EDISON

Pixium Vision

Mid-year update

Key Iris II and Prima catalysts for H217

Healthcare equipment & services

Pixium is building up a sales channel across Europe for its Iris II device, and is working on securing reimbursement and generating initial product sales in H217. It is also planning to start first-in-human trials for the next-generation Prima implant in H217. Using a risk-adjusted NPV model, we obtain a pipeline rNPV of €129.3m, compared to €131.4m, previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	3.3	(15.6)	(1.23)	0.0	N/A	N/A
12/16	2.5	(12.4)	(0.98)	0.0	N/A	N/A
12/17e	3.8	(12.6)	(0.95)	0.0	N/A	N/A
12/18e	14.9	(17.9)	(1.33)	0.0	N/A	N/A

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

Interim Iris II data can support French reimbursement

Pixium plans to provide interim six-month data from its 10-patient European Iris II study in Q317, which it believes will support its application for provisional Iris II reimbursement in France under the Forfait Innovation (FI) programme. A positive decision could potentially support up to 40 funded implantations at French hospitals and the associated rehabilitation training.

Prima slated to start human studies in H217

After completing preclinical work, Pixium engaged with both French (ANSM) and US (FDA) regulatory authorities to start Prima human feasibility studies. The ANSM requested more safety and other data, which Pixium has provided, and it now expects to start the European feasibility trial in H217 (from H117, previously). This pushes back our potential EU launch estimate to H220 (from H120, previously). Progress has also been made with the FDA on a US early feasibility study programme.

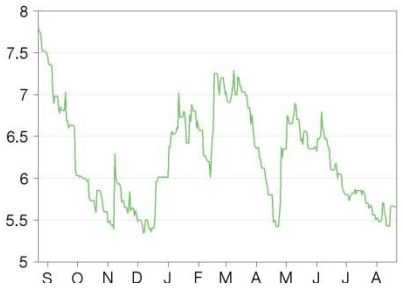
Valuation: rNPV of €129.3m

We value Pixium using a risk-adjusted net present value (rNPV) approach, using a 12.5% cost of capital and applying a 70% probability of success for Iris II and a 12.5% success probability for Prima. The effects on our valuation of pushing back our estimates for the timing of the EU Prima launch are offset by rolling forward our forecasts. After applying a $1.18/€ exchange rate forecast (vs $1.07/€ previously), we now obtain a pipeline rNPV (enterprise value) of €129.3m, down from €131.4m, previously. After including €5.4m in net cash at H117 (€14.9m gross cash minus €1.4m in conditional advances and €8.1m in long-term debt), we obtain an equity valuation of €134.7m, or €10.08 per share (down from €11.31, previously). While we believe Pixium's cash on hand is sufficient for it to maintain operations into H118, we expect it will draw the last remaining €3m tranche from its €11m Kreos financing facility in H217 to strengthen its runway. For the same reason, we also continue to assume that it will raise an additional €10m in H217. Beyond this, we continue to expect the company to raise €15m in 2018 and €30m in 2019. For illustrative purposes only, we have added our forecast funding requirements to long-term debt.

22 August 2017

Price	**€5.66**
Market cap	**€76m**
	€/US$1.18
Net cash (€m) at H117	5.4
Shares in issue	13.4m
Free float	18%
Code	PIX
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(0.7)	(13.7)	(27.6)
Rel (local)	(0.1)	(10.3)	(37.8)
52-week high/low		€7.82	€5.34

Business description

Pixium Vision is a French medical device company developing retinal implants for patients with retinitis pigmentosa and macular degeneration. CE Mark clearance was received in 2016 on its initial product, Iris II. A sub-retinal implant, Prima, is also being developed simultaneously.

Next events

Start Prima human feasibility study	H217
Decision from French agency on conditional Iris II reimbursement	H217

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Edison profile page

Awaiting Iris II sales and Prima human studies in H217

Pixium is continuing to build the commercial case for the Iris II bionic vision system (BVS) device, intended primarily for severely blind patients with retinitis pigmentosa (RP). Iris II received CE Mark approval in 2016 and commercialisation efforts in Europe and the Middle East are underway. Pixium is building up a sales channel across Europe, and is working on securing insurance reimbursement and generating initial product sales. Given the expected high cost of the implant (we model average net revenue of €78,000 per implant for Europe), we believe that payer/insurer coverage will be the primary channel for Iris II purchases.

Exhibit 1: Pixium Vision product pipeline

Product	Indication	Development status	Product highlights
Iris II epi-retinal implant	End-stage retinitis pigmentosa	CE Mark received in July 2016	Provides crude visual recovery, with patients capable of detecting lights and shapes. Implant is designed to be explantable and potentially upgradeable.
Prima sub-retinal implant	End-stage age-related macular degeneration (ARMD) and RP	Human feasibility study expected to start in H217	May potentially offer superior visual acuity than Iris II and surgical implantation procedure expected to be quicker since implant is wireless and miniaturized. ARMD market is much larger than RP.

Source: Company documents

Interim Iris II data can drive Forfait Innovation (FI) decision

Pixium plans to provide interim six-month data from its 10-patient, European Iris II study in Q317, which it believes will also support its application for provisional Iris II reimbursement in France under the FI programme. The final patient in the 10-patient European Iris II study was implanted in early 2017. The 10 treated patients will receive post-operative visual rehabilitation training and will be assessed at predefined intervals (at up to 18 months post-implantation), and compared to pre-treatment levels on functional areas including visual acuity, standardised picture recognition and image localisation.

Pixium had first applied under the FI programme in France to cover up to 40 implantations over a five-year period at up to 10 French hospitals. Pixium anticipated that such coverage would be contingent on the monitoring of approximately half of these patients over a two-year period, to build robust data supporting the efficacy of the implant, and which could be used to obtain more permanent reimbursement coverage. Pixium announced in May 2017 that while the French Haute Autorité de Santé (HAS) agreed that the Iris II meets the FI eligibility criteria of providing a sufficiently novel treatment for a significantly unmet medical need, it had requested additional clinical data before agreeing to provide reimbursement under the FI programme at that time. Pixium believes the interim Iris II study data will fulfil this requirement. Hence we believe a decision from HAS on potential Iris II reimbursement could occur in Q417. Pixium's FI request is similar to a funding structure in place for Second Sight's Argus II, where up to 36 patients are being covered by this programme. We model that the initial FI-reimbursed Iris II implantations will occur in 2018.

Iris II sales in Germany expected in H217

We continue to expect that initial Iris II sales in Germany will occur in H217. In February 2017, Pixium received a positive decision from the German Institute for the Hospital Remuneration System (InEK), whereby it was granted NUB (Neue Untersuchungs- und Behandlungsmethoden) Status-1 (full approval) for Iris II as an epi-retinal device. The NUB Status-1 decision allows for selected hospitals in Germany (five hospitals were covered under Pixium's application) to negotiate with insurance providers to obtain maximum coverage for Iris II implantations (including both the implant cost and for the medical procedures and rehabilitation). Pixium continues to engage with

the five participating hospitals and with applicable insurers, and anticipates that initial sales will occur in H217.

Prima slated to start human studies in H217

Pixium's next-generation BVS platform, Prima, targets a broader potential market, namely dry age-related macular degeneration. Prima is a miniaturized, photovoltaic, totally wireless sub-retinal implant that could potentially offer better visual resolution than Iris II, while also requiring a less complex surgical procedure for instillation. Instead of stimulating retinal ganglion cells (more downstream in the visual signal processing) as Iris II does, Prima aims to stimulate bipolar cells (more mid-stream in physiological visual signal processing), resulting in lower energy needs (eliminating the need for permanent trans-scleral wires, as needed by Iris II).

Pixium completed preclinical studies for Prima development, including thermal and electrical safety studies, and submitted a feasibility study protocol to regulatory agencies in the US and Europe. It initially submitted a proposed study protocol in H216 for a five-patient feasibility study in ARMD patients with the French regulatory authorities (ANSM), and had previously planned to start a human study in H117. However, the agencies requested more safety and other data, and Pixium has submitted the required information for feasibility study registration. It now expects to start the first EU implantation before year-end 2017.

In the US market, Pixium has been having constructive discussions with the US FDA for the appropriate clinical trial pathway. Following FDA guidance, Pixium has submitted a proposal under the FDA's Early Feasibility Study (EFS) programme to start an EFS for Prima in dry ARMD. EFSs are small-size (n<15), proof-of-concept trials on devices in novel indications and/or for which there are significant unknowns on performance. EFS data are required by the FDA before allowing the start of a traditional US feasibility (pilot) study, which is carried on a larger number of subjects and often precedes a pivotal US study. Having received constructive FDA guidance thus far, Pixium is pursuing parallel pathways for the feasibility study programme for dry ARMD in the EU, and also under the US EFS programme, to potentially accelerate the overall pathway in the US. Beyond this, we believe the FDA would require a pilot study of about 30 patients and a pivotal study thereafter.

Exhibit 2: Projected Prima clinical development pathways for EU and US

EU clinical pathway	US clinical pathway
Clinical studies needed	
1. Small-size (~5-pt) feasibility study	1. Medium-size (~30-pt) pilot study
2. Medium-size (~30-pt) pivotal trial	2. Larger (~60-80pt) pivotal trial
Projected characteristics and requirements for pivotal trial	
Start in H218	Start in H218
6-12 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	
H220	2022

Source: Edison Investment Research estimates

In an ideal scenario, Pixium could combine data from sites participating in the EU pivotal trial into a US premarket approval (PMA) registration file. Our model assumes this will be the case, and that Pixium will start recruiting US sites as part of a US pivotal study starting in H218. We expect that CE Mark clearance (and EU launch) would still occur 18-24 months earlier than US PMA approval and launch. We continue to model US approval and launch in 2022.

Exhibit 3: Pixium Vision upcoming catalysts	
Event	**Timing**
Start human feasibility studies for Prima implant (Europe)	H217*
Initial Iris II sales in Europe (such as in Germany)	H217**
Start recruitment in EU for Prima pivotal study	H218**
Start US recruitment for Prima pivotal study	H218**
CE Mark approval and EU launch for Prima	H220**
PMA Approval and US launch for Prima	2022**

Source: *Company guidance. **Edison Investment Research estimates.

H117 financial results largely within expectations

Pixium Vision reported H117 results on 27 July 2017, with R&D costs of €4.0m, an EBITDA loss of €5.6m and a net loss of €6.4m. These results compared to our H117 estimates for €4.0m in R&D costs, a €4.2m EBITDA loss and a €4.7m net loss. Pixium also reported €1.3m of subsidy, tax credit and other revenues, compared to our forecast of €1.5m of subsidy, tax credit and related revenue. While the reported net and EBITDA losses were higher than expected, Pixium's H117 cash burn rate (operating cash flows minus net interest costs and net capex) was €7.2m, in line with our forecast for a €7.2m cash burn rate, as capex costs were lower than projected.

In H117, Pixium exercised €8m (two tranches of €4m each) of the €11m debt facility it entered into in September 2016 with Kreos Capital. The bonds are secured by Pixium's tangible and intangible assets and bear an annual 11.5% interest rate. Each tranche is to be repaid in 33 monthly payments.

Pixium finished H117 with €14.9m in gross cash, which we believe will be sufficient for it to maintain operations into H118.

Valuation

With the commencement of the Prima first-in-human feasibility study (in the EU) having been pushed back to H217 (from previous guidance and our prior forecast of H117), we have pushed back our key EU Prima development and launch milestone estimates by about six months. While we previously forecast completion of the feasibility study by year-end 2017 and the potential start of a pivotal EU Prima study for ARMD in H118, we now expect the EU Prima pivotal study to start in H218. We also now expect CE Mark approval and EU launch in H220 (vs H120, previously). Our timelines for the start of a US pivotal study and a potential US launch (H218, and 2022, respectively) are unchanged.

As the FI programme is not likely to be in place until Q417, we have also lowered our 2017 Iris II sales forecasts. Whereas we previously expected €1.9m in initial Iris II sales in 2017, we now expect €1.0m in product sales revenue (all projected for H217). Our Iris II projections for 2018 and future years are largely unchanged. While our model assumes average net revenue of €78,000 per implant for Europe, Pixium anticipates that initial invoicing for the implants could be at a higher price range (up to €100,000 per implant). However, until the initial sales occur and until better visibility is obtained on specific reimbursement or pricing levels in certain European markets (such as in France, Germany and the UK), we are maintaining our existing pricing forecasts.

Exhibit 4: Pixium Vision rNPV assumptions

Product contributions (net of R&D and marketing costs)	Indication	Status	rNPV (€m)	rNPV/ share (€)	Probability of success	Launch year
Iris II	Retinitis pigmentosa	CE mark approval	75.9	5.68	70.0%	2017
Prima	Retinitis pigmentosa	Preclinical	33.5	2.51	12.5%	H220 (EU) and 2022 (US)
Prima	Age-related macular degeneration	Preclinical	134.1	10.03	12.5%	H220 (EU) and 2022 (US)
Corporate costs & expenses						
G&A expenses			(28.4)	(2.12)		
Net capex, NWC & taxes			(85.7)	(6.42)		
Total rNPV			129.3	9.68		
Net cash (debt) (H117)			5.4	0.41		
Total equity value			134.7	10.08		
FD shares outstanding (000) (H117)			13,365			

Source: Edison Investment Research

We value Pixium using a risk-adjusted net present value (rNPV) approach, using a 12.5% cost of capital and applying a 70% probability of success for Iris II (given market acceptance and reimbursement risks) and a 12.5% success probability for Prima. The effects of pushing back our estimates for the timing of the EU Prima launch are offset by rolling forward our forecasts. Given the above change and after applying a $1.18/€ exchange rate forecast (vs $1.07/€ previously), we now obtain a pipeline rNPV (enterprise value) of €129.3m, down from €131.4m, previously. After including €5.4m in net cash at H117 (€14.9m gross cash minus €1.4m in conditional advances and €8.1m in long-term debt), we obtain an equity valuation of €134.7m, or €10.08 per share (compared to €11.31, previously). Pixium also issued 0.615m new shares in H117, increasing its shares outstanding to 13.36m.

Financials

We now assume a 2017 and 2018 operating cash burn rate (excluding net interest) of €13.4m and €15.1m, respectively, compared to our previous estimates of €11.7m and €14.8m, respectively. While we believe Pixium has enough gross cash to maintain operations into H118, we expect it will draw the last remaining €3m tranche from the €11m Kreos financing facility in H217 to strengthen its runway. For the same reason, we also continue to assume that Pixium will raise an additional €10m in H217. Beyond this, we continue to expect Pixium will raise €15m in 2018 and €30m in 2019. Much of the funding should go towards Prima clinical studies and Iris II commercialisation. For illustrative purposes only, we have added our forecast funding requirements to long-term debt. Our financial and valuation models do not include the potential dilutive impacts of future equity offerings.

Exhibit 5: Financial summary

€000s	2015	2016	2017e	2018e	2019e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	3,296	2,516	3,765	14,920	31,330
Cost of Sales	0	(141)	(1,319)	(6,488)	(12,072)
General & Administrative	(2,680)	(2,953)	(4,213)	(7,078)	(15,168)
Research & Development	(15,169)	(10,869)	(8,991)	(15,000)	(16,000)
EBITDA	(14,552)	(11,448)	(10,757)	(13,647)	(11,910)
Depreciation	(1,144)	(1,051)	(1,006)	(1,133)	(2,712)
Amortization	0	0	0	0	0
Operating Profit (before exceptionals)	(15,697)	(12,499)	(11,764)	(14,780)	(14,621)
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(15,697)	(12,499)	(11,764)	(14,780)	(14,621)
Net Interest	52	58	(813)	(3,111)	(5,699)
Profit Before Tax (norm)	(15,644)	(12,441)	(12,577)	(17,891)	(20,320)
Profit Before Tax (FRS 3)	(15,644)	(12,441)	(12,577)	(17,891)	(20,320)
Tax	0	0	0	0	0
Profit After Tax and minority interests (norm)	(15,644)	(12,441)	(12,577)	(17,891)	(20,320)
Profit After Tax and minority interests (FRS 3)	(15,644)	(12,441)	(12,577)	(17,891)	(20,320)
Average Number of Shares Outstanding (m)	12.7	12.7	13.2	13.5	13.6
EPS - normalised (€)	(1.23)	(0.98)	(0.95)	(1.33)	(1.49)
EPS - normalised and fully diluted (€)	(1.23)	(0.98)	(0.95)	(1.33)	(1.49)
EPS - (IFRS) (€)	(1.23)	(0.98)	(0.95)	(1.33)	(1.49)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	11,087	10,184	9,563	12,430	16,718
Intangible Assets	8,822	8,205	7,942	7,942	7,942
Tangible Assets	2,265	1,979	1,621	4,488	8,776
Current Assets	27,682	17,405	25,548	21,002	27,482
Short-term investments	0	0	0	0	0
Cash	24,354	14,244	20,734	13,520	18,123
Other	3,328	3,161	4,814	7,481	9,359
Current Liabilities	(3,498)	(2,836)	(1,005)	(1,407)	(1,671)
Creditors	(3,498)	(2,836)	(1,005)	(1,407)	(1,671)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(315)	(1,505)	(22,678)	(37,678)	(67,678)
Long term borrowings	(164)	(1,333)	(22,490)	(37,490)	(67,490)
Other long term liabilities	(151)	(172)	(187)	(187)	(187)
Net Assets	34,956	23,248	11,429	(5,653)	(25,148)
CASH FLOW					
Operating Cash Flow	(15,584)	(11,188)	(13,431)	(15,102)	(12,699)
Net Interest	52	58	(813)	(3,111)	(5,699)
Tax	0	0	0	0	0
Capex	(2,106)	(148)	(176)	(4,000)	(7,000)
Acquisitions/disposals	0	0	0	0	0
Financing	56	(0)	(38)	0	0
Net Cash Flow	(17,582)	(11,279)	(14,458)	(22,214)	(25,398)
Opening net debt/(cash)	(41,965)	(24,190)	(12,911)	1,756	23,970
HP finance leases initiated	0	0	0	0	0
Other	(193)	(0)	(209)	0	0
Closing net debt/(cash)	(24,190)	(12,911)	1,756	23,970	49,367

Source: Edison Investment Research, Pixium Vision accounts. Note: 2015 and 2016 revenues include tax credits and subsidies, which are forecast at approximately $3m per year through 2018.

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