EDISON

Ultimovacs

Initiation of coverage

Cancer vaccine with virtually universal potential

Pharma & biotech

Ultimovacs is a biotechnology company focused on developing a next generation cancer vaccine with virtually universal potential. Lead asset, UV1, activates the immune system to recognise cancer cells that express human telomerase reverse transcriptase (hTERT, or telomerase), which is present in over 85% of all cancer types. For this reason, UV1 has broad potential in a variety of cancers and in combination with other treatments. Ultimovacs' R&D strategy is to combine UV1 with checkpoint inhibitors (CPIs) due to an expected treatment synergy. The broad R&D programme includes four Phase II trials in different solid tumours, which will enrol more than 500 patients in total. Readouts are expected over 2022/2023, all within cash reach. Our Ultimovacs valuation is NOK3.18bn or NOK99.4 per share.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/19	0.0	(61.2)	(2.67)	0.0	N/A	N/A
12/20	0.0	(120.6)	(3.98)	0.0	N/A	N/A
12/21e	0.0	(152.5)	(4.77)	0.0	N/A	N/A
12/22e	0.0	(159.0)	(4.97)	0.0	N/A	N/A

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

Phase II with data from 500+ patients

Two Phase II trials in first-line metastatic melanoma (INITIUM, n=154) and second-line mesothelioma (NIPU, n=118) have been enrolling patients since June 2020. Another two further Phase II trials were announced recently and are about to start recruiting patients. The Durvalumab Olaparib Vaccine (DOVACC) trial (n=184) will evaluate UV1 in second-line maintenance treatment of ovarian cancer and the FOCUS trial (n=75) in first-line head and neck cancer. The trials will enrol more than 500 patients, which will provide a significant amount of data, and will be invaluable in partnering discussions.

Eventful 2022/2023; large pharma already on board

The readouts are expected in 2022 and 2023 from all trials and all are within cash reach, which investors will find reassuring. Ultimovacs is sponsoring its flagship INITIUM trial, while the other three are led by investigators that are reputable European oncology organisations. Most of the expensive combination immunoncology drugs are either supplied by large pharma companies or are a standard of care. Existing drug-supply agreements with Bristol Myers Squibb and AstraZeneca mean there are at least two large pharma companies watching the trials closely.

Valuation: NOK3.18bn or NOK99.4 per share

We value Ultimovacs at NOK3.18bn or NOK99.4 per share (rNPV analysis using a 12.5% discount rate, net cash of NOK441m at end-2020). Our model includes UV1 in all four indications being evaluated in the Phase II trials, with a probability of reaching the market of 20%. We use a bottom-up approach to calculate the market sizes and industry average data for the basis of our other assumptions (Exhibits 6 and 7). We assume a full out-licensing deal for UV1 with the partner taking over the Phase III development and commercialisation.

17 March 2021

Price	**NOK67**
Market cap	**NOK2,144m**
Net cash, at end-2020	NOK441m
Shares in issue	32.0m
Free float	90%
Code	ULTI
Primary exchange	Oslo Stock Exchange
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(10.9)	(9.5)	92.0
Rel (local)	(16.0)	(19.4)	24.0
52-week high/low	NOK88	NOK41	

Business description

Ultimovacs is a biotechnology company developing novel immunotherapies against cancer. The lead product candidate, UV1, is a peptide-based vaccine against the universal cancer antigen telomerase (hTERT). Around 85% of all cancer types express high levels of hTERT. Therefore, UV1 has a broad potential in a variety of different settings and combinations with other cancer treatments.

Next events

First patient in the DOVACC trial	Q221
First patient in the FOCUS trial	Q221
Q1221 report	11 May 2021
AGM	15 April 2021
Interim safety and efficacy data from the US Ph I trial in melanoma	Q421

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Edison profile page

Ultimovacs is a research client of Edison Investment Research Limited

Ultimovacs summary

Ultimovacs is a biotechnology company developing novel immunotherapies against cancer. The origins of its proprietary technology stem from research conducted at the Oslo University Hospital by professor of immunology Gustav Gaudernack, who joined Ultimovacs as CSO after it was established in 2011. Ultimovacs is located at the Oslo Cancer Cluster Innovation Park in Oslo, Norway. Ultimovacs has a Swedish subsidiary, Ultimovacs AB, in Uppsala, Sweden, which it acquired in 2018 from Immuneed to access TET platform technology. In 2019 Ultimovacs was listed on the Oslo Stock Exchange.

UV1: hTERT cancer vaccine with universal potential

The lead product is UV1, a peptide-based therapeutic cancer vaccine that activates the immune system to recognise hTERT. Chromosomes are capped with sections of so-called telomeres, which gradually shorten after each normal cell division cycle, causing a finite replicative capacity. Malignant cells develop the ability to maintain telomeres through the expression of hTERT, which enables them to replicate infinitely. So, hTERT is a self-antigen that is known to be overexpressed in over 85% of cancer types. In these malignancies, cell reproduction relies exclusively on hTERT maintaining the length of telomers. For this reason, UV1 has a broad potential in a variety of cancers, in different stages and in combination with other treatments. The vaccine is easy to use, requires no sophisticated hospital infrastructure and will be manufactured as an off-the-shelf product with a long shelf life.

UV1 has an interesting history of discovery. UV1 epitopes were selected based on insights from large clinical trials that investigated another, unrelated, telomerase vaccine. The patients who lived longest in those trials had specific T-cells against three epitopes, none of which were included in the original vaccine. So, UV1 was constructed using real-world evidence.

Phase I programme complete; long-term follow-ups

Three Phase I/IIa trials with UV1 have been completed at Oslo University Hospital. In total, 52 patients with metastatic prostate cancer, metastatic non-small cell lung cancer (NSCLC) or metastatic malignant melanoma received the vaccine. UV1 was immunogenic, with c 80% of the patients developing T helper (Th) cells recognising one or more of the three peptides in the vaccine. The safety profile was good. Initial efficacy data from long-term follow-ups have also been reported (vs historical survival rates). Latest updates include five-year follow-up results. A fourth Phase I study is ongoing in the United States.

Phase II programme ongoing

Ultimovacs' R&D strategy is to combine UV1 with CPIs due to an expected synergy. Treatment with CPIs relies on spontaneous antitumour immune responses for the therapy to be effective. Vaccination with UV1 is expected to augment the antitumour immune response against tumour-related antigens, which could improve the effectiveness of CPIs. The current R&D pipeline (Exhibit 1) includes four Phase II trials:

- The **INITIUM trial** (n=154) with UV1 plus ipilimumab and nivolumab in first-line metastatic melanoma. As of the Q420 results presentation in February 2020, 24 patients have been enrolled. The trial is fully sponsored by the company and results are **expected in H222**.
- The **NIPU trial** (n=118) with the same combination as above in second-line mesothelioma. As of the Q420 results presentation in February 2020, 18 patients have been enrolled. The trial is

led by Oslo University Hospital network with the combination drugs supplied by Bristol Myers Squibb. Results are **expected in H222**.

- The **DOVACC trial** (n=184) with UV1 plus durvalumab and olaparib in second-line maintenance in ovarian cancer. The trial is led by the Nordic Society of Gynaecological Oncology (NGSO) supported by the European Network of Gynaecological Oncological Trial Groups (ENGOT) with drugs supplied by AstraZeneca. Results are **expected in 2023**.
- The **FOCUS trial** (n=75) with UV1 plus standard-of-care pembrolizumab in first-line head and neck cancer. The trial is led by University of Medicine Halle, part of Martin Luther University. Results are **expected in 2023**.

These trials will enrol a total of more than 500 patients. In our view, this amount of proof-of-concept data will be more than enough to inform the late-stage R&D strategy, but also will be invaluable in partnering discussions. The INITIUM and NIPU trials are already up and running, while the DOVACC and FOCUS trials should start recruiting patients in H121. Proof-of-concept trials carry significant R&D risk (historical pass-through success probabilities are 33–54%). But the pipeline is diversified across indications and different combinations and the result readouts are within cash reach, which the investors will find reassuring. However, we expect there to be some read-across effect, ie in the case of positive data from one trial, confidence in good outcomes from the other trials will increase and vice versa.

Ultimovacs is sponsoring its flagship INITIUM trial (UV1 plus ipilimumab and nivolumab in melanoma), whereas the other three are led by investigators that are top European oncology organisations. Ultimovacs' out-of-pocket costs to support these investigator-led trials vary, but the company noted that costs per patient are still lower compared to a fully sponsored trial. Most of the expensive combination immunoncology drugs are either supplied by large pharma companies or standard of care. Although technically the data will be owned by the investigators, Ultimovacs has been closely involved in clinical trial design, with the idea that it will be able to carry on late-stage development if the data are supportive. In our view, the ability to forge relationships with different stakeholders has allowed such an expansion of the pipeline and will ensure eventful years in 2022 and 2023.

TET platform: First-in-class cancer vaccine solution

Ultimovacs' second product in preclinical development is a first-in-class cancer vaccine solution using the proprietary Tetanus-Epitope Targeting (TET) platform technology. The TET technology represents new mechanism of action, where the vaccine immunisation builds on the patient's existing antibodies from the common tetanus vaccination in childhood. This is a highly differentiated and novel approach that allows incorporation of adjuvant and vaccine into one molecule. Ultimovacs acquired this technology from Immuneed in July 2018. The related assets are structured as the wholly owned subsidiary Ultimovacs AB based in Uppsala, Sweden.

The first-in-human, dose-escalation Phase I TENDU study in prostate cancer has started and recruited the first patient on 18 February 2020. Patients will receive the vaccine prior to standard-of-care treatment with radiation and antihormone therapy and will then be followed for six months after the last dose of the vaccine to assess immunological responses. Patient enrolment is expected to be completed in H122. Preliminary safety results are expected by the end of this year.

Exhibit 1: R&D pipeline

	Indication	Clinical trial information	Preclinical	Phase I	Phase II	Phase III	Partner/Collaboration
UV1	Prostate cancer	Conducted at OUS, 22 patients. Completed in 2015		✓			Oslo University Hospital
	Non-small cell lung cancer (NSCLC)	Conducted at OUS, 18 patients. Completed in 2016		✓			Oslo University Hospital
	Metastatic malignant melanoma	Conducted at OUS, 12 patients. UV1 in combination with Ipilimumab. Completed in 2016		✓			Oslo University Hospital
	Metastatic malignant melanoma	First line phase I trial with combination UV1/pembrolizumab). 30 patients, enrolment completed in Aug-20		○			
	Metastatic malignant melanoma	**INITIUM:** Phase II proof of concept trial (first line metastatic malignant melanoma with triple combination ipilimumab/nivolumab/UV1) 154 patients			○		
	Mesothelioma	**NIPU:** Phase II proof of concept trial (second line mesothelioma with triple combination ipilimumab/nivolumab/UV1) 118 patients			○		Bristol Myers Squibb and Oslo University Hospital (OUS)
	Ovarian cancer	**DOVACC**: Phase II proof of concept trial (randomized, second line maintenance in ovarian cancer with combination durvalumab/Olaparib/UV1) 184 patients			○		AstraZeneca and NSGO/ENGOT
	Head and Neck cancer	**FOCUS:** Phase II proof of concept trial (first line head and neck cancer with combination pembrolizumab/UV1) 75 patients			○		University Medicine Halle (Saale) / Martin-Luther-University
TET	Prostate cancer	**TENDU:** phase I study to assess the safety of the TET platform		○			
	Various	First-in-class cancer vaccine solutions based on the TET-platform technology	○				

Source: Ultimovacs. Note: NSGO/ENGOT – the Nordic Society of Gynaecological Oncology and the European Network of Gynaecological Oncological Trial Groups.

hTERT vaccines and how UV1 is different

Cancer immunotherapy and rationale for cancer vaccines

During a malignant process, as cancer cells die the composite proteins/antigens are taken up by a patient's own antigen-presenting cells, such as dendritic cells or macrophages, and presented to T-cells. This can lead to the activation and production of populations of T-cells capable of recognising and attacking cancerous cells that display the antigens. However, this process is not perfect, which is why not every malignant process is stopped. Once a tumour develops, it often also has multiple ways to suppress an immune response and enable the tumour to evade immune cells. The goal of cancer immunotherapies is to expose the tumour microenvironment (TME) as foreign to the patient's immune system, so the tumour is recognised, immunologically attacked and turned from 'cold' to 'hot'.

CPIs were the first successful approved cancer immunotherapies that changed treatment paradigms in many solid cancers. Although very effective in certain subsets, many patients do not respond to this treatment, as CPIs rely on existing cancer-specific T-cells. In cases where the T-cells are not primed, the consensus in the immunoncology community is that there is a need to find ways to increase the supply of such primed, cancer-specific T-cells. One approved and successful approach is CAR T-cells, where the T-cells are taken from the patient via apheresis, genetically modified to recognise the cancer, then administered back to the patient. Although very effective in certain leukaemias, this process is complicated, long and costly.

The search for effective immunotherapies led to the exploration of different approaches, one of which is cancer vaccines. Various options explored so far include peptide-based, oncolytic viruses and allogeneic or autologous dendritic cell vaccines, but Dendreon's Provenge (dendritic cell vaccine, approved in 2010) and Amgen's Imlygic (oncolytic virus, approved in 2015) are the only approved cancer vaccines. The relative lack of more successful examples, however, could be explained by the variability in vaccine design, antigen selection and understanding of the inhibitory barriers presenting by immunosuppressive TMEs. In addition, more and more preclinical studies

support the idea that the backbone strategy in immunoncology should be combination treatments exploiting different steps in the immunity cycle (Schlom and Gulley, 2018).

Peptide-based cancer vaccines, such as UV1, work by presenting antigenic material expressed by the cancer and aim to strengthen the ability of the immune system to recognise and eliminate the malignant cells. Because peptide vaccines act as immune primers, it is rational to combine them with therapies that act late in the cancer immunity cycle, such as CPIs. Various peptide vaccines have also been shown to be well tolerated in early trials. This characteristic will be crucial in combining them with CPIs with known side effects that have presented hurdles to developing double or triple CPI combinations.

Cancer antigens can be divided into two broad categories. Tumour-specific antigens (TSAs) are only found in cancer cells, not healthy cells. Tumour-associated antigens (TAAs) are peptides from normal proteins, which are overexpressed when cancer develops. So, peptide vaccines that are developed using TSAs are patient specific, which means this type of therapy is highly personalised and involves very complicated logistics. Because of this complexity, few attempts have been made to progress them into the clinic. Peptide vaccines that use TAAs can be used in all patients who have cancers with known overexpressed TAAs. These types of vaccines have the advantages of being convenient, off-the-shelf, manufacturing costs are low, and logistics and administration (subcutaneous) are straightforward.

hTERT: A hallmark of cancer

Telomeres provide cells with a mechanism that prevents the abnormal proliferative capacity that can lead to the development of cancer. During normal cell division, chromosomes are capped with sections of so-called telomeres that are not fully replicated and gradually shorten after each cycle, causing a finite replicative capacity. TERT is one of two major components of the enzyme telomerase, which maintains telomere length in the dividing cells. One of the hallmarks of cancer is the ability to maintain telomeres in this process through the overexpression of hTERT, which enables cancer cells to replicate infinitely.

hTERT is expressed in up to 85% of all cancers (haematopoietic and solid) while being absent in most normal tissue and has been an attractive prospect for cancer immunotherapies with scope to treat a broad range of cancers. hTERT is immunogenic and considered a universal TAA and has been focus of several vaccines that have reached clinical development across various solid tumours (Exhibit 2).

Exhibit 2: Clinical hTERT peptide-based vaccines

Product	Company/sponsor	Indication(s)/ trial phase	Notes
UV1	Ultimovacs	Completed trials Prostate cancer (Phase I/IIa); Melanoma (Phase I/IIa); NSCLC (Phase I/IIa); Ongoing trials (all in combination with various CPIs) Melanoma (Phase I, Phase II), Mesothelioma (Phase II), Ovarian cancer (Phase II), Head and neck cancer (Phase II)	Peptide-based vaccine (hTERT691-705, hTERT660-689 and hTERT652-665), MHC class I/II (unrestricted)
GV1001 (RIAVAX)	KAEL-GemVax	Pancreatic cancer (Phase III, TeloVac) HCC (Phase II) Other solid tumours (Phase I/II)	Peptide-based vaccine (hTERT611-626), MHC class II (restricted)
Gx-301	Mediolanum	Prostate/Renal (Phase I/II)	Peptide-based vaccine (hTERT540-548, hTERT611-626 , hTERT672-686 & hTERT766-780), MHC class I/II (unrestricted)
Vx-001	Vaxon Biotech	NSCLC (Phase II) Other solid tumours (Phase I/II)	Peptide-based vaccine (hTERT572-580 & R572Y hTERT572-580), MHC class I (restricted)

Source: Edison Investment Research, adapted from Mizukoshi et al 2019. Note: HCC, hepatocellular carcinoma; MHC, major histocompatibility complex.

GV1001 is a peptide-based hTERT vaccine being developed by KAEL-GemVax and has been the most extensively investigated vaccine of this type. Collectively, trial data suggest hTERT vaccines

are capable of inducing a T-cell response in patients, but broadly speaking, when used in mono therapy, this has been insufficient to effectively control cancer progression. Importantly, data so far highlight the minimal risk of adverse events with the strategy, potentially lending hTERT vaccines to combination regimens with other cancer immunotherapies, such as CPIs, where historically the potential for additive efficacy has had to be carefully balanced with additive toxicity.

We highlight data from the Phase III TeloVac trial, which investigated GV1001 with concurrent chemotherapy (gemcitabine plus capecitabine) as a first-line intervention for pancreatic cancer patients. Despite eliciting immune responses, the concurrent combination showed no improvement overall survival or progression-free survival/time to progression. Investigators speculated that for a cancer vaccine to be effective, sufficient time is required for an immune response to develop and the early metastasising and rapidly progressive nature of pancreatic cancer might partly explain the absence of efficacy for GV1001 in the TeloVac trial.

Finding the right epitopes is key: Learning from GV1001

Given hTERT is an intracellular protein and is not expressed on the surface of cells, it can only be recognised by T-cells through shorter peptide sequences (epitopes), which are antigenic determinant sections of antigens. These are processed inside cells and presented as part of the major histocompatibility complex (MHC), also called human leukocyte antigen (HLA). MHC class I molecules are recognised by CD8+ cytotoxic T lymphocytes (CTLs) expressing a complementary T-cell receptor and MHC class II molecules are recognised by CD4+ 'helper' T-cells. Cancer cells can present hTERT peptides recognised by either MHC I or II and peptide-based vaccines developed to date have been designed for both epitope classes.

Although inducing an MHC class I response and activation of CD8+ CTLs through immunisation is considered the major mechanism for inducing an antitumor immune response, insufficient CD4+ T activation can lead to dampening of this. Hence, induction of an MHC class II immune response and CD4+ T activation can enhance the ability for CD8+ CTLs to attack tumours, but also promote immunological memory that translates to long-term cancer immunity.

So far, many peptide cancer vaccines have been aimed at activating CD8+ T-cells via MHC I. Given the lack of encouraging clinical data with this approach, as described above, CD4+ T-cell influence in anticancer immune response is receiving renewed interest in the scientific community. UV1 contains three long peptides, so it induces hTERT specific CD4+ T-cells (via MHC II) producing cytokines associated with T helper cell type 1 (Th1) immune responses, which triggers a strong anti-tumour immune response and expansion of secondary effector cells, including induction of CD8+ anti-tumour T-cell response.

Findings from a long-term follow-up of a Phase I/II trial of GV1001 in NSCLC patients guided the design and composition of UV1, which can be considered a second-generation hTERT vaccine that is distinct and unrelated to GV1001. Blood samples from these long-term survivors in the trial showed expression not only of GV1001-specific T-cells, but also T-cells primed to distinctly different hTERT-derived peptides, which were not part of the GV1001 vaccine. Crucially, the patients, who had these T-cells primed for non-GV1001 hTERT-derived peptides also demonstrated improved survival. The patients, who did not have these T-cells, did not show the clinical benefit from the vaccination, although they did demonstrate T-cell response against GV1001 peptide. UV1 consists of these peptides (hTERT691-705, hTERT660-689 and hTERT652-665). Ultimovacs' hypothesis is that because T-cell responses against these peptides were only observed in patients with a favourable clinical course, it indicates these specific peptides could be responsible for the tumour eradication in patients.

The three long peptides that UV1 consists of have been shown to contain multiple T-cell epitopes that can fit with the HLA type of the vaccinated patient. Data from numerous patients' samples indicated there is no HLA bias and immune responses against the vaccine peptides occur across

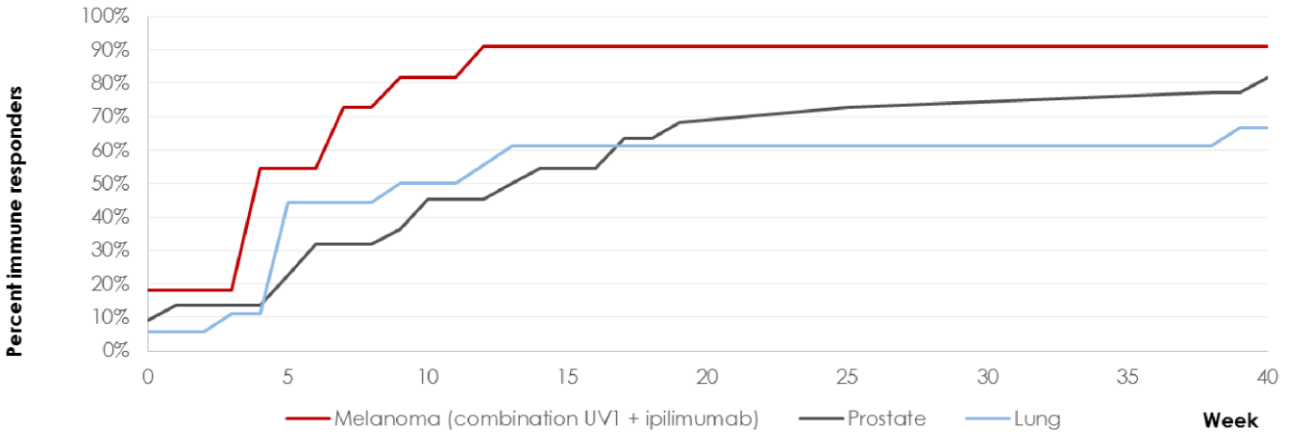
multiple HLA allele types (the peptides are promiscuous with respect to HLA). Therefore, the UV1 vaccine peptides ensure broad population coverage, circumventing the need for HLA screening.

Phase I/IIa data include five-year follow-ups

Ultimovacs has completed fairly extensive Phase I development of UV1. Three Phase I single-arm trials with 52 patients in total were conducted at Oslo University Hospital between 2013 and 2015. **Primary objectives** in these trials were to assess the safety/tolerability of UV1 and immunological response to the vaccine. A **secondary objective** of the studies was to select the dose of UV1 for further clinical development. In the prostate cancer and NSCLC studies, three different dose levels of UV1 were used (100, 300 and 700µg). In the malignant melanoma study, 300µg UV1 was given in combination with ipilimumab. UV1 was administered intradermally with GM-CSF (75µg) as an adjuvant. After the treatment phase the results showed that:

- UV1 was generally well tolerated and there were no dose-limiting toxicities.
- Five patients (10%) experienced allergic reactions that were considered serious. These events occurred after repeated dosing of UV1 and adjuvant GM-CSF (minimum nine doses). Three reactions were in the highest UV1 dose (700µg) group and two in the 300µg group, but allergic reactions are also a known potential side effect of the adjuvant GM-CSF. The reactions occurred immediately after the injections, so patients received care and there were no lasting effects.
- Across all three studies, UV1-induced immune response (hTERT specific T-cells) was observed in 78% of patients. Specifically, 91% in the melanoma trial; 82% in prostate cancer trial; and 67% in NSCLC trial (Exhibit 3).

Exhibit 3: Responders to UV1 vaccination in Phase I/IIa trial (Th cell response)



Source: Ultimovacs. Note: Some patients had immune response already at baseline.

Of note is that the largest percentage of patients (91%) showing immune response was in the melanoma trial (this group also had highest percentage of patients with immune response at baseline). In addition, the responses appeared earlier, required fewer vaccinations and were stronger and more long lasting compared to vaccination with UV1 alone. This is in line with the scientific rationale behind the UV1 plus CPI combination, where UV1 acts as an immune primer and ipilimumab blocks CTLA-4 checkpoints and induces an expansion of UV1-specific T-cells. The 300µg dose of UV1 was selected for the Phase II trials.

Five-year follow-up results

Ultimovacs has also evaluated overall response rates (ORR) and kept following up the patients for overall survival (OS) and median progression-free survival (mPFS). The follow-up phase is ongoing, but available five-year data are summarised in Exhibit 4.

- **Melanoma trial** (last update in December 2020). This was the only study of the three completed where UV1 was given in combination with a CPI. In total 12 patients received 300µg of UV1 plus ipilimumab (for eight out of these 12 patients this was the first-line treatment). Five years after the end of treatment, the results showed that ORR was 44% (four out of nine evaluable patients): one complete response (CR) and three partial responses (PRs); mPFS was 6.7 months; and overall survival (OS) was 50%, while median OS has not been reached yet. The survival results compare favourably to historical ipilimumab monotherapy study results (KEYNOTE-006, Robert et al, 2019), which showed OS at year five around 20%. When this study was initiated, ipilimumab monotherapy was the standard of care. In the ongoing Phase II INITIUM, UV1 is combined with ipilimumab plus nivolumab, which has become the standard of care in the first-line treatment of advanced metastatic melanoma.
- **NSCLC trial** (last update in October 2020). In total 18 patients with late-stage NSCLC, who received at least two prior treatments and showed no progression at the time of the inclusion in this trial, were assigned to three different UV1 dose levels (six patients each). This trial evaluated UV1 as a maintenance monotherapy. After five years of follow-ups, the results showed that mPFS was 10.7 months; OS at five years was 33% (6/18), while median OS was 28.2 months. When the study started, CPIs were not available for patients in this setting. Five-year survival prognosis for patients receiving second-line chemotherapy was less than 5% (IFCT-1103 ULTIMATE study, Cortot et al, 2020). None of the long-term surviving patients have received checkpoint therapy after vaccination.
- **Prostate cancer trial**. In total, 22 patients with metastatic prostate cancer receiving androgen-blockade treatment have been enrolled and assigned to the same three dose levels as in NSCLC cancer. mOS almost 62 months, which also compared well with historical data (36–42 months, LATITUDE trial, Fizazi et al, 2019).

Exhibit 4: Completed clinical trials with UV1

	Ultimovacs trials			Historical comparisons		
	OS*	Median OS	Median PFS	OS	Median OS	Median PFS
Prostate (n=22)	50%	61.8	NA**	NA	36-42	NA
NSCLC (n=18)	33%	28.2	10.7	<5%	c 12	3-4
Melanoma (n=12)	50%	Will be >54 months	6.7	c 20%	c 16	3.5-4

Source: Ultimovacs. Note: OS, overall survival; mPFS, median progression free survival. * Some patients have received other treatments after trial ended and the cancer progressed, which could have affected the OS, therefore comparison versus historic data is only indicative. **PFS was not possible to measure in in the prostate cancer trial; patients are followed using PSA levels. References to historical comparisons: Prostate: Fizazi K et al. Lancet Oncol. 2019; 20: 686-700; NSCLC: Cortot AB et al. Eur J Cancer. 2020; 131: 27-36; malignant melanoma: Robert C et al. Lancet Oncol. 2019; 20: 1239-1251.

Phase I/II melanoma study with UV1 plus CPI ongoing in the US

Ultimovacs used the accumulated preclinical and clinical Phase I/IIa data package and applied for an IND with the FDA, which was approved in July 2017. In July 2018, the company initiated a second Phase I/II melanoma study in a front-line setting with UV1 in combination with an anti-PD-1 checkpoint inhibitor pembrolizumab, this time in the United States.

From a regulatory perspective, it is a good R&D strategy to start including US centres as early as possible in the development process. However, this study will also gather more data than the Phase I trial conducted in Norway. The combination CPI is different, but there are two arms with patients receiving two different doses of the adjuvant GM-CSF: the standard dose of 75µg (10-patient arm) and half of that 37.5µg (20-patient arm). Different GM-CSF doses will provide more insight on how the adjuvant influences the frequency of allergic reactions.

The first interim results were released in September 2020, which was a one-year follow-up after the treatment. The OS rate was 85%. For comparison, the one-year OS in the Norwegian melanoma study was 75%. So, these early interim results from the US study also indicate that a lower dose of the adjuvant did not decrease efficacy so far (caveat is that this trial includes a different CPI). Next follow-up will be reported in Q421.

Ongoing Phase II stage trials; data from 500+ patients over 2022/23

The Phase II INITIUM trial

The INITIUM trial fully sponsored by Ultimovacs is enrolling patients with metastatic malignant melanoma (n=154, two arms with 77 patients in each). The trial is randomised, where 77 patients are receiving first-line treatment with nivolumab (anti-PD-1) and ipilimumab (anti-CTLA-4), while the other 77 patients are receiving the combination of nivolumab, ipilimumab and UV1. Patients in the active arm will receive eight UV1 vaccinations over four cycles of nivolumab and ipilimumab. In the control arm, the patients will receive the four cycles of nivolumab and ipilimumab. Subsequently, all patients in both arms will proceed to maintenance therapy (nivolumab every four weeks). The recruitment centres are based in Europe and the United States. The first patient received the treatment in June 2020 and, according to the latest update during the Q420 results presentation, 24 patients have been recruited so far. The readout of the primary endpoint PFS is expected in H222.

Melanoma

Melanoma is a cancer of melanocytes, pigment-producing cells in the bottom layer of the skin. If diagnosed early, surgery is the treatment of choice. A subsequent adjuvant therapy is administered if stage III melanoma is diagnosed, meaning the cancer has started spreading to local or regional lymph nodes.

For a long time, melanoma was characterised by two extremes: completely curable disease if diagnosed early, or virtually incurable as soon as spreading starts. The advent of CPIs revolutionised the treatment of the advanced melanoma. Ipilimumab (Yervoy, anti-CTLA-4, Bristol-Myers Squibb) was the first to receive the FDA's approval, in March 2011. Since then, nivolumab (Opdivo, anti-PD-1, Bristol-Myers Squibb) and pembrolizumab (Keytruda, anti-PD-1, Merck & Co) have also been approved. CPIs quickly gained popularity and comprise the bulk of the market share.

Novel targeted therapies have also been developed and approved over the past several years. The choice of therapy depends on whether the tumour contains a driver BRAF mutation (although some CPIs are approved in BRAF-mutated melanoma as well). Around 40–50% of all metastatic melanomas have the driver BRAF mutation, in which case BRAF inhibitors are used in combination with MEK inhibitors to decrease MAPK-driven acquired resistance (dabrafenib/trametinib or vemurafenib/cobimetinib). In patients with no BRAF mutation, the guidelines from the National Comprehensive Cancer Network recommend combination therapy, with nivolumab plus ipilimumab as the first choice or single-agent immunotherapy with pembrolizumab or nivolumab.

Before CPIs were introduced, patients with metastatic melanoma had a median survival of six to nine months with five-year overall survival of <10%. The CPIs significantly improved the outcomes. For example, the first-line combined treatment with nivolumab and ipilimumab improved five-year overall survival to 52% versus 44% in nivolumab versus 26% in ipilimumab (from follow-up of CheckMate 067 study patients). Median overall survival was more than 60 months (median not reached) in the nivolumab plus ipilimumab group, 37 months in the nivolumab group, and 20

months in the ipilimumab group. So, although the survival rate improved significantly, even with new treatments, it remains one of the most aggressively spreading cancers.

According to the National Cancer Institute, c 100k new melanoma cases were estimated to be diagnosed and around 6,850 people were estimated to have died of melanoma in 2020 in the United States alone. In the top 15 European countries, which we include in our model, c 116k new cases are estimated to have been diagnosed in 2020 (GLOBOCAN). Around 83% of patients present with localised disease, which means around 17% of new cases involve melanoma that has started spreading. Around half of all metastatic melanomas will have the driver BRAF mutation. Ultimovacs is positioning its UV1 as part of first-line combination treatment with CPIs. We therefore calculate the addressable patient population in the United States and key 15 European countries (top five, Ireland, Benelux, Scandinavia, Austria and Switzerland) is more than 18,000 patients.

The Phase II NIPU trial

The randomised NIPU trial is enrolling patients with malignant mesothelioma (n=118, two arms with 59 patients in each), who receive the same combination treatment as in the INITIUM trial (UV1 plus ipilimumab plus nivolumab), but as second-line treatment. The objective of the study is to achieve a meaningful PFS after the progression on first-line standard platinum doublet chemotherapy. Patients must be CPI naive. The first patient was enrolled in June 2020 and, in total, 18 patients have been recruited so far, as per the Q420 results announcement. Oslo University Hospital is the sponsor of the NIPU study, while Bristol-Myers Squibb is supplying the drugs. The readout of the primary endpoint, PFS, is expected in H222.

Mesothelioma

Mesothelioma is a rare cancer of the mesothelium, a sheet that covers most internal organs. Most often the location of mesothelioma is pleural mesothelium, a double layer that covers the lungs and the inside of the pleural cavity, forming a pleural space. Breathing difficulty and pain are the hallmark symptoms of mesothelioma, with death occurring due to infection or respiratory failure.

It is a rare cancer with c 3,400 cases estimated to have been diagnosed in the US and c 12,600 cases (GLOBOCAN) in the key European countries (as per our definition above and in Exhibit 7) in 2020. Incidence of mesothelioma ranges from about seven to 40 per 1,000,000 in industrialised Western countries, depending on the amount of asbestos exposure in the past, which is major risk factor. Therefore, the focus in managing mesothelioma is on prevention measures. Surgery, radiation therapy and chemotherapy with cisplatin and pemetrexed are still the mainstay treatment options. Mesothelioma is one of the deadliest cancers, with a five-year survival rate of around 10%.

Classical chemotherapy drugs were only available options for decades. The major recent development, however, was the FDA's approval of nivolumab in combination with ipilimumab in October 2020 for first-line treatment of unresectable metastatic mesothelioma. Approval was based on the Phase III CheckMate-743 clinical trial, in which the combination of nivolumab and ipilimumab had an OS benefit compared to platinum-based standard of care chemotherapy. Patients who received nivolumab plus ipilimumab survived a median of 18.1 months, while patients who underwent chemotherapy survived a median of 14.1 months. The successful approval despite the modest four-month benefit exemplifies the unmet need in this indication. Other CPIs are also in Phase III trials.

Ultimovacs' NIPU study is evaluating the same CPI combination with UV1, but in a second-line setting and the patients must be CPI naive. Because the FDA approved this combination as first-line therapy recently, we believe it will take some time for it to become standard of care (modest clinical benefit vs high price may be also challenged by payors in some cases). So, Ultimovacs will be able to access patients who underwent platinum-based chemotherapy to fully enrol the NIPU trial. Furthermore, because it is evaluating the same CPI combination, the accumulated data, if

positive, will help to inform how to position UV1 for front-line treatment in later trials. Since virtually all patients progress after the first-line treatment, many will choose to undergo a second-line treatment, so in our model we assume around 80% will receive a second-line treatment. We therefore calculate the addressable patient population in the United States and key 15 European countries is around 12,800 patients.

The Phase II DOVACC study

The DOVACC study, announced on 11 January 2021, is the latest addition to Ultimovacs' R&D pipeline. In total, 184 patients with BRCA-negative, relapsed, high grade ovarian cancer are expected to be enrolled in three arms (active – UV1 plus olaparib plus durvalumab; control I – olaparib plus durvalumab; control II – olaparib). UV1 will be administered in combination with olaparib (PARP inhibitor) and durvalumab (anti-PD-L1). The patients will have relapsed after the first-line of platinum-based treatment, received second-line platinum-based chemotherapy and, after partial or complete response, will receive the experimental maintenance treatment (so second maintenance setting). The goal of the trial is to evaluate PFS benefit in the active arm, with the triple combination versus the olaparib monotherapy. The reason behind the third arm (olaparib plus durvalumab) is to clearly establish each of the three combination drugs' contribution to efficacy. This trial is run by the NSGO Clinical Trial Unit in collaboration with the ENGOT (an umbrella organisation for groups such as NSGO) and AstraZeneca, which is supplying the combination drugs. The first patient should be enrolled in H121. Primary endpoint (PFS in the active arm versus olaparib monotherapy) readout is expected in 2023.

