EDISON

Targovax

Q219 update

Multiple data readouts over next 12 months

Pharma & biotech

Two ONCOS-102 readouts are expected in the next 12 months: mesothelioma Phase I/II data around new year 2020, and data from the Phase I melanoma study in H120. Targovax is also conducting preclinical trials with its new oncolytic viruses, with first results likely to be released in H219. This will support its move to becoming a focused oncolytic virus company. In addition, it provided an update on the Phase I/II trial with ONCOS-102 + Imfinzi (durvalumab) in patients with advanced peritoneal malignancies in collaboration with the Ludwig Institute for Cancer Research, where the expansion part has now started. Our Targovax valuation is virtually unchanged at NOK1.18bn or NOK18.6/share (vs NOK18.9/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	(140.2)	(2.4)	0.0	N/A	N/A
12/20e	0.0	(137.2)	(2.2)	0.0	N/A	N/A

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

Preclinical data on new viruses expected H219

The highlight of the quarter was the announced overall response rate (33%) and immune activation data from Part 1 of the Phase I study with ONCOS-102 in patients with advanced, unresectable, anti-PD1 refractory melanoma (n=9). We discussed this in detail in our previous update. The other ONCOS-102 trial in mesothelioma is progressing according to plan and Targovax expects to report results around new year 2020. Targovax's preclinical pipeline is also maturing, with three new oncolytic viruses in *in vivo* testing. Patents have been filed on these viruses but not yet published, so little information about the mechanism of action has been disclosed at the moment. Preclinical data will be announced in H219 and will help guide Targovax towards specific indications. Management plans to select one virus to take into Phase I.

Financials: Cash reach to 2020

Targovax reported immaterial revenues and an operating loss of NOK44.6m in Q219, compared to NOK36.7m in Q218, largely in line with our expectations. External Q219 R&D expenses were NOK22.0m versus NOK14.5m a year ago, indicating more intensive clinical R&D. Targovax had cash and cash equivalents of NOK135m at the end of Q219 and guided that this should be sufficient to reach 2020, which is in line with our model. We make no changes to our estimates.

Valuation: NOK1.18bn or NOK18.6/share

Our Targovax valuation is virtually unchanged at NOK1.18bn or NOK18.6/share compared to NOK1.20bn or NOK18.9/share due to rolling our model forward, which was offset by a lower net cash position. All other assumptions for our rNPV model are unchanged. There will be several data readouts over the next 12–18 months (Exhibit 3) starting with preclinical data on new oncolytic viruses in H219.

4 September 2019

Price	**NOK5.10**
Market cap	**NOK323m**
Net cash (NOKm) at end Q219	129.8
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	(13.3)	(5.6)	(56.9)
Rel (local)	(12.3)	(3.0)	(51.3)
52-week high/low	NOK11.4		NOK4.3

Business description

Targovax is an immunoncology company headquartered in Oslo, Norway, with an oncolytic virus platform, ONCOS. ONCOS-102 is currently 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	Q120
Cohort 2 data from Phase I melanoma	H120

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Edison profile page

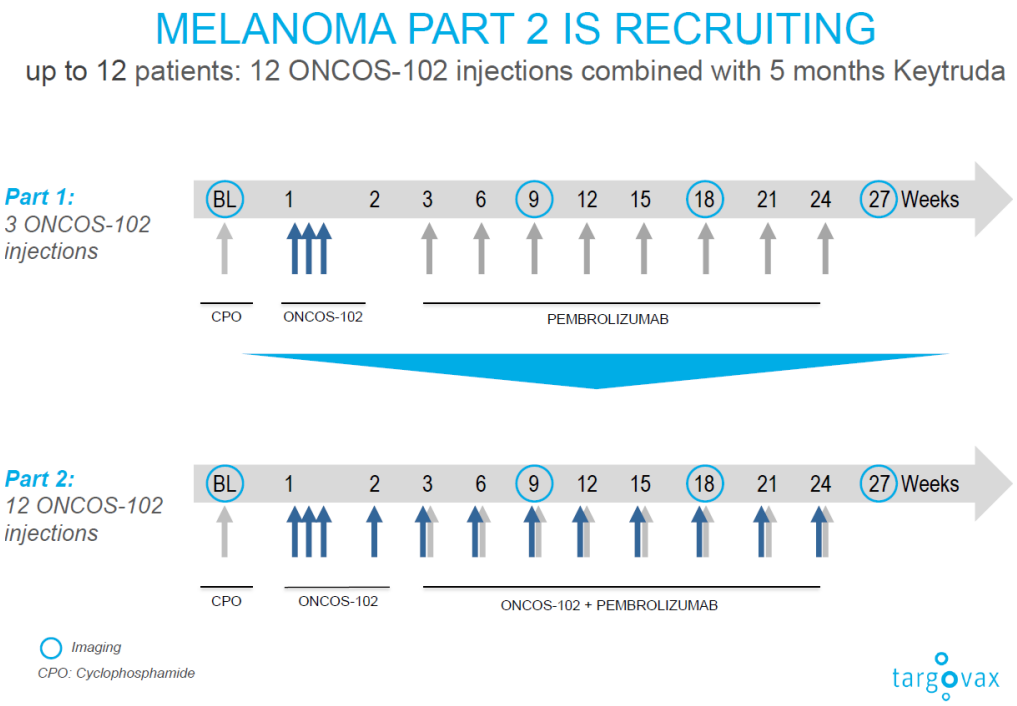
Adjusting the treatment regime in melanoma study

With its Q219 results, Targovax presented data from Part 1 of the Phase I melanoma trial, which we discussed in our last note. Three of the nine anti-PD1-resistant patients in Part 1 responded to the ONCOS-102 and subsequent Keytruda treatment.

The Part 2 – of the Phase I melanoma trial is currently enrolling patients (six recruited, up to 12 expected). These patients will be on a different treatment regime, which management described as more optimal compared with Part 1 (Exhibit 1). Rather than receiving three injections of ONCOS-102 at week 1 followed by eight doses of Keytruda, patients in Part 2 will continue to receive doses of ONCOS-102 in combination with Keytruda, which means these patients will receive a total of 12 ONCOS-102 injections rather than three.

The rationale for combining an oncolytic virus with a checkpoint inhibitor is to overcome resistance to the checkpoint inhibitor, eg by releasing tumour antigens via direct tumour cell lysis, priming the immune response and increasing T-cell infiltration. To give continued injections of the virus could enhance and maintain these mechanisms to maximise the potential for overcoming resistance. Targovax expects to report data from Part 2 of the trial during H120.

Exhibit 1: Design of the Phase I melanoma study



Source: Targovax

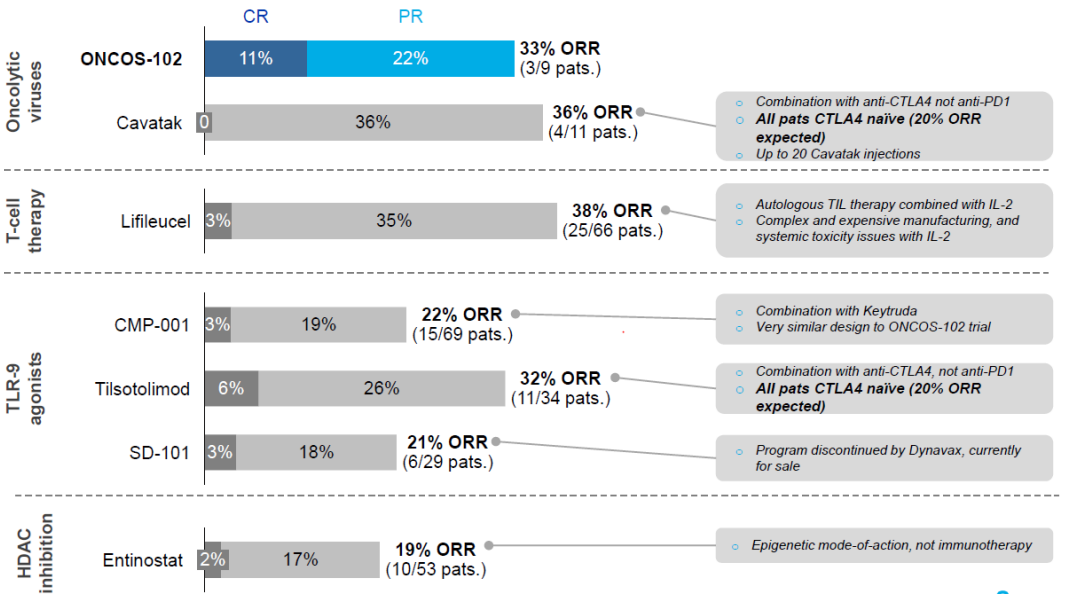
How ONCOS-102 plus Keytruda data compare with other similar studies

Targovax provided a comparison of the ONCOS-102 plus Keytruda data from Part 1 of the melanoma trial (n=9) with data from other studies in the same patient population (ie melanoma patients that have progressed after a checkpoint inhibitor). These included Cavatak (oncolytic virus), lifileucel (T-cell therapy), CMP-001, tilsotolimod and SD-101 (TLR-9 agonists), and entinostat (HDAC inhibitor).

Although not directly comparable in terms of technology or clinical trial design, it is encouraging to see that ONCOS-102 produced a similar ORR (33%) to these other drugs (ORRs ranging from 19% to 38%) and we look forward to performing more meaningful comparisons at a later stage once more data are available.

In comparing clinical trial design, we would single out Checkmate Pharmaceuticals, a biotech company developing a TLR-9 agonist, a class of immunotherapy drugs, in combination with CPIs. Targovax's ONCOS-102 is also a TLR-9 agonist. Checkmate Pharmaceuticals is conducting a Phase Ib study of intratumoral administration of its lead product CMP-001 in combination with Keytruda in patients with advanced melanoma who were considered refractory to Keytruda treatment. Published interim data (not complete) include an ORR rate of 22% (15/69).

Exhibit 2: ONCOS-102 plus Keytruda data cross-trial comparison



Source: Targovax

Exhibit 3: Targovax R&D pipeline

Product candidate	Preclinical	Phase I	Phase II	Phase III	Next expected event
ONCOS-102	Mesothelioma Combination w/ pemetrexed/cisplatin				New year 2019-20 Randomized data
	Melanoma Combination w/Keytruda				1H 2020 Part 2 data
	Peritoneal metastasis Collaborators: Ludwig, CRI & AZ Combination w/Imfinzi				*Update by collaborator*
	Prostate Collaborator: Sotio Combination w/DCvac				*Update by collaborator*
Next-gen ONCOS	3 new viruses Double transgene				2H 2019 First pre-clinical data

Source: Targovax. Note: Trials sponsored by collaborators highlighted in grey.

Valuation

Our updated valuation is NOK1.18bn or NOK18.6/share, compared to NOK1.20bn or NOK18.9/share previously, which is based on a risk-adjusted NPV analysis using a 12.5% discount rate, including NOK129.8m net cash. We continue to exclude other long-term debt of NOK53.5m 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 4: 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	2,634.6	41.6	15%	652.2	10.3
ONCOS-102 – mesothelioma	2026	424	2,094.0	33.0	10%	398.5	6.3
Net cash, last reported			129.8	2.0	100%	129.8	2.0
Valuation			**4,858.4**	**76.7**		**1,180.5**	**18.6**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. Note: Excludes conditional government long-term debt of NOK48.8m.

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)	(55,567)	(50,103)
EBITDA	(119,630)	(145,804)	(139,856)	(136,929)
Operating Profit (before amort. and except.)	(119,926)	(146,100)	(140,152)	(137,225)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(119,926)	(146,100)	(140,152)	(137,225)
Net Interest	(2,347)	(1,249)	0	0
Profit Before Tax (norm)	(122,273)	(147,349)	(140,152)	(137,225)
Profit Before Tax (reported)	(122,273)	(147,349)	(140,152)	(137,225)
Tax	328	334	0	0
Profit After Tax (norm)	(121,945)	(147,015)	(140,152)	(137,225)
Profit After Tax (reported)	(121,945)	(147,015)	(140,152)	(137,225)
Average Number of Shares Outstanding (m)	47.3	52.6	58.0	63.3
EPS - normalised (NOK)	(2.58)	(2.79)	(2.42)	(2.17)
EPS - normalised fully diluted (NOK)	(2.58)	(2.79)	(2.42)	(2.17)
EPS - reported (NOK)	(2.58)	(2.79)	(2.42)	(2.17)
Dividend per share (ore)	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	89,381	16,320
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	261,573	151,189	74,061	1,000
Other	14,620	15,320	15,320	15,320
Current Liabilities	(28,295)	(59,377)	(46,070)	(47,018)
Creditors	(28,295)	(50,250)	(33,181)	(34,129)
Short term borrowings	0	(9,127)	(12,889)	(12,889)
Long Term Liabilities	(108,156)	(103,565)	(105,805)	(156,791)
Long term borrowings	(48,806)	(43,933)	(46,173)	(97,159)
Other long-term liabilities	(59,350)	(59,632)	(59,632)	(59,632)
Net Assets	507,157	374,696	314,294	189,032
CASH FLOW				
Operating Cash Flow	(111,093)	(112,816)	(144,884)	(124,018)
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)	(77,128)	(124,047)
Opening net debt/(cash)	(131,915)	(212,767)	(98,129)	(14,999)
HP finance leases initiated	0	0	0	0
Other	0	0	(6,002)	0
Closing net debt/(cash)	(212,767)	(98,129)	(14,999)	109,048

Source: Targovax accounts, Edison Investment Research

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