2023 Third Quarter Report







Introduction

Ultimovacs is a clinical-stage biotechnology company developing novel immunotherapies against cancer. The lead product candidate, UV1, is a therapeutic cancer vaccine being developed as a combination therapy with checkpoint inhibitors, aiming to increase treatment efficacy and extend the benefits of immunotherapy to more cancer patients. UV1 triggers an immune response against telomerase, a target present throughout tumors in 85-90% of all cancer types, making the UV1 vaccine potentially applicable as a therapy across most cancer indications. UV1 is off-the-shelf, easy to use, and does not require sophisticated hospital infrastructure.

Ultimovacs is advancing a broad clinical development program with five Phase II randomized clinical trials in which the universal cancer vaccine UV1 is combined with different checkpoint inhibitors. More than 670 patients in the U.S., Europe, and Australia will be enrolled in the program. The first three randomized Phase II studies in malignant melanoma (INITIUM), pleural mesothelioma (NIPU), and head and neck squamous cell carcinoma (FOCUS) have completed enrollment. In October 2023, the UV1 Phase II trial NIPU in malignant mesothelioma reported a clinically meaningful overall survival benefit in patients receiving UV1 vaccination, with no added toxicities. Per protocol, the results were statistically significant, demonstrating Proof of Concept for the UV1 cancer vaccine.

Ultimovacs is listed on Euronext Oslo Stock Exchange (ULTI.OL).

Third Quarter 2023 Highlights

Ultimovacs' universal cancer vaccine UV1 achieved the first demonstration of clinically meaningful prolonged survival over standard of care immunotherapy in NIPU, the first randomized Phase II clinical trial for UV1 – a remarkable milestone for the Company.

Phase II study NIPU in malignant mesothelioma

NIPU trial principal investigator, Professor Åslaug Helland, MD, PhD, reported the results from the study in second-line treatment of patients with malignant mesothelioma as an oral presentation at the ESMO Congress 2023 in Madrid in October. The data presented showed that UV1, as add-on to the checkpoint inhibitors ipilimumab and nivolumab, demonstrated a clinically meaningful overall survival benefit after a relevant observation period, with no added toxicities compared to ipilimumab and nivolumab alone. The study also reported that 31% of the patients treated with UV1 experienced an objective response, as compared to 16% in the control arm. An analysis of the Hazard Ratio in Overall Survival showed that UV1 cancer vaccination combined with ipilimumab and nivolumab reduced the risk of death by 27% and met the protocol's predefined threshold for statistical significance.



• On October 9, 2023, Ultimovacs announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation (ODD) to the Company's therapeutic cancer vaccine UV1 for the treatment of patients with mesothelioma.

Phase II study INITIUM in unresectable or metastatic malignant melanoma

- On October 31, 2023, Ultimovacs announced that the protocol for the UV1 Phase II INITIUM study in malignant melanoma has been amended based on acceptance by relevant regulatory authorities. This confirms topline readout from the study in the first half of 2024, as previously communicated. By mid-January 2024, the last enrolled patient will have completed follow-up for 18 months, and all patients will have achieved a mean follow-up time of approximately 24 months. The topline readout is expected to be announced two to three months later. As per the original trial protocol, data analysis would be conducted after cancer progression had been verified in 70 patients. The amendment follows the observation that it takes longer than anticipated for patients in the study to experience progression of the disease. The protocol amendment will maintain the integrity of the study statistics without materially affecting the scientific value of the clinical trial.
- On November 2, 2023, the Company announced the completed enrollment of 21 patients in the INITIUM supplementary single-arm study in malignant melanoma. The objective of the study is to elucidate and describe that an immune response specific to the UV1 vaccine transfers into anti-tumor activity and clinical benefit for the patients.

Phase II study FOCUS in head and neck cancer

 On August 3, 2023, the Company announced that the Phase II FOCUS study had completed enrollment of 75 patients with head and neck cancer (also reported in the Q2-2023 report). The study will provide randomized data on the benefit of UV1 vaccination as addon to standard pembrolizumab treatment. The topline readout, including Progression Free Survival (PFS) and Overall Survival (OS), will be disclosed after 12 months minimum followup, expected during H2 2024.

Phase I study UV1-103 in malignant melanoma

 On October 12, 2023, Ultimovacs reported sustained long-term overall survival in patients treated with UV1 cancer vaccine in the UV1-103 Phase I study in malignant melanoma. No confirmed patient deaths occurred in Cohort 1 between the 3-year and 4-year follow-up period.

Intellectual Property

 Ultimovacs received a Decision to Grant from the Japanese patent office (PN822210JP) in July 2023. The patent is the Japanese counterpart of the European and US patents previously granted. These patents protect UV1 cancer vaccine-checkpoint inhibitor combinations until at least 2037, and covers UV1 combined with CTLA-4, PD-1 or PD-L1 checkpoint inhibitors.



Clinical trials update

UV1 Phase II program

- **INITIUM (malignant melanoma):** The enrollment of 156 patients was completed in July 2022. Readout is expected in the first half of 2024.
- **INITIUM Supplementary Study:** Enrollment of the single arm supplementary study, which will not be included in the INITIUM topline readout, was completed in October 2023, with a total of 21 patients.
- **NIPU (metastatic pleural mesothelioma):** The enrollment of 118 patients was completed in January 2023. The positive overall results from the study were reported in October 2023.
- **FOCUS (head and neck cancer):** The enrollment of 75 patients was completed in August 2023. The readout is expected in the second half of 2024.
- **DOVACC (ovarian cancer):** 46 out of 184 patients have been enrolled to date, up from 37 as of the previous quarterly report.
- LUNGVAC (non-small cell lung cancer): 13 out of 138 patients have been enrolled to date, up from 11 as of the previous quarterly report.
- An update on the expected timeline for readout from the Phase II studies DOVACC and LUNGVAC will be provided with the Q4 2023 report.

TENDU Phase I trial (prostate cancer) based on the TET technology platform:

• The enrollment of 12 patients was completed in mid-December 2022. The results from the study will be reported in Q4 2023.

Financial update

- Ultimovacs expects that the current cash resources will support operations to H2 2024, based on current programs and plans, through the topline readouts in INITIUM and FOCUS.
- Total operating expenses amounted to **MNOK 54.7** in Q3 2023 and **MNOK 156.1** YTD. Total loss was **MNOK 55.8** for the period and **MNOK 133.3** YTD.
- Net negative cash flow from operations was MNOK 40.7 in Q3 2023, and net decrease in cash and cash equivalents, not including currency effects, was MNOK 37.6 during Q3 2023. Cash and cash equivalents amounted to MNOK 300.3 as of September 30, 2023.

Key financials

NOK (000) Unaudited	Q3-23	Q3-22	YTD-23	YTD-22	FY22	
Total revenues	-	-	-	-	-	
Total operating expenses	54 705	44 055	156 109	111 376	183 631	
Operating profit (loss)	(54 705)	(44 055)	(156 109)	(111 376)	(183 631)	
Profit (loss) for the period	(55 822)	(38 303)	(133 308)	(97 279)	(167 792)	
Diluted and undiluted earnings / (loss) per share (NOK)	(1.6)	(1.1)	(3.9)	(2.8)	(4.9)	
Net increase / (decrease) in cash and cash equivalents	(37 583)	(29 726)	(138 721)	(113 289)	(155 426)	
Cash and cash equivalents at end of period	300 273	469 063	425 309	469 063	425 309	
NOK/EUR - 11.2535						
Cash and cash equivalents at end of period - EUR (000	26 683					



CEO Statement

The recent months mark a major inflection point in the clinical development of Ultimovacs' universal therapeutic cancer vaccine UV1. We've successfully demonstrated Proof of Concept for UV1 as a clinically meaningful therapy, underpinned by a statistically significant survival benefit for cancer patients suffering from a hard-to-treat form of cancer, malignant mesothelioma.

The recent announcement of the full results from the NIPU trial in malignant mesothelioma, presented at the ESMO Congress 2023 in Madrid, by the Principal Investigator, Professor Åslaug Helland, MD,



Ph.D., stands as a testament to UV1's potential. We extend our sincere appreciation to Professor Helland for her exceptional professionalism and unwavering commitment to improving the survival and quality of life of her patients. The NIPU trial's design, adding UV1 to current standard of care ipilimumab and nivolumab, two of the most effective immunotherapies available, as a second-line treatment post-chemotherapy failure, showed a clinically meaningful prolonged survival. For patients with bleak prognosis and a median overall survival of just over one year, a four-month increase in survival is an important benefit. Learning UV1's positive impact on these patients has been truly inspiring. Based on the challenges many companies have experienced in developing effective treatments for malignant mesothelioma, our initially modest expectations of the outcome from the NIPU study have been greatly exceeded.

NIPU unexpectedly became the first Phase II study to release data, taking precedence over the Ultimovacs-sponsored INITIUM Phase II trial in malignant melanoma. The event-driven design in INITIUM is based on published historical statistics, but fortunately for the patients, the disease progression reported is much slower than expected. We are thus pleased that the regulatory authorities have agreed to a protocol amendment, enabling us to commence data analysis in mid-January 2024. The slow progression in patients with metastatic melanoma in INITIUM, coupled with positive survival results in malignant mesothelioma, fuels our optimism and strengthens our belief in UV1's potential to make a positive impact on cancer patients. The enduring survival rates from the 4-year follow-up in the UV1-103 trial further underscore UV1's durability when combined with checkpoint inhibitors.

In the current turbulent economic landscape, the Ultimovacs team extends our appreciation to our shareholders, whose continuous support allows us to continue our mission of making a difference for cancer patients. These past months signify a new chapter in our journey, but more importantly, we eagerly await what lies ahead. On behalf of the dedicated Ultimovacs team that is tirelessly working to create value for patients and shareholders, we confirm our commitment; we plan to continue to deliver.

Carlos de Sousa, Chief Executive Officer



Operational Review

Lead product candidate: UV1

The Company's lead product candidate, UV1, is a second-generation peptide-based therapeutic cancer vaccine. UV1 induces a specific T cell response against the universal cancer antigen telomerase (hTERT), expressed at a high level in 85-90% of human tumors. hTERT activation is considered a Hallmark of Cancer due to its selective activation and vital function in cancer. UV1 may potentially be applied universally across cancer types, in different stages of disease, and in combination with different cancer treatments.

The UV1 vaccine stimulates the immune system to expand T cells specific to fragments of hTERT. The T cells induced by UV1 have been shown to persist in patients for many years after vaccination, and a T cell response against hTERT correlates with improved survival in human cancer studies.

UV1 is being developed across multiple cancer indications as a baseline for other immuneoncology drugs, which require an ongoing T cell response for their mode of action. Considering the evolving immune-oncology landscape, it would be attractive to investigate the use of UV1 in adjuvant and neo-adjuvant settings in a longer term.

Treatment with UV1 has been assessed in three early Phase I studies (metastatic prostate cancer, metastatic non-small cell lung cancer and metastatic malignant melanoma) in 52 patients at the Oslo University Hospital. The observed clinical outcomes from these three trials served as a strong basis for the clinical development of UV1 with respect to safety, immune response, and signals of clinical effect. In addition, Ultimovacs is the sponsor of the fully enrolled and ongoing fourth Phase I clinical study UV1-103 in the U.S. evaluating the safety and tolerability of treatment with UV1 and the PD-1 checkpoint inhibitor pembrolizumab in 30 patients with metastatic malignant melanoma.

UV1 is currently being evaluated in five Phase II randomized clinical trials in five different cancer types and in combination with different checkpoint inhibitors. In October 2023, the UV1 Phase II trial NIPU in malignant mesothelioma reported a clinically meaningful overall survival benefit in the patients receiving UV1 vaccination, with no added toxicities. Per protocol, the results were statistically significant, demonstrating Proof of Concept for the UV1 cancer vaccine. The full Phase II program will enroll more than 670 patients at approximately 100 hospitals in Europe, the U.S. and Australia. In total, more than 300 cancer patients have received, so far, treatment with UV1 in Phase I and Phase II trials. No safety concerns have been reported with the use of UV1 to date.

UV1 is manufactured as an off-the-shelf product with a long shelf life. The vaccine is easy to use and does not require sophisticated hospital infrastructure, enabling patient access to therapy also in community centers and in rural and underserved communities.



A commercial scale manufacturing process is established with well renowned CMOs. This important milestone is crucial to establish before initiating phase III trials and for future partnering discussions.

UV1 is a patented, proprietary technology owned by Ultimovacs.

Regulatory designations

Fast Track designation

In October 2021, Ultimovacs announced that its universal cancer vaccine, UV1, in combination with checkpoint inhibitors, received Fast Track designation from the U.S. FDA for the treatment of unresectable or metastatic melanoma, either as add-on therapy to pembrolizumab or as add-on therapy to ipilimumab. Ultimovacs is currently evaluating UV1 as add-on therapy to ipilimumab and nivolumab as first-line treatment for unresectable or metastatic melanoma in the INITIUM trial.

Orphan Drug designations

In October 2023, Ultimovacs announced that the FDA has granted Orphan Drug designation (ODD) to the Company's therapeutic cancer vaccine UV1 for the treatment of patients with mesothelioma. The designation was granted based on the initial data from the Phase II clinical trial, NIPU.

In December 2021, Ultimovacs announced that UV1 received Orphan Drug designation from the U.S. FDA for the treatment of malignant melanoma stage IIB-IV. UV1, as add-on therapy to checkpoint inhibitors ipilimumab and nivolumab, is currently being studied as first-line treatment for unresectable or metastatic malignant melanoma in INITIUM.



UV1 clinical program

The INITIUM Phase II trial in metastatic malignant melanoma

INITIUM is an Ultimovacs-sponsored randomized, comparative, multi-center Phase II trial in which the universal cancer vaccine UV1 will be evaluated in combination with the checkpoint inhibitors ipilimumab and nivolumab for first-line treatment of patients with unresectable or metastatic malignant melanoma.



The first patient received treatment in the INITIUM trial in June 2020, and the last patient was enrolled in July 2022. The study is being conducted at 39 hospitals across the U.S., UK, Belgium, and Norway. The initial study design called for enrollment of 154 patients. Two additional patients were enrolled, bringing the total number of patients in the study to 156.

Half of the 156 patients enrolled in the trial have been dosed with UV1 plus the PD-1 checkpoint inhibitor nivolumab and the CTLA-4 checkpoint inhibitor ipilimumab, while the other half received nivolumab and ipilimumab. Analysis of data from the study follows after disease progression or death has been observed in 70 patients, which has not yet occurred as per Q3 2023 reporting.

With the current development in patient progression, reaching these 70 events could take a long time, which justifies a decision to implement a protocol amendment.

The protocol has been amended to allow data readout based on a minimum of 18-month follow-up of all evaluable patients, at which time the patients have a mean follow-up time of approximately 24 months. The protocol amendment will maintain the integrity of the study statistics without materially affecting the scientific value of the clinical trial.

The protocol amendment was submitted to the regulatory authorities in the countries where the INITIUM trial is conducted, the U.S. Food and Drug Administration (FDA) and regulatory bodies in Belgium, Norway, and the U.K. Based on the recent acceptance from regulators, the data can now be analyzed from mid-January 2024. The topline readout is expected to be announced two to three months later.

The primary endpoint in the study is progression-free survival. Secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety.

In September 2022, Ultimovacs initiated a supplementary single-arm study to the INITIUM trial. The study was fully enrolled in October 2023 with a total of 21 patients. The single-arm study was designed to elucidate and describe the mechanisms leading to improved clinical effect in patients treated with UV1 vaccination. The single-arm study will provide in-depth data on biologic activity and mode of action of the T cells induced by the UV1. All patients will receive experimental treatment (i.e., the triple combination of UV1, ipilimumab and nivolumab). Data collected from the supplementary study will not be part of the primary and secondary endpoint analyses of INITIUM and will not affect the timeline for topline read-out.



Seven patients in the INITIUM study will also be part of the INITIUM supplementary study, for a total of 28 patients.

The NIPU Phase II trial in malignant pleural mesothelioma (MPM)

NIPU is an investigator-initiated randomized, open-label, multicenter Phase II trial in malignant pleural mesothelioma (MPM) where patients received immunotherapy as a second-line treatment after first-line treatment with platinum-based chemotherapy. The study was designed to investigate if UV1 vaccination, on top of the checkpoint inhibitors ipilimumab and nivolumab from Bristol-Myers Squibb, would provide a benefit compared to ipilimumab and



nivolumab alone. Professor Åslaug Helland, MD PhD, is the principal investigator for the trial, which is sponsored by Oslo University Hospital (OUS). Bristol-Myers Squibb and Ultimovacs have supported the trial.

The positive results reported from the NIPU study are the first demonstration of clinically meaningful prolonged survival for the UV1 vaccine in a randomized Phase II trial and the first time a comparative study reports efficacy on a universal cancer vaccine.

Malignant mesothelioma is a rare and aggressive cancer that occurs in the thin layer of tissue that surrounds the lungs and inside of the chest. It is considered an aggressive, complex form of cancer with a high mortality rate and few therapeutic options. Patients affected have often been occupationally or environmentally exposed to asbestos, and the disease can take several decades to develop. Despite the banning of asbestos in many countries, mesothelioma continues to pose a medical challenge with significant unmet medical need. Malignant mesothelioma patients have a very severe prognosis, and the median overall survival is just over one year. About 3,000 new cases are diagnosed each year in the United States (*source: American Cancer Society, 2019*).

Over the past few decades, substantial efforts have been made to improve the survival outcomes of patients with MPM. However, the results of these investigations have not been very encouraging. There is currently no established standard of care in second-line treatment. Telomerase is expressed in mesothelioma cells and is, therefore, a relevant target for therapeutic vaccination with UV1.

The first patient received treatment in the NIPU trial in June 2020, and the last patient was enrolled in January 2023. The study is being conducted in five countries (Australia, Denmark, Norway, Sweden, and Spain), and 118 patients have been enrolled in the study. Half of the patients in the trial have been treated with the combination of UV1, ipilimumab and nivolumab, and the other half have been treated with ipilimumab and nivolumab alone.

The primary endpoint in the study is progression-free survival (PFS). Secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety.

The first overall survival results from the NIPU trial

The results from the NIPU trial were shared in a late-breaking abstract and as an oral presentation by the Principal Investigator at the ESMO Congress 2023 in Madrid in October. The NIPU study showed that patients receiving UV1 vaccination as add-on to nivolumab and ipilimumab experienced an increased objective response rate and a clinically meaningful prolonged survival. The data provides a foundation for further advancing clinical development with UV1 vaccination in mesothelioma patients.

The results showed that UV1 plus ipilimumab and nivolumab improved overall survival (OS), reducing the risk of death by 27% (HR=0.73 [80% CI, 0.53-1.00]). The median OS was 15.4 months (95% CI, 11.1-22.6) for UV1 plus ipilimumab and nivolumab (treatment arm) versus 11.1 months (95% CI, 8.8-18.1) for ipilimumab and nivolumab alone (control arm), with a median observation time of 17.3 months. This degree of improvement met protocol predefined threshold for statistical significance.

The data further demonstrated a benefit in terms of objective response rate, as determined by blinded independent central review. In the UV1 arm, 31% of the patients experienced an objective response, as compared to 16% in the control arm (odds ratio 2.44 [80% CI, 1.35-4.49]).

Based on blinded independent central review (BICR), the study did not meet the primary endpoint of PFS. Investigator assessment, a pre-defined supportive analysis of the primary endpoint performed by specialized radiologists at the study hospitals, showed a statistically significant positive PFS benefit for the patients in the UV1 arm.

The safety profile of the combination of UV1 plus ipilimumab and nivolumab observed in the trial was consistent with the safety profile of ipilimumab and nivolumab alone, confirming the good safety profile for UV1. The patients will continue to be monitored for efficacy and safety endpoints over the next years.

In October 2023, Ultimovacs announced that FDA had granted Orphan Drug designation for UV1 in the treatment of mesothelioma (based on the NIPU data from June 2023). The updated results from the NIPU study will be discussed with the regulatory authorities.

The FOCUS Phase II trial in head and neck cancer

The FOCUS trial (First-line metastatic **O**r recurrent HNSCC/**C**heckpoint inhibitor **U**V1 **S**tudy) is an investigator-initiated, randomized Phase II clinical trial. The cancer vaccine UV1 will be evaluated in combination with the checkpoint inhibitor pembrolizumab as first-line treatment of patients with recurrent or metastatic PD-L1 positive head and neck squamous cell carcinoma. Prof. Mascha Binder is the principal investigator for the trial, which is sponsored by University Medicine Halle in Germany.



The first patient received treatment in the FOCUS trial in August 2021, and the last patient was enrolled and received the first dose of treatment in August 2023. The study is being conducted in ten hospitals in Germany, and a total of 75 patients have been enrolled. The patients are randomized 2-to-1 so that 50 patients will receive UV1 and pembrolizumab, and 25 patients will receive pembrolizumab alone.

The FOCUS trial is a landmark study. The primary endpoint of the study is progression-free survival rate at 6 months after the last patient has been included. For the secondary endpoints, including overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety, patients will be followed until 12 months after the last patient has been enrolled. The data, including PFS and OS, will be analyzed 12 months after inclusion of last patient, and the results are expected to be reported in the second half of 2024.

The DOVACC Phase II trial in ovarian cancer

DOVACC (**D**urvalumab **O**laparib **VACC**ine) is an investigator-initiated, randomized, comparative Phase II clinical collaboration trial with the Nordic Society of Gynaecological Oncology – Clinical Trial Unit (NSGO-CTU), the European Network of Gynaecological Oncological Trial Groups (ENGOT), supported by AstraZeneca and Ultimovacs. The cancer vaccine UV1 will be evaluated in combination with AstraZeneca's durvalumab, a PD-L1 checkpoint inhibitor, and



ultimovacs

olaparib, a PARP inhibitor, which is approved for the patient population in this trial. This second-line maintenance study will enroll patients with high-grade BRCA-negative ovarian cancer after partial or complete response following the second round of chemotherapy. MD Manzoor Raza Mirza is the principal investigator for the trial, which is sponsored by NSGO-CTU.

The first patient received treatment in the DOVACC trial in December 2021. A total of 46 out of 184 patients have been enrolled in DOVACC. The trial will be conducted at more than 40 hospitals in more than 10 European countries. Ultimovacs will provide the UV1 vaccine, and AstraZeneca will provide durvalumab and olaparib for the study.

The study includes three arms treating a total of 184 patients. The first arm will enroll 46 patients receiving the PARP inhibitor olaparib. The 46 patients enrolled in the second arm will receive olaparib and the checkpoint inhibitor durvalumab. The third arm will include 92 patients who will receive Ultimovacs' UV1 vaccine in combination with both AstraZeneca drugs.

The primary endpoint is progression-free survival (PFS) in the treatment arm with PARP inhibitor olaparib monotherapy, versus PFS in the triple combination treatment arm. Secondary endpoints will include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety. Updated guidance on topline results will be provided with the Q4 2023 report.



The LUNGVAC Phase II trial in non-small cell lung cancer (NSCLC)

The LUNGVAC trial is an investigator-initiated, randomized, comparative Phase II clinical trial in which the cancer vaccine UV1 will be evaluated in combination with the checkpoint inhibitor cemiplimab as first-line treatment of NSCLC patients with advanced or metastatic disease. The trial will enroll previously untreated patients with adenocarcinoma or squamous NSCLC, where tumor biopsies show a PD-L1-expression score equal to or above 50%. These



subgroups represent approximately 30% of all advanced and metastatic NSCLC patients. Professor Odd Terje Brustugun is the principal investigator for the trial, which is sponsored by Drammen Hospital in Vestre Viken Hospital Trust, Norway.

The LUNGVAC study will be conducted at approximately 10 clinical centers in Norway. The first patient received treatment in the LUNGVAC trial in October 2022. In December 2022, the Norwegian health authorities changed the reimbursement in the indication from pembrolizumab to cemiplimab. Following this decision, the LUNGVAC study changed the PD-1 inhibitor in the study from pembrolizumab to cemiplimab. 13 out of 138 patients have been enrolled in the study since the change to cemiplimab on 1 January 2023. The three patients enrolled prior to 1 January 2023 will continue treatment with pembrolizumab and will be maintained as a separate sub-group in the trial.

