EDISON

Pixium Vision

Prima to start EU study

Pixium cleared to start EU Prima feasibility study

Healthcare equipment & services

Pixium has received clearance from the French regulatory agency (Agence Nationale de Sécurité du Médicament et des Produits de Santé, or ANSM) to start a feasibility study of its Prima sub-retinal bionic vision system (BVS) on up to five patients with advanced Dry-ARMD. It plans to complete the first implantation before YE17, and obtain six-month study data in H218. If results are positive, Pixium expects to start an EU pivotal study in H119. We have reinstated our Prima probability of success estimate in our model to 12.5% (from 10%), leading to an increase in our pipeline rNPV to €82.6m (from €63.0m, 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	2.8	(13.3)	(1.01)	0.0	N/A	N/A
12/18e	3.0	(18.8)	(1.39)	0.0	N/A	N/A

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

Feasibility trial on patients with severe Dry-ARMD

The study will take place at Fondation Ophtalmologique Rothschild and Hôpital des Quinze-Vingt in Paris, and recruit up to five patients with advanced dry age-related macular degeneration (Dry-ARMD). Eligible patients will be required to have the most severe form of the disease, including a visual acuity (VA) of 20/400 or worse, with no light perception in the foveal (central portion of the retina) region, and an area of central retinal atrophy of at least 3-disc-diameters (approximately 5mm in length). If six-month results (expected H218) are positive, Pixium plans to start an EU pivotal study in early 2019. Pixium is currently also in discussions with the FDA and aims to obtain approval by YE17 to start a US feasibility study.

Dry-ARMD represents large opportunity for Prima

The prevalence of ARMD in adults above age 45 is estimated at 8.0%, and late stage Dry-ARMD (with best-corrected vision acuity of 20/200, or 10% or worse) affects about 0.4% of this age group. This represents about 815,000 people in Europe and 517,000 in the US. We continue to anticipate peak sales in Dry-ARMD of €722m in 2025.

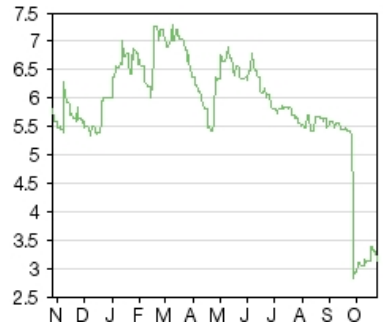
Valuation: Risked-rNPV up to €73.4m

Our forecasts are unchanged but with the EU feasibility study now cleared, we reinstated our Prima probability of success estimate in our model to 12.5% (from 10%). We had previously lowered this probability to 10%, following the suspension of Iris II (due to its unexpectedly short lifespan). We now obtain a pipeline rNPV (enterprise value) of €82.6m, up from €63.0m, 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 €88.0m, or €6.58 per share (compared to €5.12, previously). We estimate that Pixium will raise €25m before YE18, €30m in 2019, and €40m in 2020. We have added these forecast funding requirements to long-term debt.

24 October 2017

Price	**€3.14**
Market cap	**€42m**
	US$1.18/€
Net cash (€m) at 30 June 2017	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	(41.6)	(44.9)	(46.3)
Rel (local)	(42.7)	(47.5)	(55.1)
52-week high/low		€7.3	€2.8

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	Q417
Start Prima EU pivotal study	H119

Analysts

Pooya Hemami, CFA +1 646 653 7026

Maxim Jacobs, CFA +1 646 653 7027

healthcare@edisongroup.com

Edison profile page

Prima receives clearance to start EU feasibility study

Pixium announced on 19 October 2017 that it has received authorisation from the French regulatory agency, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), to start a feasibility clinical study of its next-generation Prima wireless sub-retinal bionic vision system (BVS). The study will recruit up to five patients with advanced dry age-related macular degeneration (Dry-ARMD). To be eligible for the trial, patients will be required to have the most advanced forms of Dry-ARMD, thus requiring a visual acuity (VA) of 20/400 (5%) or worse, as well as no light perception in the foveal (central portion of the retina) region, and an area of central retinal atrophy of at least 3-disc-diameters (approximately 5mm in length).

Interim six-month data anticipated in H218

The Prima device is a micro photovoltaic chip of 2 millimetres in size, and equipped with 378 electrodes. The implant converts pulsed near infra-red invisible light signal received from the external glasses with an integrated mini-camera into electrical signals transmitted to the brain via the optic nerve. Compared to Pixium's Iris II epi-retinal BVS, Prima will be implanted under the retina (as opposed to on the surface of the retina) using a less invasive surgical procedure, which should be quicker and easier for surgeons to perform (the procedure is expected to be completed in under 90 minutes).

