

REGAINING VISION, REGAINING LIFE

Jefferies Healthcare conference New York, June 2 & 3 2015

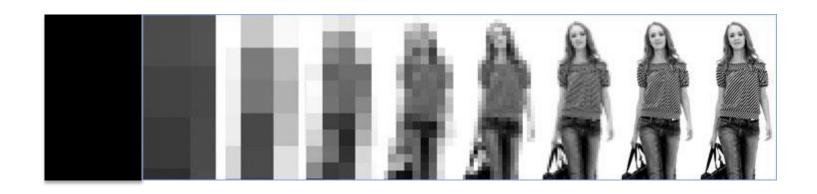
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#### Pixium Vision: our mission

Pixium Vision's mission is to provide the best-in-class vision restoration systems enabling the blind to regain greater autonomy





### An experienced management team

#### Bernard Gilly, Chairman



- 20+ years experience in the lifesciences sector
- Fovea Pharma (2005-2009)
   Chairman & CEO sold to Sanofi
- Sofinova (2000-2005) Managing Partner
- Transgene (1992-2000) -Chairman & CEO

#### Khalid Ishaque, CEO



- 20+ years experience in the medtech industry in neuromodulation
- Boston Scientific (1997-2014) -General Manager
   Neuromodulation International

#### Pierre Kemula, CFO



- 14 years experience in Corporate Finance / Financial Markets
- Ipsen VP IR, Finance & Treasury
- Strategy Consulting (Bossard; Roland Berger)

Guillaume Buc,



Robert Hill,



Sylvie Murgo, IP Director





### Pixium Vision

- Proprietary systems combining French & international scientific & technological excellence
- Attractive addressable 1 Billion Euro + market opportunity\*
- 3 Two differentiated systems:
  - IRIS® on track for launch in 2015
  - PRIMA to further expand the market opportunity after 2018

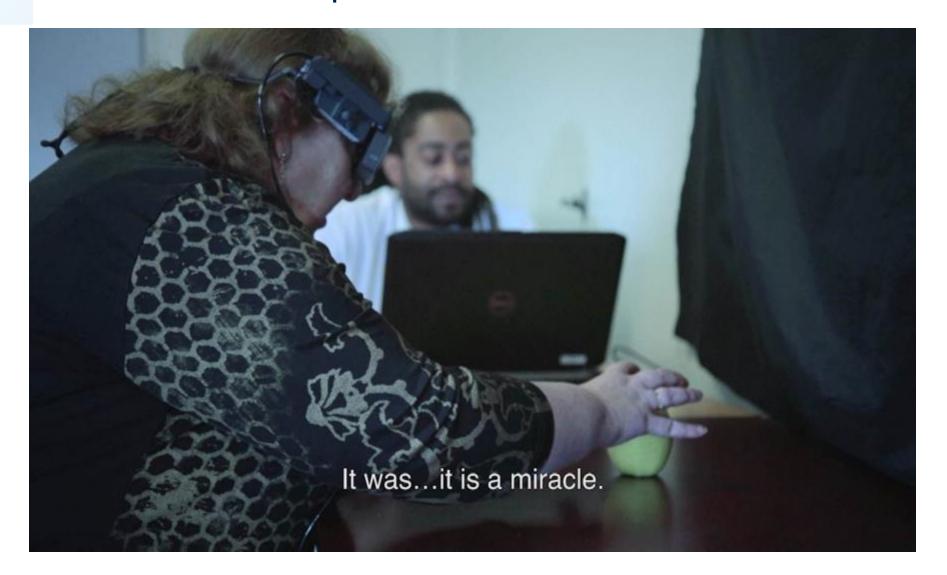
Strong and dedicated management

Establish Pixium Vision's position as a leader in Vision Restoration Systems



# Imagine how much blind people miss out on...

## Case Reports : of patients in the clinical trial – 6 months after implant





## **Rehabilitation Program**







### Progress 15-17 months Observations



Patients one year or more after implantation (long version):



**Short version** 





#### **Blindness**

Costs and target pathologies

## Solving blindness represents a major market opportunity

285 million people in the world are visually impaired

40–45 million people in the world are totally blind

In the US and Europe, blindness costs exceed tens of billions of USD per annum



No treatment exists for blind patients

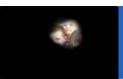
Retinitis Pigmentosa (RP) and Age-Related Macular Degeneration (AMD)

are major causes of blindness

Sources: World Health Statistics. World Health Organization -http://www.amd.org - NORC Cost of Vision Problems: The Economic Burden of Vision Loss and Eye Disorders in the United States -Study commissioned by Prevent Blindness in America and conducted by University of Chicago -European Forum Against Blindness (EFAB)



## Two major pathologies lead to photoreceptor degeneration and ultimately, blindness



#### Retinitis Pigmentosa (RP)

- Genetic disease
- Blindness occurrence: ~ 35 40 years old
- Worldwide prevalence: 1.5 to 2 million
- Prevalence in the US + EU:350,000 400,000
- Incidence (US + EU): 15k-20k patients annually



## Age-related Macular Degeneration (AMD)

- Age-related disease
- Later blindness occurence: 70+ years old
- Worldwide prevalence: 12 to 15 million
- Prevalence in the US + EU:4 million
- Incidence (US + EU): 350k 400k patients annually

Retinitis Pigmentosa is Pixium Vision's initial target market



## The loss of the photoreceptor function is a major cause of blindness

The eye transforms light into electric signals

Cornea

Cornea

Pupil

G

H

T

Ciliary body

Choroid

Retina

Optic nerve

- Photoreceptor degeneration does not affect the rest of the retina

- Photoreceptor cells convert light into signals
- The human retina contains 6 million cone cells responsible for central vision

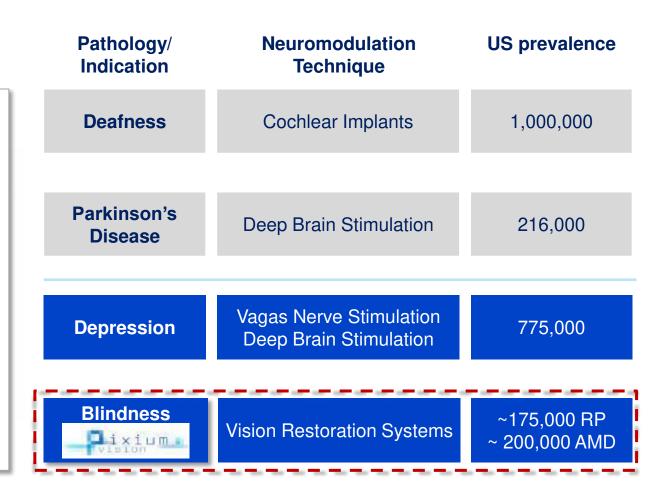
- RP and AMD are linked to photoreceptor degeneration
- However, bipolar cells, ganglion cells and downstream visual pathways remain INTACT and FUNCTIONAL in the vast majority of RP and AMD patients



## With its technology, Pixium Vision is well positioned in the fast growing neuromodulation market

## What is **Neuromodulation?**

- Induction of biological responses from electrical stimulation on nerves or zone where nerve activity is affected
- \$5Bn+ market by 2018 implying a high double digit growth rate (around 15%)







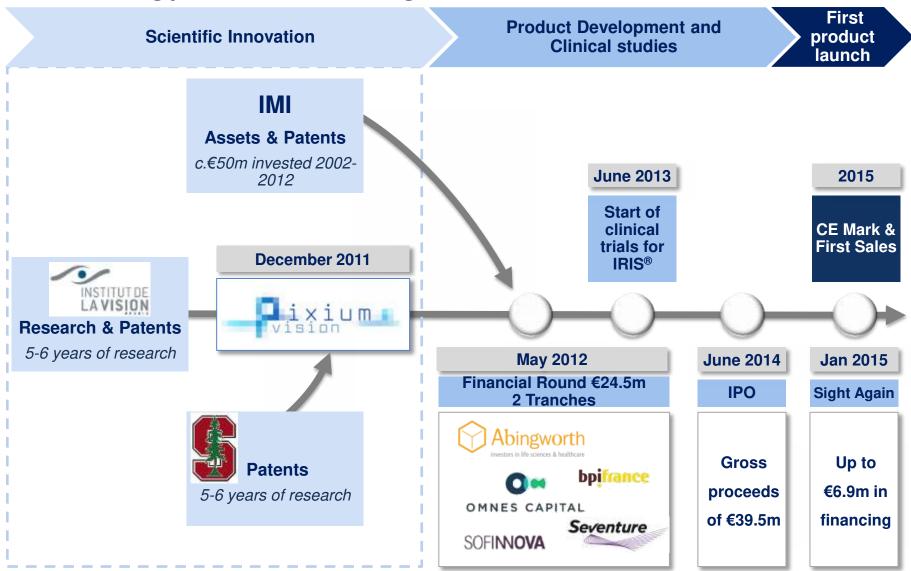




#### **Pixium Vision**

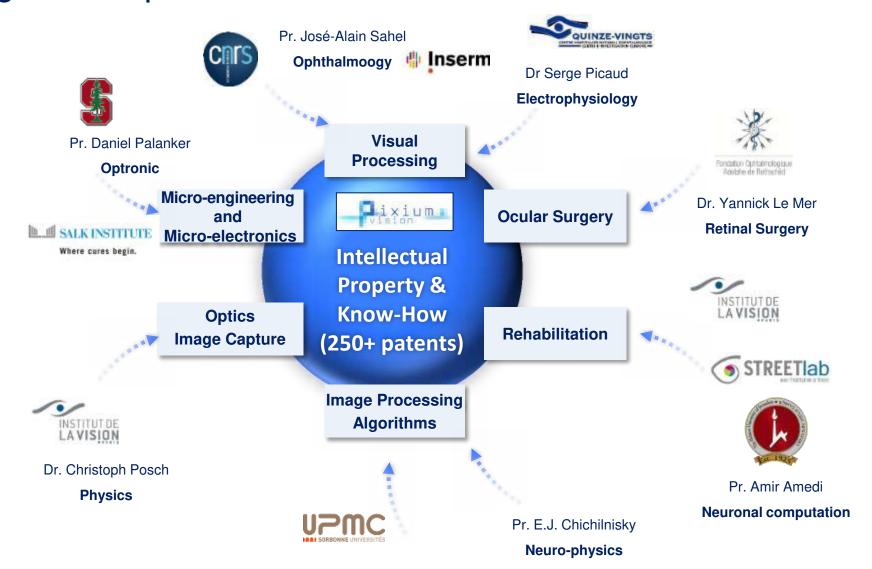
The convergence of excellence

## The Pixium Vision story relies on the convergence of technology and financing





## Pixium Vision is supported by French excellence and global expertise





Dr. Ryad Benosman

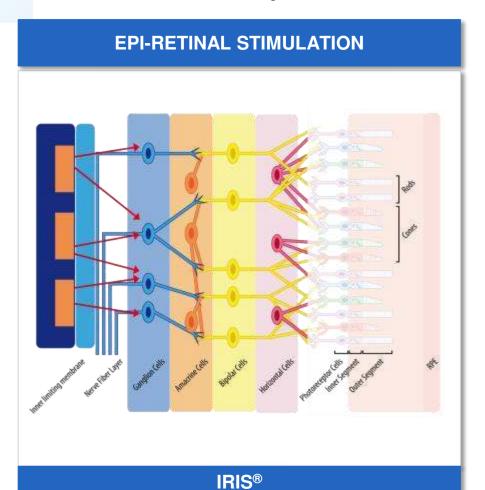
Mathematics / Robotics

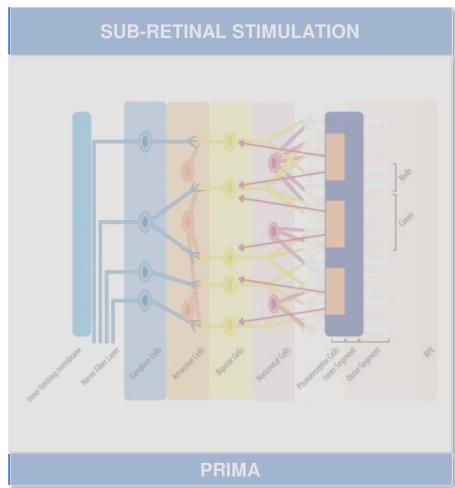


### **IRIS®**

A state of the art Vision Restoration System

## Pixium Vision is developing two differentiated Vision Restoration Systems





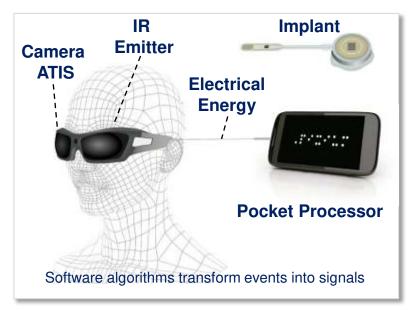






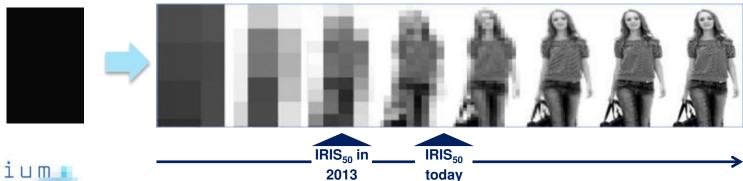
### The IRIS® Vision Restoration System

A technically advanced system designed to deliver important clinical benefits





Initial goal is to deliver light and shape perception, and to localize objects giving the patient the ability to negotiate an unfamiliar environment



## A unique proprietary *event-based* camera, functioning like the human eye

Our eyes only see changes in our environment (contrast, intensity, luminance, etc.)

Photoreceptors are activated independently



#### **Camera Features**

- Breakthrough bio-mimetic camera
- Neuromorphic asynchronous, eventbased: light is encoded into asynchronous impulses (-1,0,+1)
- Output relates directly to signals observed in the corresponding levels of biological retinas

#### **Benefits**

- Replicates normal vision in real time
- Reduces energy consumption and brandwith
- Visual information can be directly understood by the visual cortex



### IRIS®, a technically advanced epi-retinal implant

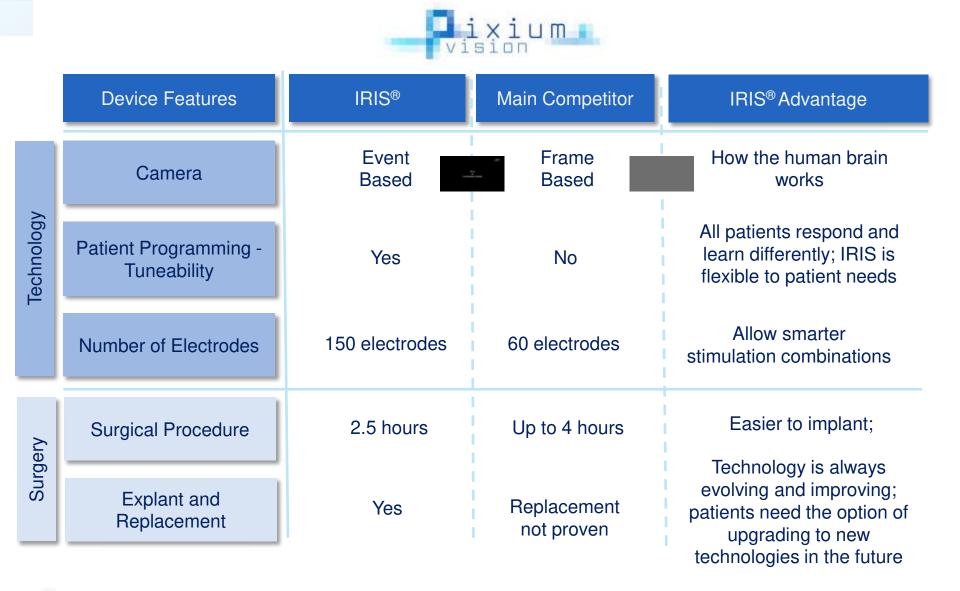


- Epi-retinal implant
- 150 electrodes in the commercial version
- Electrical power by induction
- Simple surgical procedure
- Compatible with
  - Next-generation vision sensors
  - Signal-processing algorithms
- Well tolerated by patients so far





### IRIS®: A technically advanced and differentiated VRS







## IRIS®: A clear path to market Aiming for a leading market position

### IRIS®: Continue to build evidence for CE Mark

#### **Ongoing Clinical Trial**

- Incidence, severity and duration of all adverse events at 4, 6, 9, 12 and 18 months
- Assessment of the capability of patients to *perform visual tasks* with and without the device at 4, 6, 9, 12 and 18 months

#### **Regulatory Path**



#### **Clinical Centers**



Paris & Nantes



Graz



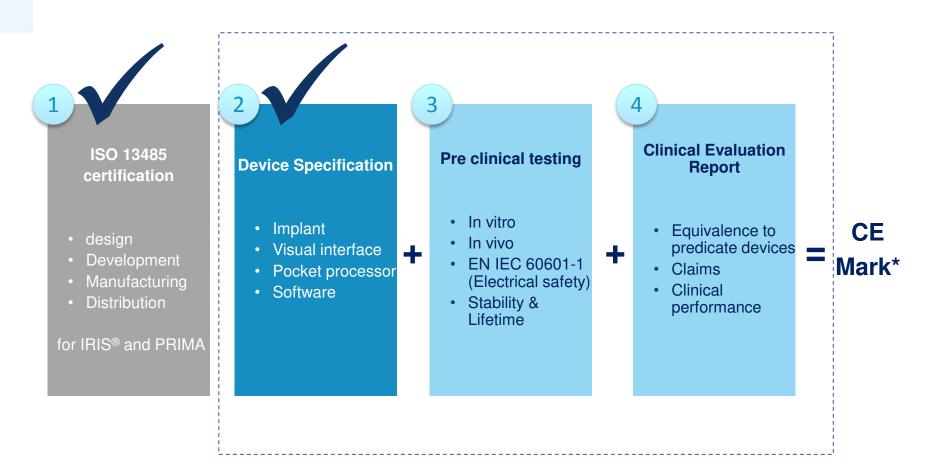
Hamburg & Bonn

#### **Rehabilitation Program**

- Programs tailored for each patient
- Rehabilitation programs will enable further software improvements
- Patients' vision improves during the course of their rehabilitation program



### IRIS®: First module of CE Mark dossier filed

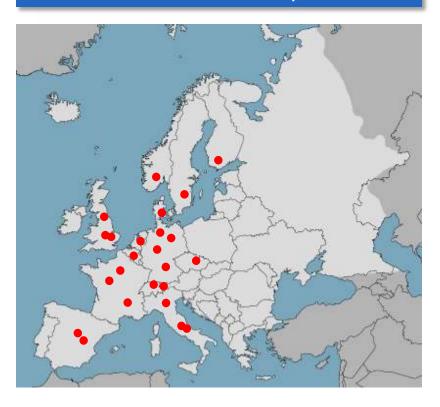


IRIS development moving forward for a CE Mark approval in 2015



### A lean and specialized commercial organization

#### 25 to 30 key ophthalmic surgery centers in Europe



These centres give access to ~80% of qualifying patients\*

#### Market development process

#### **Ongoing:**

- KOL engagement Discussions with patient associations Participation in major scientific and medical conferences



**Country/market assessments** to select and prioritize centers



Recruitment of a lean internal technical/clinical specialist sales team focused on:

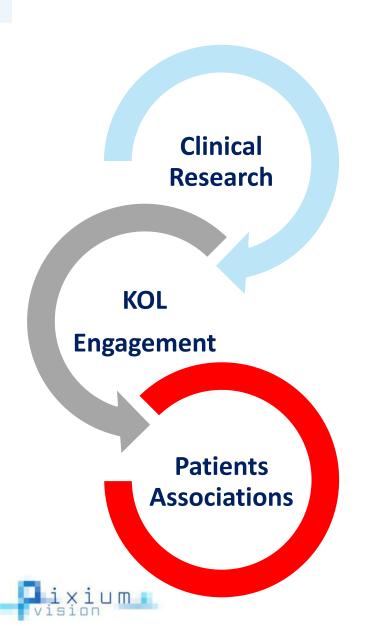
- Commercial & educational activities
- Training & support of orthoptists



Sales team to reach a peak of 2 to 3 team members per country & sales admin employees



## Market Development 2015 3 Pillars:



Publications +Podium SAB+MAB
Add Clinical Sites:

- Clinical on-going
- Post-Market Registry



















**Engaging Patient Associations and Talks at Key** 

**Medical Conferences** 

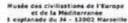




Le rendez-vous annuel des innovations en ophtalmologie "Malvoyance et retour à la vue"



Mardi 28 Octobre 2014 Auditorium du MUCEM - Marseille de 14h à 19h















The 8th Biennial World Congress on

the Relationship between Neurobiology and Nano-Electronics Focusing on Artificial Vision, Registration Information

The Eye and The Chip





PROGRAM SUMMARY

MAY A - B | TREAMON ROBER

After 2015 Award Shalling



#### Congrès Vision-Innovation

14 hrs · Edited · @

#VISIONINNOVATION 2015, Discours d'ouverture

#JOSEALAINSAHEL #Institutdelaysion #Saatchi #VanessaPerez

https://www.youtube.com/watch...



#### L'innovation sociale, scientifique et technologique au service du patient

Pr. José-Alain Sahel Directeur Institut de la Vision Mme. Vanessa Perez Directrice Content Design Saatchi & Saatchi Wellness Session enregistrée lors du Cong...

YOUTUBE.COM





- ~ 300+ participants
- ~ 40 journalists

25 speakers

Humanism and out of the box thinking – combining social, scientific and technological innovation updates



AAAS 2015 American Assoc for Advancing Science San José, 13-15 Feb

#### Bionic eyes

A new device may restore vision to those whose sight is dwindling Feb 21st 2015  $\mid$  SAN JOSE  $\mid$  From the print edition

MACULAR degeneration is a form of sight loss caused by the death of photoreceptor cells in the macula—the central part of the retina. It afflicts 30m-50m people, most of them elderly. The result is a shadowlike void in the centre of a sufferer's visual field. Many solutions have been proposed, from injecting a patient's eyes with stem cells that will grow into new photoreceptors to building small telescopes into spectacles or contact lenses.

Another is to implant a light-sensitive chip in the affected part of the retina—a promising idea in principle, but one that has not worked well in practice. Daniel Palanker of Stanford University thinks he can do better. He has developed a chip-based system which, although it will not fully restore vision, may bring someone back to a point where he is no longer legally blind.



Confidential 30

### Staged launch planned for IRIS®

**European IRIS®** Launch

Wave 1

IRIS® CE Mark 2015

First European Sales Launch: 2015



- IRIS<sup>®</sup> clinical sites subject to reimbursement
- Expand across Wave 1 launch countries



**European IRIS®** Launch

Wave 2

Second European Launch: 2016



- Subject to reimbursement Expand across Wave 2 countries



**US IRIS®** Launch

US Launch: early 2018





### IRIS® path to the US market

**Gather results** from European clinical trial

2

## File an Investigational Device Exemption (IDE)

- Planned for 2015
- Pixium Vision anticipates that FDA will require clinical results from at least 30 patients with 2 years followup





3

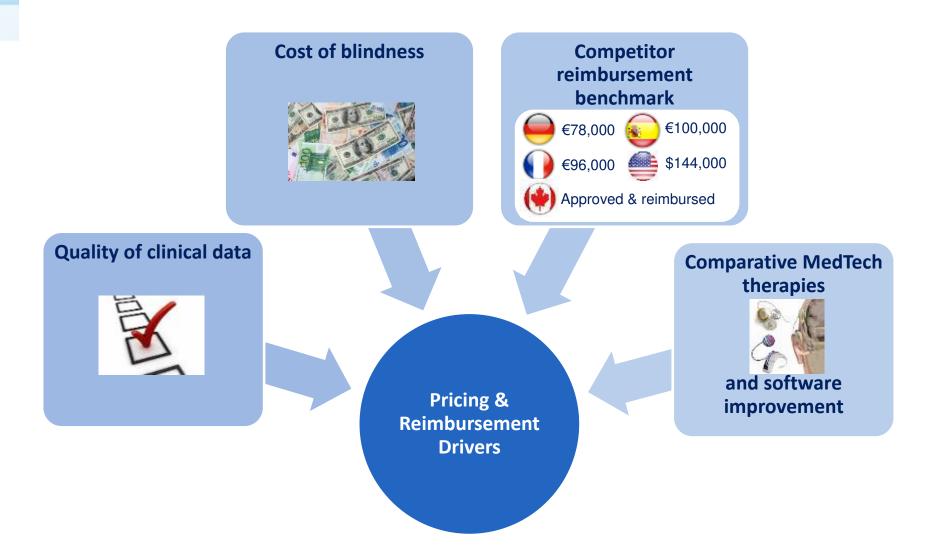
#### Obtain Pre-Market Approval (PMA)

 US launch of IRIS<sup>®</sup> to start 2018





## IRIS® pricing and reimbursement drivers





## Software upgrades and support services will generate an additional revenue stream

#### **Software & support services sales**

Illustration with key role of software evolution in Cochlear implant market



- Improve performance and patient benefit
- Enhance product life cycle management



Develop GPS, reading and other applications



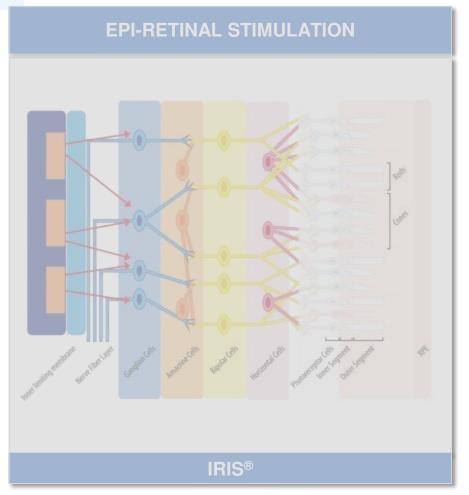


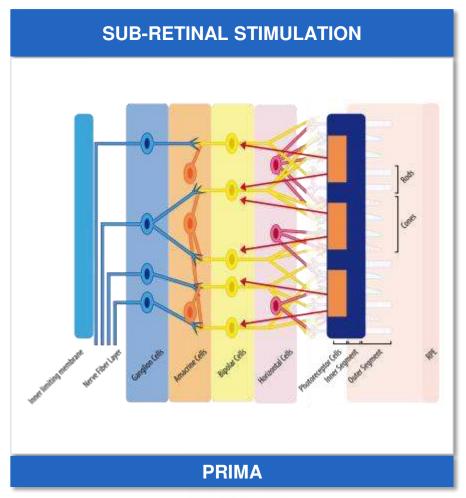


### **PRIMA Vision Restoration System**

Building on IRIS® leading market position

## Pixium Vision is developing two differentiated Vision Restoration Systems





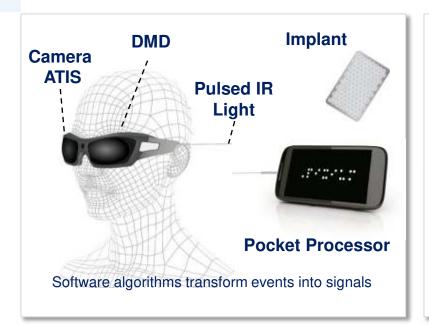


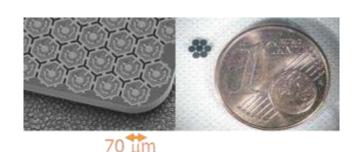




# The PRIMA Vision Restoration System

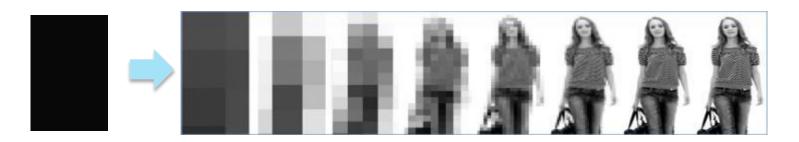
A technically advanced system designed to deliver further clinical benefits





- Physiological signal processing
- Simpler and shorter surgical procedure
- Retinal chips in modules up to 5,000 electrodes
- Advanced processing algorithms
- Reduced energy requirements enabling miniaturization of components

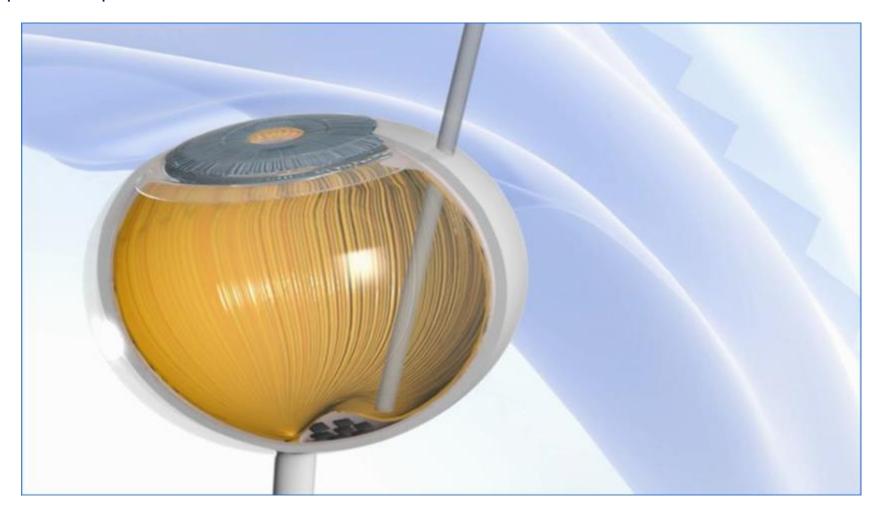
## Goal is to deliver improved visual perception to the level of direct facial recognition





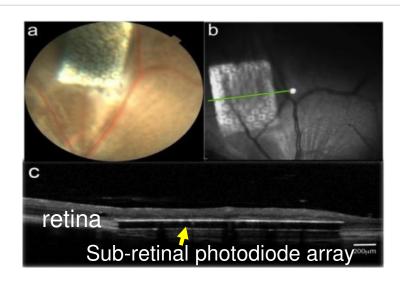
# PRIMA, a sub-retinal implant

Sub-retinal implants directly stimulate the retinal cells that used to be connected to the photoreceptors

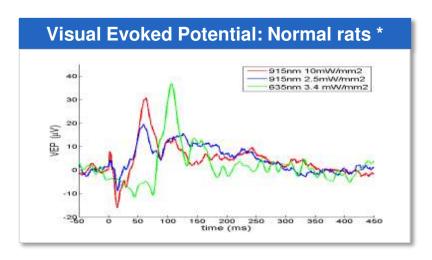


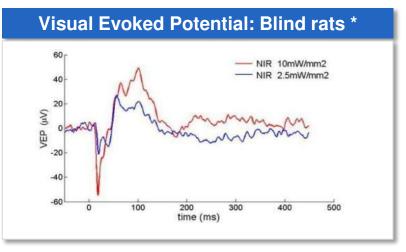


# PRIMA: Validated in pre-clinical models



- Proof of concept achieved in rats
- Safety demonstrated in rats and pigs
- Scale-up of manufacturing process ongoing
- First in man expected in 2016

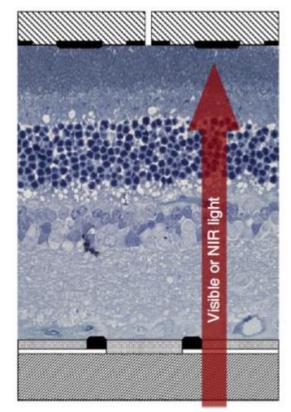






# PRIMA rat data, published in Nature Medicine, show restoration of half of normal visual acuity

- 70 μ m-wide pixels provide highly localized stimulation of retinal neurons in rats
- Electrical receptive fields recorded in retinal ganglion cells were similar in size to the natural visual receptive fields
- Similarly to normal vision, the retinal response to prosthetic stimulation exhibited:
  - flicker fusion at high frequencies
  - adaptation to static images
  - nonlinear spatial summation



PRIMA implant

photoreceptors

Inner nuclear layer

Ganglion cells (GCL)

Multi-electrode array (MEA)

Healthy rat retina sandwiched between a transparent MEA which records electrical field at the ganglion cell layer (GCL) level

In rats with retinal degeneration, PRIMA elicited retinal responses with a spatial resolution of  $64 \pm 11$  mm, corresponding to *half of the normal visual acuity in healthy rats* 





# A lot has happened so far, more to come

# Main achievements over the last year

### Company

- ISO 13485 certification confirmed in 2015
- R&D strengthening with 6 additional HC for PRIMA
- New governance

#### **Products**

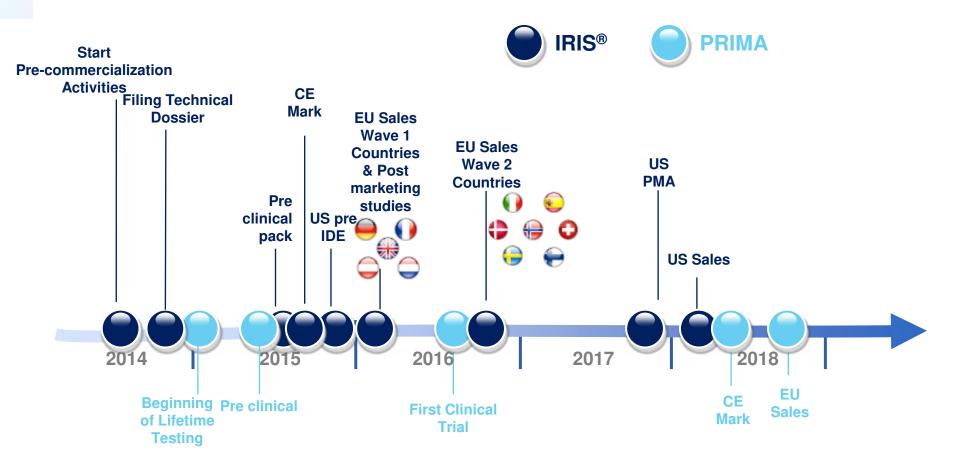
- IRIS<sub>50</sub>:
  - Clinical trial ongoing
  - 8 patients lined up
  - Potential to re-implant
- IRIS<sub>150</sub>:
  - Manufactured and working
  - Simpler design
  - In accelerated aging
  - Laser retinal marker
- PRIMA:
  - Technological transfer complete
     & first batches
  - First batch manufactured and being tested
  - Rat data published in Nature Medicine
  - Started larger animal study in May 2015

#### Market development

- Engaging with new hospitals:
  - UK
  - France
  - Germany
- Engaging with patient associations
- Attending congresses



# Pixium to complete IRIS® clinical trial and prepare for commercial launch in 2015; Prima to follow



Multiple major value-creation milestones anticipated in the next 2 years







## Thank You





@PixiumVision
#PixiumVision

**Pixium-Vision.com** 





# Appendix

## FY 2014 Financial statements

P&L summary

in thousand euros	2014	2013
Operating income / other income	2 426.6	1 478.2
Research and Development	(10 963.0)	(6 590.0)
General and Administrative	(3 111.4)	(1 034.9)
Operating income	(11 647.8)	(6 146.6)
Net profit	(11 611.3)	(6 145.8)
Earnings per share	(1.18)€	(0.22)€

Cash flow statement summary

in thousand euros	2014	2013
Opening cash and cash equivalents	9 420.2	3 088.6
(Decrease) / Increase in cash position	32 711.5	6 331.6
O/W net cash flows from operating activities	(8 389.5)	(5 187.4)
Closing cash and cash equivalents	42 131.7	9 420.2



# Q1 2015 Financials

### Sales of the first quarter

	First quarter	
in thousand euros	2015	2014
Operating income / other income	971.9	625.9

### Cash flow statement summary

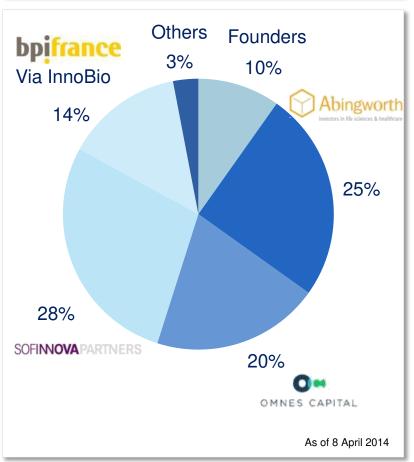
	First quar	First quarter		
in thousand euros	2015	2014		
Opening cash and cash equivalents	42 131.7	9 420.2		
(Decrease) / Increase in cash position	(5 493.4)	(3 196.1)		
O/W net cash flows from operating activities	(4 790.6)	(3 157.6)		
Closing cash and cash equivalents	36 638.3	6 224.1		



## Shareholder structure

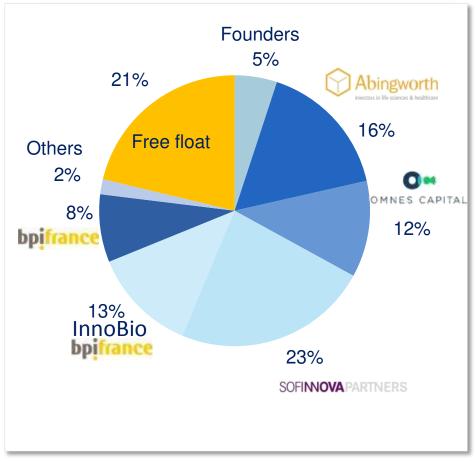
## Pre-IPO shareholder structure

On a non-diluted basis



#### Post-IPO shareholder structure

On a non-diluted basis
(with full exercise of the extension clause and overallotment option exercised at 95.8%)





# Competitive landscape

System	Number of Electrodes	Epi-Retinal Or Sub-Retinal	Features & Benefits	Clinical Results	Regulatory Status
Pixium naieium	<ul> <li>IRIS®: 50 to 150</li> <li>PRIMA: up to 5000</li> </ul>	<ul> <li>IRIS<sup>®</sup>: Epi-Retinal</li> <li>PRIMA: Sub- retinal</li> </ul>	<ul> <li>2h surgery</li> <li>Explantable</li> <li>Neuromorphic Camera</li> <li>Tunable software</li> </ul>	<ul> <li>Short term study on 19 patients</li> <li>10 Patients CE mark study ongoing</li> </ul>	CE Mark filing end of 2014
Second Sight	Argus II : 60     electrodes	• Epi-retinal	CMOS camera	<ul><li>Argus I: 6 patients</li><li>Argus II: IDE on 30 patients</li></ul>	<ul><li>Argus-II CE Mark Feb 2011</li><li>FDA HDE Feb 2013</li></ul>
retina implant	Alpha IMS	Sub-Retinal	<ul><li>Visual field of 12°</li><li>Non explantable</li></ul>	<ul><li>11 patients from 2005 to 2009</li><li>30 patients CE mark</li></ul>	• CE Mark July 2013
Na Retina	• 500 electrodes	Insufficient data	No camera	<ul> <li>Launch scheduled for 2016</li> </ul>	Pre-clinical     phase

