EDISON

Targovax

Company update

Steady progress across pipeline

Pharma & biotech

Targovax delivered a steady stream of newsflow in 2018 from R&D projects in its pipeline, and from the recent KOL event in New York and capital markets day in Oslo. Highlights include the announcement of interim data from the Phase I trial with ONCOS-102 (an oncolytic virus) and Keytruda combination in melanoma, and the full dataset from the Phase I/IIa trial with TG01 (a neoepitope cancer vaccine) with gemcitabine combination in resected pancreatic cancer. Our valuation is marginally higher at NOK1.41bn or NOK26.8/share.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/16	0.0	(122.7)	(3.55)	0.0	N/A	N/A
12/17	0.0	(122.3)	(2.58)	0.0	N/A	N/A
12/18e	0.0	(140.8)	(2.67)	0.0	N/A	N/A
12/19e	0.0	(141.0)	(2.67)	0.0	N/A	N/A

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

First response data from ONCOS-102 melanoma trial

On 27 September 2018, Targovax announced the interim data readout from its open-label Phase I study with ONCOS-102 in melanoma in combination with pembrolizumab (Keytruda, Merck & Co). The results included ORR data from six patients and biomarker data from four. One of the six showed complete response (RECIST 1.1 and irRECIST), correlated with an increase in intratumoural T cells; five of the six progressed, but, notably, these were pre-treated patients with relapsed, unresectable disease. Targovax plans to recruit an additional 12 patients to test a modified dosing schedule and will open two new US centres. This will extend the trial timeline, but is necessary to understand the best dosing regimen to increase the likelihood of seeing efficacy in later trials.

Mature TG01 dataset released; focus on TG02 in CRC

The complete dataset from the Phase I/II resected pancreatic cancer trial was presented on 15 October 2018 at the CMD. This included updated immune activation and survival data. Targovax is exploring options for further development of TG01 after it decided to reconsider the R&D path for this asset earlier this year. Potential options include investigator-led studies in pancreatic cancer; TG01 in different pancreatic cancer populations or using a different primary endpoint, eg disease-free survival rather than overall survival; and combination trials with CPIs in other indications. The Phase I trial with the second asset in this platform TG02 in colorectal cancer (CRC) is progressing as planned and the first data are expected in H119.

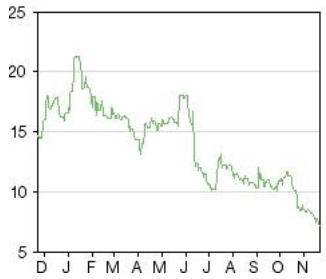
Valuation: NOK1.41bn or NOK26.8/share

Our valuation is slightly higher, at NOK1.41bn or NOK26.8/share, from NOK1.31bn or NOK24.9/share, due to rolling our model forward, which was partially offset by a lower net cash position. We maintain our other assumptions and see continued interest in the space, as evidenced by the recent deal where Boehringer Ingelheim acquired oncolytic virus developer ViraTherapeutics for €210m in September 2018, whose VSV-GP virus candidate was still in the preclinical stage.

21 November 2018

Price	**NOK7.15**
Market cap	**NOK376m**
Cash (NOKm) end-Q318 (excludes government long-term debt of NOK49m repayable only on product launch)	173
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	(29.1)	(35.6)	(51.0)
Rel (local)	(23.5)	(29.9)	(52.1)
52-week high/low	NOK21.3	NOK7.2	

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 Ib interim data	H120
ONCOS-102 melanoma Phase I interim data	H119
TG02 colorectal cancer Phase I interim data readout	H119
TG02+PD-1 combination preclinical data	H119

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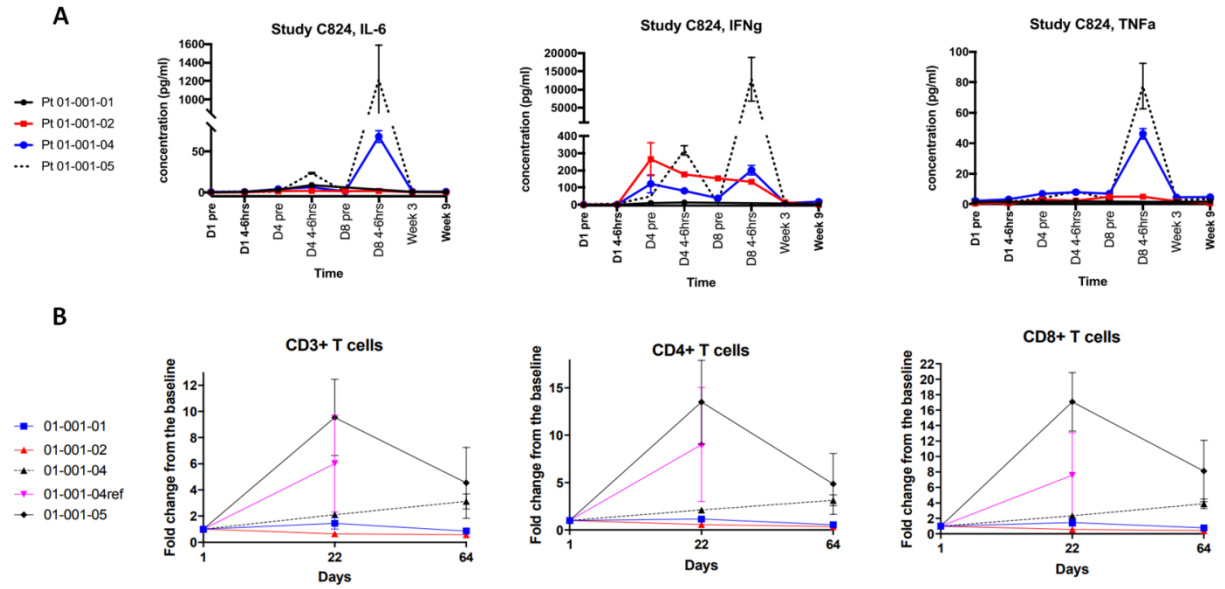
ONCOS-102 update

Second interim data readout from the Phase I melanoma study

As a reminder, Targovax is carrying out an open-label Phase I study with ONCOS-102 in combination with pembrolizumab (PD1 inhibitor) in melanoma at Memorial Sloan Kettering Cancer Center and Fox Chase Cancer Center. The first safety review showed that ONCOS-102 is well tolerated (December 2018). Data from the first four patients (out of 12) at week three (January 2018) showed increased levels of pro-inflammatory cytokines, cytotoxic CD8+ T-cells and expression of PD-1 on CD8+ T-cells (see our March 2018 note). On 27 September 2018, Targovax announced some additional data from the same four patients at week nine and the ORR has now been evaluated in a total of six patients.

- **First ORR data (1/6 complete response)**: one patient showed complete response (RECIST 1.1 and irRECIST) after treatment with ONCOS-102 and two doses of pembrolizumab. The patient had prior surgery and treatment with ipilimumab and pembrolizumab. All other patients showed disease progression; however, it is important to note all these patients have already been previously treated with a PD1 inhibitor and later relapsed, hence at the time of ONCOS-102 administration all had advanced, unresectable disease and few treatment options.
- **Correlation between ONCOS-102, mechanism of action and response:** the patient with complete response also showed the greatest relative increase in pro-inflammatory cytokines (during the injection days) and intratumoural CD3+, CD4+ and CD8+ T cells (when measured at week three and week nine), which are biomarkers for innate immune response and immune activation in the tumour respectively (Pt 01-001-05, Exhibit 1). However, it cannot yet be attributed with certainty that this increase in T-cells seen at day 22 is due to ONCOS-102, as pembrolizumab was also given prior to day 22. Lower levels of intratumoural T cells were observed in two patients, who received a lower dose of ONCOS-102 (less than three injections), which also points to a correlation.

Exhibit 1: (A) Cytokine biomarker analysis; (B) T cell biomarker analysis from first four patients to week nine

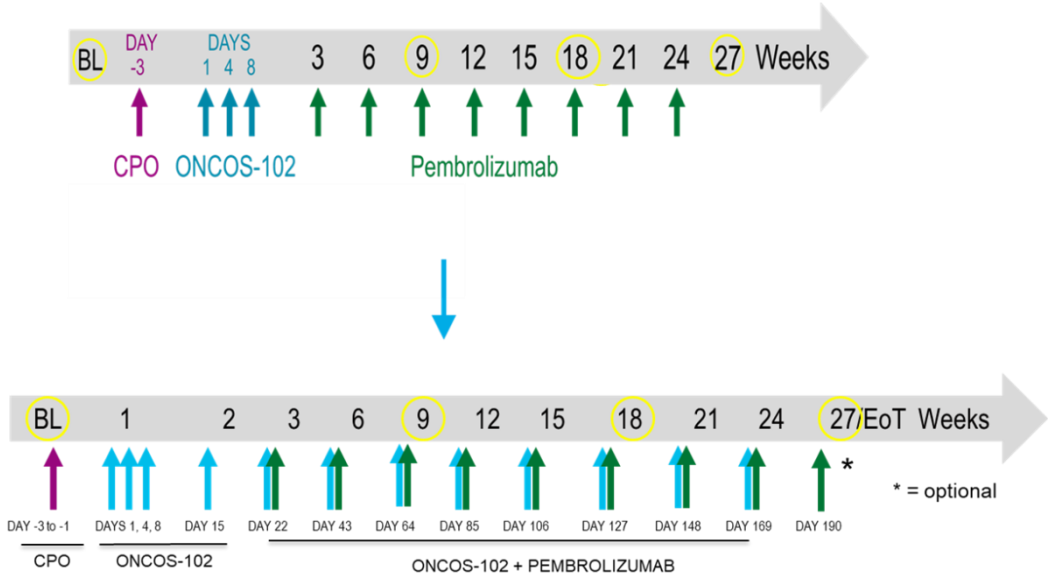


Source: Targovax CMD presentation 11 October 2018

Up to 12 additional patients on new dosing schedule

Based on the data above, management believes an increased number of ONCOS-102 injections could improve response rates in patients. Therefore, Targovax is updating the study protocol, where ONCOS-102 will be given to new patients for the duration of treatment with pembrolizumab, compared with three injections prior to treatment with pembrolizumab (Exhibit 2). Up to 12 additional patients will be enrolled. This will extend the trial timeline, but in our view it will be beneficial to understand the best dosing regimen to increase the likelihood of seeing efficacy in later trials. The first dataset from the first patient cohort (n=8) is expected in H119, which will include ORR and immune data.

Exhibit 2: Updated Phase I ONCOS-102 melanoma trial protocol for new cohort



Source: Targovax CMD presentation 11 October 2018

TG platform update

TG01 full dataset released

On 15 October 2018, Targovax announced the full and final data from the Phase I/II trial with TG01 in two cohorts of resected pancreatic cancer patients (total n=32) in combination with standard of care chemotherapy gemcitabine. The two cohorts differed in dosing regimen of TG01 and survival data at different maturity stages have been published before (see our last note). The complete two-year follow-up data now include OS, median OS (mOS) and median disease-free survival (mDFS) from the both cohorts and was presented during the capital markets day in October 2018:

- Both cohorts combined, n=32
  - 16.1 months median mDFS
  - 33.4 months mOS
  - 72% OS (23/32 patients were alive two years after surgery)
- First cohort, n=19
  - 13.9 months mDFS
  - 33.1 months mOS
  - 68% OS (13/19 were alive two years after surgery)
- Second cohort, n=13

- 19.5 months mDFS
- mOS not yet reached at time of analysis
- 77% OS (10/13 patients were alive two years after surgery)

This was Phase I/II trial, so a small patient group, and the absence of a comparator arm means we cannot yet draw any definitive conclusions about clinical efficacy of TG01 in this patient group; however, the survival data looks better when comparing to historical data from the ESPAC4 trial for gemcitabine alone, which showed 13.1 months mDFS and 27.6 months mOS.

In June 2018, a third party released new Phase III data at ASCO that suggested an almost two-year improvement in overall survival in the FOLFIRINOX arm with resected pancreatic cancer patients compared to gemcitabine. This is likely to become a new standard of care and with median overall survival in this specific indication (resected pancreatic cancer) approaching five years, such a long clinical trial became impractical for a small biotech. The CMD presentations sent a message that Targovax remains committed to the TG platform as a whole, and specifically for TG01 asset management outlined a few ideas that are being evaluated for the future development strategy for this asset:

- Targovax indicated it has received interest from various institutions, such as cancer networks, to conduct further testing of TG01 in pancreatic cancer. An **investigator-initiated trial** could be a realistic and cost-effective solution (Targovax already has two such trials running), but this means the timelines of the project would be beyond the company's control.
- Other potential options include the use of (i) **different endpoint** in resected pancreatic cancer that could reduce the timelines, exploring (ii) **TG01 in different pancreatic cancer patient populations** or in (iii) **combination trials with checkpoint inhibitors in various other indications.**

Until more details emerge, we remain conservative and do not make any new additions to our SOTP valuation table, but we will revisit TG01 once more details emerge. Meanwhile, data generated from the ongoing CRC study with TG02 will also help to clarify the TG platform strategy, in our view. The next data from this trial will be released in H119 and will include immune activation and mechanistic data (Exhibit 3).

Exhibit 3: 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[1]				Phase Ib safety lead-in cohort, incl. immune activation and ORR data (6 pts)	**1H 2020** Randomized ORR data 30 pts
		Melanoma Comb. w/KEYTRUDA®				ORR and immune activation (6 pts), 1/6 CR	**1H 2019** ORR and immune data first cohort (n=8)
		Peritoneal cancers[2,3] Partner: Ludwig, CRI & AZ Comb. w/IMFINZI®				First dose escalation cohort safety review (4 pts)	*Update by partner, expected 2019*
		Prostate[3] Partner: Sotio Comb. w/DCVAC				First patient dosed	*Update by partner, expected 2019*
	Next-gen ONCOS	**3 viruses** undisclosed				Virus construct cloning and *in vitro* validation	**2H 2019** Target disclosure and *in vivo* data
TG neo-antigen cancer vaccine	TG01	**Pancreatic cancer** Comb. w/gemcitabine				mOS 33.4 months Demonstrated mutant RAS-specific immune activation	TBD
	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
	TG02	**CPI synergy** TG + PD-1					**1H 2019** TG02 + PD-1 combination *in vivo* data

Source: Targovax CMD presentation 11 October 2018. Note: Trials sponsored by collaborators highlighted in grey.

Financials and valuation

With its Q318 results, Targovax reported immaterial revenues, while external R&D expenses were NOK17.3m, compared with NOK10.6m in Q317. As of end-Q318, Targovax's cash position was NOK173.2m. Given TG01 will not immediately progress into the next trial, there could be a reduction in cash burn in the near term. We have removed the R&D costs associated with the TG01 resected pancreatic cancer trial, which extended cash reach to end-2019/early 2020. Targovax may decide to use additional funds to expedite other programmes in the pipeline, in which case we will revise our estimates accordingly.

Our updated valuation is NOK1.41bn or NOK26.8/share compared to NOK1.31bn or NOK24.9/share previously. Our valuation is based on a risk-adjusted NPV analysis using a 12.5% discount rate, including NOK173.2m gross cash at end-Q318 (Targovax booked long-term debt of NOK48.8m in Finnish government grants, but repayment is needed only if the products are sold or launched). The assumptions relating to the remaining projects in our rNPV model are unchanged. Upcoming near-term catalysts are:

- ONCOS-102 mesothelioma Phase I interim data expected in H120
- ONCOS-102 melanoma Phase I interim data readout data expected in H119
- TG02 CRC Phase I interim data readout data expected in H119
- TG02 + PD-1 combination pre-clinical data expected in H119

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	604	2,378.6	45.2	10	423.3	8.0
ONCOS-102 - mesothelioma	2026	434	1,894.2	36.0	10	322.4	6.1
TG02 - CRC	2026	1,744	3,780.6	71.9	10	493.4	9.4
Net cash at end-Q318			173.2	3.3	100%	173.2	3.3
Valuation			**8,226.5**	**156.3**		**1,412.3**	**26.8**

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

NOK000s	2016	2017	2018e	2019e
December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	37	37	0	0
Cost of Sales	0	0	0	0
Gross Profit	37	37	0	0
Research and development	(45,001)	(45,571)	(60,000)	(55,567)
EBITDA	(119,226)	(119,630)	(142,601)	(140,655)
Operating Profit (before amort. and except.)	(119,510)	(119,926)	(142,897)	(140,951)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(119,510)	(119,926)	(142,897)	(140,951)
Net Interest	(3,203)	(2,347)	2,060	0
Profit Before Tax (norm)	(122,713)	(122,273)	(140,838)	(140,951)
Profit Before Tax (reported)	(122,713)	(122,273)	(140,838)	(140,951)
Tax	260	328	0	0
Profit After Tax (norm)	(122,453)	(121,945)	(140,838)	(140,951)
Profit After Tax (reported)	(122,453)	(121,945)	(140,838)	(140,951)
Average Number of Shares Outstanding (m)	34.5	47.3	52.7	52.8
EPS - normalised (NOK)	(3.55)	(2.58)	(2.67)	(2.67)
EPS - normalised fully diluted (NOK)	(3.55)	(2.58)	(2.67)	(2.67)
EPS - reported (NOK)	(3.55)	(2.58)	(2.67)	(2.67)
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	339,512	367,415	367,203	366,966
Intangible Assets	338,213	366,250	366,250	366,250
Tangible Assets	1,299	1,165	953	716
Investments	0	0	0	0
Current Assets	185,832	276,193	146,527	18,731
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	171,629	261,573	131,907	4,111
Other	14,203	14,620	14,620	14,620
Current Liabilities	(29,184)	(28,295)	(27,034)	(27,732)
Creditors	(29,184)	(28,295)	(27,034)	(27,732)
Short term borrowings	0	0	0	0
Long Term Liabilities	(94,992)	(108,156)	(108,156)	(108,156)
Long term borrowings	(39,714)	(48,806)	(48,806)	(48,806)
Other long term liabilities	(55,278)	(59,350)	(59,350)	(59,350)
Net Assets	401,168	507,157	378,540	249,809
CASH FLOW				
Operating Cash Flow	(112,892)	(111,093)	(131,643)	(127,737)
Net Interest	3,203	2,347	2,060	0
Tax	0	0	0	0
Capex	(37)	(56)	(84)	(59)
Acquisitions/disposals	0	0	0	0
Financing	114,593	194,407	0	0
Other	(8,738)	(4,753)	1	0
Dividends	0	0	0	0
Net Cash Flow	(3,871)	80,852	(129,666)	(127,796)
Opening net debt/(cash)	(135,786)	(131,915)	(212,767)	(83,101)
HP finance leases initiated	0	0	0	0
Other	(0)	0	0	0
Closing net debt/(cash)	(131,915)	(212,767)	(83,101)	44,695

Source: Targovax accounts, Edison Investment Research

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