EDISON

Pixium Vision

H118 update

H118 update reflects continued Prima progress

Healthcare equipment & services

Pixium's Prima sub-retinal wireless implant continues to advance through human feasibility trials. The EU study recently reached full enrolment and a US study is slated to start implantations in Q318. Using a risk-adjusted NPV model, we obtain a pipeline rNPV of €90.6m, vs €77.4m previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	2.5	(12.4)	(0.98)	0.0	N/A	N/A
12/17	2.5	(13.2)	(1.00)	0.0	N/A	N/A
12/18e	2.2	(7.1)	(0.40)	0.0	N/A	N/A
12/19e	2.5	(17.1)	(0.83)	0.0	N/A	N/A

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

Prima EU feasibility reaches full enrolment

In late 2017, Pixium started the five-patient European feasibility study for its Prima sub-retinal device in advanced Dry-ARMD (dry age-related macular degeneration). On 10 July 2018, Pixium announced that it had completed the fifth and final implantation of the feasibility study and expected the final patient to have their device activated in the coming weeks. All of the four previous implantations in the study resulted in successful activations and light perception. These successful activations are encouraging as an early suggestion of proof-of-concept that the device can interface with retinal cells to restore some visual perception. Interim data from the EU study, which should include safety and some functional vision measures, are expected near the end of Q418. A five-patient US feasibility trial was opened recently and initial implantations are expected in Q318.

H118 results show cost containment

Pixium reported H118 results on 26 July 2018, which showed a significantly lower operating expense rate than the prior-year period, due largely to Pixium's decision to halt further development of its Iris II implant in order to focus its resources on the Prima device. Pixium reported a €3.57m operating loss (vs €5.27m in H117), and a €2.99m net loss (€0.20 per share), versus a €6.44m net loss in H117. Pixium's losses, and its R&D and G&A costs, were lower than we anticipated.

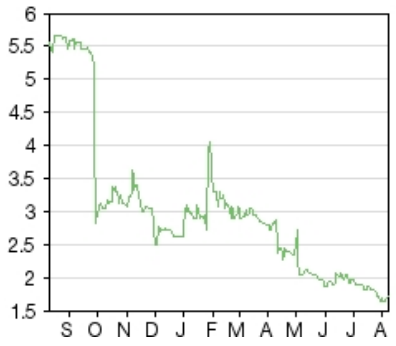
Valuation: €99.2m in equity, or €4.75 per share

Pixium raised €10.6m in equity through a shareholder rights offering in Q218, which we estimate will fund its operations at least through Q419. We continue to value Pixium using an rNPV approach, employing a 12.5% cost of capital, and applying a 15% probability of success estimate for Prima. After rolling forward our estimates, adjusting forex and reducing our G&A forecasts, we now obtain a pipeline rNPV (enterprise value) of €90.6m, up from €77.4m, previously. After including €8.5m in net cash at 30 June 2018 (€16.7m gross cash minus €8.2m in debt), we obtain an equity valuation of c €99.2m, or €4.75 per share (compared to €5.44 previously). The lower per-share valuation is also due to the increase in share count from our March 2018 outlook note, due primarily to the €10.6m financing described above, as well as exercises by Kepler Cheuvreux from its equity line of credit.

9 August 2018

Price	**€1.71**
Market cap	**€36m**
	$1.16/€
Net cash (€m) at 30 June 2018	8.5
Shares in issue	20.9m
Free float	49%
Code	PIX
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(9.2)	(16.7)	(67.6)
Rel (local)	(11.6)	(16.5)	(69.5)
52-week high/low		€5.3	€1.6

Business description

Pixium Vision develops bionic vision systems for patients with severe vision loss. Its lead product, Prima, a wireless sub-retinal implant system designed for Dry-ARMD, is already in human feasibility study in Europe and is expected to start implantations for a US feasibility study in Q318.

Next events

Start implantations for US feasibility study	Q318
Interim data from EU feasibility study	Q418

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H118 results show lower costs as Prima trials proceed

Pixium reported H118 results on 26 July 2018, which as expected, showed a significantly lower operating expense rate versus the prior-year period. Pixium disclosed in February 2018 that it was halting further development of its Iris II epi-retinal implant and that it would devote its resources and strategy entirely on advancing its next-generation Prima sub-retinal device, thereby reducing its operating cost spend level.

Pixium reported €0.91m in H118 revenue (primarily from subsidies and research tax credits), down from €1.26m in H117, a €3.57m in operating loss (vs €5.27m in H117), and a €2.99m net loss (€0.20 per share), versus a €6.44m net loss in H118. Pixium benefited from a €1.37m positive revaluation charge of its stock-based compensation expense in H118, which explains why its reported net loss was lower than its operating loss. Excluding this positive charge, the adjusted net loss would have been €4.36m (€0.30 per share).

Pixium's results compare favourably to our expectations of operating and net losses of €4.7m and €5.2m respectively. R&D (€3.05m) and G&A costs (€1.33m) were also both lower than our expectations. Operating cash flow was negative €5.49m, 21% lower than the negative €6.96m reported in H117.

EU feasibility study now reached complete enrolment

Prima is a miniaturised photovoltaic wireless sub-retinal implant that is implanted underneath the retina in a surgical procedure that may take less than 90 minutes under local anaesthesia. The device intends to replace the signal processing functions of photoreceptors damaged by degenerative conditions. It does so by electrically stimulating other healthy retinal cells, which would then transmit the information towards the brain via the optic nerve.

In late 2017, Pixium started the five-patient European feasibility study for its Prima photovoltaic wireless sub-retinal device advanced Dry-ARMD (Dry Age-related macular degeneration). On 25 January 2018, it announced the first human Prima activation as part of this feasibility study following a device implantation approximately one month previously (as per study protocol).

Following activation, the patient reported light perception in the central visual field, where there had been none previously, and proceeded to the visual re-education stage of the study (to improve interpretation of the elicited light signals emitted by Prima).

On 10 July 2018 Pixium announced that it has completed the fifth and final implantation of the feasibility study and that it expected the final patient to have his device activated in the coming weeks. All of the four previous implantations in the EU study resulted in successful consecutive activations and light perception, including the perception of white-yellow patterns with adjustable brightness, in areas where no central vision remained prior to implantation. The training and education programme, implemented as per the protocol, is intended to assist patients in interpreting the new light perception patterns. The firm indicates that results to date are in line with the theoretical and preclinical data and expectations. In our view, these successful activations are encouraging as an early suggestion of proof-of-concept that the device can interface with retinal cells to restore some visual perception in an area where vision had been lost due to prolonged degenerative disease. Interim data from the EU feasibility study, which should include safety and some functional vision measures, are expected near the end of Q418.

The firm also plans to present and discuss initial experiences of the involved surgical technique and observations from the Prima human implantations at upcoming retinal surgery and ophthalmology

conferences, including EURETINA and EVER in September 2018 in Europe, and the American Academy of Ophthalmology (AAO) annual meeting in October 2018 in Chicago.

US feasibility study to start implantations in Q318

A single centre five-patient US feasibility trial (PRIMA FS-US), conducted at the University of Pittsburgh Medical Center (UPMC), is actively recruiting and screening potentially eligible patients. The first implantations are expected in Q318. The primary endpoint will be elicitation of visual perception of the Prima device, while secondary endpoints will include visual acuity (VA), measured by methods such as ETDRS (Early Treatment Diabetic Retinopathy Study) and FrACT (Freiburg Visual Acuity & Contrast Test) scales. Management is confident that all five US patients will be implanted by YE18. As stated in our March 2018 outlook report, the firm believes that 12-month safety and performance data on all five patients will likely be sufficient for US regulators to allow a larger US (pilot) study to be started. We anticipate that study data from the US feasibility study would be available in H219 and that recruitment for the US pilot study can begin in H120 (vs our prior estimate of H219).

Review of clinical development timelines

Following attainment of six-month data from the EU feasibility study by YE18, Pixium's European regulatory strategy anticipates starting an EU pivotal study in H119. We estimate it will require 12 months of follow-up safety and efficacy data for European regulators to provide CE Mark approval. While CE Mark approval was attained for Pixium's Iris II epi-retinal implant using completed study data from only 10 implanted patients, Iris II was targeting a much more narrow rare/orphan disease market (retinitis pigmentosa and related rare dystrophies) and an existing predicate epi-retinal device (Argus II) had already been approved. For Prima, which is aiming to treat the demonstrably larger advanced Dry-ARMD market (we estimate late-stage ARMD's prevalence is over 6x higher than all-stage RP) and for which no comparable predicate device exists, we estimate that the EU pivotal study may require between 50-60 patients. However, the true size will not be known until the current EU feasibility study is completed, as the final recruitment size for the EU pivotal study will likely depend upon the safety and level of visual improvement shown within the EU feasibility study. We reiterate that generally, to obtain CE Mark approval, product safety is the primary consideration for regulators (CE Mark approval generally does not require demonstration of long-term clinical efficacy). We continue to estimate that EU pivotal study data will be available in early 2021, leading to potential EU commercialisation (CE Mark approval) in H122.

The US regulatory pathway for medical devices is more comprehensive. Our expectation is that following the attainment of 12-month data from the current US feasibility study, a larger US pilot study would need to be carried on a larger number of subjects (we estimate approximately 30 patients in total) prior to the start of a US pivotal study. As stated previously, we now estimate that US recruitment for this pilot study would start in H120.

Under an ideal scenario, Pixium could potentially also include data from sites participating in the EU pivotal trial as part of the US pilot study, which would reduce the need for duplicate or overlapping studies on similar patient populations. We assume this will be the case, thus allowing for the completion of the US pilot study in H121 (from H220, previously). We assume a US registration-enabling pivotal study would then start in 2021, which we believe will likely require 60-80 subjects and 18-24 months of follow up. Hence, we now assume the earliest possible date for US approval and launch will be 2024 (vs H223 previously).

Exhibit 1: Projected clinical development pathways for EU and US	
EU clinical pathway	**US clinical pathway**
Clinical studies needed	
1. Small-size (~5-patient) feasibility study	1. Medium-size (~30-patient) pilot study
2. Medium-size (~50-60-patient) pivotal trial	2. Larger (~60-80patient) pivotal trial
Projected characteristics and requirements for pivotal trial	
6-12 months of follow-up data	18-24 months of follow-up data
Study must show product safety	Study must show safety and efficacy
Projected commercial launch timeline	
H122	2024
Source: Edison Investment Research estimates	

We expect that CE Mark clearance (and EU launch) would occur approximately two years earlier than US pre-market approval (PMA) and launch.

€10.6m financing bolsters cash runway through 2019

Pixium announced a capital increase initiative through a shareholder rights issue first announced in April 2018, whereby existing shareholders were given rights to purchase up to three new shares for every eight held at a subscription price of €1.87 per share (a 35.07% discount to the closing price on 9 April 2018). As announced on 3 May 2018, the offer was fully subscribed as, although overall shareholder demand totalled €14.1m, the offer size was capped at €10.6m, thereby leading to the issue of 5.677m new shares (for €10.6m in gross proceeds). Pixium intends to use the proceeds from the offering towards further advancing its Prima bionic vision system through clinical development. More specifically, funds are being allocated to fund the ongoing five-patient European feasibility study, to prepare for the CE Mark-enabling European pivotal study and to support the US feasibility study.

Financials

Following the H118 results, which showed the firm was able to curtail its G&A costs, we have reduced our G&A expense forecasts. We now anticipate G&A costs of €1.97m and €1.94m in 2018 and 2019, versus our prior estimates of €3.50m and €3.59m, respectively. We expect R&D costs of €6.5m and €15.0m respectively in 2018 and 2019. R&D costs are expected to rise significantly y-o-y in 2019, given our view that costs for the EU Prima pivotal study will be significantly higher than the costs borne in 2018 for the feasibility trials.

While H118 G&A costs were lower than we had expected, net working capital (NWC)-related effects resulted in a larger H118 operating cash burn rate (€5.49m) than anticipated (€4.65m). While our working model had forecast NWC-related effects to provide a €0.9m source of cash in H118, Pixium in fact reported a €1.8m net use of cash from NWC-related effects in H118. Given the above, we now forecast 2018 and 2019 operating cash burn rates (excluding net interest) of €7.9m and €17.1m respectively, versus our prior estimates of €7.3m and €17.3m respectively.

Our financial model had previously anticipated that Pixium would raise €10m in debt in 2018 to fund its operations. With the recently completed €10.6m equity financing in Q218, we no longer forecast any additional funds (debt or equity) will need to be raised in 2018. We believe that gross cash and equivalents on hand (€16.7m as of 30 June 2018), and noting that Pixium has €8.2m total debt at H118, should be sufficient for Pixium to maintain its operations and fund its Prima strategy at least through Q419.

Our model continues to estimate that Pixium will raise €20m in 2019, €30m in 2020 and €25m in 2021. We forecast that all 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 2022).

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-ARMD. We continue to apply a probability of success estimate for Prima-ARMD in our model of 15%. We have also adjusted our forex assumptions for US sales, by using a spot rate of $1.16/€, vs $1.25/€ previously. As stated earlier we have reduced our G&A expense forecasts.

After rolling forward our estimates, we now obtain a pipeline rNPV (enterprise value) of €90.6m, up from €77.4m, previously. After including €8.5m in net cash at 30 June 2018 (€16.7m gross cash minus €1.6m in conditional advances and €6.6m in long-term debt), we obtain an equity valuation of c €99.2m, or €4.75 per share (compared to €5.44 previously). The lower per-share valuation is also due to the increase in share count from our 8 March 2018 research note, due primarily to the €10.6m financing described above, as well as exercises by Kepler Cheuvreux of the equity line of credit secured in October 2017 (as of 30 June 2018, 1.29m shares were purchased out of 2m allocated within the line). These effects increased shares outstanding to 20.896m at H118 (versus an estimated 14.5m shares in our previous note).

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	Human feasibility trials	171.2	8.19	15.00%	H122 (EU) and 2024 (US)	1,050 in 2028
Corporate costs and expenses							
G&A expenses			(18.4)	(0.88)			
Net capex, NWC & taxes			(62.2)	(2.98)			
Total rNPV			90.6	4.34			
Net cash/(debt) (Q218)			8.5	0.41			
Total equity value			**99.2**	**4.75**			
FD shares outstanding (000s) (Q218)			20,896				

Source: Edison Investment Research

Exhibit 3: Financial summary

€'000s	2015	2016	2017	2018e	2019e	2020e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	3,296	2,516	2,535	2,163	2,500	0
Cost of Sales	0	(141)	(1,254)	(37)	0	0
General & Administrative	(2,680)	(2,953)	(4,526)	(1,969)	(1,944)	(3,600)
Research & Development	(15,169)	(10,869)	(8,486)	(6,549)	(15,000)	(16,000)
EBITDA	(14,552)	(11,448)	(11,397)	(6,392)	(14,444)	(19,600)
Depreciation	(1,144)	(1,051)	(936)	(931)	(880)	(872)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(15,697)	(12,499)	(12,333)	(7,323)	(15,324)	(20,472)
Exceptionals	0	0	0	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(15,697)	(12,499)	(12,333)	(7,323)	(15,324)	(20,472)
Net Interest	52	58	(876)	236	(1,804)	(4,619)
Profit Before Tax (norm)	(15,644)	(12,441)	(13,208)	(7,087)	(17,129)	(25,091)
Profit Before Tax (FRS 3)	(15,644)	(12,441)	(13,208)	(7,087)	(17,129)	(25,091)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(15,644)	(12,441)	(13,208)	(7,087)	(17,129)	(25,091)
Profit After Tax and minority interests (FRS 3)	(15,644)	(12,441)	(13,208)	(7,087)	(17,129)	(25,091)
Average Number of Shares Outstanding (m)	12.7	12.7	13.3	17.5	20.6	20.1
EPS - normalised (€)	(1.23)	(0.98)	(1.00)	(0.40)	(0.83)	(1.25)
EPS - normalised and fully diluted (€)	(1.23)	(0.98)	(1.00)	(0.40)	(0.83)	(1.25)
EPS - (IFRS) (€)	(1.23)	(0.98)	(1.00)	(0.40)	(0.83)	(1.25)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	11,087	10,184	9,649	8,821	8,741	10,269
Intangible Assets	8,822	8,205	7,680	7,417	7,417	7,417
Tangible Assets	2,265	1,979	1,970	1,404	1,324	2,852
Current Assets	27,682	17,405	14,241	17,943	18,275	20,232
Short-term investments	0	0	0	0	0	0
Cash	24,354	14,244	10,532	14,350	14,683	16,640
Other	3,328	3,161	3,710	3,592	3,592	3,592
Current Liabilities	(3,498)	(2,836)	(2,752)	(2,030)	(807)	(807)
Creditors	(3,498)	(2,836)	(2,752)	(2,030)	(807)	(807)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(315)	(1,505)	(9,302)	(8,368)	(28,368)	(58,368)
Long term borrowings	(164)	(1,333)	(9,130)	(8,211)	(28,211)	(58,211)
Other long term liabilities	(151)	(172)	(172)	(157)	(157)	(157)
Net Assets	34,956	23,248	11,836	16,366	(2,159)	(28,675)
CASH FLOW						
Operating Cash Flow	(15,584)	(11,188)	(10,605)	(7,907)	(17,063)	(21,024)
Net Interest	52	58	(876)	236	(1,804)	(4,619)
Tax	0	0	0	0	0	0
Capex	(2,106)	(148)	(191)	(170)	(800)	(2,400)
Acquisitions/disposals	0	0	0	0	0	0
Financing	56	(0)	519	12,930	0	0
Net Cash Flow	(17,582)	(11,279)	(11,153)	5,089	(19,668)	(28,043)
Opening net debt/(cash)	(41,965)	(24,190)	(12,911)	(1,401)	(6,139)	13,528
HP finance leases initiated	0	0	0	0	0	0
Other	(193)	(0)	(357)	(351)	0	0
Closing net debt/(cash)	(24,190)	(12,911)	(1,401)	(6,139)	13,528	41,572

Source: Pixium accounts, Edison Investment Research

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