EDISON

Onxeo

Company update

Progress with both REVOCAN and DRIIV-1b trials

Pharma & biotech

Despite the restrictions caused by the ongoing COVID-19 pandemic, Onxeo has managed to initiate a new Phase Ib/II REVOCAN study in relapsed ovarian cancer, which evaluates AsiDNA's potentially unique ability to reverse tumour resistance to the PARP inhibitor, niraparib. First data are expected in early 2021. Onxeo also reported updated results from the second cohort in the Phase Ib study with AsiDNA plus chemotherapy in various solid tumours. Onxeo's second lead product from the platON platform has been successfully advancing through early preclinical development and could enter the clinic within the next 18–24 months. Our valuation is €160m or €2.04 per share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/18	6.1	(4.2)	0.05	0.0	N/M	N/A
12/19	4.3	(11.5)	(0.15)	0.0	N/A	N/A
12/20e	1.1	0.4	(0.01)	0.0	N/A	N/A
12/21e	0.0	(10.8)	(0.14)	0.0	N/A	N/A

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

Phase Ib/II REVOCAN study recruited first patient

The REVOCAN study is the most advanced trial in Onxeo's R&D pipeline. It was specifically designed to evaluate AsiDNA's potentially unique ability to abrogate acquired resistance to PARP inhibitors, specifically niraparib, in relapsed ovarian cancer. The trial will enrol up to 26 platinum-sensitive, relapsed ovarian cancer patients in six French centres. Depending on the impact of the COVID-19 pandemic, preliminary results are expected in early 2021.

Phase Ib DRIIV combination study update

The ongoing Phase Ib DRIIV combination study is the first study testing AsiDNA in combination with carboplatin alone (first cohort) and carboplatin plus paclitaxel (second cohort). In November 2020, Onxeo released an update with initial results from the pooled first and second cohort of patients (7/9 patients were analysed). A good safety profile was confirmed. Of the seven patients analysed, four had a partial response (PR) or longer periods of control of their disease than with previous treatment lines. Notably, these patients were heavily pre-treated with advanced metastatic tumours and had a progressive disease at inclusion. So, caveating the small sample size, the data seem encouraging.

Valuation: €160m or €2.04 per share

Our valuation of Onxeo is €160m or €2.04 per share vs €134m or €2.00 per share previously due to rolling the model forward and a higher cash position. The valuation per share is largely unchanged due to the private placement and use of the equity financing line, which brought in a total of €10.5m net in H120. We have made no other changes to our valuation, although we may revise it once the final three patients in the DRIIV-1b have treatment results, expected at some point in H121. Upcoming catalysts include final results from the Phase Ib triple combination trial (H121) and the first data from the Phase Ib/II REVOCAN study.

18 November 2020

Price	**€0.72**
Market cap	**€56m**
Net cash (€m) at end H120	19.6
Shares in issue	78.3m
Free float	80%
Code	ONXEO
Primary exchange	Euronext Paris
Secondary exchange	OMX Copenhagen

Share price performance

%	1m	3m	12m
Abs	5.3	4.2	26.5
Rel (local)	(5.1)	(5.4)	36.2
52-week high/low	€0.84	€0.33	

Business description

Onxeo has a proprietary platON platform based on a unique decoy technology in the field of DNA damage repair inhibition. The lead asset AsiDNA is in a Phase Ib triple combination trial with chemotherapy in solid tumours and a second Phase Ib/II trial that aims to demonstrate AsiDNA's potential to abrogate tumour resistance to PARP inhibitors. The second compound OX401 is in late preclinical development, optimised to target PARP and also capable of activating the STING pathway.

Next events

Final results from Phase Ib DRIIV triple combination cohort	H121
Phase Ib/II REVOCAN trial first data	Early-2021
OX401 preclinical development updates	2021

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Edison profile page

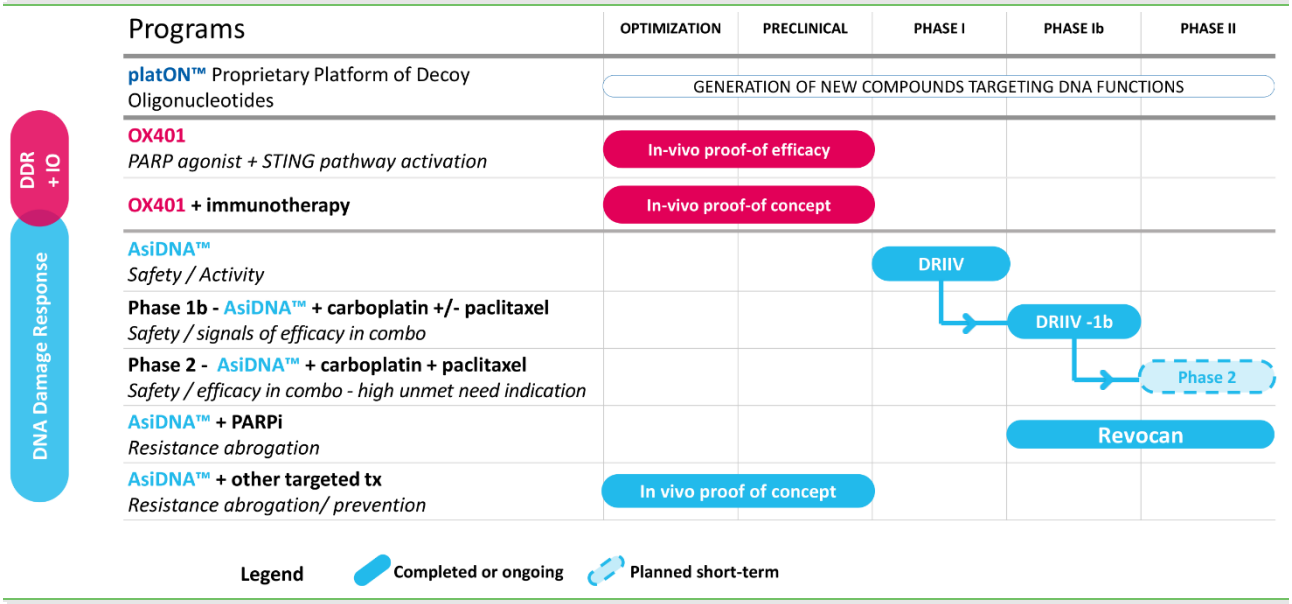
First patient recruited in Phase Ib/II REVOCAN study

Following the out-licensing of belinostat in April 2020, Onxeo's main value driver is R&D work, which is centred on the platON platform. The two disclosed assets are AsiDNA and OX401. AsiDNA is in Phase Ib/II stage trials, while the more recently introduced OX401 is in preclinical development with in vivo proof-of-concept studies ongoing.

The most advanced asset, AsiDNA, belongs to the DNA damage repair inhibitor class, like PARP inhibitors, but has a unique mechanism of action. It is the only oligonucleotide decoy agonist in development that disrupts and exhausts the tumour DNA damage response mechanism. The combination of AsiDNA with DNA-damaging chemotherapies, such as platinum-based anticancer drugs, is expected to produce synergies.

Currently, Onxeo is running a triple combination Phase Ib study (n=6; AsiDNA plus carboplatin plus paclitaxel). Top-line results should be available in H121, subject to the impact of the COVID-19 pandemic and the duration of control for three patients still being treated. A major expansion of the R&D programme is the new Phase Ib/II REVOCAN trial. This new study is evaluating AsiDNA's potentially unique ability to reverse tumour resistance to the PARP inhibitor, niraparib. The first patient was recruited on 21 October 2020. First data are expected in mid-2021.

Exhibit 1: Onxeo's R&D pipeline

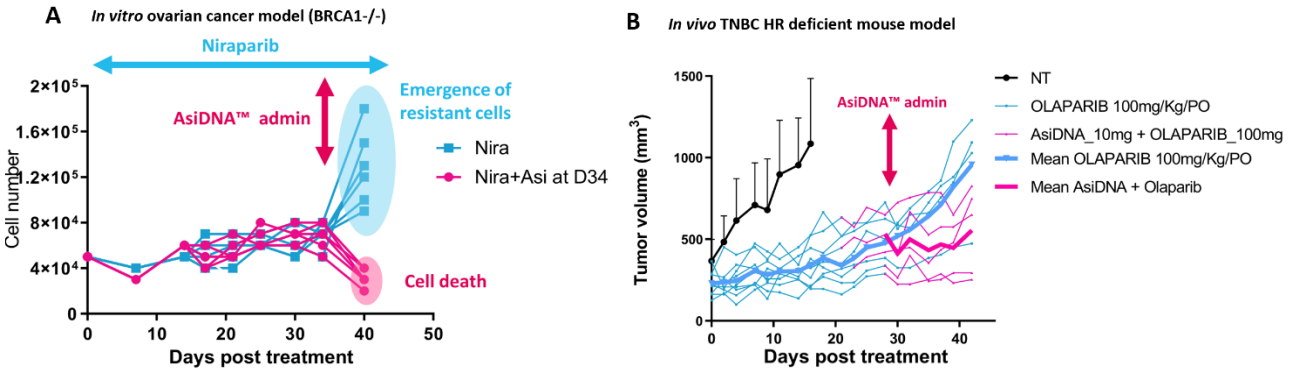


Source: Onxeo

REVOCAN study

In its preclinical studies, Onxeo identified AsiDNA's potentially unique ability to abrogate acquired resistance to PARP inhibitors. Some of the accumulated proof-of-concept preclinical data were presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2019. More recently, Onxeo released a fresh set of in vitro and in vivo data, where AsiDNA allowed resistance to PARP inhibitors to be overcome, even when it was introduced after resistance had emerged (Exhibits 2A and B).

Exhibit 2: AsiDNA abrogates acquired resistance to PARP inhibitors in preclinical models



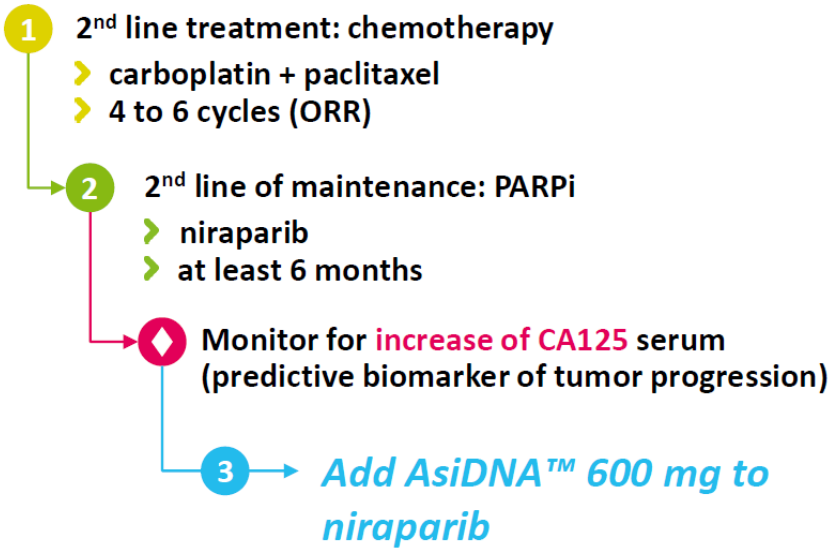
Source: Onxeo corporate presentation

Onxeo has demonstrated that the underlying mechanism whereby AsiDNA prevents resistance to PARP inhibitors relies on the fact that AsiDNA acts on so-called drug-tolerant cancer cells (DTCs). With its preclinical studies, Onxeo showed that resistance to PARP inhibitors evolves from DTCs, ie those cells that are not responsive to PARP therapy, which then leads to cancer recurrence. Those same DTCs are eradicated with AsiDNA. These data were presented at this year's AACR conference in June 2020.

Onxeo is exploring this strategy in a clinical setting for the first time in the Phase Ib/II study, REVOCAN (**REV**ersion of resistance in **O**varian **C**ancer with Asi**DNA** and **N**iraparib). In this study AsiDNA is used to abrogate resistance to the PARP inhibitor niraparib (Zejula, Tesaro/GSK; consensus sales forecast of $2bn in 2026, source: EvaluatePharma). To date, there are four approved PARP inhibitors and, while commercially successful drugs, they still suffer from rapid development of resistance. If the ability to abrogate resistance can be proven, AsiDNA could be a suitable partner drug because of its benign safety profile.

In the REVOCAN study Onxeo plans to enrol up to 26 platinum-sensitive, relapsed ovarian cancer patients in up to six French centres; the first patient was recruited on 21 October 2020. AsiDNA will be given to the patients once the serum biomarker (CA125) for tumour progression starts to rise. **Primary endpoints** are safety/tolerability and a decrease in CA125. **Secondary endpoints** are progression-free survival and overall survival. Preliminary results are expected in early 2021.

Exhibit 3: Timing of intervention with AsiDNA in REVOCAN study (n = up to 26)

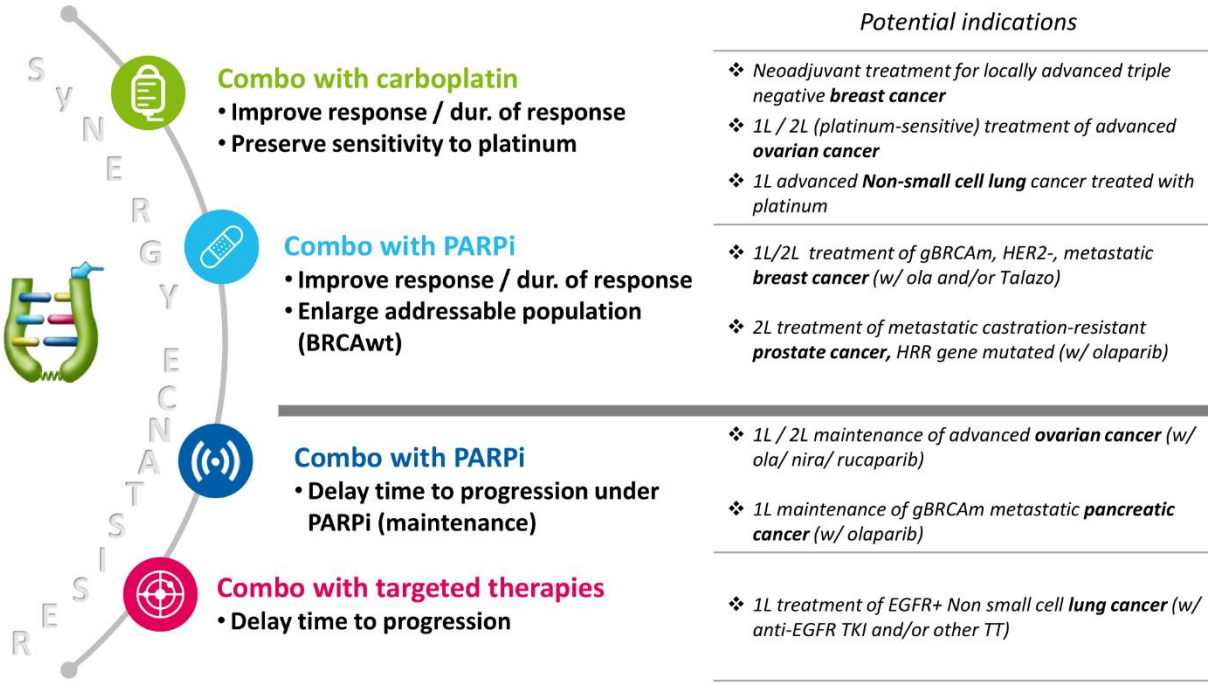


Source: Onxeo

Potential for expansion to other combinations

Based on extensive preclinical data (which we have reviewed in our previous reports), Onxeo has presented a potential pathway to expand the use of AsiDNA in different combinations. Synergy with classic chemotherapy, like carboplatin, and the ability to counter acquired resistance to PARP inhibitors are being explored in the ongoing Phase Ib and Phase Ib/II REVOCAN trials, respectively. The outcomes of these studies will define AsiDNA's mid- to late-stage development, so they represent substantial catalysts for the share price. Onxeo could prioritise several different indications with these combinations depending on the available funding. The range of potential indications is summarised in Exhibit 4.

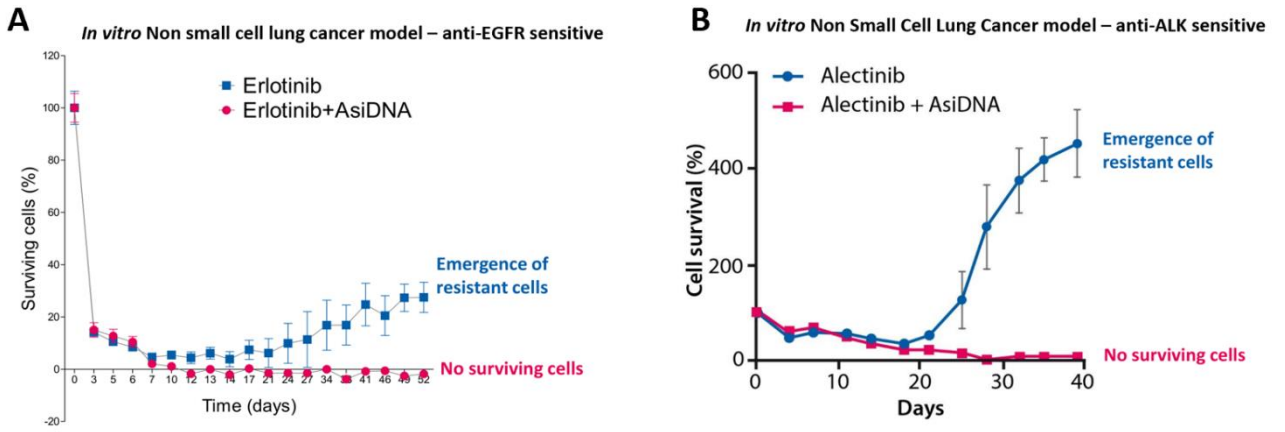
Exhibit 4: AsiDNA's potential for expansion



Source: Onxeo

Newer preclinical data published this year opened yet another potential pathway – combinations with targeted therapies, such as tyrosine kinase inhibitors (TKIs). In the in vitro models of non-small cell lung cancer, AsiDNA prevented the emergence of resistance to two different TKIs, erlotinib (anti-EGFR) and alectinib (anti-ALK) (Exhibits 5A and 5B). This is the first time Onxeo has reported proof-of-concept data showing that such a mechanism of action is not limited to PARP inhibitors, but also includes TKIs. If confirmed, this could substantially broaden AsiDNA's potential use in combination with anticancer treatments. The underlying mechanism is the same – DTCs are an established cause of resistance to TKIs and since AsiDNA is effective against those cells, it could potentially counter DTC-driven acquired resistance to a wide range of targeted therapies.

Exhibit 5: AsiDNA abrogates acquired resistance to TKIs in preclinical models



Source: Onxeo corporate presentation

Triple combo Phase Ib DRIIV-1b study ongoing

The Phase I dose-escalation trial (n=22) showed that intravenous administration of AsiDNA had no serious drug-related side effects and had a positive effect on activity biomarkers (increased levels of γH2AX and pHSP90) at the optimal dose of 600mg.

The ongoing Phase Ib DRIIV combination study is the first study testing AsiDNA in combination with carboplatin alone in **the first cohort** and carboplatin plus paclitaxel (standard of care in many solid tumours) in **the second cohort**. Patients with various solid tumours have been included. Notably, these patients were heavily pre-treated with advanced metastatic tumours and had a progressive disease at inclusion.

In September 2019, Onxeo released initial results from the first cohort of patients (n=3) in the DRIIV Phase Ib study. According to the latest update (November 2020), the trial is now fully enrolled with the second cohort (n=6). Onxeo pooled the results from both cohorts and provided an initial assessment.

- A good safety profile was confirmed (no serious drug-related adverse events and no dose-limiting toxicities observed).
- Of the first seven patients (out of a total of nine), four had a partial response (PR) or longer periods of control of their disease than with previous treatment lines.

With the caveat that the patient sample is too small for efficacy analysis, the first signs of efficacy are encouraging. A good efficacy profile is a substantial positive as AsiDNA will be combined with standard-of-care chemotherapy. Three patients are still being treated and Onxeo should report the final results in H121. However, the company has already mentioned that it has started working on a potential design for the Phase II study with AsiDNA plus chemotherapy and will announce more details in the coming months.

Exhibit 6: DRIIV-1b study preliminary data safety and initial efficacy

	AsiDNA™ 600mg	Tumor	Treatment line in DRIIV-1b	Treatment duration	Response	Preliminary safety overview and best responses (4/7 evaluable patients to date)
Cohort 1 3 pts	+ carboplatin	TNBC	6th line	5.5 months	Stable Disease	› No DLT and very good tolerance of the combination › In 2/3 patients, disease controlled with AsiDNA™ combo for significantly longer than with any of the prior treatment lines
↓ (n=3) completed		NSCLC *(Epidermoid)*	3rd line	8.5 months	Stable Disease	
Cohort 2 6 pts	+ carboplatin + paclitaxel	NSCLC *(Adenocarcinoma)*	4th line	3 months	Partial Response (-40%)	› No DLT and very good tolerance of the combination *(interim results)* › In 2/4 evaluable patients to date, disease controlled with AsiDNA™ for significantly longer than with any of the prior treatment lines › Last 2 patients enrolled in 10-11/2020, to be followed until disease progression: 3 patients still under treatment
(n=6) *ongoing*		NSCLC *(Adenocarcinoma)*	2nd line	8,5 months *Ongoing*	Stable Disease	

Source: Onxeo

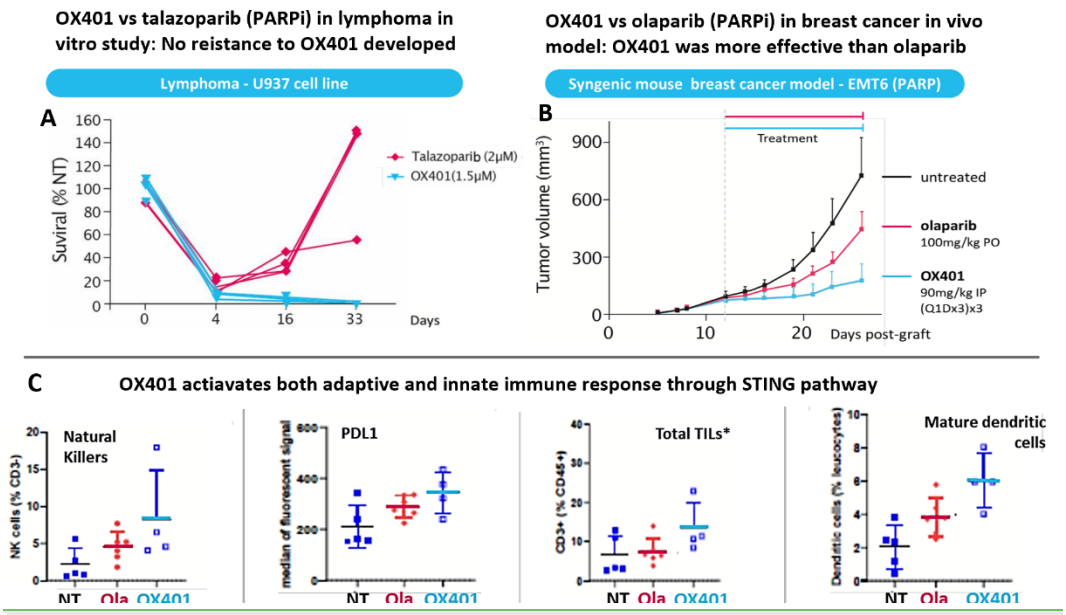
OX401: Second asset from platON

The second asset that Onxeo has chosen to progress from its platON platform is OX401. The first detailed preclinical data were presented at the PARP & DDR Inhibitors Summit in Boston, MA, on 29–30 January 2020, which we summarised in our last published report. In June 2020, Onxeo released an update describing the preclinical profile in more detail and confirmed that OX401 was ready to enter the final stages of preclinical validation. If all goes well, the first clinical study could start within 18–24 months.

Like AsiDNA, OX401 comprises double-strand oligonucleotides, a linker (coupling agent) and a cellular uptake facilitator (cholesterol). An oligonucleotide is composed of 16 DNA base pairs, and is optimised to bind and activate PARP signalling enzymes. This is the main difference to AsiDNA, which is composed of 32 DNA base pairs and has a broader effect (hyperactivates PARP and DNA-PK). Like AsiDNA, OX401 acts as decoy agonist. However, while AsiDNA binds mainly DNA-PK and to a lesser extent PARP and other proteins, OX401 binds PARP proteins specifically and then hyperactivates them, thus distracting it from its role in cancer cells. PARP is a major component in the DNA repair mechanism and PARP inhibitors have been proven clinically successful. In addition, preclinical data show that OX401 is able to activate the cGAS-STING pathway, which makes OX401 a very differentiated approach from existing PARP inhibitors. In preclinical in vivo studies, Onxeo demonstrated that OX401 had a higher potency of activity than current PARP inhibitors in controlling tumour growth. Like AsiDNA, preclinical findings also show that OX401 does not induce tumour resistance to treatment, which is another differentiating characteristic from PARP inhibitors.

The cGAS-STING pathway is a component of the innate immune system, which detects cytosolic DNA. DNA is normally found in the nucleus of the cell. The appearance of DNA in cytosol is associated with carcinogenesis or viral infections. A STING receptor is a known mediator of the immune system which, when activated, induces expression of interferon and other T-cell recruitment factors. This results in the activation of dendritic cells, which act as antigen-presenting cells. The ultimate outcome is a tumour-specific immune response with 'trained' CD8+ T-cells attacking the cancer.

Exhibit 7: Selected preclinical OX401 data



Source: Onxeo

The cGAS-STING pathway is still a relatively new area in immunoncology with only a handful of Phase I–II trials ongoing. However, preclinical research is active, with large pharma also involved. The strategic opportunity for STING activating therapies, and for OX401, could be combinations with anticancer therapies that act late in the immunity cycle, like checkpoint inhibitors (which make the tumour 'visible' to T-cells), as the STING pathway should prime the production of cancer-specific T-cells, so both technologies are potentially synergistic. Onxeo indicated that as a next step it will explore the combination of OX401 and checkpoint inhibitors in in vivo studies, which will inform clinical development.

Financials

Onxeo booked revenues of €1.1m in H120, mainly direct sales of Beleodaq (recognized up to the date of the agreement signed with Acrotech in April 2020). Following the royalty sale agreement with SWK and the updated licensing deal with Acrotech, Beleodaq-related sales growth is no longer a value driver for Onxeo (agreement details in our last published report).

Total operating expenses amounted to €5.5m in H120 vs €8.6m in H119. The y-o-y decrease is due to lower spending on preclinical research, but also lower AsiDNA Phase I trial-related spending, which was partly due to the COVID-19 pandemic causing slower progress of the trials. Onxeo also booked other non-current operating income and expenses totalling €10.0m, which is related to the out-licensing of Beleodaq to Acrotech Biopharma in April 2020 and treated as a disposal of belinostat-related assets according to IFRS.

Our revenues for 2020 are lower compared to 2019, as Onxeo booked Beleodaq sales only for the period January to April 2020, which is when the agreement with Acrotech was signed. We have lowered our total forecast operating spend to €10.6m from €14.0m in 2020 and to €10.8m from €14.0m in 2021. This is subject to further revisions depending on the development of the COVID-19 pandemic and how it affects clinical R&D activity.

Onxeo reported a cash position of €19.6m at the end of H120 vs €5.7m at the end of 2019. The increase is due to the private placement of €7.3m in June 2020 and proceeds of €3.2m from an equity financing line with Nice & Green. The updated licensing deal with Acrotech Biopharma

brought in another €5.1m net. A research tax credit of €1.4m was also received in H120. Onxeo estimates that its existing cash position is sufficient to finance operations until Q122, in line with our model.

Valuation

Our valuation of Onxeo is €160m or €2.04 per share vs €134m or €2.00 per share previously. The changes include rolling the model forward and a higher cash position. The valuation per share is largely unchanged due to the private placement and use of the equity financing line. We have made no other changes to our valuation assumption, although we may revise it once the final three patients in the DRIIV-1b have treatment results, expected at some point in H121.

We continue to include AsiDNA in two indications, although there is potential to expand beyond that as the R&D pipeline develops. More details on our valuation assumptions are in included in the our published outlook report. We do not yet include OX401 in our rNPV model due to the preclinical stage of the project, but Onxeo has guided that this product could enter clinical development within the next 18–24 months.

Exhibit 8: Onxeo rNPV valuation

Product	Indication	Launch	Peak sales (US$m)	NPV (€m)	Probability (%)	rNPV (€m)	NPV/share (€/share)
AsiDNA	Ovarian cancer	2026	1,850	392.4	15%	68.4	0.87
AsiDNA	TNBC and metastatic, HER2-, BRCA-mutated breast cancer	2026	4,060	783.2	15%	127.0	1.62
Validive milestones				52.6	25%	13.2	0.17
Net cash (last reported)				19.6	100%	19.6	0.25
Valuation				**855.5**		**159.8**	**2.04**

Source: Edison Investment Research. Note: TNBC = triple negative breast cancer.

Exhibit 9: Financial summary

€000s	2018	2019	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	6,127	4,288	1,076	0
Cost of Sales	(215)	(350)	(175)	0
Gross Profit	5,912	3,938	901	0
EBITDA	(3,435)	(9,124)	1,044	(10,122)
Operating Profit (before amort. and except.)	(19,189)	(3,527)	(3,527)	(9,795)
Intangible Amortisation	0	0	0	0
Exceptionals	(12,117)	(24,543)	0	0
Operating Profit	(15,644)	(34,338)	373	(10,793)
Other	5,176	(39)	0	1
Net Interest	(690)	(1,677)	(3)	(3)
Profit Before Tax (norm)	(4,217)	(11,472)	370	(10,796)
Profit Before Tax (reported)	(11,158)	(36,054)	370	(10,795)
Tax	1,760	2,324	(823)	0
Profit After Tax (norm)	2,719	(9,187)	(453)	(10,796)
Profit After Tax (reported)	(9,398)	(33,730)	(453)	(10,795)
Average Number of Shares Outstanding (m)	53.4	61.3	72.7	78.3
EPS - normalised (€)	0.05	(0.15)	(0.01)	(0.14)
EPS - normalised fully diluted (€)	0.05	(0.15)	(0.01)	(0.14)
EPS - (reported) (€)	(0.18)	(0.55)	(0.01)	(0.14)
Dividend per share (€)	0.0	0.0	0.0	0.0
Gross Margin (%)	96.5	91.8	83.7	N/A
EBITDA Margin (%)	N/A	N/A	97.0	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	42,874	26,346	23,634	23,634
Intangible Assets	38,573	23,358	20,533	20,533
Tangible Assets	296	109	109	109
Investments	4,005	2,879	2,992	2,992
Current Assets	20,376	11,284	20,386	9,093
Stocks	47	64	64	64
Debtors	1,479	3,353	7,442	5,000
Cash	11,253	5,708	11,158	2,307
Other	7,597	2,159	1,722	1,722
Current Liabilities	(8,393)	(6,200)	(10,787)	(10,787)
Creditors	(7,943)	(5,030)	(9,934)	(9,934)
Short term borrowings	(450)	(1,170)	(853)	(853)
Long Term Liabilities	(9,454)	(14,233)	(8,491)	(8,491)
Long term borrowings	0	0	0	0
Other long-term liabilities	(9,454)	(14,233)	(8,491)	(8,491)
Net Assets	45,403	17,197	24,742	13,449
CASH FLOW				
Operating Cash Flow	(10,191)	(6,413)	(9,663)	(8,851)
Net Interest	6,148	(1,077)	(1,423)	0
Tax	(1,764)	(2,324)	0	0
Capex	(45)	(26)	0	0
Acquisitions/disposals	0	0	6,100	0
Financing	2,508	4,745	10,436	0
Dividends	0	0	0	0
Net Cash Flow	(3,344)	(5,095)	5,450	(8,851)
Opening net debt/(cash)	(14,147)	(10,803)	(4,538)	(10,305)
HP finance leases initiated	0	0	0	0
Other	(0)	(1,170)	317	0
Closing net debt/(cash)	(10,803)	(4,538)	(10,305)	(1,454)

Source: Onxeo accounts, Edison Investment Research

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