EDISON

Pixium Vision

Clinical outlook

Prima gearing up for a pivotal year

Healthcare equipment & services

Pixium Vision is developing Prima, a potentially breakthrough wireless sub-retinal implant that generates electrical impulses at the retinal bipolar cell level to restore a form of central visual perception. Pixium is on track to start an EU pivotal study for its Prima bionic vision system (BVS) in H219 for the treatment of advanced dry age-related macular degeneration (Dry-AMD) involving geographic atrophy (GA). This follows the release of positive six-month data in January 2019 for its five-patient EU feasibility study. Using a risk-adjusted NPV model, we obtain a pipeline rNPV (including net cash) of €99.5m, vs €99.0m previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	2.5	(13.5)	(1.02)	0.0	N/A	N/A
12/18	1.6	(8.1)	(0.44)	0.0	N/A	N/A
12/19e	1.6	(10.6)	(0.48)	0.0	N/A	N/A
12/20e	0.0	(21.7)	(0.98)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Prima can provide benefit in severe Dry-AMD cases

Prima seeks to address a large unmet market indication, advanced stages of Dry-AMD involving GA. Feasibility data suggests the current Prima iteration provides visual acuity (VA) in the 20/460 to 20/550 range (about 4% of normal vision), which we estimate could potentially provide benefit in a target market of about 63,000 patients in Europe and 49,500 in the US with severe GA stages and lower pre-implantation VA. The level of vision provided by Prima in such cases can potentially enable the recognition of shapes and symbols in patients who may not have been able to identify them before the implantation. Providing such functional benefit may support reimbursement discussions if the product obtains regulatory approval.

EU pivotal study expected to start in H219

Pixium plans to begin discussions with regulators to conduct a pan-European pivotal trial across several countries and multiple centres. Pixium's goal is to start recruitment for the pivotal study in H219, potentially resulting in initial implantations before YE19. We estimate it will require 12 months of follow-up data within this trial for European regulators to provide CE mark approval. We believe that EU commercialisation (CE mark approval) may occur in H222.

Valuation: €99.5m in equity, or €4.49 per share

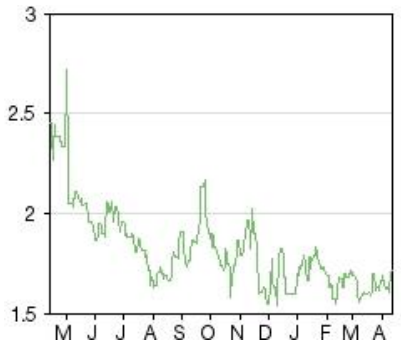
We believe Pixium's cash on hand should be sufficient for it to maintain its operations into Q220. We continue to estimate that Pixium will raise €75m through 2021 to fund Prima development. As per Edison policy, we model these as debt financing. We continue to value Pixium using an rNPV approach, employing a 12.5% cost of capital and applying a 15% probability of success estimate for Prima. Following minor changes to our market size, forex and EU pricing assumptions, we now obtain a pipeline rNPV (enterprise value) of €91.7m, up from €91.2m, previously. After including €7.8m net cash at 31 December 2018, we obtain an equity valuation of €99.5m, or €4.49 per share (compared to €4.50 previously).

12 April 2019

Price	**€1.71**
Market cap	**€38m**

Net cash (€m) at 31 December 2018	7.8
Shares in issue	22.2m
Free float	49%
Code	PIX
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	7.9	(1.5)	(35.8)
Rel (local)	3.8	(12.5)	(36.7)
52-week high/low		€2.7	€1.5

Business description

Pixium Vision develops bionic vision systems for patients with severe vision loss. Its lead product, Prima, is a wireless sub-retinal implant system designed for Dry-AMD. The firm has completed a human feasibility study in Europe and expects to start implantations in a US feasibility study in H119.

Next events

Initial implantations for US feasibility study	H119
Start EU pivotal study	H219

Analysts

Pooya Hemami, CFA +1 646 653 7026

Maxim Jacobs, CFA +1 646 653 7027

healthcare@edisongroup.com

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Investment summary

Company description: Restoring sight to Dry-AMD patients

Pixium Vision was founded in France in 2011 and initially raised €24.3m in venture funding. It then raised €39.5m in its IPO in 2014. The firm purchased Iris epi-retinal implant assets from Intelligent Medical Implants in 2012 for €11m, and initially worked on advancing this device for severely blind patients with retinitis pigmentosa (RP). Pixium since shifted its focus to a more advanced sub-retinal implant, Prima, which was developed in conjunction with Stanford University. The wireless Prima platform is theoretically capable of approaching facial recognition levels of VA and as such is being advanced for the much larger and currently unmet market need of patients with severe vision loss from advanced Dry-AMD involving geographic atrophy (GA). Positive data from an EU feasibility study was reported in early 2019, and the firm plans to start an EU pivotal study in H219.

Valuation: Pipeline rNPV of €99.5m

We value Pixium using an rNPV approach, applying a 12.5% cost of capital. Our valuation is entirely based on the Prima opportunity in advanced Dry-AMD involving GA, in the EU and US geographies. We continue to apply a 15% probability of success estimate for Prima (which embeds both regulatory risk and the risk of obtaining satisfactory reimbursement coverage to meet our market penetration forecasts). Following minor changes to our market size, forex and EU pricing assumptions, we now obtain a pipeline rNPV (enterprise value) of €91.7m, up from €91.2m, previously. After including €7.8m net cash at 31 December 2018, we obtain an equity valuation of €99.5m, or €4.49 per share (compared to €4.50 previously).

Financials: Funded into Q220, more capital needed

We believe that Pixium's funds on hand (€15.6m) should be sufficient for the company to maintain its operations and fund its Prima strategy into Q220. Given that the firm reported €7.9m in total gross debt on 31 December 2018 (€2.4m in conditional advances and €5.5m in long-term debt), we calculate €7.8m in net cash. We expect EU pivotal study patient recruitment and implantations to increase significantly in 2020, and that implantations will then also begin for the US pilot study, resulting in a yearly increase in R&D costs in 2020. We expect that Pixium will need to raise funds to expand its financial runway to fund the EU pivotal study. Our model continues to estimate that Pixium will raise €20m in 2019, €30m in 2020 and €25m in 2021. As per usual Edison policy, our model shows this as illustrative debt. We forecast that all this funding should enable Pixium to complete the registration-enabling Prima clinical studies in the EU to reach commercialisation in Europe.

Sensitivities: Regulatory, commercial and funding

Much development risk lies with Prima as it has only been implanted in a small number of patients to date, and in vivo longevity will need to be confirmed over time in future studies. Further, the visual improvements offered must be sufficient to persuade patients and insurers to cover the implant, and be competitive vs potential emerging alternatives. The EU feasibility study showed the device can enable recognition of shapes and symbols in patients who previously had no light perception in the treated eye; such functional benefit may support discussions for obtaining reimbursement coverage upon approval. Pixium will also depend on maintaining access to additional capital to fund Prima development. While our model accounts for these financings as long-term debt, the firm may have difficulties raising funds or need to issue equity instead, and there is a potential risk that pricing is not favourable for current shareholders, which would lead to significant dilution.

