EDISON

Pixium Vision

Clinical trial update

Pixium completes 10th implantation of Iris II study

Healthcare equipment & services

Pixium announced this week that it has completed the 10th and final implantation as part of its ongoing European Iris-II study. This trial began in January 2016 and will assess the Iris II epi-retinal implant in patients with retinitis pigmentosa (RP) and certain other retinal dystrophies. While the study will assess the device for at least 18 months, interim data could be available in mid-2017 and would support reimbursement applications in European countries such as the UK, France and Germany.

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	(15.3)	(1.20)	0.0	N/A	N/A

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

Following their Iris-II implantations, the 10 treated patients will receive visual rehabilitation/re-education training and will be assessed, compared to pre-treatment levels, on functional areas including visual acuity, standardised picture recognition and image localisation. Iris-II has a higher electrode count than Second Sight's Argus II (150 vs 60), which could potentially provide improved visual function. Pixium is seeking reimbursement in France and Germany and could potentially receive responses in H117. Interim data from the current study could support these applications as well as those for other European countries including the UK.

Pixium's next milestone, potentially occurring in Q117, would be clearance from European regulatory agencies to start a five-patient feasibility study for its next-generation Prima sub-retinal implant. Prima could potentially offer higher visual clarity than the Iris-II, making it more suitable for the much larger macular degeneration market. Upon completion of the Prima feasibility study, Pixium could potentially start a pivotal CE trial in late 2017 or early 2018. Discussions with the FDA on a regulatory pathway for Prima are also underway and Pixium could potentially receive an Investigational Device Exemption (IDE) clearance in H217, which would permit the start of a US Prima pilot study. Our forecasts and valuation are unchanged.

12 January 2017

Price	**€6.59**
Market cap	**€84m**
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

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 July 2016 on its initial product, Iris II. A sub-retinal implant, Prima, is also being developed simultaneously.

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