EDISON

Pixium Vision

Clinical update

ANSM approval to start PRIMAvera pivotal study

Healthcare equipment & services

Pixium Vision announced on 20 November that it has received approval from the French regulatory health authority, ANSM, to start its PRIMAvera European pivotal study of its Prima Bionic Vision System (BVS) in patients with dry age-related macular degeneration with geographic atrophy (GA-AMD), a largely unmet market indication. This is an important milestone for Pixium as we believe the PRIMAvera European registration study may provide top-line 12-month data in H222, supporting our estimate of potential CE mark and European launch in H223.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/18	1.6	(7.7)	(0.42)	0.0	N/A	N/A
12/19	1.8	(9.8)	(0.44)	0.0	N/A	N/A
12/20e	1.7	(8.6)	(0.28)	0.0	N/A	N/A
12/21e	1.6	(11.0)	(0.25)	0.0	N/A	N/A

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

PRIMAvera pivotal study to start before year-end

Pixium expects to start the PRIMAvera study by the end 2020. It will be an open-label, non-randomized, multi-centre, prospective, single-arm study that will implant and assess the Prima BVS in 38 patients. Top-line 12-month data could be sufficient for approval purposes, although patients will be followed for three years. Pixium remains in discussions with US regulatory authorities to explore the possibility of conducting this study in parallel in Europe and the US, which, if accepted by the FDA, could lead to a US launch earlier than our baseline estimate of H225.

Primary endpoint likely achievable given data to date

The primary efficacy endpoint is the proportion of subjects with an improvement of visual acuity of logMAR 0.2 or more from baseline to 12 months (after implantation), which refers to two lines on the logMAR visual acuity (VA) scale. 18-month data from the ongoing European feasibility study (n=5) showed that on average, the Prima BVS provided a logMAR of 0.5 (representing five lines of improvement vs baseline). If this data is reproduced in the PRIMAvera study, we expect the primary endpoint would be readily met. We believe this level of amelioration should provide functional benefits (such as recognizing shapes and symbols) and potentially improve patient independence.

Valuation: Raising rNPV to €134.0m

We have updated our valuation by increasing our probability of success estimate for the European market to 25% (from 20% previously), while keeping our US estimate unchanged at 20%. We now obtain a pipeline rNPV (enterprise value excluding net cash) of €134.0m versus €115.4m previously. After including €5.6m in estimated Q320 pro forma net cash (excluding lease liabilities), we obtain an equity valuation of €139.7m, or €3.19 per share (versus €2.82 previously). We continue to assume that Pixium will need to raise €37.5m in funds between Q420 and year-end 2023, modelled as illustrative debt, to bring Prima to commercial launch.

25 November 2020

Price	**€0.66**
Market cap	**€29m**
	$1.18/€
Net debt (€m) at 30 June 2020 (excluding lease liabilities)	0.9
Shares in issue	43.8m
Free float	60%
Code	PIX
Primary exchange	Euronext Growth Paris
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	4.7	25.0	16.2
Rel (local)	(7.3)	12.7	22.5
52-week high/low		€1.11	€0.47

Business description

Pixium Vision develops bionic vision systems for patients with severe vision loss. Its lead product, Prima, is a wireless sub-retinal implant system designed for dry-AMD. The company completed five implantations in an EU feasibility study and recently started a US feasibility study.

Next events

Start PRIMAvera pivotal study	Q420
36-month data from EU feasibility study	Q121

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Edison profile page

Prima heading for European pivotal study

With approval from the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) in France, Pixium intends to start the 38-patient multicentre European pivotal study (PRIMAvera) before the end of 2020. Filings with other European regulators are underway, which are expected to allow other European countries to participate in the trial.

The primary efficacy endpoint is the proportion of subjects with a VA improvement of logMAR 0.2 or greater from baseline to 12 months post-implantation, and the primary safety endpoint is the number and severity of device and procedure related serious adverse events at 12 months follow-up. The study will include three years of follow-up, but we believe that CE mark approval and market launch can occur if the 12-month primary safety and efficacy endpoints are met. We expect that 12-month top-line primary endpoint data could be available in H222, which could lead to European approval and launch in H223, which is consistent with our existing estimates.

For the primary efficacy endpoint to be met, we believe that 72% of the evaluable patients will need to demonstrate a logMAR 0.2 or above improvement. Given the robust 18-month data shown in the five-patient European feasibility study (PRIMA-FS), where on average the five evaluable patients had logMAR 0.5 change (representing five lines of vision improvement) and the range of improvement was between three and seven lines, we believe there is a high likelihood that the primary efficacy endpoint can be met if the trends shown in PRIMA-FS are replicated in PRIMAvera.

We believe the level of VA amelioration already shown in PRIMA-FS, if reproduced in the pivotal study, should provide functional benefits (such as recognizing shapes, letters and symbols) and potentially improve patient independence, supporting potential market adoption.

US market pathway may still require a separate US pivotal study

Pixium remains in discussions with US regulators to explore the possibility of including or adding US sites to the PRIMAvera study such that the trial could potentially serve as a registration-enabling study for the US market. Our baseline forecast continues to assume that the FDA will require a separate pivotal study to support US Premarket Approval (PMA) registration for the Prima BVS, but at minimum, we expect that PRIMAvera study data could be used to supplement or support the eventual US PMA application. Our baseline estimate continues to assume a potential US launch of H225, but there continues to be a possibility that this could be pushed earlier if the FDA agrees to an approach that would allow the PRIMAvera trial to serve as a registration-enabling study in this market.

Financials and valuation

Our financial forecasts have not changed since our 29 October note , aside from a minor update in the company's net cash position as an additional c €0.1m of the ESGO convertible debt has since been converted to equity in early November. We hence now estimate Q320 pro-forma net cash of c €5.6m (vs €5.5m previously). We believe Pixium's funds on hand should be sufficient to support its ongoing operations into Q421, thus including at least several months of initial ramp-up of the PRIMAvera pivotal study.

We continue to assume that Pixium will need to raise €37.5m in funds between Q420 and year-end 2023, modelled as illustrative long-term debt, to complete the PRIMAvera pivotal study, all EU-related regulatory and preparatory commercial activities, and bring Prima to commercial launch. We

expect that part of this requirement will be fulfilled using the remaining (or unused) €6.25m in tranches from the ESGO funding facility. All together, we model that Pixium will raise a further €2.5m in the remaining months of 2020, €12.5m in both 2021 and 2022, and €10m in 2023 (all these amounts are shown as long-term debt for illustrative purposes).

Given the planned start of the PRIMAvera study and the acceptance by ANSM of the study protocol, we have increased our European market probability of success estimate to 25% (from 20% previously) and have kept our US market probability at 20%. We may further adjust our European market probability estimate following the pace and progress of PRIMAvera trial recruitment and based on interim safety updates.

We now obtain a pipeline rNPV (enterprise value excluding net cash) of €134.0m versus €115.4m previously, with the increase attributable to the raised probability estimate for the European market. After including €5.6m in estimated Q320 net cash (excluding €1.2m in estimated lease liabilities), we obtain an equity valuation of €139.7m, or €3.19 per share (versus €2.82 previously). Given that we now assume a higher probability of success for Europe than for the US in our model, we are showing a separate breakdown of the valuation contributions of the two market regions.

Exhibit 1: Pixium Vision rNPV assumptions

Product contribution	Indication	Status	NPV (€m)	Probability of success	rNPV (€m)	rNPV/ share (€)	Launch year	Peak sales (€m)
Prima (net of R&D and SG&A costs) in EU Market	Age-related Macular degeneration with Geographic Atrophy	Entering pivotal study	637.9	25.00%	154.7	3.53	H223	515
Prima (net of R&D and SG&A costs) in US Market	Age-related Macular degeneration with Geographic Atrophy	Human feasibility trials	400.2	20.00%	79.3	1.81	H225	531
Net capex, NWC & taxes (Global)			(398.2)		(100.0)	(2.28)		
Total			639.9		134.0	3.06		
Net cash (Q320e) pro-forma			5.6		5.6	0.13		
Total equity value			645.5		139.7	3.19		
FD shares outstanding (000) (5 November 2020)			43,829					

Source: Edison Investment Research

Exhibit 2: Financial summary

€(000)	2017	2018	2019	2020e	2021e	2022e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	2,535	1,598	1,782	1,700	1,600	1,600
Cost of Sales	(1,124)	(41)	0	0	0	0
General & Administrative	(5,324)	(2,019)	(3,815)	(2,889)	(2,961)	(3,835)
Research & Development	(7,817)	(5,297)	(6,320)	(6,260)	(8,000)	(10,400)
EBITDA	(11,731)	(5,758)	(8,352)	(7,449)	(9,361)	(12,635)
Depreciation	(936)	(677)	(448)	(426)	(480)	(580)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(12,666)	(6,435)	(8,801)	(7,875)	(9,841)	(13,215)
Exceptionals	0	(5,859)	(69)	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(12,666)	(12,294)	(8,870)	(7,875)	(9,841)	(13,215)
Net Interest	(876)	(1,277)	(1,006)	(740)	(1,146)	(2,209)
Profit Before Tax (norm)	(13,542)	(7,712)	(9,806)	(8,616)	(10,987)	(15,424)
Profit Before Tax (FRS 3)	(13,542)	(13,571)	(9,876)	(8,616)	(10,987)	(15,424)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(13,542)	(7,712)	(9,806)	(8,616)	(10,987)	(15,424)
Profit After Tax and minority interests (FRS 3)	(13,542)	(13,571)	(9,876)	(8,616)	(10,987)	(15,424)
Average Number of Shares Outstanding (m)	13.3	18.5	22.3	31.3	44.2	45.0
EPS - normalised (€)	(1.02)	(0.42)	(0.44)	(0.28)	(0.25)	(0.34)
EPS - normalised and fully diluted (€)	(1.02)	(0.42)	(0.44)	(0.28)	(0.25)	(0.34)
EPS - (IFRS) (€)	(1.02)	(0.73)	(0.44)	(0.28)	(0.25)	(0.34)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	9,649	3,666	4,507	4,021	3,765	3,228
Intangible Assets	7,680	2,623	2,361	2,268	2,268	2,268
Tangible Assets	1,970	1,042	2,145	1,753	1,497	961
Current Assets	14,241	17,756	9,107	15,315	16,793	14,968
Short-term investments	0	0	0	0	0	0
Cash	10,532	15,629	6,792	13,376	14,815	12,990
Other	3,710	2,126	2,316	1,939	1,978	1,978
Current Liabilities	(2,752)	(2,044)	(2,880)	(2,203)	(1,360)	(1,360)
Creditors	(2,752)	(2,044)	(2,880)	(2,203)	(1,360)	(1,360)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(9,302)	(8,023)	(7,033)	(11,396)	(23,896)	(36,396)
Long term borrowings	(9,130)	(7,870)	(5,787)	(10,282)	(22,782)	(35,282)
Other long term liabilities	(172)	(153)	(1,246)	(1,114)	(1,114)	(1,114)
Net Assets	11,836	11,355	3,700	5,736	(4,699)	(19,560)
CASH FLOW						
Operating Cash Flow	(10,605)	(6,174)	(7,282)	(6,218)	(9,691)	(12,073)
Net Interest	(876)	(1,277)	(1,006)	(740)	(1,146)	(2,209)
Tax	0	0	0	0	0	0
Capex	(191)	(31)	(34)	(222)	(224)	(44)
Acquisitions/disposals	0	0	0	0	0	0
Financing	519	14,068	2,034	10,667	0	0
Net Cash Flow	(11,153)	6,587	(6,288)	3,487	(11,061)	(14,325)
Opening net debt/(cash)	(12,911)	(1,401)	(7,760)	(1,004)	(3,094)	7,967
HP finance leases initiated	0	0	0	0	0	0
Other	(357)	(228)	(468)	(1,397)	0	(0)
Closing net debt/(cash)	(1,401)	(7,760)	(1,004)	(3,094)	7,967	22,292
Lease debt	N/A	N/A	1,346	1,215	1,215	1,215
Closing net debt/(cash) inclusive of IFRS16 lease debt	(1,401)	(7,760)	342	(1,879)	9,182	23,507

Source: Company accounts, Edison Investment Research

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