

# Pixium Vision

## Pixium Vision to combine with Second Sight

On 6 January Pixium Vision announced it and Second Sight (EYES, Nasdaq) had entered a memorandum of understanding (MoU) to combine their businesses. Second Sight is developing the Orion Visual Cortical Prosthesis System, which is in a US feasibility study and is designed to provide useful artificial vision by sending electric impulses directly to the visual cortex. The stock-based transaction, which will also comprise a c \$25m capital raise, will enable both companies to pool their resources in complementary sight-restoration neuromodulation technologies and build a one-company solution for many causes of blindness. The combined company's Nasdaq listing may also provide broader access to future financing sources. The transaction is subject to shareholder and French regulatory approval, the attainment of a \$25m capital raise (not yet committed) and is guided to close by early Q221. We are maintaining our valuation and financial forecasts for Pixium Vision (standalone and excluding any contribution from Second Sight) at this time but will revise them on transaction completion.

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	(8.6)	(0.28)	0.0	N/A	N/A
12/21e	1.6	(11.0)	(0.25)	0.0	N/A	N/A

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

### Mechanics of the MoU

Pixium Vision will become a holding company that owns 60% of the combined company's assets (which includes Pixium's retinal neuromodulation assets and 40% of a subsidiary containing the Orion-related assets), before the consideration of \$25m financing that will be carried out at the level of the newly combined company. Second Sight shareholders will receive 60% of the Orion-related subsidiary before the combination with Pixium and will own 40% of the combined company on a pre-financing basis. Importantly, the combined company will have an exclusive right of first refusal to commercialise the Orion system.

### Prima remains lead asset

In late 2020 Pixium started the PRIMAvEra European pivotal study of the Prima Bionic Vision System in patients with dry age-related macular degeneration with geographic atrophy, a largely unmet market indication. Management expects implantations to be completed by YE21, with potential top-line 12-month data in H222, supporting our estimate of potential CE mark and European launch in H223.

### Valuation: Awaiting transaction close

We maintain our pipeline rNPV (enterprise value excluding net cash) for Pixium Vision (standalone) of €134.0m but will revisit our assumptions once the necessary steps for the proposed MoU are finished and/or the transaction reaches completion.

## Business combination

### Healthcare equipment & services

11 January 2021

**Price** €1.07

**Market cap** €47m

\$1.23/€

Net debt (€m) at 30 June 2020 (excluding lease liabilities) 0.9

Shares in issue 44.0m

Free float 60%

Code ALPIX

Primary exchange Euronext Growth Paris

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs 30.2 87 45.2

Rel (local) 26.8 61.7 52.4

52-week high/low €1.25 €0.50

### 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 company recently started a European pivotal study.

### Next events

36-month data from EU feasibility study Q121

Closing of transaction with Second Sight H121

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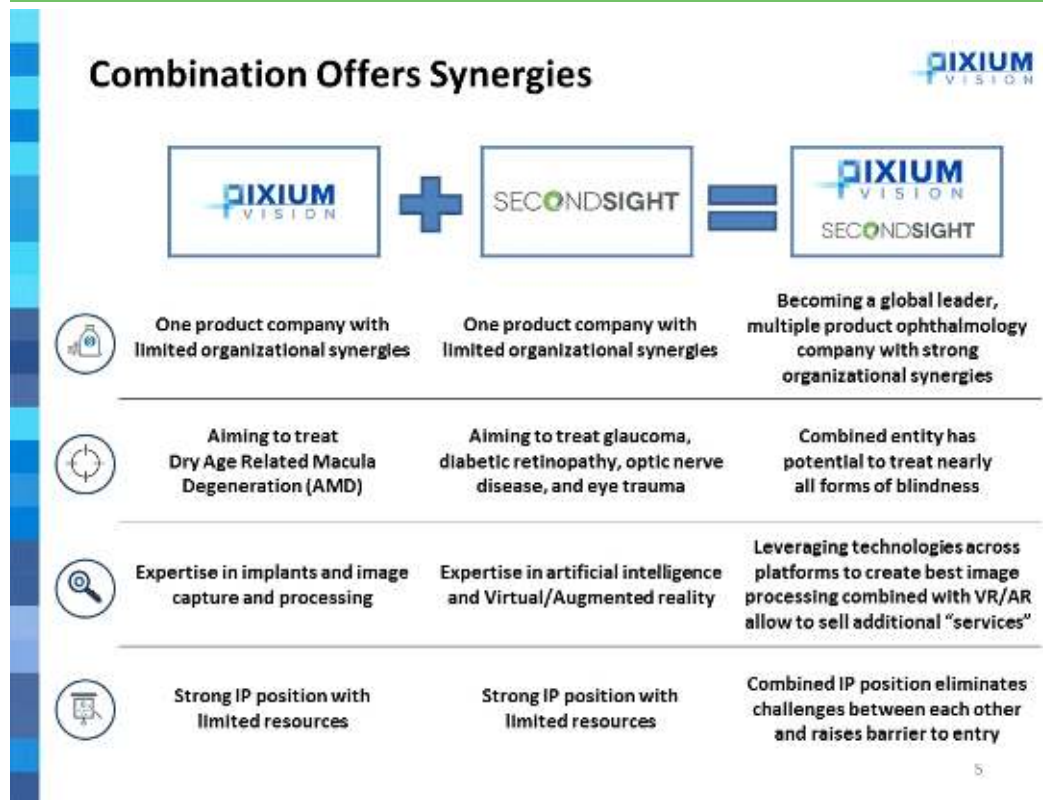
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## Combining two different sight-restoration technologies