Company description: New-generation retinal implant

Pixium Vision is a French medical device company, which is advancing a retinal implant, or bionic vision system (BVS), that aims to provide a new form of vision to those with profound vision loss attributable to retinal diseases. These diseases permanently damage photoreceptor cells and impair their ability to translate visual stimuli into electrical signals transmittable into the optic nerve. The BVS intends to replace the signal processing functions of damaged photoreceptors by electrically stimulating other healthy retinal cells. These cells would then transmit the information towards the brain via the optic nerve.

Having brought its initial BVS, the Iris II epi-retinal[1] implant, to CE mark commercial stage in 2016, with market access innovation reimbursement in Germany and France, Pixium is now directing its attention to its new generation Prima BVS. Prima is a tiny wireless sub-retinal chip powered by near-infrared light, which delivers the electrical impulses at a more upstream level in retinal signal processing than epi-retinal devices, allowing a more natural neural network mediation of the information. This could potentially provide superior VA while involving a less invasive and time-consuming surgical technique. These attributes make it more suitable for the advanced Dry-AMD market, a substantially larger opportunity than the RP market targeted by Iris II, and currently without a proven treatment.

Following positive results in early 2019 from the five-patient European feasibility study, Pixium is planning to file applications to commence an EU pivotal study in mid-2019 (the first implantations could occur in H219), which, in our view, could support a potential EU market approval and launch in H222.

Prima: A sub-retinal device targeting the AMD market

Prima is a miniaturised photovoltaic wireless sub-retinal implant that is implanted underneath the retina in a surgical procedure that may take less than 90 minutes under local anaesthesia. The current Prima iteration under human clinical development is a 2mm × 2mm wireless chip (with 30 micron thickness) consisting of 378 electrodes (pixels) in total, with each pixel being roughly 100 microns (0.1mm) in length and width. Each photovoltaic pixel is independently controlled and self-powered by near-infrared light projected from glasses worn by the patient (the glasses consist of a camera and digital mirror projector, which emit a near infrared light pattern through the patient's eye carrying the Prima implant, designed to be processed by the Prima pixels).

Located underneath the retina, the pixels embedded on the device aim to stimulate the patient's bipolar cells, which are located mid-stream in physiological visual signal processing. In normal visual function, photoreceptor cells (located on the outer portion of the retina, or closer to the choroid) send information to bipolar cells (located within the retina), which then relay information into retinal ganglion cells (RGCs, which are on the inner portion of the retina), and onto the brain through the optic nerve. The Pixium system is designed to restore the function of individuals whose retinal photoreceptors have been damaged by retinal disease such as severe geographic atrophy associated with Dry-AMD. The Prima system is powered by pulsed near infrared light projected through a miniaturised projector integrated in a pair of augmented reality-like glasses (incorporating a mini-camera) worn by the patient.

1 Located at the surface of the retina.

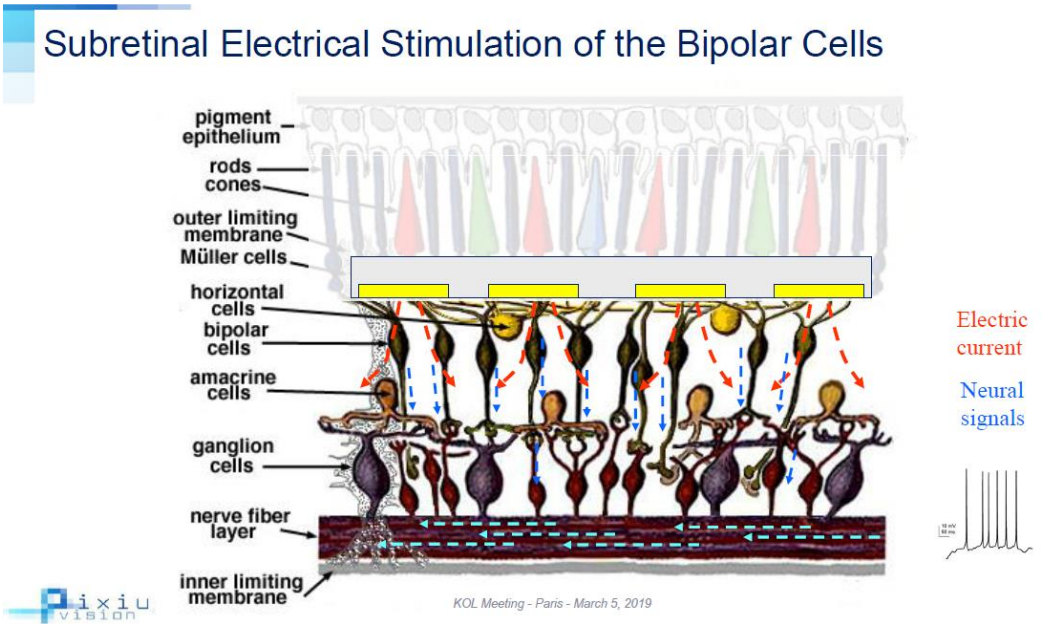
Exhibit 1: Diagram of Prima including camera integrated into specialised glasses

Source: Pixium Vision presentation

Fully wireless chip enables optimal sub-retinal placement

While epi-retinal implants (Pixium's Iris II and Second Sight's Argus II) reached commercial stages for advanced RP, a rare blinding disease, a sub-retinal wireless chip such as Prima can provide potential benefits such as a less invasive surgical approach. While the existing epi-retinal implants stimulate RGCs, the more biomimetic sub-retinal approach applied by Prima enables a more upstream level of interfacing in vision processing (by aiming to stimulate bipolar cells in the visual pathway). This can potentially lead to improved vision and helps enable a wireless implant solution (thereby reducing surgical complexity), as explained below.

Exhibit 2: Location of sub-retinal implant and intended communication with bipolar cell layer



Source: Company reports

Prima aims for a more physiological neural network mediation or natural image signal processing. By intending to stimulate first the bipolar cells (as opposed to RGCs), Prima leverages the retina's existing intrinsic physiological pathways, as bipolar cells require lower electric neural activation

thresholds to elicit a perceptual response (compared to RGCs). Prima's proximity to the bipolar cell network and the independent electrical circuit design of each pixel are designed to enable precise control of the emitted electrical signals. As Prima is powered with near-infrared light, it does not require permanent trans-scleral wires or cables (as needed by the wired epi-retinal implant designs such as Iris II and Argus II). Prima's fully wireless approach aims to ensure a less invasive surgical procedure, while also mitigating the risk of potential long-term complications that can result from permanent scleral openings (a potential risk with wired epi-retinal implant designs). Altogether, the surgical procedure to implant the Prima device into the human eye should likely take under two hours.

Prima requires clear optical media to function effectively, so patients with significant central corneal scarring may be contraindicated (and cataracts would need to be removed prior to implantation).

Improved resolution opens door to larger Dry-AMD market

Prima is intended to offer deliver VA superior to what is currently commercially available epi-retinal implants (eg Argus II). This level could be sufficient to provide meaningful improvements and justify implantations in patients in late stages of Dry-AMD, such as those with retinal scarring or geographic atrophy (GA) reducing best-corrected VA in each eye to below 20/400 (5% of normal vision[2]). For instance, Prima can enable the recognition of symbols, letters and objects in patients who have lost the capacity to recognise those forms due to the severity of their disease; this can provide quality-of-life improvements for such patients. This potential for visual improvement, in our view, is superior to those offered by the epi-retinal devices cited above, which generally only provide very crude vision (such as recognition of basic movements and illumination), with the theoretical limit of the Argus II being only four degrees (corresponding to about 0.4% of the resolution seen by healthy individuals). This restrained resolution generally limits that device's applicability to candidates with more profound (or near-total) central and peripheral vision loss, such as advanced stages of rare retinal dystrophies (such as RP).

Preclinical studies demonstrated safety and stimulation

Data studied on ex-vivo[3] blind primate retina confirmed that there are localised, pixel (location-specific) responses in the RGCs, following sub-retinal stimulation using a Prima prototype. Animal model thermal[4] and electrical safety studies completed in 2016 successfully showed that the system meets the safety thresholds for thermal and electrical safety requirements for the eye. Pixium also presented data[5] in autumn 2017 at The Eye and the Chip (TEATC) conference in Detroit, MI, where it had implanted a Prima prototype in 11 cat eyes, six pig eyes, and 19 monkey eyes, with the retina remaining attached at the end of surgery in 100% of cat eyes, 95% of monkey eyes and 86% of pig eyes. The animals were exposed to multiple illumination powers, including pulsed near infrared light, and visual evoked potentials in the cortex (brain) of the animals demonstrated that they perceived a visual stimulus when the Prima was illuminated with pulsed near infrared light. After three months in vivo, the implant showed no degradation and after euthanasia, histology analysis showed no degradation or damage to bipolar or ganglion cells in treated animals compared to the control group.

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[2] Patients with such severe visual impairment would generally not be capable of working in their prior occupations at comparable levels of productivity. They generally cannot read or write easily, even with the use specialised magnification devices. In many cases, patients with this level of central vision loss may also require living assistance for day-to-day tasks.

3 Living cells, but tested outside the host organism.

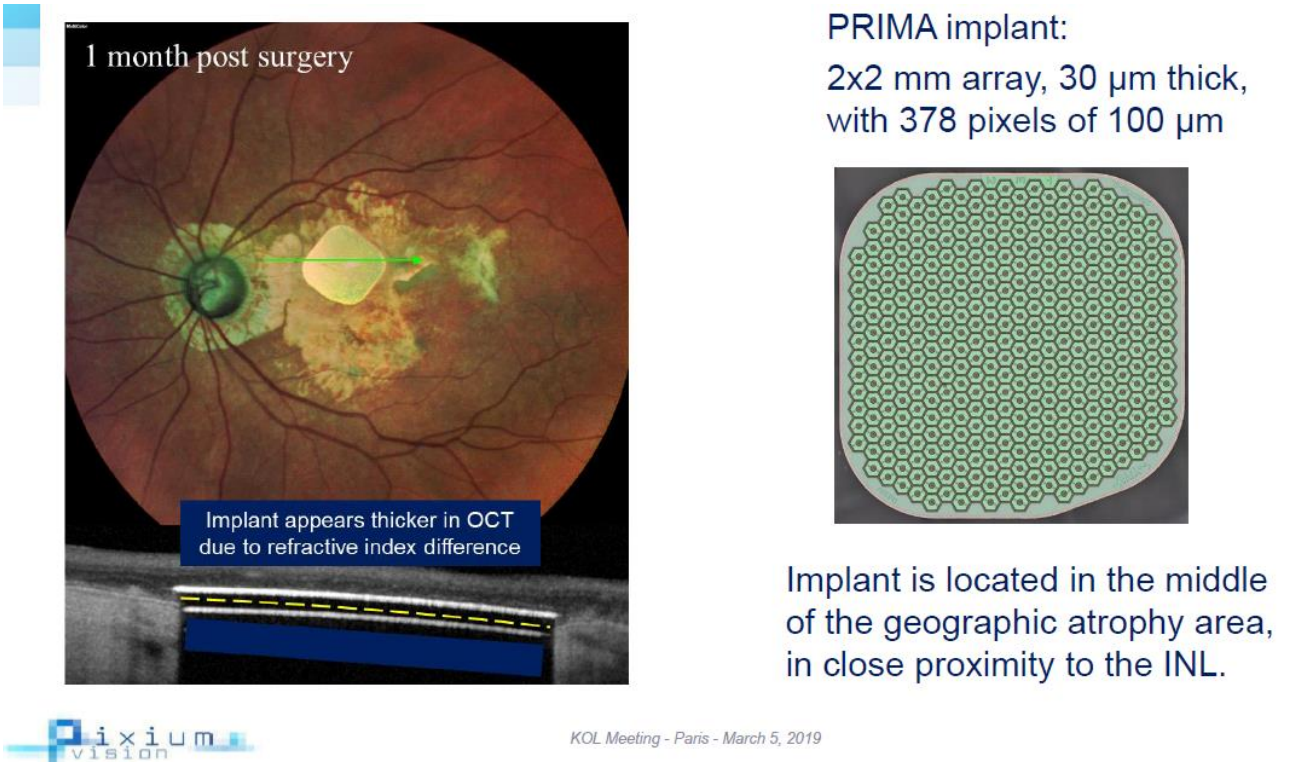
4 Lorach H, Wang J, Lee DY, et al. *Biomed Opt Express*. 2015 Dec 4;7(1):13–21. doi: 10.1364/BOE.7.000013.

5 Le Mer Y, Picaud S, Hubschman J, et al. Surgical and First Behavioral Test Results from the Sub-Retinal PRIMA Wireless chip implantations. Presented at TEATC conference 2017.

EU feasibility interim data to date shows signs of perception

In late 2017, Pixium started the five-patient, single-site,[6] 36-month European feasibility study for its Prima device in patients with advanced Dry-AMD. In July 2018, Pixium announced that it had completed the fifth and final implantation, and on 30 August 2018 it confirmed that all five implantations in the EU study resulted in successful consecutive activations and light perception, including the perception of white-yellow patterns with adjustable brightness, in areas where no central vision remained prior to implantation. Following activation, all patients proceeded to the visual re-education stage of the study, implemented as per study protocol, which is intended to assist patients in interpreting the new light perception patterns emitted by Prima.

Exhibit 3: Schematic of 378-pixel Prima and implantation into retina, at 1-month post surgery



Source: Company reports

On 8 January 2019, Pixium announced that Prima successfully met the endpoints of the five-patient EU feasibility study at interim six months follow-up after implantation, in patients with Dry-AMD. Pixium indicated that these results exceeded its initial expectations, as all five implantations resulted in successful activations and light perception in areas where no central vision remained prior to implantation. Most patients were able to identify different visual patterns, symbols or letter sequences, and recognition speed improved throughout the post-implantation rehabilitation phase. Safety measures to date suggest the implant is stable and well-tolerated, as there were no device-related serious adverse events and the device does not impair residual natural peripheral vision.

