

# Pixium Vision

## Signalling an intent to access US investors

Business update

Pixium provided a minor business update on 2 June, indicating that it is seeking to capitalise on increased interest from US investors in recent months and that it has hired a US investment bank to advise on possible options, including a mechanism to list on the Nasdaq. The core operational focus remains on advancing the Prima Bionic Vision system (BVS) through the ongoing PRIMAvEra pivotal EU study, with top-line data now guided for early 2023 (from late 2022 previously), with a potential European launch in late 2023. We have slightly pushed back our commercialisation forecasts and moderated our pricing assumptions, resulting in a new rNPV of €122.5m.

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	2.4	(10.7)	(0.23)	0.0	N/A	N/A
12/22e	1.6	(15.5)	(0.32)	0.0	N/A	N/A

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

## Still aiming for European launch before YE23

Pixium began the PRIMAvEra European pivotal trial for Prima in late 2020 and it announced the first successful implantation in April 2021. The company now expects to release top-line data in early 2023, aiming for a CE mark submission in Europe in H123, leading to a potential European approval and launch in late 2023. This new timing for top-line PRIMAvEra data is slightly pushed back from the prior guidance of late 2022.

## More conservative stance on Prima pricing

We have revised our net Prima device pricing assumptions lower given the company's recent presentations where management signalled that device pricing at launch could potentially be \$75,000. We continue to expect a higher price point than this, but have revised our at-launch pricing projections from €95,000 and \$157,000 in Europe and the US, respectively, to €80,000 and \$112,000, respectively. Given the changes and minor revisions to ramp estimates and forex, we now estimate 2028 net global sales of €694m, versus €929m, previously.

## Valuation

We now obtain an rNPV of €122.5m (from €142.8m, previously), with the largest driver being adjustments to our Prima pricing and timing estimates. We believe that Pixium's current funds on hand (€9.7m at Q121) should last into Q122, and assume it will need to raise €31.8m (from €33.7m, previously) in additional funds before year-end 2023, modelled as illustrative long-term debt, to bring Prima to commercial launch. We believe the company's recent hiring of a US investment bank is well-timed given the upcoming near-term funding need, and we believe the company is looking at multiple possibilities to extend its runway and fund the PRIMAvEra trial and potentially enable a US market listing. We believe a US listing likely would expand Pixium's access to capital as it may provide a wider pool of potential investors for future financing initiatives.

Healthcare equipment & services

8 June 2021

Price €0.99

Market cap €48m

\$1.22/€

Net cash (€m) at 31 December 2020 (excluding lease liabilities) 3.3

Shares in issue 48.6m

Free float 60%

Code ALPIX

Primary exchange Euronext Growth Paris

Secondary exchange N/A

## Share price performance



% 1m 3m 12m

Abs (19.5) (25.4) 50

Rel (local) (21.2) (33.5) 20

52-week high/low €2.09 €0.50

## 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 recently started a European pivotal study.

## Next events

36-month data from European feasibility study Q421/Q122

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## Pixium eyes US investors

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Pixium [announced](#) a minor business update on 2 June, signalling its aim to capitalise on increased interest from US investors and potentially list on Nasdaq through its recent engagement of a US investment bank. We believe a US listing likely would expand Pixium's access to capital as it may provide a wider pool of potential investors for future financing initiatives than Pixium's current Euronext listing.

## Prima on track for potential European launch before YE23

Pixium began the [PRIMAvera](#) European pivotal trial for Prima in late 2020 and it [announced](#) the first successful implantation in April 2021. The open-label, baseline-controlled, prospective, single-arm confirmatory trial is designed to enrol 38 patients, and 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 and the primary safety endpoint is the number and severity of device and procedure related serious adverse events at 12 months follow-up. The company now expects to release top-line data in early 2023, aiming for a CE mark submission in Europe in H123, leading to a potential European approval and launch in late 2023. This new timing for top-line PRIMAvera data is slightly pushed back from the prior guidance of late 2022, but the potential European launch guidance is little changed from prior guidance of H223.

