

Pixium Vision

PRIMAvera recruitment timing pushed out

Pixium has announced that given longer than expected regulatory approvals for the PRIMAvera European pivotal study due to COVID-19 and delayed clinical centre openings, it now expects to complete recruitment by year-end 2022 (versus its prior guidance of year-end 2021) and plans to report top-line, 12-month data around the end of 2023. We have pushed back our timelines for European and US launches of Prima by one year, to H125 and H226, respectively, hence our valuation has declined.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	1.8	(9.8)	(0.44)	0.0	N/A	N/A
12/20	2.1	(8.7)	(0.26)	0.0	N/A	N/A
12/21e	2.6	(10.8)	(0.22)	0.0	N/A	N/A
12/22e	1.6	(11.0)	(0.19)	0.0	N/A	N/A

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

Management confident in new PRIMAvera timelines

[PRIMAvera](#) is a registration-enabling study designed to assess the Prima wireless bionic vision system (BVS) in 38 patients with severe geographic atrophy due to age-related macular degeneration (GA-AMD). The study began in Q420 and the first implantation occurred in France in March 2021. Implantations in H121 were slower than the company expected due to COVID-19 and related restrictions on elective procedures, as well as the associated delays for gaining additional competent authority approvals and clinical site inclusions. Fortunately, the pace of recruitment has picked up in recent months as new sites have opened. Study sites now include seven locations in France and six in Germany. The company [announced the first implantation at Moorfields Eye hospital](#) in London, UK, and expects to add additional sites in Spain, the Netherlands and Italy in H122.

Revising commercialisation timelines

Assuming no significant new COVID-19 restrictions affect the European study sites, we are confident that Pixium can meet its revised timelines, given the number of sites that have joined the PRIMAvera study in H221 and the future expected study location additions. We now anticipate primary 12-month data in late 2023 or early 2024, leading to CE Mark submission in H124 and European approval in H125 (vs H124 previously). We continue to anticipate that a separate study will be needed for US approval, and we model that the US launch will occur in H226 (vs H225 previously).

Valuation: Revised to reflect new launch timing

After adjusting for forex and our new timing assumptions, we obtain a pipeline rNPV of €115.1m (vs €134.2m previously). After adding €8.5m in Q321e net cash, we obtain an equity value of €123.6m (€2.11 per basic share). The company believes its current funds can maintain operations through Q422. We increased our projected total financing need by €15m given the additional time it would take to reach commercialisation. We now expect Pixium will raise €44.4m by year-end 2025 and have modelled a €12.5m raise in 2022 (all modelled as illustrative debt).

Clinical study guidance update

Healthcare equipment & services

15 December 2021

Price **€0.83**

Market cap **€49m**

\$1.13/€

Net cash (€m) at 30 June 2021 (excluding lease liabilities and July 2021 fund-raising) 0.65

Shares in issue 58.5m

Free float 60%

Code ALPIX

Primary exchange Euronext Growth Paris

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (18.7) (17.9) 13.9

Rel (local) (16.0) (20.0) (6.9)

52-week high/low €2.09 €0.63

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 started implantations as part of a European pivotal study in early 2021.

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Financials

Given our new launch timing estimates, our financial forecasts for Prima sales have been revised, and are shown below.

Exhibit 1: Financial forecast for Prima in GA-AMD					
	2025e	2026e	2027e	2028e	2029e
Europe					
EU patients with Dry AMD with GA (000)	1,595	1,617	1,640	1,663	1,686
Percentage with 20/400 or worse visual acuity	15.0%	15.0%	15.0%	15.0%	15.0%
Percentage meeting all Prima eligibility criteria	30.0%	30.0%	30.0%	30.0%	30.0%
GA-AMD patients meeting all Prima eligibility criteria (000)	71.8	72.8	73.8	74.8	75.9
Prima unit sales in EU	561	1,326	2,685	4,049	5,148
Average revenue per treatment (€)	81,099	82,725	84,341	85,997	87,688
Total EU revenue (€000) for PRIMA-AMD	45,496	109,696	226,489	348,234	451,404
United States					
US patients with Dry AMD with GA (000)	1,341	1,367	1,395	1,423	1,451
Percentage with 20/400 or worse visual acuity	15.0%	15.0%	15.0%	15.0%	15.0%
Percentage meeting all Prima eligibility criteria	30.0%	30.0%	30.0%	30.0%	30.0%
GA-AMD patients meeting all Prima eligibility criteria (000)	60.3	61.5	62.8	64.0	65.3
Prima unit sales in US	-	215	889	2,010	3,343
Average revenue per treatment (\$)	N/A	112,000	113,558	115,784	118,048
Total US revenue (\$000) for PRIMA-AMD	-	24,080	100,985	232,744	394,680
Assumed \$/€ rate	1.13	1.13	1.13	1.13	1.13
Worldwide total revenue (€000)	45,496	131,006	315,857	554,202	800,678

Source: Edison Investment Research

Pixium had an H121 net cash position of €0.65m (€10.13m in gross cash and €9.48m gross debt), excluding €1.1m in lease liabilities. The company [raised €8m](#) (€7.376m net) through a capital increase in July 2021, resulting in the issuance of 8.097m shares and 4.0486m warrants, as well as converting c €1.1m of its European Select Growth Opportunities Fund (ESGO) convertible financing debt into equity. Pixium reported a [30 September 2021 gross cash](#) position of €16.9m. Given the reduction in ESGO debt since H121 described above, we estimate Q321 gross debt of c €8.4m and hence we estimate Q321 net cash of €8.5m.

As PRIMavera timelines have been extended, we have pushed back some of our R&D expense forecasts, leading to lower R&D spending in FY22 than previously expected (€7.2m vs €10.4m). We have also pushed back our anticipated start time of a separate US Prima pivotal study from FY22 into FY23. Our FY23 R&D cost estimates are slightly lowered (to €9.4m from €9.8m previously) as cost reductions from the timing change of the US pivotal study offset the effects of continued PRIMavera activity through FY23. Our estimated 2021 net operating cash burn rate of €11.7m is unchanged, but we now expect a 2022 operating cash burn rate of €8.0m (vs €11.2m previously).

However, given the additional time it will take for Prima to reach commercialisation, we have also increased our projected total financing need by €15m. We now expect Pixium will raise €44.4m (modelled as illustrative debt) by year-end 2025 (up from €29.4m by year-end 2023), to complete the PRIMavera study and all EU-related regulatory and preparatory commercial activities to bring Prima to commercial launch.

Valuation

Our valuation for Pixium Vision uses an rNPV approach, employing a 12.5% cost of capital, based on the Prima opportunity in GA-AMD. We continue to apply a 25% probability of success estimate for Prima in Europe and a 20% probability in the US market.

Exhibit 2: Pixium Vision rNPV assumptions

Product contribution	Indication	Status	NPV (€m)	Probability of success	rNPV (€m)	rNPV/share (€)	Launch year	Peak sales (€m) in 2030
Prima (net of R&D and SG&A costs) in EU market	Age-related macular degeneration with geographic atrophy	Pivotal study	540.6	25.00%	121.8	2.08	H125	474
Prima (net of R&D and SG&A costs) in US market	Age-related macular degeneration with geographic atrophy	Human feasibility trials	394.9	20.00%	81.0	1.39	H226	477
Net capex, NWC & taxes (global)			(354.3)		(87.7)	(1.50)		
Total			581.2		115.1	1.97		
Net cash (Q321e)			8.5		8.5	0.15		
Total equity value			589.7		123.6	2.11		
Basic shares outstanding (000)			58,490					

Source: Edison Investment Research

After adjusting for forex and our new timing assumptions, we obtain a pipeline rNPV of €115.1m (vs €134.2m previously). After adding €8.5m in estimated Q321 net cash, we obtain an equity value of €123.6m, or €2.11 per basic share (vs €2.45 previously). Assuming full exercise of the July 2021 warrants, our fully diluted equity valuation would be €2.06 per share (versus €2.37 previously).

Below we provide a sensitivity analysis demonstrating how our per basic share valuation would be affected by using different Prima pricing and probability of success assumptions (for Europe).

Exhibit 3: Pixium Vision per-share equity value (€) analysis based on European net Prima pricing versus probability of success in Europe

	70,000	75,000	80,000	85,000	90,000
15.0%	1.01	1.11	1.20	1.30	1.39
20.0%	1.40	1.53	1.66	1.78	1.91
25.0%	1.80	1.96	2.11	2.27	2.43
30.0%	2.20	2.39	2.57	2.76	2.95
35.0%	2.60	2.82	3.04	3.26	3.48

Source: Edison Investment Research. Note: Left-hand column represents European probability of success and top row represents European net Prima pricing at launch (€).

Exhibit 4: Financial summary

	€'000s	2018	2019	2020	2021e	2022e	2023e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue		1,598	1,782	2,092	2,601	1,600	800
Cost of Sales		(41)	0	0	0	0	0
General & Administrative		(2,019)	(3,572)	(4,017)	(4,785)	(4,000)	(5,000)
Research & Development		(5,297)	(6,563)	(5,711)	(7,092)	(7,200)	(9,400)
EBITDA		(5,758)	(8,352)	(7,636)	(9,276)	(9,600)	(13,600)
Depreciation		(677)	(448)	(366)	(443)	(447)	(338)
Amortization		0	0	0	0	0	0
Operating Profit (before exceptionals)		(6,435)	(8,801)	(8,003)	(9,719)	(13,247)	(10,047)
Exceptionals		(5,859)	(69)	(448)	(624)	0	0
Other		0	0	0	0	0	0
Operating Profit		(12,294)	(8,870)	(8,450)	(10,343)	(10,047)	(13,938)
Net Interest		(1,277)	(1,006)	(700)	(1,043)	(990)	(1,996)
Profit Before Tax (norm)		(7,712)	(9,806)	(8,703)	(10,762)	(11,037)	(15,935)
Profit Before Tax (FRS 3)		(13,571)	(9,876)	(9,150)	(11,386)	(11,037)	(15,935)
Tax		0	0	0	0	0	0
Profit After Tax and minority interests (norm)		(7,712)	(9,806)	(8,703)	(10,762)	(14,252)	(11,037)
Profit After Tax and minority interests (FRS 3)		(13,571)	(9,876)	(9,150)	(11,386)	(14,252)	(16,593)
Average Number of Shares Outstanding (m)		18.5	22.3	34.0	48.1	58.5	58.5
EPS - normalised (€)		(0.42)	(0.44)	(0.26)	(0.22)	(0.19)	(0.27)
EPS - normalised and fully diluted (€)		(0.42)	(0.44)	(0.26)	(0.22)	(0.19)	(0.27)
EPS - (IFRS) (€)		(0.73)	(0.44)	(0.27)	(0.24)	(0.19)	(0.27)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed Assets		3,666	4,507	3,411	2,898	2,495	2,176
Intangible Assets		2,623	2,361	1,727	1,534	1,534	1,534
Tangible Assets		1,042	2,145	1,684	1,364	961	643
Current Assets		17,756	9,107	12,721	15,260	19,751	13,155
Short-term investments		0	0	0	0	0	0
Cash		15,629	6,792	10,566	11,929	16,420	9,911
Other		2,126	2,316	2,155	3,332	3,332	3,244
Current Liabilities		(2,044)	(2,880)	(3,795)	(4,946)	(7,246)	(4,061)
Creditors		(2,044)	(2,880)	(3,260)	(2,553)	(4,853)	(1,668)
Short term borrowings		0	0	(536)	(2,394)	(2,394)	(2,394)
Long Term Liabilities		(8,023)	(7,033)	(7,851)	(7,008)	(19,508)	(31,382)
Long term borrowings		(7,870)	(5,787)	(6,695)	(5,989)	(18,489)	(30,363)
Other long-term liabilities		(153)	(1,246)	(1,157)	(1,019)	(1,019)	(1,019)
Net Assets		11,355	3,700	4,485	6,204	(4,509)	(20,112)
CASH FLOW							
Operating Cash Flow		(6,174)	(7,282)	(6,206)	(10,627)	(6,975)	(16,366)
Net Interest		(1,277)	(1,006)	(700)	(1,043)	(990)	(1,996)
Tax		0	0	0	0	0	0
Net Operating Cash Flow		(7,450)	(8,288)	(6,906)	(11,670)	(7,965)	(18,363)
Capex		(31)	(34)	(82)	(57)	(44)	(20)
Acquisitions/disposals		0	0	0	0	0	0
Financing		14,068	2,034	9,055	14,324	0	0
Net Cash Flow		6,587	(6,288)	2,068	2,597	(8,009)	(18,383)
Opening net debt/(cash)		(1,401)	(7,760)	(1,004)	(3,336)	(3,546)	4,463
HP finance leases initiated		0	0	0	0	0	0
Other		(228)	(468)	264	(2,387)	0	0
Closing net debt/(cash)		(7,760)	(1,004)	(3,336)	(3,546)	4,463	22,846
Lease debt		N/A	1,346	1,258	1,141	1,141	1,141
Closing net debt/(cash) inclusive of IFRS 16 lease debt		(7,760)	342	(2,078)	(2,405)	8,819	27,860

Source: Company reports, Edison Investment Research

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