EDISON

Pixium Vision

Funding update

Raises up to €11m in debt to extend runway

Healthcare equipment & services

Pixium entered an agreement to issue up to €11m in bonds bearing 11.5% interest, with warrants for up to 207,817 shares. The funding should support the firm's Iris II and Prima vision restoration system programmes. Our rNPV, inclusive of estimated Q316 net cash, is €10.78 per share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	2.4	(11.6)	(1.18)	0.0	N/A	N/A
12/15	3.3	(15.6)	(1.23)	0.0	N/A	N/A
12/16e	2.9	(14.2)	(1.11)	0.0	N/A	N/A
12/17e	5.5	(15.3)	(1.20)	0.0	N/A	N/A

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

€11m debt financing extends cash runway into 2018

Pixium entered an agreement to issue up to €11m in 33-month bonds bearing 11.5% interest to Kreos Capital, with attached warrants for up to 207,817 new shares at a per-share subscription price of €5.2931. The funding should support the ongoing 10-patient European clinical trial of the Iris II epi-retinal implant in patients with retinitis pigmentosa (RP) and the firm's planned human study on its Prima sub-retinal implant in patients with age-related macular degeneration (ARMD). The financing is composed of two €4m tranches and an optional €3m tranche. Given that Pixium had H116 net cash of €16.1m and our projected operating 2016 and 2017 cash burn rates of €15.1m and €15.2m, respectively, we expect the facility, if fully drawn, should support operations into H118.

Prima feasibility study could start by YE16

Pixium recently completed preclinical thermal and electrical safety studies on Prima and has submitted a proposal to start human feasibility studies to regulators, and plans to commence the first in-human implantation by YE16. Given the preclinical success and its potential advantages vs Iris II (improved clarity and less invasive surgery), the firm is re-examining its strategy for its first US market approach. Pixium might delay initiating US clinical Iris II development for RP, and dedicate its US strategy and resources to advancing Prima first for the ARMD market.

Valuation: Risk-adjusted pipeline NPV of €125.5m

We have removed potential US Iris II sales from our forecasts. As we now only consider the EU market for Iris II, we have raised our Iris II success probability estimate to 70% (from 55%). We have also raised our Prima probability of success estimate to 12.5% (from 10%). As we no longer model US Iris II clinical trials, our R&D cost estimates for 2017 and 2018 are reduced by €7-8m. Our pipeline rNPV is €125.5m (from €132.3m previously). After including €12.2m estimated Q316 net cash, we obtain an equity valuation of €137.7m, or €10.78 per share. Beyond the announced €11m financing (which we estimate will be fully drawn by mid-2017), we assume Pixium will raise an additional €25m in 2017 and €20m in 2018. For illustrative purposes only, we added these requirements to long-term debt. Our model does not include the potential dilutive impacts of future equity offerings.

19 October 2016

Price	**€5.73**
Market cap	**€73m**

Net cash (€m) at 30 June 2016)	16.1
Shares in issue	12.8m
Free float	25.86%
Code	PIX
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(15.9)	(25.3)	(0.5)
Rel (local)	(18.6)	(28)	2.6
52-week high/low		€8.4	€4.5

Business description

Pixium Vision is a French medical device company developing retinal implants for patients with retinitis pigmentosa and macular degeneration. CE mark clearance was recently received on its initial product, Iris II. A sub-retinal implant, Prima, is also being developed simultaneously.

Next events

First in-human dosing (feasibility study) for Prima	H216
Start pivotal study for Prima	H217

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Edison profile page

€11m debt financing extends cash runway into 2018

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Iris II European human study continues to advance

The firm recently received approval from the Spanish Ministry of Health to enrol patients as part of the company's ongoing 10-patient clinical trial with the Iris II implant in patients with retinitis pigmentosa (RP). Barcelona's Institute of Ocular Microsurgery has joined other European Iris II study sites, including centres in France, Austria, Germany, and the UK (including Moorfields Eye Hospital). The company has implanted four patients thus far and is confident that it will complete recruitment before YE16. The study started in January 2016 and will assess the effectiveness of the device for at least 18 months. Interim data from the trial should further assist reimbursement applications in EU territories.

In parallel, the company is working with public reimbursement authorities, initially in France and Germany, to have preliminary or "conditional" Iris II reimbursement prior to the completion of the ongoing study. Under such a scenario, Pixium envisions that it can potentially obtain funding for a predetermined number of Iris II implantations, under the assumption that efficacy data will be collected from these treated patients, to support a more permanent form of state funding for the Iris II. Management believes it may receive decisions on potential conditional Iris II reimbursement from these territories in H117. We assume that such preliminary reimbursement will be achieved, as this drives our (unchanged) 2017 Iris II sales forecast of €2.5m.

Prima inching closer towards starting feasibility study by YE16

Animal model thermal[1] and electrical safety studies were recently completed and, according to management, successfully showed that the system meets the safety thresholds for thermal and electrical safety requirements for the eye. After completing these and other studies, the firm believes it has successfully completed all the required steps needed before first in-human testing for ARMD patients in Europe. It is also seeking to have the study investigators publish the Prima animal thermal and electrical safety data in a research paper or scientific seminar.

Pixium has submitted a proposed study protocol for a five-patient feasibility study in ARMD patients with French regulatory authorities. It hopes to have the first implantation competed by YE16 and potentially complete the feasibility trial by mid-2017. The firm could potentially start a registration-enabling, multi-centre pivotal EU Prima study for ARMD in H217.

As it relates to the US Prima opportunity, the company is scheduling discussions with the FDA for possible clinical trial design and parameters. Under an ideal scenario, it could potentially bridge or combine US recruitment sites with EU sites participating in the pivotal EU study, and subsequently, the US premarket approval (PMA) registration file could include data from both EU and US

[1] Lorach H, Wang J, Lee DY, et al. Biomed Opt Express. 2015 Dec 4;7(1):13-21. doi: 10.1364/BOE.7.000013.

participating patients. The firm expects to have further clarity on the US regulator's view on the potential design for the registration pathway for Prima in the US in or around H117.

In terms of study size, we note that the Second Sight's Argus II device intended for RP or severely-vision impaired patients required 30 implantations and follow-up to obtain US Humanitarian Device Exemption (HDE) level approval. The Prima device would be targeting the much larger late-stage ARMD market (the prevalence of late-stage ARMD is up to 10x higher than RP), and we estimate that US regulators would likely require a study to provide detailed follow-up and monitoring for up to 18-24 months on approximately 60-80 patients for approval.

Progress on Prima prompts re-think of US Iris II development

As Pixium has increased confidence (based on successful preclinical development) of Prima's potential, and as this device has several advantages compared to Iris II (potentially improved vision resolution or clarity, while using a simpler and less invasive surgical technique better suited to the typically older ARMD patient), the firm is re-examining its strategy for the timing of Iris II development in the US. The company reserved the right to proceed with a US PMA study for Iris II in RP, but given the resource requirements and the fact that Prima appears to be progressing well in the ARMD indication, the firm appears to be dedicating its US development strategy and resources first to Prima, for the ARMD indication. Hence, the company may delay running a US PMA study for Iris II in RP, which differs from our previous forecasts (which had assumed that such a study would start in 2017). Instead, the company could potentially start US recruitment for a PMA-enabling Prima study in H217 or H118.

Financial forecasts and valuation

With the company no longer planning a US Iris II study in 2017, our R&D expenditure forecasts for 2017 and 2018 have decreased. Whereas we previously budgeted €20m in 2017 and €22m in 2018 R&D spending, which assumed pivotal clinical trials for both Iris II (in the US only) and Prima, we now assume R&D spending of only €12m in 2017 and €15m in 2018. The large majority of projected 2017 and 2018 R&D costs are expected to be allocated to the Prima programme, with a much smaller proportion to the ongoing European post-CE Mark Iris II study.

Exhibit 1: Pixium Vision SA upcoming catalysts

Event	Timing
Start human feasibility studies for Prima implant (Europe)	Q416*
Initial Iris II sales in Europe	2017**
Start recruitment in EU for Prima pivotal study	H217**
Start US recruitment for Prima pivotal study	H118**
CE Mark approval and EU launch for Prima	2019**
PMA Approval and US launch for Prima	2021**

Source: *Company guidance; **Edison Investment Research estimates

In terms of timelines, even in the event that the US and EU Prima clinical sites can be combined towards a "global" registration study, we continue to expect that CE Mark clearance (and EU approval and launch) would still occur 18-24 months earlier than US PMA approval and launch, given we expect that European regulators could allow approval of the device following interim (six- to 12-month) safety and performance data on a smaller number of implanted patients, than would be required for the US counterparts (ie full 18-24 month follow-up data, including efficacy, on the full study cohort). Hence, we continue to model potential EU Prima launch in 2019 and US Prima launch in 2021.

Our model now excludes US Iris II sales, but our European Iris II and our global (US and EU) Prima sales forecasts are unchanged.

Exhibit 2: Financial forecasts for Iris II and Prima

	2017e	2018e	2019e	2020e	2021e	2022e	2023e	2024e
Iris in Retinitis pigmentosa (RP)								
EU population (m)	512	513	514	516	517	518	520	521
Retinitis pigmentosa prevalence (%)	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025
Total EU RP population (000)	127.9	128.3	128.6	128.9	129.3	129.6	129.9	130.3
Unit sales in EU	32	249	683	869	806	590	427	329
Average revenue per treatment (€)	78,000	78,811	80,214	81,758	83,354	85,022	86,723	88,468
Total EU revenue (€000) for IRIS-RP	**2,525**	**19,607**	**54,789**	**71,086**	**67,206**	**50,152**	**37,041**	**29,141**
Prima in Retinitis pigmentosa								
Unit sales in EU	-	-	108	391	719	874	876	878
Average revenue per treatment (€)	na	na	81,900	81,900	81,900	82,922	84,580	86,272
Total EU revenue (€000) for PRIMA-RP	**-**	**-**	**8,881**	**32,050**	**58,903**	**72,469**	**74,108**	**75,784**
US population (m)	330	332	335	337	340	342	345	347
Retinitis pigmentosa prevalence (%)	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Total US RP proportion (000)	98.9	99.7	100.4	101.2	101.9	102.7	103.4	104.2
Unit sales in US	-	-	-	-	94	346	618	702
Average revenue per treatment ($)	na	na	na	na	151,200	153,276	156,241	159,272
Total US revenue ($000) for PRIMA-RP	**-**	**-**	**-**	**-**	**14,277**	**52,992**	**96,576**	**111,735**
Prima in Macular degeneration								
Prevalence of Late ARMD in >45 age group (%)	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Estimated EU treatment population (000)	818.9	821.0	823.1	825.2	827.3	829.4	831.5	833.7
Unit sales in EU	-	-	176	640	1,395	2,797	3,738	3,748
Total EU revenue (€000) for PRIMA-ARMD	**-**	**-**	**14,399**	**52,423**	**114,241**	**232,115**	**316,192**	**323,343**
Estimated US treatment population (000)	527.5	531.5	535.5	539.5	543.5	547.6	551.7	555.9
Unit sales in US	-	-	-	-	336	1,229	2,198	2,494
Total US revenue ($000) for PRIMA-ARMD	**-**	**-**	**-**	**-**	**50,764**	**188,415**	**343,380**	**397,281**
Assumed $/EUR rate	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11
Worldwide total revenue (€000)	**2,525**	**19,607**	**78,069**	**155,560**	**298,946**	**572,220**	**823,696**	**886,840**

Source: Edison Investment Research

We have made certain adjustments to our valuation approach for Pixium. We have removed the US contribution to Iris II sales and in doing so, we have increased our Iris II probability of success estimate from 55% to 70%, given that the Iris II regulatory risk embedded in our discount was attributed to US regulatory risk. This factor has now been removed (no longer applicable), given that Iris II already has CE Mark clearance and is approved for sale in Europe. Remaining Iris II risk-adjustment factors include commercialisation risks (market acceptance, reimbursement).

For Prima, as the company indicates that it has successfully completed preclinical thermal and electrical safety studies and expects clearance to commence human feasibility studies shortly, we have increased our probability of success estimate to 12.5% (from 10%, previously). We anticipate that a formal announcement from regulators permitting the commencement of Prima human studies could trigger another upward adjustment to our Prima probability of success estimate.

Given the above changes and after rolling forward our forecasts we now obtain a pipeline rNPV (enterprise value) of €125.5m, down from €132.3m previously. After including €12.2m estimated Q316 net cash, we obtain an equity valuation of €137.7m, or €10.78 per share (down from €11.62, previously).

Exhibit 3: 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)
Iris II	Retinitis Pigmentosa	CE mark application filed	75.5	5.92	70.0%	2017	71 in 2020
Prima	Retinitis Pigmentosa	Preclinical	36.5	2.86	12.5%	2019 (EU) and 2021 (US)	176 in 2024
Prima	Age-related Macular degeneration	Preclinical	139.3	10.91	12.5%	2019 (EU) and 2021 (US)	681 in 2024
Corporate costs & expenses							
G&A expenses			(29.5)	(2.31)			
Net capex, NWC & taxes			(96.4)	(7.55)			
Total rNPV			125.5	9.83			
Net cash (debt) (Q316e)			12.2	0.96			
Total equity value			137.7	10.78			
FD shares outstanding (000) (Q316e)			12,770				

Source: Edison Investment Research

Financials

Pixium's H116 net cash position was €16.1m (€16.2m gross cash minus €0.2m in short-term advances), and given its H116 operating cash burn rate of €8.1m, we estimate Q316 net cash of approximately €12.2m. We have increased our interest expense forecasts given the higher than anticipated cost of debt associated with the announced financing. Given the reduction in our R&D cost forecasts, we now assume a lower cash burn rate in 2017 and 2018 than previously. We now assume a 2017 and 2018 operating cash burn rate (excluding net interest) of €15.2m and €13.3m, respectively, compared to our prior estimates of €25.2m and €22.3m, respectively.

Beyond the announced €11m financing (which we estimate will be fully drawn by mid-2017), we assume Pixium will raise an additional €25m in 2017 and €20m in 2018. For illustrative purposes only, we have added these requirements to long-term debt. Note that our financial and valuation models do not include the potential dilutive impacts of future equity offerings. We do not expect Pixium to start generating sustainable positive recurring operating cash flows until H219, at which point we forecast Prima will start generating meaningful sales for the company (in addition to Iris II).

Exhibit 4: Financial summary

€000s	2014	2015	2016e	2017e	2018e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	2,427	3,296	2,866	5,525	22,607
Cost of Sales	0	0	0	(1,894)	(10,438)
General & Administrative	(2,299)	(2,680)	(3,893)	(4,495)	(7,100)
Research & Development	(10,963)	(15,169)	(12,301)	(12,000)	(15,000)
EBITDA	(10,835)	(14,552)	(13,328)	(12,864)	(9,930)
Depreciation	(813)	(1,144)	(1,086)	(1,265)	(1,430)
Amortization	0	0	0	0	0
Operating Profit (before exceptionals)	(11,648)	(15,697)	(14,414)	(14,129)	(11,361)
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(11,648)	(15,697)	(14,414)	(14,129)	(11,361)
Net Interest	37	52	232	(1,166)	(4,861)
Profit Before Tax (norm)	(11,611)	(15,644)	(14,182)	(15,295)	(16,222)
Profit Before Tax (FRS 3)	(11,611)	(15,644)	(14,182)	(15,295)	(16,222)
Tax	0	0	0	0	0
Profit After Tax and minority interests (norm)	(11,611)	(15,644)	(14,182)	(15,295)	(16,222)
Profit After Tax and minority interests (FRS 3)	(11,611)	(15,644)	(14,182)	(15,295)	(16,222)
Average Number of Shares Outstanding (m)	9.8	12.7	12.8	12.8	12.8
EPS - normalised (€)	(1.18)	(1.23)	(1.11)	(1.20)	(1.27)
EPS - normalised and fully diluted (€)	(1.18)	(1.23)	(1.11)	(1.20)	(1.27)
EPS - (IFRS) (€)	(1.18)	(1.23)	(1.11)	(1.20)	(1.27)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	9,932	11,087	11,106	12,341	14,911
Intangible Assets	9,259	8,822	8,494	8,494	8,494
Tangible Assets	673	2,265	2,613	3,848	6,417
Current Assets	44,866	27,682	21,270	32,544	35,416
Short-term investments	0	0	0	0	0
Cash	42,132	24,354	16,492	25,590	23,411
Other	2,735	3,328	4,778	6,955	12,005
Current Liabilities	(4,051)	(3,498)	(2,325)	(1,231)	(1,977)
Creditors	(4,051)	(3,498)	(2,325)	(1,231)	(1,977)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(245)	(315)	(8,337)	(36,337)	(56,337)
Long term borrowings	(167)	(164)	(8,165)	(36,165)	(56,165)
Other long term liabilities	(78)	(151)	(172)	(172)	(172)
Net Assets	50,503	34,956	21,714	7,318	(7,987)
CASH FLOW					
Operating Cash Flow	(8,426)	(15,584)	(15,060)	(15,236)	(13,318)
Net Interest	37	52	232	(1,166)	(4,861)
Tax	0	0	0	0	0
Capex	(1,772)	(2,106)	(1,097)	(2,500)	(4,000)
Acquisitions/disposals	0	0	0	0	0
Financing	42,705	56	63	0	0
Net Cash Flow	32,543	(17,582)	(15,863)	(18,903)	(22,179)
Opening net debt/(cash)	(9,420)	(41,965)	(24,190)	(8,327)	10,576
HP finance leases initiated	0	0	0	0	0
Other	1	(193)	0	0	0
Closing net debt/(cash)	(41,965)	(24,190)	(8,327)	10,576	32,754

Source: Edison Investment Research, Pixium Vision accounts. Note: 2014 and 2015 revenues include tax credits and subsidies, which are forecast at approximately $3m per year through 2018.

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