Ovarian cancer

The American Cancer Society estimates that 21,750 new cases of ovarian cancer were diagnosed in 2020 and c 13,940 women have died from the disease. In key European markets c 33,400 women were diagnosed in 2020 (GLOBOCAN). Ovarian cancer is characterised by minimal, nonspecific or no symptoms at all. Therefore, most cases are diagnosed in an advanced stage. Prognosis in ovarian cancer is closely related to the stage at diagnosis; thus, overall prognosis for these patients remains poor (OS across all stages is 46%).

The treatment involves aggressive debulking surgery followed by chemotherapy and novel cancer targeted therapies. The surgery is considered curative only for a small percentage of patients (certain histology type tumours in stage I), so most will receive some form of chemotherapy after the surgery (neoadjuvant chemotherapy is also being used). The standard-of-care first-line chemotherapy for epithelial ovarian cancer is a combination of paclitaxel and carboplatin. Despite optimal surgery and appropriate first-line chemotherapy, 70–80% of patients will relapse, therefore a maintenance therapy is considered following the standard-of-care platinum-based chemotherapy.

In this so-called maintenance setting, the three approved PARP inhibitors became standard of care (in patients who are still sensitive to platinum). Approximately 20% of high-grade serous ovarian cancer (most prevalent histology type, c 70–74% of all new cases; also DOVACC target population) cases have the mutated BRCA gene. This group of patients was the original target population for the new successful class of PARP drugs. But PARP inhibitors were also shown to be effective in non-BRCA mutated ovarian cancers and are now approved for patients despite BRCA status. The rapid adoption of these new drugs in ovarian cancer was underpinned by impressive PFS in patients with the BRCA mutation. In patients with no BRCA mutations, the incremental PFS advantage was smaller, which is why this subgroup of patients is the focus in the DOVACC trial. VEGF inhibitor bevacizumab monotherapy or in combination with PARP inhibitors can also be used during as a maintenance therapy.

Subsequent chemotherapy after the relapse depends on how quickly the patients relapse after the primary chemotherapy. If the relapse occurs after **more than six months**, then platinum-based

regimen is used again. If **sooner than six months**, the disease is considered platinum resistant and other various chemotherapy drugs are considered

So, in the DOVACC trial, Ultimovacs is enrolling patients with high-grade (c 70–74% of all new cases), BRCA wild type (c 80%) ovarian cancer. The setting is second-line maintenance therapy, which is after the second round of platinum-based therapy (70-80% relapse). Around one-quarter of patients relapse during or within six months after end of primary chemotherapy and 60% relapse after six months, so the latter is the target population as they will receive a second round of platinum chemotherapy. Using the patient journey described above, we calculate that the addressable patient population in the United States and key European countries is c 14,500.

The Phase II FOCUS study

Announced in December 2020, the FOCUS study will recruit recurrent or metastatic, PD-L1 positive squamous cell carcinoma of the head and neck (SCCHN). In total, 75 patients will be enrolled into two arms (n=25 control, n=50 active). The goal is to evaluate the addition of UV1 to a standard-of-care treatment with pembrolizumab (anti-PD-1) compared to pembrolizumab monotherapy. The study will be conducted in Germany and will be sponsored by the investigator University Medicine Halle. Primary endpoint readout is expected in 2023.

SCCHN

SCCHN represents a group of aggressive tumours that arise from epithelial cells and occur in the oral cavity, pharynx and larynx. If detected early, the cancer is highly curable. However, nearly 66% of patients present with advanced disease (stage III and IV) and less than 30% of these patients are cured. In advanced cases, combination treatment includes surgery, chemotherapy and radiation therapy. Alcohol and tobacco use are thought to cause 75–85% of the new cases.

Few patients (<5%) present with upfront metastases, so surgery with curative intent or radiation therapy are the key first step in the treatment. Around 50% of patients with locally advanced SCCHN will relapse after primary treatment. Pembrolizumab and nivolumab were both approved in 2016 for patients with recurrent or metastatic SCCHN with disease progression on or after a platinum-based therapy. In 2019, pembrolizumab was approved for first-line monotherapy in patients with tumours expressing PD-L1 or as first-line treatment in combination with platinum and fluorouracil. The ORR rates in the clinical trials were modest at <20%, so the unmet need for novel treatment approaches remains high.

Of the estimated 41,000 patients in the United States who develop SCCHN each year, 13,000 are believed to die from the disease. Because SCCHN is a group of cancers, the patient populations can be defined differently by various databases. For consistency and due to regional similarities, we extrapolate the US incidence data to the key European markets and calculate the total addressable first-line patient population is c 60,300.

Exhibit 5: Phase II trial summaries

Product	Notes
INITIUM – sponsored by Ultimovacs	NIPU – Sponsored by Oslo University Hospital in collaboration with BMS
First-line treatment of patients with metastatic malignant melanoma	Second-line malignant pleural mesothelioma
N=154, two arms (77 pts each)	N=118, two arms (59 pts each)
Active arm – UV1 plus nivolumab ipilimumab; Control – nivolumab ipilimumab	Active arm – UV1 plus nivolumab ipilimumab; Control – nivolumab ipilimumab
Start date (first patient in) in June 2020	Start date June 2020
Top-line results expected H222	Top-line results expected H222
Primary endpoint: PFS	Primary endpoint: PFS
Secondary endpoints: OS, ORR, DOR, safety	Secondary endpoints: OS, ORR, DOR, safety
	Patients must be CPI-naïve
DOVACC – Sponsored by NSGO/ENGOT in collaboration with Astra Zeneca	FOCUS
Second-line, maintenance trial in BRCA-negative ovarian cancer patients	First line metastatic or recurrent, PDL1 positive head and neck cancer
N=184, three arms 46:46:92 (active)	N=75, two arms 25:50 (active)
Active arm – UV1 plus olaparib plus durvalumab; Control I – olaparib plus durvalumab; Control II – olaparib	Active arm – UV1 plus pembrolizumab; Control – pembrolizumab
Start date H121	Start date 2021
Top-line results expected 2023	Top-line results expected 2023
Primary endpoint: PFS	Primary endpoint: PFS
Secondary endpoints: OS, ORR, DOR, safety	Secondary endpoints: OS, ORR, DOR, safety
Patients must be CPI-naive, but are allowed to have been treated with PARP inhibitors before as long as they did not show resistance to this class of drugs	

Source: Ultimovacs. Note: DOR, duration of response

Sensitivities

Ultimovacs is subject to typical biotech company-development risks, including the unpredictable outcome of trials, regulatory decisions, success of competitors, financing and commercial risks. Our model assumes that UV1 will be out-licensed; therefore, our valuation is sensitive to potential licensing timing and actual deal terms, although typically the timing of licensing deals is difficult to forecast.

Ultimovacs is yet to obtain clinical proof of concept, therefore the near-term R&D sensitivities are tied to the ongoing Phase II clinical trials. Although the R&D programme is fairly well diversified across four different cancers, once the first clinical data emerge (either positive or negative), there could be a read-across (equally positive or negative) to remaining indications being evaluated in the trials. A significant unknown is how the Phase III programme could look, because theoretically UV1 can be developed for many cancer types. In out-licensing, this would be in the partner's hands. Ultimovacs' budget allows it to run operations until the expected readout of all trials, which will provide opportunities for share price inflection. Further funding needs will depend on the interplay between the strength of data, partner interest and Ultimovacs' ambitions to participate in Phase III development.

We believe Ultimovacs' current market value is primarily based on UV1. So, volatility in the share price should be expected and will depend on the progress of the Phase II programme over the next two years. In time, however, there is potential for the TET platform to gain value, especially now the first product UV2 has entered a Phase I trial. The technology is unrelated to UV1, so this will help to diversify the R&D risk.

Valuation

We value Ultimovacs at NOK3.18bn or NOK99.4 per share, which is based on risk-adjusted NPV analysis using a 12.5% discount rate, including net cash of NOK441m at end-2020. Our model includes four rNPV projects with UV1 being evaluated in the Phase II trials in all four indications.

We use a bottom-up approach to calculate the market sizes and industry average data for the basis of our other assumptions (eg, probability of success, eligible patient population, pricing; Exhibit 6 and 7). We have allocated the existing budget (NOK441m at the end of Q420) to each of the projects as clinical trial costs to get the true rNPV value. We then assume a full out-licensing deal for UV1 in 2024 with the partner taking over the Phase III development and commercialisation. We do not assign any value to UV2 yet, but will reconsider this once the asset progresses through clinical development. Historical pass-through success probabilities for proof-of-concept trials are 33–54%. We use a 20% cumulative probability to reach the market in our model.

Exhibit 6: Ultimovacs valuation

Product	Launch	Peak sales* ($m)	NPV (NOKm)	NPV/share (NOK/share)	Probability	rNPV (NOKm)	rNPV/share (NOK/share)
UV1 – Malignant melanoma	2028	1,010	2,912.0	91.1	20.0%	777.7	24.3
UV1 – Mesothelioma	2028	460	1,396.2	43.7	20.0%	391.6	12.2
UV1 – Ovarian cancer	2028	625	1,875.7	58.7	20.0%	545.5	17.1
UV1 – H&N cancer	2028	1,090	3,413.6	106.8	20.0%	1,023.2	32.0
Net cash, last reported			440.9	13.8	100.0%	440.9	13.8
Valuation			**10,038.4**	**314.0**		**3,178.9**	**99.4**

Source: Edison Investment Research. Note: Peak sales rounded to the nearest $10m.

Exhibit 7: Assumptions for UV1 valuation

Asset/indication	Comments
Target populations in target geographies*	■ First-line melanoma. 18,000 patients, 60% peak penetration due to first-line setting and combination with first-choice CPIs. ■ Second-line mesothelioma: 12,800 patients, 50% peak penetration due to small market size and aggressive nature of the disease. ■ Second maintenance ovarian cancer: c 14,500, 50% peak penetration due to limited other effective options for second maintenance setting. ■ First-line head and neck: c 60,300, 20% peak penetration, lower penetration as large market, so fragmentation can be expected.
Pricing	■ Pricing: $90k per patient per year in the United States, 50% discount in Europe. Peak sales reached in six years. Price is comparable to that of Provenge (dendritic cell vaccine, Dendreon) price tag and higher than Imlygic (oncolytic virus, Amgen), which was guided at launch. Provenge was ultimately not successful as a drug due to complicated logistics and survival benefit similar to chemotherapy. Imlygic was approved on durable response rate endpoint and showed no survival benefit, so a modest clinical effect.
Trial timelines and R&D cost	■ Current budget is around NOK440m until 2023. We then model a full out-licensing. Partner takes over the Phase III development during 2024–2027; launch in 2028.
Licensing deal assumptions	■ We assume a deal in 2024 and use the median values of benchmark deals in Exhibit 8. Upfront payment of $250m, $1.4bn in total milestones (one third allocated to R&D-related payments; the rest are commercial milestones). Tiered 14–18% royalty rates used. The deal values are split proportionally (using peak sales) and allocated to all four projects to get true rNPV per share value.
IP	■ UV1. Composition of matter patent expires in 2031, but there is likelihood this could be extended by five years until 2036. Ultimovacs filed combination with CPIs patents (pending) more recently. In addition, biologicals are expected to have a long tail. ■ UV2. Composition of matter patent expires in 2031, but there is also potential for extension until 2036

Source: Edison Investment Research. Note: *Target countries used in the model are the US, and top 15 European countries (EU4 + the UK, Ireland, Netherlands, Belgium, Luxembourg, Denmark, Finland, Norway, Sweden, Austria and Switzerland).

The partnering strategy is a key element in our rNPV valuation of Ultimovacs. We note that partnering deals can vary widely from co-development and co-commercialisation to full out-licensing globally or for specific territories. Ultimovacs is likely to go with an optimal strategy depending on the strength of the data. The timing of any deal is uncertain, but in our model we assume a global out-licensing deal in 2024.

Because theoretically UV1 could be evaluated in many different cancer types, we use historical licensing deal details for assets that the deal terms stipulated many potential indications. Based on deals that have occurred since 2015 for Phase III-ready immunoncology assets (Exhibit 8), we assume an upfront payment of c $250m and milestones totalling up to c $1.4bn. We allocate one-third of the milestones to R&D-related payments such as completion of the Phase III trial and NDA approval; the rest are commercial milestones. We assume tiered royalty rates of 14–18% on sales. The deal values are split proportionally (using peak sales) and allocated to all four projects to get a true rNPV per share value.

Also worth mentioning is the Vaccibody deal with Genentech/Roche. Vaccibody is the latest Norwegian biotech IPO, which listed on the Oslo stock exchange's Merkur Market on 7 October 2020, only a few days after it had signed a licensing and collaboration agreement with Genentech/Roche for $715m. Vaccibody is developing a cancer vaccine technology using tumour-

specific antigens (TSAs, as explained above), which is highly personalised for each patient, but the treatment process involves complicated logistics. The approach is very different from UV1, which is an off-the-shelf vaccine that can be offered virtually to all patients. Nevertheless, the deal shows the large pharma interest in cancer vaccines in general is high.

Exhibit 8: Phase II oncology deals used as a benchmark

Date	Licensor	Licensee	Product	Pharmacological class/target	Upfront ($m)	Milestones ($m)
04/09/2020	AbbVie	I-Mab	lemzoparlimab (TCJ4)	anti-CD47 mAb	200	1,740
27/05/2020	Gilead	Arcus Biosciences	zimberelimab (AB122) domvanalimab (AB154)	anti-PD-1 mAb anti-TIGIT mAb*	175	1,225
05/02/2019	GSK	Merck KGaA	bintrafusp alfa (M7824)	TGF-βxPD-L1 bsAb	354	4,012
05/07/2017	Celgene	BeiGene	tislelizumab (BGB-A317)	anti-PD-1 mAb	263	980
10/02/2017	Seattle Genetics	Immunomedics	sacituzumab govitecan (Trodelvy)	TROP2 ADC	250	1,700
15/10/2015	BMS	Five Prime	Cabiralizumab (FPA008)	CSF-1R mAb	350	1,390
24/04/2015	AstraZeneca	Innate	Monalizumab (IPH2201)	anti-NKG2A mAb	250	1,025
Median					c 250	c 1,390

Source: Edison Investment Research, EvaluatePharma. Note: *Gilead/Arcus deal includes options for additional assets not listed; we had excluded the licensing deals signed between BMS/Nektar and AstraZeneca/Daiichi Sankyo as outliers.

Financials

Ultimovacs reports no income, while the operating spend was NOK124m in 2020, up from NOK66m in 2019, due increasing R&D activities. The company had cash of NOK441m at the end of 2020 and no debt. According to Ultimovacs, and in line with our model, the cash will be sufficient to fund the budgeted activities until 2023. By that time the readouts from all four Phase II trials should be announced, which will be significant catalysts for the share price. Ultimovacs has NOK11.8m booked as goodwill as of end-2020, which was allocated after it acquired TET platform-associated assets in July 2018 from Immuneed (currently Ultimovacs AB).

Exhibit 9: Financial summary

Year end 31 December	NOK'000s	2018	2019	2020	2021e	2022e
			IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Total revenues		0	0	0	0	0
Cost of sales		0	0	0	0	0
Gross profit		0	0	0	0	0
SG&A (expenses)		(27,078)	(20,160)	(50,989)	(58,637)	(60,103)
R&D costs		(28,844)	(43,995)	(70,438)	(95,091)	(99,846)
Other income/(expense)		0	0	0	0	0
Exceptionals and adjustments		0	0	0	0	0
Reported EBITDA		(55,922)	(64,155)	(121,427)	(153,729)	(159,949)
Depreciation and amortisation		(601)	(2,063)	(2,720)	(3,114)	(2,991)
Reported Operating Profit/(loss)		(56,523)	(66,218)	(124,147)	(156,842)	(162,940)
Finance income/(expense)		1,242	5,051	3,593	4,322	3,958
Other income/(expense)		0	0	0	0	0
Exceptionals and adjustments		0	0	0	0	0
Reported PBT		(55,281)	(61,167)	(120,554)	(152,520)	(158,983)
Income tax expense		0	0	0	0	0
Reported net income		(55,281)	(61,167)	(120,554)	(152,520)	(158,983)
Basic average number of shares, m		15.6	22.9	30.3	32.0	32.0
Basic EPS (NOK)		(3.55)	(2.67)	(3.98)	(4.77)	(4.97)
Diluted EPS, (NOK)		(3.55)	(2.67)	(3.98)	(4.77)	(4.97)
BALANCE SHEET						
Property, plant and equipment		736	536	377	359	341
Intangible assets		56,418	55,519	64,551	61,737	59,046
Other non-current assets		0	3,523	3,630	3,630	3,630
Total non-current assets		68,135	70,429	80,353	77,521	74,812
Cash and equivalents		115,540	399,607	440,925	299,590	149,304
Trade and other receivables		0	0	0	0	0
Other current assets		6,184	8,004	8,438	8,438	8,438
Total current assets		121,724	407,611	449,363	308,028	157,742
Non-current loans and borrowings*		0	0	0	0	0
Total non-current liabilities		10,981	13,152	13,870	13,870	13,870
Trade and other payables		2,978	11,768	8,611	10,190	9,400
Other current liabilities		15,996	7,164	17,149	17,149	17,149
Total current liabilities		18,974	20,257	27,467	29,046	28,256
Equity attributable to company*		159,904	444,632	488,380	342,637	190,431
CASH FLOW						
Operating Profit/(loss)		(56,523)	(66,218)	(124,147)	(156,842)	(162,940)
Depreciation and amortisation		601	2,063	2,720	3,114	2,991
Other adjustments		0	0	0	0	0
Movements in working capital		5,528	(1,862)	6,395	1,579	(789)
Interest paid / received		0	0	0	0	0
Income taxes paid		0	0	0	0	0
Cash from operations (CFO)		(50,389)	(62,989)	(108,224)	(141,051)	(150,004)
Capex		(513)	(172)	(282)	(282)	(282)
Acquisitions & disposals net		0	0	0	0	0
Other investing activities		1,247	4,490	(455)	0	0
Cash used in investing activities (CFIA)		(3,852)	4,318	(737)	(282)	(282)
Net proceeds from issue of shares		0	344,582	152,933	0	0
Movements in debt		0	0	0	0	0
Other financing activities		0	(1,579)	(1,916)	0	0
Cash from financing activities (CFF)		0	343,003	151,017	0	0
Increase/(decrease) in cash and equivalents		(54,269)	284,067	41,317	(141,333)	(150,286)
Cash and equivalents at beginning of period		169,808	115,539	399,606	440,923	299,590
Cash and equivalents at end of period		115,539	399,606	440,923	299,590	149,304
Net (debt) cash		115,540	399,607	440,925	299,590	149,304

Source: Ultimovacs accounts, Edison Investment Research. Note: *Long-term debt used instead of equity issue.

Contact details	Revenue by geography
Ullernchausséen 64 0379 Oslo Norway mail@ultimovacs.com +47 413 80 080	N/A

Key team members

CEO: Carlos de Sousa

Carlos de Sousa is a medical doctor by training, having obtained his degree at the School of Medicine, University of Lisbon, and holds an Executive MBA from the Stern School of Business, New York University. He has more than 25 years of senior-level experience in the global pharmaceutical and biotech industry, including business development, mergers & acquisitions, global marketing and clinical development. He has held senior positions at Nycomed/Takeda, Pfizer and Novartis, among other pharma and biotech companies.

CFO: Hans Vassgård Eid

Hans Vassgård Eid has more than 20 years of experience within business development and venture- and private equity investments across multiple industries. He has held senior management positions in business development, most recently at PHARMAQ, the global leader in aquatic animal health. Previously, he gained consulting experience at McKinsey & Company.

CMO: Jens Bjørheim

Jens Bjørheim MD, PhD is a trained medical doctor with experience and scientific achievements in clinical oncology, immunology and cancer genetics. He has more than 10 years of experience in the pharmaceutical industry, with senior positions at Pronova Biopharma (now part of BASF), Novartis, Clavis Pharma and AstraZeneca.

CSO: Gustav Gaudernack

Professor Gustav Gaudernack was head of unit for Immunotherapy at Radiumhospitalet from 1995 to 2011. He initiated more than 20 clinical studies in cancer vaccination, including the first ever trial with a peptide cancer vaccine (mutant RAS). He has authored more than 50 patents and 15 licences for monoclonal antibodies, cancer vaccines and cancer diagnostics. Professor Gaudernack has published more than 200 peer-reviewed articles during his career.

CBO: Ton Berkien

Ton Berkien has more than 15 years of experience in healthcare business development, both pharmaceuticals and biotech. He has held senior executive management roles in Nycomed, Takeda, Nuevolution and Amgen. Previously, he gained experience working in venture capital and corporate finance. Mr Berkien holds a BA in economics from Saxion University and LSiD diploma from PwC/Harvard/IMD.

Top 10 shareholders	(%)
Gjelsten Holding	19.30
Canica	7.93
Inven2	5.74
Watrium	5.44
Radiumhospitalets Forskningsstiftelse	4.69
Langøya Invest	4.22
Folketrygdfondet	3.66
Helene Sundt	2.76
CGS Holding	2.76
Sundt	2.25

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