EDISON

Pixium Vision

Clinical trial update

Building feasibility data on way to pivotal study

Healthcare equipment & services

28 October 2019

Patients in the ongoing, five-patient European feasibility trial on Prima are starting to use the second-generation Prima 2 glasses, which may further enhance the visual experience of patients implanted with the current 378-electrode Prima chip. Initial implantations for the US feasibility study are anticipated shortly. Data accumulated from these studies should help inform the pivotal study programme, expected to start in mid-2020. We obtain an equity valuation of €78m (vs €76m previously).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	2.5	(13.5)	(1.02)	0.0	N/A	N/A
12/18	1.6	(8.1)	(0.44)	0.0	N/A	N/A
12/19e	1.9	(11.0)	(0.49)	0.0	N/A	N/A
12/20e	1.6	(14.4)	(0.64)	0.0	N/A	N/A

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

Feasibility data on Prima 2 expected in H120

We believe that functional data on the EU patients using the new Prima 2 glasses could be available in H120. Before starting a pivotal study, Pixium prefers to have results on hand from feasibility studies with the upgraded Prima system (ie whether the new analytics and other features from Prima 2 glasses will improve visual functionality and quality of life parameters; the actual 378-electrode Prima implant chip has not changed). The company believes that having such data would raise the likelihood of success in the pivotal programme.

Potential simplification of US regulatory pathway

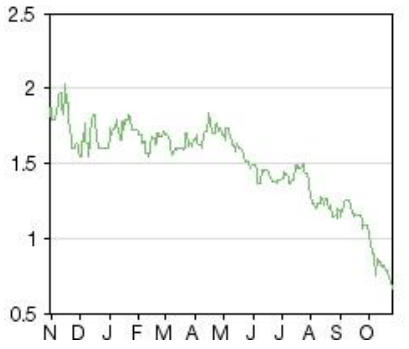
Pixium has had productive discussions with the FDA in recent months and no longer believes that a separate US pilot study is required as part of the regulatory pathway. That is, following the current US feasibility study, it anticipates its next trial involving US centres to be a registration-enabling pivotal study. Pixium intends to start a pivotal study in European sites by mid-2020, and its preferred objective would be to harmonise study design requirements between the FDA and European regulators such that it can combine trial sites from Europe and the US into a single pivotal study that would satisfy registration requirements in both territories. This could potentially result in initial US implantations for the US portion of a pivotal trial before year-end 2020, which would bring our US launch estimate forward to H223. Our base case assumes launches in 2023 in the EU and 2025 in the US.

Valuation: Slight uplift of equity valuation to €78m

We believe Pixium's cash on hand should be sufficient for it to maintain its operations into Q220, and we estimate that it will raise €65m (vs €83m previously due to lower expected future costs) through 2021 to fund Prima development. We model this as debt financing. We obtain a €78m rNPV valuation that, after adjusting for €0.1m Q319 estimated net debt, translates to a similar equity valuation, or €3.46 per share (vs €3.39 previously). If US and EU sites can be combined into a common pivotal study, bringing the US launch forward to H223, this could add €0.97 per share to our equity valuation.

Price	**€0.66**
Market cap	**€15m**
	$1.11/€
Net cash (€m) at 30 June 2019	3.4
Shares in issue	22.6m
Free float	49%
Code	PIX
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(37.6)	(54.2)	(61.3)
Rel (local)	(39.2)	(55.3)	(65.5)
52-week high/low		€2.03	€0.66

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 has completed a human feasibility study in Europe and expects to start implantations in a US feasibility study in Q419.

Next events

Start US feasibility study implantations	Q419
Initial feasibility data on Prima 2 system	H120

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Edison profile page

Feasibility studies using Prima 2 glasses on track

As stated in our 6 August 2019 update note, Pixium is starting feasibility studies in both the EU and the US on its second-generation Prima system (employing the Prima 2 glasses) in patients with advanced dry-AMD with geographic atrophy (GA). As a reminder, the Prima system consists of the implanted sub-retinal chip as well as a specialised pair of augmented reality (AR) eyeglasses, whereby each photovoltaic pixel (on the implant) is independently controlled and self-powered by near-infrared light projected from glasses worn by the patient (the glasses consist of a camera and digital mirror projector, which emit a near-infrared light pattern through the patient's eye carrying the Prima implant, designed to be processed by the Prima implant's pixels/electrodes). The Prima 2 glasses are a second-generation version of the AR glasses and, in combination with a new pocket computer employing improved algorithms, designed to incorporate more advanced image processing and artificial intelligence functionality to enhance the visual experience of patients implanted with the current 378-electrode Prima chip. We believe the Prima 2 glasses should enable implanted dry-AMD patients to better combine both prosthetic and natural residual (ie peripheral) vision.

As a reminder, in late 2017, Pixium started the five-patient, single-site, 36-month European feasibility study for its Prima device in patients with advanced dry-AMD and reported positive 12-month data in July 2019. Pixium applied for an amendment to its ongoing EU feasibility study to enable the patients (already enrolled and implanted with the Prima chip) to now use the second-generation Prima 2 glasses instead of the first-generation glasses (which they had been using up until this point). The company has received the requisite regulatory approvals for the amendment and is in the process of transitioning the five EU patients to start using the Prima 2 glasses and then undergo the necessary rehabilitation/training for using the device. We believe that functional data on the EU patients using the new Prima 2 glasses could be available in H120. Before starting a pivotal study, Pixium prefers to have results on hand from feasibility studies with the upgraded Prima system (ie whether the new analytics and other improvements from Prima 2 will improve visual functionality and quality of life parameters). It believes that having such data would raise the likelihood of success in the pivotal programme.

The five-patient US feasibility study being conducted at the University of Pittsburgh Medical Center and at Bascom Palmer Eye Institute (Miami, Florida) will also employ the Prima 2 glasses. Efforts to recruit eligible patients have accelerated in recent months, in conjunction with the FDA relaxing some of the inclusion criteria, and management expects the first implantations to occur before year-end 2019.

Possibility of streamlined US regulatory pathway

Pixium has had productive discussions with the FDA in recent months regarding the eventual pathway towards US registration for Prima and, according to management, there is a potentially clearer regulatory pathway than previously. Previously, the company had disclosed that to achieve US regulatory approval, it would require three US clinical trials: first, a small (n=5) feasibility trial (like the current one underway), followed by a medium-size (approximately 20–40 patients) US pilot study, and finally, a registration-enabling pivotal study. Given the progress of recent talks with regulators and the potential to use some of the clinical data from the European trials, Pixium no longer believes that a separate US pilot study is required as part of the regulatory pathway. That is, following the current US feasibility study, it anticipates its next study involving US study centres to be a registration-enabling pivotal study.

Pixium intends to start a pivotal study in European sites by mid-2020, and its preferred objective would be to harmonise study design requirements between the FDA and European regulators such

that it can combine facilities from Europe and the US into a single pivotal trial that would satisfy registration requirements in both territories. This could potentially result in initial US implantations for the US portion of a pivotal study before year-end 2020. The company plans to discuss steps with regulators in the coming months to work towards this unified regulatory approach, and the best-case scenario would be a single registration-enabling trial (which we estimate would involve between 50 and 70 implantations in total across both regions). If it encounters challenges in obtaining agreement for this unified study approach, Pixium will at minimum start the European portion of the pivotal programme by mid-2020 and finalise the appropriate mechanism(s) for US registration afterwards.

Maintaining current US launch timing forecasts for now

While there is the possibility that a single pivotal study programme involving both US and European sites (and potentially enabling registration in both regions) may begin in 2020, our base case continues to assume that European market registration and launch will occur earlier than US approval. We await further clarity on the US registration process over the coming months before revising our assumptions.

Hence, our base case assumes the EU pivotal study may require 40–50 patients and will require 12 months of follow-up safety and efficacy data for European regulators to provide CE mark approval. We estimate that 12-month data from the EU pivotal study will be available in H122, leading to potential EU commercialisation (CE mark approval) in 2023. Our base case assumes a separate US pivotal study programme starting in 2021, leading to US launch in 2025.

