EDISON

Pixium Vision

Q421 update

Moving ahead as expected

Healthcare equipment & services

Pixium's FY21 results were mostly in line with our forecasts, as the company continues to advance its wireless Prima bionic vision system (BVS) through the PRIMAvera pivotal study. The company finished 2021 with €14.5m gross cash, which we believe should fund operations into 2023. After rolling forward our estimates and adjusting forex and net cash, we obtain an equity valuation of €135.1m or €2.31 per basic share.

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	(11.1)	(0.23)	0.0	N/A	N/A
12/22e	1.6	(11.5)	(0.19)	0.0	N/A	N/A
12/23e	0.8	(16.2)	(0.27)	0.0	N/A	N/A

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

European feasibility study highlighted in Nature

A recent article in Nature highlighted 18–24 month interim data from the five-patient, 36-month European feasibility study (PRIMA-FS). The authors concluded that the PRIMA-FS study confirmed the safety and stability of the Prima BVS over the study period and noted that all patients with subretinal implantation and electronic magnification could demonstrate visual acuity (VA) exceeding 20/100. Altogether, while assisted by magnification, these measures are markedly superior to the baseline pre-implantation VA levels. The authors also reiterated that the Prima-implanted patients were able to simultaneously use their prosthetic vision and their residual natural vision from both the study eye and the other eye.

FY21 in line, 2022 to focus on PRIMAvera study

Pixium's FY21 results were generally in line with our forecasts, as the operating loss of €10.3m exceeded our €9.7m projection, but net operating cash ouflows (€8.8m) were better than our estimate (€11.7m outflow). We expect the company to prioritise continued advancement of the PRIMAvera registration-enabling pivotal study, designed to assess the Prima BVS in 38 patients with geographic atrophy (GA) associated with dry age-related macular degeneration (dry-AMD). Assuming no significant new COVID-19 restrictions affect the European study sites, we are confident that Pixium can meet its guidance of enrolment completion by year-end FY22. We maintain our estimate that primary 12-month data will be released in late 2023 or early 2024, leading to potential European approval in H125.

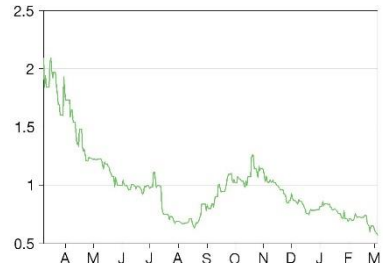
Valuation: Rolling forward our forecasts

After rolling forward our estimates and making minor adjustments to our model (including adjusting our forex assumptions to $1.10/€, from $1.13/€ previously), we obtain a pipeline rNPV of €130.0m (vs €115.1m previously). After adding €5.1m in Q421e net cash (€14.5m gross cash minus €9.4m estimated Q421 debt), we obtain an equity value of €135.1m or €2.31 per basic share (versus €2.11 previously). Assuming full exercise of the July 2021 warrants, our fully diluted equity valuation would be €2.24 per share (versus €2.06 previously).

7 March 2022

Price	**€0.57**
Market cap	**€34m**
	$1.10/€
Estimated net cash (€m) at 31 December 2021 excluding leases	5.1
Shares in issue	58.7m
Free float	60%
Code	ALPIX
Primary exchange	Euronext Growth Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(18.5)	(34.3)	(39.0)
Rel (local)	(6.8)	(26.4)	(40.1)
52-week high/low		€2.09	€0.57

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.

Next events

Completion of recruitment for PRIMAvera study	H222

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Edison profile page

Clinical results highlighted in Nature article

A recent article (Palanker et al) published in Nature highlights interim data from the five-patient, 36-month European feasibility study (PRIMA-FS), which began in late 2017.[1] As a reminder, the study is assessing the Prima BVS in patients with GA associated with advanced dry-AMD who had no remaining central visual activity at the time of enrolment in the study eye. In January 2019, Pixium announced that Prima's study endpoints had been successfully met at interim six-month follow-up after implantation. The data showed that the Prima device can interface with retinal cells to restore some visual perception in an area where vision had been lost due to prolonged degenerative disease. Pixium then transitioned study participants to second-generation Prima system external components to work alongside the same (current-generation) 378-electrode implant chip, which would better allow patients to combine both prosthetic and natural residual (ie peripheral) vision, as the initial-generation glasses were opaque. The second-generation components include an enhanced and transparent version of the augmented reality (AR) glasses (Prima 2 glasses), and a new pocket computer employing improved algorithms, designed to incorporate more advanced image processing, magnification and artificial intelligence (AI) features to enhance the functional visual experience of patients.

In Q120, the company reported 18-month data on four EU patients implanted in PRIMA-FS (one of the five patients had passed away due to health reasons unrelated to Prima), showing continued safety and tolerability, and that use of the second-generation components led to some measurable improvements in VA, in part due to the improved magnification capabilities (up to 8x magnification/ zoom).

The Palanker et al article summarised study data at 18–24 months post-implantation with the Prima 2 components. We note that the surgical technique (estimated duration between one and two hours) is designed to position the Prima chip implant into the subretinal space (between the ganglion cell nerve fibre layer and the retinal pigment epithelium layer). Palanker et al noted that in one of the five subjects, the implant shifted to the choroidal space because of the patient's accidental movement during surgery and this patient had no discernible post-implantation VA. Hence, as with any retinal surgery, proper patient behaviour and compliance is needed. Altogether, there were three evaluable subjects, and VA was measured using the Landolt C optotype (the type of figures or symbols used to measure VA).

Exhibit 1: Landolt C optotype

Source: Wikimedia commons; attribution to Visuoloog/CC BY-SA

[1] All surgical implantations at the EU feasibility study took place at the Fondation Ophtalmologique Adolphe de Rothschild/Hôpital des Quinze-Vingts, based in Paris, France.

Effective device-assisted prosthetic VA with active magnification (at 18–24 months post-implantation), was measured at values between log MAR 0.5 (approximately 20/60, or c 33% of normal VA expected in healthy subjects) and logMAR 0.69 (approximately 20/100, or c 20% of normal VA). Each 0.1 increment on the logMAR scale represents the next lower VA line of the VA chart (ie the higher the logMAR value, the lower the effective VA). Specifically, the three subjects had device-assisted VA of 20/98, 20/71, and 20/63, respectively, which compared to their pre-implantation VA levels in the study eye of 20/800, 20/500, and 20/500, respectively. Altogether, these measures are markedly superior to the baseline results, even given that they were assisted to a degree by the device's magnification features. We reiterate that legal blindness is generally defined as 20/200 (10% of normal VA) and we assume that the Prima device will be targeting dry-AMD patients with significant GA having a baseline VA level no better than 20/400 (5% of normal VA).

Palanker at al also reiterated that the Prima-implanted patients were able to simultaneously use their prosthetic vision and their residual natural vision from both the study eye and the other eye. The authors conclude the PRIMA-FS study confirmed the safety and stability of the Prima BVS over 18–24 months follow-up and noted that all patients with subretinal implantation and electronic magnification could demonstrate VA exceeding 20/100. Longer-term (up to 24–30 months) data were provided in Q121, which showed that VA improvements from the Prima chip were maintained at 24–30 months follow-up post-implantation, suggesting continued safety and stability of the implant over this period.

Interestingly, Palanker et al concluded by discussing potential advancements in photovoltaic pixel design, to potentially enable an implant with five times higher pixel density, which we discussed in our Outlook note, and which the authors estimate could potentially enable electronic zoom capability approaching 20/20 (100% of normal VA). As a reminder, Pixium's strategy remains to bring the current 378-pixel Prima chip iteration to market then work on a follow-on iteration carrying much higher pixel densities. In September 2021, Pixium announced that it had expanded the collaboration with its Stanford research partners to develop the next generation of Prima implants, which are intended to use a similar design to the current iteration, while allowing for a significant increase in the number of pixels (electrodes). We reiterate that while higher pixel density could potentially extend the market reach of Prima technology to patients with less severe forms of atrophic AMD, our models and forecasts only consider the implications and market opportunities for the current (initial-generation) 378-electrode Prima device.

