EDISON

Targovax

Company update

Growing list of collaborations and more data in H2

Pharma & biotech

An update from Targovax's Phase I/II study in unresectable mesothelioma with OCOS-102 was the highlight of Q220 (described in our last note). Median over survival (OS) data are still not mature and the next update in expected by year-end. Another catalyst expected this year is the results of Part 2 from the Phase I melanoma trial in H220. The trial aims to show ONCOS-102 can activate the immune response in anti-PD1 refractory patients. Following the cost-reduction programme implemented in 2019, Targovax is now sharply focused on its oncolytic virus platform. However, after signing a string of new collaborations, the company is now involved in multiple projects, which significantly increase profit opportunities. Our valuation is unchanged at NOK1.65bn or NOK21.6/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	(124.5)	(1.8)	0.0	N/A	N/A
12/21e	0.0	(126.3)	(1.7)	0.0	N/A	N/A

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

More newsflow from both trials this year

On 22 June 2020, Targovax reported additional data from its Phase I/II study in unresectable mesothelioma (follow-up to the first data published in January 2020). There were no new safety issues and the efficacy signals seen in the first set of data were confirmed. The immune and gene sequencing data provided strong support for ONCOS-102's ability to activate the immune system and remodel the tumour microenvironment. Median OS data are still not mature and the next update is expected before the end of 2020. Targovax should also report Part 2 results from the Phase I melanoma trial in H220. In this study patients are administered a combination of ONCOS-102 and Keytruda with the goal to show ONCOS-102 can activate the immune response in anti-PD1 refractory patients.

Growing list of collaborations

Targovax's focus and investment areas are the ongoing lead clinical trials with ONCOS-102 and preclinical work on the new generation of oncolytic viruses. Over the past year, however, the company has established a number of partnerships focused on early-stage exploratory projects. In these types of collaborations, Targovax typically provides access to its technology and support, but financial involvement is limited. Because the company still contributes its intellectual property, any potentially successful combination therapies would mean a licensing deal for Targovax. So, it is a good way to enhance future profit opportunities in a cost-efficient manner.

Valuation: NOK1.65bn or NOK21.6/share

Our valuation is unchanged at NOK1.65bn or NOK21.6/share, as lower cash position offset rolling the model forward. Cash and cash equivalents were NOK101m at the end of Q220, which secures funding into 2021.

17 September 2020

Price	**NOK7.2**
Market cap	**NOK551m**
Net cash (NOKm) at end Q220	101.5
Shares in issue	76.1m
Free float	90%
Code	TRVX
Primary exchange	Oslo Stock Exchange
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	13.1	-2.8	40.6
Rel (local)	14.8	-4.4	58.3
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

Cohort 2 data from Phase I melanoma	2020
Patient survival update from Phase I/II study	H220
Q320 results	5 November 2020

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Targovax's key collaborations

Although all current collaborations are fairly early stage (except IOVaxis, which could start a clinical stage trial soon), as we described above, it is a cost-efficient way to increase future opportunities. One additional benefit is that many of these collaborations include Targovax's TG platform. Although the company has deprioritised this technology in favour of ONCOS, the mutant RAS target is one of the most promising, but also difficult, targets in oncology and attracts a lot of attention due to its involvement in many major cancer indications. The high interest in this target is demonstrated by the fact that four of Targovax's collaborations are centred on mutant RAS (Exhibit 1).

