EDISON

Ultimovacs

Company update

New large indication for UV1

Pharma & biotech

Ultimovacs has made the decision to expand its R&D pipeline with a new indication, non-small cell lung cancer (NSCLC), for its lead asset the therapeutic cancer vaccine, UV1. The sponsorship arrangement will be similar to most of the other Phase II trials: Ultimovacs will work closely with the lead investigator and will provide financial support. The company will be able to continue the development if the Phase II data are positive. Despite significant progress being made with the advent of immunotherapies, NSCLC is still a challenging cancer to manage. Ultimovacs aims to position UV1 as a combination therapy with Keytruda in a first-line setting, which means it is targeting the biggest share of the large NSCLC market. We adjust our model to include the new opportunity and increase our valuation to NOK6.13bn or NOK179/sh (from NOK128/sh).

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	(150.0)	(4.53)	0.0	N/A	N/A
12/22e	0.0	(194.2)	(5.67)	0.0	N/A	N/A

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

Another set of good data from Phase I in melanoma

At the cut-off date of 12 October 2021, every patient in the first cohort (n=20) of the Phase I trial (Exhibit 1; UV1 plus Keytruda in metastatic melanoma) had been followed for at least 24 months from the start of their treatment. In this group the overall survival (OS) was 80%, progression-free survival (PFS) of 18.9 months was reported previously. This compares favourably with historical comparable data, OS of 58% and PFS 5.5–11.6 months (Robert et al 2019; FDA label; see our analysis of previous results in our last published report). We note that Ultimovacs recently received a fast-track designation for UV1 in combination with checkpoint inhibitors (CPIs) in advanced melanoma, as well as orphan drug designation for the treatment of stage IIB–IV melanoma, both from the FDA.

Entering an active newsflow period

These findings and previously reported follow up data from the Phase I trial were a significant driver behind the share price rally in H221. The final readout (after 24 months of follow up) from the second cohort is expected in 2022. This will set expectations for Ultimovacs' Phase II trial INITIUM, where melanoma patients in the active arm are treated with triple combination UV1 plus nivolumab plus ipilimumab. Readouts are expected every year over the next several years from all Phase II trials, so Ultimovacs is entering an active newsflow period.

Valuation: NOK6.13bn or NOK179 per share

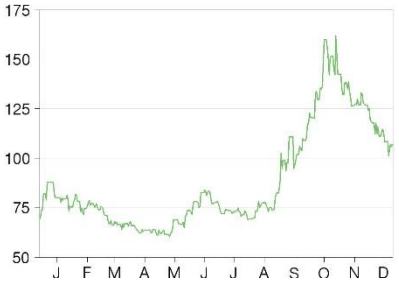
Our updated valuation is NOK6.13bn or NOK179/share (NOK4.08bn or NOK128/share previously). We have added an rNPV model to assess the potential of the new NSCLC indication. The new indication, the improved cash position and rolling our model forward more than offset the dilution from the share issue. The company is now financed until early 2024. Some of the key readouts from the Phase II trials should be announced before that (Ultimovacs intends to update guidance in the Q421 report, more details below).

13 December 2021

Price	**NOK107**
Market cap	**NOK3,659m**

Net cash (NOKm) at end Q321 plus share issue	618
Shares in issue	34.2m
Free float	91%
Code	ULTI
Primary exchange	Euronext Oslo
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(16.4)	(1.8)	75.4
Rel (local)	(13.5)	(4.8)	43.5

52-week high/low	SEK162	SEK60

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

Cohort 2 24-month follow-up data from Phase I trial of UV1 plus CPI in melanoma	2022
Top line results Phase II INITIUM	H222
Top line results Phase II NIPU	H222

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Edison profile page

Both fast-track and orphan drug designations received

Ultimovacs recently received a fast-track designation for UV1 in combination with CPIs in advanced melanoma, as well as orphan drug designation for the treatment of stage IIB–IV melanoma, both awarded by the FDA. Orphan drug designation provides such benefits as seven-year market exclusivity after regulatory approval, exemption from FDA application fees and tax credits for qualified clinical trials. The fast-track designation enables early and frequent communication with the FDA to support UV1's development and provides eligibility for accelerated approval and priority review in certain cases. It also allows a rolling review of the biologic licence application (BLA) by the FDA (ie the BLA can be submitted even when the data package is not full, which shortens the regulatory review time).

