Clinical Trial

The LEAD trial has validated the safety and efficacy of Ellex 2RT® retinal rejuvenation laser as an intervention for many people with intermediate Age-Related Macular Degeneration (iAMD) and provides a platform for Ellex to access a large commercial opportunity.

- Double-masked, randomised, sham-controlled trial over 36 months in 292 patients with iAMD across six sites with 1:1 randomisation to Ellex 2RT® or sham treatment received at six monthly intervals¹
- **Sub Group** – *post hoc* analysis on patients without coexistent reticular pseudodrusen (RPD) deposits representing 76% of enrolled patients versus 24% with RPD at baseline – **clinically significant 77% reduction** in rate of progression to advanced AMD ($p=0.002$) over 36 months
- **Primary endpoint** – progression to advanced AMD in treated eye of Ellex 2RT® patients versus sham patients
 - **Secondary endpoints** – safety, change in drusen volume and visual function, progression to advanced AMD in non-study eye (only safety reported to date)
 - Largest ever randomised study conducted in iAMD patients with a non-thermal, non-invasive pulse laser intervention and to show significant efficacy in this population
 - Excellent safety profile noted
 - Results are applicable only to Ellex 2RT® – authors discourage extrapolation of results to other thermal or non-thermal lasers
 - Important new clinical information to guide retinal specialists in patient selection towards those without evidence of RPD



The Commercial Opportunity for Ellex

- Ellex 2RT® has multiple approvals and is patent protected to 2035:
 - CE Mark: AMD in 2014 and DME* in 2012
 - FDA (510(k)): CSME** in 2013
- Where Ellex 2RT® is approved for AMD, these markets represent an addressable 15 million patients per annum for screening and then treating those early stage patients without detectable RPD¹
- Addressable market similar in size (patients) to late stage ‘wet’ AMD – 15 million patients
- Ellex's commercialisation plan will be developed based on physician feedback, peer-to-peer educational programs focused on disease diagnosis, patient selection and treatment protocols
- Future regulatory clearances in the US, Japan and China will increase the pool of treatable patients to 25 million per annum²
- No currently approved treatments for iAMD – only dietary and lifestyle modifications (a standard that resulted from analysis of the AREDS1 and AREDS2 studies^{3,4})
- AREDS2 showed an 18% reduction in progression
- Therapeutic approvals have been limited to late stage ‘wet’ AMD, which represents the minority of AMD patients

* DME – Diabetic Macular Edema; “CSME” – Clinically Significant Macular Edema

¹ Marketscope Report August 2017 Ophthalmic Laser Report Table 2 “Global Forecast for AMD in all its Forms”, adjusted for Ellex estimates on RPD patients

² 3m in the USA, 6m in China and 1m in Japan

³ Age-Related Eye Disease Study Research Group. AREDS Report No. 8: A Randomized, Placebo-Controlled, Clinical Trial of High-Dose Supplementation With Vitamins C and E, Beta Carotene, and Zinc for Age-Related Macular Degeneration and Vision Loss. Archives of Ophthalmology 2001; 119 (10): 1417–1436.

⁴ Age-Related Eye Disease Study 2 Research Group. Lutein + zeaxanthin and omega-3 fatty acids for age-related macular degeneration: the Age-Related Eye Disease Study 2 (AREDS2) randomized clinical trial. JAMA. 2013 May 15;309(19):2005-15.

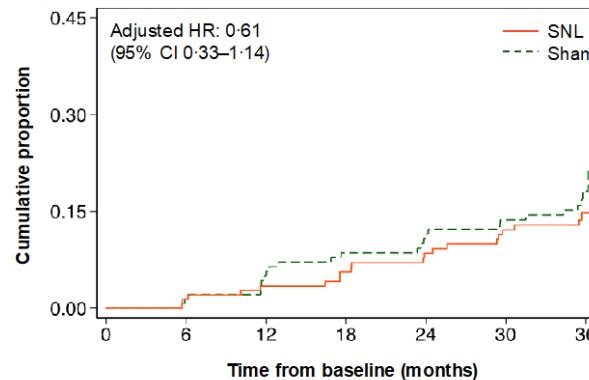


Highlights of Announcement of the LEAD Study Results

- The study results were published in “Ophthalmology” the journal of the American Academy of Ophthalmology and presented on 20 September 2018 by Prof. Guymer at EURETINA in Vienna, Austria
- Significant interest from doctors in the dramatic reduction in progression seen in RPD minus patients
- To provide such exquisite precision in ideal patient for treatment was of high clinical interest (noting the RPD positive patients may not be candidates for therapy)
- Applauded the use of Multi Modal Imaging (MMI) techniques in monitoring progression of iAMD – remains a guiding tool for treatment decisions by clinicians
- Given the strength of the study, Ellex intends to meet with the FDA to determine next steps required for US commercial launch in AMD

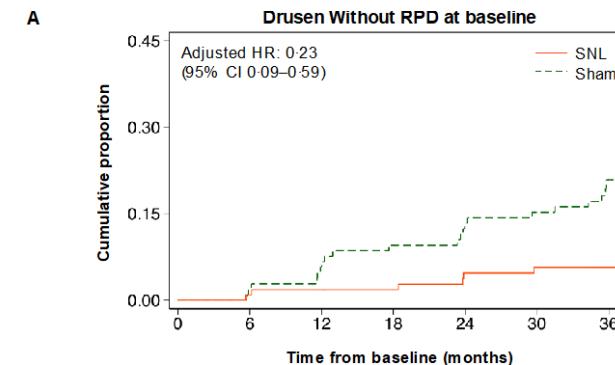
Ellex 2RT® LEAD Summary Results

PRIMARY ENDPOINT (ITT*)



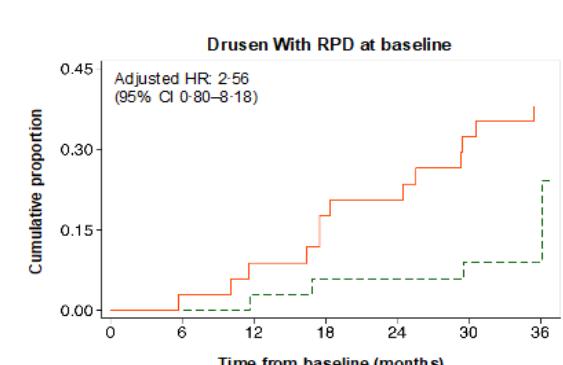
Number at risk								
	Sham	145	143	137	128	127	120	117
	SNL	147	145	140	133	128	123	119

RPD⁻ (ITT)



Number at risk								
	Sham	110	108	102	96	95	90	88
	SNL	112	111	108	103	101	99	97

RPD⁺ (ITT)



Number at risk								
	Sham	35	35	35	32	32	30	29
	SNL	35	34	32	30	27	24	22

- Primary Endpoint:** No significant difference in progression to late AMD under ITT analysis ($p=0.122$); Non-significant trend in favour of 2RT®
- RPD(-) Group:** A clinically meaningful 77% reduction in the rate of progression (HR=0.23); significant treatment effect in this patient population ($p=0.002$); RPD is a key biomarker of retinal pigment epithelium (RPE) dysfunction and has a high association with progression to late-stage AMD
- RPD(+) Group:** Non-significant ($p=0.112$) Increased rate of progression to late-stage AMD in the 2RT® treatment group; data is clinically valuable in selecting patients who are likely to respond to Ellex 2RT®

ellex.com

*ITT – Intent to Treat; Adjusted Hazard Ratio (HR) - The potential confounders of baseline age (as a continuous measure), sex, intake of Lutein-Vision® or Macu-Vision® at baseline (yes vs. no for each), presence of RPD and pigmentary abnormalities (definitely present vs. absent/questionable) were additionally included as covariates in a fully adjusted model as specified *a priori*



Ellex Group Summary FY18

- Group sales growth of 13%¹ compared to prior year to \$79.1m
- Implementation of targeted glaucoma sales growth strategy demonstrating tangible results with 39%¹ growth in the year and four-year CAGR of 28%
- \$11.4m¹ of Ellex iTrack™ sales accelerating with solid growth in the last quarter of 20%¹. Ellex iTrack™ achieved 48% revenue growth in the USA and 20% outside the USA for the year. EBITDA-level loss of \$5.2m as a result of investment in USA sales and marketing infrastructure.
- Ellex Laser & Ultrasound sales up 10.4%¹ for the year, driven by strong glaucoma laser sales combined with improvement in divisional EBITDA to \$8.3m.
- Reduction in corporate costs in FY18 of \$0.5m (13.5%) compared to prior corresponding period (pcp)
- Despite the investment in Ellex iTrack™, as a result of good working capital management, cash flow from operations was up \$4million compared with pcp to a positive \$0.5million, indicating the self-sustaining nature of the growth strategy
- Cash at bank of \$23m at 30 June 2018

	\$Am				
	Lasers & Ultrasound	2RT®	iTrack™	Corporate Costs	Total
FY18					
Revenue	67.5	0.5	11.1	--	79.1
EBITDA/(loss)	8.3	(1.0)	(5.1)	(3.4)	(1.2)
FY17					
Revenue	62.5	0.9	8.2		71.6
EBITDA/(loss)	7.3	(0.4)	(1.3)	(4.1)	1.5

(1) Based on constant currency, converting FY18 at FY17 average A\$ exchange rates for USD, EUR, YEN



Ellex Group Performance by Business Segment in FY18

Segment	Revenue FY18	Segment EBITDA \$Am/(loss)	Business Model	Current Market Size per annum	Current Estimated Market Growth Rate	Ellex Revenue Growth in FY18 in Constant Currency
Ellex Core Laser & Ultrasound	67.5	8.3	Capital equipment sales	US\$350m	2% ⁽¹⁾	10.4%
Ellex iTrack™	11.1	(5.1)	Consumable product	US\$300m ⁽²⁾	35% ⁽²⁾	39%
Ellex 2RT® for early AMD	0.5	(1.0)	Capital equipment & procedure fee	US\$5bn to US\$10bn ⁽³⁾	7.1% growth ⁽³⁾ in 7 major economies	0%
Corporate & other		(3.4)				
Total EBITDA		(1.2)				

(1) Combination MarketScope Ophthalmic Lasers Report June 2017 and MarketScope Diagnostic Equipment Report July 2018.

(2) MarketScope "Glaucoma Surgical Device Report" dated August 2017 estimates for MIGS and canal-based devices 2017 to 2022.

(3) PharmaPoint: Macular Edema and Macular Degeneration- Global Drug Forecast and Market analysis to 2023" published in Dec 2014



Ellex Accessing Large, Rapidly-Growing Markets

1

CURRENT -GLAUCOMA GROWTH STRATEGY

Glaucoma is the **second-leading** cause of blindness in the developed world.

1. Increased uptake of Ellex Tango™ as primary therapy
2. Increased market penetration of Ellex iTrack™ MIGS device
3. Exploit synergies between Ellex Tango™ and Ellex iTrack™

2

NEAR TERM - 2RT® REJUVENATIVE LASER THERAPY FOR EARLY AMD

Age related macular degeneration is the **leading** cause of blindness in the developed world.

1. Outcome of clinical trial reported on 21 September 2018
2. Addressable market of 15 million patients annually in existing 2RT® markets (equivalent in size to wet AMD market)
3. Leverage existing global sales channel to commercialize Ellex 2RT® in key markets

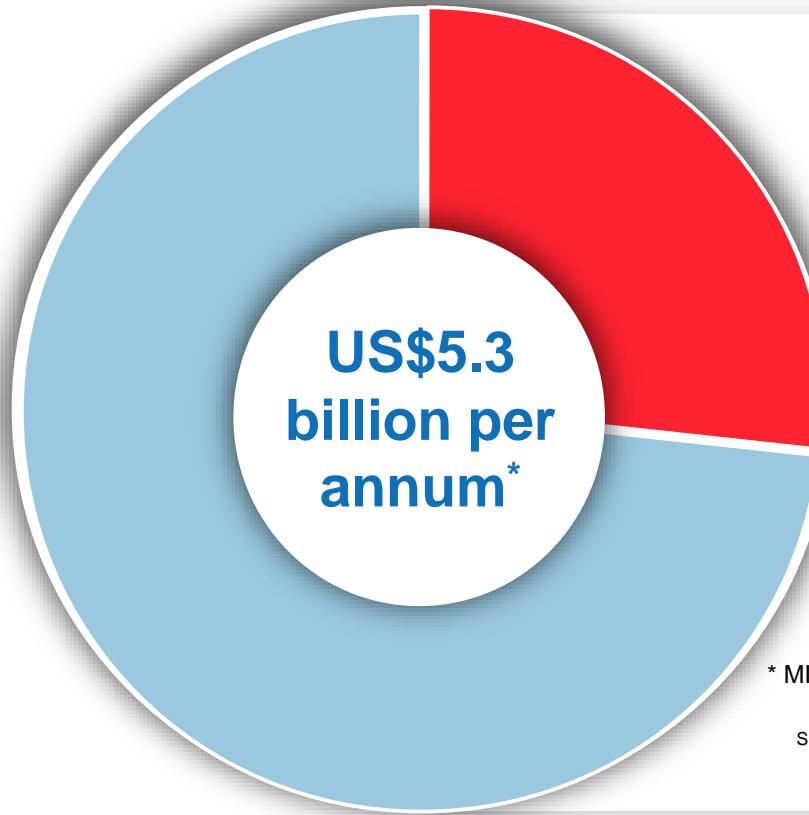


Glaucoma Devices Market - Growth

CURRENT MARKET¹ (in US millions)

- MIGS*
US\$263m
- PHARMA
US\$4600m

US\$4.9
billion per
annum*



PROJECTED MARKET IN 2022¹ (in US millions)

- MIGS*
US\$1423m
- PHARMA
US\$ 3900m

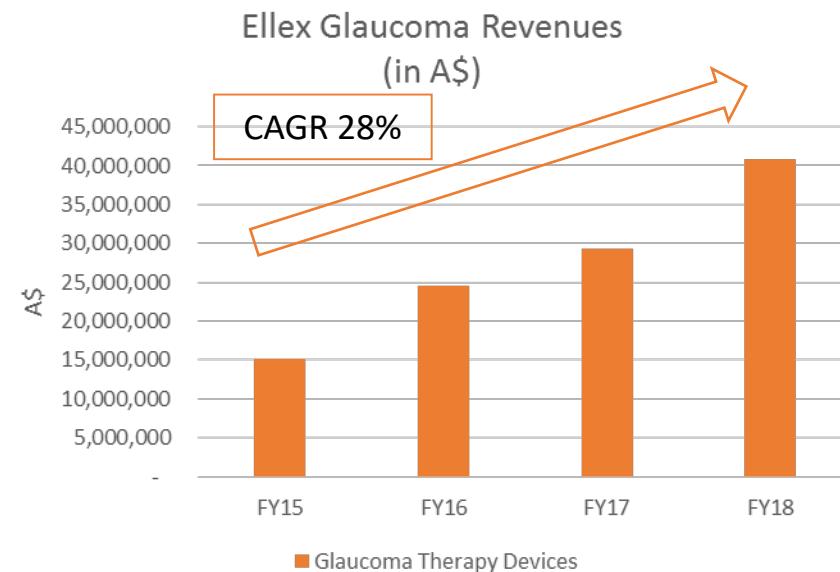
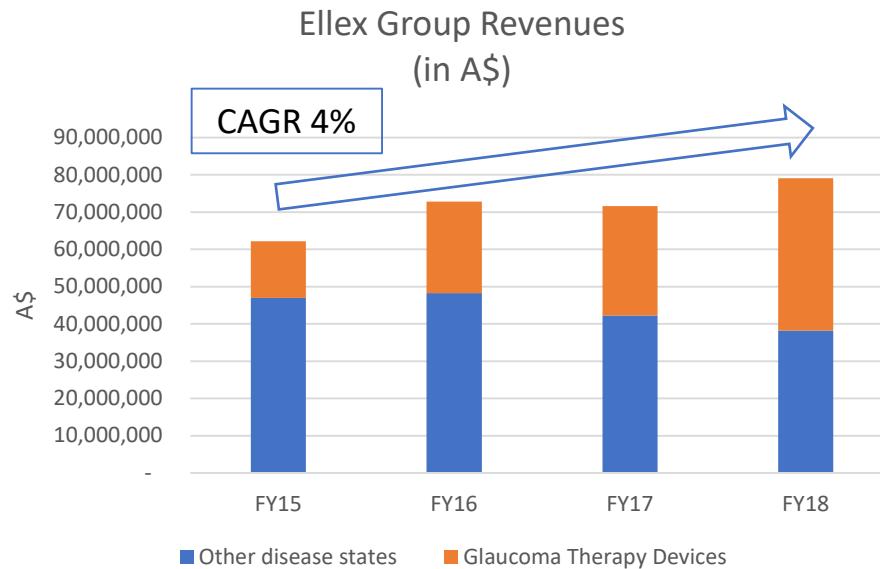
* MIGS market includes SLT.

1. MarketScope 2017 Glaucoma
Surgical Devices, Early to Moderate
Glaucoma Therapy Devices



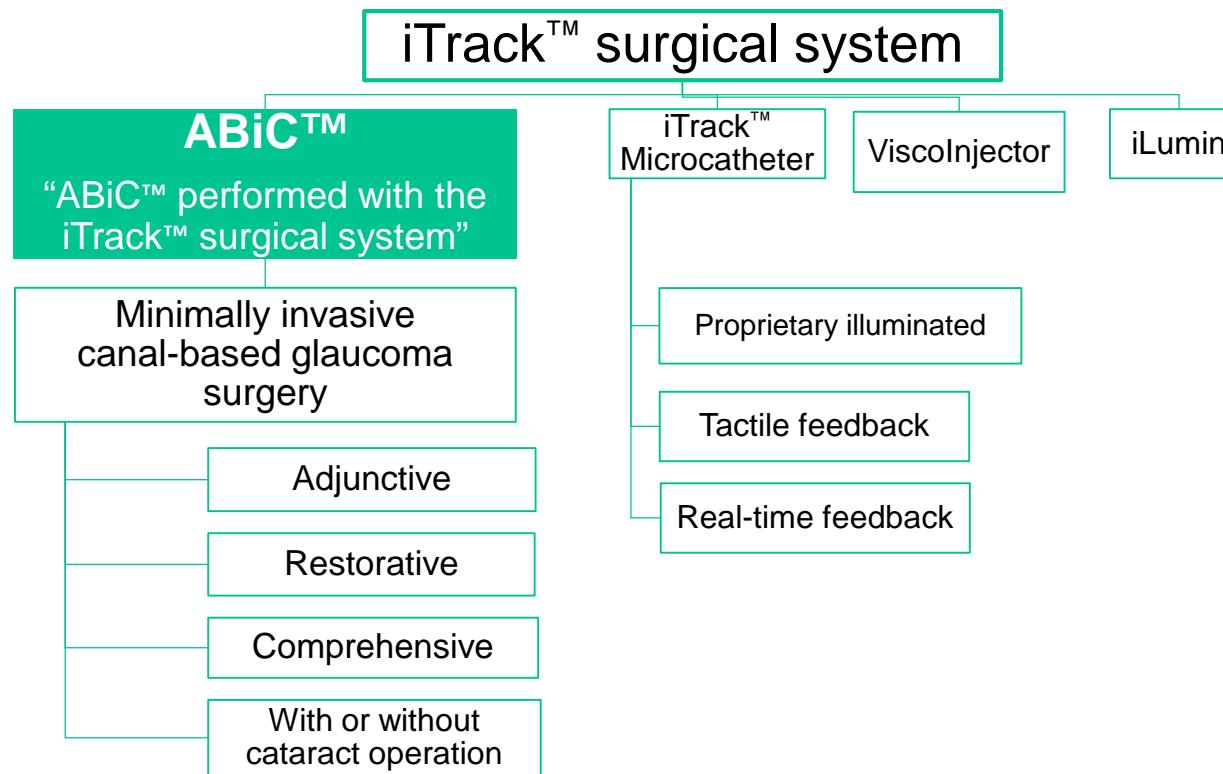
Growth in glaucoma device demand driven by emerging recognition of poor patient compliance and side effects associated with topical medication.

Ellex Restorative Glaucoma Therapy Device Revenue Drives Growth

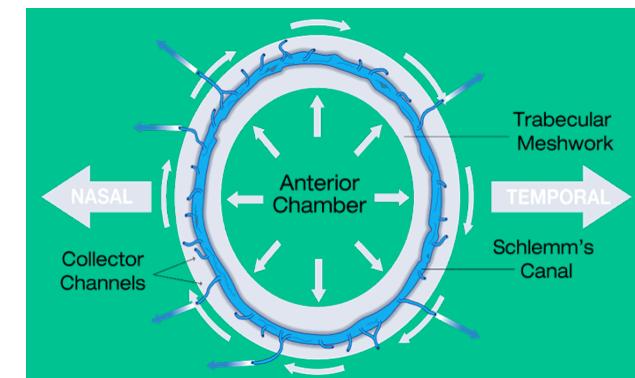


- Over the 4 years to FY18, Ellex achieved a CAGR of 28% for glaucoma revenues. MarketScope estimates the current US\$350m per annum market will grow to US\$1.4bn per annum at a CAGR of 33%.
- With Ellex Tango™ and Ellex iTrack™, Ellex has a demonstrated capacity to compete and grow sales in this fast-growing market.

Ellex iTrack™ Unique Characteristics Drives Customer Targeting

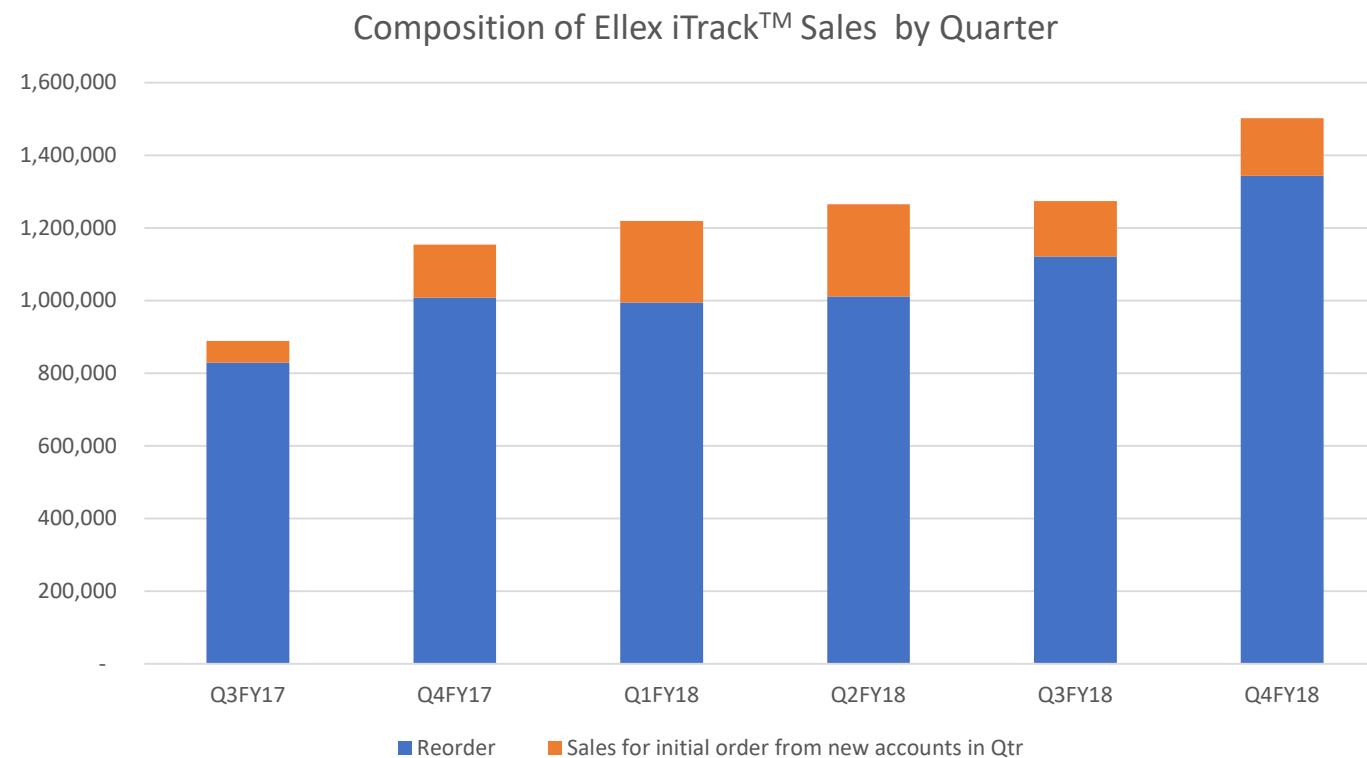


- There are now a large number of ophthalmic physicians considering options for minimally invasive interventional glaucoma surgeries ahead of eye drops and invasive surgery, and many options being presented.
- Ellex is targeting a segment of physicians for whom the clinical benefits of the Ellex iTrack™ surgical system resonate and for whom the device fits into the physicians surgery and practice pattern.
- We estimate that there are many physicians in the USA alone and Ellex iTrack™ penetration is currently low but growing.





Ellex iTrack™ – USA sales

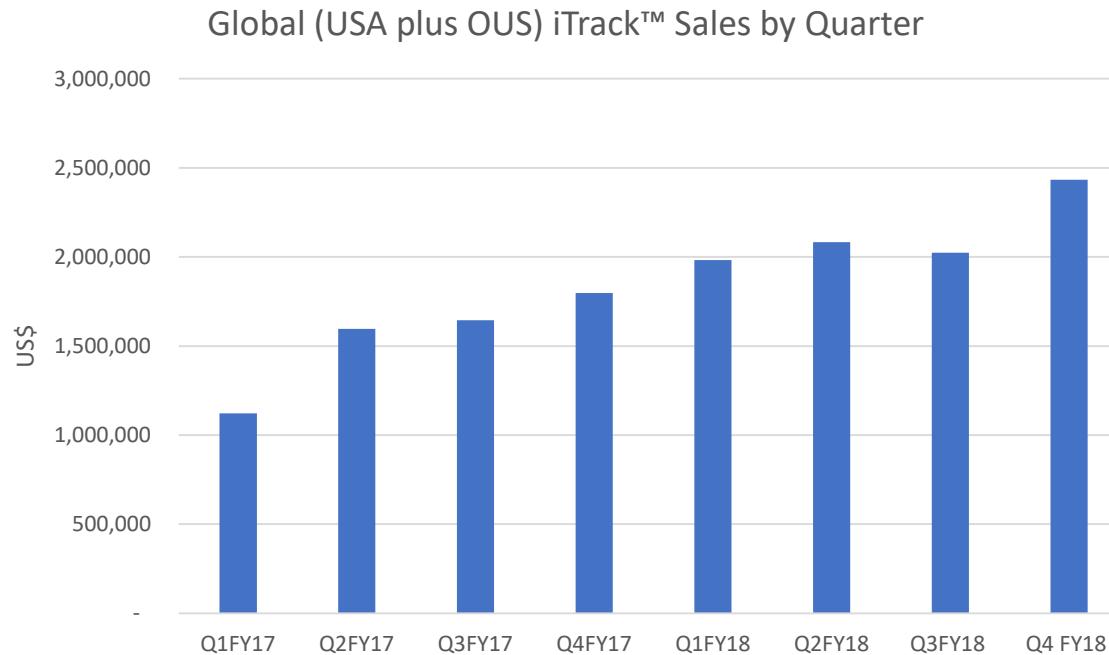


Improved sales and re-orders in the USA due to:

- Improved experience of sales team;
- Investment in sales team management;
- Specific targeting of physicians for whom the benefits of iTrack™ resonate;
- Consultative selling to physicians focussing on surgical technique, patient selection and helping physicians determine their treatment approach for glaucoma;
- Deployment of capital on additional marketing since January 2018 to improve podium presence and communication of the restoration and rejuvenative message.



Ellex iTrack™ – Global Sales



OUS sales growth from:

- Additional take up from doctors in China. We continue to work with our distribution in China to advance physician training and hospital approvals. During the 8 months to August 2018, Ellex iTrack™ was presented by our Chinese Key Opinion Leaders at 14 ophthalmic conferences in 7 major Chinese cities.
- Advancement of the ABiC technique with German physicians.

	12 months to 30 June 2018		
	2017	2018	Growth
Units:			
USA	4,347	6,392	47%
China	1,165	1,550	33%
Rest of world	4,143	4,695	13%
	9,655	12,637	31%
US\$ sales revenue:			
USA	3,604,816	5,322,153	48%
China	555,000	752,250	36%
Rest of world	2,046,254	2,456,505	20%
	6,206,070	8,530,908	38%



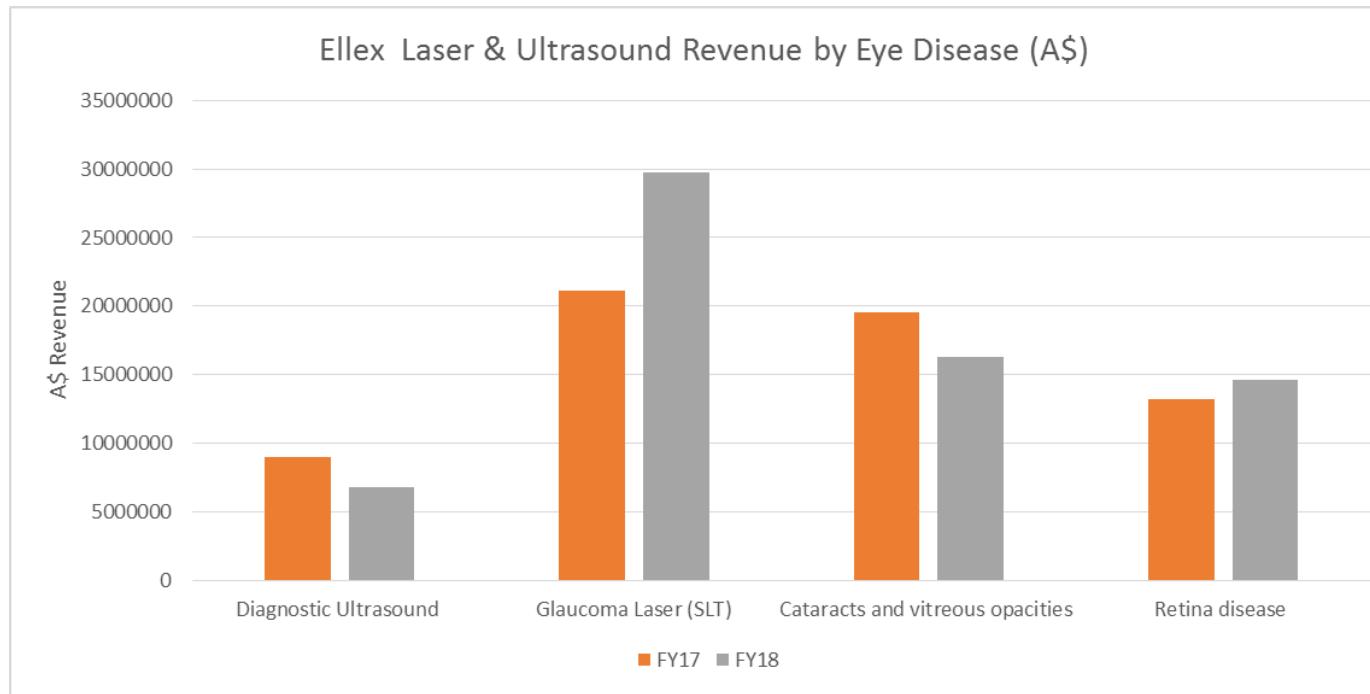
Ellex Laser & Ultrasound Market

Disease	Current Ellex Devices	Total annual spend on disease treatment with pharma and devices	Current device-market accessible to Ellex ⁽¹⁾	Assessed device-market position against competition ⁽²⁾
Glaucoma – early stage	SLT with TangoReflex™, Tango™	US\$4.6bn ⁽¹⁾	US\$46m (CAGR 1.5%)	1. Ellex 2. Lumenis
Cataracts and Vitreous Floaters	Ultra Q™ and Ultra Q Reflex™	US\$3.3bn plus 25.3 million cataract operations per year ⁽¹⁾	US\$66m (CAGR 2% plus more with vitreous floater treatment)	1. Ellex 2. Lumenis 3. Nidek
Diabetic Disease of Retina	Integre Pro™, Integre Pro Scan™ and Solitaire	US\$1.9bn ⁽¹⁾	US\$221m (CAGR 2%)	Ellex, Nidek, Lumenis, Topcon & Iridex
Diagnostic Ultrasound	Eyecubed™ and Eyeone	Included above	US\$140m (CAGR 5%)	Ellex, Sonomed & Quantel

(1) MarketScope Ophthalmic Lasers Report 2017

(2) Assessment conducted by Ellex based on publicly available information

Ellex Laser & Ultrasound Sales by Eye Disease



- 41% growth in glaucoma laser sales (MarketScope estimates market growth rate at 1.5%). Some impact on cataract and vitreous opacities laser growth due to TangoReflex™, the combined glaucoma and floater treatment laser. This performance has been driven by technical benefits of product vs competitors and the rejuvenative glaucoma therapy message.
- Despite lower selling prices, thermal lasers for retinal disease grew marginally.
- Improvement in operating margin for the business segment as a result of focus on glaucoma therapy device strategy and careful cost management.



Ellex Group Outlook for FY19

- Ellex expects to grow group sales and have an improved operating result in FY19 subject to global economic conditions and foreign exchange rates.
- Glaucoma growth strategy is expected to be primary growth driver in FY19.
- Ellex iTrack™ will continue to grow in FY19 with an improvement in operating result expected as the benefits of FY17 and FY18 sales and marketing investments crystallise.
- Ellex Laser & Ultrasound segment sales are expected to grow primarily due to on-going glaucoma laser sales growth.



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