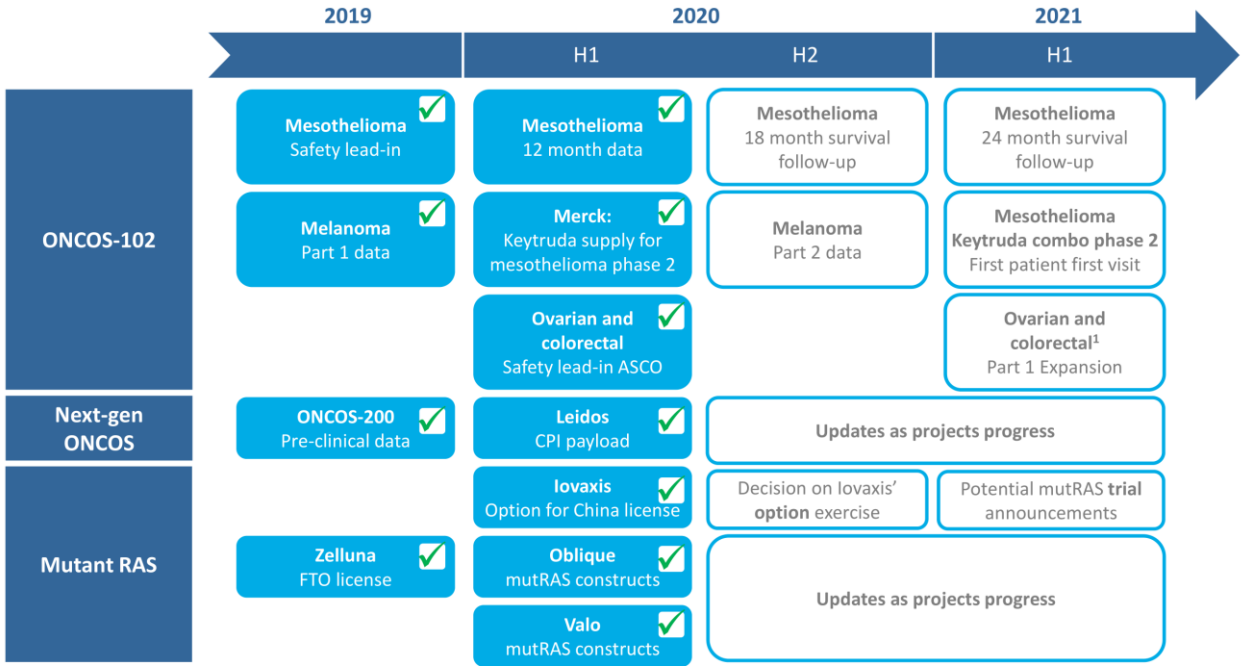
The current list of collaborations includes:

- **Leidos.** In June 2020, Targovax signed a collaboration agreement with the Explorations in Global Health (ExGloH) Division of Leidos Holdings (NYSE/Nasdaq, market cap $13bn). ExGLoH has developed a unique portfolio of peptides that can bind checkpoint receptors and act as antagonists, called Microtide technology. Because the structure of these peptides is much smaller than traditional checkpoint inhibitors (CPIs, monoclonal antibodies), they can be encoded in viral vectors, in this case Targovax's ONCOS. This could potentially result in a 'two-in-one' approach instead of administering ONCOS and CPIs separately. According to current agreement terms, Leidos and Targovax will conduct in vitro and in vivo feasibility studies. In our view, although this is still a relatively early exploration project, the approach is cutting-edge science in immunoncology. In addition, Leidos is a large company, so a strong partner if the project should advance. Targovax is already focused on developing its ONCOS-102 in combinations with CPIs, as there is a strong rationale for such combinations. Immune primers, such as ONCOS-102, help to generate the anti-tumour immune response, while CPIs block the tumour's defence mechanism against the patient's immune system.
- **IOVaxis Therapeutics.** In January 2020, Targovax signed an exclusive option agreement with IOVaxis Therapeutics, a spin-off from China-based, privately owned ImmuOn Therapeutics. IOVaxis acquired an option to in-license the rights to Targovax's mutant RAS vaccines TG01 and TG02 in China, Hong Kong, Macau and Singapore. The option is exercisable as soon as the regulator approves the first clinical trial, but no later than one year after the agreement (so that Targovax would avoid delays). The option deal is structured to take into account the uncertainty over how the Chinese regulatory authority treats therapies such as cancer vaccines. Targovax received $250k for the option and another $3m is due as an upfront payment on exercise of the option. Total potential development and commercial milestones are up to $100m, plus mid double-digit royalties. Targovax has deprioritised its TG vaccines against mutant RAS to focus on its ONCOS platform even though the Phase II data were promising (described in detail in our previous reports). Although the agreement involves only China rights, we believe that if this project is successful and delivers another batch of promising data, the interest in the TG rights to other regions would increase significantly.
- **Oblique.** In June 2020, Targovax singed a collaboration with a privately held Swedish biotech Oblique Therapeutics. Oblique has developed a proprietary antibody platform Abiprot, which can identify high-affinity antibody binding sites in any given protein. One of the targets Oblique is interested in is mutant RAS. Oblique's challenge is to introduce its antibodies into the cells with mutated RAS. The collaboration aims to evaluate in vitro and in vivo the potential of using ONCOS oncolytic adenoviruses as a vector to encode and deliver Abiprot antibodies intracellularly to boost the efficacy.
- **Valo.** In April 2020, Targovax entered in a collaboration agreement with Valo Therapeutics to work on a project, where Valo's peptide-coating technology PeptiCDAd will be used to coat

ONCOS oncolytic adenoviruses with Targovax's TG mutant RAS peptides. Valo, with headquarters in Helsinki, Finland, and Oxford, UK, has developed a platform, PeptiCRAd, that allows the coating of oncolytic viruses with antigens. This is a simpler process than genetically engineering antigens into an oncolytic virus genome and is very adaptive – the same carrier virus can be coated with different antigens and target different mutations. The rationale is that coated oncolytic viruses deliver the antigens directly into the tumour, which results in increased immunogenicity and CD8+ T-cell response against tumour tissue. Targovax has IP on both components, the oncolytic virus (ONCOS) and the mutant RAS peptides (TG), so there will be no need to in-license any other technology. Initially, the collaboration is focused on technical feasibility, in vitro activity and in vivo immune activation studies. If successful, this project could result in a new generation of Targovax's ONCOS oncolytic viruses.

- **Zelluna**. Targovax has another agreement in place with a Norwegian biotech Zelluna Immunotherapy, which is working on T cell receptor guided natural killer cell (TCR-NK) technology. Zelluna engineers allogeneic NK cells to expresses a TCR of choice, which would result in a novel cell immunotherapy theoretically able to recognise any antigen on a surface of a cancer cell. One of the projects Zelluna is working on is mutant RAS TCRs therapy, for which Targovax agreed to out-license its IP and know how. Zelluna has been granted a global, non-exclusive license to relevant patents, while the potential deal value for Targovax is up to NOK100m and royalty payments.

Exhibit 1: Targovax's partnerships

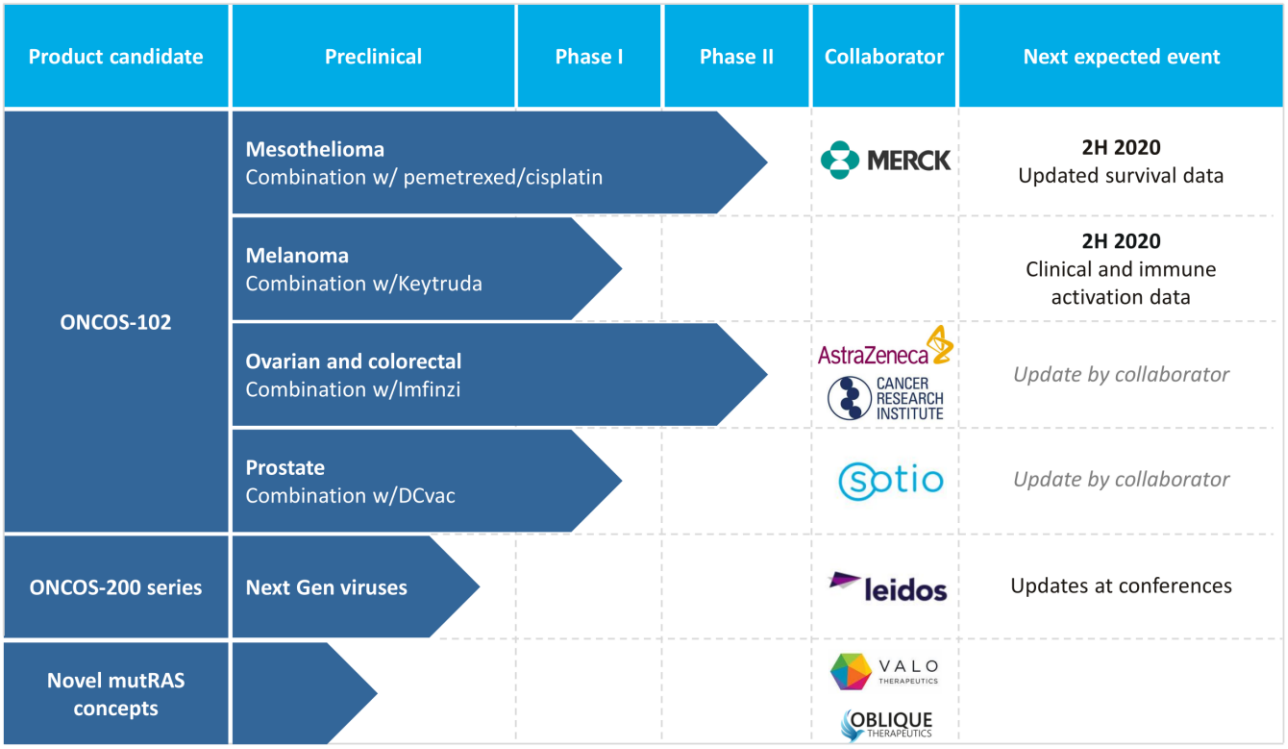


Source: Targovax

Upcoming newsflow

We provided a detailed discussion about Targovax's R&D progress in our previous reports. 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.

Exhibit 2: Targovax's R&D pipeline and upcoming newsflow



Source: Targovax

Mesothelioma: Patient survival update by end-2020

On 22 June 2020, Targovax reported additional data from its Phase I/II study in unresectable mesothelioma (follow-up to the first data published in January 2020). There were no new safety issues and the efficacy signals seen in the first set of results were confirmed. Importantly, the immune and gene sequencing data provided strong support for ONCOS-102's ability to activate the immune system and remodel the tumour microenvironment. Detailed analysis is presented in our last report. Median OS data are still not mature and a **patient survival update is expected before the end of 2020**.

Targovax reiterated its plans to explore ONCOS-102 in triple combination with a CPI and standard chemotherapy in first line. These plans are still at a preliminary stage, but there is potential for the study to become a registrational programme due to a high unmet need in mesothelioma. One significant positive step towards the triple combination trial was the announcement that Merck & Co will supply Keytruda (pembrolizumab, anti-PD-1). Because of high costs, combinations with CPIs can rapidly inflate the cost of clinical trials, 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 their 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 fully enrolled and the readout from it 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 presented preclinical in vitro and in vivo data at the American Association for Cancer Research Virtual Annual Meeting in June 2020 from its studies with the ONCOS-210 and 212 viruses demonstrating anti-cancer properties and that the double transgenes act synergistically. We expect more data in the near future, including more details about positioning in the clinic and which indications will be prioritised. In addition, the new collaboration with Leidos, as described above, could potentially lead to a new generation ONCOS virus.

Financials and valuation

Targovax's Q220 operating expenses were NOK30.0m, which were significantly lower than NOK44.6m in Q219 following the cost-reduction programme (R&D spend down to NOK14.1m from NOK22.0m; payroll down to NOK11.0m from NOK17.5m). We had already cut our spending forecasts to an operating loss of NOK134.5m and NOK136.6m in 2020 and 2021 respectively and now further fine-tune by lowering operating loss to NOK124.5m and NOK126.3m in 2020 and 2021 respectively.

Targovax had cash and cash equivalents of NOK101m at the end of Q220, which secures funding into 2021 according to our model. The funding gap in 2021 (NOK81m) is covered in our model by increasing long-term debt (as per our principles; Exhibit 4).

Our valuation is unchanged at NOK1.65bn or NOK21.6/share, as lower cash position offset rolling the model forward. We continue to exclude other long-term debt of €7m in Finnish government grants from our valuation, as repayment is only required if the products are sold or launched.

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	3,003.9	39.4	15%	764.4	10.0
ONCOS-102 – mesothelioma	2026	424	2,377.9	31.2	25%	781.7	10.3
Net cash, last reported			101.5	1.3	100%	101.5	1.3
Valuation			**5,483.3**	**72.0**		**1,647.6**	**21.6**

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

Exhibit 4: 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)	(124,508)	(126,250)
Operating Profit (before amort. and except.)	(146,100)	(150,273)	(124,508)	(126,250)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(146,100)	(150,273)	(124,508)	(126,250)
Net Interest	(1,249)	2,423	0	0
Profit Before Tax (norm)	(147,349)	(147,850)	(124,508)	(126,250)
Profit Before Tax (reported)	(147,349)	(147,850)	(124,508)	(126,250)
Tax	334	321	0	0
Profit After Tax (norm)	(147,015)	(147,529)	(124,508)	(126,250)
Profit After Tax (reported)	(147,015)	(147,529)	(124,508)	(126,250)
Average Number of Shares Outstanding (m)	52.6	60.8	69.6	75.9
EPS - normalised (NOK)	(2.79)	(2.43)	(1.79)	(1.66)
EPS - normalised fully diluted (NOK)	(2.79)	(2.43)	(1.79)	(1.66)
EPS - reported (NOK)	(2.79)	(2.43)	(1.79)	(1.66)
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	52,014	16,429
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	151,189	70,429	36,585	1,000
Other	15,320	15,429	15,429	15,429
Current Liabilities	(59,377)	(50,690)	(39,756)	(43,469)
Creditors	(50,250)	(53,931)	(42,997)	(46,710)
Short term borrowings	(9,127)	0	0	0
Long Term Liabilities	(103,565)	(109,263)	(109,263)	(190,569)
Long term borrowings	(43,933)	(50,441)	(50,441)	(131,747)
Other long term liabilities	(59,632)	(58,822)	(58,822)	(58,822)
Net Assets	374,696	296,955	274,045	153,441
CASH FLOW				
Operating Cash Flow	(112,816)	(140,094)	(129,796)	(116,891)
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)	(33,844)	(116,891)
Opening net debt/(cash)	(212,767)	(98,129)	(19,988)	13,856
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(98,129)	(19,988)	13,856	130,747

Source: Targovax accounts, Edison Investment Research

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