EDISON

Ultimovacs

FY22 update

Gathering steam with multiple inflections in FY23

Pharma and biotech

Ultimovacs' Q422 and FY22 results reflected another busy period marked by continued development of its lead cancer vaccine, UV1, across multiple indications. Top-line results from the Phase II clinical trials INITIUM (in metastatic malignant melanoma) and NIPU (in metastatic pleural mesothelioma) are expected in H123 and are key catalysts for a potential licensing deal, should data be positive. Another clinical milestone will be the readout from the Phase I TENDU trial (prostate cancer), expected in H223. However, data readouts for the other Phase II trials have been adjusted due to the delayed initiation of DOVACC, change in standard of care for LUNGVAC and a minor delay in FOCUS (end FY23 to H124). We roll forward our model and adjust our estimates, resulting in a valuation of NOK7.4bn or NOK216/share (NOK7.9bn or NOK231/share previously). Our estimates do not include consideration for preclinical assets, which may offer upside on successful clinical progress. The end-FY22 cash position stood at NOK425.3m, which should provide funding to mid-2024, according to management.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS** (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/21	0.0	(164.7)	(5.09)	0.0	N/A	N/A
12/22	0.0	(167.8)	(4.89)	0.0	N/A	N/A
12/23e	0.0	(217.1)	(6.31)	0.0	N/A	N/A
12/24e	0.0	(279.3)	(8.12)	0.0	N/A	N/A

Note: *PBT is reported. **EPS is fully diluted.

Catalysts approaching in H123

The most significant near-term catalysts for Ultimovacs are top-line readouts from the Phase II INITIUM trial (first-line advanced/metastatic malignant melanoma in combination with ipilimumab and nivolumab) and the NIPU trial (in second-line metastatic pleural mesothelioma, with the same combination), both expected in H123. The INITIUM study is fully enrolled (n=156), and the last patient was enrolled for the NIPU study (n=118) in January 2023. We view the upcoming results as key milestones for UV1 as a potential treatment for patients with unmet clinical need.

Cash runway to support operations to mid-2024

We continue to anticipate increased R&D costs in FY23, due to the continued enrolment and treatment of patients across the five Phase II studies. The company had a net cash position of NOK425.3m at end-Q422, down from NOK469.1m at end-Q322. Based on the multiple ongoing clinical trials, Ultimovacs expects its current cash resources to provide a runway into mid-2024, by which time we expect to see progress on the partnering/licensing front, provided data are positive.

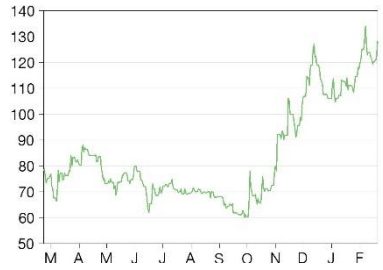
Valuation: NOK7.4bn or NOK216/share

We have revised our estimates for UV1's clinical progress following the mostly minor readout delays for three Phase II programmes with the FY22 results. We also make adjustments to our operating expense estimates based on management guidance of increased expenses over FY23 and FY24. Overall, our valuation resets to NOK7.4bn or NOK216/share, from NOK7.9bn or NOK231/share previously, including a net cash position at end-FY22 of NOK425.3m.

21 February 2023

Price	**NOK128.2**
Market cap	**NOK4,410m**
	NOK10.35/US$
Net cash (NOKm) at end-December 2022 (excluding leases)	425.3
Shares in issue	34.4m
Free float	56%
Code	ULTI
Primary exchange	Oslo Stock Exchange
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	15.5	28.2	53.9
Rel (local)	11.6	23.9	52.6
52-week high/low	NOK134	NOK60	

Business description

Ultimovacs is developing novel immunotherapies against cancer. Its lead product candidate, UV1, is a peptide-based vaccine against the universal cancer antigen telomerase (hTERT), which is expressed in c 85% of all cancer types. UV1 therefore has a broad potential in a variety of different settings and combinations.

Next events

Phase II INITIUM top-line data	H123
Phase II NIPU top-line data	H123
Phase I TENDU initial data	H223

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Edison profile page

Multiple trials in action for UV1

Ultimovacs is a clinical-stage biotechnology company developing novel immunotherapies against cancer. More specifically, it is focused on the development of a cancer vaccine with universal application, UV1. This vaccine triggers an immune response through recognition of human telomerase reverse transcriptase (hTERT), a protein that is estimated to be overexpressed in up to 90% of human cancers but not in healthy tissues. Aiming to demonstrate the combinational synergies between UV1's immune priming ability and immune checkpoint inhibitors (ICIs), which can turn 'cold' (immunosuppressive) tumours to 'hot' (vulnerable to the immune system), Ultimovacs is pursuing the development of UV1 in combination with well-known ICIs, in multiple indications. These include ipilimumab, nivolumab, durvalumab and pembrolizumab.

While the expected INITIUM and NIPU updates represent important near-term readouts for UV1, three further Phase II studies are currently ongoing: FOCUS (head and neck cancer), DOVACC (ovarian cancer) and LUNGVAC (NSCLC). However, the timelines for these have been pushed back to H124, H224 and H225, respectively (previously end FY23, end FY23 and end FY24, respectively), driven by slower-than-expected enrolment due to regulatory requirements. We do not expect this to influence the ultimate potential of the cancer vaccine.

In addition to UV1, Ultimovacs is also evaluating the safety and tolerability of the first product candidate from the company's second technology platform, TET (tetanus-epitope targeting). Patient enrolment for the Phase I TENDU trial (prostate cancer) was completed in mid-December 2022 and is expected to readout in H223.

UV1 gearing up for first Phase II readouts

In what is set to be a busy year of clinical activity for Ultimovacs, the most significant near-term catalysts for the company are top-line data from the INITIUM and NIPU studies in H123. The primary endpoint for the studies is progression-free survival (PFS), with overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety being key secondary endpoints.

Exhibit 1: Ultimovacs' clinical pipeline

	Indication	Checkpoint inhibitor(s)	Patients (#)	Recruited	Expected topline readout	Phase I	Phase II	Phase III	Contributors
UV1	Malignant melanoma	Ipilimumab	12	Completed	Completed	UV1-ipi			
	Malignant melanoma	Pembrolizumab	30	Completed	Completed	UV1-103			
	Malignant melanoma	Ipilimumab & nivolumab	156	**Completed**	**H1 2023**		INITIUM		
	Pleural mesothelioma	Ipilimumab & nivolumab	118	**Completed**	**H1 2023**		NIPU		Bristol Myers Squibb[3], Oslo University Hospital
	Head and neck cancer	Pembrolizumab	75	**67%[1]**	H1 2024		FOCUS		Martin-Luther-Universität Halle-Wittenberg
	Ovarian cancer	Durvalumab & olaparib	184	**<10%[1]**	H2 2024		DOVACC		NSGO-CTU, AstraZeneca[3], ENGOT
	Non-small cell lung cancer (NSCLC)	Cemiplimab[4]	138	**<10%[1]**	H2 2025		LUNGVAC		VESTRE VIKEN
TET	Prostate cancer	Dose finding trial, monotherapy	12	**Completed**	H2 2023	TENDU			

Source: Ultimovacs Q422 results presentation deck

Phase II INITIUM trial

The Phase II INITIUM trial in metastatic malignant melanoma, fully sponsored by Ultimovacs, completed patient recruitment in June 2022 (n=156). The trial is randomised, where 78 patients receive first-line treatment with nivolumab (anti-PD-1) and ipilimumab (anti-CTLA-4), while the other 78 patients receive 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 four cycles of nivolumab and ipilimumab. Subsequently, all patients in both arms will proceed to maintenance therapy (nivolumab every four weeks).

Phase II NIPU study

The randomised NIPU trial in metastatic pleural mesothelioma (n=118, two arms with 59 patients in each) completed patient enrolment in January 2023, with patients receiving 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 recruited in the trial must not have undergone previous treatment with ICIs (naïve). Bristol Myers Squibb (BMS) is supporting the study with the provision of its ICI therapies.

Melanoma a potentially low hanging fruit for vaccines

The existing standard of care for the treatment of metastatic melanoma depends on whether a tumour contains a driver BRAF mutation (ICIs are more commonly used in metastatic melanoma when there is no BRAF mutation). 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 single-agent immunotherapy with pembrolizumab or nivolumab or combination therapy, with nivolumab plus ipilimumab as the first choice (Exhibit 2). In February 2022, Opdualag was the second ICI combination treatment approved for first-line metastatic melanoma.

Exhibit 2: ICIs approved for first-line metastatic melanoma

Company	Drug	Target/s	2028 estimated sales according to EvaluatePharma	FDA approval basis
Bristol Myers Squibb	Nivolumab (Opdivo)	PD-1	$2.6bn	mPFS 5.1 months
Bristol Myers Squibb	Ipilimumab (Yervoy)	CTLA-4	$540m	Two-year survival rate 24%
Bristol Myers Squibb	Nivolumab plus ipilimumab	PD-1 / CTLA-4	See above	mPFS 11.5 months
Bristol Myers Squibb	Nivolumab plus relatlimab (combo brand name Opdualag)	PD-1/ LAG-3	$2.4bn	mPFS 10.1 months
Merck	Pembrolizumab (Keytruda)	PD-1	$2.5bn	ORR 34%

Source: EvaluatePharma, Edison Investment Research. Note: mPFS = median progression-free survival.

As melanoma is one of the most immunogenic tumour types, melanoma patients who are eligible to receive immunotherapy often respond well to ICI treatments. In contrast, historically, attempts to develop cancer vaccines as immunotherapies have been met with disappointing results. However, with the evolution of ICIs, there is potential for a synergistic relationship between ICIs and cancer vaccines, with the former making tumour cells vulnerable to attack by the immune system cells and the latter priming the body's immune cells to fight tumours. In our view, this combinational approach opens the potential for cancer vaccines to begin realising their clinical utility.

Long-term survival data for UV1 provides encouraging signs

What we believe represents one the most significant clinical validations of Ultimovacs' technology, to date, is the long-term survival data the company reported in October 2022 from its open-label

Phase I study (UV1-103) in metastatic melanoma. The trial is investigating UV1 in combination with Merck's ICI, pembrolizumab (Keytruda), in the first-line setting. The three-year OS rate from patients in cohort one of the study was 71% (12/17). This result builds on the consistently high OS rates already observed from the trial: 85% (17/20) after one year and 80% (16/20) after two-year follow-up. The UV1-103 trial had previously met its primary endpoints for safety and tolerability, and the latest data from cohort one patients demonstrate the long-term clinical efficacy of UV1. Of note, the three-year OS rate from the KEYNOTE-006 study investigating pembrolizumab as a monotherapy in first-line patients with metastatic melanoma was 51%.

Merck/Moderna combo further validates vaccines in melanoma

Merck and Moderna released highly encouraging results in December 2022 from a Phase II study (KEYNOTE-942) investigating the jointly developed, personalised mRNA vaccine (mRNA-4157/V940) in combination with Merck's ICI, Keytruda, for the treatment of stage III/IV melanoma. Notably, the combination therapy reduced the risk of tumour recurrence, or death, in patients by 44% compared to Keytruda alone. The partners intend to initiate a Phase III study in melanoma in 2023 with the intention of moving into additional tumour indications. While we caution against direct read-across between studies, the results provide further clinical validation for the application of cancer vaccines in the treatment of advanced melanoma and an encouraging precedent for the INITIUM study.

Universal treatment approaches may offer differentiation

While personalised therapy approaches may offer improved efficacies, with treatments tailored to an individual's specific disease profile, it is likely that, from a cost and manufacturing perspective, patient-specific vaccines will encounter manufacturing issues similar to those faced by patient-specific cell therapies. Today, personalised cell therapies continue to struggle with production bottlenecks and timely supply of treatments, a serious issue for patients with aggressive cancers. In our view, the operational infrastructure to support the mass production of personalised treatments is not currently in place and may not be for quite some time. In the case of cancer vaccines, which aim to target larger patient populations across a broad range of indications, we believe more universal approaches looking to provide timelier, upfront access to treatment for patients offer significant potential to differentiate in the market.

With the advantages that 'off-the-shelf' therapies such as UV1 might possess, we believe this makes the upcoming readouts from the INITIUM study of even greater significance. Should UV1 demonstrate statistically significant improvements in PFS versus the nivolumab/ipilimumab combination, it not only may potentially disrupt existing first-line ICI treatment regimens, but, in our view, would provide UV1 with a distinct competitive advantage over personalised vaccine approaches and open up potential licensing opportunities. Positive clinical data may heighten the interest of BMS, whose ICI combination, nivolumab plus ipilimumab, is being used alongside UV1 in the INITIUM trial. BMS has publicly voiced support for the continued development of cancer vaccine technology and, if BMS looks to compete with Merck and Moderna's mRNA candidate in melanoma, UV1 may be viewed as an attractive asset, provided upcoming clinical study readouts are positive.

Valuation

We value Ultimovacs based on a risk-adjusted net present value (rNPV) analysis using a 12.5% discount rate, including net cash of NOK425.3m. Our current valuation is wholly attributable to the five ongoing Phase II trials for UV1 and excludes other early-stage clinical (such as the Phase I TENDU trial) and preclinical assets, each of which offers upside on successful clinical progress.

The rNPV valuation for all five indications is based on a similar bottom-up approach (for further details, see our initiation report). Following the announcement of the adjustment in the timelines for three of the Phase II readouts, as described earlier, we have updated our estimates for the clinical development timelines for these three programmes, pushing out the approval and launch estimates for each of these by around six months to a year. We continue to assume that a global out-licensing deal for UV1 across all indications will be secured by end-2024. Our updated valuation now stands at NOK7.4bn or NOK216 per share (NOK7.9bn or NOK231 per share previously).

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	1,270	5,510.4	160.2	25.0%	1,491.8	43.4
UV1 – mesothelioma	2028	570	2,573.9	74.8	25.0%	694.5	20.2
UV1 – ovarian cancer	2029	787	2,936.5	85.4	25.0%	818.5	23.8
UV1 – head and neck cancer	2029	1,370	5,335.3	155.1	25.0%	1,456.3	42.3
UV1 – NSCLC	2030	2,683	9,417.9	273.8	25.0%	2,544.2	74.0
Net cash, last reported			425.3	12.4	100.0%	425.3	12.4
Valuation			**26,199.3**	**761.7**		**7,430.6**	**216.0**

Source: Edison Investment Research

Financials

Total operating expenses for FY22 came in at NOK183.6m, a 12.1% increase year-on-year and higher than our estimate of NOK170.5m. This increase was primarily driven by a 15% growth in payroll expenses, specifically related to higher share-based payments. External R&D expenses remained broadly unchanged compared to the previous year (NOK95.2m versus NOK96.7m in FY21) likely due to patient enrolment on certain trials temporarily slowing down, as highlighted in the previous sections. Net cash flow from operating activities stood at NOK167.7m in FY22 (NOK125.8m in FY21, although the figure was affected by the release of working capital in FY21). Management expects operating expense levels to rise in the coming years, as patient enrolment to the remaining Phase II trials increases. We have updated our FY23 estimates for R&D and other operating expenses to reflect this guidance and have now introduced FY24 estimates as we roll forward our model by a year. Ultimovacs ended the year with a net cash position of NOK425.3m, which management expects to be sufficient to fund operations to mid-2024, by which time we expect to see progress on the partnering/licensing front for the most clinically advanced assets, should trial outcomes be positive. Since our model assumes an out-licensing deal by end-2024, we estimate that the company would be required to raise c NOK150m in funds in H224. We account for this raise as illustrative debt in our model. Alternatively, if the funding is realised through an equity issue instead (assuming at the current trading price of NOK128/share), Ultimovacs would have to issue 1.25m shares, resulting in our per share valuation coming down to NOK208.5 from NOK216 currently (shares outstanding would increase from 34.4m to 35.7m).

Exhibit 4: Financial summary

Accounts IFRS; year end 31 December; NOKm	2019	2020	2021	2022	2023e	2024e
Income statement						
Total revenues	0.00	0.00	0.00	0.00	0.00	0.00
Cost of sales	0.00	0.00	0.00	0.00	0.00	0.00
Gross profit	0.00	0.00	0.00	0.00	0.00	0.00
SG&A (expenses)	(20.16)	(50.99)	(61.92)	(71.47)	(85.76)	(102.91)
R&D costs	(35.53)	(64.66)	(96.74)	(95.18)	(109.52)	(136.90)
Other income/(expense)	(8.47)	(5.78)	(2.48)	(14.34)	(27.38)	(34.22)
Exceptionals and adjustments	0.00	0.00	0.00	0.00	0.00	0.00
Reported EBITDA	(64.15)	(121.43)	(161.13)	(180.98)	(222.65)	(274.03)
Depreciation and amortisation	(2.06)	(2.72)	(2.70)	(2.65)	(2.44)	(2.38)
Reported Operating Profit/(loss)	(66.22)	(124.15)	(163.83)	(183.63)	(225.09)	(276.41)
Finance income/(expense)	5.05	3.59	(0.89)	15.84	8.02	(2.93)
Other income/(expense)	0.00	0.00	0.00	0.00	0.00	0.00
Exceptionals and adjustments	0.00	0.00	0.00	0.00	0.00	0.00
Reported PBT	(61.17)	(120.55)	(164.72)	(167.79)	(217.08)	(279.34)
Income tax expense	0.00	0.00	0.00	0.00	0.00	0.00
Reported net income	(61.17)	(120.55)	(164.72)	(167.79)	(217.08)	(279.34)
Basic average number of shares, m	22.93	30.26	32.37	34.31	34.40	34.40
Basic EPS (NOK)	(2.67)	(3.98)	(5.09)	(4.89)	(6.31)	(8.12)
Diluted EPS (NOK)	(2.67)	(3.98)	(5.09)	(4.89)	(6.31)	(8.12)
Balance sheet						
Property, plant and equipment	0.536	0.377	0.212	0.220	0.125	0.007
Intangible assets	66.370	76.346	71.119	68.429	66.280	64.211
Other non-current assets	3.523	3.630	1.951	5.444	5.444	5.444
Total non-current assets	70.429	80.353	73.282	74.093	71.849	69.662
Cash and equivalents	399.607	440.925	574.168	425.309	212.206	87.189
Trade and other receivables	0.000	0.000	0.000	0.000	0.000	0.000
Other current assets	8.004	8.438	8.087	10.270	10.270	10.270
Total current assets	407.611	449.363	582.255	435.579	222.476	97.459
Non-current loans and borrowings	2.301	2.075	0.457	3.713	3.713	153.713
Deferred tax liabilities	10.851	11.795	11.031	10.701	10.701	10.701
Total non-current liabilities	13.152	13.870	11.488	14.414	14.414	164.414
Trade and other payables	11.768	8.611	22.555	7.655	9.383	11.523
Other current liabilities	8.489	18.856	28.342	38.252	38.252	38.252
Total current liabilities	20.257	27.467	50.897	45.907	47.635	49.775
Equity attributable to company	444.632	488.380	593.152	449.351	232.276	(47.067)
Cashflow statement						
Operating Profit/(loss)	(66.217)	(124.146)	(163.833)	(183.630)	(225.093)	(276.412)
Depreciation and amortisation	2.063	2.720	2.703	2.648	2.439	2.382
Other adjustments	(2.023)	3.215	12.331	4.437	(8.506)	(4.244)
Movements in working capital	(1.862)	6.395	23.860	(6.988)	1.728	2.139
Interest paid / received	0.000	0.000	0.000	0.000	0.000	0.000
Income taxes paid	0.000	0.000	0.000	0.000	0.000	0.000
Cash from operations (CFO)	(62.988)	(108.223)	(125.828)	(167.694)	(221.414)	(279.066)
Capex	(0.172)	(0.282)	(0.085)	(0.195)	(0.195)	(0.195)
Acquisitions & disposals net	0.000	0.000	0.000	0.000	0.000	0.000
Other investing activities	4.490	(0.455)	3.062	8.887	8.506	4.244
Cash used in investing activities (CFIA)	4.318	(0.737)	2.977	8.692	8.311	4.049
Net proceeds from issue of shares	344.582	152.933	261.852	5.484	0.000	0.000
Movements in debt	0.000	0.000	0.000	0.000	0.000	150.000
Other financing activities	(1.579)	(1.916)	(1.895)	(1.907)	0.000	0.000
Cash flow from financing activities	343.003	151.017	259.957	3.577	0.000	150.000
Increase/(decrease) in cash and equivalents	284.333	42.057	137.106	(155.425)	(213.103)	(125.017)
Cash and equivalents at beginning of period	115.540	399.608	440.925	574.168	425.310	212.206
Cash and equivalents at end of period	399.608	440.925	574.168	425.310	212.206	87.189
Net (debt) cash (including lease liabilities)	395.982	437.143	572.083	419.830	206.726	(68.291)

Source: company reports, Edison Investment Research

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