FY21 financial update

Pixium recently announced its FY21 results, which were generally in line with our forecasts. Revenue (predominantly research tax credits and grants) of €2.66m mildly exceeded our €2.60m forecast, but with G&A costs (€5.1m excluding depreciation) and R&D costs (€7.3m) above our expectations of €4.8m and €7.1m, respectively, the overall operating loss of €10.3m exceeded our €9.7m projection. Cash management was better than anticipated, as net operating cash flow (including net interest) was a €8.8m loss, compared to our forecast of an €11.7m loss. Capex was relatively minor (€0.05m), in line with our forecast and with prior years. The company did not provide an audited balance sheet but reported a gross cash balance of €14.5m. Assuming no substantial changes in the debt structure since our prior note, and given that financing cash inflows (€12.8m) were comparable to our €13.1m estimate, we estimate Q421 gross debt of €9.4m, hence we estimate Q421 net cash of €5.1m (excluding leases).

Maintaining Prima timing and launch forecasts

We continue to expect that the company's upcoming activities will be largely focused on continuing to advance the PRIMAvera registration-enabling pivotal study. PRIMAvera is designed to assess

the Prima 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 in gaining additional competent authority approvals and clinical site inclusions. Fortunately, the pace of recruitment appears to have picked up in recent months as new sites have opened. Study sites now include seven locations in France and six in Germany and the company announced in December 2021 the first implantation at Moorfields Eye hospital in London, UK, and it expects to add additional sites in Spain, the Netherlands and Italy in H122.

Assuming no significant new COVID-19 restrictions affect the European study sites, we are confident that Pixium can meet its guidance of enrolment completion by year-end FY22. We maintain our estimate that primary 12-month data will be released in late 2023 or early 2024, leading to CE Mark submission in H124 and European approval in H125. We continue to anticipate that a separate study will be needed for US approval and continue to assume that the US launch will occur in H226. We believe that Pixium remains in discussions with US regulatory authorities to explore the possibility of conducting this US study in parallel with the European pivotal trial which, if accepted by the FDA, could lead to a US launch earlier than our baseline estimate of H226.Our overall sales forecasts in local currency terms are unchanged and as highlighted in our prior note.

Financials and valuation

We have made very minor adjustments to our FY22 estimates, as we have slightly increased our G&A and R&D expectations by €0.2m each following the FY21 results, to €4.2m and €7.4m, respectively. We now estimate net operating cash burn rates of €8.2m and €18.5m for FY22 and FY23, respectively, up from our prior forecasts of €8.0m and €18.4m.

We believe Pixium's gross cash on hand (€14.5m) should be sufficient for it to maintain its operations and fund its Prima development plants into 2023. We continue to expect that the company will raise €44m (modelled as illustrative debt) by year-end 2025, to complete the PRIMAvera study and all EU-related regulatory and preparatory commercial activities to bring Prima to commercial launch. As part of this funding assumption, we assume the company will raise €12.5m by year-end 2022.

Our valuation of 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	562.1	25%	131.0	2.24	H125	474
Prima (net of R&D and SG&A costs) in US market	Age-related macular degeneration with geographic atrophy	Human feasibility trials	420.1	20%	81.7	1.40	H226	490
Net capex, NWC & taxes (global)			(363.4)		(82.7)	(1.41)		
Total			618.8		130.0	2.22		
Net cash (Q421e)			5.1		5.1	0.09		
Total equity value			623.9		135.1	2.31		
Basic shares outstanding (000s)			58,490					

Source: Edison Investment Research

After rolling forward our estimates and making minor adjustments to our model (including adjusting our forex assumptions to $1.10/€ from $1.13/€ previously), we obtain a pipeline rNPV of €130.0m (vs €115.1m previously). After adding €5.1m in Q421e net cash, we obtain an equity value of

€135.1m, or €2.31 per basic share (vs €2.11 previously). Assuming full exercise of the July 2021 warrants, our fully diluted equity valuation would be €2.24 per share (versus €2.06 previously).