## Pixium continues discussions with the FDA on a US pathway

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. While discussions have been slower than expected due to the COVID-19 pandemic, the company is hopeful on obtaining better visibility on this consideration by YE21. 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. Meanwhile, [the US feasibility study](#) remains underway, with top-line data guided for H222.

Our baseline estimate continues to assume a potential US launch of H225, but there continues to be a possibility that this could be brought forward if the FDA agrees to an approach that would allow the PRIMAvera trial to serve as a registration-enabling study in this market. Nonetheless, we continue to model that a separate US pivotal study will start implantations in H122, and that a US PMA and launch will occur in H225.

## Revisions to Prima sales forecasts

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Given the new guidance on the completion of the PRIMAvera study, we have slightly pushed back our Prima European launch forecasts by a quarter; we now expect launch in Europe in Q423 (from H223 previously). We have also revised our net Prima device pricing assumptions lower given the company's recent presentations where management signalled that device pricing at launch could potentially be \$75,000. We continue to expect a higher price point than this, but have revised our at-launch pricing projections from €95,000 and \$157,000 in Europe and the US, respectively, to €80,000 and \$112,000, respectively. Our lowered pricing estimate is partly offset by a reduced post-2030 annual sales decline rate in our model (20% vs 40%, previously), as we believe that our prior post-peak sales decline assumptions were likely too severe given that certain Prima patents will

remain unexpired at this point and that there is no Dry-AMD therapeutic product in the development pipeline that, in our view, would materially dampen the incidence of late-stage geographic atrophy due to Dry-AMD by 2030–35 (in the US and Europe). We have also made minor changes in our ramp rate modelling assumptions between launch and revenue peak.

**Exhibit 1: Financial forecasts for Prima in Dry-AMD**

	2023e	2024e	2025e	2026e	2027e	2028e	2029e
<b>Europe</b>							
EU patients with Dry AMD with GA (000)	1,471	1,486	1,501	1,516	1,531	1,546	1,562
Percentage with 20/400 or worse visual acuity	15.0%	15.0%	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%	30.0%	30.0%
GA-AMD patients meeting all Prima eligibility criteria (000)	66.2	66.9	67.5	68.2	68.9	69.6	70.3
Prima unit sales in EU	94	644	1,505	2,810	4,016	4,816	4,894
Average revenue per treatment (€)	80,000	81,103	82,719	84,330	85,994	87,677	89,430
Total EU revenue (€000) for PRIMA-AMD	7,544	52,211	124,526	236,954	345,347	422,255	437,690
<b>United States</b>							
US patients with Dry AMD with GA (000)	1,156	1,168	1,179	1,191	1,203	1,215	1,227
Percentage with 20/400 or worse visual acuity	15.0%	15.0%	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%	30.0%	30.0%
GA-AMD patients meeting all Prima eligibility criteria (000)	52.0	52.5	53.1	53.6	54.1	54.7	55.2
Prima unit sales in US	-	-	186	762	1,705	2,809	3,724
Average revenue per treatment (\$)	N/A	N/A	112,000	113,557	115,783	118,047	120,359
Total US revenue (\$000) for PRIMA-AMD	-	-	20,792	86,505	197,454	331,626	448,195
Assumed \$/€ rate	1.22	1.22	1.22	1.22	1.22	1.22	1.22
<b>Worldwide total revenue (€000)</b>	<b>7,544</b>	<b>52,211</b>	<b>141,569</b>	<b>307,859</b>	<b>507,195</b>	<b>694,079</b>	<b>805,063</b>

Source: Edison Investment Research

## Financials

Pixium had a Q420 net cash position of €3.3m (€10.6m in gross cash and €7.2m gross debt), excluding €1.3m in lease liabilities. Since YE20, the company raised another €1.25m tranche from its ESGO financing facility, followed by two €1m tranches (announced in April), and converted about €1.28m of its outstanding ESGO debt into equity. Pixium reported Q121 gross cash of €9.7m and a Q121 operating cash burn rate of €3.6m, up from €2.5m in Q120 due to the start of the PRIMAvera trial and costs borne in relation of the proposed (and now terminated) business combination with Second Sight. On 8 April, Pixium received a \$1m payment from Second Sight, but Pixium considers this payment insufficient to compensate the loss it has sustained due to Second Sight's unilateral termination and plans to seek additional compensation through the Paris Commercial Court system.

We estimate Q121 net cash of c €0.5m (€9.7m gross cash offset by €9.2m estimated current gross debt), or €1.3m pro forma after including the April Second Sight payment. We believe that Pixium's funds on hand should last into Q122. Our model assumes Pixium will need to raise €31.8m (from €33.7m, previously, given that €2m in new debt from the ESGO facility has been announced since our [7 April note](#)) in additional funds before 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 part of this requirement will be fulfilled using the remaining (or unused) €3.0m in tranches from the ESGO funding facility. All in, we model a €9.3m funding raise in H221, €12.5m in 2022 and €10m in 2023. We believe the company's recent hiring of a US investment bank is well-timed given the upcoming near-term funding need, and we believe the company is looking at multiple possibilities to extend its runway and potentially enable a US market listing.

## Valuation

We now obtain an rNPV to €122.5m (from €142.8m, previously), with the largest driver of the change being adjustments to our Prima pricing estimates and launch timing forecasts, as cited above. We have made no significant local currency changes to our operating expense forecasts, but have adjusted our forex assumptions to \$1.22/€ (from \$1.18/€ previously). We have also adjusted the net cash component of our valuation, to reflect our Q121 pro forma net cash estimate of €1.3m (versus €2.1m, previously). After including net cash, we obtain an equity valuation of €123.9m, or €2.55 per share (vs €3.07 previously). The per-share valuation is also affected by increased shares outstanding compared to [our prior note](#).

### 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 2029
Prima (net of R&D and SG&A costs) in EU market	Age-related macular degeneration with geographic atrophy	Pivotal study	596.3	25.00%	142.3	2.93	Q423	438
Prima (net of R&D and SG&A costs) in US market	Age-related macular degeneration with geographic atrophy	Human feasibility trials	339.0	20.00%	67.5	1.39	H225	367
Net capex, NWC & taxes (Global)			(349.4)		(87.3)	(1.80)		
Total			586.0		122.5	2.52		
Net cash (Q121e) pro forma including \$1m Second Sight payment			1.3		1.3	0.03		
Total equity value			587.3		123.9	2.55		
FD shares outstanding (000) (31 May 2021)			48,558					

Source: Edison Investment Research

Below we provide a sensitivity analysis demonstrating how our per-share valuation would be affected 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%	1.20	1.31	1.43	1.54	1.60
20.0%	1.68	1.84	1.99	2.14	2.21
25.0%	2.17	2.36	<b>2.55</b>	2.74	2.83
30.0%	2.66	2.89	3.12	3.34	3.46
35.0%	3.15	3.42	3.68	3.95	4.08

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**

	€(000)	2017	2018	2019	2020e	2021e	2022e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>							
Revenue		2,535	1,598	1,782	2,092	2,440	1,600
Cost of Sales		(1,124)	(41)	0	0	0	0
General & Administrative		(5,324)	(2,019)	(3,572)	(4,017)	(3,800)	(4,345)
Research & Development		(7,817)	(5,297)	(6,563)	(5,711)	(8,400)	(10,400)
EBITDA		(11,731)	(5,758)	(8,352)	(7,636)	(9,760)	(13,145)
Depreciation		(936)	(677)	(448)	(366)	(409)	(497)
Operating Profit (before exceptionals)		(12,666)	(6,435)	(8,801)	(8,003)	(10,169)	(13,642)
Exceptionals		0	(5,859)	(69)	(448)	0	0
Operating Profit		(12,666)	(12,294)	(8,870)	(8,450)	(10,169)	(13,642)
Net Interest		(876)	(1,277)	(1,006)	(700)	(554)	(1,888)
Profit Before Tax (norm)		(13,542)	(7,712)	(9,806)	(8,703)	(10,723)	(15,530)
Profit Before Tax (FRS 3)		(13,542)	(13,571)	(9,876)	(9,150)	(10,723)	(15,530)
Tax		0	0	0	0	0	0
Profit After Tax and minority interests (norm)		(13,542)	(7,712)	(9,806)	(8,703)	(10,723)	(15,530)
Profit After Tax and minority interests (FRS 3)		(13,542)	(13,571)	(9,876)	(9,150)	(10,723)	(15,530)
Average Number of Shares		13.3	18.5	22.3	34.0	47.5	49.2
Outstanding (m)							
EPS - normalised (€)		(1.02)	(0.42)	(0.44)	(0.26)	(0.23)	(0.32)
EPS - normalised and fully diluted (€)		(1.02)	(0.42)	(0.44)	(0.26)	(0.23)	(0.32)
EPS - (IFRS) (€)		(1.02)	(0.73)	(0.44)	(0.27)	(0.23)	(0.32)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>							
Fixed Assets		9,649	3,666	4,507	3,411	3,226	2,772
Intangible Assets		7,680	2,623	2,361	1,727	1,727	1,727
Tangible Assets		1,970	1,042	2,145	1,684	1,499	1,046
Current Assets		14,241	17,756	9,107	12,721	13,890	11,766
Cash		10,532	15,629	6,792	10,566	11,650	9,527
Other		3,710	2,126	2,316	2,155	2,240	2,240
Current Liabilities		(2,752)	(2,044)	(2,880)	(3,795)	(2,559)	(2,559)
Creditors		(2,752)	(2,044)	(2,880)	(3,260)	(2,023)	(2,023)
Short term borrowings		0	0	0	(536)	(536)	(536)
Long Term Liabilities		(9,302)	(8,023)	(7,033)	(7,851)	(19,071)	(31,571)
Long term borrowings		(9,130)	(7,870)	(5,787)	(6,695)	(17,915)	(30,415)
Other long term liabilities		(172)	(153)	(1,246)	(1,157)	(1,157)	(1,157)
Net Assets		11,836	11,355	3,700	4,485	(4,514)	(19,592)
<b>CASH FLOW</b>							
Operating Cash Flow		(10,605)	(6,174)	(7,282)	(6,206)	(10,637)	(12,692)
Net Interest		(876)	(1,277)	(1,006)	(700)	(554)	(1,888)
Tax		0	0	0	0	0	0
Net Operating Cash Flow		(11,481)	(7,450)	(8,288)	(6,906)	(11,192)	(14,580)
Capex		(191)	(31)	(34)	(82)	(224)	(44)
Acquisitions/disposals		0	0	0	0	0	0
Financing		519	14,068	2,034	9,055	1,280	0
Net Cash Flow		(11,153)	6,587	(6,288)	2,068	(10,136)	(14,624)
Opening net debt/(cash)		(12,911)	(1,401)	(7,760)	(1,004)	(3,336)	6,800
HP finance leases initiated		0	0	0	0	0	0
Other		(357)	(228)	(468)	264	0	0
Closing net debt/(cash)		(1,401)	(7,760)	(1,004)	(3,336)	6,800	21,424
Lease debt		N/A	N/A	1,346	1,258	1,258	1,258
Closing net debt/(cash) inclusive of IFRS16 lease debt		(1,401)	(7,760)	342	(2,078)	8,058	22,682

Source: Company accounts, Edison Investment Research

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