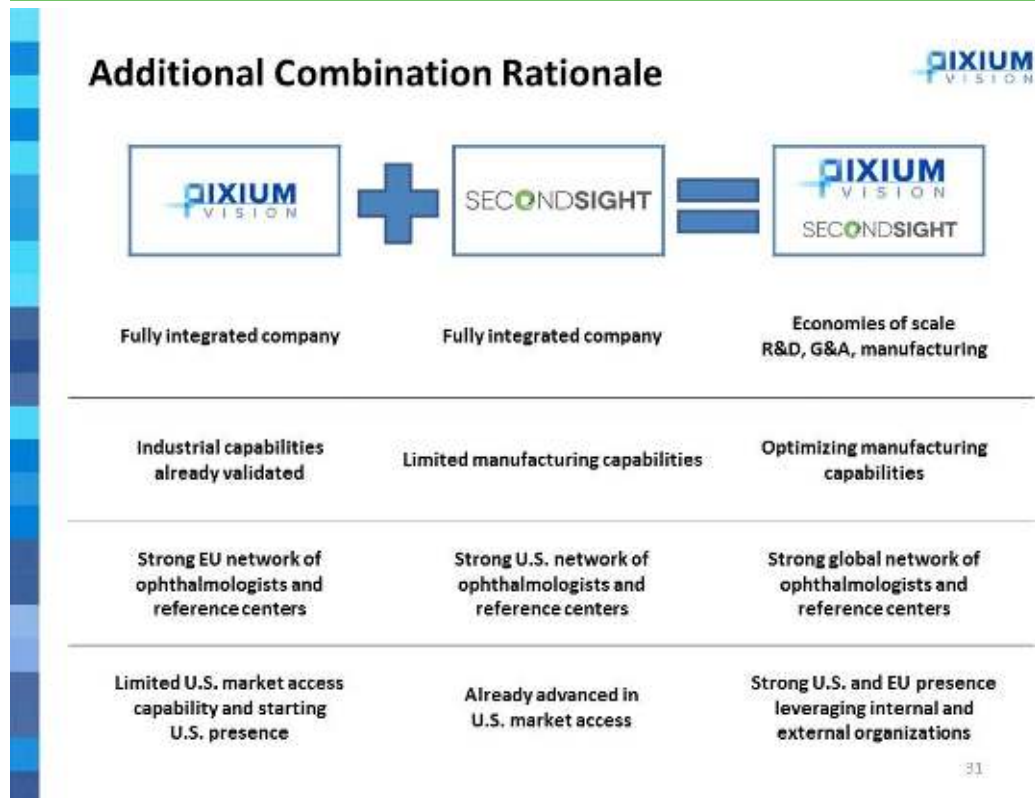
The proposed transaction between Pixium Vision and Second Sight provides an opportunity to pool the complementary sight-restoration technology assets of both firms, strengthen Pixium's access to networks of US ophthalmologists and reference centres and its market access expertise and, more importantly, provide a platform via Second Sight's current US market listing for gaining access to US-based investors for future fundraising needs. Operationally, there will be effectively no change in Prima's advancement as the core Prima-related operations will remain at their current location in France and no major changes in R&D and operations headcount are anticipated.

**Exhibit 1: Business combination rationales presented by both companies**



Source: Pixium Vision and Second Sight presentation

Exhibit 1: Additional business combination rationales presented by both companies



Source: : Pixium Vision and Second Sight presentation

Second Sight's earlier efforts focused on the development of Argus II, the world's first FDA- and CE Mark-approved retinal implant device, intended for patients with late-stage retinitis pigmentosa. The Argus II is an epiretinal implant and, as mentioned in [our prior reports](#), Pixium's Prima subretinal implant has several advantages over it, such as a higher resolution on the implant chip and a less invasive surgical insertion procedure. Second Sight launched the Argus II system in Europe in 2011 and in the US in 2014 but, due to a relatively limited market size for Argus II (in 2019 there were 28 units implanted versus 69 in 2018), it decided in 2019 to suspend production of Argus and direct its development focus to the Orion Visual Cortical Prosthesis System (Orion).

## Overview of the Orion system

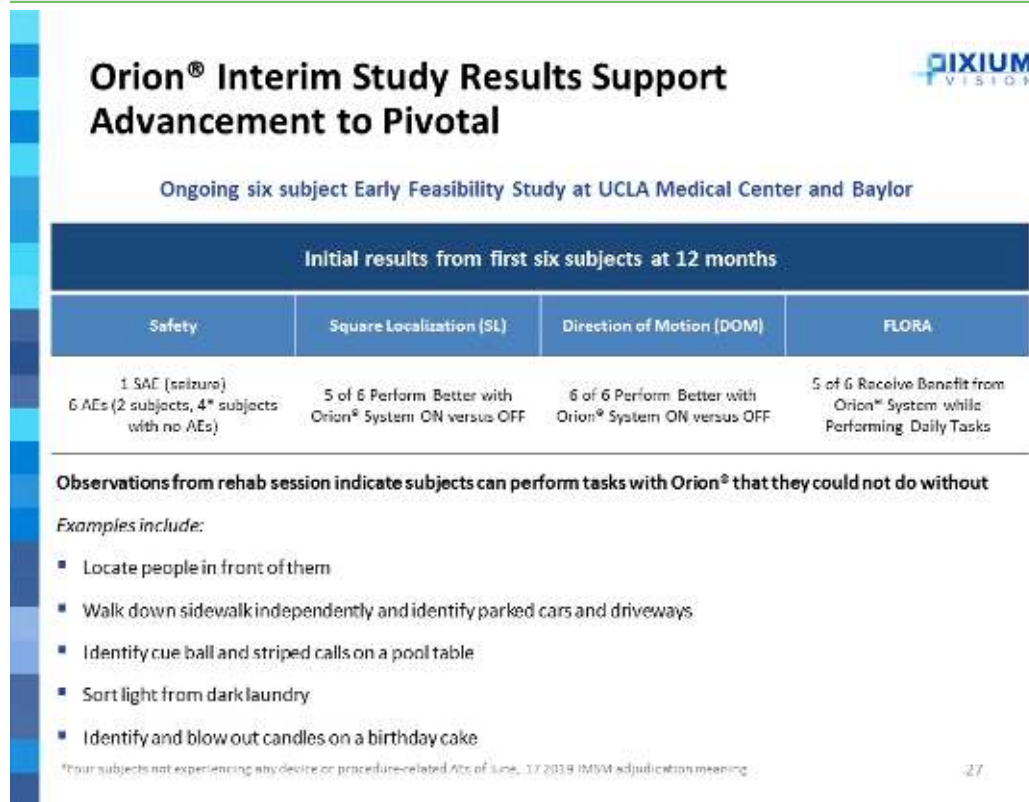
Orion is an implanted cortical stimulation (prosthetic cortical neuromodulation) device intended to provide useful artificial vision to individuals who are blind due to a wide range of causes. Orion is designed to convert images captured by a miniature video camera mounted on glasses into a series of small electrical pulses that bypass the diseased or injured eye anatomy. The pulses are communicated wirelessly to an array of electrodes implanted on the surface of the brain's visual cortex (where it is intended to provide the perception of patterns of light).

The Orion system's focus is different than Prima, in that it stimulates an area downstream on the retino-cortical axis than Prima, and is more suited towards addressing different causes of vision loss. Prima is designed to provide electrical signals at the retinal level to compensate for retinal injury (say, due to atrophic dry age-related macular degeneration) but it relies on a functioning optic nerve to relay that information to the visual cortex (so Prima cannot provide a benefit in patients with end-stage glaucoma, for instance). We expect Prima to provide a higher level of visual resolution and functionality than Orion given among other factors, the more precise level of resolution afforded by its 378-electrode chip (implanted in the retina), compared to the 60-electrode array that comprises the Orion system. That said, Orion is still designed to allow otherwise blind

subjects to potentially identify and differentiate light from dark objects and improve mobility and independence. In practice, we view Orion as best suited for instances where there is an optic nerve or optic tract disease or injury and the preferred approach for providing prosthetic vision would be to bypass the nerve/tract pathway and directly stimulate the visual cortex. Hence, end-stage glaucoma, optic nerve disease, neuropathies or related tumours could be potential indications for Orion. From a corporate strategy point of view, combining both the Second Sight and Prima businesses provides the opportunity for the pooling of resources for separate and complementary neuromodulation approaches (Prima based on stimulating the retina and Orion based on the visual cortex) for sight restoration. We expect the two products to continue to exist separately (especially the core implantation components of the systems) and target different sight-restoration markets (Prima for Dry-AMD, Orion largely for conditions affecting the optic nerve or tract) although it is possible that there may be some eventual synergies for the non-implanted external hardware or augmented reality analytics or components of either system (ie there could be future revisions to the augmented reality glasses or pocket computer/image processing analytics), but this would not affect the time-to-market for Prima BVS.

A six-subject Early Feasibility Study of the Orion device is underway at the Ronald Reagan UCLA Medical Center in Los Angeles and Baylor College of Medicine in Houston. Regularly scheduled visits at both sites were placed on hold in mid-March due to COVID-19; however, visits at UCLA resumed in Q320. Second Sight reports that 12-month results for the six subjects indicate a good safety profile with encouraging efficacy data and benefits in helping subjects perform their daily living tasks. The data have not yet been peer reviewed but Second Sight indicated previously in prior comments it may support advancement of Orion into a larger pivotal clinical trial. At this point we believe it is premature to predict when Orion could be commercialised because it is also possible that further revisions or trials will be undertaken before a pivotal trial is started.

**Exhibit 3: Orion interim results of early feasibility study**



**Orion® Interim Study Results Support Advancement to Pivotal**

Ongoing six subject Early Feasibility Study at UCLA Medical Center and Baylor

Initial results from first six subjects at 12 months

Safety	Square Localization (SL)	Direction of Motion (DOM)	FLORA
1 SAE (seizure) 6 AEs (2 subjects, 4* subjects with no AEs)	5 of 6 Perform Better with Orion® System ON versus OFF	6 of 6 Perform Better with Orion® System ON versus OFF	5 of 6 Receive Benefit from Orion® System while Performing Daily Tasks

**Observations from rehab session indicate subjects can perform tasks with Orion® that they could not do without**

Examples include:

- Locate people in front of them
- Walk down sidewalk independently and identify parked cars and driveways
- Identify cue ball and striped balls on a pool table
- Sort light from dark laundry
- Identify and blow out candles on a birthday cake

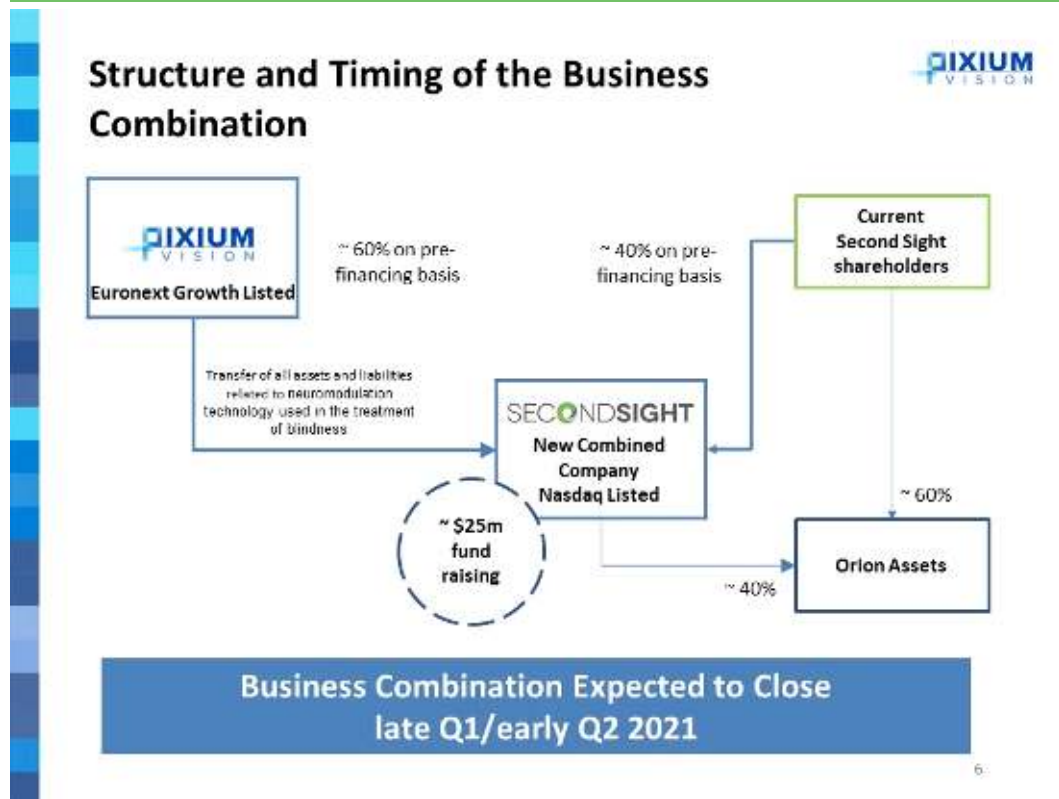
\*Four subjects not experiencing any device or procedure-related AEs of SAE... 17 2019 IMVM adjudication meeting

Source: Pixium Vision and Second Sight presentation

## Mechanics of the Second Sight transaction

The MoU lists several steps whereby Pixium Vision will become a holding company that owns 60% of the combined company's assets (which includes Pixium's retinal neuromodulation assets and 40% of a subsidiary containing the Orion-related assets), before the consideration of a \$25m financing that will be carried out at the level of the new combined company.

### Exhibit 4: Structure of business combination



Source: Pixium Vision and Second Sight presentation

Under the MoU, Second Sight will form a subsidiary, SpinCo, and enter into a separation and distribution agreement and an exclusive licence agreement with SpinCo whereby:

- Second Sight will transfer to SpinCo certain intellectual property related to its Orion system and other related assets and liabilities;
- SpinCo grants Second Sight an exclusive right of first refusal to commercialise the Orion system; and
- a total of 60% of SpinCo's shares will be spun off to Second Sight shareholders before any combination with Pixium Vision.

In parallel to (and as a condition for) the formal combination, approximately \$25m is expected to be raised through a capital increase that will be carried out at the combined company (CombCo) level. Pixium will transfer all of its assets and liabilities relating to its Prima-related retinal neuromodulation technology to Second Sight in exchange for 34.88m newly issued Second Sight shares (currently there are 23.12m Second Sight shares outstanding). This would provide Pixium 60% ownership (pre-financing) of the new Second Sight (CombCo), but this process is contingent on:

- securing a \$25m financing at the CombCo level (investment commitments have not yet been secured);

- a positive shareholder approval vote by both parties (30% of Second Sight shares have already entered into a voting agreement to vote in favour of the MoU; shareholder votes are expected in March); and
- clearance from the French Minister for the Economy (for Pixium Vision to contribute to Second Sight all its assets and liabilities in relation to its retinal neuromodulation technology).

After the transaction, Pixium Vision will effectively become a holding company and maintain its Euronext Growth listing and will hold a 60% interest (pre-financing) in CombCo. Pixium Vision intends to consolidate the financials of CombCo. Pixium CEO Lloyd Diamond will become the CEO of CombCo (to remain Nasdaq listed) and a general director of Pixium Vision, and Second Sight CEO Matt Pfeffer will be CEO of SpinCo. There is a \$1m break fee for each side if one of the parties decides to discontinue the MoU.

Pre-financing, Pixium and its board will have effective control over CombCo's operations. However, depending on the share price and terms of the planned \$25m CombCo financing, Pixium may no longer be the majority shareholder after the financing (as we do not expect Pixium to participate in this financing), although it would still very likely be the controlling shareholder. Given Second Sight's widespread shareholder base (collectively owning 40% of CombCo pre-financing), we believe it would be very unlikely for Pixium to lose effective control over CombCo, even after the \$25m financing. Below we provide a sensitivity analysis of what Pixium's ownership stake of CombCo would be after a \$25m financing, at different share price assumptions. On 7 January 2020, Second Sight's closing price was \$1.75.

#### Exhibit 5: Scenario analysis for Pixium Vision ownership stake of CombCo after financing

Share price assumption (\$) for CombCo's \$25m capital raise	0.75	1.25	1.75	2.25	2.75
Number of CombCo shares held by Pixium Vision (m)	34.9	34.9	34.9	34.9	34.9
Total CombCo shares outstanding pre-financing (m)	58.0	58.0	58.0	58.0	58.0
Pre-financing ownership by Pixium Vision of CombCo (%)	60.1	60.1	60.1	60.1	60.1
Number of shares issued as part of \$25m financing (m)	33.3	20.0	14.3	11.1	9.1
Total CombCo shares outstanding post-financing (m)	91.3	78.0	72.3	69.1	67.1
Pixium Vision ownership stake of CombCo post-financing (%)	38.2	44.7	48.3	50.5	52.0

Source: Edison Investment Research

## Key win for Pixium is potentially expanded access to financing

On a strategic and operational level, there are synergies in pooling the firm's respective neuromodulation technologies to position CombCo as an integrated potential provider of sight restoration prostheses for different stages of the retino-cortical axis. The combination may also facilitate Prima's future US development and commercialisation objectives by gaining access to the US ophthalmologist and reference centre networks fostered by Second Sight over the years, and potentially benefiting from Second Sight's US regulatory and reimbursement experience (given its prior successes with Argus II in this regard).

Before the 6 January announcement, Second Sight's closing price was \$2.23 and it had a market cap of \$51.7m (c €41.9m) and Pixium had a share price of €0.873 and a market cap of €38.4m. Second Sight's Q320 net cash was \$2.4m and we [previously estimated](#) Q320 Pixium net cash at €5.6m. Given the above logistics of the transaction and without considering the \$25m capital increase (investment commitments have not yet been made), Second Sight shareholders will have a 40% pre-financing interest in the Pixium's contributory assets (ie Prima assets) and 76% interest (pre-financing) in Orion assets (because the Second Sight shareholders will receive 60% of SpinCo and will have a 40% pre-financing interest in CombCo, which holds the remaining 40% of SpinCo). Pixium Vision shareholders will have the equivalent pre-financing ownership of 60% of the Prima assets and 24% in the Orion assets.

From the perspective of Pixium Vision shareholders, the key potential benefit is expanded access to future fundraising options from US investors for Prima and related assets if or as required. CombCo will retain its Nasdaq listing and this platform may provide a potentially wider pool of potential investors for future financing initiatives than Pixium's current Euronext listing.

We previously estimated that Pixium's funds on hand should be sufficient to support its ongoing operations into Q421, thus including at least several months of initial ramp-up of the PRIMAvera pivotal study. Pixium's management believes that even without considering the proposed deal with Second Sight (and the embedded \$25m financing initiative), the remaining (or unused) €6.25m in tranches from the ESGO funding facility and other financing options at its disposal would have provided it with sufficient capital through the end of FY22. We reiterate our [prior assumptions](#) that modelled Pixium would raise €37.5m between Q420 and year-end 2023 (all these amounts were shown as long-term debt for illustrative purposes).

One opportunity that may arise from Pixium's transition into a holding company structure is that it could also seek to raise capital independently from CombCo and/or potentially acquire other complementary technologies.

Further, for Pixium Vision shareholders who are residents of France, given Pixium Vision as a holding company will retain its Euronext Growth listing and its headquarters in France, management expects the listed shares to remain eligible for the French tax-incentivised PEA-PME (plan d'épargne en actions destiné au financement des petites et moyennes entreprises) and FCPI (fonds communs de placement dans l'innovation) investment vehicles. Hence, the holding company arrangement allows French investors or investment vehicles who may have certain restrictions on holding foreign or US listed shares, to participate in CombCo.

## Financials and valuation

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Our financial forecasts and valuation for Pixium Vision as a standalone entity (pre-merger) are unchanged and we will revisit our assumptions once the necessary steps for the proposed MoU are completed and/or the transaction reaches completion. Please refer to our [prior note](#) for a review of our financial and valuation assumptions.

**Exhibit 6: Financial summary**

	€(000)	2017	2018	2019	2020e	2021e	2022e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>							
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)	(2,889)	(2,961)	(3,835)
Research & Development		(7,817)	(5,297)	(6,320)	(6,260)	(8,000)	(10,400)
EBITDA		(11,731)	(5,758)	(8,352)	(7,449)	(9,361)	(12,635)
Depreciation		(936)	(677)	(448)	(426)	(480)	(580)
Amortization		0	0	0	0	0	0
Operating Profit (before exceptionals)		(12,666)	(6,435)	(8,801)	(7,875)	(9,841)	(13,215)
Exceptionals		0	(5,859)	(69)	0	0	0
Other		0	0	0	0	0	0
Operating Profit		(12,666)	(12,294)	(8,870)	(7,875)	(9,841)	(13,215)
Net Interest		(876)	(1,277)	(1,006)	(740)	(1,146)	(2,209)
Profit Before Tax (norm)		(13,542)	(7,712)	(9,806)	(8,616)	(10,987)	(15,424)
Profit Before Tax (FRS 3)		(13,542)	(13,571)	(9,876)	(8,616)	(10,987)	(15,424)
Tax		0	0	0	0	0	0
Profit After Tax and minority interests (norm)		(13,542)	(7,712)	(9,806)	(8,616)	(10,987)	(15,424)
Profit After Tax and minority interests (FRS 3)		(13,542)	(13,571)	(9,876)	(8,616)	(10,987)	(15,424)
Average Number of Shares Outstanding (m)		13.3	18.5	22.3	31.3	44.2	45.0
EPS - normalised (€)		(1.02)	(0.42)	(0.44)	(0.28)	(0.25)	(0.34)
EPS - normalised and fully diluted (€)		(1.02)	(0.42)	(0.44)	(0.28)	(0.25)	(0.34)
EPS - (IFRS) (€)		(1.02)	(0.73)	(0.44)	(0.28)	(0.25)	(0.34)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>							
Fixed Assets		9,649	3,666	4,507	4,021	3,765	3,228
Intangible Assets		7,680	2,623	2,361	2,268	2,268	2,268
Tangible Assets		1,970	1,042	2,145	1,753	1,497	961
Current Assets		14,241	17,756	9,107	15,315	16,793	14,968
Short-term investments		0	0	0	0	0	0
Cash		10,532	15,629	6,792	13,376	14,815	12,990
Other		3,710	2,126	2,316	1,939	1,978	1,978
Current Liabilities		(2,752)	(2,044)	(2,880)	(2,203)	(1,360)	(1,360)
Creditors		(2,752)	(2,044)	(2,880)	(2,203)	(1,360)	(1,360)
Short term borrowings		0	0	0	0	0	0
Long Term Liabilities		(9,302)	(8,023)	(7,033)	(11,396)	(23,896)	(36,396)
Long term borrowings		(9,130)	(7,870)	(5,787)	(10,282)	(22,782)	(35,282)
Other long term liabilities		(172)	(153)	(1,246)	(1,114)	(1,114)	(1,114)
Net Assets		11,836	11,355	3,700	5,736	(4,699)	(19,560)
<b>CASH FLOW</b>							
Operating Cash Flow		(10,605)	(6,174)	(7,282)	(6,218)	(9,691)	(12,073)
Net Interest		(876)	(1,277)	(1,006)	(740)	(1,146)	(2,209)
Tax		0	0	0	0	0	0
Capex		(191)	(31)	(34)	(222)	(224)	(44)
Acquisitions/disposals		0	0	0	0	0	0
Financing		519	14,068	2,034	10,667	0	0
Net Cash Flow		(11,153)	6,587	(6,288)	3,487	(11,061)	(14,325)
Opening net debt/(cash)		(12,911)	(1,401)	(7,760)	(1,004)	(3,094)	7,967
HP finance leases initiated		0	0	0	0	0	0
Other		(357)	(228)	(468)	(1,397)	0	(0)
Closing net debt/(cash)		(1,401)	(7,760)	(1,004)	(3,094)	7,967	22,292
Lease debt		N/A	N/A	1,346	1,215	1,215	1,215
Closing net debt/(cash) inclusive of IFRS16 lease debt		(1,401)	(7,760)	342	(1,879)	9,182	23,507

Source: Company accounts, Edison Investment Research



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