

Pixium Vision

First Prima implantation in Italy

Clinical trial update

Pixium Vision announced the successful first implantation of a patient in Italy as part of the PRIMAVera pivotal trial assessing the wireless Prima System in patients with geographic atrophy due to age-related macular degeneration (GA-AMD). The expansion of PRIMAVera to Italy follows implantations occurring at sites in France, Germany, the UK and the Netherlands. The company reiterated its guidance that it expects to complete PRIMAVera study patient enrolment by year-end FY22, and to report primary endpoint data at around year-end 2023. The PRIMAVera study is the final clinical trial needed before European market authorisation can be sought, and we continue to estimate that Pixium could receive potential European market approval and launch the product in H125.

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 designed to enrol 38 patients with severe GA-AMD, with the first implantation occurring in France in March 2021. The first study implantation in Italy follows the study's approval by the Italian Ministry of Health and the opening of the first Italy-based clinical study site, the San Giovanni Addolorata Hospital in Rome.

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 visual acuity (VA) exceeding 20/100. While assisted by magnification, these measures are markedly superior to the baseline pre-implantation VA levels. We view this data as highly supportive of the potential utility and benefit of the Prima System in GA-AMD patients with severely compromised vision and for which no alternative treatment is available. The company's [recent announcement](#) of an approved remote rehabilitation system with apps designed to improve patient engagement may further optimise the realisation of the functional benefits of the PRIMA system.

Healthcare equipment and services

14 September 2022

Price €0.21

Market cap €14m

Pro forma net debt (€m) at 30 June 2022 excluding €0.9m in lease liabilities 0.3

Shares in issue 62.5m

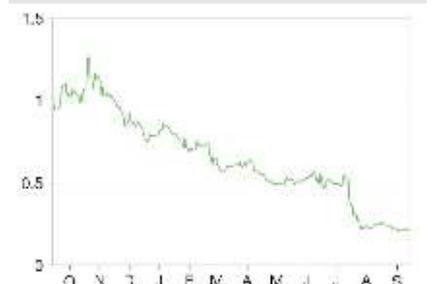
Free float 67%

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.

Analysts

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