

Pixium Vision

Forfait Innovation decision postponed

Commercial update

Pixium announced on 24 May 2017 that the French Haute Autorité de Santé (HAS) has requested additional clinical data before agreeing to provide exceptional reimbursement under the Forfait Innovation (FI) programme for Pixium's Iris II implant system. The HAS agreed that the Iris II meets the critical FI eligibility criteria of providing a sufficiently novel and innovative treatment for a significantly unmet medical need (patients severely visually impacted by retinitis pigmentosa). Pixium now plans to provide interim six-month data from its ongoing 10-patient [European Iris-II study](#), which should be available in Q317, to fulfil this requirement. Hence we believe a decision from HAS on potential Iris-II reimbursement under FI is not likely before late Q317 or early Q417.

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	4.9	(10.8)	(0.85)	0.0	N/A	N/A
12/18e	14.9	(17.3)	(1.35)	0.0	N/A	N/A

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

As part of Pixium's initiatives to obtain Iris II reimbursement in Europe, it had applied under the FI programme in France to cover potentially up to 40 implantations over a five-year period at up to 10 French hospitals. It expects such coverage would be contingent on the post-implantation monitoring of approximately half of these patients over a two-year period, to build data supporting the efficacy of the implant. This 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.

The HAS also recommended that Pixium amend its proposed post-implantation monitoring protocol for FI-covered patients to also evaluate quality of life. Pixium agrees to enhance this post-implantation protocol and is confident that it will meet the FI eligibility requirements. As the FI decision has been pushed back to late Q317 or Q417, we believe that the initial FI-reimbursed Iris-II implantations will occur in 2018.

Healthcare equipment & services

26 May 2017

Price €6.35

Market cap €84m

Net debt (€m) at 31 December 2016 12.9

Shares in issue 13.2m

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

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