The current study will be conducted at Fondation Ophtalmologique Rothschild and Hôpital des Quinze-Vingt in Paris with vitreoretinal surgeon Dr Yannick Le Mer acting as the principal investigator performing the implantations. Patients will be evaluated for safety and efficacy measures (including ability to elicit light-perception and VA) for 36 months, but interim data will be available at 6, 12, 18 and 24 months as well. Pixium anticipates completing the first implantation before YE17 and potentially complete recruitment by mid-2018. If six-month data (anticipated H218) is positive (showing some signs of visual perception or improved VA), Pixium plans to start an EU pivotal trial in early 2019 (consistent with our existing forecasts). With the EU clinical strategy now underway, the firm reiterates that it is pursuing discussions in parallel with the FDA to obtain approval to start a US feasibility study. Pixium believes it could receive US Investigational Device Exemption (IDE) approval by YE17, and a US study could potentially begin in Q118.

Potentially better vision than Iris II

Prima could potentially provide better visual resolution than Iris II, as instead of directly stimulating retinal ganglion cells (RGCs, located 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). 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 RGCs (which are on the inner portion of the retina). Because Prima functions more upstream, it allows for more physiological or natural image signal processing. Directly stimulating bipolar cells (as opposed to RGCs) involves lower electrical stimulation thresholds (to elicit a perceptual response), since the functioning inner retinal cells amplify the raw electrical signals before sending them to the optic nerve. The reduced energy requirement allows Prima to operate through a wireless approach, through micro photodiodes, thus eliminating the need for permanent trans-scleral wires (as needed by Iris II). Given its wireless mode of operation and lack of need for trans-scleral wiring, we do not expect the durability issues that have affected Iris II are likely to occur with Prima.

In addition, Prima uses a higher electrode count than Iris II (378 versus 150), which also supports the potential attainment of higher VA. Animal studies suggest Prima could reach up to 20/250 in

humans (reflecting 8% of the resolution seen by healthy individuals). If replicated in humans, this could be sufficient to provide meaningful improvements and justify implantations in patients in late stages of the Dry-ARMD, such as those with geographic retinal atrophy reducing best-corrected VA in both eyes to below 20/200. This leads to much wider potential clinical use than the retinitis pigmentosa (RP) or retinal dystrophy markets targeted for Iris II. The prevalence of ARMD in adults above age 45 is estimated at 8.0%, and late-stage ARMD (with best-corrected vision acuity of 20/200, or 10% or worse) affects about 0.4% of this age group.[1] This represents about 815,000 people in Europe and 517,000 in the US.

Valuation and financials

The attainment of regulatory clearance to start the Prima study is a de-risking step. Pixium had originally guided in H216 that it had expected this milestone to occur by YE16, but French regulators then requested additional data, causing some uncertainty to the timing of this event. With clearance now secured, Pixium can concentrate on starting first-in human implantations. Our Prima development and commercialisation timelines (potential EU launch in 2021) and sales forecasts are unchanged (please refer to our 5 October 2017 update note for further details). With the EU feasibility study about to start, we have raised our Prima probability of success estimate in our model from 10% to 12.5%.

Exhibit 1: Pixium Vision rNPV assumptions

Product contributions (net of R&D and marketing costs)	Indication	Status	rNPV (€m)	rNPV/share (€)	Probability of success	Launch year	Peak WW sales (€m)
Iris-II	Retinitis pigmentosa	CE mark but sales suspended	17.3	1.30	40.0%	Relaunch in 2019	48 in 2022
Prima	Retinitis pigmentosa	Preclinical	31.0	2.32	12.5%	2021 (EU) and H222 (US)	185 in 2025
Prima	Age-related macular degeneration	Preclinical	125.5	9.39	12.5%	2021 (EU) and H222 (US)	722 in 2025
Corporate costs & expenses							
G&A expenses			(28.4)	(2.12)			
Net capex, NWC & taxes			(62.9)	(4.70)			
Total rNPV			82.6	6.18			
Net cash (debt) (H117)			5.4	0.41			
Total equity value			**88.0**	**6.58**			
FD shares outstanding (000) (H117)			13,365				

Source: Edison Investment Research

Given the above changes, we now obtain a pipeline rNPV (enterprise value) of €82.6m, up from €63.0m, 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 €88.0m, or €6.58 per share (compared to €5.12, previously).

