

# Ellex Medical Lasers Limited (ASX:ELX)

Presentation to Annual General  
Meeting

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ADELAIDE, AUSTRALIA





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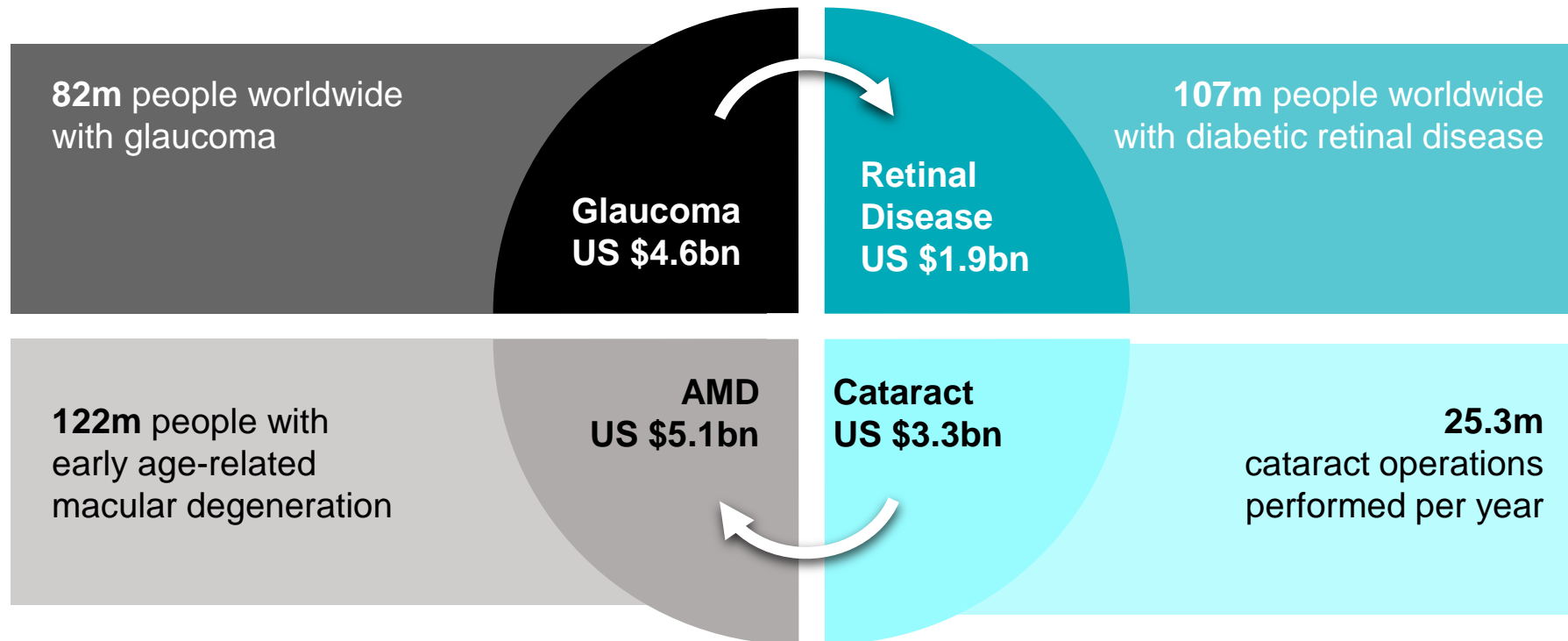
# Our Business

Today, over 35,000 Ellex ophthalmic laser and ultrasound systems are in use around the globe; and we have sold over 20,000 consumable devices to treat patients with glaucoma

- Our network of over 50 distributors in over 100 countries provides us with an ability to efficiently and effectively market and sell our innovative treatments and technologies to ophthalmologists globally
- Ellex now offers breakthrough treatments across a range of eye pathologies, including glaucoma, diabetic eye disease, secondary cataract, age-related macular degeneration (AMD) and vitreous opacities
- The major growth opportunities for Ellex sit within its glaucoma and age-related macular degeneration (AMD) segments



# Our Business



Today most of these markets are dominated by pharmaceutical treatments. Ellex currently markets and sells medical devices within each of these different segments that aims to replace current pharmaceutical treatments.



# Our Strategies

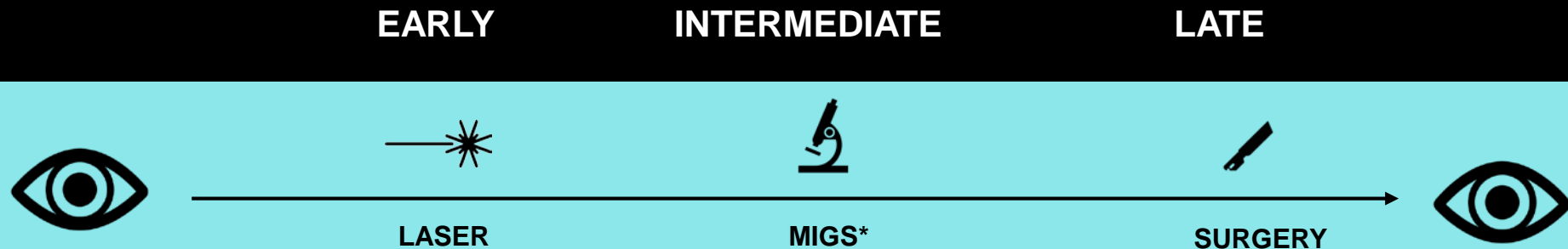
1. **Ellex Laser & Ultrasound:** we will continue to provide a strong base for our business using our well-known industry heritage and strong market position through a combination of technological innovation, new product releases, marketing and cost management to drive growth in both sales and earnings.
2. **Ellex iTrack:** we will leverage the Ellex Laser & Ultrasound base to exploit the proprietary, comprehensive and rejuvenative method of action of the Ellex iTrack™ surgical system to deliver 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.**



# Our Strategies - Glaucoma

Ellex is the only ophthalmic company globally with products to treat across the full spectrum of the glaucoma disease process.




**tango reflex**  
Treating both Angle Closure and primary open angle glaucoma



**iTrack.**  
Clinical Ophthalmology  
ORIGINAL RESEARCH  
Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach



**iTrack.**  
ORIGINAL RESEARCH  
Canaloplasty: Three-year results of circumferential viscodilation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma

MEDICATION AS AN ADJUNCT TREATMENT, AS REQUIRED

\*MIGS – minimally invasive glaucoma surgery



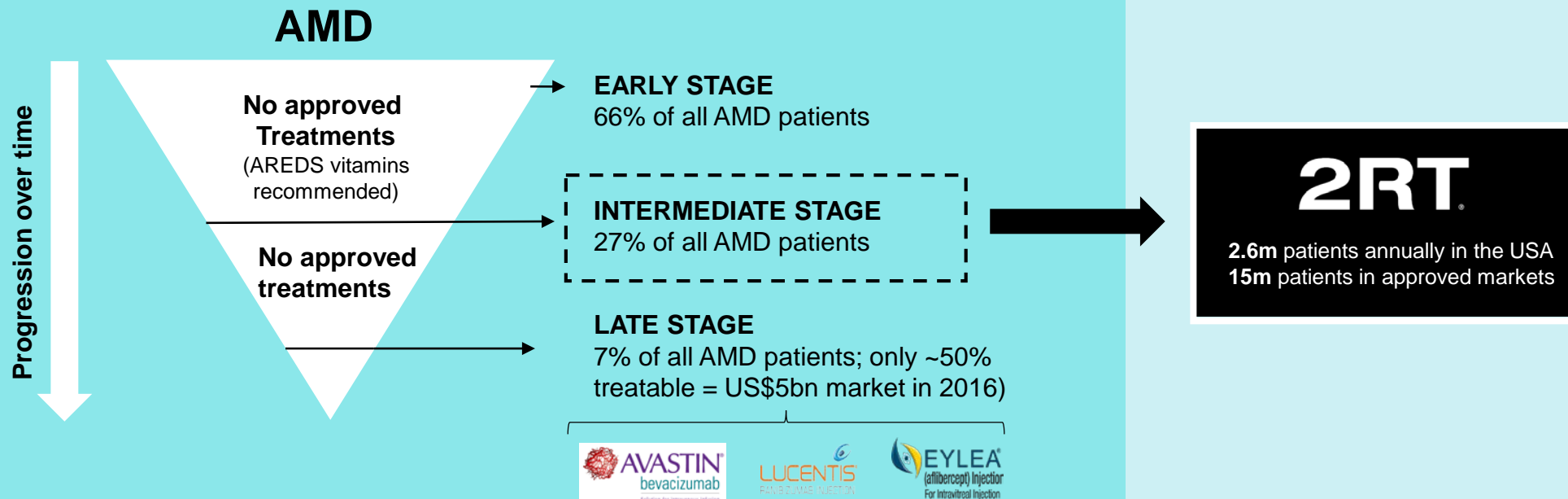
# Our Strategies - Glaucoma

- Two major trends driving growth in Ellex glaucoma products:
  - (1) Market shift from eye drops to SLT (laser) treatment in early patients and
  - (2) Widespread adoption of MIGS
- Glaucoma market expected to grow from US\$4.9bn to US\$5.3bn in 2022, driven by a ~six fold expansion of MIGS/SLT at cost of pharma (eye drops)
- Our strategy is to grow and strengthen our strong laser position globally, and materially expand our MIGS position with iTrack™ through enhancements of product marketing, and growth in experience & productivity of our sales team



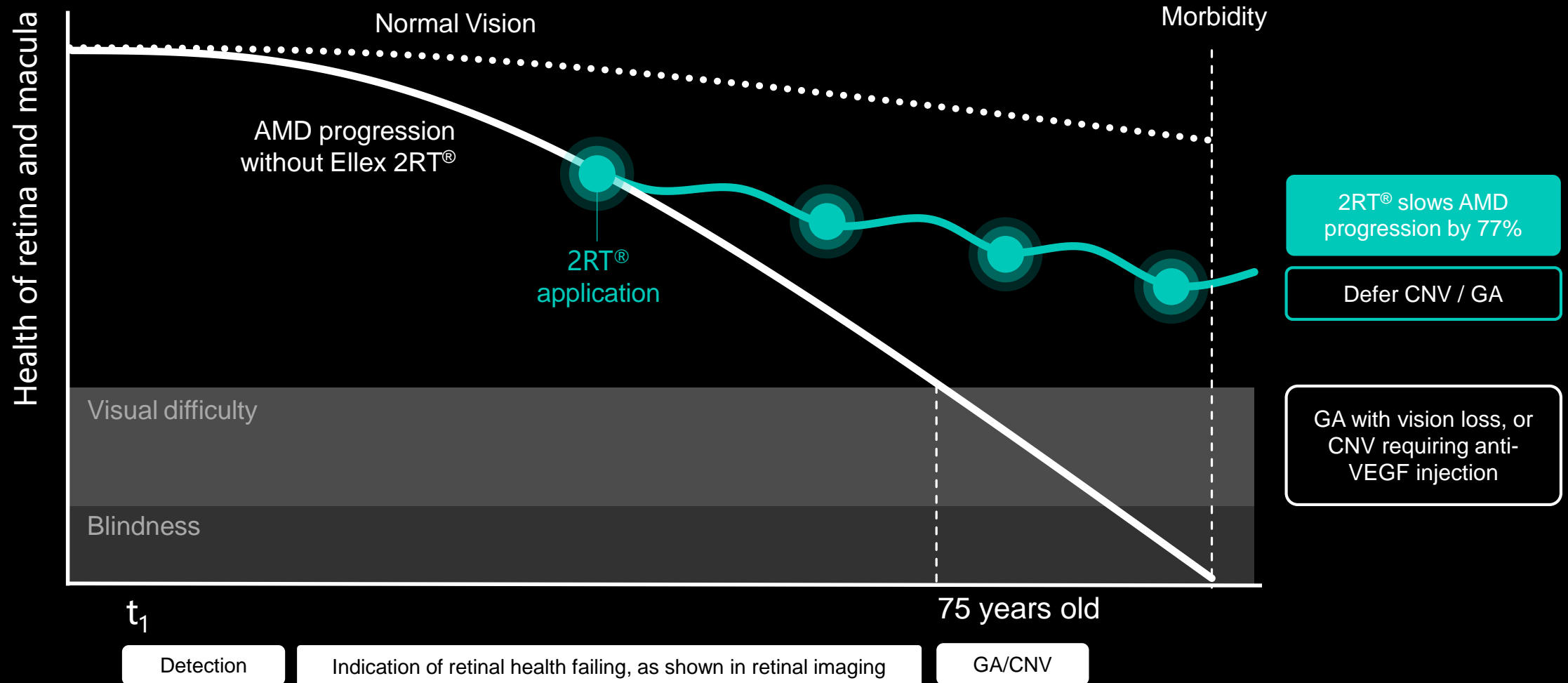
# Our Strategies – AMD

Ellex is the only ophthalmic company globally with a laser-based intervention in intermediate AMD (iAMD) which has shown clinical efficacy in a large, randomized controlled clinical study, the LEAD study.



# Our Strategies – AMD

## 2RT<sup>®</sup> intervention to prevent blindness



# Our Strategies - AMD

1. **Our short term strategy is to increase our European, Australian and NZ footprint, where Ellex 2RT<sup>®</sup> is approved for iAMD (leveraging LEAD)**
2. **Our medium term strategy (<12 months) is to identify a pathway from the FDA for registration of Ellex 2RT<sup>®</sup> in the United States**
3. **Our long term strategy is to receive US FDA clearance, and become the standard of care treatment for iAMD in all approved markets**





# FY18 Operating Highlights

- Expanded China footprint for Ellex iTrack™ - only approved MIGS
- Raised \$23.6M in additional capital from share placement & SPP
  - Major expansion of Ellex iTrack™ sales and marketing in the USA & other markets
  - Increased production capacity and invested into product development for iTrack™ surgical system
- Strengthened Board with appointment of two highly experienced US Medical Device Executives
  - Mike Southard – 25 years with world’s largest ophthalmology company, Alcon
  - Mike Mangano – 23 years in devices; President of ReShape Medical & Sirtex Medical, Inc.
- Executed major facility upgrades in Adelaide, Australia and Fremont, California – on time and on budget
- Strengthened Ellex’s corporate structure to meet long term growth objectives and enhance culture
- Improved sales force cross-selling synergies, particularly in rapidly growing glaucoma franchise



# FY18 Financial Results

**Constant currency (cc)<sup>1</sup> sales growth of 13% to \$79.1M compared to prior corresponding period (pcp), driven by:**

- 39% cc growth in Ellex iTrack™ sales to \$11.4M (incl. 48% growth in USA)
- 10.4% cc growth Laser & Ultrasound sales to \$67.5M

**Group EBITDA loss of \$1.2M comprised of:**

- Lasers & Ultrasound EBITDA of \$8.3M
- Ellex 2RT® loss of \$1.0M
- Ellex iTrack™ loss of \$5.1M
- Corporate costs of \$3.4M (lower than pcp)

<sup>1</sup> Constant currency (cc) was determined by converting FY18 at FY17 average A\$ exchange rates for USD, EUR, YEN

**\$4M improvement in operating cash flow to \$0.5M versus pcp**

**Cash at bank of \$23.1M**



# FY18 Financial Results – Ellex iTrack™

## Strong performance at the unit level, with 31% growth versus pcp

- Revenue growth in US\$ outpaced volumes due to beneficial mix effects (higher volumes in US market)
- Pricing remained stable
- Available reimbursement remained strong
- Gross margin (ex-labour) showed significant improvement (84% v 78% in pcp) – mix benefits

	12 months to 30 June in US\$		
	2017	2018	Growth
<b>Units:</b>			
USA	4,347	6,392	47%
China	1,165	1,550	33%
Rest of world	4,143	4,695	13%
	<b>9,655</b>	<b>12,637</b>	<b>31%</b>

<b>US\$ sales revenue:</b>			
USA	3,604,816	5,322,153	48%
China	555,000	752,250	36%
Rest of world	2,046,254	2,456,505	20%
	<b>6,206,070</b>	<b>8,530,908</b>	<b>38%</b>

<sup>1</sup> Constant currency (cc) was determined by converting FY18 at FY17 average A\$ exchange rates for USD, EUR, YEN

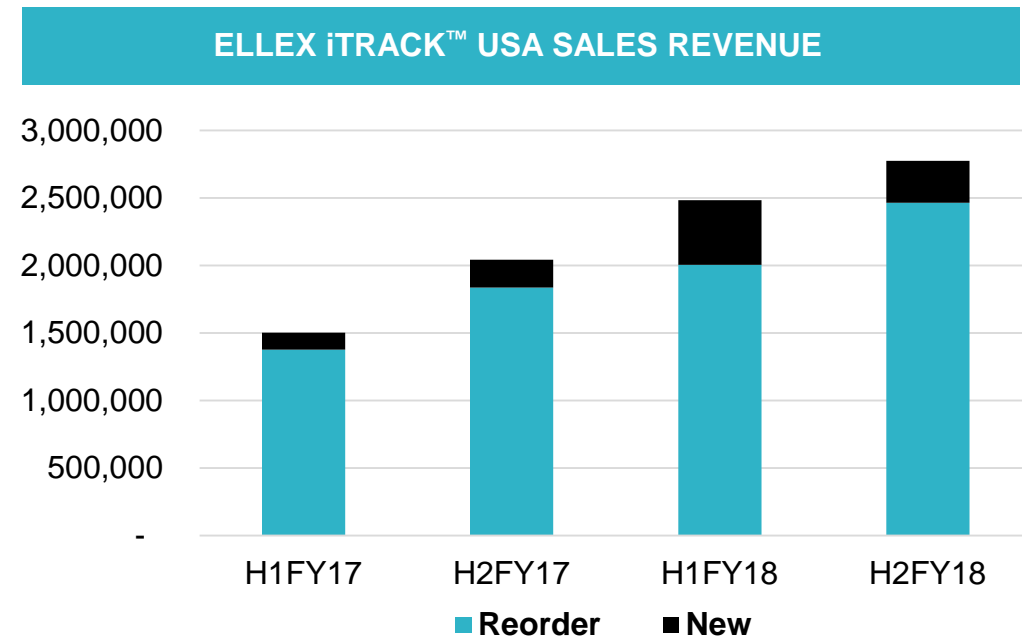


# FY18 Financial Results – Ellex iTrack™

**Strong growth in re-orders from US clinicians, highlighting greater adoption and throughput at the centre level**

- New account orders comprise 15% of mix (compared to 9% FY17)
- 39% growth in reorders compared with pcp
- Gross margin (ex-labour) showed significant improvement (84% compared to 78% in pcp) – mix benefits
- 17 USA sales reps in place

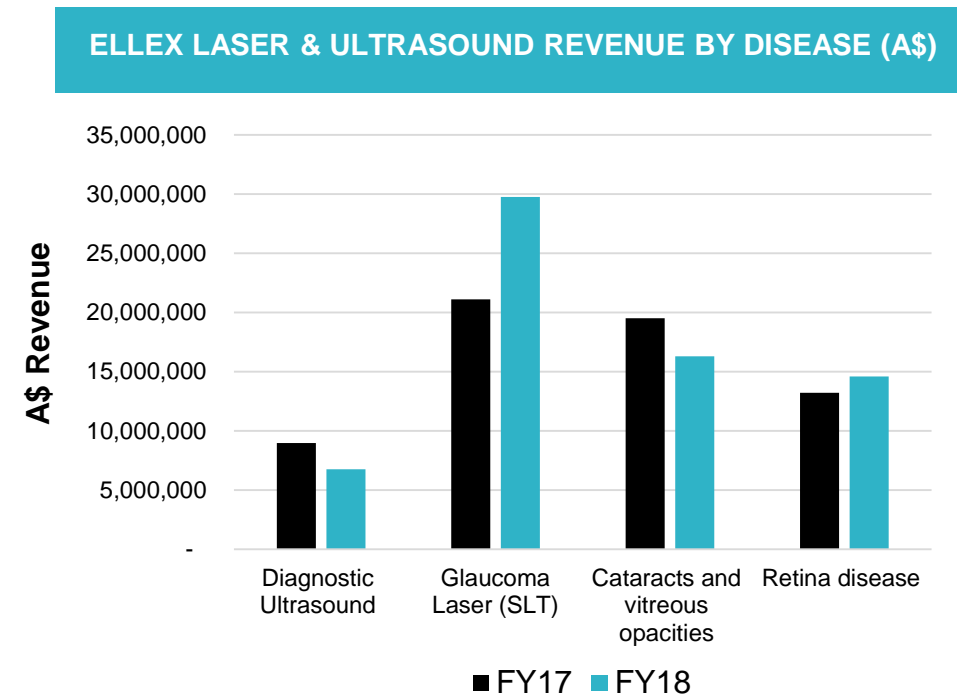
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# FY18 Financial Results – Lasers & Ultrasound

## Segment revenue CAGR over FY13-FY18 of 8%

- Strong performance from Tango™ and Tango Reflex™ SLT lasers to treat glaucoma, with growth of 41% to \$3.0M compared to pcp
  - [Improved adoption in USA of SLT in place of pharmaceutical interventions \(eye drops\)](#)
  - [Launch of Ellex Tango Reflex™ provides added floater indication](#)
- Retinal disease lasers, principally to treat diabetic eye disease grew 10% to \$14.6M, reflecting higher volumes albeit lower pricing due to competitive pressures
- Cataract and vitreous opacity laser sales declined 16% to \$16.3M, resulting from clinicians electing to purchase Ellex Tango Reflex™ to treat opacities and subsequent product cannibalisation of Ellex Ultra Q™
- Diagnostic ultrasound sales declined 25% to \$6.8M, reflecting purchasing delays ahead of new product introductions planned for FY19

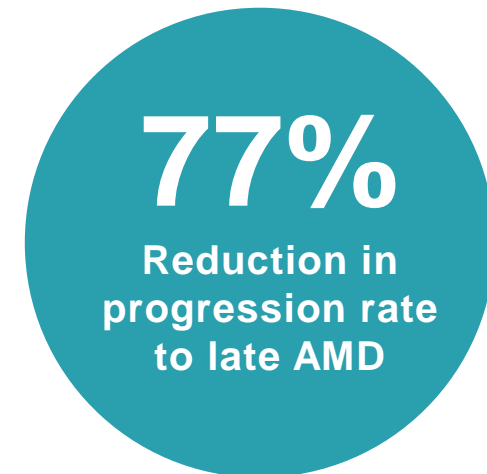
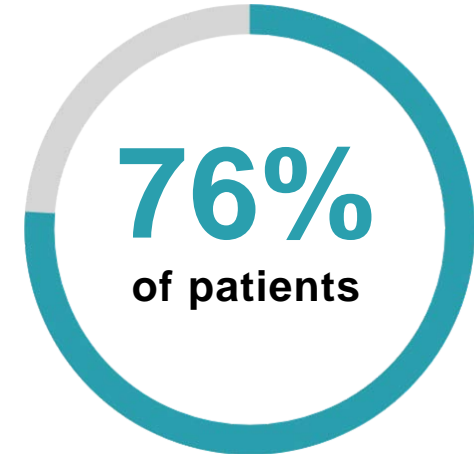






# 2RT<sup>®</sup> for Intermediate AMD

- Ellex released the LEAD clinical results in September 2018
- LEAD was the first ever study to show a significant efficacy effect in an iAMD population
  - Over three-quarters of patients treated every six months exhibited a 77% reduction in the rate of progression to late stage AMD over 3 years, with no safety concerns
  - This result is highly clinically meaningful and the treatment effect in these patients was remarkable
- In markets with regulatory approval, this represents an **annual addressable market opportunity of 15 million patients**
- Other than 2RT<sup>®</sup> there are currently no regulatory approved treatments for patients with early or iAMD – significant first mover advantage
- 2RT<sup>®</sup> is underpinned by robust patent position until at least 2035, and no applicability of existing competitive lasers to treat AMD

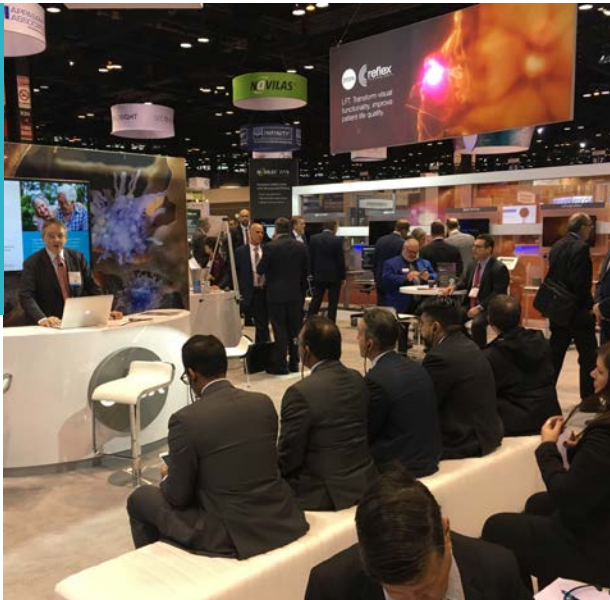


# Presentation of LEAD Study

**Significant physician education and marketing campaign at AAO, Chicago (~25,000 attendees) and EURETINA, Vienna (~5,000 attendees)**

- Hosted an AAO Roundtable with experts in AMD to generate enduring educational content for clinicians

Prof. Andrea Cusumano (Italy), ophthalmologist to the Pope, shares his clinical experience with 2RT®



Roundtable discussion at AAO featuring a panel of leading AMD researchers and Ellex CMO, Dr. David Lubeck



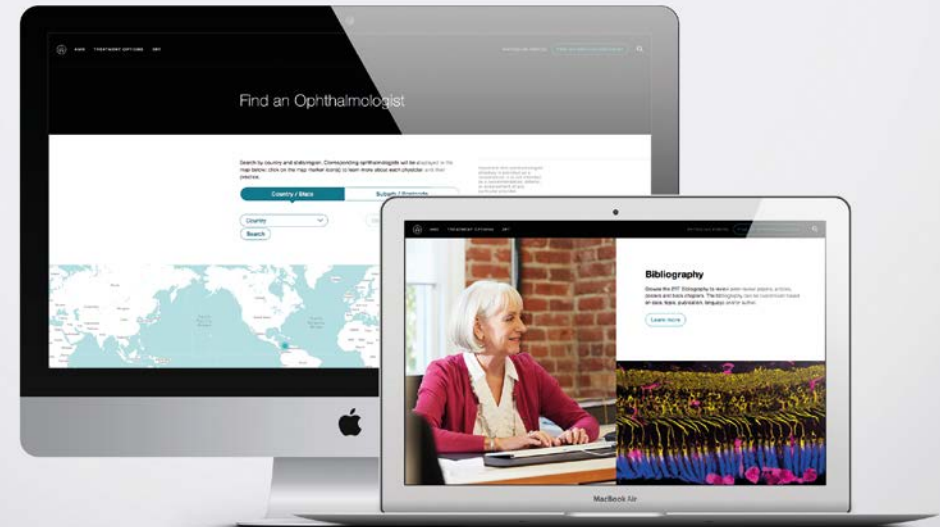
AMERICAN ACADEMY™  
OF OPHTHALMOLOGY



# Presentation of LEAD Study

Major focus on practice development via patient education and referral tools

- Online tools to capture significant patient traffic i.e. [www. Retinal-Rejuvenation.com](http://www.Retinal-Rejuvenation.com)





## 2RT<sup>®</sup> Next Steps – EU, AUS, NZ

- Since 2014, Ellex has European (CE Mark) clearance for 2RT<sup>®</sup> in the treatment of early AMD
- Limited installed base in Europe, as clinicians were waiting for LEAD data
- Since LEAD, our strategies in these three markets have focused on:
  - Generating support from Key Opinion Leaders
  - Driving education and awareness programs at the clinician and patient level
  - Training our key sales and marketing staff and distributors on LEAD data
  - Establishing 2RT<sup>®</sup> centres of excellence at key academic sites across Europe
- Ellex anticipates significant interest generated post LEAD data to translate to materially higher revenues in FY19 and beyond



# 2RT<sup>®</sup> Next Steps - USA

- Ellex 2RT<sup>®</sup> has clearance for 2RT<sup>®</sup> in Clinically Significant Macular Edema (CSME), but not iAMD
- To allow Ellex to promote and sell 2RT<sup>®</sup> on-label in the USA for iAMD requires an additional claim on its approved label (to include iAMD)
  - Prioritized engagement with FDA to understand requirements for regulatory clearance
- One of three outcomes likely (most desirable to least desirable):
  1. Approvable, based on LEAD clinical data
  2. A second registration-directed clinical study, replicating LEAD study endpoints – multi modal imaging (MMI)
  3. A second registration-directed clinical study, only using accepted FDA endpoints for AMD studies – visual acuity (VA)
- In parallel, Ellex is examining whether or not 2RT<sup>®</sup> may qualify for some of the recently announced accelerated FDA approval pathways
- FDA registration pathway is expected to be defined during CY19



# FY19 Trading Update

- 4 month group sales to 31 October have increased 27% to \$24.7M [17% on constant currency (cc)<sup>1</sup>]
- Sales growth driven by key glaucoma franchise comprising Ellex iTrack™ and SLT laser portfolio (Ellex Tango™ / Ellex Tango Reflex™ )
  - Ellex iTrack™ USA sales were up 38% (+26% cc) to \$2.2M, China sales were up 38% cc, sales in the rest of the world were flat in constant currency
  - Rest of world sales growth temporarily impacted by pending takeover by Hoya Corporation of German distributor
  - Worldwide Ellex Tango™ and Tango Reflex™ sales were up 39% (+25% cc) to \$8.9M
- Sales and marketing expansion of Ellex iTrack™ continues with 18 sales reps and 4 clinical trainers in place, revenue from new account has grown 21% (compared to FY18)
- First four months of FY19 for Ellex 2RT® delivered revenue of \$0.6M compared with \$0.1M pcp

<sup>1</sup> Constant currency (cc) was determined by converting 4 month FY19 at 4 month average FY18 A\$ exchange rates for USD, EUR, YEN





# Outlook

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

- Multi-product glaucoma segment will remain the primary driver of sales growth in FY19
- Ellex iTrack™ will show continued growth in FY19, with an improved operating result expected as sales and marketing investments made in FY18 crystallise
- Ellex Laser & Ultrasound segment growth expected due to continued clinical adoption of Ellex Tango™ / Ellex Tango Reflex™ in glaucoma disease management
- Based on LEAD clinical results, Ellex 2RT® sales are expected to grow significantly, albeit off a low base



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## QUESTIONS/DISCUSSION