Half of the patients in the trial will be treated with UV1 + cemiplimab, and the other half will be treated with cemiplimab monotherapy.

The primary endpoint of the trial will be progression-free survival. Secondary endpoints will include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety. Updated guidance on topline results will be provided with the Q4 2023 report.

The UV1-103 Phase I trial in metastatic malignant melanoma

This U.S.-based Phase I clinical trial is evaluating UV1 in combination with the PD-1 checkpoint inhibitor pembrolizumab as a first-line treatment in patients with unresectable or metastatic malignant melanoma. Thirty patients in the U.S. were treated in the study in two cohorts that differed only in the concentration of GM-CSF used as vaccine adjuvant. The 20 patients in the first cohort received a 37.5 mcg GM-CSF adjuvant dose per UV1 vaccination. The 10 patients in the second cohort received the standard 75 mcg GM-CSF



adjuvant dose per UV1 vaccination. The study has completed the enrollment of 30 patients, as announced on August 18, 2020.

UV1 has demonstrated a good safety profile in the study, and no unexpected safety issues related to UV1 have been observed. Compiled clinical results for the 30 patients enrolled are:



- Objective response rate (ORR): 57%
- Complete response rate (CR): 33%
- Median Progression Free Survival (mPFS): 18.9 months (as measured by iRECIST)
- Overall survival rate after 12 months: 87% (N=26/30)
- Overall survival rate after 24 months: 73% (N=22/30)
- Overall survival rate after 36 months: 67% (N=18/27)
- Overall survival rate after 48 months for Cohort 1: 69% (N=11/16)

After the study ended at two years follow-up, the protocol was amended to allow extended follow-up of patients for up to five years to evaluate overall survival. Three patients in Cohort 1 chose not to be followed up further after two years, changing the number of participating patients in Cohort 1 from 20 to 17. Out of the 17 patients included in the 4-year follow-up, one patient could not be reached temporarily, and the status is pending. Employing a conservative approach, 11 out of 16 patients were confirmed alive after 4 years.

The inclusion criteria in the UV1-103 trial are similar to the UV1 Phase II trial INITIUM.

The UV1-103 trial – biomarker analyses

The analyses of five different biomarkers in the UV1-103 trial, published in Q4 2022 in the Journal of Translational Medicine, signal efficacy in patients treated with UV1 in combination with pembrolizumab. These results are supportive of the addition of UV1 to checkpoint inhibitors, with the potential for improving both efficacy in current target patient populations and extending the use of immunotherapy to broader patient populations in multiple cancer types that are underserved by existing therapies. The potential value of expanding the number of patients that can benefit from UV1 could be substantial.

Clinical analyses from the UV1-103 study indicate efficacy of the UV1-pembrolizumab combination in patients with low levels of PD-L1 (<1%). Low PD-L1 levels are a key predictive biomarker associated with lower efficacy for pembrolizumab and other anti-PD-1 therapies in some tumor types. The analyses showed robust responses in patients treated with the combination of UV1 and pembrolizumab, regardless of patients' PD-L1 status.

Population	ORR (%)	iCR (%)	iPR (%)
PD-L1 (≥1%) (n=8)	4 (50.0%)	3 (37.5%)	1 (12.5%)
PD-L1 (<1%) (n=14)	8 (57.1%)	5 (35.7%)	3 (21.4%)
Stage III B/C (n=11)	8 (72.7%)	5 (45.5%)	3 (27.3%)
Stage IV (n=19)	9 (47.4%)	5 (26.3%)	4 (21.1%)

ORR = Objective Response Rate, iCR = Complete Response Rate according to iRECIST, iPR = Partial Response Rate according to iRECIST

In addition to the sub-analysis of PD-L1 status, the study also evaluated four other key biomarkers that, in other historical studies, have indicated how responsive patients may be to

pembrolizumab monotherapy: baseline tumor mutational burden (TMB), predicted neoantigens, interferon-gamma (IFN-gamma) gene signature, and levels of tumor-infiltrating lymphocytes (TILs). In the UV1-103 study, objective responses were also observed in patients with low TMB, in patients with low neoantigen tumors, and in patients with tumors that were not enriched for IFN-gamma. These patient groups have tumors that previous clinical data have shown would be less responsive to treatment with pembrolizumab monotherapy in various cancer types. Lastly, the study also showed that clinical responders did not have higher levels of TILs prior to treatment.

Earlier UV1 Phase I trials (in long-term follow-up)

In addition to UV1-103, Ultimovacs has conducted three Phase I trials with UV1: in metastatic prostate cancer (n=22 patients), in metastatic non-small cell lung cancer (n=18 patients), and in metastatic malignant melanoma with UV1 in combination with ipilimumab (named 'UV1-ipi', n=12 patients). Enrollment of patients in these trials took place during 2013-2015.

Data from these clinical trials showed that UV1 was generally well tolerated, and there were no dose-limiting toxicities. UV1 immune monitoring data from these studies showed a robust immune response induction with dynamic T cell responses lasting up to 9.5 years.

The observed clinical outcomes from these three completed trials served as a strong basis for the further clinical development of UV1 with respect to safety, immune response and signals of clinical effect.

The TET technology platform

Ultimovacs is developing a vaccine adjuvant technology platform, TET (Tetanus-Epitope Targeting). The patent-protected TET-platform combines antigens and a vaccine adjuvant in the same molecule. This allows a beneficial safety profile and easy administration, offering a promising approach to inducing T cell responses against cancer-specific peptides. The platform can generate multiple first-in-class cancer vaccine candidates that harness pre-existing antibody responses against tetanus induced by standard tetanus vaccination. TET vaccine candidates can be tailored to many types of cancer and potentially to infectious diseases.

The TENDU Phase I clinical trial

The TENDU trial is the first Phase I trial exploring the TET technology. In TENDU, the TET technology incorporates prostate-cancer-specific antigens, and the trial will provide valuable safety and immune activation data that will support the further development of new vaccine solutions based on the TET technology.

The TENDU trial is being conducted at Oslo University Hospital. The first patient was treated in February 2021, and the last patient was enrolled in December 2022. A total of 12 patients have been enrolled. Three different doses of TENDU have been investigated: 40mcg (3)

patients), 400mcg (3 patients), and 6 patients received the highest dose (960mcg). All patients are followed up for 6 months after their last treatment. So far, the TENDU treatment has been shown to be safe and well tolerated. Readout of safety and immune responses is expected during the fourth quarter of 2023.

🖢 ultimovacs

Patents and IP

In July 2023, Ultimovacs received a Decision to Grant from the Japanese patent office concerning its Japanese patent application PN822210JP (*post-period event*). These patents are the European and Japanese counterparts of the U.S. patent No. 11419927, which was granted in April 2022. The Company has similar patent applications pending in other territories worldwide, including Japan, Canada and Australia. They cover synergistic cancer treatments that include the UV1 peptide vaccine in combination with an anti-CTLA-4, anti-PD-1 or anti-PD-L1 antibody checkpoint inhibitor. The primary patents of many of the current CTLA-4 and PD-1/PD-L1 checkpoint inhibitors face expiry over the course of the next several years. (also reported in the Q2 2023 report)





Outlook

Ultimovacs' UV1 vaccine triggers an immune response against telomerase, which is present in 85-90% of cancers in all stages of tumor growth, making it a potential universal vaccine that may have an effect across most types of cancer and could be used in combination with different types of cancer treatment. The cancer vaccine is expected to generate immune responses across the general population (i.e., regardless of HLA type). The vaccine is easy to manufacture and does not require sophisticated hospital infrastructure to be administered. If the ongoing clinical development and testing of Ultimovacs' cancer vaccine demonstrates that UV1 provides clinical benefit to cancer patients, the potential clinical use of UV1 and related financial benefits could be highly attractive.

As of now, UV1 is being investigated in five randomized Phase II trials in five different cancer types in combination with different checkpoint inhibitors, with Ultimovacs sponsoring one of the trials. The five Phase II clinical trials will enroll more than 670 patients in total, representing a strong potential foundation for Ultimovacs to support a possible registration path of the universal cancer vaccine, UV1. The main study objectives are efficacy and safety data on combination therapies.

Guidance for expected timeline readout from the UV1 Phase II clinical program is as follows:

- INITIUM (metastatic malignant melanoma): H1 2024. Based on the recent acceptance of protocol amendments from regulators, the INITIUM data can now be analyzed in early 2024, enabling Ultimovacs to maintain its guidance on reporting the results in the first half of 2024.
- FOCUS (head and neck cancer): H2 2024
- DOVACC (ovarian cancer): H2 2024 (to be updated with the Q4 2023 reporting)
- LUNGVAC (non-small cell lung cancer): H2 2025 (to be updated with the Q4 2023 reporting)

Ultimovacs expects that the current cash resources will support operations to H2 2024 based on current programs and plans, through the reporting of the topline readouts in INITIUM and FOCUS.

Ultimovacs continues to pursue strategic collaborations with cancer institutions and pharmaceutical companies to document the effect and safety of UV1 in a range of cancer types and in combination with different cancer treatments. Ultimovacs makes clinical development choices based on the universal nature of UV1 as a cancer vaccine. UV1 can potentially play a role across most cancer types, in most patients, in different stages of cancer and in combination with many cancer treatments. Positive results from ongoing randomized clinical trials would reinforce the significant potential of UV1 to improve the treatment of cancer.

Ultimovacs is also seeking to broaden its pipeline of drug candidates. The Company's research activities are currently focused on the development of new first-in-class cancer vaccine

solutions, building on Ultimovacs' base technology, the TET-platform, and the development of new molecules and technologies based on biobank material from the ongoing and planned clinical studies conducted with UV1. Pending final confirmation of the safety of the TET technology through the Phase I TENDU trial and further preclinical development, Ultimovacs' ambition is to apply the TET technology to identify new cancer vaccine program candidates and to advance them into clinical development.

Risks and uncertainties

Ultimovacs is a clinical stage biotechnology company conducting research and development. The Company has not generated revenues historically and is not expected to do so in the near term. The product development process, from research and development up to regulatory approval, is subject to considerable risk and is a capital-intensive process. The Company's candidates for cancer vaccines and technology platforms are dependent on research and development and may be delayed and/or incur higher costs than currently expected. Competing biopharmaceutical products can capture market shares or reach the market faster than Ultimovacs. If competing projects have a better product profile (e.g., better efficacy and/or less side effects), the future value of Ultimovacs' product offerings may be lower than expected. Operations may also be impacted negatively by changes or decisions regarding laws and regulations. In addition, the Company is also dependent upon intellectual property rights.

The primary financial risks are foreign exchange risks and financing risks. The Company is affected by foreign exchange risk as the research and development costs for UV1 are mainly paid in USD and EUR. In addition, the Company has invested in foreign operations, the net assets of which are exposed to currency translation risk. Adequate sources of funding may not be available when needed or may not be available on favorable terms. The Company's ability to obtain such additional capital or financing will depend in part upon prevailing market conditions as well as conditions of its business and its operating results, and those factors may affect its efforts to arrange additional financing on satisfactory terms. The Board of Directors works continuously to secure the business operation's need for financing.

Ultimovacs' financial risk exposures are described in more detail in the Annual Report 2022. No significant changes have occurred that affect these reported risks.



Financial review

Financial results

Ultimovacs does not yet generate revenues, as the Company is in a research and development phase.

Total payroll and payroll related expenses were higher in Q3 2023 (**MNOK 24.5**) compared to the same period in FY 2022 (MNOK 14.1). Regular salaries not including option expenses were higher in Q3 2023 compared to Q3 2022 as the third quarter in 2023 had one more full-time equivalent (FTE) employed compared to Q3 2022. However, option expenses and the social security tax accrual related to share options, which fluctuates with the company share price, was MNOK 9.6 higher in Q3 2023 compared to Q3 2022, explaining most of the difference in the total payroll expenses these two quarters.

Other operating expenses (**MNOK 29.5** in Q3 2023 vs. MNOK 29.3 in Q3 2022) are primarily comprised of R&D related expenses. These expenses, including IP and external R&D expenses, offset by government grants, amounted to **MNOK 26.8** in Q3 2023 vs. MNOK 24.7 in Q3 2022. The main contributors to the increase in R&D expenses so far in FY 2023 were the INITIUM and NIPU trials, and chemistry, manufacturing and controls (CMC) activities.

Net financial items amounted to **MNOK -1.1** in Q3 2023, compared to MNOK 5.8 in Q3 2022. Financial items are primarily comprised of currency fluctuations from EUR at bank and the value of EUR currency future contracts swapped on a quarterly basis, in addition to interest gain from cash at bank accounts. In Q3 2023, the net financial loss is mainly comprised of MNOK 3.7 in interest from bank, loss of MNOK 1.4 from cash held in EUR and MNOK 3.7 in currency loss from the EUR currency future contracts.

Total loss for the Q3-23 period amounted to **MNOK 55.8**, compared to MNOK 38.3 in Q3-22. Total loss YTD-23 amounted to **MNOK 133.3** compared to a loss of MNOK 97.3 YTD-22.

Financial position

Total assets per 30 September 2023 were **MNOK 387.7**, a decrease of MNOK 121.9 from 31 December 2022, primarily as a consequence of negative operational cashflow. The Company has entered into EUR swap contracts to mitigate the foreign exchange risk related to expected future costs in ongoing projects. By the end of the quarter, the EUR swaps amounted to MEUR 9.2, and **MNOK 0.2** of 'Receivables and prepayments' are related to the fair value of these EUR swap contracts by the end of the quarter.

Total liabilities as of 30 September 2022 amounted to **MNOK 46.1**, of which MNOK 13.2 are non-current.



Total equity equaled **MNOK 328.4** as of 30 September 2023. Total equity has, since year-end 2022, been decreased by the period's operating loss and currency translation, amounting to **MNOK 132.1**, and has in addition been increased by the recognition of share-based payments/stock options of **MNOK 11.1**.

Cash flow

The total net decrease in cash and cash equivalents in Q3 2023, not including currency effects, was **MNOK 37.6**, which is primarily related to net negative cash-flow from operations amounting to **MNOK 40.7**.

Total cash and cash equivalents were **MNOK 300.3** per September 2023, of which MNOK 12.9 (**MEUR 1.1**) is held on EUR account.

Key financials

NOK (000) Unaudited	Q3-23	Q3-22	YTD-23	YTD-22	FY22
Total revenues	-	-	-	-	-
Total operating expenses	54 705	44 055	156 109	111 376	183 631
Operating profit (loss)	(54 705)	(44 055)	(156 109)	(111 376)	(183 631)
Profit (loss) for the period	(55 822)	(38 303)	(133 308)	(97 279)	(167 792)
Diluted and undiluted earnings / (loss) per share (NOK)	(1.6)	(1.1)	(3.9)	(2.8)	(4.9)
Net increase / (decrease) in cash and cash equivalents	(37 583)	(29 726)	(138 721)	(113 289)	(155 426)
Cash and cash equivalents at end of period	300 273	469 063	425 309	469 063	425 309
	NOK/EUR - 11.2	535			
Cash and cash equivalents at end of period - EUR (000)	26 683				

19

The Board of Directors and CEO of Ultimovacs ASA

Oslo, 7 November 2023

Jónas Einarsson Chairman of the Board (Sign.)

Henrik Schüssler Board member (Sign.) Kari Grønås Board member (Sign.)

Ketil Fjerdingen Board member (Sign.)

Haakon Stenrød Board member (Sign.) Eva S. Dugstad Board member (Sign.)

Leiv Askvig Board member (Sign.)

Carlos de Sousa CEO (Sign.)



Aitana Peire Board member

(Sign.)

Interim condensed consolidated statement of comprehensive income

NOK (000) Unaudited	Note	Q3-23	Q3-22	YTD-23	YTD-22	FY22
Other operating income		-	-	-	-	-
Total revenues		-	-	-	-	-
Payroll and payroll related expenses	3, 5	24 518	14 112	49 879	39 836	71 466
Depreciation and amortization		691	678	2 082	1 954	2 648
Other operating expenses	4, 5	29 496	29 264	104 148	69 586	109 517
Total operating expenses		54 705	44 055	156 109	111 376	183 631
Operating profit (loss)		(54 705)	(44 055)	(156 109)	(111 376)	(183 631)
Financial income		4 229	6 158	11 085	15 362	17 375
Financial expenses		5 346	406	(11 717)	1 265	1 536
Net financial items		(1 117)	5 752	22 801	14 097	15 839
Profit (loss) before tax		(55 822)	(38 303)	(133 308)	(97 279)	(167 792)
Income tax		-	-	-	-	-
Profit (loss) for the period		(55 822)	(38 303)	(133 308)	(97 279)	(167 792)
Other comprehensive income (loss) - Currency tr	anslation	(2 158)	(102)	1 234	(289)	(1 889)
Total comprehensive income (loss) for the	period	(57 980)	(38 405)	(132 074)	(97 568)	(169 681)
Diluted and undiluted earnings/(loss) pr share (N	OK) 6	(1.6)	(1.1)	(3.9)	(2.8)	(4.9)

Interim condensed consolidated statement of financial position

NOK (000) Unaudited	Note	30 Sep 2023	30 Sep 2022	31 Dec 2022
ASSETS				
Goodwill		10 948	10 993	10 701
Licenses		53 148	53 362	51 944
Patents		5 218	5 973	5 784
Property, plant and equipment		140	265	220
Right to use asset	11	4 032	1 729	5 444
Total non-current assets		73 487	72 322	74 093
Receivables and prepayments	7	13 983	8 206	10 270
Bank deposits		300 273	469 063	425 309
Current assets		314 256	477 269	435 579
TOTAL ASSETS		387 742	549 592	509 672
EQUITY				
Share capital		3 440	3 427	3 440
Share premium		1 076 308	1 072 212	1 076 308
Total paid-in equity		1 079 747	1 075 639	1 079 747
Accumulated losses		(805 421)	(601 600)	(672 113)
Other equity		51 837	36 449	40 752
Translation differences		2 198	2 564	964
TOTAL EQUITY	6, 9	328 360	513 051	449 350
LIABILITIES				
Lease liability	11	2 297	935	3 713
Deferred tax		10 948	10 993	10 701
Non-current liabilities		13 245	11 928	14 414
Accounts payable		6 404	10 527	7 655
Lease liability	11	1 872	861	1 767
Other current liabilities		37 861	13 224	36 485
Current liabilities	8	46 137	24 613	45 907
TOTAL LIABILITIES		59 382	36 541	60 321
TOTAL EQUITY AND LIABILITIES		387 742	549 592	509 672

Interim condensed consolidated statement of changes in equity

NOK (000) Unaudited	Share Capital	Share Premium	Accum. Iosses	Other equity	Transl. differenc.	Total equity
Balance at 1 Jan 2022	3 422	1 070 841	(504 321)	20 358	2 853	593 152
Loss for the period	-	-	(97 279)	-	-	(97 279)
Issue of ordinary shares	4	1 371	-	-	-	1 375
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	16 092	-	16 092
Translation differences	-	-	-	-	(289)	(289)
Balance at 30 Sep 2022	3 427	1 072 212	(601 600)	36 449	2 564	513 051
Balance at 1 Jan 2023	3 440	1 076 308	(672 113)	40 752	964	449 350
Loss for the period	-	-	(133 308)	-	-	(133 308)
Issue of ordinary shares	-	-	-	-	-	-
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	11 084	-	11 084
Translation differences	-	-	-	-	1 234	1 234
Balance at 30 Sep 2023	3 440	1 076 308	(805 421)	51 837	2 198	328 360

Interim condensed consolidated statement of cash flow

NOK (000) Unaudited	Q3-23	Q3-22	YTD-23	YTD-22	FY22
Loss before tax	(55 822)	(38 303)	(133 308)	(97 279)	(167 792)
Non-cash adjustments			-		
Depreciation and amortization	691	678	2 082	1 954	2 648
Interest received incl. investing activities	(3 709)	(1 680)	(10 377)	(4 584)	(8 887)
Net foreign exchange differences	4 735	(4 098)	(12 723)	(9 716)	(7 176)
Other finance expense	91	26	298	82	105
Share option expenses	3 172	4 303	11 084	16 092	20 395
Working capital adjustments:			-		
Changes in prepayments and other receivables	2 594	3 681	(4 598)	1 310	(1 859)
Changes in payables and other current liabilities	7 506	3 104	125	(25 517)	(5 129)
Net cash flow from operating activities	(40 743)	(32 289)	(147 417)	(117 659)	(167 695)
Purchase of property, plant and equipment	-	-	(25)	(195)	(195)
Interest received	3 696	1 680	10 331	4 584	8 887
Net cash flow used in investing activities	3 696	1 680	10 306	4 389	8 691
Proceeds from issuance of equity	-	1 375	-	1 375	5 484
Share issue cost	-	-	-	-	-
Interest paid	(91)	26	(298)	(30)	(105)
Payment of lease liability	(446)	(518)	(1 312)	(1 364)	(1 802)
Net cash flow from financing activities	(537)	883	(1 610)	(20)	3 577
Net change in cash and cash equivalents	(37 583)	(29 726)	(138 721)	(113 289)	(155 426)
Effect of change in exchange rate	(6 248)	12 452	13 684	8 184	6 567
Cash and cash equivalents at beginning of period	344 104	486 338	425 309	574 168	574 168
Cash and cash equivalents at end of period	300 273	469 063	300 273	469 063	425 309



Notes

1. General information

Ultimovacs ASA (the Company or Ultimovacs) and its subsidiary (together the Group) is a clinical-stage biotechnology Group developing novel immunotherapies against cancer. The Company is a public limited liability company listed on the Oslo Stock Exchange in Norway.

Ultimovacs is headquartered at the Oslo Cancer Cluster Innovation Park in Oslo, Norway, and is an active member of the Oslo Cancer Cluster and The Life Science Cluster.

2. Basis for preparations and accounting principles

The Group's presentation currency is NOK (Norwegian kroner).

These interim condensed financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. The accounting policies applied in the preparation of these financial statements are consistent with those followed in connection with the Company's 2022 financial statements. These condensed interim financial statements should therefore be read in conjunction with the 2022 financial statements.

The Group uses derivative financial instruments to hedge its risks associated with foreign exchange rates. Derivatives are initially and subsequently measured at fair value. Derivatives are carried as assets when the fair value is positive and as liabilities when the fair value is negative. The gain/(loss) arising from changes in fair value of currency derivatives is presented as part of "Financial income/expenses" in the consolidated statement of comprehensive income.

The Group does not have any derivatives that are used for hedge accounting.

The consolidated financial statements comprise the financial statements of Ultimovacs ASA and its 100% owned subsidiary, Ultimovacs AB, as of the reporting date.

These interim financial statements were approved for issue by the Board of Directors on 7 November 2023. The figures in the statements have not been audited.



3. Personnel expenses

Personnel expenses

NOK (000)	Q3-23	Q3-22	YTD-23	YTD-22	FY22
Salaries	11 537	10 243	31 432	27 781	38 215
Social security tax	2 164	2 886	5 855	6 056	9 142
Social security tax related to options	6 862	(2 187)	(721)	(9 102)	2 016
Pension expenses	959	741	2 741	2 163	2 818
Share-based compensation	3 172	4 303	11 084	16 092	20 395
Other personnel expenses	91	109	183	486	702
Government grants	(267)	(1 983)	(694)	(3 639)	(1 822)
Total personnel expenses	24 518	14 112	49 879	39 836	71 466
Number of FTEs at end of period	24	23	24	23	23

Please refer to note 10 for additional information regarding the share-based compensation.

4. Operating expenses

The Group's programs are in clinical and preclinical development and the majority of the Group's costs are related to R&D. These costs are expensed in the statement of comprehensive income.

Operating expenses

NOK (000)	Q3-23	Q3-22	YTD-23	YTD-22	FY22
External R&D expenses	26 422	24 176	89 534	54 216	95 175
Clinical studies	19 174	10 349	47 249	30 205	66 772
Manufacturing costs	5 273	11750	34 802	17 899	19 899
Other R&D expenses	1975	2 077	7 483	6 112	8 504
IP expenses	1 210	857	3 390	2 433	3 571
Rent, office and infrastructure	971	921	3 622	3 069	4 221
Accounting, audit, legal, consulting	788	2 699	4 947	7 421	9 246
Other operating expenses	906	902	4 097	3 357	5 020
Government grants	(801)	(291)	(1 442)	(909)	(7 717)
Total other operating expenses	29 496	29 264	104 148	69 586	109 517

5. Government grants

The following government grants have been received and recognized in the statement of profit and loss as a reduction of operating expenses and personnel costs.

Government grants

NOK (000)	Q3-23	Q3-22	YTD-23	YTD-22	FY22
Skattefunn from The Research Council of Norw ay (RCN)	-	-	-		4 750
Innovation Norw ay	-	-	-		-
Innovation Project grant from the RCN	1 068	2 076	2 136	4 152	4 194
Other grants	-	198	-	396	594
Total government grants	1 068	2 274	2 136	4 548	9 538

Please refer to note 3 and 4 for information on how the government grants have been attributed to (i.e., deducted from) personnel expenses and other operating expenses.

6. Earnings per share

The basic earnings per share are calculated as the ratio of the profit/loss for the period divided by the weighted average number of ordinary shares outstanding.

Earnings per share

NOK (000)	Q3-23	Q3-22	YTD-23	YTD-22	FY22
Loss for the period	(55 822)	(38 303)	(133 308)	(97 279)	(167 792)
Average number of shares during the period ('000)	34 396	34 236	34 396	34 227	34 247
Earnings/loss per share (NOK)	(1.6)	(1.1)	(3.9)	(2.8)	(4.9)

The share options issued to employees as a part of the Ultimovacs Employee Share Option Program have a potential dilutive effect on earnings per share. No dilutive effect has been recognized as potential ordinary shares only shall be treated as dilutive if their conversion to ordinary shares would decrease earnings per share or increase loss per share from continuing operations. As the Group is currently loss-making, an increase in the average number of shares would have anti-dilutive effects. Diluted and basic (undiluted) earnings per share are therefore the same.

Please see note 10 for more information regarding the option program.



7. Current assets

Receivables and prepayments

	30 Sep	30 Sep	31 Dec
NOK (000)	2023	2022	2022
Government grants	-	-	4 990
Prepayments	1 507	1 001	2 916
Financial instruments	199	2 189	1 083
Other receivables	12 277	5 016	1 280
Total receivables and prepayments	13 983	8 206	10 270

8. Current liabilities

Current liabilities

	30 Sep	30 Sep	31 Dec
NOK (000)	2023	2022	2022
Accounts payable	6 404	10 527	7 655
Public duties payable	2 948	1 974	3 698
Public duties payable related to options	14 182	3 787	14 904
Lease liability	1 872	861	1 767
Other current liabilities	20 731	7 464	17 883
Total current liabilities	46 137	24 613	45 907

9. Shareholder information

The share capital as of 30 September 2023 was NOK 3,439,646.1, with 34,396,461 ordinary shares, all with equal voting rights and a nominal value of NOK 0.10 per share. As of 30 September 2023, Ultimovacs ASA has more than 5,000 shareholders and the 20 largest shareholders as of this date are listed below:

Share register as per 30 September 2023

	# of	
Shareholder	shares	Share-%
Gjelsten Holding AS	6 495 866	18.9 %
Canica AS	2 705 957	7.9 %
Watrium AS	1 780 575	5.2 %
Radforsk Investeringsstiftelse	1 519 263	4.4 %
Inven2 AS	1 424 127	4.1 %
Langøya Invest AS	1 396 006	4.1 %
Folketrygdfondet	1 201 000	3.5 %
Helene Sundt AS	965 802	2.8 %
CGS Holding AS	882 132	2.6 %
Sundt AS	803 321	2.3 %
Danske Invest Norge Vekst	710 093	2.1 %
Stavanger Forvaltning AS	578 104	1.7 %
Prieta AS	533 988	1.6 %
Verdipapirfondet Nordea Avkastning	448 573	1.3 %
SEB Prime Solutions Sissener Canopus	369 717	1.1 %
Myrlid As	260 000	0.8 %
Wiarom AS	250 000	0.7 %
Verdipapirfondet Nordea Kapital	246 178	0.7 %
Gade, Leif Johan	229 000	0.7 %
Sw edbank AB	224 132	0.7 %
20 Largest shareholders	23 023 834	66.9 [%]
Other shareholders	11 372 627	33.1%
Total	34 396 461	100.0%

10. Share-based payments

Share option program

The Ultimovacs Employee Share Option Program was introduced in June 2019. The share option program is groupwide and includes all employees. At the Annual General Meeting held on 20 April 2023, the Board was authorized to increase the Company's share capital in connection with the share incentive arrangement by up to NOK 343,964.6. The authorization is valid until the next ordinary General Meeting in 2024. After the distribution of 160,000 new options on 21 April 2023, a total of 2,298,885 share options have been granted, corresponding to 6.68% of the outstanding number of shares in the Company.

Each option gives the right to acquire one share in the Company and is granted without consideration. Pursuant to the vesting schedule, 25% of the options will vest one year after the day of grant, 25% of

the options will vest two years after the day of grant and the remaining 50% will vest three years after the day of grant. The options granted in 2020 to the CEO, Carlos de Sousa, will vest with 33.33% one year following the grant date, 33.33% after two years, and the remaining 33.34% on the third anniversary following the grant date. Vesting is dependent on the option holder still being employed in the Company.

The exercise price was NOK 31.25 for the options granted in 2019, NOK 39.15 for the options granted in 2020, NOK 61.99 for the options granted in 2021, NOK 83.46 for the options granted in 2022 and NOK 128.61 for the options granted in 2023. Options that are not exercised within 7 years from the date of grant will lapse and become void.

The Ultimovacs Employee Share Options' fair value is calculated according to the IFRS-2 regulations. As stated in IFRS-2 Appendix B §B5, the Black-Scholes-Merton Option Pricing Model ("B&S Model") may be used to estimate the fair value of employee share options, which is therefore used to estimate the fair value of the Ultimovacs Employee Share Options. The model uses the following parameters: the exercise price, the current price of the underlying shares, the life of the option, the expected volatility of the share price, the dividends expected on the shares, and the risk-free interest rate for the life of the option.

Equity-settled share-based payments are measured at the fair value of the equity instruments at the grant date. The cost of equity-settled transactions is recognized in payroll and other payroll related expenses, together with a corresponding increase in equity over the period in which the service and, where applicable, the performance conditions are fulfilled (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest. The expense or credit in the statement of profit or loss and other comprehensive income for a period represents the movement in cumulative expense recognized as of the beginning and end of that period.

	Number of share options	Weighted average strike
Outstanding at opening balance 1 January 2023	2 138 885	54.55
Granted	160 000	128.61
Exercised	-	-
Forfeited	-	-
Outstanding at closing balance 30 September 2023	2 298 885	59.70
Vested at closing balance	1 478 881	46.00

Movement of share options

The total IFRS cost recognized for the option program in Q3 2023 is MNOK 3.2, and the accrual for social security tax related to the options is MNOK 6.9. YTD 2023, the total IFRS costs are MNOK 11.1, and the reversal of in social security accruals is MNOK 0.7.



11. IFRS 16 – rental contracts

The agreements classified as operating leases are the rental agreement for office premises in Oslo with 3 years left of the rental contract as of 31 December 2022, and four car-leasing contracts. The weighted average discount rate applied is 8.3%. Please see the 2022 Annual report for more information.

12. Events after the balance sheet date

No events with significant accounting effect have occurred after the balance sheet date.

Glossary

Words/terms	Description
General/basic terms	
UV1	UV1 is Ultimovacs' synthetic peptide vaccine
Peptides	Peptides are short or long-chains of amino acids, and amino acids are the
	building blocks of protein.
Adjuvant	A medical substance used to enhance the effect of another medical
	substance.
GM-CSF	"Granulocyte-macrophage colony-stimulating factor". Ultimovacs uses GM-
	CSF as adjuvant together with UV1 to strengthen the ability of UV1 to
	stimulate the immune system.
Immune checkpoint	Medicines that "takes the brakes off the immune system". The immune
inhibitors	system has brakes necessary to balance a normal immune response. The
	downside to these brakes is that it makes it easier for a tumor to grow because
	the immune system becomes less able to fight the tumor. By "blocking the
	brakes", the immune system becomes more potent in killing tumor cells. PD-
	1 / PDL-1 inhibitors (e.g., pembrolizumab, cemiplimab and nivolumab) and
	The activity of the immune system against foreign substances (antigens)
immune response	The activity of the immune system against foreign substances (antigens).
Investigational New	The United States Food and Drug Administration's Investigational New Drug
	(IND) program is the means by which a biopharmaceutical company obtains
	nermission to start human clinical trials and to shin an experimental drug
	across state lines (usually to clinical investigators) before a marketing
	application for the drug has been approved. Similar procedures are followed
	in the European Union, Japan, and Canada.
CTLA-4	A protein found on T cells (a type of immune cell) that helps balancing a
	normal immune response. The balance is needed to avoid collateral damage
	of normal cells. When CTLA-4 is bound to another protein called B7, it helps
	keep T cells from multiplying and killing other cells, including cancer cells.
	Ipilimumab works by making it difficult for the CTLA-4 to bind to B7.
	Ipilimumab was the first checkpoint inhibitor to reach the market.
PARP inhibitor	PARP inhibitors are a group of pharmacological inhibitors of the enzyme poly
	ADP ribose polymerase. They are developed for multiple indications, including
	the treatment of heritable cancers. Several forms of cancer are more
	dependent on PARP than regular cells, making PARP an attractive target for
	cancer therapy.
PD-1 / PD-L1	A protein found on T cells (a type of immune cell) that helps balancing a
	normal immune response. The balance is needed to avoid collateral damage
	of normal cells. When PD-1 is bound to another protein called PD-L1, it helps
	keep T cells from killing other cells, including cancer cells. Some anticancer
	drugs, called immune checkpoint inhibitors, are used to block PD-1 or PD-L1.
	When this checkpoint is blocked, the "brakes" on the immune system are
	released and the ability of T cells to kill cancer cells is increased.
Telomere	To prevent the loss of genes as chromosome ends wear down, the tips of
	eukaryotic chromosomes have specialized DNA "caps" called telomeres.



Telomerase	Some cells have the ability to reverse telomere shortening by expressing
	human telomerase (hTERT), an enzyme that extends the telomeres of
	chromosomes. Telomerase is expressed at a high level in 85-90% of human
	tumors. UV1 uses telomerase (hTERT) as an immune therapy target.
Tetanus	Tetanus is a serious illness contracted through exposure to the spores of the
	bacterium, Clostridium tetani, which live in soil, saliva, dust, and manure. The
	bacteria can enter the body through deep cuts, wounds or burns, affecting
	the nervous system. The infection leads to painful muscle contractions,
	particularly of the jaw and neck muscle, and is commonly known as "lockjaw".
	Tetanus vaccination protects against the disease.
Checkpoint and PARP	
inhibitors	
Ipilimumab	CTLA-4 checkpoint inhibitor from BMS (Bristol-Myers Squibb)
Nivolumab	PD-1 checkpoint inhibitor from BMS (Bristol-Myers Squibb)
Pembrolizumab	PD-1 checkpoint inhibitor from Merck (Merck & Co. Inc.)
Durvalumab	PD-L1 checkpoint inhibitor from AstraZeneca
Cemiplimab	PD-L1 checkpoint inhibitor from Regeneron Pharmaceuticals
Olaparib	PARP inhibitor from AstraZeneca
Clinical trial terms	
CR	Complete response (The disappearance of all signs of cancer in response to
	treatment. Also called complete remission.)
PR	Partial response (A decrease in the size of a tumor, or in the extent of cancer
	in the body, in response to treatment. Also called partial remission.)
SD	Stable disease (Cancer that is neither decreasing nor increasing in extent or
	severity.)
PD	Progressive disease (Cancer that is growing, spreading, or getting worse.)
ORR	Objective response rate = CR + PR
DOR	Duration of response (The length of time that a tumor continues to respond
	to treatment without the cancer growing or spreading.)
OS	Overall survival (The length of time from either the date of diagnosis or the
	start of treatment for a disease, such as cancer, that patients diagnosed with
	the disease are still alive. In a clinical trial, measuring the overall survival is
	one way to see how well a new treatment works.)
PFS	Progression-free survival (The length of time during and after the treatment
	of a disease, such as cancer, that a patient lives with the disease but it does
	not get worse. In a clinical trial, measuring the progression-free survival is one
	way to see how well a new treatment works.)
mOS	Median overall survival means (The length of time during and after the
	treatment of a disease, such as cancer, that half of the patients in a group of
	patients diagnosed with the disease are still alive.)
mPFS	Median progression-free survival (The length of time during and after
	the treatment of a disease, such as cancer, that a patient lives with the
	disease but it does not get worse. In a clinical trial, measuring the
	progression-free survival is one way to see how well a new treatment
	works.)
Medical terms	
Intradermal	In order to initiate an immune response, a vaccine must be taken up by
	antigen presenting cells (dendritic cells). UV1 is administered via the

E



	intradermal route, i.e., injection in the dermis, one of the layers of the skin.
	This layer, underneath the epidermis, is highly vascularized and contains a
	large number of immune cells, mainly dermal dendritic cells.
Biopsy	A piece of tissue, normal or pathological removed from the body for the
	purpose of examination.
Metastasis /	The development of malignant growths at a distance from a primary site
Metastatic cancer	of cancer / Metastatic cancer is cancer that spreads from its site of origin
	to another part of the body.
SAE	A serious adverse event (SAE) in human drug trials is defined as any
	untoward medical occurrence that at any dose
	1. results in death,
	2. is life-threatening
	3. requires inpatient hospitalization or causes prolongation of
	existing hospitalization
	4. results in persistent or significant disability/incapacity
	5. is a congenital anomaly/birth defect, or
	6. requires intervention to prevent permanent impairment or
	damage.
	The term "life-threatening" in the definition of "serious" refers to an
	event in which the patient was at risk of death at the time of the event;
	it does not refer to an event which hypothetically might have caused
	death if it were more severe. Adverse events are further defined as "Any
	untoward medical occurrence in a patient or clinical investigation
	subject administered a pharmaceutical product and which does not
	necessarily have to have a causal relationship with this treatment."
PSA	Prostate-specific antigen (PSA) is an enzyme (protein) important for
	reproduction. PSA is present in small quantities in the serum of men with
	healthy prostates but is often elevated in the presence of prostate
	cancer or other prostate disorders.



Disclaimer

The information in this presentation has been prepared by Ultimovacs ASA ('Ultimovacs' or the 'Company').

The presentation is based on the economic, regulatory, market and other conditions as in effect on the date hereof and may contain certain forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect Ultimovacs' current expectations and assumptions as to future events and circumstances that may not prove accurate. It should be understood that subsequent developments may affect the information contained in this document, which neither Ultimovacs nor its advisors are under an obligation to update, revise or affirm. Important factors that could cause actual results to differ materially from those expectations include, among others, economic and market conditions in the geographic areas and industries that are or will be major markets for the Company's businesses, changes in governmental regulations, interest rates, fluctuations in currency exchange rates and such other factors.

This presentation has not been reviewed or approved by any regulatory authority or stock exchange.

Contact us





ir@ultimovacs.com



About Ultimovacs

Ultimovacs is a clinical-stage biotech company. It seeks to become a leader in developing immune-stimulatory vaccines to treat a broad range of cancers. Ultimovacs' lead universal cancer vaccine candidate, UV1, leverages the high prevalence of the human telomerase (hTERT) to be effective across the dynamic stages of the tumor's growth and its microenvironment. By directing the immune system to hTERT antigens that are present in 85-90% of all cancers, UV1 drives CD4 helper T cells to the tumor with the goal of activating an immune system cascade to increase anti-tumor responses.

Ultimovacs' strategy is to clinically demonstrate UV1's impact in many cancer types and in combination with other immunotherapies. The Company will expand its pipeline using its novel TET-platform, which is a next-generation vaccine technology that could generate multiple vaccine candidates designed to achieve increased T cell responses to a broad range of target antigens and cancers.

Ultimovacs was established in 2011 and is a public limited liability company listed on the Euronext Oslo Stock Exchange in Norway. The Company and its proprietary technology are based on preclinical and clinical research on immunotherapies conducted at the Oslo University Hospital. Ultimovacs is headquartered at the Oslo Cancer Cluster Innovation Park in Oslo, Norway, and also has an office in Uppsala, Sweden. Ultimovacs is an active member of the Oslo Cancer Cluster and the Life Science Cluster.

