EDISON

# Targovax

Company update

## ONCOS-102 plus durvalumab trial in spotlight

Pharma & biotech

**Targovax has announced that one of the trials with ONCOS-102, which is sponsored by Ludwig Institute for Cancer Research, will be in the spotlight at this year's ASCO meeting. This is an open-label Phase I/II trial that is exploring the combination of intraperitoneally delivered ONCOS-102 and systemically administered checkpoint inhibitor durvalumab (anti-PD-L1, Imfinzi, AstraZeneca) in patients with ovarian or colorectal cancers metastasised to the peritoneum. An abstract from the dose-escalation part of the trial will be presented at ASCO. Although Targovax is not sponsoring the trial, this may become a new opportunity for the company. Targovax's two lead trials with ONCOS-102 in melanoma and mesothelioma are on track to deliver data later this year. Our valuation is virtually unchanged at NOK1.52bn or NOK20.0 per share.**

| Year end | Revenue (NOKm) | PBT* (NOKm) | EPS* (NOK) | DPS (NOK) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/18 | 0.0 | (147.3) | (2.8) | 0.0 | N/A | N/A |
| 12/19 | 2.3 | (147.9) | (2.4) | 0.0 | N/A | N/A |
| 12/20e | 0.0 | (134.5) | (1.9) | 0.0 | N/A | N/A |
| 12/21e | 0.0 | (136.6) | (1.8) | 0.0 | N/A | N/A |

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

## Peritoneal malignancies uniquely suitable indication

The abstract was published online last week and describes the dose-escalation part of the study. The combination treatment had an acceptable tolerability profile and no dose-limiting toxicities were observed. As a result, the high dose level was selected for the expansion phase, which is ongoing. Targovax has not confirmed its future intention in this setting, which we believe will depend on the data and any potential interest from partners. Patients with peritoneal metastasis can be treated with intraperitoneal chemotherapy, but there are limited number of chemotherapy options available. ONCOS-102 can also be used for intraperitoneal therapy and, if successful, this trial can open up opportunities with administration into cavities and address significant unmet needs.

## Two lead trials on track to deliver data in 2020

Targovax started 2020 with the first randomised data readout from its Phase I/II trial with oncolytic virus ONCOS-102 in unresectable mesothelioma. It will present further data by mid-2020. Interim results released in July 2019 from Part 1 of the Phase I trial with ONCOS-102 in refractory melanoma were the hallmark event last year. More data from this trial are expected later this year (H220). In addition, Targovax has hired Dr Victor Levitsky, a medical doctor with a PhD in virology, as chief scientific officer. One of his key focus areas will be the new generation of oncolytic viruses, so we expect this programme to gain importance as it advances towards clinical trials.

## Valuation: NOK1.52bn or NOK20.0 per share

Our valuation is virtually unchanged at NOK1.52bn or NOK20.0/share. The timely private placement of NOK101m in January 2020 ensured funding for 2020. In our view, this and the upcoming newsflow from both key clinical trials helped the share price to rebound to pre-COVID-19 levels.

**28 May 2020**

| | |
|---|---|
| **Price** | **NOK8.00** |
| **Market cap** | **NOK608m** |
| Net cash (NOKm) at end Q120 (excludes government loans) plus private placement | 135.3 |
| Shares in issue | 76.0m |
| Free float | 90% |
| Code | TRVX |
| Primary exchange | Oslo Stock Exchange |
| Secondary exchange | N/A |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | 8.7 | 38.9 | 52.4 |
| Rel (local) | 2.6 | 46.9 | 74.6 |
| 52-week high/low | NOK10.2 | | NOK3.7 |

### Business description

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

| | |
|---|---|
| Additional ONCOS-102 mesothelioma Phase I data | Mid-2020 |
| Cohort 2 data from Phase I melanoma | H220 |
| More preclinical data on new oncolytic viruses | 2020 |
| Q120 results | 20 August 2019 |

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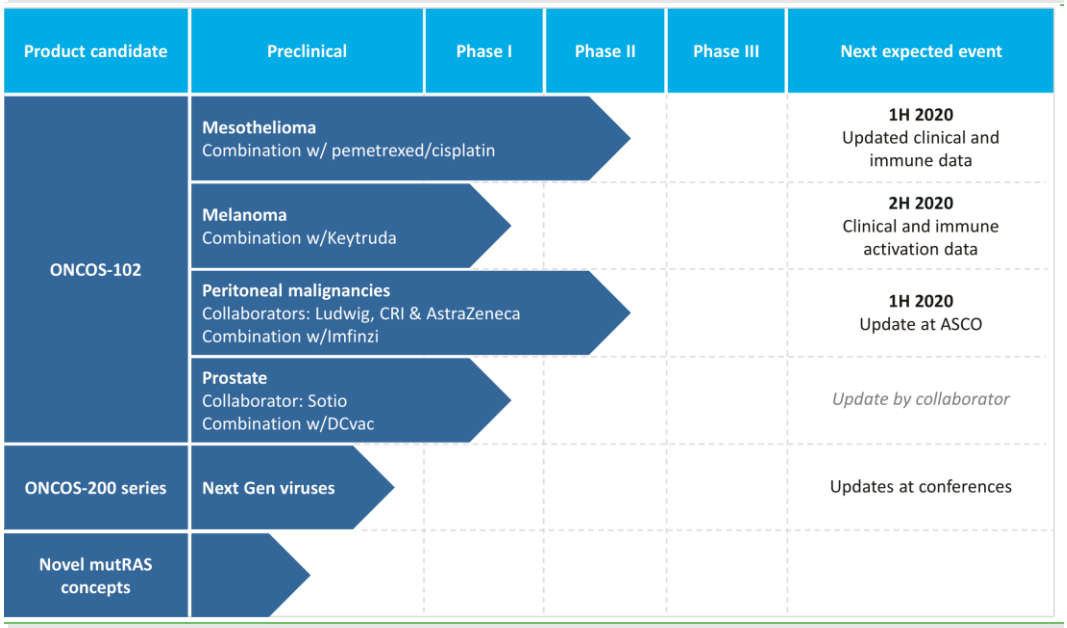
## ONCOS-102 plus durvalumab (Imfinzi) dose escalation abstract to be presented at ASCO

Targovax reported that an abstract from the ongoing investigator-led Phase II trial in peritoneal malignancies had been selected for the poster discussion session 'Developmental Therapeutics – Immunotherapy' and will be presented on 29 May at the ASCO 2020 virtual meeting. The abstract was published online last week and describes the dose escalation part of the study. This trial is a collaboration among Ludwig Institute for Cancer Research, Cancer Research Institute (CRI, New York City), AstraZeneca and Targovax. Ludwig Institute is the official sponsor that runs the study. AstraZeneca supplies durvalumab and Targovax supplies ONCOS-102.

**Exhibit 1: Key Targovax Phase I/II data vs historical controls**




Source: Targovax

**Exhibit 2: Targovax's ONCOS-102 collaborations, current status and upcoming newsflow**

| Indication and collaborator | Stage | Combo with | Trial design and upcoming events |
|---|---|---|---|
| ■ Ovarian and colorectal cancer (sponsored by Ludwig/CRI) | Phase I/II | CPI (durvalumab) | ■ Rather large open-label clinical trial (n=78) sponsored by US Ludwig Institute for Cancer Research and the CRI. In combination with durvalumab supplied by AstraZeneca.<br>■ Endpoints: safety/tolerability, clinical efficacy benefit at week 24, ORR, PFS, OS.<br>■ **Study completion date: 2022** |

Source: Edison Investment Research, Targovax. Notes: CPI: checkpoint inhibitor; ORR: objective response rate; PFS: progression-free survival, OS – overall survival.

This is an open label Phase I/II trial, which is exploring the combination of intraperitoneally delivered ONCOS-102 and systemically administered checkpoint inhibitor durvalumab (anti-PD-L1, Imfinzi, AstraZeneca) in patients with platinum-resistant ovarian or colorectal cancers that have metastasized to the peritoneal cavity. The trial design includes a dose-escalation phase assessing three different dosing levels. This is followed by an expansion phase with a total of up to 78 patients enrolled into ovarian and colorectal cancer arms.

The ASCO abstract presents safety, immune activation and clinical response data from the three dose escalation cohorts. In total, 17 patients were recruited into three cohorts: A (low dose, four patients), B (middle dose, five patients) and C (high dose, eight patients). The combination treatment had an acceptable tolerability profile and no dose-limiting toxicities were observed. As a result, the high dose level was selected for the expansion phase, which is ongoing. Preliminary

immune response findings indicate the treatment is triggering immune activation and has clinical activity, which were more pronounced in higher dose cohorts B and C.

Because it was the dose escalation part of the trial, no conclusions about the clinical efficacy can be made yet. The fact that the combination was well tolerated and the highest dose was selected for the expansion phase was the best possible outcome of this part of the trial. Phase II part of the trial is now enrolling patients.

## Peritoneal malignancies: Potentially large commercial opportunity

The peritoneum is a tissue (membrane) that lines organs in the abdominal cavity. Due to its proximity to several other organs, a primary tumour in these organs can easily metastasise to the peritoneum. Primary tumours can also originate in the peritoneum, but this is very rare. Colorectal cancer and ovarian cancer are common primary tumours that are known to metastasise to the peritoneum. Although survival rates have improved somewhat with the introduction of new treatments, the prognosis of these patients is still very poor due to the advanced stage of the disease. Specific treatments for peritoneal metastases are cytoreductive surgery and hyperthermic intraperitoneal chemotherapy, but patients will likely be receiving additional treatments for their primary tumours. Patients with peritoneal metastasis can be treated with intraperitoneal chemotherapy, but there are limited number of chemotherapy options available. ONCOS-102 can also be used for intraperitoneal therapy and, if successful, this trial can open up opportunities with administration into cavities and address significant unmet needs.

### Potentially large patient population

Epithelial ovarian cancer is the most common type of ovarian cancer, making up around 90% of cases (cancer.org). The majority of patients who are diagnosed have advanced disease (around 87%; Narod, 2016), where the tumour has spread beyond the pelvic tissues, for example to the lymph nodes or peritoneum (stage III), or further to liver or spleen parenchyma (stage IV). Most patients with advanced disease have peritoneal metastases (one study found this to be 76% of patients) and it is ultimately regarded as part of the disease.

Colorectal peritoneal metastases are not as common as in ovarian cancer. Around 16% of metastatic colorectal cancer cases have peritoneal metastases. Treatment with cytoreductive surgery and hyperthermic intraperitoneal chemotherapy can improve survival from around five months (untreated) to 12–18 months (Koumpa et al, 2019).

Given the early stage of the study, it is too early to estimate the potential precise positioning of ONCOS-102 for treatment of patients with peritoneal metastasis, but our initial evaluation reveals a relatively large accessible patient population given the rather specific peritoneal chemotherapy approach (Exhibit 3). We estimate that the number of patients with advanced ovarian cancer with peritoneal metastases to be around 13k in US and 19k in Europe. Applying the same pricing as we have done for ONCOS-102 in other indications ($75k in US and €52.5k in Europe) would indicate a potential market of $1bn in the US and the same in Europe (assuming 100% penetration). We estimate the number of patients with colorectal peritoneal metastases to be lower, around 4k in the US and 5k in Europe, which would translate into an addressable market of around $300m in US and the same in Europe.

**Exhibit 3: Patient number estimates for peritoneal metastases from CRC and epithelial ovarian cancer (2018 estimates, 000s)**

| Colorectal cancer | | US | Europe | Epithelial ovarian cancer | | US | Europe |
|---|---|---|---|---|---|---|---|
| Incidence of CRC | | 96 | 116 | Incidence of ovarian cancer | | 22 | 32 |
| Metastatic CRC | 25% | 24 | 29 | Epithelial ovarian cancer | 90% | 20 | 28 |
| Peritoneal metastases | 16% | 4 | 5 | Advanced stage | 87% | 17 | 25 |
| | | | | Peritoneal metastases | 76% | 13 | 19 |

Source: cancer.gov, Globocan, Jacobson et al, 2018, Bhatt et al, 2016. Note: Europe numbers include the top five European countries, Benelux, Scandinavia, Austria and Switzerland.

# Upcoming newsflow

We provided a detailed discussion about Targovax's R&D progress in our March 2020 report. Both key clinical trials will continue generating data in the near term. Targovax's preclinical development of the new generation of oncolytic viruses is also advancing.

## Mesothelioma: 12-month follow-up by mid-2020

The Phase I/II (n=31) open-label trial compares ONCOS-102 plus standard of care (pemetrexed/cisplatin) versus standard of care treatment in first- and second-line settings. Targovax reported first randomised data (six-month follow-up) from this on 22 January 2020, which we analysed in our January 2020 report and concluded the immunological activation data, in combination with the clinical response seen in patients, show the mechanistic effect of ONCOS-102 is potentially associated with clinical improvement. In the recently released announcement (18 May) Targovax confirmed that after nine-month follow up the first-line patients continue to perform well and will be the target population in further trials. Median progression free survival remained in line with previously published data.

The next update will be 12-month follow-up data with more extensive immune activation and biomarker findings expected to be released by mid-2020. Meanwhile, it has started working on the next stage. The next trial will focus on the first-line patients and will assess ONCOS-102 in a triple combination including standard chemotherapy and checkpoint inhibitors (CPIs) (likely to become a new standard of care in the near future). In addition, Targovax has indicated it is already in discussions with a prospective pharma partner for a study collaboration, although the extent of the possible partnership is not yet confirmed but it is likely this will be in the form of a CPI supply agreement. Because of high costs, combinations with CPIs can inflate the cost of clinical trials significantly, so a supply agreement has a direct positive financial effect for the trial sponsor.

## Melanoma: Results from Part 2 of Phase I study in H220

The ongoing Phase I trial enrolled patients with advanced, unresectable melanoma, who progressed on treatment with anti-PD1 checkpoint inhibitors. ONCOS-102 is administered in combination with the CPI pembrolizumab (Keytruda, Merck & Co). The trial aims to show ONCOS-102 can activate the immune response in anti-PD1 refractory patients, trigger relevant T-cell production and enhance infiltration into the tumour. The goal is to allow the patients to benefit from treatment with CPI again.

Part 2 of the Phase I melanoma trial is now fully enrolled and the readout from this part will be the key catalyst expected in H220. Patients are being administered with significantly extended dosing of ONCOS-102 compared to patients in Part 1. Data from the Part 1 demonstrated 33% overall response rate, which compared well with other similar studies, and evidence of systemic anti-tumour response.

### ONCOS-200: New oncolytic viruses

In second-generation ONCOS viruses, Targovax was able to add double transgenes (the first-generation ONCOS-102 has granulocyte macrophage colony stimulating factor). These new viruses have different properties and are optimised to inhibit tumour growth and vascularisation, counteract the immunosuppressive tumour microenvironment or have enhanced cell-killing properties. Targovax also presented some in vivo data from its studies with the ONCOS-210 and 212 viruses and we expect more data in the near future, including more details about positioning in the clinic and which indications will be prioritised.

In April 2020, Targovax announced it had hired Dr Victor Levitsky as chief scientific officer. Dr Levitsky is a medical doctor with a PhD in virology and post-doctoral training in tumour biology at Karolinska Institute, Sweden. One of his key focus areas will be the new generation of Targovax's oncolytic viruses, so we expect this programme to gain importance as it advances towards clinical trials.

## Financials and valuation

Targovax's Q120 operating expenses were NOK29.6m, which were significantly lower than NOK39.6m in Q120 following the cost reduction programme. Q120 external R&D spending was NOK13.4m. We lower our external R&D spending estimates to NOK60m from NOK70m for 2020 and 2021. Our operating loss forecasts now are NOK135m and NOK137m for 2020 and 2021, respectively (versus NOK145m and NOK147m previously).

Targovax had cash and cash equivalents of NOK135m at the end of Q120. In January 2020, it raised NOK101m via a private placement, which secured funding for 2020, according to our model and in line with the company's guidance. The funding gap in 2021 is covered in our model by increasing long-term debt (as per our principles; Exhibit 5).

Our valuation is virtually unchanged at NOK1.52bn or NOK20.0/share, which is based on a risk-adjusted NPV analysis using a 12.5% discount rate, including NOK135m net cash. We continue to exclude other long-term debt of NOK64.m in Finnish government grants from our valuation, as repayment is only required if the products are sold or launched. Our valuation is due to be revised after the data readouts from both lead clinical trials.

**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 | 2,894.5 | 38.0 | 15% | 736.5 | 9.7 |
| **ONCOS-102 – mesothelioma** | 2026 | 424 | 2,291.3 | 30.1 | 20% | 650.7 | 8.6 |
| Net cash, last reported | | | 135.3 | 1.8 | 100% | 135.3 | 1.8 |
| **Valuation** | | | **5,321.1** | **69.9** | | **1,522.5** | **20.0** |

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

**Exhibit 5: Financial summary**

| NOK'000s | 2018 | 2019 | 2020e | 2021e |
|---|---|---|---|---|
| December | IFRS | IFRS | IFRS | IFRS |
| **PROFIT & LOSS** | | | | |
| Revenue | 27 | 2,251 | 0 | 0 |
| Cost of Sales | 0 | 0 | 0 | 0 |
| Gross Profit | 27 | 2,251 | 0 | 0 |
| Research and development | (64,006) | (80,286) | (60,103) | (59,913) |
| EBITDA | (145,804) | (146,247) | (134,508) | (136,550) |
| Operating Profit (before amort. and except.) | (146,100) | (150,273) | (134,508) | (136,550) |
| Intangible Amortisation | 0 | 0 | 0 | 0 |
| Exceptionals | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Operating Profit | (146,100) | (150,273) | (134,508) | (136,550) |
| Net Interest | (1,249) | 2,423 | 0 | 0 |
| Profit Before Tax (norm) | (147,349) | (147,850) | (134,508) | (136,550) |
| Profit Before Tax (reported) | (147,349) | (147,850) | (134,508) | (136,550) |
| Tax | 334 | 321 | 0 | 0 |
| Profit After Tax (norm) | (147,015) | (147,529) | (134,508) | (136,550) |
| Profit After Tax (reported) | (147,015) | (147,529) | (134,508) | (136,550) |
| Average Number of Shares Outstanding (m) | 52.6 | 60.8 | 69.6 | 75.9 |
| EPS - normalised (NOK) | (2.79) | (2.43) | (1.93) | (1.80) |
| EPS - normalised fully diluted (NOK) | (2.79) | (2.43) | (1.93) | (1.80) |
| EPS - reported (NOK) | (2.79) | (2.43) | (1.93) | (1.80) |
| 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 | 371,129 | 371,050 | 371,050 | 371,050 |
| Intangible Assets | 370,240 | 367,083 | 367,083 | 367,083 |
| Tangible Assets | 889 | 726 | 726 | 726 |
| Investments | 0 | 3,241 | 3,241 | 3,241 |
| Current Assets | 166,509 | 85,858 | 42,407 | 16,429 |
| Stocks | 0 | 0 | 0 | 0 |
| Debtors | 0 | 0 | 0 | 0 |
| Cash | 151,189 | 70,429 | 26,978 | 1,000 |
| Other | 15,320 | 15,429 | 15,429 | 15,429 |
| Current Liabilities | (59,377) | (50,690) | (40,149) | (43,874) |
| Creditors | (50,250) | (53,931) | (43,390) | (47,115) |
| Short term borrowings | (9,127) | 0 | 0 | 0 |
| Long Term Liabilities | (103,565) | (109,263) | (109,263) | (210,465) |
| Long term borrowings | (43,933) | (50,441) | (50,441) | (151,643) |
| Other long term liabilities | (59,632) | (58,822) | (58,822) | (58,822) |
| Net Assets | 374,696 | 296,955 | 264,045 | 133,141 |
| **CASH FLOW** | | | | |
| Operating Cash Flow | (112,816) | (140,094) | (139,403) | (127,180) |
| Net Interest | 1,249 | (2,423) | 0 | 0 |
| Tax | 0 | 0 | 0 | 0 |
| Capex | 0 | (134) | 0 | 0 |
| Acquisitions/disposals | 0 | 0 | 0 | 0 |
| Financing | (30) | 66,863 | 95,950 | 0 |
| Other | (3,041) | (2,353) | 2 | 0 |
| Dividends | 0 | 0 | 0 | 0 |
| Net Cash Flow | (114,638) | (78,141) | (43,451) | (127,180) |
| Opening net debt/(cash) | (212,767) | (98,129) | (19,988) | 23,463 |
| HP finance leases initiated | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Closing net debt/(cash) | (98,129) | (19,988) | 23,463 | 150,643 |

Source: Targovax accounts, Edison Investment Research

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