In early March 2019, study investigators presented some further clinical results at a key opinion leader (KOL) event held in Paris. A summary of VA measures of three of the five implanted patients was included (these were the three subjects within the study for whom VA had been consistently measurable). The data below showed that Prima provided meaningful VA improvements vs. pre-implantation. At least one patient reported VA measures of up to 20/460, which to our knowledge is among the highest level recorded with a prosthetic retinal implant device

6 All surgical implantations at the EU feasibility study took place at the Fondation Ophtalmologique A de Rothschild/Hopital des Quinze Vingts, based in Paris, France.

Exhibit 4: Pre-operative and post-operative visual acuity (VA) data from selected patients from EU Feasibility study

Subject identifier	Pre-operative VA	Post-operative VA
A	20/800 (2.5%)	20/550 (3.6%)
B	20/1000 (2.0%)	20/500 (4.0%)
C	20/500 (4.0%)	20/460 (4.3%)

Source: Company reports. Note: VA measured using "Landolt C" standardized scale, expressed in Snellen and "Percentage of normal" scales. Subjects A, B, and C are the three subjects within the study for whom VA had been consistently measurable

The data shows that the Prima device can interface with retinal cells to restore some visual perception in an area where vision had been lost due to prolonged degenerative disease. Further, while the objective of the feasibility study was to establish safety, the data also suggested that Prima provides some visual benefit in those patients with severe Dry-AMD, which was above the company's initial expectations for such a study. We expect the upcoming (larger) EU pivotal trial should provide more comprehensive data on efficacy in terms of quantitative and functional visual improvements.

We also highlight that Pixium is working to develop advancements in the external glasses worn by the patient. The firm anticipates that future iterations of the glasses will be integrated with improved analytics and image processing functionality that can potentially improve the artificial vision and visual perception experienced by the patient, in patients who will have been implanted with the first-generation 378-electrode Prima chip.

US feasibility study to commence implantations shortly

A single-centre, five-patient US feasibility trial (PRIMA FS-US), conducted at the University of Pittsburgh Medical Center, is actively recruiting and screening potentially eligible patients. Management expects the first implantations to occur in H119. The public release of interim data from the European feasibility study could encourage patient recruitment for this US study. Pixium believes that 12-month safety and performance data on all five patients will likely be sufficient for US regulators to allow a larger US (pilot) study to be started. We expect that study data from the US feasibility study should be available in H220 (vs. our prior expectations of H120) and that recruitment for the US pilot study can potentially also begin in H220 (unchanged vs. prior expectations). The study's primary endpoint will be elicitation of visual perception of the Prima device, while secondary endpoints will include VA, measured by methods such as the Early Treatment Diabetic Retinopathy Study and Freiburg Visual Acuity & Contrast Test scales.

EU pivotal study expected to start in H219

The regulatory pathway for a European CE Mark approval is shorter than in the US and Pixium is confident the interim safety data from the European feasibility study can be used to enable the design of the protocol for a larger, multi-centre, CE mark-enabling European pivotal study. The company plans to work with study investigators and statisticians in coming weeks to analyse full study data and formulate a pivotal study design. It will then begin discussions with regulators to conduct a pan-European pivotal trial across several countries and multiple centres. Pixium's goal is to start recruitment for the pivotal study in H219, potentially resulting in initial implantations before YE19. The firm expects the EU pivotal study to involve sites in several countries, including France, UK, Italy and Spain.

We continue to estimate it will require 12 months of follow-up safety and efficacy data within the EU pivotal trial for European regulators to provide CE mark approval. We estimate that the EU pivotal study may require 40–50 patients. We reiterate that to obtain CE mark approval product safety is generally the primary consideration for regulators (although longer term safety and clinical efficacy data is expected to be collected in the post market-approval surveillance protocol). We continue to

estimate that 12-month data from the EU pivotal study (which we estimate is the minimum required for approval) will be available in H221, leading to potential EU commercialisation (CE mark approval) in H222. We expect that CE mark clearance (and EU launch) would still occur 18–24 months earlier than US pre-market approval (PMA) and launch.

Exhibit 5: Projected clinical development pathways for the EU and US

	EU clinical pathway	US clinical pathway
Clinical studies needed	1. Small-size (c five-patient) feasibility study	1. Medium-size (c 30-patient) pilot study
	2. Medium-size (c 40–50 patient) pivotal trial	2. Larger (c 60–80 patient) pivotal trial
Projected characteristics and requirements for pivotal trial	12 months of follow-up data	18–24 months of follow-up data
	Study must show product safety	Study must show safety and efficacy
Projected commercial launch timeline	H222	2024

Source: Edison Investment Research estimates

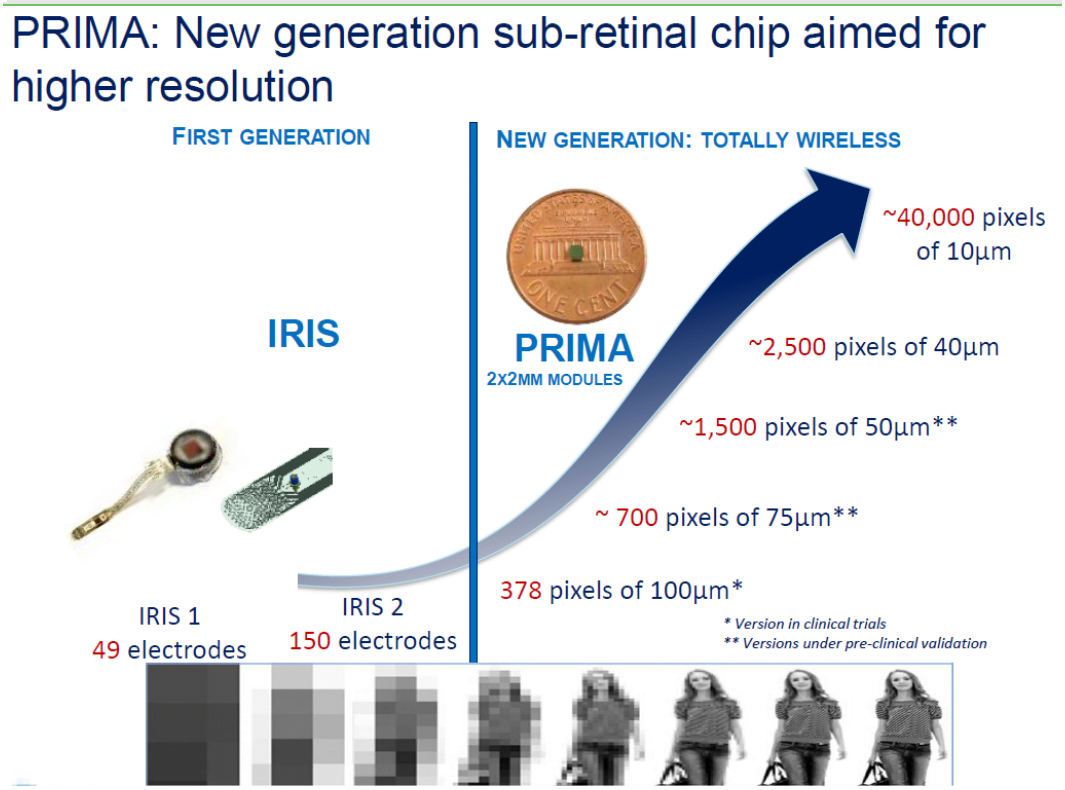
Follow-on implant could have higher pixel densities

The current Prima iteration in clinical trials (378 electrode) uses electrodes (or 'pixels') that are individually approximately 100 microns (0.1mm) in length, but the company and its research partners at Stanford University have been researching higher-density chips that use smaller individual electrodes and can hold higher electrode/pixel densities, and can theoretically provide higher visual resolution when implanted in patients. As stated earlier, Pixium is working on developing advancements to the external glasses used as part of the Prima system, which may provide some improvements to the vision perceived by patients compared to the current iteration of companion Prima glasses (with the 378-electrode current Prima iteration). However, more substantive or pronounced improvements in VA may require an implant chip with (much) higher electrode densities. A higher level of VA could potentially extend the market reach of Prima technology to patients with less severe forms of atrophic AMD, as the current 378-electrode iteration appears to be only appropriate for those who already have severe forms of geographic atrophy (and incoming VA of under 5% or 20/400).

Using the current manufacturing process used for Prima, it may be possible to reduce the individual electrode size down to 50 or 70 microns, whereas using even smaller electrode sizes (such as 10 microns, which would result in up to 40,000 pixels for a 2mm × 2mm chip) would require a different manufacturing process (what the company refers to as "honeycomb arrays"). The company's current strategy is to bring the current 378-pixel Prima to market and to then work on a follow-on iteration carrying much higher pixel densities. The firm's ultimate goal would be to achieve VA in the 20/100 or superior range (greater than 20% VA) using 20 micron honeycomb pixels; approximately 10,000 pixels can theoretically exist in a 2mm × 2mm chip array.

However, using higher-density Prima chips may entail some added risk, as the activation energy thresholds required to the device to function (as emitted through the pulsed near-IR light projected by the specialised AR glasses worn by the patient) will increase, given the need to stimulate a significantly increased amount of electrodes in the implant. Furthermore, even if a Prima device can theoretically emit signals corresponding to a higher level of resolution, the ability of the patient to resolve such fine details will depend on many factors, including the precision in the communication between the Prima chip and the external projection transmitted by the glasses worn by the patient; and the efficacy and precision of communication and interfacing between retinal cells and the electrical signals emitted by the Prima chip. Hence, it is not assured that a higher-density Prima chip would necessarily provide improved vision to the patient. At this point, our models and forecasts only consider the implications and market opportunities for the current (first-generation) 378-electrode Prima device.

Exhibit 6: Scalable nature of Prima technology



Source: Company reports

Competitive analysis

Pixium's products will need to compete with other implants on the market or in development.

Second Sight

Second Sight's Argus II was approved only for the RP indication, and uptake to date has been limited, as despite its presence on the market since 2011 in Europe (with US approval occurring in 2013), only 69 implants ($6.9m in revenue was recognised) were sold worldwide in 2018 (vs 75 in 2017 and 42 in 2016). We believe the limited level of vision provided by the 60-electrode device (patients may still require mobility assistance) could help explain the limited uptake to date.

Retina Implant AG

Retina Implant was a private German company developing a sub-retinal implant limited for the RP indication. Alpha IMS earned a CE mark in 2013 and a follow-on product, Alpha AMS, received CE mark clearance in 2016. Alpha AMS intended to replace the functionality of degenerated photoreceptors by stimulating other retinal cells and its core chip measured 3.2mm ×x 4 mm and was equipped with 1,600 photodiodes (which convert the incident light into an electrical signal). Unlike Prima, the Alpha AMS relied on external cabling to provide power to the device, and patients were required to have a conducting cable implanted through a section of the ocular globe, as well as a receptor implanted behind the ear in the cranial bone. These steps resulted in the need for two separate surgeries to implant the device, which is considerably more involved and time-consuming than what is required for Prima. At an extraordinary meeting on 19 March 2019, the shareholders of Retina Implant AG resolved to dissolve the company. One of the cited reasons was that its work had "been hampered by the innovation-hostile climate of Europe's rigid regulatory and health systems."

Nano Retina

Nano Retina is an Israel-based firm that is developing a miniature chip retinal implant, NR600, which is currently in preclinical development. The company claims that the product can be implanted using a minimally invasive surgical procedure in under one hour. Like Prima, the product would be self-powered, as its energy needs are met by photovoltaic elements generating operating voltage from infrared laser light delivered by the Nano Retina eyeglasses worn by the patient. The device candidate may support implantations at the epi-retinal and/or sub-retinal level, and we believe it is being designed to stimulate bipolar cells (similar to Prima).

iBionics

Based in Ottawa and founded in 2015, iBionics is designing an epi-retinal implant that stimulates the retina via diamond electrodes. The current iteration has 256 electrodes, with the possibility of increasing up to 1,024. The firm believes that a 1,024-pixel version could enable patients to recognise faces, read and navigate freely. Human trials are planned to start in 2020.

Other competing technologies

Alternate therapies (beyond electronic implants) are being developed to restore sight to patients with retinal diseases that, if successful, could compete with Iris Prima. These include:

- **Retinal transplantation or cell therapy** (ie transplantation of retinal cells or of immature retinal stem cells). This line of development is very premature and speculative with limited human data to date, but there have been reports of vision loss in some experimental treatments on AMD patients.[7] Reneuron is undertaking a Phase I/IIa clinical trial of its proprietary human retinal progenitor stem cell therapy (delivered via a single, subretinal injection) in advanced RP, with the aim of potentially preserving existing photoreceptors, potentially halting further vision loss. If successful, it could be possible for a form of this technology to be considered for treating AMD.
- **Neurological visual cortex stimulation**. Second Sight is developing a follow-on product (Orion) that stimulates the visual cortex of the brain rather than the retina. By bypassing the optic nerve, Orion could help patients with diseased optic nerves (eg glaucoma, optic neuropathy etc). The firm began an Orion human feasibility study in January 2018 under the FDA's Breakthrough Devices Program programme and has implanted six patients to date and plans to enrol additional subjects in 2019. It is also evaluating the design of a pivotal trial and plans to reach consensus with the FDA on design specifics during 2019. Neurosurgery is more invasive than retinal surgery, so we estimate that unless Orion can provide better VA than Prima for retinal diseases, its potential use would likely be concentrated towards optic nerve diseases and thus it may not directly compete with Prima.
- **Optogenetics.** Optogenetics involves the transfer of a gene ("gene therapy") encoding for a light-sensitive protein be applied to provoke neuronal cells to respond to light stimulation. GenSight Biologics's GS030 candidate uses this process to encode a photoactivatable channelrhodopsin protein, delivered via a modified AAV2 vector into the eye (through intravitreal injection). The intent is to confer a photoreceptive function to target functioning RGCs by enabling them to respond to light stimulation. A companion medical device is used (specialised "biomimetic goggles") to deliver light at the proper intensity and wavelength to stimulate the transduced RGCs so that they can transmit the visual signals to the brain. The firm started in October 2018 a Phase I/II study of GS030 at Moorfields Eye Hospital in London, UK, in 18 patients with RP. Top-line results are expected in Q420. The company believes that

7 Kuriyan AE, Albini TA, Townsend JH, et al. *N Engl J Med*. 2017 Mar 16;376(11):1047–1053.

this technology can be applicable to RP and GA-AMD, or other diseases in which photoreceptors are lost while functioning RGCs remain.

