

Pixium Vision

Iris II receives CE mark clearance

Pixium announced on 25 July that its Iris II epi-retinal implant has received CE mark clearance from European regulatory authorities. This pivotal step helps validate the device's safety and can enable the first stage of a commercial roll-out of this device in certain European markets. Our rNPV, inclusive of net cash, is €11.62 per share (vs €10.28 previously).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	2.4	(11.6)	(1.18)	0.0	N/A	N/A
12/15	3.3	(15.6)	(1.23)	0.0	N/A	N/A
12/16e	2.9	(14.2)	(1.11)	0.0	N/A	N/A
12/17e	5.5	(24.1)	(1.89)	0.0	N/A	N/A

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

Clinical trial and reimbursement activities underway

We expect Pixium to implement the first phase of an EU commercial roll-out and seek reimbursement in Germany, France, the UK, Spain and Austria. Emphasis will be placed on selected ophthalmic surgery centres of excellence, particularly those sites that have participated in earlier trials of the earlier-generation Iris I implant. We believe that Second Sight's Argus II implant is reimbursed at €96,000 in France (Pixium's home market). We believe this can bode well for Pixium, as the Iris II has significantly more electrodes than the Argus II (150 vs 60), which may improve the level of visual resolution perceived by the user.

Iris II study underway, discussions with FDA in H216

A multi-centre 10-patient European [study](#) of Iris II in visually blind patients with retinal disease started in January 2016 and will assess the effectiveness of the device for at least 18 months. Interim data from the trial should further assist reimbursement applications in EU territories. Pixium plans to discuss the US clinical development strategy for both Iris II and its next-generation Prima sub-retinal implant with the FDA in H216. We continue to model US Iris II commercialisation in 2018 and Prima launches in 2019 for the EU and in 2021 for the US.

Valuation: Raising rNPV to \$132m

Following CE mark clearance, we have raised our Iris II commercial probability of success estimate to 55% (from 40%, previously), with US regulatory risk and commercialisation risks (market acceptance, reimbursement) remaining as risk-adjustment factors. Our pipeline rNPV is €132.3m (vs €113.5m, previously). After including H116 net cash of €16.1m (€16.2m gross cash minus €0.2m in short-term advances), we obtain an equity valuation of €148.3m, or €11.62 per share (vs €10.28 previously). We model a 2016 operating cash burn rate of €15.1m, and continue to assume Pixium will raise €20m in financing in 2016 and €30m in both 2017 and 2018. For illustrative purposes only, we added these requirements to long-term debt, and our model does not include the potential dilutive impacts of future equity offerings.

Update – CE mark

Healthcare equipment & services

27 July 2016

Price €8.07

Market cap €103m

Net cash (€m) at 30 June 2016 16.1

Shares in issue 12.8m

Free float 26%

Code PIX

Primary exchange Euronext Paris

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 11.5 3.3 28.9

Rel (local) 4.4 6.3 47.2

52-week high/low €8.40 €4.48

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 recently received on its initial product, Iris. A sub-retinal implant, Prima, is also being developed simultaneously.

Next events

First in-human dosing for Prima H216

Discussions with FDA on Iris and Prima H216
US clinical trial requirements

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Pixium Vision is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

	€000s	2014	2015	2016e	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		2,427	3,296	2,866	5,525	25,875
Cost of Sales		0	0	0	(1,894)	(12,154)
General & Administrative		(2,299)	(2,680)	(3,893)	(6,495)	(9,600)
Research & Development		(10,963)	(15,169)	(12,301)	(20,000)	(22,000)
EBITDA		(10,835)	(14,552)	(13,328)	(22,864)	(17,878)
Depreciation		(813)	(1,144)	(1,086)	(1,265)	(1,430)
Amortization		0	0	0	0	0
Operating Profit (before exceptionals)		(11,648)	(15,697)	(14,414)	(24,129)	(19,308)
Exceptionals		0	0	0	0	0
Other		0	0	0	0	0
Operating Profit		(11,648)	(15,697)	(14,414)	(24,129)	(19,308)
Net Interest		37	52	240	16	(401)
Profit Before Tax (norm)		(11,611)	(15,644)	(14,174)	(24,113)	(19,710)
Profit Before Tax (FRS 3)		(11,611)	(15,644)	(14,174)	(24,113)	(19,710)
Tax		0	0	0	0	0
Profit After Tax and minority interests (norm)		(11,611)	(15,644)	(14,174)	(24,113)	(19,710)
Profit After Tax and minority interests (FRS 3)		(11,611)	(15,644)	(14,174)	(24,113)	(19,710)
Average Number of Shares Outstanding (m)		9.8	12.7	12.8	12.8	12.8
EPS - normalised (€)		(1.18)	(1.23)	(1.11)	(1.89)	(1.54)
EPS - normalised and fully diluted (€)		(1.18)	(1.23)	(1.11)	(1.89)	(1.54)
EPS - (IFRS) (€)		(1.18)	(1.23)	(1.11)	(1.89)	(1.54)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		9,932	11,087	11,106	12,341	14,911
Intangible Assets		9,259	8,822	8,494	8,494	8,494
Tangible Assets		673	2,265	2,613	3,848	6,417
Current Assets		44,866	27,682	33,279	37,735	47,298
Short-term investments		0	0	0	0	0
Cash		42,132	24,354	28,501	30,780	34,044
Other		2,735	3,328	4,778	6,955	13,254
Current Liabilities		(4,051)	(3,498)	(2,325)	(1,231)	(2,156)
Creditors		(4,051)	(3,498)	(2,325)	(1,231)	(2,156)
Short term borrowings		0	0	0	0	0
Long Term Liabilities		(245)	(315)	(20,337)	(50,337)	(80,337)
Long term borrowings		(167)	(164)	(20,165)	(50,165)	(80,165)
Other long term liabilities		(78)	(151)	(172)	(172)	(172)
Net Assets		50,503	34,956	21,723	(1,491)	(20,284)
CASH FLOW						
Operating Cash Flow		(8,426)	(15,584)	(15,060)	(25,236)	(22,335)
Net Interest		37	52	240	16	(401)
Tax		0	0	0	0	0
Capex		(1,772)	(2,106)	(1,097)	(2,500)	(4,000)
Acquisitions/disposals		0	0	0	0	0
Financing		42,705	56	63	0	0
Net Cash Flow		32,543	(17,582)	(15,854)	(27,720)	(26,737)
Opening net debt/(cash)		(9,420)	(41,965)	(24,190)	(8,335)	19,385
HP finance leases initiated		0	0	0	0	0
Other		1	(193)	0	0	(0)
Closing net debt/(cash)		(41,965)	(24,190)	(8,335)	19,385	46,122

Source: Edison Investment Research, Pixium Vision accounts. Note: 2014 and 2015 revenues include tax credits and subsidies, which are forecast at approximately \$3m per year through 2018.

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