EDISON

Pixium Vision

PRIMAvera reaches full enrolment

Clinical trial enrolment update

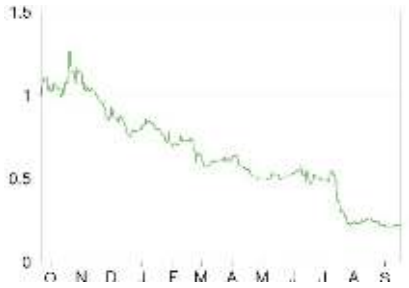
Healthcare equipment and services

20 September 2022

Price	**€0.22**
Market cap	**€14m**

Pro forma net debt (€m) at 30 June 2022 excluding €0.9m in lease liabilities	0.2
Shares in issue	62.7m
Free float	67%
Code	ALPIX
Primary exchange	Euronext Growth Paris
Secondary exchange	N/A

Share price performance



Business description

Pixium Vision develops bionic vision systems for patients with severe vision loss. Its lead product, Prima, is a wireless subretinal implant system designed for dry-AMD. The company started implantations as part of a European pivotal study in early 2021.

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Meeting its prior guidance, Pixium Vision announced that it has now reached its enrolment target of 38 patients for the PRIMAvera pivotal trial assessing the wireless Prima System in patients with geographic atrophy due to age-related macular degeneration (GA-AMD). The company has also established a waiting list for additional patients in the event that any of the currently enrolled 38 patients become ineligible for implantation or drop out of the study. Pixium expects to complete all implantation procedures of the Prima sub-retinal photovoltaic device by year-end FY22, and to report primary endpoint data at around year-end 2023.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	2.1	(8.7)	(0.26)	0.0	N/A	N/A
12/21	2.7	(10.9)	(0.23)	0.0	N/A	N/A
12/22e	1.8	(12.3)	(0.22)	0.0	N/A	N/A
12/23e	0.8	(18.2)	(0.29)	0.0	N/A	N/A

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

The PRIMAvera study began in Q420, and is the final clinical trial needed before Pixium can seek European market authorisation. Patients have been enrolled in clinical sites in France, Germany, the UK, the Netherlands and, most recently, Italy.

The primary efficacy endpoint of the study is the proportion of subjects with an improvement of visual acuity (VA) of logMAR 0.2 or greater from baseline 12 months following implantation. The PRIMAvera study will include three years of follow-up, but we expect the company can submit a CE mark regulatory approval application in Europe following the 12-month primary efficacy data. We continue to estimate that Pixium could receive potential European market approval and launch the product in H125.

As a reminder, 18–24 month interim data from the five-patient, 36-month European feasibility study (PRIMA-FS) confirmed the safety and stability of the Prima System over the PRIMA-FS study period. Study authors noted that all patients with subretinal implantation and electronic magnification could demonstrate VA exceeding 20/100. While assisted by magnification, these measures are markedly superior to the baseline pre-implantation VA levels. We view this PRIMA-FS data as highly supportive of the potential utility and benefit of the Prima System in GA-AMD patients with severely compromised vision for which no alternative treatment is available.

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