- **Implantable telescope**. VisionCare Ophthalmic Technologies offers an FDA-approved implantable miniature telescope for AMD, providing 2.2–2.7 times magnification, but it does not improve the ability of the damaged retina to resolve details.
- **Alternate sensory reproduction**. Wicab's BrainPort Vision Pro is an oral electronic vision aid that provides electro-tactile stimulation by projecting an image recorded by a video camera mounted on a pair of sunglasses, on to a tongue array containing about 400 electrodes. This device can offer functionality in patients with severely damaged optic nerve transmission.

Market opportunity for Dry-AMD

Age-related macular degeneration (AMD) is the leading cause of blindness in adults over the age of 55 in western countries, and is characterised by damage to the macular[8] region of the retina, leading to central vision loss. Prevalence increases with age, as about 2% of the population have the condition at age 40, rising to c 25% by age 80.[9] AMD patients generally maintain their peripheral vision but the damage to central vision can be so severe in advanced cases as to restrict a patient's ability to work, read, recognise faces or independently perform other habitual tasks.

While the exact pathophysiology is not fully understood, AMD is believed to be caused by oxidative stress, mitochondrial dysfunction, inflammatory processes, and/or cardiovascular (lipid-cholesterol pathway) factors. Genetic and environmental factors (such as smoking history or prolonged exposure to ultraviolet light) may also play a role in pathogenesis. There are two forms of AMD: dry (non-exudative) and wet (exudative).

- The dry form of AMD accounts for about 80–90% of cases (all AMD cases start as Dry-AMD) and cellular atrophy is the primary cause of vision loss and photoreceptor damage in this form. This condition often evolves relatively slowly but currently has no proven treatment, although lifestyle factors and dietary or nutritional supplement changes may help decelerate progression. As the dry form of the condition advances, it can lead to geographic atrophy (GA), where there is irreversible scattered or confluent areas of degeneration of the retinal pigment epithelium (RPE) cells, damaging the overlying photoreceptors and resulting in a loss of visual function. While some patients with GA may have near-normal VA levels, most will at minimum have reductions in contrast sensitivity and in many cases, GA patients will have sharp reductions in VA (20/80, or 25% of normal vision, or lower). The 378-electrode Prima is intended for instances of Dry-AMD where there is significant GA and VA below 5% acuity (20/400).
- The wet form (also called neovascular AMD, or NVAMD) is characterised by exudative and neovascular changes, such as the formation of choroidal neovascularization (CNV). CNV refer to newly immature blood vessels from the eye's choroid layer growing into the overlying retina, which often leaks fluid and can lead to macular scarring, damaging photoreceptors and resulting in rapid vision loss. The wet form is always preceded by dry form, and it accounts for about 10–20% of AMD cases. Prior to the usage of anti-VEGF (vascular endothelial factor)

[8] The macula is the central region of the retina, containing the highest density of photoreceptors compared to other regions, thus accounting for the high level of resolution and colour perception associated with the central vision. Photoreceptor cells in the retina absorb light photons, resulting in a biochemical reaction that leads to the generation of an electrical signal that stimulates downstream neurons (retinal ganglion cells) which then travel through the optic nerve and into the visual pathway leading to the occipital cortex of the brain.

[9] Friedman DS, O'Colmain BJ, Muñoz B, Tomany SC, McCarty C, de Jong PT, Nemesure B, Mitchell P, Kempen J, Eye Diseases Prevalence Research Group. *Arch Ophthalmol*. 2004 Apr; 122(4):564–72

injection treatments, the current standard of care for NVAMD, it accounted for over 80% of AMD patients with legal blindness.[10]

Late-stage AMD is often defined as patients who develop NVAMD and/or GA. In general, RPE dysfunction and atrophy precedes the late stages of AMD (GA or CNV).

Globally, the prevalence of AMD (all stages) in adults above age 45 is estimated at 8.0%,[11] affecting about 13 million people across Western Europe, and the US prevalence of all-stage AMD was approximately 7.2m in 2008.[12] Individuals with Caucasian or European ancestry are believed to be more prone to developing AMD. The prevalence of Caucasians in the United States with NVAMD, GA, and Late-AMD has been estimated at 1.1m, 1.0m, and 2.0m,[13] respectively. Based on US NIH data[14] that estimates that Caucasians account for 89% of all US AMD cases, we estimate that the US prevalence of NVAMD, GA, and Late-AMD would be approximately 1.2m, 1.1m and 2.2m, respectively. In Europe, it has been estimated that the number of people with Late-AMD was 2.7m in 2013, and that it will rise to 3.9m by 2040 (1.4% CAGR).[15] Given this, we estimate that the prevalence of GA in Europe is approximately 1.4m.

Prima financial forecasts

Given that the current Prima iteration appears to provide VA in the 20/460 to 20/550 range, we estimate that the target population will be those GA patients with below 20/400 (5%) VA, and we estimate that this would represent about 15% of GA patients. In other words, we estimate 15% of patients with GA would have sufficiently poor central vision to warrant potential consideration for Prima. Of these, we estimate that 30% would meet all remaining inclusion criteria and/or be suitable as potential responders (ie this considers that many of the AMD patients are in poor general health and/or have concomitant eye diseases, such as glaucoma or poor optical media transparency, which would render them ineligible for Prima). Given the above, we now estimate the target eligible GA-AMD treatment population for the current 378-electrode Prima to be currently about 63,000 in Europe and 49,500 in the US. This compares to our previous estimates of the eligible treatment populations of about 73,200 in Europe and 46,500 in the US. Our new estimates reflect more recent and specific epidemiology data that suggest smaller differences in the AMD prevalence in the US versus Europe than our previously-used data sources. Our peak market share forecasts (of the eligible treatment population) remain unchanged at 7%.

We have also increased our initial net per-implant EU Prima pricing estimates to €95,000, from €90,000 previously. Following these changes, our EU revenue forecasts (such as in years 2022–27) have decreased by c 4–7%, and our US Prima revenue forecasts (2024–27) have increased by about c 5–6%. We continue to forecast the EU launch will occur in H222 and a US launch in 2024.

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10 Legal blindness refers to patients with a central VA of 20/200 (10%) or worse in the better eye when a patient is wearing their best-corrected prescription lenses, or those with a visual field of less than 20 degrees.

11 Wong WL, Su X, Li X et al. *Lancet Glob Health*. 2014 Feb;2(2):e106–16.

12 Klein R, Chou CF, Klein BEK, et al. *Arch Ophthalmol*. 2011;129(1):75–80. doi:10.1001/archophthalmol.2010.318

13 Rudnicka AR, Kapetanakis VV, Jarrar Z et al. *Am J Ophthalmol*. 2015 Jul;160(1):85–93.e3. doi: 10.1016/j.ajo.2015.04.003. Epub 2015 Apr 6.

