EDISON

Targovax

Company update

Data from both lead trials due H120

Pharma & biotech

Both lead clinical trials with ONCOS-102 are expected to deliver results over the next few months, which will make H120 one the most eventful periods in Targovax's history. Data from Phase I/II trial in mesothelioma are expected in January 2020, whereas data from the Phase I melanoma study are expected in H120 or 'before summer', according to Targovax. Clinical data readouts should be supplemented by preclinical studies with the second-generation oncolytic viruses, which Targovax introduced for the first time in the Q319 results presentation. Our valuation is almost unchanged at NOK1.18bn or NOK18.7/share (vs NOK18.6/share previously).

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/17	0.0	(122.3)	(2.6)	0.0	N/A	N/A
12/18	0.0	(147.3)	(2.8)	0.0	N/A	N/A
12/19e	0.0	(136.2)	(2.4)	0.0	N/A	N/A
12/20e	0.0	(120.7)	(1.9)	0.0	N/A	N/A

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

More intensive dosing in Part 2 of melanoma trial

Interim results released in July 2019 from Part 1 of the Phase I trial with ONCOS-102 in melanoma were the hallmark event in Q319 (detailed analysis in our previous reports). The patients, who were previously treated with checkpoint inhibitors (CPIs) and then relapsed, were given three intratumoural injections of ONCOS-102 then received up to eight infusions of Keytruda. The key finding was that 3/9 patients demonstrated a clinical response, ie a 33% overall response rate, which compares well with similar studies. Such results were achieved after dosing with ONCOS-102 only three times before administering Keytruda. In Part 2 patients will continue to receive ONCOS-102 throughout treatment with Keytruda, which means they will receive a total of 12 ONCOS-102 injections rather than three. According to Targovax, results should be available 'before summer' 2020.

Data from Phase I/II mesothelioma trial due January

The randomised data from the Phase I/II study (n=31) in unresectable malignant pleural mesothelioma represent the nearest significant catalyst for the share price. According to the latest update, enrolment has completed and Targovax is on track to report data in January 2020. There is a clear unmet need in this indication, given the aggressive nature of the cancer and a lack of innovative treatment options. If the data are positive data, ONCOS-102 could be positioned as a front-line treatment with the potential for accelerated approval.

Valuation: NOK1.18bn or NOK18.7/share

Our Targovax valuation is virtually unchanged at NOK1.18bn or NOK18.7/share due to rolling our model forward, which is offset by a lower net cash position. All other assumptions in our rNPV model are unchanged. Both Phase I/II mesothelioma and Phase I melanoma trials are key catalysts in H120.

3 December 2019

Price	**NOK5.41**
Market cap	**NOK343m**
Net cash (NOKm) at end Q319 (excludes government loans)	104.0
Shares in issue	63.4m
Free float	90%
Code	TRVX
Primary exchange	Oslo Stock Exchange
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	10.4	6.7	(36.6)
Rel (local)	13.4	4.4	(34.2)
52-week high/low	NOK11.04		NOK4.30

Business description

Targovax is an immunoncology company headquartered in Oslo, Norway, with 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

Preclinical data on new oncolytic viruses	H219
ONCOS-102 mesothelioma Phase I data	January 2020
Cohort 2 data from Phase I melanoma	H120
Q419 results	11 March 2019

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Edison profile page

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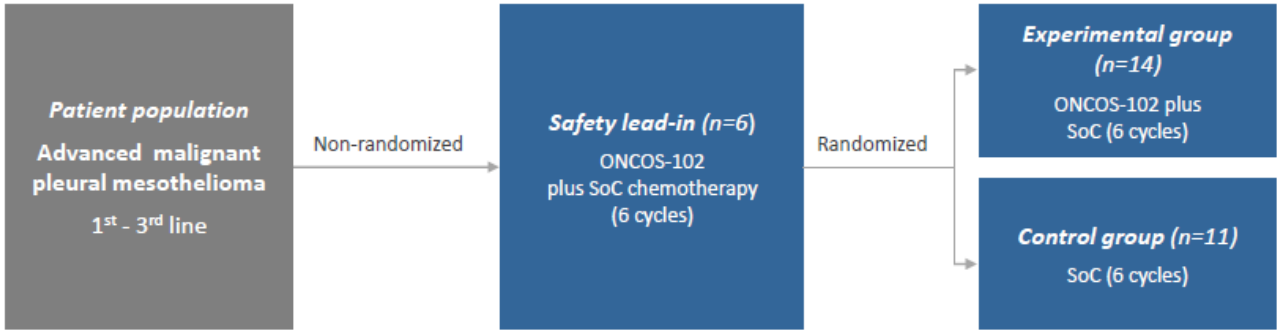
R&D update

Randomised data from Phase I/II mesothelioma trial expected in January 2020

The trial compares ONCOS-102 plus standard of care (pemetrexed/cisplatin) versus standard of care treatment in first- and second-line settings. The primary goal of the study is to evaluate the safety and tolerability of ONCOS-102, which is typical for this stage. Secondary endpoints will evaluate the initial efficacy of the treatment as well as overall response rate at six months, immune activation, progression-free survival and overall survival. According to the latest update, enrolment has completed and Targovax is on track to report data in January 2020. During the Q319 results presentation, management indicated (in the Q&A session) that an accelerated approval pathway is a possibility, although it is too early to confirm this.

Exhibit 1: Phase I/II mesothelioma study design



Source: Targovax

In February 2018, Targovax announced results from the safety lead-in (n=6) part of the study. No concerns were raised over safety. Where available, the data demonstrated an increase in systemic cytokines (in 3/3 analysed patients), which indicates activation of innate immune response. There was also an increase in the relative level of tumour infiltrating CD8+ T-cells (in 2/2 patients analysed), which indicates activation of the adaptive immune system. The activation of both the innate and adaptive immune response is consistent with the goal to make the cancer 'visible' to the immune system.

Targovax chose mesothelioma as one of the lead indications for its oncolytic virus treatment due to a combination of positive preclinical findings in in vivo models (Kuryk et al., 2018) and because treatment of mesothelioma remains one the largest unmet needs.

It is a rare cancer with c 3,000 cases diagnosed in the US annually. Most often the location of mesothelioma is the pleural mesothelium, a double-layer sheet that covers the lungs and the inside of the pleural cavity, forming a pleural space. Incidence of mesothelioma ranges from about seven to 40 per 1,000,000 in industrialised Western countries, depending on the amount of asbestos exposure in the past, which is a major risk factor. The five-year survival rate is only around 8%. Surgery, radiation therapy and chemotherapy with cisplatin and pemetrexed are the main treatment options, as there are no novel drugs proven to be efficacious.

Pemetrexed (Alimta, Eli Lilly; folate antimetabolite) was approved by the FDA for the treatment of malignant pleural mesothelioma in 2004, with patents starting to expire in 2022 (although they are challenged). In 2018, Alimta brought in $237m in sales in the mesothelioma indication (it is also approved for non-small cell lung cancer). There is a clear unmet need in this indication, given the aggressive nature of the cancer and lack of innovative treatment options.

New oncolytic viruses

With its Q319 results Targovax released new preclinical data for the first time, revealing details about its next-generation oncolytic viruses. The lead, ONCOS-102, is based on the common cold adenovirus serotype 5, which was genetically engineered in three ways:

- To increase the virus's ability to infect cancer cells, a knob domain from the surface of adenovirus 3 has been added, which improves viral adhesion to cancer cell surface.
- A 24bp deletion in the E1A region enhances selective viral replication in actively dividing cells.
- A transgene encoding a well-known immune stimulator granulocyte macrophage colony stimulating factor (GM-CSF) was also added. Once the virus starts replicating in the cancer cells, the GM-CSF is released, which stimulates tumour antigen processing by antigen presenting cells.

In the second-generation ONCOS viruses, Targovax was able to add a second transgene. The company has released in vitro and in vitro data from three new viruses. Depending on the second transgene, these viruses have different properties (Exhibit 2).

Targovax also presented some in vivo data from its studies with the ONCOS-210 and 212 viruses. The results indicate that two transgenes seem more potent than one and have synergistic activity in various cancer mouse models. We expect much more data from studies with all second-generation oncolytic viruses, including more details about positioning in the clinic and which indications will be prioritised.

Exhibit 2: Next generation of ONCOS viruses with double transgenes

	Mode of action	Target cancers types
ONCOS 210 and 212 Inhibition of tumour growth and vascularisation	■ Interfere with tumour's ability to break down surrounding tissue ■ Induce cell cycle arrest ■ Inhibit angiogenesis	Highly invasive or metabolic tumours
ONCOS 211 Counteract immune suppressive tumour microenvironment	■ Decrease inhibitory factors from tumour microenvironment ■ Activate T-cells	'Cold' tumours
ONCOS 214 Enhanced cell-killing properties	■ Induce immunogenic cell death ■ Extend cell killing ability to neighbouring non-infected cells	High stroma tumours (eg, epithelial malignant tumours with poor prognosis)

Source: Targovax

Financials and valuation

Targovax reported immaterial revenues and an operating loss of NOK26.7m in Q319, which was substantially lower than NOK33.7m in Q318 and NOK44.6m in Q219. It implemented a cost-cutting programme this summer, which was the main reason behind lower spending (number of full-time employees reduced by one-third). Targovax had cash and cash equivalents of NOK104m at the end of Q319. We fine-tuned our estimates, with 2019 operating expenses now totalling NOK136m (from NOK140m previously). As before, our model suggests a cash reach well into 2020.

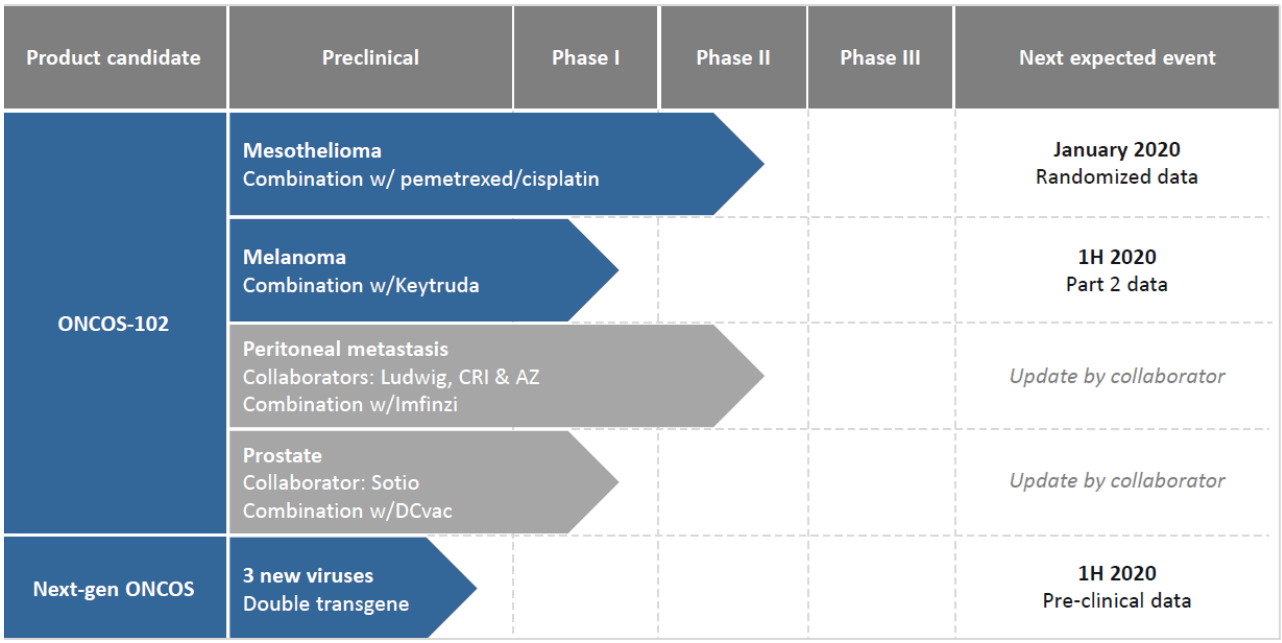
Our valuation is virtually unchanged at NOK1.18bn or NOK18.7/share (versus NOK18.6/share previously), which is based on a risk-adjusted NPV analysis using a 12.5% discount rate, including NOK104m net cash. We continue to exclude other long-term debt of NOK55.6m in Finnish government grants from our valuation, as repayment is only required if the products are sold or launched. Our financial forecasts are unchanged.

Exhibit 3: 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	2,704.3	42.7	15%	669.5	10.6
ONCOS-102 – mesothelioma	2026	424	2,149.4	33.9	10%	409.0	6.5
Net cash, last reported			104.0	1.6	100%	104.0	1.6
Valuation			**4,957.8**	**78.2**		**1,182.6**	**18.7**

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

Exhibit 4: Targovax R&D pipeline and expected newsflow



Source: Targovax

Exhibit 5: Financial summary

NOK'000s	2017	2018	2019e	2020e
December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	37	27	0	0
Cost of Sales	0	0	0	0
Gross Profit	37	27	0	0
Research and development	(45,571)	(64,006)	(67,567)	(50,103)
EBITDA	(119,630)	(145,804)	(135,856)	(120,449)
Operating Profit (before amort. and except.)	(119,926)	(146,100)	(136,152)	(120,745)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(119,926)	(146,100)	(136,152)	(120,745)
Net Interest	(2,347)	(1,249)	0	0
Profit Before Tax (norm)	(122,273)	(147,349)	(136,152)	(120,745)
Profit Before Tax (reported)	(122,273)	(147,349)	(136,152)	(120,745)
Tax	328	334	0	0
Profit After Tax (norm)	(121,945)	(147,015)	(136,152)	(120,745)
Profit After Tax (reported)	(121,945)	(147,015)	(136,152)	(120,745)
Average Number of Shares Outstanding (m)	47.3	52.6	58.0	63.3
EPS - normalised (NOK)	(2.58)	(2.79)	(2.35)	(1.91)
EPS - normalised fully diluted (NOK)	(2.58)	(2.79)	(2.35)	(1.91)
EPS - reported (NOK)	(2.58)	(2.79)	(2.35)	(1.91)
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	367,415	371,129	376,788	376,521
Intangible Assets	366,250	370,240	370,240	370,240
Tangible Assets	1,165	889	604	337
Investments	0	0	5,944	5,944
Current Assets	276,193	166,509	93,224	16,320
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	261,573	151,189	77,904	1,000
Other	14,620	15,320	15,320	15,320
Current Liabilities	(28,295)	(59,377)	(45,913)	(46,371)
Creditors	(28,295)	(50,250)	(33,024)	(33,482)
Short term borrowings	0	(9,127)	(12,889)	(12,889)
Long Term Liabilities	(108,156)	(103,565)	(105,805)	(136,958)
Long term borrowings	(48,806)	(43,933)	(46,173)	(77,326)
Other long term liabilities	(59,350)	(59,632)	(59,632)	(59,632)
Net Assets	507,157	374,696	318,294	209,512
CASH FLOW				
Operating Cash Flow	(111,093)	(112,816)	(141,041)	(108,028)
Net Interest	2,347	1,249	0	0
Tax	0	0	0	0
Capex	(56)	0	(31)	(29)
Acquisitions/disposals	0	0	0	0
Financing	194,407	(30)	67,785	0
Other	(4,753)	(3,041)	1	0
Dividends	0	0	0	0
Net Cash Flow	80,852	(114,638)	(73,285)	(108,057)
Opening net debt/(cash)	(131,915)	(212,767)	(98,129)	(18,842)
HP finance leases initiated	0	0	0	0
Other	0	0	(6,002)	0
Closing net debt/(cash)	(212,767)	(98,129)	(18,842)	89,215

Source: Targovax accounts, Edison Investment Research

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