

# Targovax

Q417 results

## Key catalysts in 2018

Q417 saw the release of several reports indicating a good safety profile and consistent immune activation signs by ONCOS-102, an oncolytic virus for melanoma and mesothelioma, and TG02, a neo-antigen vaccine for colorectal cancer. 2018 catalysts include full two-year survival data from the pancreatic cancer trial (Phase I/II) with TG01 and interim data readouts from the melanoma (Phase I) and mesothelioma (Phase Ib/II) trials with ONCOS-102. Our valuation is marginally higher at NOK1.78bn or NOK33.8/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	(147.5)	(2.80)	0.0	N/A	N/A
12/19e	0.0	(170.3)	(3.23)	0.0	N/A	N/A

Note: \*Normalised, excluding amortisation of acquired intangibles and exceptional items.

## Early consistent immune activation signs

Targovax runs four trials across its two platforms and supports an additional two trials led by partners. Targovax's most advanced Phase I/IIa trial with TG01 for pancreatic cancer is due to report final data and the company has presented potential design of the next trial, which will be part of the registration programme. According to early findings, both ONCOS-102 and TG02 have been found to consistently activate the innate and adaptive immune system. While the patient numbers were small at the time of the analysis, Targovax expects to report more mature interim data with ONCOS-102 in both indications in 2018 (Exhibit 1).

## FY18 spend expected somewhat higher than in FY17

Targovax reported immaterial revenues and an operating loss of NOK32.5m in Q417, compared to NOK31.3m in Q416, largely in line with our expectations. External Q417 R&D expenses were NOK12.2m versus NOK11.8m a year ago. Targovax had cash and cash equivalents of NOK262m at the end of Q417. Our total operating loss estimates for 2018 and 2019 are NOK150m and NOK170m, respectively. The increase is mainly due to ramping up R&D activities. We expect a cash position of NOK126m by end-2018. According to our model, this should extend well into 2019.

## Valuation: Marginally up to NOK1.78bn or NOK33.8/sh

Our Targovax valuation is slightly higher at NOK1.78bn or NOK33.8/share, from NOK1.69bn or NOK32.1/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. We note the recent industry news about Merck & Co's acquisition of Viralytics with the lead product Cavatac, which previously we [described as a peer](#) to the ONCOS platform. Merck & Co agreed to pay A\$502m, which compares well with our valuation of Viralytics of A\$469m (published in December 2017) + A\$29.6m placement by Viralytics in January 2018.

## Pharma & biotech

16 March 2018

**Price** **NOK16.38**
**Market cap** **NOK862m**

NOK7.87/US\$

Net cash (NOKm) at end-Q417 212.8

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 (0.4) (8.0) (39.5)

Rel (local) (0.7) (9.6) (46.1)

52-week high/low NOK28.4 NOK13.9

## Business description

Targovax is an immuno-oncology company headquartered in Oslo, Norway, with two technology platforms that are being developed in a number of 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

Full results from Phase I/II trial with TG01 in pancreatic cancer H118

Interim data from Phase I trial ONCOS-102 in melanoma H218

Interim data from Phase Ib/II trial ONCOS-102 in mesothelioma H118

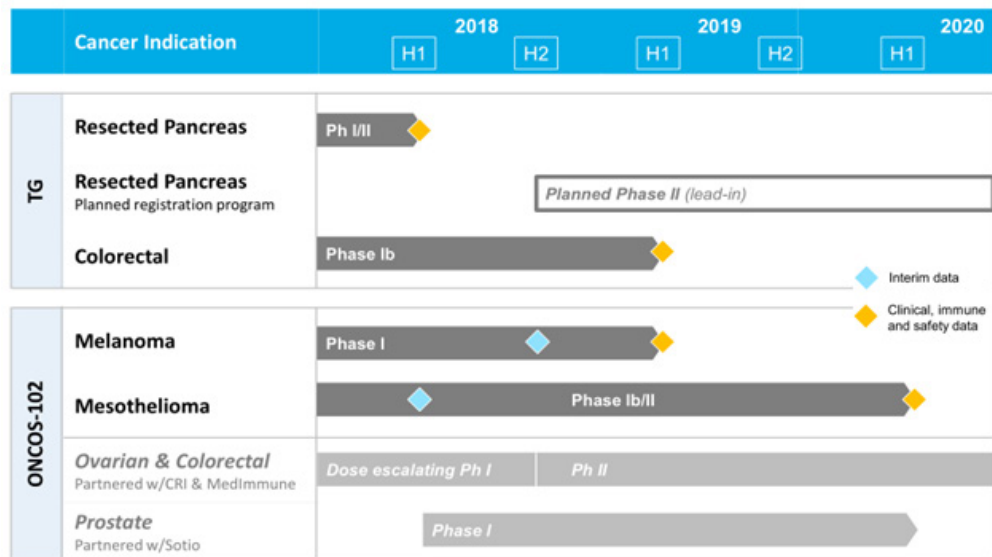
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Exhibit 1: Targovax's R&D pipeline update



Source: Targovax

## First ONCOS-102 data in melanoma and mesothelioma

In the ONCOS platform, Targovax explores ONCOS-102 in combinations with other drugs for the first time. Both the Phase I in melanoma and the Phase Ib/II in mesothelioma trials have passed the first independent safety reviews in December 2017 after recruiting four (out of 12) melanoma and three mesothelioma (out of 30) patients. ONCOS-102 was well tolerated with both Keytruda (pembrolizumab, an anti-PD-1) in melanoma trial and new standard of care chemotherapy with pemetrexed/cisplatin in mesothelioma trial. Trials with ONCOS-102 in ovarian/colorectal and prostate cancers are being run by partners. Targovax supplies its product, but has no control over the studies (more details in [our initiation report](#)). Following the initial safety review, the company reported first immunogenicity findings as well.

- In January 2018, Targovax reported the first immune activation observations at week 3 from four patients from the **melanoma** trial. The findings include increased levels of several pro-inflammatory cytokines (shows activation of innate immune response), cytotoxic CD8+ T-cells and the expression of PD-1 on CD8+ T-cells (shows activation of adaptive immune system). Together, these findings suggest innate and adaptive immune activation by ONCOS-102. The melanoma trial is an open-label Phase I trial intended to investigate whether the immune system of patients who have already failed to respond to checkpoint inhibitors can be reactivated by priming with ONCOS-102, making the patients responsive to the CPIs. Interim clinical data is expected to be released in H218.
- In February 2018, Targovax announced results from a so-called safety lead-in (n=6) part of the Phase I/II study with ONCOS-102 in first- or second-line patients with unresectable malignant **pleural mesothelioma** in combination with standard of care pemetrexed/cisplatin. As mentioned, no concerns were raised related to safety. Where available, the data have also demonstrated an increase in systemic cytokines (three analysed patients; activation of innate immune response) and an increase in relative level of tumour infiltrating CD8+ T-cells (two patients analysed; activation of adaptive immune system). Targovax will proceed to the randomised part of the trial expected to recruit 24 patients, with interim clinical data expected to be released in H118.

## Final two-year TG01 data and TG02's initial safety signs

### TG02 first-time-in-man passes initial safety hurdle in CRC

Targovax's neo-antigen cancer vaccines TG01 and TG02 are being tested in two trials. As with ONCOS, Targovax has presented early interim safety results from the clinical trial (Phase Ib) with TG02 in colorectal cancer patients. TG02 was administered to the first three patients (up to 20 expected to be enrolled) as a monotherapy and has passed a safety review and induced an immune response with activation of tumour-infiltrating T-cells. Increased PD-1 expression was also observed in both circulating and tumour-infiltrating T-cells.

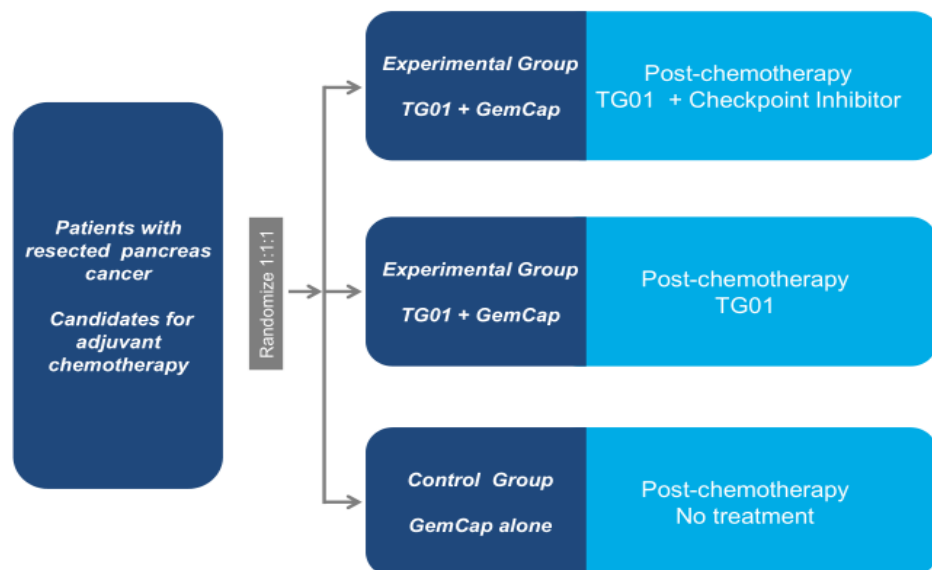
These very early exploratory clinical findings are indicative of the vaccine's expected mechanism of action and support the rationale for combination with checkpoint inhibitors. In total, 10 out of 20 patients (the first cohort) will receive TG02 as monotherapy. Afterwards, Targovax plans to proceed to the next part of the trial, which will include a second cohort of patients with RAS-mutated colorectal cancer receiving TG02 in combination with Keytruda. Final results are expected in H119. More details about the programme can be found in [our initiation report](#).

### A glimpse into TG01's future trial design

Currently, TG01 is being studied in a Phase I/II trial with gemcitabine as adjuvant therapy for patients with resected pancreatic cancer. The trial has already reported positive, in our view, interim safety and efficacy data (discussed in [our previous report](#)) and is due to report final two-year immune activation and survival data in H118.

Together with its Q417 results, Targovax has introduced a potential design for the next Phase II trial in pancreatic cancer (Exhibit 2). Preliminarily, this should be a three-arm-study exploring combinations with chemotherapy or checkpoint inhibitors. The precise timelines are yet to be clarified, but the study could start this year, presuming supportive data from the ongoing Phase I/II trial. As previously, Targovax indicated that it will explore the possibility to design a trial that would be sufficient for the registration.

**Exhibit 2: Potential Phase II trial design for TG01 in resected pancreatic cancer**



Source: Targovax

## Valuation

Our Targovax valuation is marginally higher at NOK1.78bn or NOK33.8/share, from NOK1.69bn or NOK32.1/share, due to rolling our model forward, which was partially offset by lower net cash position. We value Targovax based on risk-adjusted NPV analysis using a 12.5% discount rate, including NOK213m net cash at end-2017 (long-term debt of NOK48.8m in the Finnish government grants; repayment needed only if the products are sold or launched). We include four out of six indications currently, namely those that Targovax is running trials itself and maintain [all our assumptions](#) 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	604	2,102.7	40.0	10%	352.2	6.7
ONCOS-102 – Mesothelioma	2026	434	1,671.9	31.8	10%	270.7	5.1
TG01 – Pancreatic cancer	2024	785	2,794.0	53.1	15%	515.6	9.8
TG02 – Colorectal cancer	2026	1,744	3,352.6	63.7	10%	425.0	8.1
Net cash at end-2017			212.8	4.0	100%	212.8	4.0
<b>Valuation</b>			<b>10,134.0</b>	<b>192.6</b>		<b>1,776.2</b>	<b>33.8</b>

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations.

**Exhibit 4: Financial summary**

NOK000s	2015	2016	2017	2018e	2019e
December	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>					
Revenue	146	37	37	0	0
Cost of Sales	0	0	0	0	0
Gross Profit	146	37	37	0	0
Research and development	(25,231)	(45,001)	(45,571)	(72,948)	(91,368)
EBITDA	(89,468)	(119,226)	(119,630)	(149,276)	(169,994)
Operating Profit (before amort. and except.)	(89,616)	(119,510)	(119,926)	(149,572)	(170,290)
Intangible Amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(89,616)	(119,510)	(119,926)	(149,572)	(170,290)
Net Interest	(269)	(3,203)	(2,347)	2,060	0
Profit Before Tax (norm)	(89,885)	(122,713)	(122,273)	(147,512)	(170,290)
Profit Before Tax (reported)	(89,885)	(122,713)	(122,273)	(147,512)	(170,290)
Tax	(1,930)	260	328	0	0
Profit After Tax (norm)	(91,815)	(122,453)	(121,945)	(147,512)	(170,290)
Profit After Tax (reported)	(91,815)	(122,453)	(121,945)	(147,512)	(170,290)
Average Number of Shares Outstanding (m)	18.2	34.5	47.3	52.7	52.8
EPS - normalised (NOK)	(5.06)	(3.55)	(2.58)	(2.80)	(3.23)
EPS - normalised fully diluted (NOK)	(5.06)	(3.55)	(2.58)	(2.80)	(3.23)
EPS - reported (NOK)	(5.06)	(3.55)	(2.58)	(2.80)	(3.23)
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
<b>BALANCE SHEET</b>					
Fixed Assets	359,660	339,512	367,415	367,203	366,966
Intangible Assets	358,070	338,213	366,250	366,250	366,250
Tangible Assets	1,590	1,299	1,165	953	716
Investments	0	0	0	0	0
Current Assets	185,455	185,832	276,193	140,115	14,620
Stocks	0	0	0	0	0
Debtors	0	0	0	0	0
Cash	173,898	171,629	261,573	125,495	0
Other	11,557	14,203	14,620	14,620	14,620
Current Liabilities	(25,420)	(29,184)	(28,295)	(27,296)	(28,883)
Creditors	(25,420)	(29,184)	(28,295)	(27,296)	(28,883)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(96,821)	(94,992)	(108,156)	(108,156)	(138,906)
Long term borrowings	(38,112)	(39,714)	(48,806)	(48,806)	(79,556)
Other long term liabilities	(58,709)	(55,278)	(59,350)	(59,350)	(59,350)
Net Assets	422,874	401,168	507,157	371,866	213,796
<b>CASH FLOW</b>					
Operating Cash Flow	(81,159)	(112,892)	(111,093)	(138,055)	(156,186)
Net Interest	269	3,203	2,347	2,060	0
Tax	0	0	0	0	0
Capex	(158)	(37)	(56)	(84)	(59)
Acquisitions/disposals	1,313	0	0	0	0
Financing	200,000	114,593	194,407	0	0
Other	(47,031)	(8,738)	(4,753)	1	0
Dividends	0	0	0	0	0
Net Cash Flow	73,234	(3,871)	80,852	(136,078)	(156,245)
Opening net debt/(cash)	(62,552)	(135,786)	(131,915)	(212,767)	(76,689)
HP finance leases initiated	0	0	0	0	0
Other	0	(0)	0	0	0
Closing net debt/(cash)	(135,786)	(131,915)	(212,767)	(76,689)	79,556

Source: Targovax accounts, Edison Investment Research

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