Pixium Vision

Financial update

Wrapping up 2019 with a solid financial position

Healthcare equipment & services

19 February 2020

Pixium Vision's 2019 results showed better than anticipated cost containment, as Pixium's R&D costs were c 20% lower than expected. The company also reaffirmed that it plans to file for a pivotal study (PRIMAVERA) in mid-2020 and start implantations before YE20. We anticipate potential launches in 2023 in Europe and sometime thereafter in the US, and our rNPV increases to €85m, from €78m previously.

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	1.6	(10.0)	(0.40)	0.0	N/A	N/A
12/21e	1.6	(13.9)	(0.56)	0.0	N/A	N/A

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

Data on second-generation system expected shortly

Patients in both the European and US Prima feasibility trials will be using the second-generation augmented reality (AR) glasses and second-generation pocket computer software and analytics. These transparent AR glasses allow for the combination of both prosthetic vision and natural residual vision, and the second-generation pocket computer software provides improved algorithms, designed to incorporate more advanced image processing and artificial intelligence functionality. Pixium states that preliminary results are encouraging and initial functional data using the second-generation system are expected in Q120.

PRIMAVERA pivotal study to start in H220

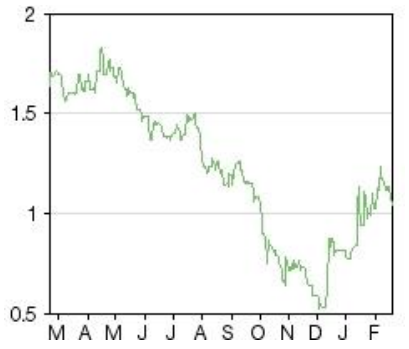
Pixium continues to intend to file for approval to start a pivotal study in European sites in mid-2020, and it expects the first implantations to occur before YE20. The firm's preferred objective would be to harmonise study design requirements between the FDA and European regulators so it can combine facilities from Europe and the US into a single pivotal trial that would satisfy registration requirements in both territories. Discussions with regulatory authorities towards this objective are ongoing. We believe that 12 months of safety and efficacy data from the pivotal study can form the basis of a European market filing, leading to potential CE Mark and European launch in 2023.

Valuation: rNPV increases to €85m

After modestly reducing our cost assumptions and rolling forward our estimates, we obtain a pipeline rNPV (enterprise value, excluding net cash) of €85.1m, versus €78.1m previously. After including €1.0m in net cash at 31 December 2019, we obtain an equity valuation of c €86.1m, or €3.46 per share. Given the reduction in our expenditure forecasts, our base case now assumes that Pixium will need to raise €50m (including the remaining or unused €8.75m in tranches from the ESGO funding facility) to bring Prima to launch (in 2023), versus our prior estimate of €60m. We model that the company will raise €25m in illustrative debt in both 2020 and 2021.

Price	**€1.04**
Market cap	**€26m**
	$1.08/€
Net cash (€m) at 31 December 2019	1.0
Shares in issue	24.9m
Free float	54%
Code	PIX
Primary exchange	Euronext Growth
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	10.5	46.5	(36.0)
Rel (local)	10.6	42.5	(45.3)

52-week high/low	€1.83	€0.53

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 firm completed five implantations in an EU feasibility study and recently began implantations in a US feasibility study.

Next events

Preliminary data on second-generation system	March 2020
Pivotal study filing	Mid-2020

Analysts

Pooya Hemami, CFA +1 646 653 7026

Maxim Jacobs, CFA +1 646 653 7027

healthcare@edisongroup.com

Edison profile page

Better than expected cost containment

Pixium Vision reported its 2019 financial results on 13 February 2020, which showed better than anticipated cost containment, as Pixium's R&D costs (excluding amortisation and depreciation) were c 20% lower than expected, slightly offset by c 18% higher than anticipated SG&A costs. The R&D costs were largely attributable to study costs for the ongoing European Prima feasibility studies (and preparation for the US feasibility study, for which the first implantation occurred in January 2020) as well as for the design and development of the second-generation (transparent) augmented reality (AR) external glasses used as part of the Prima system. SG&A costs in 2019 also included an exceptional one-time cost of €0.56m linked to the leaving cost of its former CEO in May 2019.

Altogether, the 2019 operating loss (excluding one-time items) was €8.8m, lower than our €9.7m loss estimate. Operating cash burn (excluding net interest costs) was €7.3m, lower than our €10.2m forecast.

Exhibit 1: Pixium Vision 2019 results

€000s (except where stated)	2019	2019e	Difference (%)	2018	Difference y-o-y (%)
Revenues					
Research tax credits, grants and subsidies	1,724	1,809	(4.7)	1,559	10.6
Other revenue	58	47	23.4	39	49.5
Total Revenues	1,782	1,856	(3.9)	1,598	11.5
Cost of goods sold	0	0	N/A	(41)	(100.0)
R&D Costs	(6,320)	(7,880)	(19.8)	(5,297)	19.3
SG&A Costs	(3,815)	(3,223)	18.4	(2,019)	89.0
EBITDA	(8,352)	(9,247)	(9.7)	(5,758)	45.0
Depreciation & Amortization	(448)	(478)	(6.1)	(677)	(33.8)
Operating income	(8,801)	(9,725)	(9.5)	(6,435)	36.8
Impairments and other one-time items	(69)	0	N/A	(5,859)	(98.8)
Net financial expenses	(1,006)	(749)	34.2	(1,277)	(21.2)
PBT	(9,876)	(10,474)	(5.7)	(13,571)	(27.2)
Tax expense	0	0	N/A	0	N/A
Net income	(9,876)	(10,474)	(5.7)	(13,571)	(27.2)
Reported EPS (€)	(0.44)	(0.46)	(3.4)	(0.73)	(39.7)
Adjusted EPS (€)	(0.44)	(0.46)	(4.0)	(0.42)	5.4
Year-end cash position	6,792	5,165	31.5	15,629	(56.5)
Year-end net cash/(debt)	1,004	(2,955)	(134.0)	7,760	(87.1)
Operating cash flow excluding net interest costs	(7,282)	(10,227)	(28.8)	(6,174)	18.0
Free cash flow	(8,322)	(11,930)	(30.2)	(7,481)	11.2

Source: Pixium Vision reports, Edison Investment Research

On the financing front, Pixium announced in November 2019 an agreement with a US-based investor, European Select Growth Opportunities Fund (ESGO), for the issue of up to €10m in 12-month bonds repayable in cash and/or new shares, over a period of up to 30 months. The first bond tranche (€1.25m) was issued on 6 November and has since been fully converted to common shares. As a result of this conversion to equity, and due to lower than expected 2019 cash burn, the company's net cash position at YE19 was €1.0m (€6.8m gross cash offset by €2.6m in refundable advances and €3.2m in long-term debt), compared to our prior estimate of a net debt position of €3.0m.

Initial data on second-generation Prima expected in Q120

Patients in the ongoing, five-patient European Prima feasibility trial started to be transitioned in H219 to use the second-generation AR glasses and second-generation pocket computer software and analytics. These transparent AR glasses allow for the combination of both prosthetic vision and

natural residual vision, and the second-generation pocket computer software provides improved algorithms, designed to incorporate more advanced image processing and artificial intelligence functionality to enhance the visual experience of patients implanted with the current-generation 378-electrode Prima chip. In addition, all patients in the ongoing five-patient US feasibility study will be using the second-generation AR glasses and pocket computer software (along with the 378-electrode Prima chip). Pixium states that preliminary results are encouraging and initial functional data using the second-generation system are expected in Q120. Implantations for the US feasibility study are also expected to be completed in H120.

PRIMAVERA pivotal study to begin in H220

Pixium continues to intend to file for approval to start a pivotal study (now called PRIMAVERA) at least in European sites in mid-2020, and it expects the first implantations to occur before YE20. Pixium's preferred objective would be to harmonise study design requirements between the FDA and European regulators so it can potentially combine data and facilities from Europe and the US into a single pivotal trial that would satisfy registration requirements in both territories. Discussions with both the FDA and European regulatory authorities are ongoing towards this objective and in a best case scenario, Pixium could potentially receive approval from both agencies in 2020 for a combined pivotal programme covering both EU and US sites. We estimate that a single registration-enabling trial would involve approximately 70 implantations in total across both regions.

However, our base case continues to assume that European and US pivotal studies will be separate and that European market registration and launch will occur earlier than US approval. We anticipate the European pivotal programme (PRIMAVERA) will seek to recruit about 50 patients across multiple European sites, at a study cost of c €10–12m over three years. We believe this will satisfy European regulatory authorities' requirements for CE mark approval, and continue to model that 12 months of safety and efficacy data from the pivotal study can form the basis of a European filing, leading to potential European launch in 2023. We model there will be a separate US pivotal study programme starting in 2021, potentially leading to US launch in 2025, and that the US pivotal study will cost c €10–13m.

If US and European regulators agree to a single pivotal study design containing sites in Europe and the US and satisfying both agencies' regulatory requirements, we estimate that this could potentially bring forward the US launch to H223, and would increase the PRIMAVERA study size from an estimated 50 patients to approximately 70.

Financials and valuation

As stated previously, the company finished 2019 with a stronger than expected net cash position. As implantations for the PRIMAVERA pivotal study are expected to start in H220 and we believe the recruitment pace will be modest at first, we do not expect the company's R&D costs and overall cash burn rate to increase significantly in 2020. As EU pivotal study recruitment picks up in 2021 (and as a potential US study begins), we expect these costs to increase in that year.

Given the company's reported results, we have made some modifications to our expenditure assumptions. We now assume R&D expenses of €6.7m in 2020 and €8.5m in 2021, respectively, versus our prior estimates of €9.1m and €12.1m, respectively. We have reduced our 2020 and 2021 operating cash burn rates to €8.0m and €10.6m, respectively, versus our prior estimates of €9.9m and €12.9m, respectively.

Given the reduction in our expenditure forecasts, our base case now assumes that Pixium will need to raise €50m (including the remaining or unused €8.75m in tranches from ESGO funding facility) to bring Prima to launch (in 2023), versus our prior estimate of €60m. We model that the company will

raise €25m in illustrative debt in both 2020 and 2021. We are now also publishing our 2022 financial estimates.

Exhibit 2: Pixium Vision rNPV assumptions

Product contributions (net of R&D and marketing costs)	Indication	Status	rNPV (€m)	rNPV/ share (€)	Probability of success	Launch year	Peak WW sales (€m)
Prima (net of R&D and marketing costs)	Age-related macular degeneration with geographic atrophy	Human feasibility trials	163.0	6.55	15.00%	2023 (EU) and 2025 (US)	1,102 in 2029
G&A expenses			(21.8)	(0.88)			
Net capex, NWC & taxes			(56.1)	(2.25)			
Total rNPV			85.1	3.42			
Net cash/(debt) (Q419)			1.0	0.04			
Total equity value			86.1	3.46			
FD shares outstanding (000s), 7 February 2020 data			24,903				

Source: Edison Investment Research

We continue to value Pixium using an rNPV approach, employing a 12.5% cost of capital. Our valuation is based solely on the Prima opportunity in dry-AMD. We continue to apply a probability of success estimate for Prima-AMD in our model of 15% and we now assume an FX rate, for US sales, of $1.08/€ (versus $1.11/€ previously). After rolling forward our estimates and adjusting our cost assumptions as described above, we obtain a pipeline rNPV (enterprise value, excluding net cash) of €85.1m versus €78.1m previously.

After including €1.0m in net cash at 31 December 2019, we obtain an equity valuation of c €86.1m, or €3.46 per share (unchanged, as the higher total valuation is offset by increased shares outstanding).

Exhibit 3: Financial summary

€000s	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	1,600	1,600	1,600
Cost of Sales	(1,124)	(41)	0	0	0	0
General & Administrative	(5,324)	(2,019)	(3,815)	(3,200)	(3,280)	(4,162)
Research & Development	(7,817)	(5,297)	(6,320)	(6,700)	(8,500)	(9,900)
EBITDA	(11,731)	(5,758)	(8,352)	(8,300)	(10,180)	(12,462)
Depreciation	(936)	(677)	(448)	(449)	(531)	(639)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(12,666)	(6,435)	(8,801)	(8,749)	(10,711)	(13,101)
Exceptionals	0	(5,859)	(69)	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(12,666)	(12,294)	(8,870)	(8,749)	(10,711)	(13,101)
Net Interest	(876)	(1,277)	(1,006)	(1,296)	(3,208)	(4,312)
Profit Before Tax (norm)	(13,542)	(7,712)	(9,806)	(10,045)	(13,918)	(17,413)
Profit Before Tax (FRS 3)	(13,542)	(13,571)	(9,876)	(10,045)	(13,918)	(17,413)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(13,542)	(7,712)	(9,806)	(10,045)	(13,918)	(17,413)
Profit After Tax and minority interests (FRS 3)	(13,542)	(13,571)	(9,876)	(10,045)	(13,918)	(17,413)
Average Number of Shares Outstanding (m)	13.3	18.5	22.3	25.0	25.1	25.2
EPS - normalised (€)	(1.02)	(0.42)	(0.44)	(0.40)	(0.56)	(0.69)
EPS - normalised and fully diluted (€)	(1.02)	(0.42)	(0.44)	(0.40)	(0.56)	(0.69)
EPS - (IFRS) (€)	(1.02)	(0.73)	(0.44)	(0.40)	(0.56)	(0.69)
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	4,457	4,151	3,555
Intangible Assets	7,680	2,623	2,361	2,361	2,361	2,361
Tangible Assets	1,970	1,042	2,145	2,096	1,789	1,194
Current Assets	14,241	17,756	9,107	24,489	35,420	18,996
Short-term investments	0	0	0	0	0	0
Cash	10,532	15,629	6,792	22,092	33,023	16,599
Other	3,710	2,126	2,316	2,398	2,398	2,398
Current Liabilities	(2,752)	(2,044)	(2,880)	(2,880)	(2,037)	(2,037)
Creditors	(2,752)	(2,044)	(2,880)	(2,880)	(2,037)	(2,037)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(9,302)	(8,023)	(7,033)	(32,033)	(57,033)	(57,033)
Long term borrowings	(9,130)	(7,870)	(5,787)	(30,787)	(55,787)	(55,787)
Other long term liabilities	(172)	(153)	(1,246)	(1,246)	(1,246)	(1,246)
Net Assets	11,836	11,355	3,700	(5,967)	(19,499)	(36,519)
CASH FLOW						
Operating Cash Flow	(10,605)	(6,174)	(7,282)	(8,004)	(10,637)	(12,068)
Net Interest	(876)	(1,277)	(1,006)	(1,296)	(3,208)	(4,312)
Tax	0	0	0	0	0	0
Capex	(191)	(31)	(34)	(400)	(224)	(44)
Acquisitions/disposals	0	0	0	0	0	0
Financing	519	14,068	2,034	0	0	0
Net Cash Flow	(11,153)	6,587	(6,288)	(9,700)	(14,069)	(16,424)
Opening net debt/(cash)	(12,911)	(1,401)	(7,760)	(1,004)	8,696	22,764
HP finance leases initiated	0	0	0	0	0	0
Other	(357)	(228)	(468)	0	0	0
Closing net debt/(cash)	(1,401)	(7,760)	(1,004)	8,696	22,764	39,189

Source: Company accounts, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia