EDISON

OSE Immunotherapeutics

Company update

R&D progress triggers milestone payment windfall

Pharma & biotech

OSE Immunotherapeutics now has four clinical trials running. Interim results from its Phase III Atalante 1 trial with cancer vaccine Tedopi are a key catalyst and due in Q120. Another three trials were initiated over the last 12 months, which brought OSE a total of €27m in payments from partners (plus another €5.4m from Bpifrance). These trials include a Phase I study with OSE-127 (partnered with Servier), a Phase I study with BI 765063 (previously OSE-172; with Boehringer Ingelheim, BI) and a Phase II study with Tedopi in pancreatic cancer (GERCOR). We raise our valuation of OSE to €198m or €13.2/share (previously €190m).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	6.7	(12.6)	(0.72)	0.0	N/A	N/A
12/18	24.5	4.8	0.38	0.0	N/A	N/A
12/19e	16.6	(6.1)	(0.41)	0.0	N/A	N/A
12/20e	0.0	(22.8)	(1.53)	0.0	N/A	N/A

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

Phase III Atalante 1 interim results in Q120

Although OSE has a broad and diversified R&D pipeline, much of the focus until early 2020 (Q120) will be on the Phase III Atalante 1 trial with a peptide cancer vaccine Tedopi for second- and third-line treatment of non-small cell lung cancer patients (NSCLC). OSE hosted a Tedopi-focused KOL event in New York in May 2019, where the presenters provided a detailed overview of the cancer vaccine's development and of target indications NSCLC and pancreatic cancer.

Self-sufficient R&D

In addition to Phase III Atalante 1 (funded by OSE), Tedopi is being tested in a Phase II trial in pancreatic cancer patients, which is run by OSE's partner GERCOR (a physician network). Another two trials were initiated earlier this year and both are financed by partners. These include a Phase I study with BI 765063 (OSE-172), a SIRPα antagonist for solid tumours, which is run by OSE but funded by BI, which paid €15m in milestones on initiation of the trial. According to the terms of the licensing deal with BI, OSE is still eligible to receive up to €1.1bn in milestones plus royalties if certain conditions are met. Similarly, OSE initiated a Phase I trial with its OSE-127 IL-7Rα (CD127) antagonist for autoimmune diseases, which triggered a €12m payment (Servier exercised an option; total value of the deal €272m, of which €22m has been received).

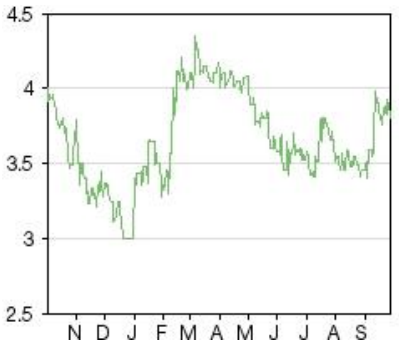
Valuation: €198m or €13.2/share

We have raised our valuation of OSE to €198m or €13.2/share from €190m or €12.8/share previously, which is due to a better cash position, rolling our model forward and increasing the probability of success to 10% for BI 765063 (OSE-172) as the Phase I trial has been initiated. The milestone payments from Servier and BI had virtually no effect as we have already included them in our model. The interim results from the Phase III Atalante 1 trials are the main catalyst in the near term.

30 September 2019

Price	**€3.80**
Market cap	**€57m**
Gross cash (€m) as of end-H119, (government debt not included)	26.3
Shares in issue	15.0m
Free float	24%
Code	OSE
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	11.4	5.8	(5.0)
Rel (local)	6.6	3.0	(5.5)
52-week high/low		€4.35	€3.00

Business description

OSE Immunotherapeutics is an immunotherapy company based in Nantes and Paris, France, and listed on the Euronext Paris exchange. OSE is developing immunotherapies for the treatment of solid tumours and autoimmune diseases and has established several partnerships with large pharma companies.

Next events

Phase III Atalante 1 interim results	Q120
First preclinical data from BiCKI platform	Q419/2020

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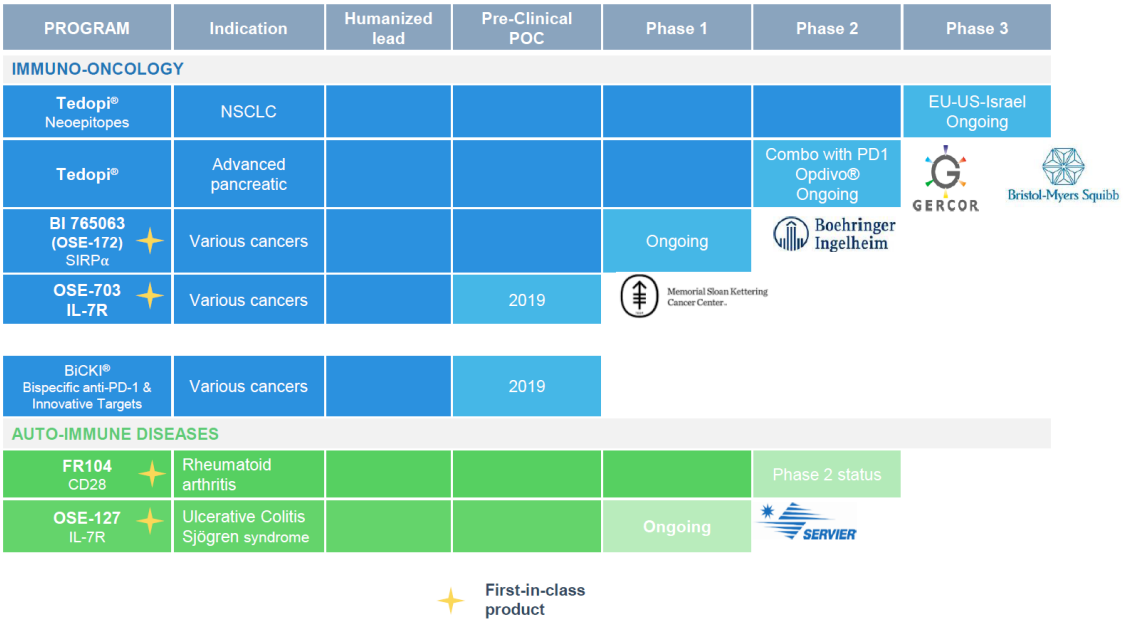
Tedopi KOL event; interim Atalante 1 trial data in Q120

On 30 May 2019, OSE hosted a KOL day in New York, which focused on Tedopi, NSCLC and pancreatic cancer. The presentations provided more detailed background on the development of Tedopi and an overview of the target cancer indications. Overall, we view the update as in line with our discussions in our initiation report. Although OSE has a well-balanced R&D pipeline in terms of asset stages and technology types, the focus on Tedopi will prevail due to a combination of factors. It is the most advanced OSE asset in development and interim analysis will be carried out in Q120, which will also include some efficacy data; this makes it a substantial catalyst for OSE.

Atalante 1 is a Phase III trial with Tedopi as second- or third-line treatment against standard of care (docetaxel or pemetrexed) in HLA-A2 positive patients with locally advanced (IIIB), unsuitable for radiotherapy or metastatic (IV) NSCLC. Post-checkpoint failure patients represent an area where no novel treatment has been approved yet. The trial aims to enrol 300 patients. Interim analysis is expected in Q120, which will include survival data from the first 84 patients. This is a significant catalyst for OSE, although the final results should come later in 2021. OSE presented case reports from three patients from the Atalante 1 trial at AACR in Atlanta on 31 March 2019, which we discussed in our last update report.

At the end of 2018, OSE's partner GERCOR (a physician network) initiated a Phase II trial with Tedopi as maintenance therapy alone or in combination with Opdivo or FOLFIRI in pancreatic cancer after induction therapy with FOLFIRINOX. Bristol-Myers Squibb is supporting the trial by providing Opdivo for free. Results are expected in 2022. Pancreatic cancer represents an unmet need with relatively little advance in treatment compared to most other cancers over the last decade. Pancreatic cancer is a 'cold' tumour, so the rationale is to combine immune-priming cancer vaccine Tedopi (stimulates specific T-cell response) with checkpoint inhibitors (makes tumours 'visible' to the immune system). OSE will evaluate options for further development and commercialisation depending on the results of this study.

Exhibit 1: OSE's pipeline



Source: OSE

BI 765063: First patient enrolled in Ph I, milestone paid

OSE announced on 17 June 2019 that the first patient had been dosed in the Phase I study with BI 765063 (OSE-172), a monoclonal antibody antagonist of SIRPα, that OSE licensed to BI. This triggered the second part of the €15m milestone payment from BI as expected (we only adjusted the milestone with 95% probability in our model). OSE is still eligible to receive up to a further €1.1bn in milestones plus royalties if certain milestones are met.

The full clinical trial design is now available (Exhibit 2). It is an open-label, dose-finding Phase I study of BI 765063 (OSE-172) as single agent and in combination with BI 754091 (anti-PD-1) to characterise safety, PK/PD and preliminary efficacy in patients with advanced solid tumours. OSE is responsible for running the trial but BI bears the costs, according to the collaboration and licensing agreement. BI will take over the development after Phase I.

In total 116 patients with advanced/metastatic tumours are expected to be enrolled. The study includes two steps and four cohorts, essentially two dose escalation cohorts and two expansion cohorts (BI 765063 standalone and BI 765063 in combination with BI's own anti-PD-1). The dose-escalation cohorts are enrolling patients with advanced/metastatic primary or recurrent malignancies who failed or are not eligible to standard therapy. Then the expansion cohorts will be restricted to selected cancers (see Exhibit 2 notes for the list).

Exhibit 2: Phase I study with BI 765063 monotherapy and in combination with BI 754091 (NCT03990233)

Number of patients	116
Treatment groups	Step 1. Cohort A – dose escalation: BI 765063 alone patients with advanced solid tumours Step 1 Cohort B – dose escalation: BI 765063 in combination with BI 754091 (PD-1 inhibitor) in patients with advanced solid tumours Step 2. Cohort C1 – expansion cohort: BI 765063 patients with selected advanced solid tumours* Step 2. Cohort C2 – expansion cohort: BI 765063 in combination with BI 75409 in patients with selected advanced solid tumours*
Endpoints	Primary endpoint: Number of patients with dose-limiting toxicities (DLTs) during the first treatment cycle; maximum tolerated dose (MTD) determination; number of patients with DLT-like events during the whole treatment Secondary endpoints: safety, tolerability, PK parameters, objective response rate (ORR), percentage and evolution of SIRPα receptor occupancy (RO) in blood at pre, on-treatment and after the end of treatment

Source: clinicaltrials.gov. Note: *NSCLC, triple negative breast cancer, pancreatic cancer, melanoma, head and neck squamous cell carcinoma, renal cell carcinoma, urothelial carcinoma, small cell lung cancer, gastric cancer, colorectal cancer and ovarian cancer.

Combining BI 765063 with a PD-1 inhibitor is based on the complementary mechanisms of action of the two agents. That is, CD47/SIRPα inhibition should lead to phagocytosis of tumour cells by myeloid cells; this leads to tumour antigen uptake and presentation, which should activate the adaptive immune system, namely, T-cells killing tumour cells, which in turn is facilitated by PD-1/PD-L1 inhibition. OSE recently published an article describing the role of SIRPα in the induction and maintenance of immune tolerance and a poster presentation supporting the combination of a SIRPα monoclonal antibody and checkpoint inhibitor (anti-PD-L1 not anti-PD-1 as in the Phase I study). These pre-clinical studies add support to OSE's strategy. As with many Phase I cancer trials, the indications are quite broad at the moment but will focus on the most promising cancers in further trials.

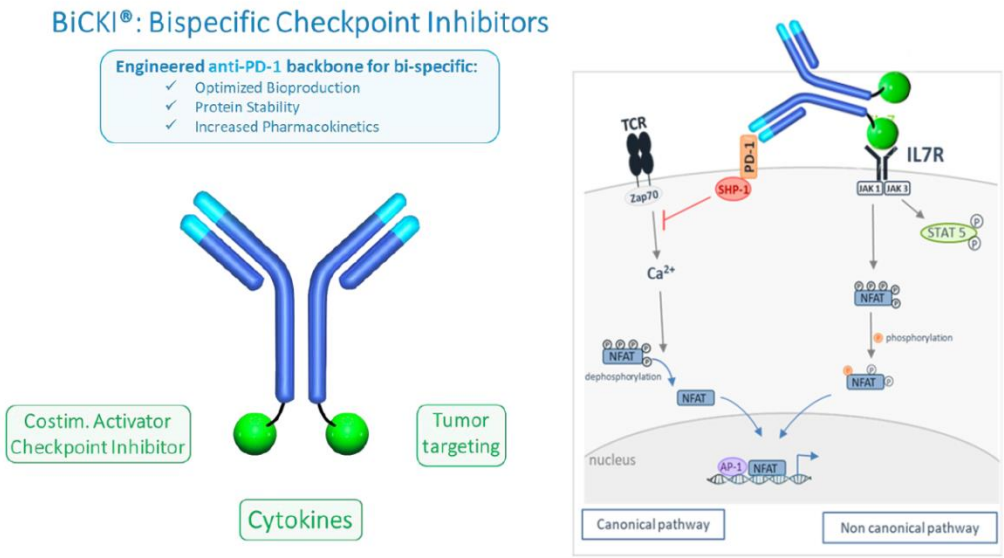
BiCKI bispecific platform: PD-1 + innovative targets

OSE presented its new BiCKI platform at the World Immunotherapy Congress in San Diego on 5 March 2019. This included some information about the bispecific/fusion antibody platform and included a lot of information on the first potential bispecific candidate, BiCKI IL-7. While we do not include any new assets in our valuation, we conducted a more detailed review of the platform and the opportunities.

Bispecifics and other types of antibodies can bind multiple targets. BiCKI is a bispecific/fusion antibody platform (Exhibit 3) that consists of:

- **A humanised high-affinity anti-PD-1 monoclonal antibody (blue Y in Exhibit 3)**. OSE has developed its own anti-PD-1 antibody that forms the 'backbone' of the bispecifics. So far there is limited information about this anti-PD-1 but OSE indicated it was chosen due to its good yield in terms of manufacturing and productivity, in particular in bispecific format. This is an IgG antibody in that it has a normal structure with heavy and light chains, where the Fab region binds to the PD-1 receptor on T-cells.
- **Engineered proteins attached to the Fc region (green circles in Exhibit 3).** The silent Fc region of the antibody (base of the heavy chains) is the effector part of the molecule. It determines what effect the antibody has once it has bound to the antigen – usually an immune response. OSE plans to engineer different proteins to the Fc region, eg IL-7, through protein fusion to target novel receptors.

Exhibit 3: BiCKI platform (left) and BiCKI IL-7 mechanism of action on T-cells (right)



Source: OSE BiCKI presentation at the World Immunotherapy Congress in San Diego on 5 March 2019

OSE hopes these anti-PD-1 bispecifics will help overcome the resistance (primary and secondary, depending on the second target) to anti-PD-1 drugs by selecting targets that are involved in different stages of the immunity cycle and so are complementary. In particular, OSE is looking for targets that would have synergistic potential.

OSE's first candidate based on this platform is BiCKI IL-7 (Exhibit 3). OSE is already working with the IL-7 receptor (IL-7R) from the OSE-703 and OSE-127 programmes, so has experience in this area with a cytotoxic agonist asset. OSE suggested a few mechanisms of action for BiCKI IL-7 during the BiCKI presentation in March 2019, but perhaps the most important is that IL-7R sustains the life of exhausted T-cells. IL-7 is a cytokine that controls the proliferation, apoptosis and activation of CD4+ and CD8+ T-cells in humans. IL-7Rα expression is reduced in exhausted T-cells. Activating the IL-7Rα receptor with IL-7 should reduce T-cell exhaustion. The main advantage of the bispecific drug (over a combination of two drugs: anti-PD-1 with IL-7) is that BiCKI IL-7 synergistically increases TCR signalling and hence antigen-specific T cells responses.

OSE presented the first preclinical data with its BiCKI IL-7 technology at the International Cancer Immunotherapy Conference (CICON; 25–28 September, 2019) in Paris. The company showed that the bifunctional anti-PD1/IL-7 fusion protein potentiates effector function of exhausted T-cells and disarms the suppressive activity of regulatory T-cells.

Large biotech/pharma are getting in early on bispecifics

Many players are trying to tackle the resistance to checkpoint inhibitors issue through developing combination therapies and bispecifics to solve the same problem. Some existing projects in the anti-PD-1 bispecifics space are listed in Exhibit 4. The most advanced candidates are in Phase I. There are a few companies trying to use bispecifics to target multiple checkpoints, eg XmAb20717 targets both PD-1 and CTLA-4, with the aim of further reducing any T-cell inhibition by tumour cells and promoting T-cell activation.

Exhibit 4: Anti-PD-1 bispecifics

	Drug	Company	Target 1	Target 1 – location	Target 2	Target 2 - location	Target 2 - mechanism of action	Indications, stage of development
Targeting multiple checkpoints	XmAb20717	Xencor	PD-1	T-cell	CTLA-4	T-cell	Promote tumour-selective T-cell activation	Advanced solid tumours (Phase I)
	RG7769	Roche	PD-1	T-cell	TIM-3	T-cell	Promote tumour-selective T-cell activation	Advanced solid tumours (Phase I)
	MEDI5752	AstraZeneca	PD-1	T-cell	CTLA-4	T-cell	Promote tumour-selective T-cell activation	Advanced solid tumours (Phase I)
	FS118	F-star	PD-1	T-cell	LAG-3	T-cell	Promote tumour-selective T-cell activation	Advanced solid tumours or haematological malignancies (Phase I)
Other	SL-279252	Takeda, Shattuck Labs	PD-1	T-cell	OX40 (bispecific contains OX40L)	T-cells	Promotes cytokine production, induces proliferation of memory and effector T-cells against tumour cells	Advanced solid tumours or lymphomas (Phase I)
	XmAb23104	Xencor	PD-1	T-cell	ICOS	T-cell	Promotes T-cell activation, enhances T-cell response against tumour cells	Advanced solid tumours (Phase I)
	BiCKI IL-7	OSE Immunotherapeutics	PD-1	T-cell	IL-7Rα	T-cell	Expands T-cells, restores exhausted T-cells	Preclinical stage

Source: Evaluate Pharma, Clinicaltrials.gov, Edison Investment Research. Note: MAb: monoclonal antibody, ICOS: inducible T-cell co-stimulator, CTLA: Cytotoxic T lymphocyte associated protein, TIM: T-cell immunoglobulin & mucin domain, TGF: transforming growth factor.

The bispecifics field has recently become a popular area. There are three bispecific antibodies (they do not target checkpoint receptors) that have been approved – Blincyto (blinatumomab, Amgen), Hemlibra (emicizumab, Roche) and Removab (catumaxomab, Fresenius now withdrawn), but there are many more in clinical stages (57 individual bispecifics according to EvaluatePharma). They are being developed for both oncology and immunology indications.

Most of the programmes are still very early stage therefore the existing deals are for bispecific platforms and pre-clinical programmes. There have been several large deals (Exhibit 5), which is promising for OSE. Most of the pre-clinical deals in Exhibit 5 include a collaboration based on the licensor's bispecific platform plus rights for their existing pre-clinical bispecific programmes. These deals achieved between $45–150m in upfront payments and $180–1,700m in milestone payments (for platform plus existing programmes), depending on the number of candidates included in the deal. As there is an appetite for bispecifics platforms and bispecific candidates from pharma, OSE's decision to invest in BiCKI seems well founded.

Exhibit 5: Pre-clinical bispecifics deals

Date	Licensor	Licensee	Product	Pharmacological class / Target	Indications included	Upfront ($m)	Milestones ($m)
08/03/2019	Xencor	Genentech (Roche)	XmAb24306	IL-15 and IL-15 receptor alpha (IL-15RA) bispecific MAb	Autoimmune disease and cancer	120	180
11/02/2019	TeneoOne	AbbVie	TNB-383B	Anti-B cell maturation antigen (BCMA) and CD3 bispecific MAb	Multiple myeloma	90	N/A
20/12/2018	Agenus	Gilead Sciences	AGEN1423 + option on four other programmes	Undisclosed bispecific MAb mechanism	Cancer indications	150 (including 30 equity)	1,700
27/11/2018	Xymeworks	BeiGene	ZW25, ZW49	HER2	Cancer indications	40	390
27/11/2018	Xymeworks	BeiGene	Azymetric and EFECT platforms	Bispecific platform	Cancer indications	20	702
03/10/2017	CytomX Therapeutics	Amgen	CytomX Probody T-cell engaging bispecific	Anti-EGFR and CD3 bispecific MAb	Cancer indications	60 (including 20 equity)	455
			+ up to three additional undisclosed targets	N/A	N/A	Up to 950 in additional upfront and milestones	
04/06/2017	F-star	Merck KGaA	FS118 + option on 4 other programmes	Anti-LAG 3 and PD-1 bispecific MAb	Cancer indications	€115	€1,000
28/06/2016	Xencor	Novartis	XmAb14045	Anti-CD3 and IL-3 alpha/CD123 bispecific MAb	Acute myeloid leukaemia	150	N/A
			XmAb 13676	Anti-CD3 and CD20 bispecific MAb	B-cell malignancies		
16/09/2015	Xencor	Amgen	AMG 424 + 5 other programs	Anti-CD3 and CD38 bispecific MAb	Multiple myeloma + other cancer /immune disorders	45	1,700

Source: Edison Investment Research, EvaluatePharma, company press releases.

Financials

OSE reported a top line of €16.0m in H119, which was mostly a milestone from BI (the rest is R&D cost reimbursement to OSE). The milestone payment of €10m from Servier was booked as prepaid income (cash balanced with deferred income plus €2m in VAT received as OSE and Servier are both French companies). Total H119 operating expenses were €12.1m, of which R&D costs and overhead expenses amounted to €9.2m and €2.9m respectively, resulting in an operating profit of €3.9m. R&D costs are mainly associated with the Tedopi Phase III NSCLC study. Our full 2019 and 2020 estimated operating expenses were €19.6m and €19.7m, which we now revise to €22.7m and €22.8m.

As of end-H119, OSE had cash, cash equivalents and financial assets of €26.5m (includes 'current financial assets'). The balance sheet also includes debt of €5.1m, which is mainly government loans. In September 2019, OSE announced it had received a €5.4m milestone payment from Bpifrance, the French public investment bank, in connection to the initiation of the Phase I trial with BI 765063 (€4.8m as a loan and €0.6m as income) as well. As part of a research consortium with the Léon Bérard cancer research centre, OSE also received a grant of €800k from the French National Research Agency, which will support preclinical research focused on validation of new targets linked to myeloid cells. Our model implies a comfortable cash reach to around end of 2020.

Valuation

We have raised our valuation of OSE to €198m or €13.2/share from €190m or €12.8/share previously. The increase is due to a better cash position and rolling our model forward, but is also a result of increased probability of success to a standard 10% for BI 765063 (OSE-172) as the Phase I trial has now been initiated (previously we used a slightly discounted probability of 7.5%). The milestone payment from Servier and BI had no effect as we have already included them in our

model (now moved from respective projects to cash in Exhibit 6). We make no other changes to our assumptions, described in detail in our initiation report.

We include Tedopi NSCLC, FR104, OSE-127 and OSE-172 in our valuation. Although GERCOR has initiated the Phase II study with Tedopi in pancreatic cancer, we still do not include this indication in the valuation because its commercial strategy has not been confirmed – OSE will evaluate this based on the Phase II results. We do not include the new bispecific platform in the valuation because it is still in a pre-clinical stage.

Exhibit 6: Sum-of-the-parts OSE valuation

Product	Launch	Peak sales ($m)	Unrisked NPV (€m)	Unrisked NPV/share (€)	Probability (%)	rNPV (€m)	rNPV/share (€)
Tedopi – NSCLC	2023	657	269.6	18.0	25	58.9	3.9
OSE-127 - ulcerative colitis	2027	843	168.7	11.3	10	21.4	1.4
OSE-172 - multiple cancer indications (TNBC)	2027	1,801	258.6	17.3	10	36.7	2.4
FR104 - rheumatoid arthritis	2026	1,056	230.0	15.4	15	55.4	3.7
Gross cash at end-H119*			25.5	1.7	100%	25.5	1.7
Valuation			**952.4**	**63.6**		**197.9**	**13.2**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. Note: *OSE's debt, not shown above, consists of government loans, which are typically repayable on commercial success only.

Exhibit 7: Financial summary

EUR'000s	2016	2017	2018	2019e	2020e
December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	383	6,682	24,456	16,579	0
Cost of Sales	0	0	0	0	0
Gross Profit	383	6,682	24,456	16,579	0
Research and development	(5,149)	(14,641)	(15,057)	(17,000)	(17,000)
EBITDA	(6,760)	(12,502)	4,963	(5,988)	(22,746)
Operating Profit (before amort. and except.)	(6,867)	(12,625)	4,847	(6,079)	(22,827)
Intangible Amortisation	24,365	0	0	0	0
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	17,498	(12,625)	4,847	(6,079)	(22,827)
Net Interest	0	0	0	(1)	(6)
Profit Before Tax (norm)	(6,867)	(12,625)	4,847	(6,080)	(22,833)
Profit Before Tax (reported)	17,498	(12,625)	4,847	(6,080)	(22,833)
Tax	3,074	2,238	783	0	0
Profit After Tax (norm)	(3,793)	(10,387)	5,630	(6,080)	(22,833)
Profit After Tax (reported)	20,572	(10,387)	5,630	(6,080)	(22,833)
Average Number of Shares Outstanding (m)	12.5	14.4	14.6	14.8	15.0
EPS - normalised (€)	(0.30)	(0.72)	0.38	(0.41)	(1.53)
EPS - normalised fully diluted (€)	(0.30)	(0.72)	0.36	(0.41)	(1.53)
EPS - reported (€)	1.64	(0.72)	0.38	(0.41)	(1.53)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0	N/A
EBITDA Margin (%)	N/A	N/A	20.3	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	19.8	N/A	N/A
BALANCE SHEET					
Fixed Assets	53,009	53,367	53,879	55,617	55,535
Intangible Assets	52,600	52,600	52,600	52,600	52,600
Tangible Assets	110	429	904	814	732
Investments	299	338	375	2,203	2,203
Current Assets	30,084	12,655	14,687	26,709	4,802
Stocks	0	0	0	0	0
Debtors	12,318	127	2,253	1,178	1,178
Cash	14,885	9,646	9,573	22,670	3,624
Other	2,881	2,882	2,861	2,861	0
Current Liabilities	(18,663)	(14,497)	(9,075)	(20,909)	(20,909)
Creditors	(18,076)	(13,908)	(8,447)	(20,253)	(20,253)
Short term borrowings	(587)	(589)	(628)	(656)	(656)
Long Term Liabilities	(6,358)	(7,409)	(6,075)	(16,324)	(16,324)
Long term borrowings	(1,197)	(4,296)	(3,832)	(9,293)	(9,293)
Other long term liabilities	(5,161)	(3,113)	(2,243)	(7,031)	(7,031)
Net Assets	58,072	44,116	53,416	45,093	23,105
CASH FLOW					
Operating Cash Flow	682	(7,995)	1,860	7,611	(21,901)
Net Interest	0	0	0	(1)	(6)
Tax	0	0	(783)	0	0
Capex	(30)	(353)	(593)	0	0
Acquisitions/disposals	0	0	0	0	0
Financing	(440)	(50)	(37)	0	0
Other	4,537	58	(95)	5,488	2,861
Dividends	0	0	0	0	0
Net Cash Flow	4,749	(8,340)	352	13,097	(19,046)
Opening net debt/(cash)	(8,352)	(13,101)	(4,761)	(5,113)	(12,721)
HP finance leases initiated	0	0	0	0	0
Other	0	0	(0)	0	0
Closing net debt/(cash)	(13,101)	(4,761)	(5,113)	(12,722)	6,325

Source: Company data, Edison Investment Research

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