



## Pixium Vision: 2015 half-year results and business update

- **Additional patients implanted in IRIS<sup>®</sup> clinical trial**
  - **IRIS<sup>®</sup> II CE mark filing before end of 2015**
  - **Strong cash position: €31 million**

**Paris, France. July 29<sup>th</sup>, 2015. 7:00 CET** – The board of directors of Pixium Vision (FR0011950641 – PIX), the only company in the world developing two distinct retinal vision restoration systems, chaired by Bernard Gilly, met on July 28, 2015 to approve the financial results for the first half of 2015. The 2015 half year financial statements were subject to a limited review by the statutory auditors and the 2015 interim financial report is available on the Company's website.

**Khalid Ishaque, CEO of Pixium Vision**, said "Our progress continues with the recent implantation of additional patients in the clinical trial of IRIS<sup>®</sup>, the Company's first vision restoration system being prepared for commercial launch. During the first half of the year we strengthened our teams with key appointments and advanced development of both IRIS<sup>®</sup> and PRIMA platforms. We now turn to a strategic phase with the completion of the IRIS<sup>®</sup> clinical study recruitment, the availability of the IRIS<sup>®</sup> 150 electrode commercial version and the completion of the filing of CE mark dossier before the end of the year. Regarding PRIMA, a tiny wireless sub-retinal photovoltaic implant developed in collaboration with Stanford University to address age-related macular degeneration (AMD), we will conduct extensive in-vivo pre-clinical safety studies in 2015 and prepare for the first human implant in 2016."

### **P&L summary**

| <i>in thousand euros</i>        | <b>H1 2015</b>  | <b>H1 2014</b>  |
|---------------------------------|-----------------|-----------------|
| Operating income / other income | 1 737.7         | 1 104.1         |
| Research and Development        | (7 999.1)       | (4 510.6)       |
| General and Administrative      | (1 766.5)       | (930.1)         |
| Operating income                | (8 027.9)       | (4 336.5)       |
| Net profit                      | (7 953.8)       | (4 325.7)       |
| <i>Earnings per share</i>       | <i>(0.63) €</i> | <i>€ (0.62)</i> |

### **Cash flow statement summary**

| <i>in thousand euros</i>                     | <b>H1 2015</b> | <b>H1 2014</b> |
|--|----------------|----------------|
| Opening cash and cash equivalents            | 42 131.7       | 9 420.2        |
| (Decrease) / Increase in cash position       | (11 050.6)     | 32 383.4       |
| O/W net cash flows from operating activities | (9 504.2)      | (4 530.1)      |
| O/W net cash flows from investing activities | (1 571.6)      | (1 629.1)      |
| Closing cash and cash equivalents            | 31 081.2       | 41 803.6       |

### **Business update**

Since the IPO of the company, the teams are focused on the development of and commercial preparedness for both IRIS<sup>®</sup> (epi-retinal implant addressing primarily Retinitis Pigmentosa - RP) and PRIMA (a tiny sub

retinal implant addressing age related macular degeneration - AMD), Pixium Vision's differentiated bionic vision systems, also named Vision Restoration Systems (VRS). Pixium Vision is the only company in the world to develop in parallel 2 distinct retinal VRSs. The 2 systems will enable the company to address a market of more than 4 million patients<sup>1</sup> in Europe and North America.

### **IRIS<sup>®</sup>, the first VRS of Pixium Vision: additional patients have been implanted**

The Regulatory and R&D teams are focused on delivering Pixium Vision's first VRS under its industrial form. From a **clinical** standpoint, **additional patients were recently implanted**. Further implants, in patients that have already been recruited, will continue in September.

In parallel, the company is **in the process of opening additional clinical sites in Europe** to accommodate strong clinician interest in its promising technology and to contribute to the future growth of the company. The objective is to double the number of active partnering centers in Europe by the end of the year.

Since late 2014, Pixium Vision has developed and prepared **IRIS<sup>®</sup> II** for commercial readiness. IRIS<sup>®</sup> II is a technologically advanced VRS with an implant design incorporating **three times more electrodes** to enable further improvement of visual acuity. IRIS<sup>®</sup> II will also have more than twice the number of electrodes than the closest competitor's marketed product. In parallel, IRIS<sup>®</sup> II design was simplified to further streamline the manufacturing process, and improve robustness and reliability. Pixium Vision also advanced the production processes of the external components of IRIS<sup>®</sup> (also incorporating the proprietary ATIS neuromorphic imaging sensor that functions like the human retina and the more ergonomic goggles and pocket computer designs). The company intends to file IRIS<sup>®</sup> II CE mark dossier in the fourth quarter of this year. Pixium Vision's first VRS targets blind patients suffering from retinitis pigmentosa, a disease causing the degeneration of the photoreceptors in the retina.

Finally, Pixium Vision continues to actively engage with key stakeholders (government bodies and patient organizations) to ensure a timely reimbursement of its VRS solutions. The company expects to benefit from the groundwork of preliminary health economic studies related to the cost of blindness<sup>2</sup>.

### **PRIMA, a tiny wireless sub retinal photovoltaic implant**

The production technology for PRIMA implants was successfully transferred from Stanford University to an advanced semiconductor manufacturer in France. Pixium received the first manufactured implants in late 2014. These have been characterized and are now being tested in vivo for electrical and optical safety. The results of these tests are estimated to become available before the end of 2015. These pre-clinical studies will enable to proceed to first in human clinical trial.

To optimize the use of its financial resources, the company will initiate a series of clinical studies with a **first implantation in human in 2016**.

With its modular design (ability to position the tiny wireless implant in the affected area and the ability of delivering multiple implant configurations), less invasive surgical approach and a large number of electrodes, **PRIMA's "Best in Class" profile is particularly suitable for the treatment of AMD**.

### **Intellectual Property**

Supporting the technology development and industrialization over the last months, Pixium Vision has also strengthened and progressed with its patent portfolio:

- 7 patents granted with IRIS<sup>®</sup> since January 2015
- 5 new patent applications filed on both IRIS<sup>®</sup> and PRIMA further strengthen the portfolio

The company has also actively sought to protect its competitive patent position with:

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<sup>1</sup> Retinitis Pigmentosa (RP) and Age related Macular Degeneration (AMD)

<sup>2</sup> The economic burden of visual impairment and blindness: a systematic review (Juliane Köberlein, Karolina Beifus, Corinna Schaffert, Robert P Finger); Early health economic evaluation of the future potential of next generation artificial vision systems for treating blindness in Germany (Schwander Health Economics Review 2014)

- 1 patent maintained in Europe following opposition claim by a competitor
- 2 US competitor patents revoked following successful oppositions led by Pixium Vision

In addition, supporting the robustness of the Quality System, the Company's **ISO 13485 certification was re confirmed** during the first half of 2015.

## 2015 half-year financial results

For the first half of 2015, the Company has recorded €1,737,691 in **other operating income** compared to €1,104,121 a year earlier. Over the period, the company recorded a net income related to Research Tax Credit (RTC) of €1,266,098 compared to a sum of €1,104,121 in the first half of 2014. This increase is due to the continued R&D investment by Pixium Vision, the only company in the world developing two retinal Vision Restoration Systems in parallel. IRIS<sup>®</sup> is currently in clinical trial and PRIMA is in pre-clinical stage. Additionally, in December 2014, the Company received 1.261 million euros as first payment for the research grant provided by Bpifrance under the SIGHT AGAIN project of which €471,593 were recognized in Other Operating Income during the first half of 2015.

In the first half of 2015, **research and development (R&D)** expenses increased to €7,999,105 compared to €4,510,565 one year earlier. This trend is mainly related to increased sub-contracting, collaboration, consultants and the research equipment expenses for the development of both IRIS<sup>®</sup> and PRIMA.

**General and administrative** expenses mainly comprise costs for administrative personnel, external expenses such as legal, audit and consultancy fees as well as communication, travel and representation expenses. In the first half of 2015, G&A amounted to €1,766,526 compared to €930,094 a year earlier. This increase is mainly explained by an unfavourable 2014 baseline with both CEO and CFO joining the company during the first half of 2014 and by the costs incurred with public listing of the company.

**Net loss** for the period amounted to €7,953,780 compared with a loss of €4,325,726 on 30 June 2014.

Consequently, the **Earnings per share** (average weighted number of shares in circulation during the period) amounted to (€0.63) and (€0.62) respectively at 30 June 2015 and 30 June 2014.

Use of **cash flow from operating activities** at 30 June 2015 and 2014 amounted to €9,504,175 and €4,530,061 respectively. Since its IPO, the Company has invested in the development of two distinct and advanced Vision Restoration Systems, IRIS<sup>®</sup> and PRIMA in parallel. Furthermore, and to accommodate its growing business, the Company has recently moved to new premises.

During the first half of 2015, use of **cash flow from investing activities** has mainly concerned the purchase of laboratory and technical equipment in addition to building fixtures and fittings for the company's new premises.

At June 30, 2015, Pixium Vision had a **positive net cash position** of €31,081,173.

**Pixium Vision is the only company in the world developing two distinct retinal VRs. The 2 systems will enable the company to address a market of more than 4 million patients<sup>3</sup> in Europe and North America.**

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<sup>3</sup> Retinitis Pigmentosa (RP) and Age related Macular Degeneration (AMD)

## Contacts

### Pixium Vision

Pierre Kemula, CFO

[investors@pixium-vision.com](mailto:investors@pixium-vision.com)

+33 1 76 21 47 30

 @PixiumVision

### About Pixium Vision ([www.pixium-vision.com](http://www.pixium-vision.com), @PixiumVision)

Pixium Vision is developing innovative Vision Restoration Systems (VRS) that aim to significantly improve the independence, mobility and quality of life of patients who have lost their sight. The Company harnesses the rapid advances in visual processing, microelectronics / nanoelectronics, optoelectronics, neurobiology and intelligent software algorithms. Pixium Vision's VRS are associated with a surgical intervention as well as a rehabilitation period.

Clinical trials are currently underway with the VRS IRIS<sup>®</sup> in several centers in Europe. Patients have tolerated their implants well so far and improvements in visual perception have been observed. Pixium Vision plans to file IRIS's CE mark dossier before the end of 2015 and expects to launch IRIS<sup>®</sup> during the first half of 2016.

Pixium Vision is also developing PRIMA, a sub retinal implant currently in preclinical trial. The Company plans to begin clinical trials of PRIMA in Europe in 2016.



Pixium Vision is listed on Euronext (Compartment C) in Paris.

ISIN: FR0011950641; Mnemo: PIX

*IRIS<sup>®</sup> is a trademark of Pixium-Vision SA*

## Disclaimer

This press release may expressly or implicitly contain forward-looking statements relating to Pixium Vision and its activity. Such statements are related to known or unknown risks, uncertainties and other factors that could lead actual results, financial conditions, performance or achievements to differ materially from Vision Pixium results, financial conditions, performance or achievements expressed or implied by such forward-looking statements.

Pixium Vision provides this press release as of the aforementioned date and does not commit to update forward looking statements contained herein, whether as a result of new information, future events or otherwise.

For a description of risks and uncertainties which could lead to discrepancies between actual results, financial condition, performance or achievements and those contained in the forward-looking statements, please refer to Chapter 4 "Risk Factors" of the company's Documents de Base filed with the AMF under number I. 14-030 on May 12, 2014 and Chapter 2 "Risk Factors related to the Offer" in the prospectus, which can be found on the websites of the AMF - AMF ([www.amf-france.org](http://www.amf-france.org)) and of Pixium Vision ([www.pixium-vision.com](http://www.pixium-vision.com)).