

# 2024

## Second Quarter Report

Ultimovacs ASA



## Introduction

Ultimovacs is a clinical-stage biotechnology company developing novel immunotherapies against cancer. The product candidate UV1 is an off-the-shelf therapeutic cancer vaccine designed to enhance the benefits of immunotherapy and improve cancer treatment efficacy for patients. UV1 triggers an immune response against the shared cancer antigen telomerase, a target present in 85-90% of all cancer indications across disease stages.

Ultimovacs is investigating the safety and efficacy of UV1 in a wide-ranging clinical development program including various cancer indications and different immunotherapy combinations. The ongoing Phase II program comprises five randomized clinical trials in melanoma, mesothelioma, head and neck cancer, ovarian cancer, and non-small cell lung cancer. More than 750 patients in the U.S., Europe, and Australia are being enrolled in all Phase I and Phase II trials in the current program.

More than 300 patients have already received treatment with UV1 in clinical trials, and no toxicity or safety concerns have been reported to date.

Furthermore, Ultimovacs is developing a novel conjugation technology, initially formed to support the expansion of our vaccine pipeline. With the objective of driving value and future pipeline growth, this flexible conjugation technology has the potential to be broadly applicable to a variety of therapeutic modalities, such as innovative drug conjugates with favorable pharmacological properties, and in multiple disease areas.

Ultimovacs is listed on the Euronext Oslo Stock Exchange (OSE:ULTI).

## Second Quarter 2024 Business Update

### Highlights

- Following the negative INITIUM result in March 2024, Ultimovacs implemented cash preservation initiatives during the second quarter of 2024 extending the anticipated cash runway to the fourth quarter of 2025, beyond the topline readout of the FOCUS trial and the anticipated topline readout of the DOVACC trial.
- In August 2024, Ultimovacs reported topline results from the Phase II FOCUS trial in head and neck cancer. The trial did not meet the primary endpoint of improved progression-free survival (PFS). Moreover, the data did not show improvement in overall survival. The safety profile was consistent between the two arms, confirming UV1's good safety profile. The key findings and analyses from the FOCUS trial will be submitted for publication in a peer-reviewed medical journal.
- Ultimovacs is currently conducting pre-clinical research on a novel drug conjugation platform. This flexible conjugation technology, initially formed to support the expansion of our vaccine pipeline, has broader potential applicability, including additional therapeutic modalities for multiple disease areas, such as innovative drug

conjugates with favorable pharmacological properties. Ultimovacs will provide an update on this technology platform to the market before the end of 2024.

## Clinical development update

### UV1 randomized controlled Phase II trials

- **FOCUS (head and neck cancer):** Evaluating pembrolizumab +/- UV1 vaccination as first-line treatment in metastatic or recurrent head and neck squamous cell carcinoma. The enrollment of 75 patients from ten hospitals in Germany was completed between August 2021 and July 2023. The topline readout was reported in August 2024. The trial did not meet the primary endpoint of improved progression-free survival (PFS). Moreover, the data did not show improvement in overall survival. The safety profile was consistent between the two arms, confirming the good safety and tolerability profile of UV1.
- **NIPU (mesothelioma):** Evaluating ipilimumab and nivolumab +/- UV1 vaccination as second-line treatment of patients with inoperable malignant pleural mesothelioma. Enrolled 118 patients from Australia, Spain and Scandinavia between June 2020 and January 2023. The study results were presented at the ESMO Congress in October 2023. An outline of the full trial results including subgroup analyses was published in the European Journal of Cancer in March 2024. The data indicate a benefit for the epithelioid subgroup, warranting further assessment of UV1 in future studies. Data from the NIPU trial with longer follow up time will be presented at ESMO 2024.
- **INITIUM (melanoma):** Evaluating ipilimumab and nivolumab +/- UV1 vaccination as first-line treatment in unresectable or metastatic malignant melanoma. Enrollment of 156 patients from 39 hospitals in the US, UK, Belgium and Norway, was completed between June 2020 and July 2022. Topline results were reported in March 2024. As previously reported, the trial did not meet the primary endpoint of improved progression-free survival (PFS). Moreover, the data did not show improvement in overall survival. The study results were presented at the ASCO Annual Meeting in June 2024.
- **INITIUM Supplementary Study:** Evaluating ipilimumab and nivolumab + UV1. Enrollment in the single arm supplementary study, which is not included in the INITIUM topline results, was completed in October 2023, with a total of 21 patients. The study will provide in-depth data on biologic activity and mode of action of the T cells induced by the UV1 vaccination on top of ipilimumab and nivolumab. The results are expected to be submitted for publication in a peer-reviewed medical journal by the end of this year.
- **DOVACC (ovarian cancer):** Evaluating olaparib and durvalumab +/- UV1 vs. olaparib alone as second-line maintenance treatment in high-grade BRCA negative ovarian cancer. As of date, 120 out of 184 patients have been enrolled in 35 participating

hospitals in ten European countries, in comparison to 99 patients as per the previous quarterly report. The readout is expected in the first half of 2025.

- **LUNGVAC (non-small cell lung cancer):** Evaluating PD-1 check point inhibitor +/- UV1 as first-line treatment of advanced or metastatic non-small cell lung cancer. As of date, 31 out of 138 patients have been enrolled in nine participating hospitals in Norway, up from 30 patients as of the previous quarterly report. The readout is expected in the first half of 2026.

#### UV1 Phase I trials

- **UV1-103 (melanoma):** on June 11, 2024, Ultimovacs ASA announced overall survival (OS) data from both cohorts in the UV1-103 Phase I clinical trial in malignant melanoma. All patients in the trial who were alive at 3 years remain alive at 4 years (69.5%) with a minimum follow-up period of 4 years (median 53.0 months). Following the readout of the 4-year survival data, the trial is concluded.

#### Financial update

- Following the negative INITIUM result in March 2024, Ultimovacs implemented cash preservation initiatives during the second quarter of 2024 extending the anticipated cash runway to the fourth quarter of 2025, beyond the anticipated topline readout of the DOVACC trial. Activity level prioritization and operational adjustments are implemented to sustain the financial runway, including a workforce reduction of approximately 40%. Based on current plans and forecast, the cash burn rate is estimated to be approximately 15 MNOK per quarter towards the end of 2025.
- Total operating expenses amounted to **MNOK 45.3** in Q2 2024, and **MNOK 74.0** YTD. Total loss was **MNOK 44.8** for the period and **MNOK 67.5** YTD.
- Net negative cash flow from operations was **MNOK 50.5** in Q2 2024, and net decrease in cash and cash equivalents, not including currency effects, was **MNOK 49.2** during Q2 2024. Cash and cash equivalents amounted to **MNOK 170.4** as per 30 June 2024.

#### Key financials

NOK (000) Unaudited	Q2-24	Q2-23	YTD-24	YTD-23	FY23
Total revenues	-	-	-	-	-
Total operating expenses	45 322	50 641	73 969	101 404	215 736
<b>Operating profit (loss)</b>	<b>(45 322)</b>	<b>(50 641)</b>	<b>(73 969)</b>	<b>(101 404)</b>	<b>(215 736)</b>
<b>Profit (loss) for the period</b>	<b>(44 767)</b>	<b>(43 375)</b>	<b>(67 519)</b>	<b>(77 486)</b>	<b>(189 239)</b>
Diluted and undiluted earnings / (loss) per share (NOK)	(1.3)	(1.3)	(2.0)	(2.3)	(5.5)
Net increase / (decrease) in cash and cash equivalents	(49 180)	(67 185)	(92 840)	(101 137)	(177 640)
<b>Cash and cash equivalents at end of period</b>	<b>170 403</b>	<b>344 104</b>	<b>170 403</b>	<b>344 104</b>	<b>266 559</b>
NOK/EUR - 11.3965					
<b>Cash and cash equivalents at end of period - EUR (000)</b>	<b>14 952</b>				

## CEO Statement

While the results from the INITIUM and FOCUS studies were disappointing for us and for patients with melanoma and head and neck cancer, they provided us with additional insights into UV1's clinical profile and confirmed its very benign safety profile. Analysis of data from these studies and the supplementary study, are important in improving our understanding of the vaccine's mechanism of action and its impact on tumors, which may in turn direct the further development strategy for UV1.



Medical progress for patients can only be achieved through rigorous clinical programs. Both positive and negative results collectively allow our industry to advance and create meaningful therapies that improve patients' lives. Our broad clinical development program was designed to analyze in which indications UV1 can provide the most value for patients. The NIPU study, for which we will present updated follow-up data at the upcoming ESMO 2024, has indicated that UV1 can improve the overall survival of patients with advanced mesothelioma. It highlights UV1's capacity to elicit meaningful clinical benefits and we still believe there is a potential in UV1 for patients. The cash preservation program we implemented earlier this year will allow us to reach another critical milestone in our broad Phase II program: the DOVACC readout in ovarian cancer that is expected during the first half of 2025.

