EDISON

Targovax

R&D news

Confirmatory 12-month mesothelioma update

Pharma & biotech

On 22 June 2020 Targovax reported data from its Phase I/II study in unresectable mesothelioma (a follow up to the first data published in January 2020). There were no new safety issues and the efficacy signals seen in the first set of data were confirmed. Importantly, the immune and gene sequencing data provided strong support for ONCOS-102's ability to activate the immune system and remodel the tumour microenvironment. Targovax reiterated its plans to explore ONCOS-102 in triple combination with a checkpoint inhibitor (CPI) and standard chemotherapy in first line. These plans are still at a preliminary stage, but there is potential for the study to become a registrational programme due to a high unmet need in mesothelioma. We increase the probability of success for ONCOS-102 and our updated valuation is NOK1.64bn or NOK21.6/share.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/18	0.0	(147.3)	(2.8)	0.0	N/A	N/A
12/19	2.3	(147.9)	(2.4)	0.0	N/A	N/A
12/20e	0.0	(134.5)	(1.9)	0.0	N/A	N/A
12/21e	0.0	(136.6)	(1.8)	0.0	N/A	N/A

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

Green light for the next stage

The mPFS for ONCOS-102-treated first-line patients remained at 8.9 months (unchanged from previously reported). mPFS in the control arm first-line patients treated with standard of care (SoC) chemotherapy only was 7.6 months (vs the 6.8 months reported previously). So, ONCOS-102 plus SoC retained the mPFS benefit. The 12-month overall survival (OS) was 64% in the ONCOS-102-treated first-line patients versus 50% in the first-line control arm. As a recent reference point, durvalumab (anti-PD-L1) plus SoC achieved 70% OS at 12 months (ASCO 2020 data). Due to the expected complementary mechanism of action between ONCOS-102 and CPIs, the triple combination of ONCOS-102 plus CPI plus SoC can be expected to have an even more pronounced survival benefit. This will be Targovax's goal in the upcoming trial.

Next steps

Median OS data are still not mature and will be reported in the future, but other than that the results can be considered final. While the size of the study limited the analysis for statistical significance of clinical effect (this was not the goal of the study), the trending mPFS and 12-month OS data and the fact that clinical outcomes seem to correlate with a cancer-specific immune response, are clearly positive signals. The good safety profile of ONCOS-102 is key for a viable triple combination therapy, as both chemotherapy and CPIs have known safety issues.

Valuation: NOK1.64bn or NOK21.6/share

Our valuation has increased to NOK1.64bn or NOK21.6/share from NOK1.52bn or NOK20.0 after increasing the success probability in our mesothelioma project to 25% from 20% and rolling the model forward. An update on the upcoming Phase I melanoma trial is the key potential catalyst this year.

22 June 2020

Price	**NOK7.8**
Market cap	**NOK593m**
Net cash (NOKm) at end Q120 (excludes government loans) plus private placement	135.3
Shares in issue	76.1m
Free float	90%
Code	TRVX
Primary exchange	Oslo Stock Exchange
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	3.9	92.8	44.7
Rel (local)	0.3	66.5	62.7
52-week high/low	NOK10.2		NOK3.7

Business description

Targovax is an immunoncology company headquartered in Oslo, Norway, developing an oncolytic virus platform, ONCOS. ONCOS-102 is prioritised in several indications including mesothelioma and melanoma. Targovax is also working on next-generation oncolytic viruses in its preclinical R&D pipeline.

Next events

Cohort 2 data from Phase I melanoma	2020
Preclinical data on new oncolytic viruses	H220
Q220 results	20 August 2020

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Edison profile page

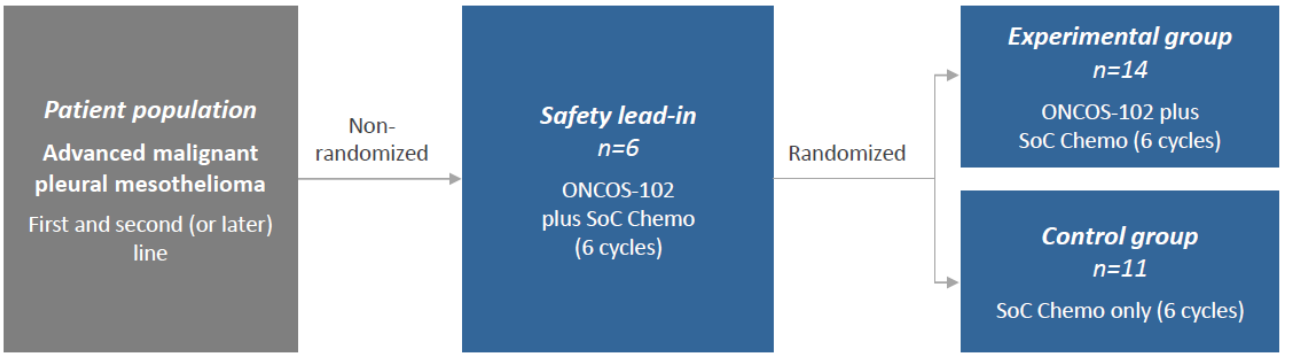
Updated Phase I/II mesothelioma trial confirms further development pathway

On 22 June 2020 Targovax reported randomised data from the Phase I/II study (n=31) in unresectable malignant pleural mesothelioma. The randomised, open-label trial compared ONCOS-102 plus SoC (pemetrexed/cisplatin) versus SoC-only treatment in first- and second-line settings. In total, 31 patients were enrolled, with 20 patients assigned to the ONCOS-102 plus SoC arm and 11 patients to the SoC-only arm. The **primary goal** of the study was to evaluate the safety and tolerability of ONCOS-102, which is typical for this stage. Key **secondary endpoints** evaluated:

- Tumour-specific immunological activation and T-cell tumour infiltration.
- Immunological activation and correlation with a clinical response.
- Overall response rate (ORR).
- Median progression-free survival (mPFS).
- OS (at 12 months available; data will continue to mature).

In addition to the overall results, first-line and second-line (or later) patient subpopulations were also evaluated.

Exhibit 1: Phase I/II mesothelioma study design



Source: Targovax

Efficacy signals at 12-month follow up: First-line patients identified as a target population

In the previously reported data (January 2020), Targovax identified first-line patients as the most rational target population and the preliminary plans for the next trial also include first-line mesothelioma patients. In addition, we believe the data were biased in the second-line patients in the control arm (unusually high response), likely due to the small number of patients (n=5). Economically, it also makes sense to focus on the front-line patients, as this ensures the largest pool of new patients. Since mesothelioma is not a crowded indication, Targovax will have a good chance competing for the front-line position, if the data in the late stage development are good.

In addition, we note that descriptive patient data showed that the experimental arm had generally more advanced patients (as shown in our January 2020 report), and there was therefore a relatively higher hurdle rate for ONCOS-102 to demonstrate efficacy against the control.

mPFS

The mPFS for ONCOS-102 treated first-line patients remained at 8.9 months (ie, the same as previously reported). mPFS in the control arm first-line patients treated with SoC chemotherapy only was 7.6 months vs 6.8 months reported previously. So, ONCOS-102 plus SoC retained the mPFS benefit. As this was a relatively early stage trial, it was not designed to check for a

statistically significant clinical effect, but the trend seems pronounced. ONCOS-102 mPFS also compares well with historical controls, which fall in the range of 5.7–7.3 months.

12-month OS

The 12-month OS was 64% in the ONCOS-102 treated first-line patients vs 50% in the first-line control arm. Median OS data are too early and will be reported in the future. For comparison, results from a Phase II study with 55 patients presented at this year's ASCO conference (May 29–31) showed that durvalumab (anti-PD-L1) plus SoC achieved 70% OS at 12 months. Mesothelioma remains one of the few cancers where the SoC is still a classical chemotherapy with no new treatments approved. There is a high interest in the use of CPIs in this indication and several trials are ongoing, but none are approved yet. Due to the expected complementary mechanism of action between ONCOS-102 and CPIs (described in our initiation report in detail), the triple combination of ONCOS-102 plus CPI plus SoC can be expected to have an even more pronounced survival benefit. This will be the primary goal for Targovax in the next trial in this indication.

Immunological data

The updated immunological data confirmed previous findings:

- The activation of both innate and adaptive immune responses was observed, which was also associated with better clinical outcomes.
- Evidence that ONCOS-102 drives favourable changes in the tumour microenvironment:
  - increase in intra-tumoral cytotoxic T-cells;
  - upregulation of adaptive immunity and cytotoxicity related gene expression;
  - macrophage phenotype polarisation from M2 to M1; and
  - upregulation of PD-L1 expression.

These changes were not observed to such an extent in patients who were treated with SoC only. This shows that patients can be sensitised to other immunoncology therapies like CPIs. We also note that in this particular trial the patients received chemotherapy and immunotherapy (ONCOS-102). Immunosuppression (or myelosuppression) is a known side effect of chemotherapy, especially in cisplatin's case. Therefore, the fact that ONCOS-102 generated a strong immune response in such a setting is encouraging.

Valuation

Our valuation has increased to NOK1.64bn or NOK21.6/share from NOK1.52bn or NOK20.0 after increasing the success probability in our mesothelioma project to 25% from 20% and rolling the model forward. An update on the upcoming Phase I melanoma trial is the key potential catalyst this year.

Exhibit 2: Sum-of-the-parts Targovax valuation

Product	Launch	Peak sales ($m)	Unrisked NPV (NOKm)	Unrisked NPV/share (NOK)	Probability (%)	rNPV (NOKm)	rNPV/share (NOK)
ONCOS-102 – advanced melanoma	2025	590	2,925.5	38.4	15%	744.4	9.8
ONCOS-102 – mesothelioma	2026	424	2,315.8	30.4	25%	761.3	10.0
Net cash, last reported			135.3	1.8	100%	135.3	1.8
Valuation			**5,376.6**	**70.7**		**1,641.0**	**21.6**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. Excludes conditional government long-term loans.

Exhibit 3: Financial summary

NOK'000s	2018	2019	2020e	2021e
December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	27	2,251	0	0
Cost of Sales	0	0	0	0
Gross Profit	27	2,251	0	0
Research and development	(64,006)	(80,286)	(60,103)	(59,913)
EBITDA	(145,804)	(146,247)	(134,508)	(136,550)
Operating Profit (before amort. and except.)	(146,100)	(150,273)	(134,508)	(136,550)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(146,100)	(150,273)	(134,508)	(136,550)
Net Interest	(1,249)	2,423	0	0
Profit Before Tax (norm)	(147,349)	(147,850)	(134,508)	(136,550)
Profit Before Tax (reported)	(147,349)	(147,850)	(134,508)	(136,550)
Tax	334	321	0	0
Profit After Tax (norm)	(147,015)	(147,529)	(134,508)	(136,550)
Profit After Tax (reported)	(147,015)	(147,529)	(134,508)	(136,550)
Average Number of Shares Outstanding (m)	52.6	60.8	69.6	75.9
EPS - normalised (NOK)	(2.79)	(2.43)	(1.93)	(1.80)
EPS - normalised fully diluted (NOK)	(2.79)	(2.43)	(1.93)	(1.80)
EPS - reported (NOK)	(2.79)	(2.43)	(1.93)	(1.80)
Dividend per share (NOK)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	371,129	371,050	371,050	371,050
Intangible Assets	370,240	367,083	367,083	367,083
Tangible Assets	889	726	726	726
Investments	0	3,241	3,241	3,241
Current Assets	166,509	85,858	42,407	16,429
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	151,189	70,429	26,978	1,000
Other	15,320	15,429	15,429	15,429
Current Liabilities	(59,377)	(50,690)	(40,149)	(43,874)
Creditors	(50,250)	(53,931)	(43,390)	(47,115)
Short term borrowings	(9,127)	0	0	0
Long Term Liabilities	(103,565)	(109,263)	(109,263)	(210,465)
Long term borrowings	(43,933)	(50,441)	(50,441)	(151,643)
Other long term liabilities	(59,632)	(58,822)	(58,822)	(58,822)
Net Assets	374,696	296,955	264,045	133,141
CASH FLOW				
Operating Cash Flow	(112,816)	(140,094)	(139,403)	(127,180)
Net Interest	1,249	(2,423)	0	0
Tax	0	0	0	0
Capex	0	(134)	0	0
Acquisitions/disposals	0	0	0	0
Financing	(30)	66,863	95,950	0
Other	(3,041)	(2,353)	2	0
Dividends	0	0	0	0
Net Cash Flow	(114,638)	(78,141)	(43,451)	(127,180)
Opening net debt/(cash)	(212,767)	(98,129)	(19,988)	23,463
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(98,129)	(19,988)	23,463	150,643

Source: Targovax accounts, Edison Investment Research

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