14 US National Institutes of Health. https://nei.nih.gov/eyedata/amd Accessed 22 February 2019.

15 Colijn JM, Buitendijk GHS, Prokofyeva E, et al. *Ophthalmology*. 2017 Dec;124(12):1753–1763. doi: 10.1016/j.ophtha.2017.05.035. Epub 2017 Jul 14.

Exhibit 7: Financial forecasts for Prima in Dry-AMD

	2022e	2023e	2024e	2025e	2026e	2027e
Europe						
EU patients with Dry AMD with GA (000)	1,457	1,471	1,486	1,501	1,516	1,531
Percentage with 20/400 or worse visual acuity	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%
Percentage meeting all Prima eligibility criteria	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%
GA-AMD patients meeting all Prima eligibility criteria (000)	65.6	66.2	66.9	67.5	68.2	68.9
Prima unit sales in EU	92	716	1,797	3,039	4,235	4,805
Average revenue per treatment (€)	95,000	96,363	98,211	100,131	102,123	104,115
Total EU revenue (€000) for PRIMA-AMD	8,711	69,035	176,438	304,319	432,525	500,293
United States						
US patients with Dry AMD with GA (000)	1,145	1,156	1,168	1,179	1,191	1,203
Percentage with 20/400 or worse visual acuity	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%
Percentage meeting all Prima eligibility criteria	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%
GA-AMD patients meeting all Prima eligibility criteria (000)	51.5	52.0	52.5	53.1	53.6	54.1
Prima unit sales in US	-	-	303	1,222	2,262	3,257
Average revenue per treatment ($)	N/A	N/A	154,320	157,118	160,174	163,336
Total US revenue ($000) for PRIMA-AMD	-	-	46,726	192,019	362,372	532,001
Assumed $/€ rate	1.12	1.12	1.12	1.12	1.12	1.12
Worldwide total revenue (€000)	**8,711**	**69,035**	**218,158**	**475,765**	**756,071**	**975,294**

Source: Edison Investment Research

As stated earlier, we expect that the Prima iteration to be launched will be the current 378 electrode version. The firm's activities on substantially smaller electrode sizes (eg around 10 microns) carrying tens of thousands of total electrodes are more likely to be explored for a potential follow-on product and are not included in our forecasts. In an ideal and optimal scenario, once the first Prima iteration reaches the market, a next-generation Prima carrying tens of thousands of electrodes could theoretically deliver VA levels in the 25–50% range (20/80 to 20/40), which could make it potentially useable in a substantially larger segment of the Dry-AMD population (than we expect for the current Prima iteration).

Financials

Pixium reported Q418 gross cash and equivalents of €15.6m and a 2018 operating cash burn rate of €6.17m excluding net interest/finance costs of €1.28m. The firm reported €1.60m in revenue in FY18 (primarily from subsidies and research tax credits), down from €2.54m in FY17. It realised a €6.81m operating loss[16] (vs a €12.67m loss in FY17), and a €13.57m net loss (€0.73 per share), vs a €13.54m net loss in FY17.

Included within the FY18 net loss was a one-time €5.48m impairment charge related to tangible and non-tangible assets relating to the now-discontinued earlier-generation Iris II epi-retinal implant programme. Excluding this impairment charge, the company's adjusted net loss was €8.09m, or €0.44 per share.

Overall, Pixium's sharply lower operating and adjusted net losses compared to FY17 were, as expected, due to the cessation of the Iris II programme, which resulted in significantly lower COGS and marketing expenses, as well as slightly lower R&D costs.

Financial outlook

We believe that Pixium's funds on hand (€15.6m) should be sufficient for the company to maintain its operations and fund its Prima strategy into Q220. Given that the firm reported €7.9m in total

[16] Please note our calculation of operating loss differs from that reported by the company, largely because we do not exclude the positive revaluation of stock-based compensation from our operating expense calculations; excluding this €1.09m revaluation, the 2018 operating loss would have been €7.9m.

gross debt on 31 December 2018 (€2.4m in conditional advances and €5.5m in long-term debt), we calculate €7.8m in net cash.

We expect EU pivotal study patient recruitment and implantations to increase significantly in 2020, and that implantations will then also begin for the US pilot study, resulting in a yearly increase in R&D costs in 2020. We continue to forecast 2019 and 2020 operating cash burn rates (excluding net interest) of €9.7m and €16.9m, respectively.

We expect that Pixium will seek to raise funds, likely in mid-2019 or H219, in order to expand its financial runway to fund the EU pivotal study. Our model continues to estimate that Pixium will raise €20m in 2019, €30m in 2020 and €25m in 2021. As per usual Edison policy, our model assumes these sources will be in debt. We forecast that all this funding should enable Pixium to complete the registration-enabling Prima clinical studies in the EU to reach commercialisation in Europe. In addition, positive cash flows resulting from EU sales should enable the completion of the US pivotal study. We continue to assume that Pixium will only start to become cash flow positive on a sustainable basis once Prima is launched (in H222).

Valuation

We continue to value Pixium using an rNPV approach, employing a 12.5% cost of capital. Our valuation is based solely on the Prima opportunity in Dry-ARMD. We continue to apply a probability of success estimate for Prima-ARMD in our model of 15% and we assume a forex rate, for US sales, of $1.12/€ (from $1.13/€ previously).

We have also mildly revised our Prima revenue assumptions (such as market size and EU pricing), as discussed above. Hence, we now obtain a pipeline rNPV (enterprise value) of €91.7m, up from €91.2m previously. After including €7.8m in net cash at 31 December 2018, we obtain an equity valuation of c €99.5m, or €4.49 per share (compared to €4.50 previously).

Exhibit 8: Pixium Vision rNPV assumptions

Product contributions	Indication	Status	rNPV (€m)	rNPV/ share (€)	Probability of success	Launch year	Peak WW sales (€m)
Prima (net of R&D and marketing costs)	Age-related Macular degeneration with geographic atrophy	Human feasibility trials	175.2	7.91	15.00%	H222 (EU) and 2024 in US	1,082 in 2028
G&A expenses			(20.1)	(0.91)			
Net capex, NWC & taxes			(63.4)	(2.86)			
Total rNPV			91.7	4.14			
Net cash (debt) (Q418)			7.8	0.35			
Total equity value			**99.5**	**4.49**			
FD shares outstanding (000) (Q119)			22,156				

Source: Edison Investment Research

Sensitivities

Development and regulatory risk. Much development risk remains with Prima as it has only recently begun to be tested on humans and longevity has not been proven. While there is favourable EU six-month feasibility study data, it is currently unknown whether Prima can consistently provide superior central vision to epi-retinal implants and/or do so without additional safety risk. In addition, Prima is being advanced in patients with intact peripheral vision and it is uncertain how well the visual system in Prima-implanted patients will interpret natural intact peripheral vision with artificial central vision. Further, degradation of the inner retinal cells over time can reduce the VA offered by a retinal implant.

Commercial and competition risk. The visual improvements offered by Prima must be sufficient to persuade patients and insurers to cover the implant and be competitive vs alternative treatment options. Particular risk lies in the need for patients to properly undergo vision rehabilitation training to make full use of the Prima; if patients do not fully engage in this process, the level of vision improvement possible could be restrained, affecting the commercial value proposition and adoption level for the device. Offsetting this risk somewhat is that the EU feasibility study showed the device can enable recognition of shapes and symbols in patients who previously had no light perception in the treated eye; such functional benefit may support discussions for obtaining reimbursement coverage upon approval.

Financing risk. Pixium's year-end 2018 gross cash of €15.6m should support its runway into Q220. We assume Pixium will raise an additional €75m through year-end 2021 to sustain its operations and maintain its Prima commercial development strategy, as we do not expect Pixium to be cash flow positive until it launches Prima in H222 in Europe. While our model accounts for these financings as long-term debt, the firm may need to issue equity instead and there is a risk that pricing may not be favourable for current shareholders and leads to significant dilution.

Exhibit 9: Financial summary

€000s	2016	2017	2018	2019e	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	2,516	2,535	1,598	1,600	0	0
Cost of Sales	(141)	(1,124)	(41)	0	0	0
General & Administrative	(2,953)	(5,324)	(1,508)	(2,800)	(2,900)	(2,973)
Research & Development	(10,869)	(7,817)	(6,184)	(7,500)	(14,000)	(17,000)
EBITDA	(11,448)	(11,731)	(6,135)	(8,700)	(16,900)	(19,973)
Depreciation	(1,051)	(936)	(677)	(600)	(397)	(803)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(12,499)	(12,666)	(6,812)	(9,300)	(17,297)	(20,776)
Exceptionals	0	0	(5,483)	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(12,499)	(12,666)	(12,294)	(9,300)	(17,297)	(20,776)
Net Interest	58	(876)	(1,277)	(1,287)	(4,424)	(7,562)
Profit Before Tax (norm)	(12,441)	(13,542)	(8,088)	(10,587)	(21,721)	(28,338)
Profit Before Tax (FRS 3)	(12,441)	(13,542)	(13,571)	(10,587)	(21,721)	(28,338)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(12,441)	(13,542)	(8,088)	(10,587)	(21,721)	(28,338)
Profit After Tax and minority interests (FRS 3)	(12,441)	(13,542)	(13,571)	(10,587)	(21,721)	(28,338)
Average Number of Shares Outstanding (m)	12.7	13.3	18.5	22.2	22.2	22.2
EPS - normalised (€)	(0.98)	(1.02)	(0.44)	(0.48)	(0.98)	(1.28)
EPS - normalised and fully diluted (€)	(0.98)	(1.02)	(0.44)	(0.48)	(0.98)	(1.28)
EPS - (IFRS) (€)	(0.98)	(1.02)	(0.73)	(0.48)	(0.98)	(1.28)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	10,184	9,649	3,666	3,866	5,869	7,066
Intangible Assets	8,205	7,680	2,623	2,623	2,623	2,623
Tangible Assets	1,979	1,970	1,042	1,242	3,246	4,442
Current Assets	17,405	14,241	17,756	25,984	32,260	27,725
Short-term investments	0	0	0	0	0	0
Cash	14,244	10,532	15,629	23,858	30,134	25,599
Other	3,161	3,710	2,126	2,126	2,126	2,126
Current Liabilities	(2,836)	(2,752)	(2,044)	(1,060)	(1,060)	(1,060)
Creditors	(2,836)	(2,752)	(2,044)	(1,060)	(1,060)	(1,060)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(1,505)	(9,302)	(8,023)	(28,023)	(58,023)	(83,023)
Long term borrowings	(1,333)	(9,130)	(7,870)	(27,870)	(57,870)	(82,870)
Other long term liabilities	(172)	(172)	(153)	(153)	(153)	(153)
Net Assets	23,248	11,836	11,355	767	(20,954)	(49,292)
CASH FLOW						
Operating Cash Flow	(11,188)	(10,605)	(6,174)	(9,684)	(16,900)	(19,973)
Net Interest	58	(876)	(1,277)	(1,287)	(4,424)	(7,562)
Tax	0	0	0	0	0	0
Capex	(148)	(191)	(31)	(800)	(2,400)	(2,000)
Acquisitions/disposals	0	0	0	0	0	0
Financing	(0)	519	14,068	0	0	0
Net Cash Flow	(11,279)	(11,153)	6,587	(11,771)	(23,724)	(29,535)
Opening net debt/(cash)	(24,190)	(12,911)	(1,401)	(7,760)	4,011	27,736
HP finance leases initiated	0	0	0	0	0	0
Other	(0)	(357)	(228)	0	0	(0)
Closing net debt/(cash)	(12,911)	(1,401)	(7,760)	4,011	27,736	57,271

Source: Pixium Vision accounts, Edison Investment Research

Contact details	Revenue by geography
74 rue du Faubourg Saint-Antoin 75012 Paris, France +33 1 76 21 47 30 www.pixium-vision.com	N/A

Management team

Chairman: Bernard Gilly	Chief executive officer: Khalid Ishaque
Bernard Gilly has over 20 years' experience in the financial and pharmaceutical sectors and as an entrepreneur. He was VP of R&D for five years at Pasteur Mérieux Connaught (now Sanofi Pasteur). He subsequently served as CEO of Transgene from 1992 to 2000. He later joined Sofinnova Partners in Paris (2000–05). In 2005, he founded and became the CEO of Fovea Pharmaceuticals. After Fovea was acquired by Sanofi in 2009, he became executive VP of the Ophthalmology division of Sanofi. He founded Pixium Vision in 2011.	Khalid Ishaque has over 20 years' experience in the medical technology sector. He joined Pixium Vision in 2014, having spent 17 years with Boston Scientific in various commercial and business development roles, and most recently as general manager of the International Neuromodulation division commercialising Spinal Cord and Deep Brain Stimulation systems for chronic pain and movement disorders. Before joining Boston Scientific in 1997, he worked for Becton Dickinson. He received a master's degree in engineering from Cranfield Institute of Technology in the UK and his master's in international economics and management from SDA Bocconi University in Italy.
Chief financial officer: Didier Laurens	**Chief technology officer: Guillaume Buc**
Prior to joining Pixium Vision, Didier served as director of IR, financing and treasury at Korian, where he also served as interim CFO. Previously, he was a financial analyst with Société Générale, covering various sectors including healthcare, where he was involved with numerous IPOs. He also served as marketing manager in the pharmaceutical industry. Didier holds a post-graduate degree in pharmacy and is a graduate of SFAF/CIIA.	Guillaume Buc has over 25 years' experience in technology development. Before joining Pixium Vision, Mr Buc held several management positions at GE Healthcare Europe. His latest role was CTO of the GE Healthcare interventional cardiology department. He received an engineering degree from the French Polytechnic Institute, in applied mathematics, and a degree from the Ecole Nationale Supérieure des Télécommunications / National Telecommunications School in Paris, in image processing and computer sciences.

Principal shareholders	(%)
Bpifrance Investissement	16.0
Sofinnovia Venture	13.4
Abingworth	9.4
FCPR InnoBio	7.2
Groupe BPI	4.7

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia