

AMD is the leading  
cause of blindness  
in the developed world  
for people over 50

# AlphaRET

AlphaRET Pty Ltd is a wholly owned subsidiary of Nova Eye Medical Limited (ASX:EYE) and was established to progress the development of 2RT®

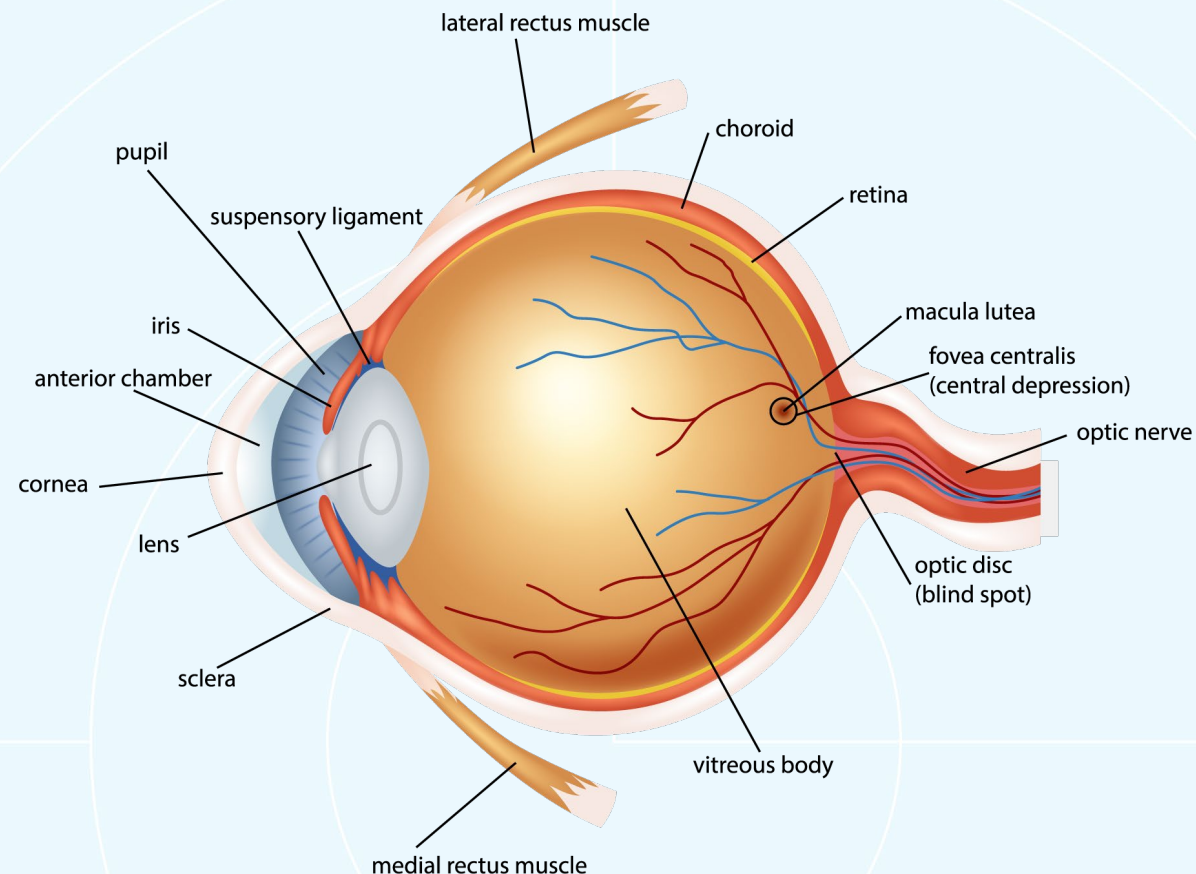
## 2RT Pivotal Study and Regulatory Pathway

May 2022

[alpha-ret.com](https://alpha-ret.com)

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# Age-Related Macular Degeneration



**Normal Vision**

**Macular Degeneration**



# 2RT® - Subthreshold Nanosecond Laser

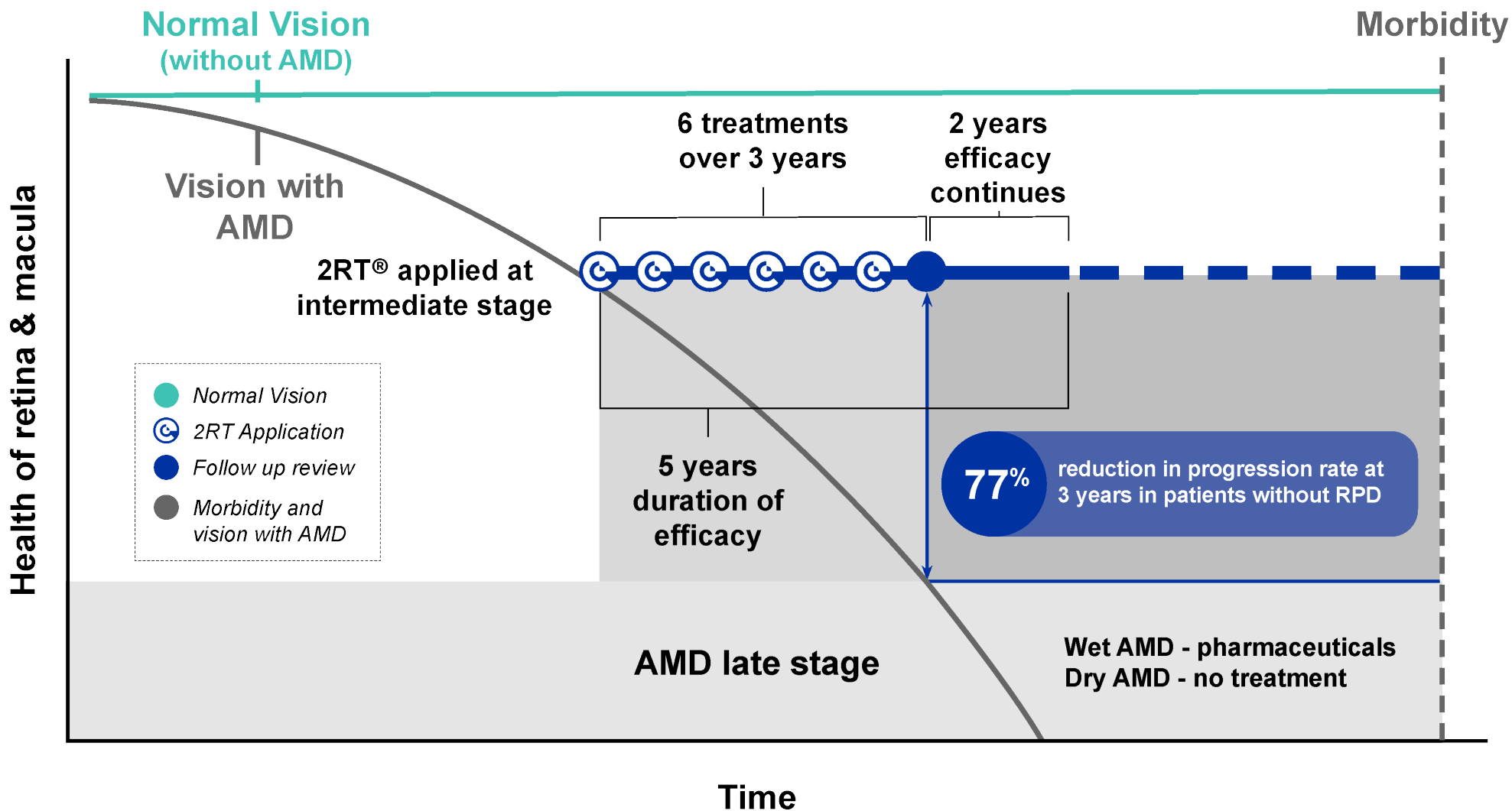
2RT® is a rejuvenative retinal laser therapy that utilizes a nanosecond laser pulse and unique pixelated laser beam profile

**“Based on the LEAD study outcomes, 2RT® is currently a leading candidate treatment in the world for slowing the progression of patients with intermediate AMD to either late stage Wet or Dry AMD.”**

*(Identified by Edison Group in its publication “Saving the sight of millions, Blindness: the underrated business case” September 2020 - <https://bit.ly/EdisonAMD>).*

*LEAD study - LEAD (Laser Intervention in Early sage Age related macular Degeneration), 292-person study conducted from 2012-2018 with follow up through to 2020*

# 2RT<sup>®</sup> for intervention in AMD progression



Intervention concept schematic based on a *post hoc* analysis reported within "Subthreshold Nanosecond Laser Intervention in Age-Related Macular Degeneration - The LEAD Randomized Controlled Clinical Trial" Robyn H. Guymer, MBBS, PhD, et al and published in peer reviewed journal *Ophthalmology* of the American Academy of Ophthalmology

This post hoc analysis found that the 77% reduction in the rate of progression occurred in patients who did not have reticular pseudodrusen (RPD) at enrolment. 24% of the study population had RPD at enrolment.

# Pivotal Clinical Study to address USA and Europe



AlphaRET's recent communications with the FDA has provided guidance on the clinical study plan and a subsequent regulatory pathway for a clearance to market 2RT® in the USA for the treatment of patients with iAMD, and who do not have RPD, to delay progression to vision threatening, late-stage AMD.

Two protocols have been defined for the pivotal clinical study:

## Protocol A

a fast-track protocol for patients with iAMD and without RPD at a higher risk of progression

- 4 treatments over 24 months with approx. 250 patients
- Aiming to build on clinical signal in LEAD Study

## Protocol B

a more extensive protocol for general iAMD without RPD patients

- 6 treatments over 36 months with approx. 500 patients
- Aiming to confirm results of the LEAD study post hoc analysis

- The protocols will be conducted concurrently
- Protocol A will provide an earlier study outcome than Protocol B

- The concurrent execution of both Protocol A and Protocol B will enable the Company to harvest data across the broader range of indications possible
- Provides greater scope for a successful study outcome

# 2RT<sup>®</sup> Roadmap Pivotal Study



**PRE-CLINICAL WORK**

**PILOT CLINICAL TRIAL**

**CE MARK (iAMD) APPROVED FOR SALE IN AUST, NZ & EUROPE**

**EFFICACY & SAFETY DEMONSTRATION CLINICAL STUDY (“LEAD”)**

**PROTOCOL PREPARATION FOR PIVOTAL STUDY TO CONFIRM LEAD**

**USA FDA FEEDBACK RECEIVED**

**ENGAGE WITH POTENTIAL PARTNERS AND FUNDING SOURCES**

**CONFIRMATORY PIVOTAL CLINICAL STUDY**

# Global Retinal Experts Support



## **Principal Investigator Professor Robyn Guymer, AM MBBS, PhD**

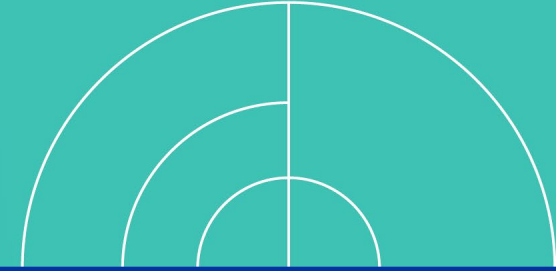
“I am pleased to be a part of this follow up study. 2RT® addresses the disease in its earlier stages. No other device or pharmaceutical in the world does this. Like all chronic disease, early detection and treatment is vital to prevent complications and the ensuing burden on health care systems, and patients and their families. The LEAD study was very encouraging but was not conclusive. I look forward to starting this work, providing additional information to the FDA and then a successful study outcome.”

## **Dr. Philip Rosenfeld, Professor of Ophthalmology at the Bascom Palmer Eye Institute of the University of Miami Miller School of Medicine in Miami**

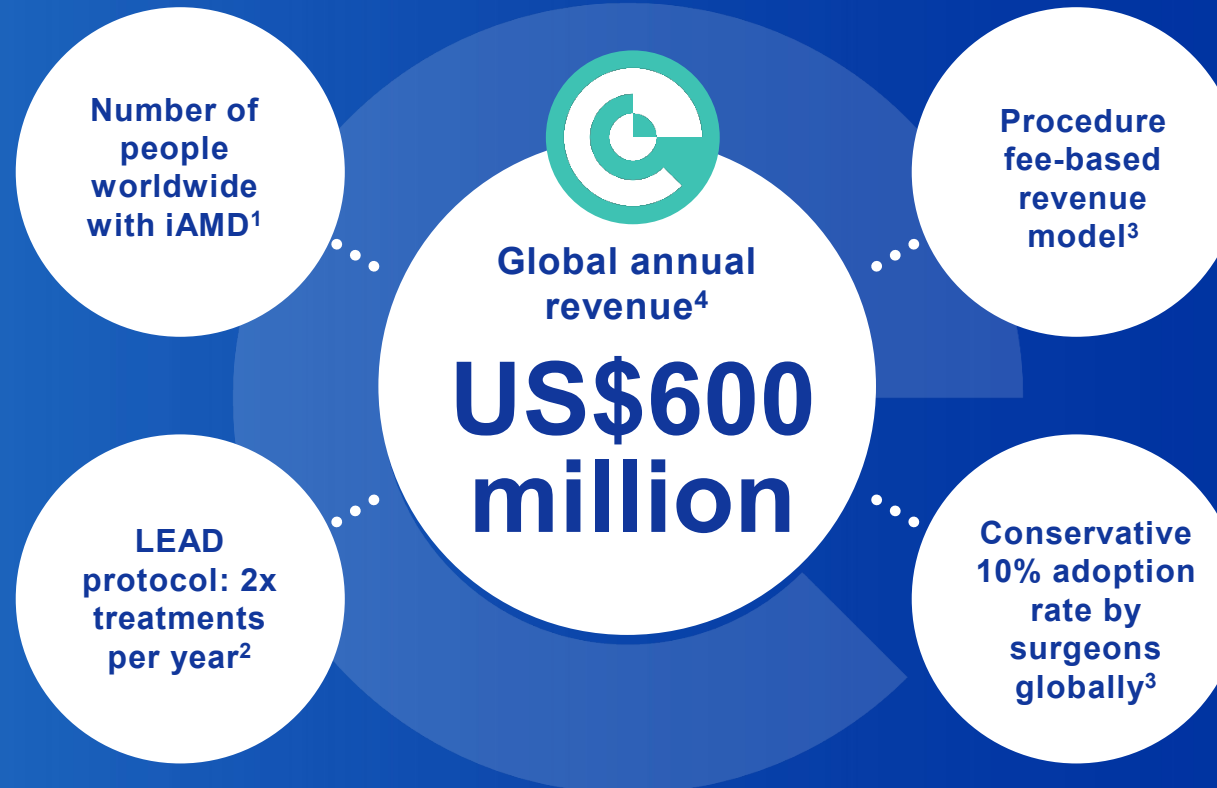
“The LEAD Study completed by Professor Guymer was a well-controlled clinical trial that showed the immense potential of 2RT®. However, a second study is required. If the second study is successful, AlphaRET will have the data needed to harness that potential and significantly change the landscape in AMD therapy in the USA and around the world. It is not unusual that the FDA is taking such a cautious approach and requesting additional data prior to establishing investigator sites in the USA. In fact, I am pleased that we now have a clear understanding of what is needed by the FDA to move 2RT® forward in the USA.”



# Estimated Revenue Opportunity for 2RT<sup>®</sup>



Subject to the completion of a pivotal study or similar to confirm results of the LEAD study (77% reduction in rate of progression to late-stage AMD in select patients with iAMD) the opportunity is very large.

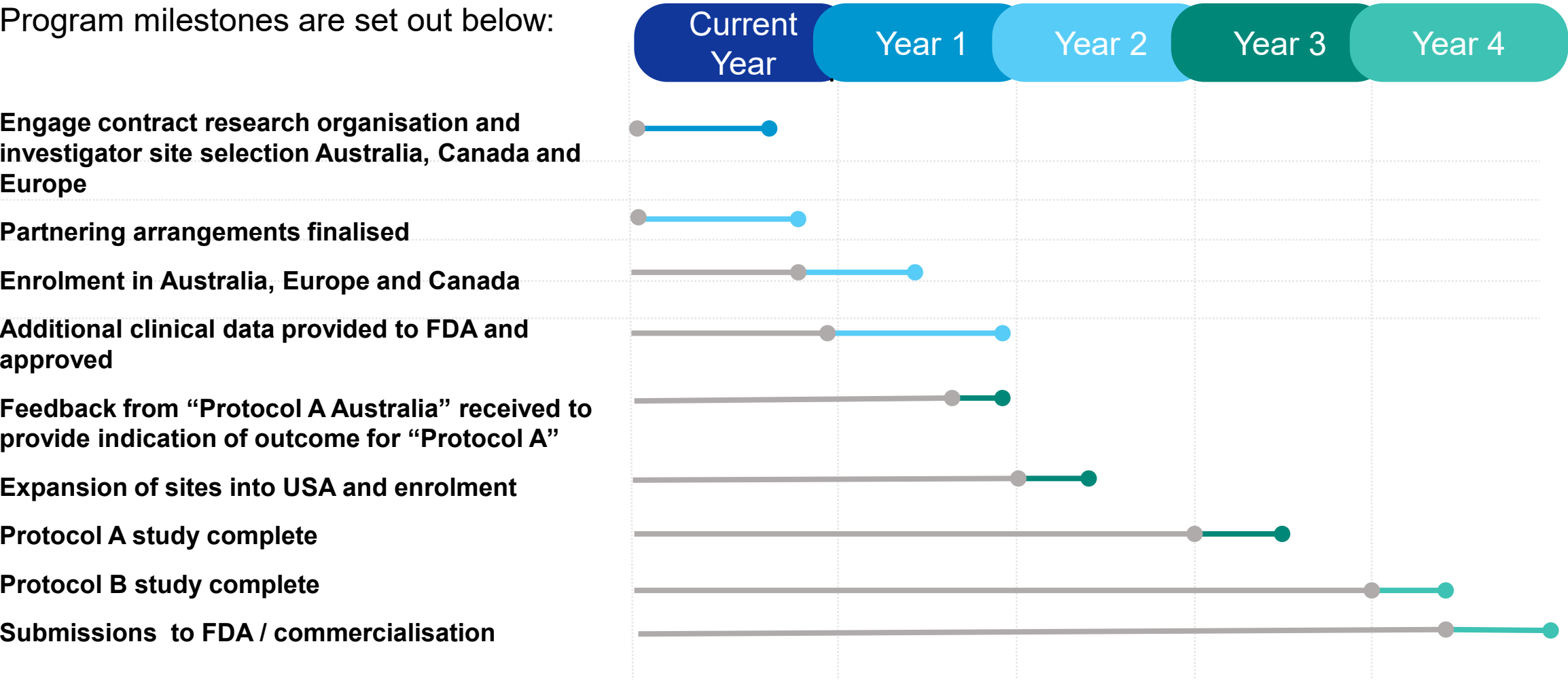


Business model comprising of capital equipment sale and procedure fee has corollary with laser vision correction technology, which was launched in the US in the early 2000s by start-up companies.

<sup>1</sup>Marketscope 2018 Ophthalmic Laser Report. <sup>2</sup> Guymer et al "Subthreshold Nano Second Laser Intervention in Age Related Macular Degeneration – The LEAD Randomised Controlled Clinical Trial". <sup>3</sup> AlphaRET estimate. <sup>4</sup> AlphaRET estimate based on 'Marketscope 2018 Ophthalmic Laser Report "for USA, Europe and Other Developed Nations by Company.

# Program milestones

Program milestones are set out below:



# AlphaRET

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