If 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 bring forward the US launch to H223.

Financials

Pixium recently reported its 30 September 2019 gross cash position of €7.0m (down from €10.2m on 30 June 2019) and its 9M19 operating cash burn rate of €7.7m. The burn rate is up from €5.2m in 9M18, due to increased clinical product expenses and a delay in the receipt of a research tax credit compared to the prior year, where a €2.1m payment was received in Q318. Pixium expects to receive a €1.3m research tax credit in Q419.

We calculate €3.4m in H119 net cash after adjusting H119 gross cash with €6.87m of gross debt (€2.49m in refundable advances and a €4.38m venture loan). We excluded €1.48m in short- and long-term lease debt (included on reported balance sheet as per IFRS 16) from our company debt calculations as it does not have an immediate cash impact. A full balance sheet was not provided for Q319, so we estimate Q319 net debt at €0.1m. We believe that Pixium's current funds on hand should be sufficient for the company to maintain its operations and fund its Prima strategy into Q220.

Following the recent Q319 financials and discussions with management, we have reduced our near-term expense forecasts and have also now included R&D grants and tax credits in our 2020 and 2021 forecasts. We continue to expect R&D costs (related to the EU pivotal study) to increase in 2020 and further in 2021 as recruitment for the study reaches completion, but we have lowered our overall cost estimates. We now assume R&D expenses of €9.1m in 2020 and €12.1m in 2021, respectively, versus our prior estimates of €13.0m and €18.0m, respectively. We have reduced our 2019, 2020, and 2021 operating cash burn rates to €10.2m, €9.9m, and €12.9m, respectively, versus our prior estimates of €10.4m and €15.8m and €20.9m, respectively. These estimates largely depend on the size of the upcoming pivotal study (or studies); we currently model a 40- to

50-patient European study to start in mid-2020 and a separate 50- to 60-patient US pivotal study to start in 2021.

We expect that Pixium will seek to raise funds in Q419 or Q120, in order to expand its financial runway to fund the EU pivotal study. Our model continues to estimate that Pixium will raise €20m in Q419, but we have reduced our 2020 and 2021 funding requirement assumptions to €25m and €20m, respectively, versus our prior estimates of €30m and €33m, respectively. As per Edison's usual policy, our model assumes these sources will be in debt. We forecast that this funding should enable Pixium to complete the registration-enabling Prima clinical studies in the EU to reach commercialisation in Europe. In addition, positive cash flows resulting from EU sales should enable the completion of the US pivotal study. We continue to assume that Pixium will only start to become cash flow positive on a sustainable basis once Prima is launched (in 2023).

In the event that Pixium would only require a single (assumed n=70) pivotal study to satisfy the requirements of both European and US regulators, our funding requirement assumptions for 2019 and 2020 would be similar, but we estimate that Pixium would then only need to raise €7.5m in 2021 (instead of €20m).

Valuation

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 $1.11/€ (versus $1.12/€ previously). We obtain a pipeline rNPV (enterprise value, excluding net cash) of €78.3m versus €74.1m previously.

After including €0.1m in estimated net debt at 30 September 2019, we obtain an equity valuation of c €78.2m, or €3.46 per share (versus €3.39 previously).

Exhibit 1: 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	150.9	6.68	15.00%	2023 (EU) and 2025 (US)	1,102 in 2029
Corporate costs & expenses							
G&A expenses			(16.6)	(0.73)			
Net capex, NWC & taxes			(56.0)	(2.48)			
Total rNPV			78.3	3.46			
Net cash (debt) (Q319e)			(0.1)	(0.00)			
Total equity value			78.2	3.46			
FD shares outstanding (000s) (31 August 2019 data)			22,606				

Source: Edison Investment Research

The above valuation reflects our base-case assumption of separate clinical pivotal study programmes for the US and Europe, resulting in respective launches in 2023 and 2025, respectively. In the event that study data from both US and European sites can be combined into a common registration-enabling programme for both territories, thus bringing forward the US launch to H223, this would result in an uplift of our pipeline rNPV valuation by €22.1m to €100.4m. This would result in an equity valuation of €100.3m, or €4.43 per share.

Exhibit 2: Financial summary

€000	2016	2017	2018	2019e	2020e	2021e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	2,516	2,535	1,598	1,856	1,600	1,600
Cost of Sales	(141)	(1,124)	(41)	0	0	0
General & Administrative	(2,953)	(5,324)	(1,508)	(3,223)	(2,400)	(2,460)
Research & Development	(10,869)	(7,817)	(6,184)	(7,880)	(9,050)	(12,100)
EBITDA	(11,448)	(11,731)	(6,135)	(9,247)	(9,850)	(12,960)
Depreciation	(1,051)	(936)	(677)	(478)	(515)	(930)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(12,499)	(12,666)	(6,812)	(9,725)	(10,365)	(13,890)
Exceptionals	0	0	(5,483)	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(12,499)	(12,666)	(12,294)	(9,725)	(10,365)	(13,890)
Net Interest	58	(876)	(1,277)	(1,288)	(4,036)	(6,560)
Profit Before Tax (norm)	(12,441)	(13,542)	(8,088)	(11,013)	(14,400)	(20,450)
Profit Before Tax (FRS 3)	(12,441)	(13,542)	(13,571)	(11,013)	(14,400)	(20,450)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(12,441)	(13,542)	(8,088)	(11,013)	(14,400)	(20,450)
Profit After Tax and minority interests (FRS 3)	(12,441)	(13,542)	(13,571)	(11,013)	(14,400)	(20,450)
Average Number of Shares Outstanding (m)	12.7	13.3	18.5	22.5	22.6	22.7
EPS - normalised (€)	(0.98)	(1.02)	(0.44)	(0.49)	(0.64)	(0.90)
EPS - normalised and fully diluted (€)	(0.98)	(1.02)	(0.44)	(0.49)	(0.64)	(0.90)
EPS - (IFRS) (€)	(0.98)	(1.02)	(0.73)	(0.49)	(0.64)	(0.90)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	10,184	9,649	3,666	5,073	6,959	8,053
Intangible Assets	8,205	7,680	2,623	2,527	2,527	2,527
Tangible Assets	1,979	1,970	1,042	2,546	4,432	5,526
Current Assets	17,405	14,241	17,756	26,340	35,152	33,707
Short-term investments	0	0	0	0	0	0
Cash	14,244	10,532	15,629	23,376	32,078	30,633
Other	3,161	3,710	2,126	2,964	3,074	3,074
Current Liabilities	(2,836)	(2,752)	(2,044)	(1,810)	(1,810)	(1,810)
Creditors	(2,836)	(2,752)	(2,044)	(1,810)	(1,810)	(1,810)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(1,505)	(9,302)	(8,023)	(28,266)	(53,266)	(73,266)
Long term borrowings	(1,333)	(9,130)	(7,870)	(26,870)	(51,870)	(71,870)
Other long term liabilities	(172)	(172)	(153)	(1,396)	(1,396)	(1,396)
Net Assets	23,248	11,836	11,355	1,337	(12,966)	(33,317)
CASH FLOW						
Operating Cash Flow	(11,188)	(10,605)	(6,174)	(10,227)	(9,862)	(12,861)
Net Interest	58	(876)	(1,277)	(1,288)	(4,036)	(6,560)
Tax	0	0	0	0	0	0
Capex	(148)	(191)	(31)	(415)	(2,400)	(2,024)
Acquisitions/disposals	0	0	0	0	0	0
Financing	(0)	519	14,068	923	0	0
Net Cash Flow	(11,279)	(11,153)	6,587	(11,007)	(16,298)	(21,445)
Opening net debt/(cash)	(24,190)	(12,911)	(1,401)	(7,760)	3,494	19,792
HP finance leases initiated	0	0	0	0	0	0
Other	(0)	(357)	(228)	(247)	0	(0)
Closing net debt/(cash)	(12,911)	(1,401)	(7,760)	3,494	19,792	41,237

Source: Pixium Vision accounts, Edison Investment Research

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