EDISON

Pixium Vision

COVID-19 update

Strategy in place to mitigate COVID-19 effects

Healthcare equipment & services

Pixium recently made prudent operational changes to contain expenditures while keeping the long-term investment thesis intact during the COVID-19 pandemic. With the feasibility studies paused and the start of a pivotal study possibly pushed to 2021, we expect these and other cost-cutting initiatives to enable Pixium to maintain its operations into late 2020. These actions should position the firm well to resume normal operations once the COVID-19 situation improves.

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	1.7	(8.1)	(0.32)	0.0	N/A	N/A
12/21e	1.6	(13.1)	(0.51)	0.0	N/A	N/A

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

Studies on pause and possible pivotal trial delay

Pixium is postponing further implantations in its US feasibility study of the Prima System, and upcoming follow-up visits for patients participating in the European feasibility study are also being adjusted. Patient safety monitoring will continue for both studies remotely. These changes are appropriate as the target patient population for Prima, generally patients aged over 65, is particularly susceptible to adverse health effects from COVID-19. We believe significant mitigation or resolution of the pandemic is needed before implantations will resume, and before the pivotal study can start. Pixium previously planned to file its regulatory submission in Q220 and have implantations occur before YE20, but we expect that while they will file with at least the European regulator by Q320, logistical issues outside of Pixium's control relating to COVID-19 and lingering effects will likely push the start of the pivotal trial into 2021.

Cost controls provide added cushion

We expect that Pixium will be able to weather the COVID-19 storm through at least Q420 and retain a positive cash balance, even in the absence of an equity offering. Many R&D activities involving lab work have been suspended and the company has delayed payments of social charges, rents and temporary unemployment for its employees unable to telecommute. Altogether, we expect that there will be an effective cost saving of slightly above €1m for 2020 from these measures.

Valuation: rNPV of €69.5m

We are pushing back our EU and US Prima launch timelines, to H223 and H225, respectively, from H123 and H125, respectively. After adjusting our cost assumptions and timelines, we obtain a pipeline rNPV (enterprise value, excluding net cash) of €69.5m versus €85.1m previously. After including €1.0m in net cash at 31 December 2019, we obtain an equity valuation of €70.5m, or €2.78 per share (versus €3.46 per share previously, partly due to increased shares outstanding).

26 March 2020

Price	**€0.67**
Market cap	**€17m**
	$1.08/€
Net cash (€m) at 31 December 2019	1.0
Shares in issue	25.4m
Free float	54%
Code	ALPIX
Primary exchange	Euronext Growth
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(25.9)	(14.7)	(56.7)
Rel (local)	(4.0)	16.4	(48.2)
52-week high/low		€1.8	€0.5

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 started a US feasibility study.

Next events

Prima 2 interim data	Q120
Q120 results	April 2020

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Edison profile page

Delays but fundamentals intact amid COVID-19 impacts

In light of the COVID-19 pandemic stretching healthcare resources globally as well as the need for organizations to protect workers and patients, Pixium recently made prudent operational changes to contain expenditures while keeping the long-term investment thesis intact during this turbulent time. The company has decided to postpone further implantations in its five-patient US feasibility study of the Prima System in patients with atrophic dry age-related macular degeneration (dry-AMD). To date, two patients have been implanted with the device, and while ongoing safety monitoring will continue, the necessary visual rehabilitation training needed for these patients to adapt to and learn how to optimally use the system is being delayed; such a delay is not expected to adversely affect the eventual visual functioning of the patients once they receive the training in the future. These adjustments are being done in particular because the target patient population for Prima, generally aged over 65 years old, is particularly susceptible to adverse health effects from COVID-19, and we believe significant mitigation or resolution of the pandemic is needed before implantations will resume, and before the pivotal study can start.

In parallel, upcoming follow-up visits for patients participating in the 36-month five-patient European feasibility study (PRIMA-FS) is also being adjusted, with the upcoming visits (mostly corresponding to 24-month follow-up) now being scheduled primarily virtually or through remote testing at this time. Fortunately, Pixium recently completed 18-month follow-up visits for the PRIMA-FS patients, and it expects to release data in Q120, including initial results from these patients transitioning to the second-generation Prima 2 glasses and pocket computer.

The US FDA recently provided guidance to industry and study investigators suggesting that due to the COVID-19 pandemic, refinements to clinical study protocols aimed at protecting patient safety during this pandemic and transitioning to remote or virtual follow-up visits, where appropriate, should not be expected to have detrimental effects to the agency's review of relevant clinical trial data in the future. European regulators have drafted similar guidance.

Prudent measures in place to ensure funds through late 2020

Most importantly, Pixium has announced measures to control its cash burn rate and we expect that the firm will be able to weather the COVID-19 storm at least into Q420 and retain a positive cash balance, even in the absence of an equity offering (which would be challenging to pursue or heavily dilutive given current market conditions). Many R&D activities involving lab work have been suspended and Pixium employees are currently generally working through virtual means/telecommuting.

In addition to the measures described above to curtail feasibility study costs during the pandemic, the company has taken early measures made possible by prompt French government action in response to the pandemic; namely, it has delayed payments of social charges, rents and temporary unemployment for its employees unable to telecommute.

Altogether, we expect that there will be effective cost savings of slightly above €1m for 2020 from these measures. Further, on a cash inflow basis, the company expects to receive about €1.7m in research tax credits in H120.

While we do not expect the company to pursue an equity offering until the COVID-19 situation improves, the company has an agreement (from November 2019) with 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, and a second (€1.25m) tranche was issued in February (and partial conversion of about €0.3m to equity has already occurred). Additional tranches may be issued throughout the year.

Altogether, Pixium is controlling costs to be in a position to resume operations to normal once the COVID-19 situation improves. Pixium CEO Lloyd Diamond has commented, 'we are doing everything we can to keep cash burn to a minimum and to ensure the resources needed are in place to step up clinical development again as soon as the situation improves.'

Pivotal study likely not to start before 2021

As it relates to the planned PRIMAvera pivotal study, the company previously planned to file its regulatory submission in Q220 and have implantations occur before YE20. We now expect it should file at least with the European regulator in mid-2020 or Q320, but it is unclear whether the agency's administrative resources will be positioned to respond and process the dossier in a timely fashion and whether individual study centres' institutional review boards would promptly provide clearance (given COVID-19 effects and these organizations' other prioritisations). Hence, we now believe it is unlikely that the European pivotal study will start implantations until 2021, and this may ultimately depend on the timing for resolution or mitigation of the COVID-19 pandemic.

As a reminder, Pixium's 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). In such a scenario where a single pivotal study would be accepted by both regulators, we expect that initial implantations would occur in Europe leading to an earlier market approval in Europe. We reiterate that 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.

Given the delays described above, we are pushing back our Prima launch forecasts by six months, but this may vary further depending on how quickly the COVID-19 situation improves and how quickly clinical studies can resume or launch (generally factors outside of Pixium's direct control). We now expect the EU pivotal study to start in H121 (vs H220 previously) and the US pivotal study to start in H221 (vs H121 previously). We are pushing back our EU and US launch timelines to H223 and H225, respectively, from H123 and H125.

Financials and valuation

Pixium finished 2019 with a net cash position of €1.0m (€6.8m gross cash offset by €2.6m in refundable advances and €3.2m in long-term debt). We have reduced our 2019 operating expenses due to the measures described above, and also pushed €0.5m of R&D expense projected for 2021, forward to 2022 (given that pivotal study clinical study costs are expected to escalate as recruitment ramps up).

We now assume R&D expenses of €6.0m in 2020 and €8.0m in 2021, respectively, versus our prior estimates of €6.7m and €8.5m. We have reduced our 2020 and 2021 operating cash burn rates to €6.8m and €9.9m versus our prior estimates of €8.0m and €10.6m.

We continue to assume Pixium will need to raise €50m (including the remaining or unused €7.5m in tranches from ESGO funding facility) to bring Prima to launch (now in H223). We believe Pixium's current funds on hand will be sufficient for the company to maintain its operations at least into Q420. If the company secures an additional tranche from ESGO (two tranches of €1.25m have been issued to date), we expect it will have sufficient funds into 2021.

For now our model assumes that the company will raise €24.7m in net illustrative debt in 2020 (versus €25.0m previously, given that €0.3m debt raised from the February 2020 ESGO tranche

has since been converted to equity). We continue to model an additional €25m in illustrative debt in 2021.

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	139.1	5.48	15.00%	H223 (EU); H225 (US)	1,096 in 2029
Corporate costs & expenses							
G&A expenses			(19.8)	(0.78)			
Net capex, NWC & taxes			(49.8)	(1.96)			
Total rNPV			69.5	2.74			
Net cash (debt) (Q419)			1.0	0.04			
Total equity value			70.5	2.78			
FD shares outstanding (000s) (22 March 2020 data)			25,399				

Source: Edison Investment Research

Our valuation for Pixium Vision is based on a rNPV approach, employing a 12.5% cost of capital and is based 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 an FX rate, for US sales, of $1.08/€. After adjusting our cost assumptions and launch timelines as described above, we obtain a pipeline rNPV (enterprise value, excluding net cash) of €69.5m versus €85.1m previously.

After including €1.0m in net cash at 31 December 2019, we obtain an equity valuation of €70.5m, or €2.78 per share (versus €3.46 previously, partly due to increased shares outstanding).

Exhibit 2: Financial summary

€000	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	1,700	1,600	1,600
Cost of Sales	(1,124)	(41)	0	0	0	0
General & Administrative	(5,324)	(2,019)	(3,815)	(2,900)	(2,973)	(3,847)
Research & Development	(7,817)	(5,297)	(6,320)	(6,000)	(8,000)	(10,400)
EBITDA	(11,731)	(5,758)	(8,352)	(7,200)	(9,373)	(12,647)
Depreciation	(936)	(677)	(448)	(449)	(531)	(639)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(12,666)	(6,435)	(8,801)	(7,649)	(9,903)	(13,286)
Exceptionals	0	(5,859)	(69)	0	0	0
Other	0	0	0	0	0	0
Operating Profit	(12,666)	(12,294)	(8,870)	(7,649)	(9,903)	(13,286)
Net Interest	(876)	(1,277)	(1,006)	(442)	(3,147)	(4,246)
Profit Before Tax (norm)	(13,542)	(7,712)	(9,806)	(8,092)	(13,050)	(17,532)
Profit Before Tax (FRS 3)	(13,542)	(13,571)	(9,876)	(8,092)	(13,050)	(17,532)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(13,542)	(7,712)	(9,806)	(8,092)	(13,050)	(17,532)
Profit After Tax and minority interests (FRS 3)	(13,542)	(13,571)	(9,876)	(8,092)	(13,050)	(17,532)
Average Number of Shares Outstanding (m)	13.3	18.5	22.3	25.4	25.5	25.7
EPS - normalised (€)	(1.02)	(0.42)	(0.44)	(0.32)	(0.51)	(0.68)
EPS - normalised and fully diluted (€)	(1.02)	(0.42)	(0.44)	(0.32)	(0.51)	(0.68)
EPS - (IFRS) (€)	(1.02)	(0.73)	(0.44)	(0.32)	(0.51)	(0.68)
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	26,443	38,242	21,699
Short-term investments	0	0	0	0	0	0
Cash	10,532	15,629	6,792	24,133	35,845	19,301
Other	3,710	2,126	2,316	2,310	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)	(31,733)	(56,733)	(56,733)
Long term borrowings	(9,130)	(7,870)	(5,787)	(30,487)	(55,487)	(55,487)
Other long term liabilities	(172)	(153)	(1,246)	(1,246)	(1,246)	(1,246)
Net Assets	11,836	11,355	3,700	(3,713)	(16,378)	(33,516)
CASH FLOW						
Operating Cash Flow	(10,605)	(6,174)	(7,282)	(6,816)	(9,917)	(12,253)
Net Interest	(876)	(1,277)	(1,006)	(442)	(3,147)	(4,246)
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	300	0	0
Net Cash Flow	(11,153)	6,587	(6,288)	(7,359)	(13,288)	(16,543)
Opening net debt/(cash)	(12,911)	(1,401)	(7,760)	(1,004)	6,354	19,643
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)	6,354	19,643	36,186

Source: Company accounts, Edison Investment Research

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