Financials

We continue to assume 2017 and 2018 operating cash burn rates (excluding net interest) of €13.4m and €13.6m, 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 and augment financial flexibility. For the same reason, we also continue to assume that Pixium will raise an additional €10m in H217 and €15m in 2018. Our model assumes that, strictly speaking, Pixium would only require €10m in funding to maintain a positive cash balance at YE18, but to maintain operational flexibility and avoid the need

[1] Wong WL, Su X, Li X et al. Lancet Glob Health. 2014 Feb;2(2):e106-16.

to pursue funding methods of last resort, we assume, as is the case for most of our coverage universe, that the firm will seek to always maintain at least six months of financial runway in terms of cash and equivalents on-hand. Hence, our model continues to assume the firm will raise €25m in total, through YE18, in funding beyond the Kreos financing facility.

For illustrative purposes only, we have added our forecast funding requirements to long-term debt. However, it is possible that Pixium may be required to raise equity instead of debt, to meet its funding needs. The company announced on 23 October 2017 that it entered into an equity line of credit with Kepler Chevreux, who has provided a firm commitment to purchase 2m common shares of Pixium (reflecting, at current pricing, c €6.2m in funding after discounts) within two years. The shares will be issued based on the lowest of the daily volume-weighted average price of the two trading days preceding each issuance, minus a discount of up to 7.5%. Pixium has the option to suspend or terminate this agreement at any time.

We continue to estimate that Pixium will raise €30m in 2019, and €40m in 2020. As above, we have added these forecast funding requirements to long-term debt. We forecast that this funding should enable the completion of registration-enabling Prima clinical studies in both the EU and the US, to meet our estimated launch timelines. This timing for these projected funding requirements can be delayed to a certain extent, should the firm plan to complete US Prima pivotal studies over a longer-time horizon than we currently anticipate (ie thus leading to a potential US launch in or after 2023). Our financial and valuation models do not include the potential dilutive effects of future equity offerings. We continue to assume that Pixium will only start to become cash flow positive on a sustainable basis once Prima is launched (in 2021).

Exhibit 2: Financial summary

€(000)	2015	2016	2017e	2018e	2019e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	3,296	2,516	2,755	3,000	3,496
Cost of Sales	0	(141)	(562)	0	(2,439)
General & Administrative	(2,680)	(2,953)	(4,213)	(3,578)	(8,168)
Research & Development	(15,169)	(10,869)	(9,491)	(14,000)	(18,000)
EBITDA	(14,552)	(11,448)	(11,510)	(14,578)	(25,110)
Depreciation	(1,144)	(1,051)	(1,006)	(1,133)	(2,712)
Amortisation	0	0	0	0	0
Operating Profit (before exceptionals)	(15,697)	(12,499)	(12,516)	(15,711)	(27,822)
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(15,697)	(12,499)	(12,516)	(15,711)	(27,822)
Net Interest	52	58	(813)	(3,099)	(5,720)
Profit Before Tax (norm)	(15,644)	(12,441)	(13,329)	(18,810)	(33,541)
Profit Before Tax (FRS 3)	(15,644)	(12,441)	(13,329)	(18,810)	(33,541)
Tax	0	0	0	0	0
Profit After Tax and minority interests (norm)	(15,644)	(12,441)	(13,329)	(18,810)	(33,541)
Profit After Tax and minority interests (FRS 3)	(15,644)	(12,441)	(13,329)	(18,810)	(33,541)
Average Number of Shares Outstanding (m)	12.7	12.7	13.2	13.6	13.8
EPS - normalised (€)	(1.23)	(0.98)	(1.01)	(1.39)	(2.42)
EPS - normalised and fully diluted (€)	(1.23)	(0.98)	(1.01)	(1.39)	(2.42)
EPS - (IFRS) (€)	(1.23)	(0.98)	(1.01)	(1.39)	(2.42)
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	24,671	18,803	11,992
Short-term investments	0	0	0	0	0
Cash	24,354	14,244	20,740	14,995	7,332
Other	3,328	3,161	3,931	3,808	4,659
Current Liabilities	(3,498)	(2,836)	(880)	(880)	(1,074)
Creditors	(3,498)	(2,836)	(880)	(880)	(1,074)
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	10,676	(7,325)	(40,041)
CASH FLOW					
Operating Cash Flow	(15,584)	(11,188)	(13,425)	(13,646)	(24,943)
Net Interest	52	58	(813)	(3,099)	(5,720)
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)	(14,452)	(20,745)	(37,662)
Opening net debt/(cash)	(41,965)	(24,190)	(12,911)	1,751	22,495
HP finance leases initiated	0	0	0	0	0
Other	(193)	(0)	(209)	0	0
Closing net debt/(cash)	(24,190)	(12,911)	1,751	22,495	60,158

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.

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
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia