



Pixium Vision announces H1 2019 financial results and provides business update

- 12-month data confirm and extend 6-month results in Prima System feasibility study
- Engaging with regulators to design development plan for Prima System in US
- Evaluating potential for parallel development in US and Europe
- Net cash position of €10.22 million at June 30, 2019

Paris, July 25, 2019 – 07:00 AM CEST - Pixium Vision (FR0011950641 - PIX), a bioelectronics company developing innovative bionic vision systems to enable patients who have lost their sight to lead more independent lives, announces its financial results for the first half of 2019, approved July 24, 2019 by the Board of Directors. The Half-Year Financial Report is available on the Company's website.

Lloyd Diamond, Chief Executive Officer stated: "Pixium Vision made strong progress in the first half of 2019, delivering on its strategy for the development of the Prima System, our breakthrough Bionic Vision System which is designed to compensate vision loss from atrophic dry age-related macular degeneration (AMD). It is particularly gratifying and exciting that 12-month data from our feasibility study with the Prima System has sustained the better-than-expected results reported at 6 months, and we are proceeding to test feasibility for new upgrades to the system in parallel in both Europe and the US. We will use these new clinical feasibility tests of the upgraded Prima System as the basis for a pivotal study starting in H1 2020. This decision was made to reduce regulatory approval and commercialization risk and to offer potentially improved quality of life for patients. In addition, we have initiated discussions with US regulators to optimize the process of pursuing US regulatory approval."

Income Statement summary (*)

In thousand Euros	H1 2019	H1 2018 Adjusted (**)	H1 2018 Reported
Revenues (***)	1,055.7	913.3	913.3
Operating expenses	(5,323.1)	(4,877.0)	(3,115.4)
Research and development	(3,869.0)	(3,146.2)	(2,314.3)
General & Administration	(1,445.2)	(1,622.4)	(692.3)
Marketing & Communication	(11.0)	(71.9)	(72.3)
Cost of goods sold	-	(36.5)	(36.5)
Current Operating Result	(4,269.4)	(3,963.8)	(3,571.1)
Non-recurring items	(805,1)	1,761.6	1,368.9
Operating Result	(5,074.5)	(2,202.2)	(2,202.2)
Net Result	(5,469.6)	(2,988.6)	(2,988.6)
Earnings per share (€)	(0.25)	(0.20)	(0.20)

(*) The financial statements for the first half of 2019 were subject to a limited review by the Statutory Auditors; (**) operating expenses 2018 were adjusted from the share-based payment – refer to the Interim Financial Report 2018; (***) of which Research Tax Credit

Cash flow statement summary

In thousand Euros	H1 2019	H1 2018
Opening cash & cash equivalent	15,629.4	10,531.6
(Decrease) / Increase in cash	(5,409.4)	6,203.6
O/W net cash flows from operating activities	(5,071.2)	(5,486.7)
O/W net cash flows from investing activities	(15.3)	77.8
O/W net cash flows from financing activities	(322.9)	11,612.5
Closing cash & cash equivalent	10,220.0	16,735.2

Business Update

[Positive 12-month data from the first feasibility study](#) of the Prima System extended the results reported at six months. Prima System was safe and met the primary endpoint of successful elicitation of light perception in the central retinal area in all subjects who had no remaining central visual activity at enrolment. This was validated by standardized clinical vision measures and tests (the Octopus visual field test). The results exceeded the study goals and demonstrated feasibility of the photovoltaic restoration of central vision in AMD patients, while preserving the peripheral natural vision intact. For example, many of the patients were able to identify letters, and the sequence of letters, with increasing speed.

Professor Daniel Palanker, Stanford University (USA), inventor of Prima System microchip, stated: "We are very pleased with the results of the feasibility trial meeting and exceeding the study milestones. They have demonstrated feasibility of the photovoltaic restoration of central vision in AMD patients, while preserving the peripheral natural vision intact. We are working now on the next generation of technology to achieve even higher acuity of prosthetic vision."

The Company also has continued to improve the Prima System and expects to announce soon its upgrades, which are designed to enable AMD patients to combine both prosthetic and natural residual (i.e. peripheral) vision.

"Thanks to the better than expected French feasibility data and the upcoming improvements in the Prima System, which we expect to announce soon, we now intend to pursue feasibility studies of the second generation upgraded Prima System in France and the US, in parallel going forward. This will allow us to ensure our timelines for launching the Prima System in Europe while pursuing development in the US," said **Lloyd Diamond, CEO of Pixium Vision**.

Pixium Vision will undertake feasibility testing of the upgraded Prima System in the five patients enrolled in the French study and amend feasibility study in a similar set of five patients in the US. Data from the studies will allow the Company to initiate the European pivotal study, which is now expected to start in H1 2020, allowing the Company to both increase the chance of success of the pivotal trials and accelerate development of the upgraded Prima System. Furthermore, testing the upgraded Prima System in the US will also allow the Company to strengthen its clinical data set aiming to design the appropriate regulatory pathway to pursue approval for the Prima System in the US.

During H1 2019 the Company hosted its first [Key Opinion Leader \(KOL\) meeting](#) in Paris, at which distinguished scientists in the field of retinal disease, AMD and prosthetic vision discussed the latest results of the Prima System and its potential for treating AMD. This further validated the positive nature of the data generated on the Prima System and its potential to help meet a significant medical need in an area with a severe lack of treatment options.

In addition, Lloyd Diamond was appointed CEO. Mr. Diamond, a seasoned executive with 25 years of disruptive technology commercialization experience in the life science industry, brings the leadership skills and operational background to successfully oversee the process of bringing the Prima System to market and to position the Company for success.

Field Code Changed

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Financial Results of the First Half 2019

Revenues increased to €1.1 million of which €1.0 million from a Research Tax Credit (CIR). CIR increased compared to 2018 reference period and reflects the sustained effort of the Company in its R&D projects, especially in the development of its bionic vision system Prima.

Research & Development (R&D) spending amounted €3.87 million compared with €3.04 million in H1 2018. In 2019, Pixium Vision sustainably invested in the technical development of its Prima system, especially its projection system which has been filed for a patent, as well as image processing algorithm. In parallel, the Company is running the feasibility studies both in France and in the USA. Spending in R&D also reflects the increase in manufacturing of Prima 2 glasses in order to serve the coming European pivotal trial. R&D spending account for 73% of global expenses.

General and Administration expenses amounted €1.45 million as of 30 June 2019 compared with €1.54 million a year earlier. G&A expenses are almost stable compared to H1 2018 as the Company is maintaining its strict cost control policy and focusing its financial efforts to R&D projects.

The spending in **Marketing & communication** reached €11 thousand (versus €72 thousand). The absence of commercial activity explains the low level of expenses during H1 2019.

In order to increase readability of its operations, Pixium Vision reports its **Current Operating Result** excluding non-recurring items and resulting in a loss of €4.27 million (compared with a €3.78 million loss at end June 2018). The 13% drop of **Current Operating Result** is driven by the increase in R&D efforts to support the development of the Prima system and prepare for the next step of its clinical development.

Non-recurring items totaled a non-cash charge of €0.81 million in H1 2019 (vs. a gain of €1.58 million in H1 2018). They included the share-based payment charge as calculated from IFRS 2 rule, a provision related to the cost of leaving of the CEO announced in April 2019. In the first half 2018, IFRS 2 rules resulted in a non-cash profit of €1.37 million. The Company also received a reimbursement of social charges related to 2014 free shares plan for €248k as well as a reversal of provision on social charges related to 2016 free shares plan for 184k€.

Net financial result showed a loss of €0.40 million (vs. €0.79 million), mostly related to the execution of the bond financing with Kreos Capital, through valuation of warrants and interest expenses.

Net cash outflow from Operating activities amounted €5.07 million and €5.47 million respectively at June 30, 2019 and June 30, 2018. In 2019, the Company increased its commitments to its key suppliers in order to prepare the manufacturing of Prima system ahead of its coming clinical development. Despite the increase in R&D spending, the cash outflow lowered by almost 8% thanks to the sustained efforts to contain G&A spending linked to a strict control policy.

As of June 30, 2019, **net cashflow from financing activities** reached (€0,32) million. According to newly applied IFRS 16, rental charges are partly booked in financing for €0.16 million. Reimbursement of the bond financing amounted for €1.0 million in the first half 2019. These items were partially by €0.9 million net proceeds from the equity line financing signed in December 2018.

During H1 2019, **cashflow from investing activities** are not significant (€15 thousand) covering tools and laboratory material. In 2018, Pixium Vision benefitted a cash deposit reversal following the reduction of the premises used by the Company.

On June 30, 2019, Pixium Vision had a **positive net cash position** of € 10.22 million.

Prima System is designed to restore sight in patients blinded by retinal dystrophies – a very significant unmet medical need. It features a miniaturized and totally wireless sub-retinal implant and augmented reality glasses. The 2x2 millimeter wide, 30-micron thick photovoltaic chip contains 378 electrodes. Implanted under the retina via a minimally invasive surgical procedure, it acts like an array of a tiny solar panel powered by pulsed near infrared light projected from a miniature projector transmitting images captured on a mini camera. The camera and projector technologies are integrated into augmented reality glasses, which together with the implant, make the Prima System. The target population includes patients with atrophic dry Age-related Macular Degeneration (dry AMD) and Retinitis Pigmentosa (RP). In addition to a clinical trial in five atrophic dry-AMD patients in France, Prima System also is authorized for clinical testing in a similar five-patient feasibility study in U.S.

Age-related macular degeneration is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America and Europe. The global impact is significant with current projected estimates for people living with AMD of around 196 million people worldwide and expected rapid growth due to ageing population. Around 1,000 new patients are diagnosed everyday in Europe and U.S. There are two forms of advanced AMD: the wet form, where treatment like anti-VEGF injections slows down the disease progression, and the dry form that is most frequent, where there is currently no curative treatment available. More than 5 million patients are afflicted with advanced dry AMD, also referred to as Geographic Atrophy. Patients suffering from this retinal dystrophy gradually lose their central vision (responsible for high visual acuity, e.g. for reading and face recognition) due to the loss of photoreceptors.

Pixium Vision is creating a world of bionic vision for those who have lost their sight, enabling them to regain visual perception and greater autonomy. Pixium Vision's bionic vision systems are associated with a surgical intervention and a rehabilitation period. Prima System sub-retinal miniature photovoltaic wireless implant is in clinical testing for patients who have lost their sight due to outer retinal degeneration, initially for atrophic dry age-related macular degeneration (dry AMD). Pixium Vision collaborates closely with academic and research partners, including some of the most prestigious vision research institutions in the world, such as: Stanford University in California, Institut de la Vision in Paris, Moorfields Eye Hospital in London, Institute of Ocular Microsurgery (IMO) in Barcelona, University hospital in Bonn, and UPMC in Pittsburgh, PA. The company is EN ISO 13485 certified and qualifies as "Entreprise Innovante" by Bpifrance.

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Pixium Vision is listed on Euronext Paris (Compartment C). Pixium Vision shares are eligible for the French tax incentivized PEA-PME and FCPI investment vehicles.

Pixium Vision is included in the Euronext CAC All Shares index

Euronext ticker: PIX - ISIN: FR0011950641 – Reuters: PIX.PA – Bloomberg: PIX:FP

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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 Registration Document filed with the AMF under number D.19-0364 on April 18, 2019 which can be found on the websites of the AMF - AMF (www.amf-france.org) and of Pixium Vision (www.pixium-vision.com).