In addition to all these benefits, we view the designations as an external validation of UV1 technology to some extent. For example, for the fast-track designation the FDA considered the available clinical data (the previously mentioned Phase I findings). Even though it is not an official assessment of UV1's efficacy, the fact that the FDA reviewed the available data and awarded the designation is reassuring for both investors and the physicians, who are involved in Ultimovacs' trials and treat the patients with UV1.

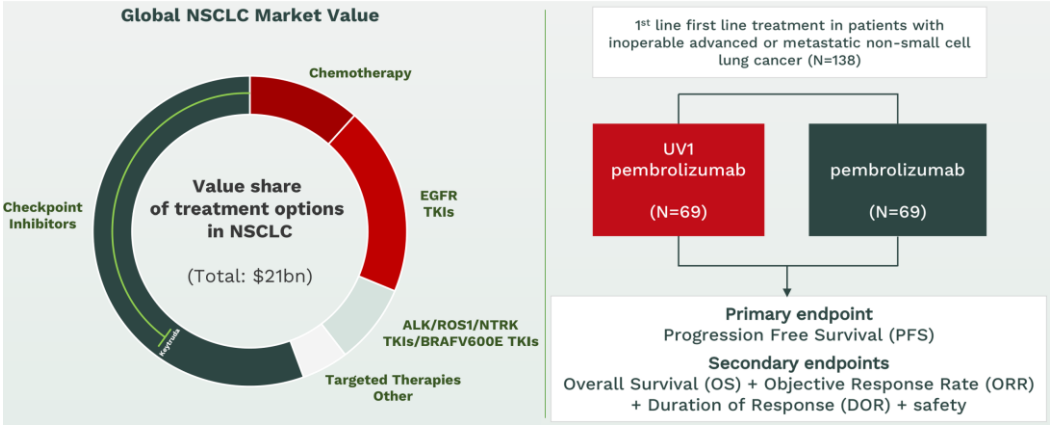
NSCLC indication expands the R&D pipeline

In October 2021, Ultimovacs announced that it will investigate UV1 in a new Phase II trial, LUNGVAC, in combination with pembrolizumab in NSCLC. This will be a Norway-based multi-centre, randomised (two equally balanced arms), open-label trial assessing the safety and efficacy of UV1 in combination with pembrolizumab versus pembrolizumab alone in NSCLC patients with advanced or metastatic disease. The trial is sponsored by Drammen Hospital, based just outside Oslo, Norway. However, as with other Phase II studies in its pipeline (except INITIUM in melanoma, which is run solely by Ultimovacs), the company is closely working with the lead investigators, will provide financial support and, if the data are positive, Ultimovacs could carry on the development. The trial will enrol 138 patients, who meet the following criteria:

- certain histological subtypes, specifically adenocarcinoma or squamous cell carcinoma,
- at least 50% of malignant cells express the PD-L1 (prerequisite for pembrolizumab monotherapy), and
- patients must be pembrolizumab (anti-PD-1) treatment-naïve (first-line setting).

These subgroups represent approximately one third of all advanced and metastatic NSCLC patients. The primary endpoint of the trial will be PFS. Secondary endpoints will include overall response rate (ORR) and OS. The first patient is expected to be treated in H122, with that data readout from LUNGVAC anticipated by the end of 2024.

Exhibit 1: NSCLC cancer treatment options and the design of the Phase II trial



Source: Ultimovacs (partially sourced from GlobalData)

NSCLC: Review of the opportunity

NSCLC generally presents late and is frequently diagnosed at stage IV when metastatic, so it is still a significant unmet need despite that fact that the management of this cancer has evolved drastically with the advent of immunotherapy. The American Cancer Society estimates 235,760 new lung cancer patients will be diagnosed in 2021 in the United States, c 85% of which will have NSCLC. While smoking is a risk factor in a percentage, driver mutations (alteration in a gene that can drive cancer growth) can lead to NSCLC even in non-smokers.

Over the last decade the treatment paradigm for NSCLC has evolved significantly with the approval of targeted therapies and immunotherapies. It is now common practice to screen NCSLC patients for biomarkers to determine the most effective treatment approach; PD-L1, EGFR and ALK status in particular. Those with addressable driver mutations (approximately 25% of NSCLC patients) receive targeted therapies specific to the mutation as first line treatment, while CPIs are increasingly used as a first-line standard of care for patients not harbouring a specific driver mutation. Keytruda is the market-leading PD-1 CPI (Merck & Co, consensus sales forecast of $27bn in 2026). Patients with PD-L1 greater than 50% are eligible for Keytruda monotherapy, while patients with PD-L1 <50% receive platinum doublet chemotherapy with or without Keytruda.

Exhibit 2: R&D pipeline

	Indication	Clinical trial information	Pre-clinical	Phase I	Phase II	Phase III	Contributors
UV1	First line metastatic malignant melanoma	With pembrolizumab 30 patients		●			
	First line metastatic malignant melanoma	With ipilimumab & nivolumab 154 patients			INITIUM ●		
	Second line mesothelioma	With ipilimumab & nivolumab 118 patients			NIPU ●		Bristol-Myers Squibb[1] Oslo University Hospital
	Second line ovarian cancer	With durvalumab & olaparib 184 patients			DOVACC ●		NSGO ENGOT AstraZeneca[2]
	First line head and neck cancer	With pembrolizumab 75 patients			FOCUS ●		Martin-Luther University Halle
	First line NSCLC	With pembrolizumab 138 patients			LUNGVAC ●		VESTRE VIKEN DRAMMEN HOSPITAL
TET	Prostate cancer	Dose finding trial, monotherapy 9-12 patients		TENDU ●			

Note: UV1 Phase II development is supported by good safety profile and signals of clinical efficacy observed in three Phase I trials where 52 patients with prostate cancer, lung cancer or malignant melanoma were included. Patients in these studies have been followed for at least five years.

Source: Ultimovacs

Valuation

Assumptions for NSCLC project

The addition of the NSCLC indication to the R&D pipeline is a significant expansion since this particular cancer type is one of the most common malignancies. Furthermore, Ultimovacs is targeting the first line treatment segment and with the most popular CPI. All this translates into high potential peak sales and NSCLC now having a significant weight in our sum-of-the-parts valuation of Ultimovacs (Exhibit 3).

To value UV1 in the new setting we used a similar approach as with other indications, risk-adjusted net present value (NPV), and developed a bottom-up model using these assumptions:

- **Target population**: we use a target population of c 135k in the selected markets (the United States and top European countries). As with other indications, we have focused on the Western markets (the United States and top 15 wealthy European countries). The drug development and approval requirements in these countries are similar, however if the data are positive, we believe the expansion into Asian markets (Japan, China and others) would be a matter of time (in large scale Phase III programmes it is possible to include recruitment centres worldwide, eg in Japan, which would likely enable registration without the need for bridging studies).
- **Assumed 25% peak penetration**.
- **Pricing**: $110k per patient per year in the United States, 50% discount in Europe (the same as other indications; for comparison, Keytruda's cost is estimated at $150k in the United States). Peak sales in six years.
- **Trial timelines and R&D cost**: we assume $5m in R&D costs per year while the Phase II study is running until out-licensing.
- **We assume a global out-licensing in 2024**: unchanged from our previous report. The timing of any deal is uncertain, but in our model we assume a global out-licensing deal in 2024. Detailed discussion about out-licensing approach and comparable transactions is in our initiation report.

- **We assume approval and launch in 2029**: one year later than the other indications we already have in our model.

With regards to the trial progress across the R&D pipeline, Ultimovacs indicated in the Q321 presentation that it will provide updated guidance on expected enrolment timelines and potential readouts together with the Q421 report. The company also reminded investors that the current guidance was issued before the pandemic, implying this may have affected recruitment speeds. Even though some delays may be expected, we see this as an industry-wide issue and not company specific. In addition, Ultimovacs is reporting how many new patients are recruited to all Phase II trials each quarter. Such transparency is rare to see.

Valuation update

Our updated valuation is NOK6.13bn or NOK179 per share (NOK4.08bn or NOK128 per share previously). Our valuation is based on risk-adjusted NPV analysis using a 12.5% discount rate, including estimated net cash of NOK618m (cash on balance sheet at end-Q321 plus share issue). Our model now includes five rNPV projects, which all are based on a similar bottom-up approach (more details in our initiation report).

Exhibit 3: Valuation of Ultimovacs

Product	Launch	Peak sales* ($m)	NPV (NOKm)	NPV/share (NOK/share)	Probability	rNPV (NOKm)	rNPV/share (NOK/share)
UV1 – malignant melanoma	2028	1,230	3,341.1	97.6	25.0%	900.3	26.3
UV1 – mesothelioma	2028	560	1,554.7	45.4	25.0%	418.0	12.2
UV1 – ovarian cancer	2028	764	2,076.4	60.7	25.0%	580.3	17.0
UV1 – Head and neck cancer	2028	1,330	3,808.0	111.3	25.0%	1,101.3	32.2
UV1 – NSCLC	2029	2,683	8,172.4	238.8	25.0%	2,516.5	73.5
Net cash, last reported			617.8	18.1	100.0%	617.8	18.1
Valuation			**19,570.4**	**571.9**		**6,134.1**	**179.2**

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

Financials

Share issue completed

Together with the announcement of the new indication for UV1, Ultimovacs has also carried out a successful share issue raising proceeds of NOK270m gross, at the high end of the range indicated before the subscription start. In total, the company issued 2,160,000 new shares (or 6.3% of the previously issued) at NOK125 per share. Ultimovacs timed the share issue well, in our view, capitalising on the share price strength after positive data readouts earlier this year. The company has secured funding for several strategic goals:

- Financing of the Phase II trial LUNGVAC,
- Developing the UV1 programme to Phase III-ready stage,
- Further development of the Tetanus-Epitope-Targeting (TET) technology platform, and
- General corporate purposes.

The existing funding should be sufficient until early 2024 and includes several key readouts. As discussed above, we assume a licensing deal in 2024, which if the data are positive, is a reasonable timing (we assume full out-licensing, but in reality, various other arrangements are possible, for example co-development or out-licensing of regional rights).

Estimate revision

Ultimovacs reports no revenues, while operating spend was NOK113m in 9M121, a modest increased from NOK99m in 9M20. The operating spend should increase further in 2022 as the new

trials start recruiting patients. We increase our operating loss estimates to NOK154m and NOK198m in 2021 and 2022, respectively.

The company had cash of NOK618m (cash on balance sheet at end-Q321 plus share issue) and no debt. This should be sufficient to fund budgeted activities until early 2024. Some of the key readouts from the Phase II trials should be announced before that time, which will be significant catalysts for the share price.

Exhibit 4: 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)	(66,708)	(68,376)
R&D costs		(28,844)	(43,995)	(70,438)	(84,526)	(126,788)
Other income/(expense)		0	0	0	0	0
Exceptionals and adjustments		0	0	0	0	0
Reported EBITDA		(55,922)	(64,155)	(121,427)	(151,234)	(195,164)
Depreciation and amortisation		(601)	(2,063)	(2,720)	(3,114)	(2,991)
Reported Operating Profit/(loss)		(56,523)	(66,218)	(124,147)	(154,347)	(198,155)
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)	(150,025)	(194,198)
Income tax expense		0	0	0	0	0
Reported net income		(55,281)	(61,167)	(120,554)	(150,025)	(194,198)
Basic average number of shares (m)		15.6	22.9	30.3	33.1	34.2
Basic EPS (NOK)		(3.55)	(2.67)	(3.98)	(4.53)	(5.67)
Diluted EPS (NOK)		(3.55)	(2.67)	(3.98)	(4.53)	(5.67)
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	572,085	386,584
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	580,523	395,022
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	615,132	427,711
CASH FLOW						
Operating Profit/(loss)		(56,523)	(66,218)	(124,147)	(154,347)	(198,155)
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)	(138,556)	(185,219)
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	270,000	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	270,000	0
Increase/(decrease) in cash and equivalents		(54,269)	284,067	41,317	131,162	(185,501)
Cash and equivalents at beginning of period		169,808	115,539	399,606	440,923	572,085
Cash and equivalents at end of period		115,539	399,606	440,923	572,085	386,584
Net (debt) cash		115,540	399,607	440,925	572,085	386,584

Source: Ultimovacs accounts, Edison Investment Research

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