As we enter the second half of 2024, we will further analyze the full FOCUS data together with our academic partners to submit the comprehensive data to a peer-reviewed publication.

We will also continue to develop a novel conjugation technology, initially formed to support the expansion of our vaccine pipeline. This platform technology may be broadly applicable to a variety of therapeutic modalities and multiple disease areas, particularly in the creation of innovative drug conjugates with favorable pharmacological properties. We are encouraged by the early data we have gathered to date and will continue the preclinical evaluation using the currently available financial resources. We look forward to providing an overview of the technology by the end of this year.

We remain steadfast in our commitment to generate value for our shareholders and make a meaningful impact on patients' lives. As we continue to assess the efficacy potential of UV1, we will further seek to realize the broad potential of our novel conjugation technology.

*Carlos de Sousa, Chief Executive Officer*

## Operational Review

### The UV1 cancer vaccine

UV1 is an off-the-shelf peptide-based therapeutic cancer vaccine. UV1 induces specific T cell responses against the nearly universal, shared cancer antigen telomerase (hTERT), expressed in 85-90% of cancer indications, across all stages of the disease. hTERT activation is considered one of the “hallmarks of cancer” due to its selective activation and essential role in continuous cell division. UV1 may potentially be used broadly across multiple 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 recognizing sequences of the hTERT enzyme. The T cells induced by UV1 have been shown to persist in patients for many years after vaccination, and T cell responses against hTERT correlates with improved survival in human cancer studies.

UV1 is being investigated across multiple cancer indications as combination treatment with checkpoint inhibitors, which require an ongoing T cell response for their mode of action. Considering the evolving immune-oncology and cancer vaccine landscape, it would be an attractive opportunity to investigate the use of UV1 in adjuvant and neo-adjuvant settings.

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 Oslo University Hospital. The observed clinical outcomes from these three trials served as basis for the clinical development of UV1 with respect to selection of dose, safety, immune response, and signals of clinical effect. In addition, Ultimovacs is the sponsor of the Phase I clinical study UV1-103 in the U.S. evaluating the safety and tolerability of treatment with UV1 as add-on to the PD-1 checkpoint inhibitor pembrolizumab in 30 patients with inoperable advanced or metastatic malignant melanoma.

UV1 is currently being evaluated in a program consisting of five Phase II randomized controlled clinical trials in various cancer types as add-on to different checkpoint inhibitors and immunotherapies. The full clinical program is enrolling more than 750 patients in Phase I and Phase II trials at approximately 100 hospitals in Europe, the U.S. and Australia. In total, more than 300 cancer patients have received treatment with UV1 in Phase I and Phase II trials so far. No safety concerns have been reported with the use of UV1 to date.

UV1 is designed as a convenient off-the-shelf product with a long shelf life, easy to use with simple intradermal administration. The use of the vaccine does not require pre-screening of patients or a sophisticated hospital infrastructure. These features extend the potential for a high level of accessibility to centers in rural and underserved communities, ensuring broad patient access to therapy.

A commercial-scale manufacturing process has been developed in collaboration with reputable manufacturers.

### The UV1 clinical development program

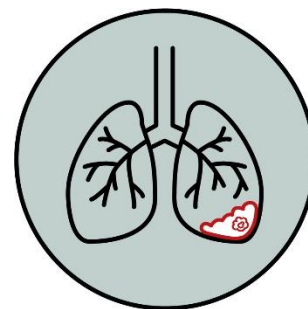
The UV1 clinical development program has been designed based on a hypothesis that the vaccine can be used broadly across multiple cancer types in different stages of the disease and in combination with different cancer treatments. Randomized controlled trials (RCTs) are the most definitive tool for this evaluation. Ultimovacs' strategy for the development of UV1 is to complete a randomized controlled Phase II program exploring diverse cancer types and immunotherapy combinations to investigate broadly how and where UV1 can demonstrate clinical improvement.

UV1 is evaluated in five Phase II RCTs in various cancer types in combination with different checkpoint inhibitors, strategically selected for broad evaluation of UV1's potential. Each trial provides valuable insights on UV1's efficacy in the individual indications, but with limited impact on other trials due to the diversity in disease characteristics and combination mechanisms across the program.

The program benefits from an extensive collaboration with academic research groups, and is conducted at hospitals across the US, Europe and Australia, supported by medical experts and leading pharmaceutical companies.

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

NIPU is an investigator-initiated randomized, open-label, multi-center 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 whether 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 118 patients from Australia, Denmark, Norway, Sweden, and Spain were enrolled in the NIPU trial between June 2020 and January 2023. 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 is progression-free survival (PFS). Secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety.

Malignant mesothelioma is a rare and aggressive cancer that occurs in the thin layer of tissue that surrounds the lungs and the 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 U.S. (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 results from the NIPU trial*

The NIPU results demonstrated 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 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.

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 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 group), at a median observation time of 17.3 months. This degree of improvement met the protocol's predefined threshold for statistical significance.

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

Epithelioid mesothelioma represents the most common type of mesothelioma, comprising up to 70% of all patients. Other types include sarcomatoid and biphasic (a mix of epithelioid and sarcomatoid). Since these mesothelioma subtypes have different prognoses and respond differently to treatments, they are well-characterized and their assessment a part of routine clinical practice. In the NIPU trial, investigators found that the survival benefit of UV1 was greatest among patients with epithelioid mesothelioma, with an investigator determined median PFS of 5.5 months vs. 2.9 months (2-sided logrank p value 0.005) as compared to 4.3 vs. 2.9 months (2-sided logrank p value 0.049) for the overall population (Haakensen et al. Eur J Cancer 2024). The data indicate that the epithelioid subgroup may be relevant for UV1 vaccination, warranting further assessment in future studies.



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.

The positive overall survival 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 an off-the-shelf cancer vaccine targeting a nearly universal, shared antigen.

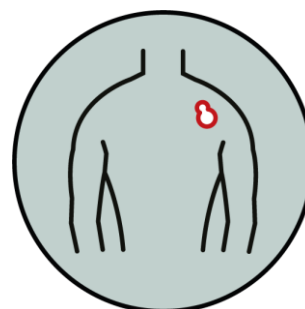
Data from the NIPU trial with longer follow up time will be presented at the ESMO Congress 2024.

#### *Publications from the NIPU trial*

- [“UV1 telomerase vaccine with ipilimumab and nivolumab as second line treatment for pleural mesothelioma – a phase II randomized trial”](#), European Journal of Cancer, March 1, 2024

#### **The INITIUM Phase II trial in metastatic malignant melanoma**

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



The 156 patients from 39 hospitals in the U.S., UK, Belgium, and Norway were enrolled in the INITIUM trial between June 2020 and July 2022. 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 is progression-free survival (PFS). Secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety.

The trial was originally designed to be analyzed when 70 patients experienced disease progression or death. However, due to the unexpectedly slow accumulation of events, the study protocol was 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 median follow-up time of approximately 24 months. The protocol amendment maintains the integrity of the study statistics without materially affecting the scientific value of the clinical trial.

#### *The results from the INITIUM trial*

In March 2024, Ultimovacs announced the topline results from the INITIUM trial. The primary endpoint of PFS was not met with a hazard ratio (HR) between the arms for PFS was 0.95 (95% CI 0.59-1.55, p value 0.845). Evaluation of secondary endpoints did not show difference in overall survival and objective response rate between the arms. UV1 maintained a positive

safety and tolerability profile. The results from the INITIUM trial were presented at the ASCO Annual Meeting in Chicago on June 1, 2024.

#### *The INITIUM supplementary study*

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 describe the mechanisms leading to improved clinical effects in patients treated with UV1 vaccination. The single-arm study was to provide in-depth data on biological activity and mode of action of the T cells induced by UV1. All patients received experimental treatment (combination of ipilimumab, nivolumab and UV1). Data collected from the supplementary study was not part of the primary and secondary endpoint analyses of INITIUM and did not affect the timeline for topline read-out. Six patients in the INITIUM study were also part of the INITIUM supplementary study, giving a total of 27 patients. The results are expected to be submitted by the end of this year for publication in a peer-reviewed medical journal.

#### **The FOCUS Phase II trial in head and neck cancer**

The FOCUS trial (**F**irst-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 in patients with metastatic or recurrent 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 enrollment of 75 patients from ten hospitals in Germany were completed in the FOCUS trial between August 2021 and August 2023. The patients are randomized 2-to-1 so that 50 patients will receive UV1 and pembrolizumab, and 25 patients will receive pembrolizumab alone.

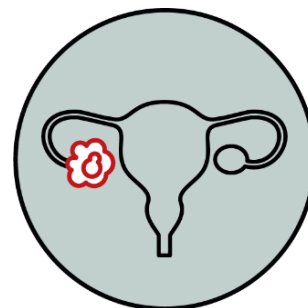
The primary endpoint in the FOCUS trial is progression-free survival (PFS) rate at 6 months after the last patient has been included. For the secondary endpoints, including overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety, patients will be followed until 12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

#### *The topline results from the FOCUS trial*

The Phase II trial did not meet its primary endpoint of improved progression-free survival (PFS). In addition, the data did not show clinical benefits on overall survival. The safety profile was consistent between the two arms and in-line with previous UV1 studies, confirming the good safety and tolerability profile for UV1.

**The DOVACC Phase II trial in relapsed ovarian cancer**

DOVACC (Durvalumab Olaparib VACCine) 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 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.



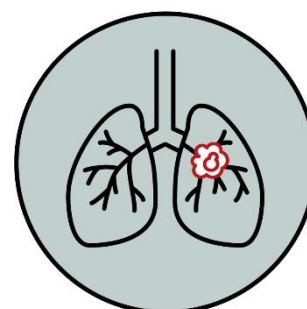
The first patient received treatment in the DOVACC trial in December 2021. Per Q2 2024 reporting date, a total of 120 out of 184 patients have been enrolled in DOVACC. The trial is conducted at approximately 35 hospitals in 10 European countries. Ultimovacs will provide the UV1 vaccine, and AstraZeneca will provide durvalumab and olaparib for the trial.

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. Topline results are expected to be reported in the first half of 2025.

**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.

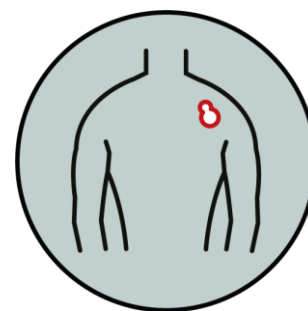


The LUNGVAC study is conducted at 9 clinical centers in Norway. The first patient received treatment in the LUNGVAC trial in October 2022. In December 2022, the Norwegian health authorities changed the reimbursement of checkpoint inhibitor in the indication from pembrolizumab to cemiplimab. Following this decision, the LUNGVAC study changed the PD-1 inhibitor in the study from pembrolizumab to cemiplimab. Half of the 138 patients in the trial will be treated with UV1 vaccination on top of the checkpoint inhibitor, and the other half will be treated with the checkpoint inhibitor alone. Per Q2 2024 reporting date, 28 patients have received treatment with cemiplimab +/- UV1, and three patients have received treatment with pembrolizumab +/- UV1.

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. Topline results are expected to be reported in the first half of 2026.

#### **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 first-line treatment in patients with unresectable or metastatic malignant melanoma. Thirty patients 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. Enrollment of 30 patients was completed as of August 2020.



UV1 has demonstrated a good safety profile in the study, with no unexpected safety issues related to UV1 observed. The objective response rate was 57%, with 33% achieving a complete response (disappearance of the tumors). The median progression-free survival was 18.9 months. The results from the trial, including biomarker analyses, have been published in [Clinical Cancer Research](#). In June 2024, Ultimovacs reported that all patients in the trial who were alive at 3 years remain alive at 4 years (69.5%) with a minimum follow-up period of 4 years (median 53.0 months). Following the readout of the 4-year survival data, the trial is now concluded.

### **Earlier UV1 Phase I trials**

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 (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, has a good safety profile, 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 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.

Results from these trials are published in peer-reviewed journals.

## **R&D pipeline**

### **The TET technology**

TET (Tetanus-Epitope Targeting) is Ultimovacs' patent protected vaccine adjuvant technology. TET ensures targeted delivery of both antigen and adjuvant signals to antigen presenting cells and is a novel strategy to effectively activate tumor specific T cells.

TET vaccines have the tumor antigen and the adjuvant signals, linked by a core, in one unit. The immunostimulatory effect is mediated by the tetanus-derived sequences. TET harness the immune activation function of immune complexes that is formed between the tetanus-derived parts of the vaccine and pre-existing antibodies against tetanus resulting from standard tetanus vaccination. Immune complex formation is known to be an effective way to initiate and amplify an immune response.

In Ultimovacs' TET vaccines, the tetanus sequences and the antigen are linked by use of an innovative conjugation technology. This conjugation technology allows for flexibility to incorporate a variety of antigens, and thereby tailoring vaccines to different types of cancer. The TET vaccine adjuvant technology may be basis for further extension of Ultimovacs' pipeline.

### *The TENDU Phase I clinical trial*

The TENDU trial is the first Phase I trial exploring the TET technology. In TENDU, the TET technology is used together with prostate-cancer-specific antigens. The trial's objective was to provide safety and immune activation data to support the further development of new vaccine solutions based on the TET technology.

The TENDU trial was conducted at Oslo University Hospital. A total of 12 patients were enrolled between February 2021 and December 2022. Three different doses of TENDU have

been investigated: 40mcg (3 patients), 400mcg (3 patients), and 960mcg (6 patients). All patients were followed for 6 months after the last treatment.

Ultimovacs announced results from the TENDU study in December 2023. The dose-escalation, first-in-human Phase I trial showed good safety and tolerability across all dose cohorts, meeting the primary endpoint. The data also included observations of immune activation with vaccine-specific T cell responses, meeting the secondary endpoint. No dose-limiting toxicities were observed, indicating a potential for increasing the dose of tetanus-based vaccines in future clinical studies. Further results from the study will be presented in a peer-reviewed publication.

### **Novel drug conjugation platform**

Ultimovacs has developed a novel conjugation technology, initially formed to support the expansion of our vaccine pipeline. This flexible conjugation technology has the potential to be broadly applicable to a variety of therapeutic modalities, such as innovative drug conjugates. The key benefits and potential favorable pharmacological properties of this technology could address central challenges currently facing the drug conjugation space. Ultimovacs is currently conducting pre-clinical research on this novel drug conjugation platform to drive value and future pipeline growth. Ultimovacs will provide an update to the market before the end of 2024.



## Patents and intellectual property

UV1 is a patented, proprietary technology owned by Ultimovacs. Recent patents cover UV1 peptide vaccine in combination with an anti-CTLA-4, anti-PD-1 or anti-PD-L1 antibody checkpoint inhibitor in the U.S., Europe, and Japan, until 2037 without considering potential extensions.

Ultimovacs is continuously working to obtain and maintain patent protection for the Company's technologies. An overview of the Company's published patents and patent application can be found in Ultimovacs Annual Report 2023 (page 28).

## Regulatory designations

### Mesothelioma

On February 19, 2024, Ultimovacs announced that the European Medicines Agency (EMA) granted Orphan Drug designation to the cancer vaccine UV1 for the treatment of mesothelioma. The designation was granted based on results from the Phase II clinical trial, NIPU evaluating UV1 added to ipilimumab and nivolumab treatment in patients with malignant pleural mesothelioma.

On February 5, 2024, Ultimovacs announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the vaccine UV1 in combination with ipilimumab and nivolumab for the treatment of patients with unresectable malignant pleural mesothelioma to improve overall survival.

In October 2023, Ultimovacs announced that the FDA has granted Orphan Drug designation (ODD) to the 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.

### Melanoma

In December 2021, Ultimovacs announced that UV1 received Orphan Drug Designation from the U.S. FDA for the treatment of stage IIB-IV melanoma. 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.

In October 2021, Ultimovacs announced that the U.S. Food and Drug Administration (FDA) had granted Fast Track designation to UV1 for the treatment of unresectable or metastatic melanoma, either as add-on therapy to pembrolizumab or as add-on therapy to ipilimumab.

## Organization and board

On August 7, 2024, deputy board member Ketil Fjerdings, resigned from his position on the Board of Directors.

During the second quarter, Ultimovacs implemented a cash preservation program with activity adjustments and operational prioritization to sustain the financial runway to the fourth quarter of 2025. The program includes a workforce reduction of approximately 40%, which is being made effective during the second half of 2024, mainly during the third quarter. The workforce reductions apply both to management and other employees.

On April 18, 2024, Ultimovacs ASA held its annual General Meeting. All the matters on the agenda were approved.

- The General Meeting re-elected the following persons as board members with an election term until the General Meeting in 2025: Jónas Einarsson (chair of the board), Kari Grønås (board member), Henrik Schüssler (board member) and Ketil Fjerdings (deputy board member).
- The General Meeting re-elected the following persons as members of the Nomination Committee with an election term until the General Meeting in 2025: Ole Kristian Hjelstuen (chair) and Hans Peter Bøhn.

*(also reported in the Q1-reporting)*

## