EDISON

Onxeo

Clinical results update

Green light for Ph Ib/II after DRIIV-1 interim data

Pharma & biotech

Onxeo's lead asset, AsiDNA, is currently being tested in a Phase I DRIIV-1 trial in patients with advanced solid tumours (n=36). Interim results were announced recently, based on which Onxeo will initiate a further Phase Ib/II development programme, likely combining AsiDNA with other standard-of-care drugs that have shown the highest potential in preclinical models. The most interesting combination seems to be with PARP inhibitors. These activities are being funded by cash raised from the recent Beleodaq royalty stream monetisation ($7.5m) and equity financing agreement, both in June 2018. Our valuation is €172m or €3.3/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	4.4	(20.4)	(0.45)	0.0	N/A	N/A
12/17	9.5	(19.7)	(0.24)	0.0	N/A	N/A
12/18e	3.4	(7.8)	(0.12)	0.0	N/A	N/A
12/19e	3.5	(11.9)	(0.23)	0.0	N/A	N/A

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

Moving to Phase Ib/II after DRIIV trial interim results

AsiDNA is part of the proprietary, novel platON platform, a major R&D expansion announced in October 2017, and is based on decoy oligonucleotides, which makes it a unique drug with no close comparators with respect to mode of action. In a broader sense, the platON platform belongs to the so-called DNA damage response (DDR) technology, a domain in which recently marketed PARP inhibitors also belong. On 5 November 2018, Onxeo reported interim results from the first clinical DRIIV-1 trial where AsiDNA was administered intravenously. After testing the first three dose levels (out of six), no serious drug-related side effects were seen and the maximum tolerated dose has not been established yet. Activity and tumour biomarker analysis allowed Onxeo to conclude that mechanism of action in humans after systemic administration has been proven and the company is now planning further Phase Ib/II studies, which will likely include combination treatments, with substantial focus on PARP inhibitors and chemotherapies.

AsiDNA + PARP inhibitor combinations

Onxeo believes that AsiDNA + PARP inhibitor combination has significant potential due to complementary mechanisms of action and positive preclinical data. On 12 July 2018, Onxeo announced a set of positive preclinical data with AsiDNA in combination with various PARP inhibitors. AsiDNA was tested with olaparib (Lynparza, AstraZeneca) and talazoparib, and consistently demonstrated synergistic effect in in vivo and in vitro models.

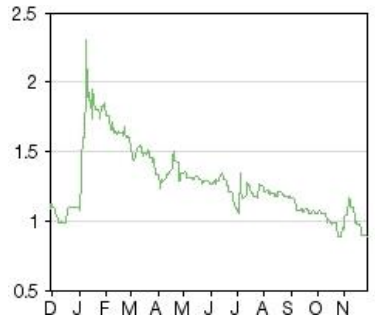
Valuation: Revised to €172m or €3.3/share

Our valuation is €172m or €3.3/share, lower than our previous value of €221m or €4.4/share, due to R&D project revisions as detailed below, mainly related to Beleodaq, which was partially offset by the increase in net cash and rolling our model forward. Trial design and initiation of the next Phase Ib/II programme and results from other preclinical AsiDNA combination studies are potential catalysts in the near term.

27 November 2018

Price	**€0.89**
Market cap	**€46m**
Net cash (€m) at end Q318	13.0
Shares in issue	52.8m
Free float	80%
Code	ONXEO
Primary exchange	Euronext Paris
Secondary exchange	OMX Copenhagen

Share price performance



%	1m	3m	12m
Abs	0.1	(24.4)	(23.2)
Rel (local)	0.0	(17.2)	(17.3)
52-week high/low		€2.3	€0.9

Business description

Onxeo is focused on orphan cancer indications, specialising in epigenetics and DNA break repair inhibition. Beleodaq, an HDAC inhibitor, is approved for PTCL in the US and partnered with Spectrum Pharmaceuticals. AsiDNA, a novel DNA break repair inhibitor from Onxeo's platON platform, is in a Phase I trial with interim data expected in 2018.

Next events

Phase Ib/II with AsiDNA start	H119
Preclinical studies with new platON candidate	H218/H119
Results from preclinical studies of other AsiDNA combinations	H218/H119

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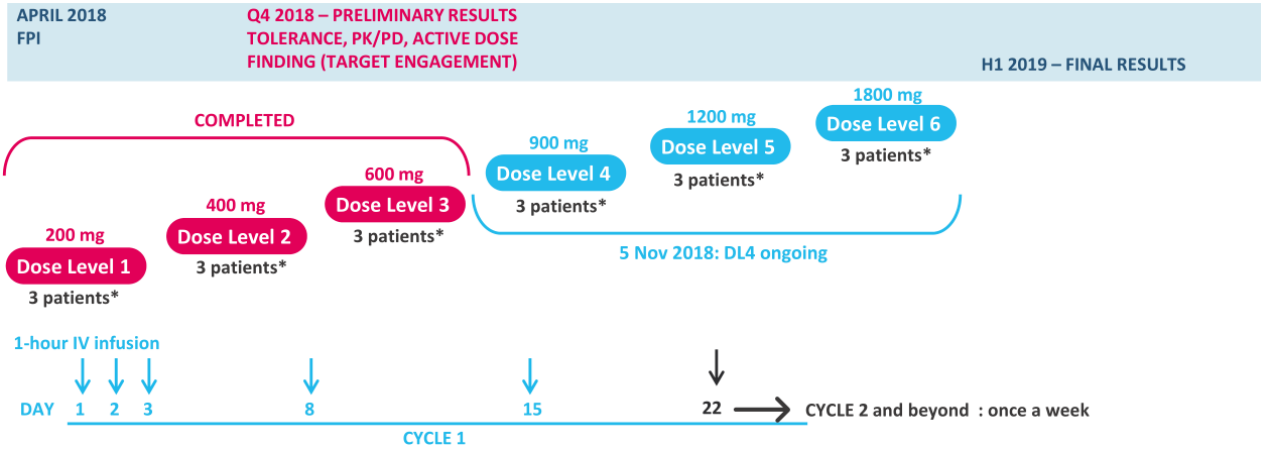
Edison profile page

DRIIV-1 study results

The open-label, dose escalation Phase I **D**NA **R**epair **I**nhibitor administered **I**ntra**V**enously (DRIIV) recruited patients with various advanced solid tumours, with the first patient treated in April 2018. This is the most advanced study where patients receive AsiDNA systemically (positive findings from the Phase I trial with topical administration of AsiDNA have already been published). The study aims to assess the safety/tolerability profile and recommended dose for subsequent efficacy trials. Onxeo also explored various biomarkers that might help to gauge the activity of AsiDNA and stratify patients in later trials.

Exhibit 1: Phase I DRIIV trial design



Source: Onxeo; *3 additional patients if a dose limiting toxicity is observed.

Exhibit 2: Biomarker analysis demonstrated proof-of-mechanism of action in man

	Tumor proliferation biomarker		Tumor proliferation biomarker
DL2 : 400mg	KI67	DL3 : 600mg	KI67
Patient 0106	↓	Patient 0202	↓↓
Patient 0109	↓	Patient 0301	→

	Activity biomarkers		Activity biomarkers	
DL2 : 400mg	γH2AX	pHSP90	DL3 : 600mg	γH2AX	pHSP90
Patient 0106	→	↑↑↑	Patient 0202	↑↑	↑
Patient 0109	↑	↑↑	Patient 0301	↑↑↑	↑↑↑

Source: Onxeo

As planned, Onxeo released interim results from the first part of the trial on 5 November 2018, which included results from the first three dose groups. The findings from a total of 10 patients who received 112 infusions of AsiDNA ranging from 200mg to 600mg include:

- No serious drug-related events and no dose-limiting toxicity.
- Maximum tolerated dose not reached yet.
- Biomarker analysis was available from four patients, who had biopsies before treatment and at the end of cycle 2:
  - All four patients demonstrated a consistent pattern in the increase of activity biomarkers (γH2AX, pHSP90) as early as the second level dose (400mg), which showed target engagement, ie the drug is doing what it was designed for. γH2AX and pHSP90 are established biomarkers of the activation of DNA-PK, one of the major targets for AsiDNA, and Ki67 is a well-known tumour proliferation biomarker.
  - Tumour proliferation biomarker Ki67 has decreased (in three patients) or stabilised (in one patients).

Our take

The rationale for this study was built on previous findings from the Phase I DRIIM, where AsiDNA has been administered intratumourally in melanoma patients, as well as extensive preclinical work to determine activity biomarkers. While the data released from the DRIIV-1 trial are still very early and no conclusions about efficacy can be made yet, we find it reassuring that no serious drug-related side effects emerged with intravenous administration. AsiDNA is a unique drug (DNA damage repair inhibitor) with no close comparators with respect to mode of action and therefore there was no visibility on the safety/tolerability profile via a systemic administration before DRIIV-1 results (safety data via local injection in the DRIIM trial was good). The consistent pattern of increase in activity biomarkers also demonstrated that the drug reaches its target after the intravenous administration.

Rationale for AsiDNA + PARP inhibitor combination

With the results announcement, Onxeo also provided an update on its AsiDNA development strategy. The company aims to initiate Phase Ib/II studies in H119 with AsiDNA in combination with other established treatment options, primarily PARP inhibitors and standard-of-care (SoC) chemotherapy regimens. Specific indications have not been announced yet, but since the acquisition of the asset in March 2016, Onxeo has conducted various preclinical studies to understand how to better position AsiDNA in the clinic.

Single strand DNA breaks are repaired by base excision repair (BER) pathway. Among other enzymes involved in BER are poly(ADP ribose) polymerase 1 and 2 (PARP1 and PARP2), which act as sensors and signal transducers. PARP inhibition therefore affects this pathway specifically. PARP inhibitors have shown promising efficacy and safety in clinical trials with BRCA mutated tumours, but the main drawback was the necessity of a dysfunctional homologous recombination (HR) pathway (cells can compensate DNA repair via this pathway). This underlies the synthetic lethality mechanism of action exhibited by PARP inhibitors, since those cancers with BRCA mutation (ovarian, breast) are not able to repair DNA damage by HR pathway. However, because of the dependence on dysfunctional HR pathway, the studies have shown that even those tumours that were initially responsive to PARP inhibitions, finally relapsed through compensatory mutations restoring the HR activity.

First-in-class AsiDNA is based on signal-interfering DNA technology, which if introduced into a cell acts as a signal mimicking the damage of the cell's own DNA. AsiDNA molecules are short double-strand DNA that mimic double-strand breaks and are recognised as "damaged DNA" by repair and signalling proteins. Namely, AsiDNA hyper-activates PARP1 and the DNA-dependent protein kinase (DNA-PK) among others leading to a cascade of repair proteins being recruited to "repair the damage", as a result of which the actual damage of a cell's DNA remains unrepaired. This action renders the HR and NHEJ pathways dysfunctional. Due to its independent mechanism of action (abrogation of the HR pathway) there is strong rationale to use AsiDNA in combination with PARP inhibitors to potentiate their effect. Inhibiting the BER pathway through PARP inhibition, in addition to HR/NHEJ pathway inhibition with AsiDNA, will cause accumulation of double-strand DNA damage in the tumour cells and tumour cell death. In addition, AsiDNA could potentially be used to sensitise BRCA non-mutated tumours to PARP inhibitors, which in turn would expand their use substantially.

Preclinical data on AsiDNA in combinations

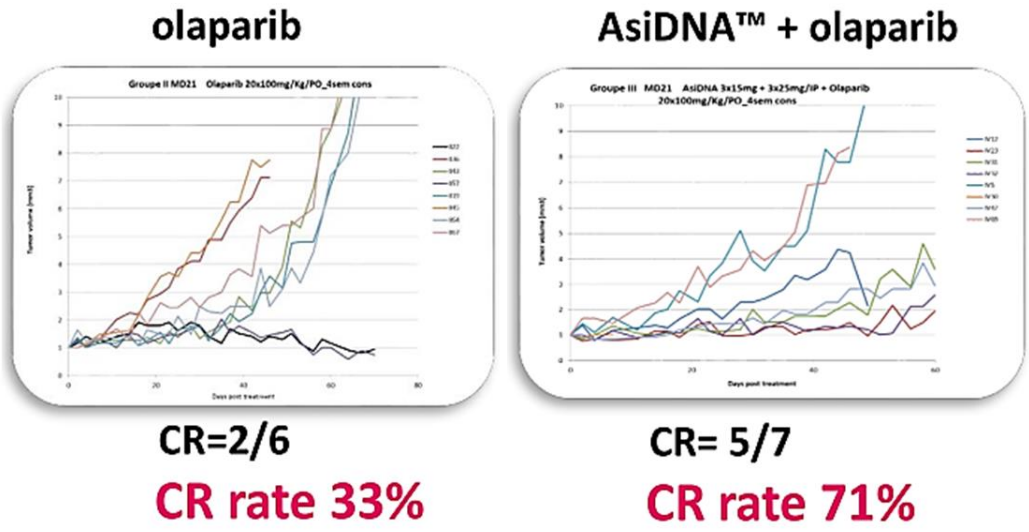
In our update note, we reviewed the preclinical *in vitro* data Onxeo presented at the AACR annual meeting in April 2018, which showed the synergistic effect of AsiDNA in combination with the company's HDAC inhibitor, belinostat. Onxeo also obtained evidence that AsiDNA may induce

'autosensitisation', ie the tumour cell's sensitivity to AsiDNA could actually increase as the treatment progresses, unlike the majority of drugs in oncology that develop resistance. Previously, Onxeo also showed that low doses of AsiDNA in combination with classical chemotherapy agent carboplatin outperformed carboplatin alone in a triple negative breast cancer (TNBC) model.

On 12 July 2018, Onxeo announced another set of positive preclinical data with AsiDNA in combination with various PARP inhibitors. AsiDNA was tested with olaparib (Lynparza, AstraZeneca, consensus estimate of $621m in 2018 sales) and talazoparib in in vivo and in vitro models. The findings suggest the following:

- AsiDNA combined with olaparib more than doubled the complete response rate (71% vs 33%) observed with olaparib alone in an in vivo model of TNBC resistant to PARP inhibitors (Exhibit 3).
- AsiDNA combined with olaparib inhibited tumour growth in an in vivo humanized Patient-Derived Xenograft (PDX) mice model of ovarian cancer resistant to olaparib.
- AsiDNA combined with PARP inhibitors prevented the development of resistance and reversed this resistance to PARP inhibitors after repeated exposure in in vitro models of TNBC and small cell lung cancer.

Exhibit 3: Synergistic effect of AsiDNA + olaparib in TNBC model



Source: Onxeo

Expanding PARP inhibitor market

Ovarian cancer and breast cancer are the only approved indications for PARP inhibitors so far. These cancers were seen as the low-hanging fruit for PARP inhibitor development, due to the link between BRCA mutation and these tumours (9% of breast cancer, 11-15% ovarian cancer is caused by BRCA1/2 mutations). The market for PARP inhibitors is currently around $1bn worldwide (source: EvaluatePharma), with ovarian cancer (Lynparza, Zejula and Rubraca) and breast cancer (Lynparza, talazoparib) driving near-term sales (Exhibits 4 and 5). According to consensus, the market for PARP inhibitors could reach $6.9bn in 2024. This will be driven by the introduction of new PARP inhibitors, possible transitioning of 2L/3L products into 1L, new indications (where prostate is expected to perform best) and combinations with other drugs. Although further indications are being explored, ovarian cancer and breast cancer are expected to remain the largest indications for PARP inhibitors into 2024. Onxeo is hoping to move into this growing market by developing AsiDNA + PARP inhibitor combinations(s) in solid tumour indications, which makes sense due to the complementary mechanism of action, but also due to the large market opportunity.

In addition, AsiDNA + PARP inhibitor combination could be used regardless of the mutation status, which would have the potential to significantly expand indications for PARP inhibitors themselves.

Exhibit 4: PARP inhibitor sales forecasts

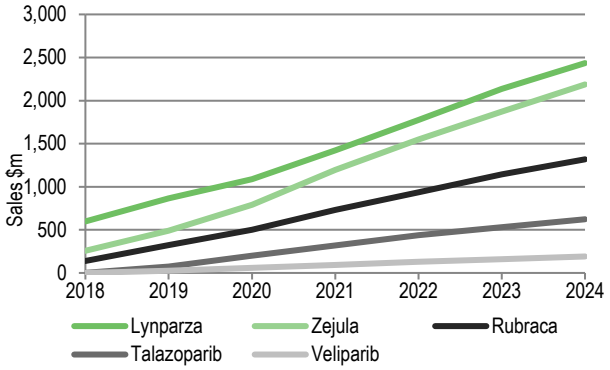
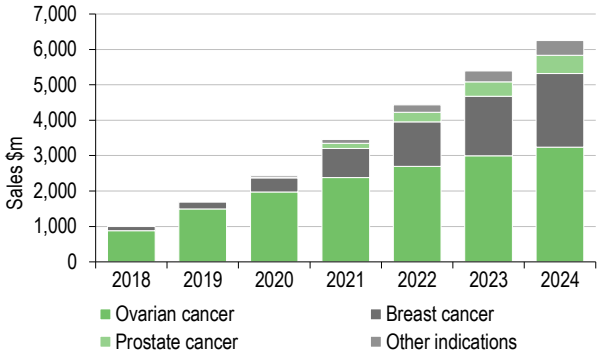


Exhibit 5: PARP inhibitor forecasts by indication



Source: Evaluate Pharma. Note: Forecasts of talazoparib by indication not available.

Exhibit 6: Marketed and late stage PARP inhibitors

Drug	Company	Pharmacological class	Indications	Stage of development	Biomarker(s)	Companion diagnostic?
Lynparza (olaparib)	Merck & Co, AstraZeneca	PARP 1,2,3 inhibitor	Breast Cancer	Marketed in US, filed in Europe	R&D: BRCA, ER-/PR-/HER2- & HER2	BRACAnalysis CDx (Myriad)
			Fallopian tube cancer	Marketed in US and Europe	BRCA (EU)	
			Ovarian cancer	Marketed in US and Europe	BRCA (US & EU) (R&D: HER2)	BRACAnalysis CDx (Myriad)
			Prostate cancer	Phase III	R&D: BRCA & ERG	
			Pancreatic cancer	Phase III	R&D: BRCA & HER2	
Rubraca (rucarparib)	Pfizer, Clovis Oncology	PARP 1,2,3 inhibitor	Ovarian cancer	Marketed in US, approved in Europe	BRCA (US)	
			Breast cancer	Phase III	R&D: BRCA	
			Prostate cancer	Phase III	R&D: BRCA	
Zejula (niraparib)	Merck & Co, Tesaro	PARP 1,2 inhibitor	Fallopian tube cancer	Marketed in US, approved in Europe	-	
			Ovarian cancer	Marketed in US and Europe	R&D: BRCA & ER-/PR-/HER2-	BRACAnalysis CDx (Myriad)
			Breast cancer	Phase III	R&D: BRCA & HER2	BRACAnalysis CDx (Myriad)
Talazoparib	Pfizer, BioMarin	PARP inhibitor	Breast cancer	Filed in US and Europe	R&D: BRCA	
			Prostate cancer	Phase III	-	
Pamiparib	BeiGene, Merck KGaA	PARP I,2 inhibitor	Stomach cancer	Phase III	-	
			Ovarian cancer	Phase III	-	
Veliparib	AbbVie	PARP inhibitor	Breast cancer	Phase III	R&D: BRCA & ER-/PR-/HER2-	
			Non-small cell lung cancer	Phase III	R&D: EGFR	
			Ovarian cancer	Phase III	-	

Source: Evaluate Pharma, ClinicalTrials.gov, Edison Investment Research. Note: Marketed drugs are approved for 2L/3L but in trials for 1L.

PARP inhibitors are the only marketed class of DNA repair inhibitor, but drugs targeting other DNA repair pathways and targets are also in clinical development. Large pharma are very active in the space, especially AstraZeneca and Merck KGaA, where AstraZeneca is developing its Lynparza franchise against PARP (Exhibit 6), but also investigating ATM (HR pathway), DNA-PK (NHEJ pathway) and WEE1. Merck is also very active in the space, developing drugs against PARP, but also ATR (HR pathway), ATM (HR pathway), DNA-PK (NHEJ pathway) and WEE1. As far as we are aware, AsiDNA is differentiated and has a unique mechanism of action as it is an agonist that acts as a decoy and affects multiple proteins in the DDR cascade, while other drug candidates in the area act as inhibitors of specific single targets.

Financials and valuation

On 7 June 2018, Onxeo announced that it had effectively sold the Beleodaq royalties from its partnership with Spectrum Pharmaceuticals to SWK Holdings Corporation in exchange for an immediate payment of $7.5m. SWK Holdings Corporation is entitled to receive $13.5m in future royalties from Spectrum. Our last published rNVP of Beleodaq (marketed) was €34.5m, which was based on a bottom-up model. Onxeo reported €1.0m in licensing income in H118 alone. We believe its future commercial potential of Beleodaq is higher than $13.5m. In such a case Onxeo would retain the residual royalties or those could be sold again. Therefore, to reflect both the received payment and the remaining value of the asset, we subtract $7.5m (€6.6m, the price paid by SWK for Beleodaq royalties) from Beleodaq's rNPV in our model and add to the cash balance. We see the deal as neutral to the company's value, however, it provided a decent increase in cash to help fund Onxeo's ongoing development programmes and signals the prioritisation of the AsiDNA programme.

As a next step, we reviewed the potential of the products since Spectrum Pharmaceuticals reported several quarterly sales data points after our last revision. Beleodaq sales in the US in Q318 were $3.2m vs $3.4m in Q317. 9M18 sales were $8.6m vs $9.7m in 9M17. This was likely due to istodax (Romidepsin, Celgene, sales of $76m in 2017), which is also indicated for peripheral T-cell lymphoma (PTCL), going off patent and the first generic forms appearing at the beginning of this year. Consensus expects that Romidepsin will still bring in sales of $51m by 2024 (source: EvaluatePharma), although it is indicated for PTCL and cutaneous T-cell lymphoma. Our previous estimate for Beleodaq FY18 US sales was $20.5m, which we now revise to $11.5m. We have also revised our peak penetration rate from 15% to 7.5%, which translates into lower peak sales expectations of $40m for Beleodaq (US, PTCL second line) and $30m for Beleodaq (EU), and lower respective NPVs. From a strategic perspective, variations in end-user sales are of less importance for Onxeo now, as the royalty sale deal ensured cash up front. The main value driver in our model is AsiDNA (Exhibit 8).

We have also decided to remove Livatag from our valuation. The results released a year ago (September 2017) showed that the primary endpoint of the Phase III trial with Livatag was not reached. We reduced the success probability to 5% as Onxeo was still considering all options for the asset but, given there were no recent updates to this end, we conservatively remove it from our valuation.

On 15 June 2018, Onxeo announced that it had obtained an equity financing line from Nice & Green by issuing new shares over a 10-month period for a maximum amount of €5.4m. The shares will be issued based on the average of the volume weighted average share price of the three trading days preceding each issue, minus a maximum discount of 5.0%. The reported cash position at end-Q318 was €13m, which includes proceeds of €2.4m from drawdown of the equity line. According to the company, this extended the cash reach into 2020, which is in line with our model. Other operating estimates were only fine-tuned.

Our valuation is €172m or €3.3/share, lower than our previous valuation of €221m or €4.4/share, mainly due to the R&D revisions as detailed above, which were offset by a higher cash position and rolling our model forward. Our assumptions for AsiDNA are unchanged although, as Onxeo progresses its preclinical development into further trials, there is potential to add more indications for AsiDNA as monotherapy or in combination with other agents such as PARPi or chemotherapy drugs.

Exhibit 7: Onxeo rNPV valuation

Product	Indication	Launch	Peak sales (€m)	NPV (€m)	Probability (%)	rNPV (€m)	NPV/share (€/share)
Core assets							
AsiDNA	TNBC	2024	2,170	405.9	15%	83.8	1.6
Beleodaq (US)	PTCL	2014	40	11.0	100%	11.0	0.2
Beleodaq (EU)	PTCL	2022	30	24.7	70%	17.3	0.3
Other assets							
Validive			67	59.2	50%	29.6	0.6
Est. earn-outs associated with Loramyc/Sitavig					49.2	30%	14.7
Net cash at end Q318 (+remaining equity financing from Nice&Green of €3.0m)				16.0	100%	16.0	0.3
Valuation				**566.0**		**172.4**	**3.3**

Source: Edison Investment Research. Note: PTCL = peripheral T-cell lymphoma, TNBC = triple negative breast cancer.

Exhibit 8: Financial summary

€000s	2015	2016	2017	2018e	2019e
Year end December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	3,482	4,423	9,505	3,350	3,518
Cost of Sales	(337)	(655)	(634)	(689)	(589)
Gross Profit	3,145	3,768	8,871	2,661	2,929
EBITDA	(20,355)	(21,304)	(17,393)	(7,203)	(11,754)
Operating Profit (before amort. and except.)	(20,574)	(21,542)	(20,574)	(21,542)	(19,189)
Intangible Amortisation	(1,600)	(1,626)	0	0	0
Exceptionals	(160)	(43)	(47,188)	(8,663)	0
Operating Profit	(22,334)	(23,211)	(66,377)	(16,466)	(11,854)
Other	(29)	0	0	0	0
Net Interest	602	1,107	(491)	(3)	(3)
Profit Before Tax (norm)	(19,972)	(20,435)	(19,680)	(7,806)	(11,856)
Profit Before Tax (reported)	(21,761)	(22,104)	(66,868)	(16,469)	(11,856)
Tax	2,353	(566)	7,797	1,711	0
Profit After Tax (norm)	(17,648)	(21,001)	(11,883)	(6,095)	(11,856)
Profit After Tax (reported)	(19,408)	(22,670)	(59,071)	(14,758)	(11,856)
Average Number of Shares Outstanding (m)	40.5	40.5	47.0	50.4	51.5
EPS - normalised (€)	(0.44)	(0.45)	(0.24)	(0.12)	(0.23)
EPS - normalised fully diluted (€)	(0.44)	(0.45)	(0.24)	(0.12)	(0.23)
EPS - (reported) (€)	(0.48)	(0.48)	(1.17)	(0.29)	(0.23)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	90.3	85.2	93.3	79.4	83.3
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	87,539	88,232	48,111	39,123	39,023
Intangible Assets	86,367	87,213	47,535	38,647	38,647
Tangible Assets	841	713	344	244	144
Investments	331	306	232	232	232
Current Assets	41,697	36,868	29,962	14,117	6,257
Stocks	106	184	30	33	28
Debtors	1,036	1,548	552	1,500	704
Cash	33,793	29,243	14,277	6,085	1,025
Other	6,762	5,893	15,103	6,500	4,500
Current Liabilities	(10,606)	(12,417)	(18,841)	(6,104)	(6,104)
Creditors	(10,537)	(12,311)	(18,711)	(5,974)	(5,974)
Short term borrowings	(69)	(106)	(130)	(130)	(130)
Long Term Liabilities	(15,831)	(18,594)	(9,358)	(10,050)	(10,050)
Long term borrowings	0	0	0	0	0
Other long term liabilities	(15,831)	(18,594)	(9,358)	(10,050)	(10,050)
Net Assets	102,799	94,089	49,874	37,086	29,126
CASH FLOW					
Operating Cash Flow	(20,067)	(16,838)	(20,974)	(17,265)	(7,973)
Net Interest	579	(1,560)	317	382	(3)
Tax	(2,448)	538	(7,801)	0	0
Capex	(410)	(316)	(65)	(84)	(84)
Acquisitions/disposals	0	0	0	0	0
Financing	611	13,589	13,533	8,775	3,000
Dividends	0	0	0	0	0
Net Cash Flow	(21,735)	(4,587)	(14,990)	(8,192)	(5,060)
Opening net debt/(cash)	(55,459)	(33,724)	(29,137)	(14,147)	(5,955)
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(33,724)	(29,137)	(14,147)	(5,955)	(895)

Source: Onxeo accounts, Edison Investment Research

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