Below we provide a sensitivity analysis demonstrating how our basic per-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%	1.15	1.25	1.35	1.45	1.55
20.0%	1.57	1.70	1.83	1.96	2.09
25.0%	1.98	2.15	2.31	2.47	2.64
30.0%	2.40	2.60	2.79	2.99	3.19
35.0%	2.82	3.05	3.28	3.51	3.74

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	2021	2022e	2023e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	1,598	1,782	2,092	2,655	1,600	800
Cost of Sales	(41)	0	0	0	0	0
General & Administrative	(2,019)	(3,572)	(4,008)	(5,084)	(4,200)	(5,210)
Research & Development	(5,297)	(6,563)	(5,704)	(7,282)	(7,400)	(9,400)
EBITDA	(5,758)	(8,352)	(7,620)	(9,712)	(10,000)	(13,810)
Depreciation	(677)	(448)	(366)	(549)	(429)	(325)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(6,435)	(8,801)	(7,986)	(10,261)	(10,429)	(14,135)
Exceptionals	(5,859)	(69)	(448)	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(12,294)	(8,870)	(8,434)	(10,261)	(10,429)	(14,135)
Net Interest	(1,277)	(1,006)	(699)	(790)	(1,043)	(2,052)
Profit Before Tax (norm)	(7,712)	(9,806)	(8,685)	(11,051)	(11,472)	(16,187)
Profit Before Tax (FRS 3)	(13,571)	(9,876)	(9,133)	(11,051)	(11,472)	(16,187)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(7,712)	(9,806)	(8,685)	(11,051)	(11,472)	(16,187)
Profit After Tax and minority interests (FRS 3)	(13,571)	(9,876)	(9,133)	(11,051)	(11,472)	(16,187)
Average Number of Shares Outstanding (m)	18.5	22.3	34.0	48.2	59.0	59.7
EPS - normalised (€)	(0.42)	(0.44)	(0.26)	(0.23)	(0.19)	(0.27)
EPS - normalised and fully diluted (€)	(0.42)	(0.44)	(0.26)	(0.23)	(0.19)	(0.27)
EPS - (IFRS) (€)	(0.73)	(0.44)	(0.27)	(0.23)	(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	2,783	2,398	2,093
Intangible Assets	2,623	2,361	1,727	1,534	1,534	1,534
Tangible Assets	1,042	2,145	1,684	1,250	864	559
Current Assets	17,756	9,107	12,721	17,842	22,052	15,366
Short-term investments	0	0	0	0	0	0
Cash	15,629	6,792	10,566	14,505	18,721	12,123
Other	2,126	2,316	2,155	3,337	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)	(8,055)	(20,555)	(32,429)
Long term borrowings	(7,870)	(5,787)	(6,695)	(7,036)	(19,536)	(31,410)
Other long-term liabilities	(153)	(1,246)	(1,157)	(1,019)	(1,019)	(1,019)
Net Assets	11,355	3,700	4,485	7,624	(3,351)	(19,031)
CASH FLOW						
Operating Cash Flow	(6,174)	(7,282)	(6,207)	(8,039)	(7,197)	(16,401)
Net Interest	(1,277)	(1,006)	(699)	(790)	(1,043)	(2,052)
Tax	0	0	0	0	0	0
Net Operating Cash Flow	(7,450)	(8,288)	(6,906)	(8,829)	(8,240)	(18,452)
Capex	(31)	(34)	(82)	(48)	(44)	(20)
Acquisitions/disposals	0	0	0	0	0	0
Financing	14,068	2,034	9,055	13,170	0	0
Net Cash Flow	6,587	(6,288)	2,067	4,293	(8,284)	(18,472)
Opening net debt/(cash)	(1,401)	(7,760)	(1,004)	(3,336)	(5,075)	3,209
HP finance leases initiated	0	0	0	0	0	0
Other	(228)	(468)	264	(2,553)	0	0
Closing net debt/(cash)	(7,760)	(1,004)	(3,336)	(5,075)	3,209	21,681
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)	(3,935)	4,349	22,822

Source: Company reports, Edison Investment Research

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