

Targovax

Q418 results

Cohort 2 starts in ONCOS-102 melanoma trial

Pharma & biotech

12 March 2019

Targovax's Q418 presentation discussed highlights from the past year, focusing on the data readouts from the TG01 study in pancreatic cancer (PC) and the ONCOS-102 melanoma Phase I data. Management's plan for 2019 is largely unchanged: data from the first cohort of the ONCOS-102 melanoma study will be published in H119, treatment of the second cohort is ongoing and early interim data from TG02 colorectal cancer study will be published in H119. Management will also present three-year survival data from the TG01 PC study in H119 and is confident in finding a partner for continued development of TG01 in PC. Cash reaches into 2020, while our valuation is marginally higher at NOK1.46bn or NOK27.7/share.

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)	(2.7)	0.0	N/A	N/A
12/20e	0.0	(137.2)	(2.6)	0.0	N/A	N/A

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

ONCOS-102 Phase I melanoma study progressing

The focus for the next 12 months will be the ONCOS-102 Phase I melanoma study in combination with Keytruda in CPI refractory patients (discussed in our [November 2018 update](#)). ORR and immune data from the first cohort (n=9) will be published in H119, and the first patient from the second cohort (up to 12 patients, increased dosing) was [treated](#) on 11 February 2019. Meanwhile, management made progress on its TG platform development strategy and is confident of securing a collaboration agreement for TG01 in pancreatic cancer, potentially as soon as this year. This is now the main development path for the TG01 project, which was modified in response to changing standard of care in pancreatic cancer management (discussed in our [June 2018 update](#)).

Financials: Cash reach to 2020

Targovax reported immaterial revenues and an operating loss of NOK42.2m in Q418, compared to NOK32.5m in Q417, largely in line with our expectations. External Q418 R&D expenses were NOK21.0m versus NOK12.2m a year ago indicating a more intensive clinical R&D. Targovax had cash and cash equivalents of NOK151m at the end of Q418 and guided this should be sufficient to reach 2020, which is in line with our model.

Valuation: NOK1.46bn or NOK27.7/share

Our Targovax valuation is modestly higher at NOK1.46bn or NOK27.7/share compared to NOK1.41bn or NOK26.8/share due to rolling our model forward, which was partially offset by lower net cash position. All other assumptions for our rNPV model are unchanged except for a small modification in the colorectal cancer project (see below). ONCOS-102 melanoma Phase I interim data expected in H119 are the nearest major catalyst for the share price, while there will be several other data readouts over the next 12–18 months (Exhibit 4).

Price **NOK8.12**
Market cap **NOK427m**

Cash (NOKm) end-Q418 (excludes government long-term debt) 151

Shares in issue 52.6m

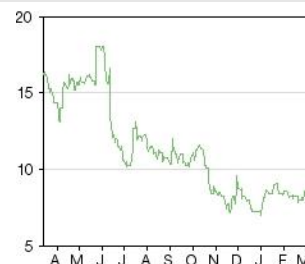
Free float 55%

Code TRVX

Primary exchange Oslo Stock Exchange

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(1.0)	(0.3)	(49.4)
Rel (local)	(3.4)	(2.8)	(50.5)

52-week high/low NOK18.0 NOK7.0

Business description

Targovax is an immunoncology company headquartered in Oslo, Norway, with two technology platforms that are being developed in oncological indications. ONCOS-102 is an oncolytic virus technology. TG is a therapeutic cancer vaccine platform comprising peptides mimicking the most common RAS oncogenic mutations.

Next events

ONCOS-102 mesothelioma Phase I data	H120
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ONCOS-102 melanoma Phase I interim data	H119
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TG02 colorectal cancer Phase I interim data readout	H119
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TG01 pancreatic cancer three-year survival data	H119
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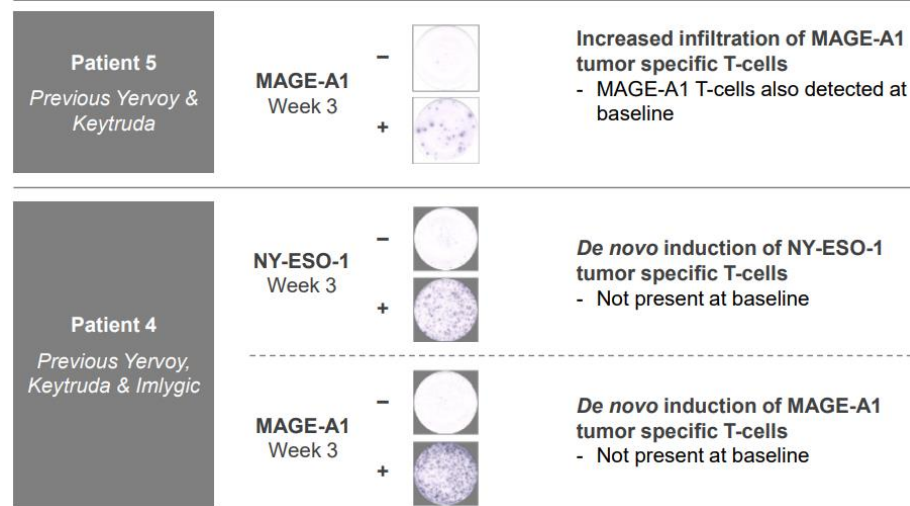
Targovax is a research client of Edison Investment Research Limited

Additional immune data from ONCOS-102 first cohort

Targovax presented some additional observations from the first cohort in Phase I melanoma trial where patients were treated with the lead asset oncolytic virus ONCOS-102. Analyses were carried out on tumour biopsies from these patients and the findings suggest ONCOS-102 could effect T-cell activation. We see the results as encouraging, especially because there is a continuing correlation with patient 5 in terms of immune response, who was the only patient with a complete response. A more detailed review of the released data is in our [November 2018 note](#), while the additional details presented during the Q418 results call include:

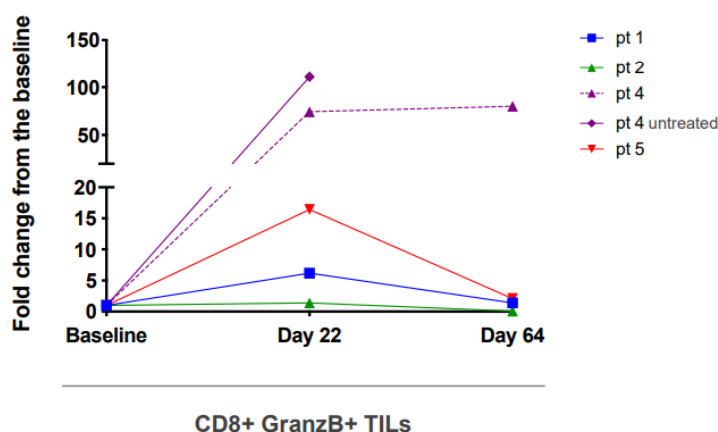
- IFN- γ ELISPOT analyses of week three biopsies from two patients showed there were increases in tumour-specific T-cells in the tumours (an apparent infiltration of T-cells) measured by the number of T-cells that recognise tumour-specific antigens MAGE-A1 or NY-ESO-1. This suggests that treatment with ONCOS-102 may have elicited a T-cell response in these patients.

Exhibit 1: Data from two patients showing potential T-cell response



Source: [Targovax Q418 presentation 14 February 2019](#)

- Granzyme B, a protease released by cytotoxic T-cells, was measured and data were presented from four patients showing a general increase in granzyme B from baseline to day 22, which had reduced again by day 64. The initial increase also suggests that treatment with ONCOS-102 may have elicited a T-cell response against the tumour. In patient 4 there was an apparent response in both the primary and non-injected tumours, a so-called 'abscopal effect'.

Exhibit 2: Granzyme B-expressing CD8+ T-cells, showing change from baseline


Source: [Targovax Q418 presentation 14 February 2019](#)

Financials and valuation

As Targovax's Q418 results were in line with our expectations, we made no major changes to our estimates. Full-year operating loss was NOK146m with external R&D expenses accounting for NOK64m. We expect the company will maintain similar or slightly less intensive clinical R&D activities (because a partner is being sought for the TG01 project) and our total operating loss estimate for 2019 is NOK140m (unchanged). Therefore, the cash position of NOK151m at the end of Q418 should reach 2020. As Targovax's R&D pipeline matures, several projects should reach mid-stage around 2021, which is when we expect another substantial increase in R&D spend. The required additional funding for 2020 is reflected in our model (Exhibit 5) as a long-term debt of NOK118m, as per our research principles.

Our updated valuation is NOK1.46bn or NOK27.7/share compared to NOK1.41bn or NOK26.8/share previously, which is based on a risk-adjusted NPV analysis using a 12.5% discount rate, including NOK151m gross cash at end-Q418 (Targovax booked total gross debt of NOK53.1m in Finnish government grants, but repayment is needed only if the products are sold or launched). We increased the required time to market for the colorectal cancer project by one year, which is mainly a result of fine-tuning our NPV model. We keep other assumptions relating to the clinical trials in our rNPV model unchanged (described in our initiation report). Upcoming near-term catalysts are (Exhibit 4):

- ONCOS-102 mesothelioma Phase I interim data expected in H120.
- ONCOS-102 melanoma Phase I interim data readout data expected in H119.
- TG02 colorectal cancer Phase I interim data readout data expected in H119.
- TG01 pancreatic cancer three-year survival data H119.
- TG02 + PD-1 combination pre-clinical data expected in H219.

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	2,475.5	47.0	10%	466.7	8.9
ONCOS-102 - mesothelioma	2026	424	1,967.5	37.4	10%	352.2	6.7
TG02 - CRC	2027	1,714	3,377.4	64.2	10%	484.9	9.2
Net cash at end-Q418			151.2	2.9	100%	151.2	2.9
Valuation			7,971.6	151.5		1,455.0	27.7

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

Exhibit 4: Targovax R&D pipeline

Platform	Product candidate	Preclinical	Phase I	Phase II	Phase III	Last event	Next expected event
ONCOS oncolytic adenovirus	ONCOS-102	Mesothelioma Comb. w/ pemetrexed/cisplatin	▶			Phase Ib safety lead-in cohort, incl. immune activation and ORR data (6 pts)	1H 2020 Randomized ORR data
		Melanoma Comb. w/Keytruda®	▶			ORR and immune activation (6 pts), 1/6 CR	1H 2019 ORR and immune data first cohort
		Peritoneal metastases ¹ Collab: Ludwig, CRI & AZ Comb. w/Imfinzi®	▶			First dose escalation cohort safety review (4 pts)	<i>Update by collaborator, expected 2019</i>
		Prostate Collab: Sotio Comb. w/DCVAC	▶			First patient dosed	<i>Update by collaborator, expected 2019</i>
	Next-gen ONCOS	3 viruses undisclosed	▶			Virus construct cloning and <i>in vitro</i> validation	2H 2019 Pre-clinical data
TG neo-antigen cancer vaccine	TG01	Pancreatic cancer Comb. w/gemcitabine	▶			mOS 33.4 months Demonstrated mutant RAS-specific immune activation	1H 2019 3-year survival data
	TG02	Colorectal cancer Proof-of-mechanism Comb. w/Keytruda®	▶			First safety review, incl. immune activation data (3 pts)	1H 2019 Immune activation and mechanistic data (mono)
	TG02	CPI synergy TG + PD-1	▶				2H 2019 Pre-clinical data

Source: [Targovax Q418 presentation 14 February 2019](#). Note: Trials sponsored by collaborators highlighted in grey.

Exhibit 5: Financial summary

	NOK'000s	2016	2017	2018	2019e	2020e
December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		37	37	27	0	0
Cost of Sales		0	0	0	0	0
Gross Profit		37	37	27	0	0
Research and development		(45,001)	(45,571)	(64,006)	(55,567)	(50,103)
EBITDA		(119,226)	(119,630)	(145,804)	(139,856)	(136,929)
Operating Profit (before amort. and except.)		(119,510)	(119,926)	(146,100)	(140,152)	(137,225)
Intangible Amortisation		0	0	0	0	0
Exceptionals		0	0	0	0	0
Other		0	0	0	0	0
Operating Profit		(119,510)	(119,926)	(146,100)	(140,152)	(137,225)
Net Interest		(3,203)	(2,347)	(1,249)	0	0
Profit Before Tax (norm)		(122,713)	(122,273)	(147,349)	(140,152)	(137,225)
Profit Before Tax (reported)		(122,713)	(122,273)	(147,349)	(140,152)	(137,225)
Tax		260	328	334	0	0
Profit After Tax (norm)		(122,453)	(121,945)	(147,015)	(140,152)	(137,225)
Profit After Tax (reported)		(122,453)	(121,945)	(147,015)	(140,152)	(137,225)
Average Number of Shares Outstanding (m)		34.5	47.3	52.6	52.6	52.6
EPS - normalised (NOK)		(3.55)	(2.58)	(2.79)	(2.66)	(2.61)
EPS - normalised fully diluted (NOK)		(3.55)	(2.58)	(2.79)	(2.66)	(2.61)
EPS - reported (NOK)		(3.55)	(2.58)	(2.79)	(2.66)	(2.61)
Dividend per share (NOK)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		100.0	100.0	100.0	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		339,512	367,415	371,129	370,844	370,577
Intangible Assets		338,213	366,250	370,240	370,240	370,240
Tangible Assets		1,299	1,165	889	604	337
Investments		0	0	0	0	0
Current Assets		185,832	276,193	166,509	21,517	15,320
Stocks		0	0	0	0	0
Debtors		0	0	0	0	0
Cash		171,629	261,573	151,189	6,197	0
Other		14,203	14,620	15,320	15,320	15,320
Current Liabilities		(29,184)	(28,295)	(59,377)	(42,308)	(43,256)
Creditors		(29,184)	(28,295)	(50,250)	(33,181)	(34,129)
Short term borrowings		0	0	(9,127)	(9,127)	(9,127)
Long Term Liabilities		(94,992)	(108,156)	(103,565)	(103,565)	(221,415)
Long term borrowings		(39,714)	(48,806)	(43,933)	(43,933)	(161,783)
Other long term liabilities		(55,278)	(59,350)	(59,632)	(59,632)	(59,632)
Net Assets		401,168	507,157	374,696	246,488	121,226
CASH FLOW						
Operating Cash Flow		(112,892)	(111,093)	(112,816)	(144,962)	(124,018)
Net Interest		3,203	2,347	1,249	0	0
Tax		0	0	0	0	0
Capex		(37)	(56)	0	(31)	(29)
Acquisitions/disposals		0	0	0	0	0
Financing		114,593	194,407	(30)	0	0
Other		(8,738)	(4,753)	(3,041)	1	0
Dividends		0	0	0	0	0
Net Cash Flow		(3,871)	80,852	(114,638)	(144,992)	(124,047)
Opening net debt/(cash)		(135,786)	(131,915)	(212,767)	(98,129)	46,863
HP finance leases initiated		0	0	0	0	0
Other		(0)	0	0	0	0
Closing net debt/(cash)		(131,915)	(212,767)	(98,129)	46,863	170,910

Source: Targovax accounts, Edison Investment Research

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