

Creating a World of Bionic Vision for Those Who Have Lost Their Sight

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## Creating a World of Bionic Vision for Those Who Have Lost Their Sight







<sup>&</sup>quot;...Simultaneous use of the prosthetic central vision and the natural peripheral vision in both the implanted eye and the fellow eye is a very important feature of the Prima System for patients with geographic atrophy and is essential for improving their quality of life,..."

## Pixium creates a world of bionic vision for those who have lost their sight





A tiny wireless neurostimulating retina implant and smartglasses capable of communicating with implant generating bionic vision for blind and partially blind patients





...to **create** meaningful **sight** and **regain** independence...

To give back meaningful vision and independence to patients suffering from Dry AMD and other retinal diseases that currently have no other solution



...and lead by a **seasoned team** which combines >100 years experience in Medtech

























...by finalizing clinical trials and commercialization of the PRIMA system...

Leveraging Pixium's cutting edge know-how created to finalize the pivotal PRIMAvera trial in the EU and lead the PRIMA system to market approvals in US, EU and other countries.



### **Key Success Factors**





#### **Breakthrough Technology**

De-risked state of the art ophthalmic neuromodulation technology



#### **Clear Way to Market**

Expected to be 1st to commercialize due to advanced clinical progress and to become the only treatment option



#### **Clinical Success**

Pivotal trial in Europe (PRIMAvera) fully enrolled expecting data readout by Q12024, Breakthrough Device Designation in US, Results exceeding expectations with up to 36-month followup in Dry AMD demonstrating the ability for clinically blind patients to read letters and words 5 peer reviewed publications



#### Reimbursement

Expect average €80,000 generated per patient



#### **Large Markets**

245k visually impaired Dry AMD patients leading to a €19b market opportunity in the U.S. and EU5 combined

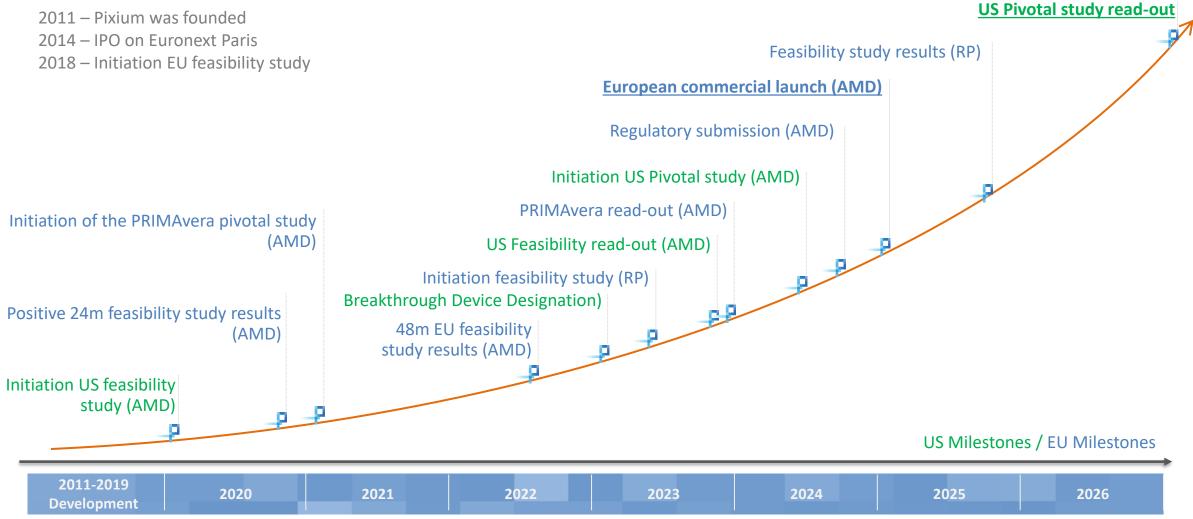


#### **Top Tier Teams**

Experienced management supported by top-tier KOL group

## Delivering on our Journey and Approaching the Next Chapter of Pixium and the Prima System





## **Experienced Management Team with over 100 years in Medtech**













**Lloyd Diamond** 

Chief Executive Officer











**Offer Nonhoff** 

Chief Financial Officer











Brian Burg, PhD

Director of R&D









**Alexandra Rocher** 

Director Manufacturing







#### Ralf Hornig, **PhD**

**Director Clinical Affairs** 





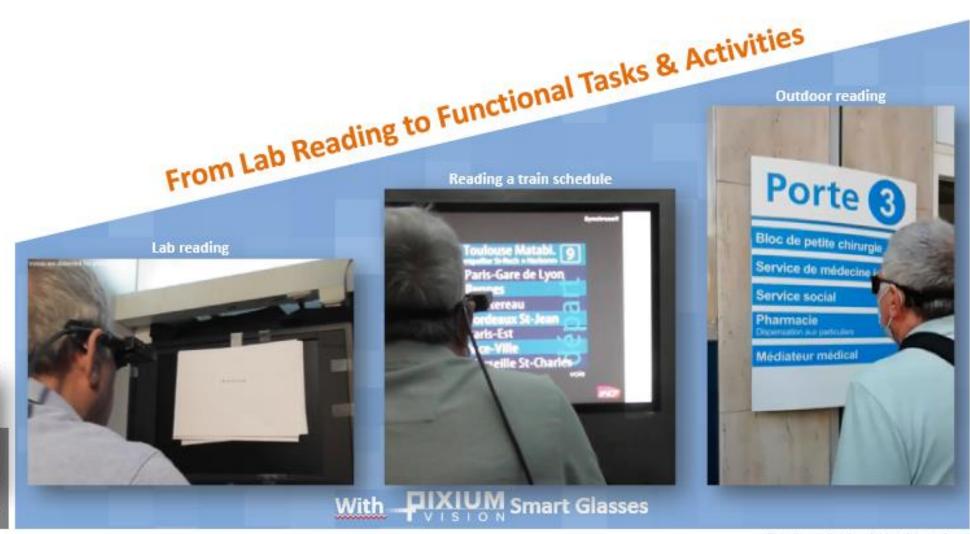
**Medical Implants** Intelligent



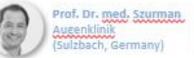


## Prima System Delivering Encouraging Results for Patients











## AMD

**Age Related Macular Degeneration** 

## Dry AMD is more common and can be as equally debilitating as well treated wet AMD



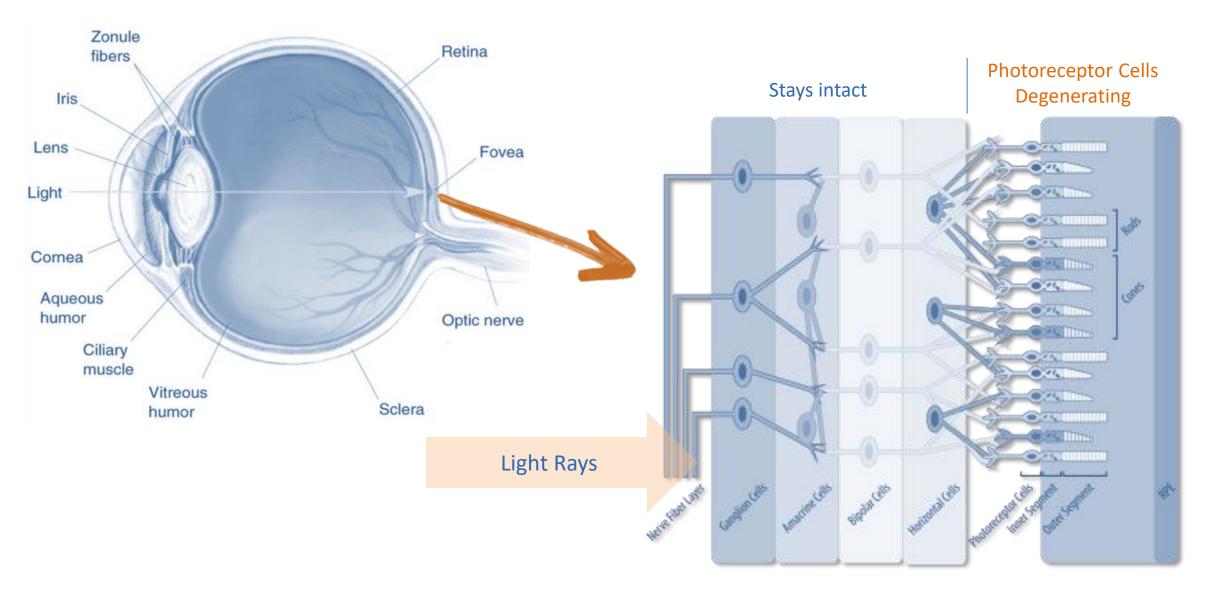
- Chronic progressive neurodegenerative eye disease leading to loss of central vision due to a degeneration of photoreceptor cells in the Retina
- Dry AMD may first develop in one or both eyes and then affects both eyes
- **Dry AMD 80% 90% / Wet AMD 10% 20%.** Dry AMD may progress to wet AMD, which can cause rapid vision loss if left untreated.
- Onset mostly around 60 years old
- Significant impact on quality of life, impeding ability to read, use transportation, social interactions, and other daily tasks
- Loss of quality of life for advanced AMD patients is comparable to dialysis, advanced prostate cancer or severe stroke<sup>1</sup>
- There is currently **no** approved **treatment** for sight restoration for Dry-AMD
- We believe Pixium's Prima System can become 1<sup>st</sup> approved Dry-AMD treatment

Total AMD population US and EU5 <sup>2</sup>

636 9m

## Degeneration of Photoreceptor Cells while Optic Nerve stays intact



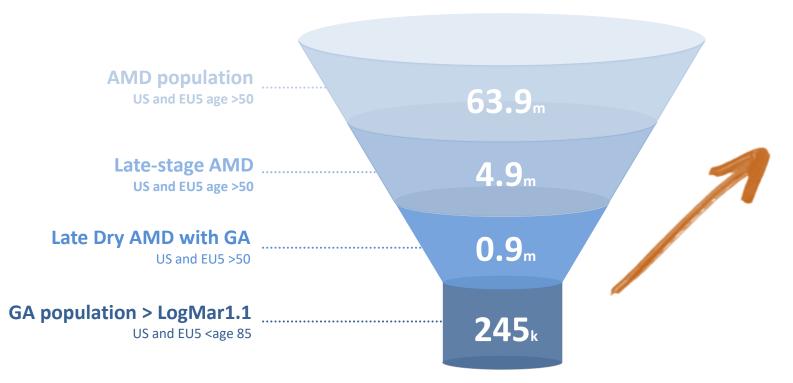


## An Extremely Large, Fast Growing and Untapped Dry AMD Market



Based on 2022 epidemiological data growing about 10% until 2028

(1) GlobalData Age Related Macular Degeneration Epidemiology Forecast 21.Dec.2021



Total Current Accessible Market
Based on Prevalence

19.6b€

**● 12.2b€** 

7.3b€

Market Size based on Incidence of 22,300
Patients per Year

1.6b€

**●** 0.7b€

**2.0b**€

Expanding indications to **Retinitis Pigmentosa** will increase market materially



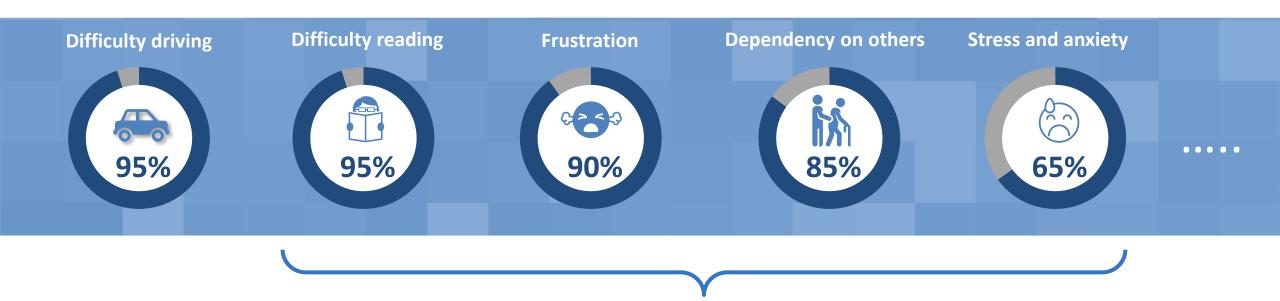
<sup>&</sup>quot;...The Prima System has the potential to significantly improve vision and quality of life for patients with dry AMD and I am looking forward to bringing it to more patients in need..."

## Significant Impact on Patients' and Their Surrounding



#### Dry AMD is amongst the most debilitating disease for patients leading to:

- Significant psychological impact
- Societal impact through high degree of dependency



## **Main Targets of Prima System**



# The Prima System

## **The Prima System**



## An Innovative Combination of an Implant and Smart Glasses

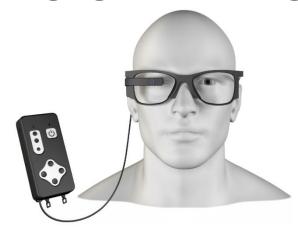
## **Implant**

**Interface to the Optic Nerve** 



### **Smart Glasses**

Camera, Projector, Computer, cutting edge Artificial Intelligence





**Implant** 



Cutting-edge Image Processing System



Minimally Invasive Implantation and Optimized Patient Training



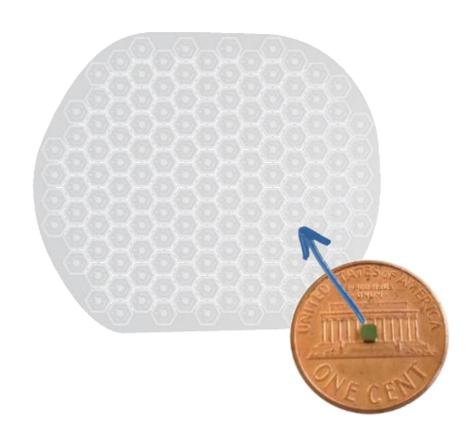
High Precision Optics and Projection

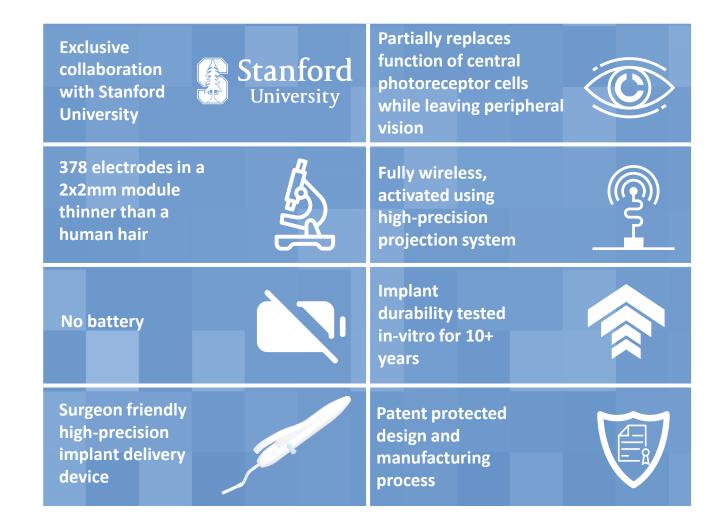


Versatile and Upgradeable

## **State of the Art Implant**









**Dr. Yannick Le Mer**Head of Vitreo-retinal Unit
Fondation Adolphe de Rothschild
(Paris, France)

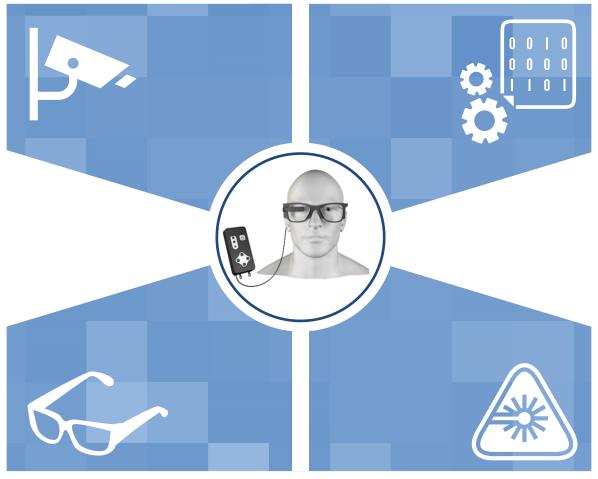
"...the implant is shown to be reliable in patients for over 36 months post implantation. These encouraging results position Pixium's PRIMA implant, and the whole Prima System, as a realistic potential solution.."

## **Glasses and Pocket Computer**



#### **MINIATURIZED CAMERA**

Captures the patient visual environment and transmits the data to the image processing stem

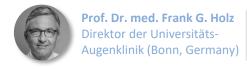


#### **PROPRIETARY ALGORITHMS**

Analyses the image stream, simplifies the contents to highlight a specific area and transforms the result into the signal to be projected on the implant

#### TRANSPARENT GLASSES

Regular-looking glasses with tunable projection module allowing to combine bionic vision and peripheral vision



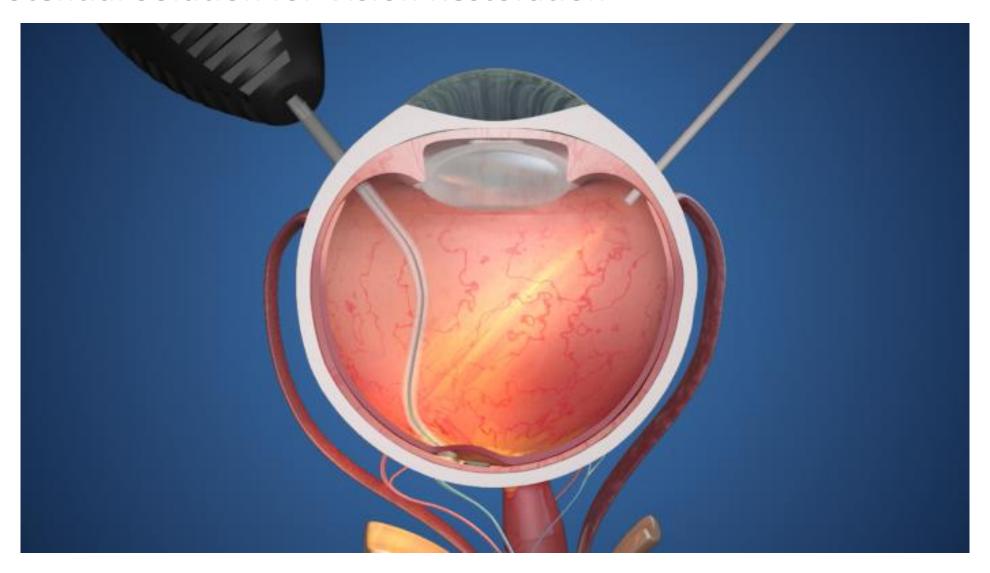
#### **SOPHISTICATED PROJECTION**

Transfers electronic signals of images to activate safely the implant electrodes with high precision

"...The bionic vision Prima System has demonstrated improved vison function and could potentially make a significant impact to patients' quality of life.."

### **A Potential Solution for Vision Restoration**





**Link to video PRIMA System operating principle on Vimeo** 

## 4 Stages of Surgery & Rehabilitation





Implantation in a **1–2-hour surgery**, outpatient, similar to retinal detachment surgery







Low vision specialists train use of device, basic shapes, reading, orientation and other daily living tasks for 3 months

remote rehab, roll out of apps, improvements, upgrades





**Dr. Koen van Overdam**Consultant Ophthalmologist and Vitreoretinal Surgeon at the Rotterdam Eye Hospital

"...The potential of the technology and the relative ease with which the small wireless implant can be surgically placed under the macula offer a real chance for patients who lost vision due to dry AMD..."

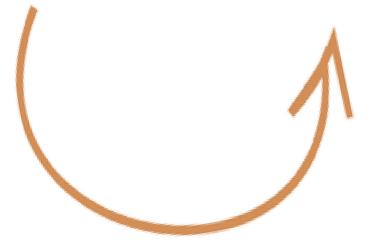
## Finding Solutions to the Activities of Daily Living for our Patients





#### **Text Reading**

Cookbooks, phone, tablet, supermarkets, letters, financial & medical interactions, etc.



#### **Face Recognition**

Being able to recognize family, friends and pets





#### **Recognition of Pictograms**

Enabling the intuitive recognition of everyday images



#### **Targeted Writing**

Shopping lists, notes, typing on phone / tablet



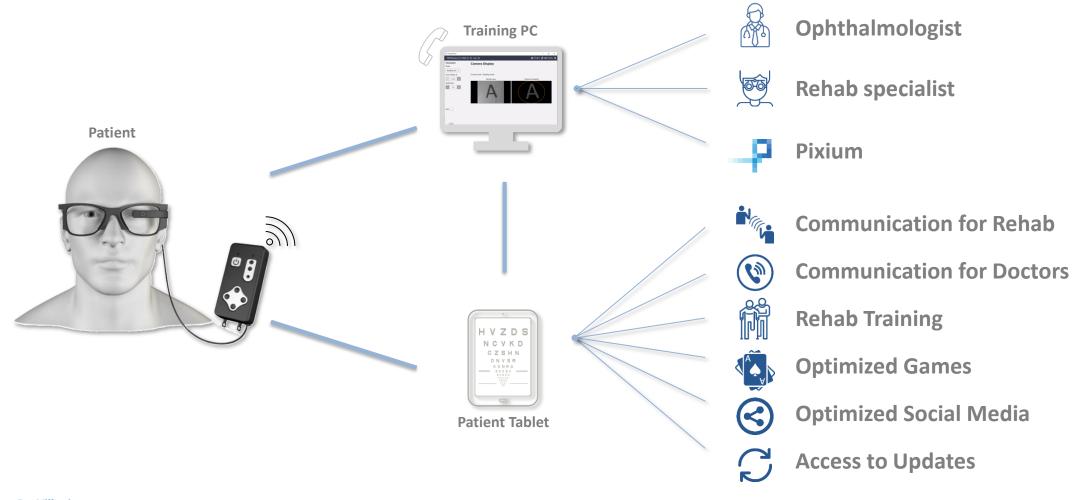
and family





## Remote Engagement Platform Targeted to Improve Rehab and QoL of our Patients







<sup>&</sup>quot;...In order to achieve the best visual function following implantation, it is paramount for patients to adhere to a comprehensive rehabilitation process...

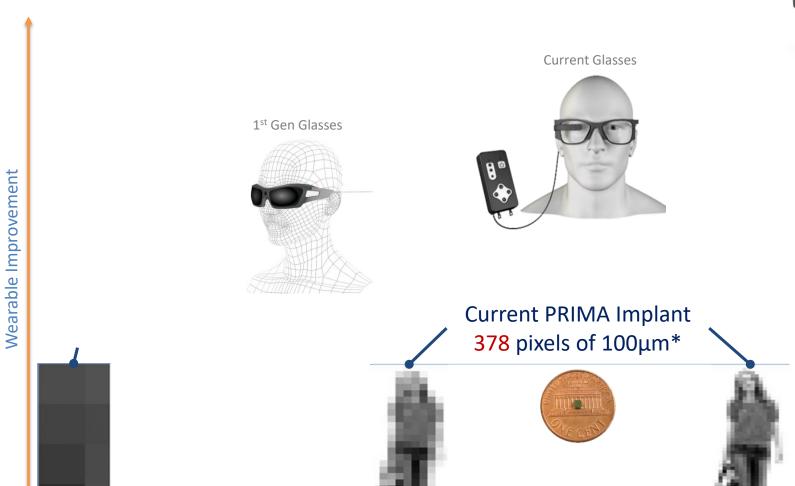
The new remote rehabilitation module of the PRIMAvera trial allows patients to train daily at home...the gaming nature of some training exercises – as well as the ability to communicate easily with physicians, nurses, family members and other patients – will further motivate patients to engage..."

## Scalable Platform and First Step Towards Face Recognition



The below pictures are for illustration purpose only

\* Version in clinical trials



Next Gen glasses



#### 2 peer reviewed publications

- New implants leverage existing PRIMA design with significant increase in spatial resolution
- Potential to restore vision to levels sufficient for face recognition and reading smaller fonts: 20/100 with no magnification and up to 20/20 with electronic magnification

## NEXT GENERATION Up to 10,000 pixels of 20μm



Chip and & Algorithm Improvement

## **Prima Technology**



## Developed with Patients and Physicians in Mind

**Wireless Neurostimulation Implant** 

**Cutting-edge Image Processing System** 

**High Precision Optics and Projection** 

Easily Implantable and Optimized Patient Training

Versatile and Upgradeable



PRIMA is a tiny neurostimulation device implantable in the subretinal space



Dedicated imaging processor with proprietary algorithm optimized to characteristics of bionic vision, to limit latency and maximize reactivity



Allows to precisely activate implant and to transfer visual content with low latency and hyper-short on-off timing



Minimally invasive surgery through a patented implant delivery device – doable by most EU/US retinal surgeons; patient's training optimized to allow independence



Potential addition of life-easing technologies on external components side such as stimulation algorithmics improvement, 5G connectivity, road mapping and direction with VR capabilities



# Clinical Data

## **Clinical Studies**



Dry AMD

	Feasibility Study	Regulatory Pathway	Pivotal Study	Regulatory Submission
****	Follow-up 6, 12, 18, 24 and 36 month showing meaningful reading continuing until 72 month	Approved	Fully Enrolled Ongoing Readout end 2023	Expected early 2024
	Ongoing Read out H2 2023	Ongoing Breakthrough Device Designation Status confirmed	Expected Start 2024	Expected 2026

## **European Pivotal Trial Underway for 2023 Read-Out**



## Fully enrolled - Data readout Q1 2024

**Objective:** Restoration of Central Vision with the PRIMA System in patients with Atrophic Age-Related Macular Degeneration and evaluate the efficacy as well as safety of PRIMA. Eligible subjects will be implanted with the PRIMA Implant.

Design: Single Arm, Open Label, patient its own control



**38** blind (logMAR > 1.1) Dry-AMD patients implanted



#### **Primary endpoint – 12 months:**

- Improvement of Visual Acuity (measured with ETDRS) of logMAR 0.2
- Number and severity of Serious Adverse Events



#### Secondary endpoint – up to 36 months:

- Improvement of Visual Acuity (measured with ETDRS) of logMAR 0.2
- Mean improvement of visual acuity compared to baseline
- Quality of life measured by IVI
- Central visual perception
- Adverse Events
- Change of natural visual acuity without the PRIMA glasses
- Proportion of compliant implantations



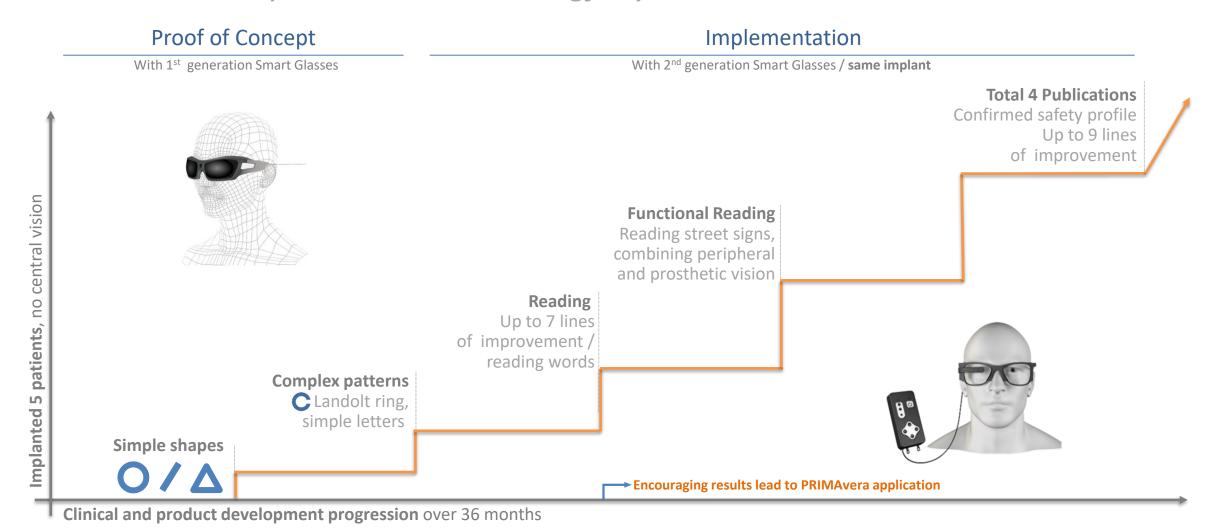
#### Next milestone - Data readout

2021	2022	2023		2024	
Inclus	Follow up	Readout	CE	Approval	

## **Encouraging Results in European First-In-Human Study**



PRIMA has the potential to meaningfully restore central vision



<sup>1 –</sup> France first-in-human study (PRIMA FS) recruited 5 patients. Primary endpoint is Elicitation of visual perception at 18 months with up to 36-month follow-up

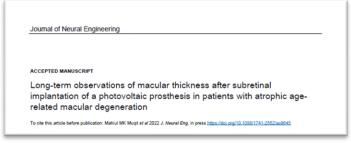
### **5 Peer Reviewed Publications**





## 2019 – PRIMA creates localized phosphenes

Monkeys were able to to localize phosphenes, that have been stimulated by a PRIMA implant, similar to a natural light stimuli.



#### 2022 - Positive results on safety

Distance between the implant and the target cells was stable over the long-term follow-up, No significant thickness changes of the retina after an initial phase of minor thinning.



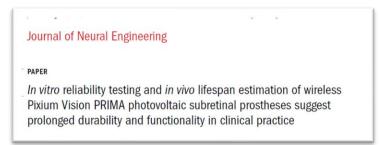
## 2020 – Positive results on efficacy and safety

Residual natural acuity did not decrease after implantation in any patient. Visual acuity up to a level close to the theoretical resolution of the implant could be measured.



#### 2022 - Positive results on efficacy

Patients implanted with a PRIMA device are able to use artificial vision and their natural peripheral vision simultaneously. Acuity of up to 20/63 has been demonstrated.



## 2020 – Demonstration of longterm reliability of the PRIMA implant

The PRIMA implant was found to be robust, with in vitro reliability of at least 10 years

Expected for 2023

## 2023 – Expect positive results on efficacy

48 months follow up of the French feasibility patients expected using the same testing methods as in the ongoing PRIMAvera pivotal study.

-> All publications after 2019 from in European First-In-Human Study



# Conclusion

## Prima System, a Cutting-Edge Technology Supported by Multi-disciplinary Partners



**Universities and Research Institutes Vision Clinics** Moorfields Eye Hospital 1155 NHS Foundation Trust Fondation Ophtalmologique Adolphe de Rothschild Inserm Bascom Palmer Eve Institute UNIVERSITY OF MIAMI HEALTH SYSTEM

## **Developments Supported and Advised by Knowledgeable Scientific and Medical Experts**





















Prof. Jose-**Alain Sahel** Vision Institute (FR) / UPMC (Pittsburgh, US)





Lisa Olmos de Koo, MD University

Washington (US) Chief Medical **Advisor Pixium** 

**UW** Medicine HARBORVIEW MEDICAL CENTER



**USC** Roski Eve Institute Keck Medicine of USC

Prof. Frank G Holz University

Hospital Bonn (DE)









Dr. Mahi Mugit Moorfield Eye Hospital (UK)

Prof. Andrea Cusumano University of Rome (IT)

Prof. Jan **Van Meurs** Rotterdam Eye Hospital (NL)















#### Conclusion



## Leveraging Solid Foundations to Deliver on our Promises



=> Cash need of further ~€60m is expected to be raised to successfully commercialize PRIMA

## Thank you

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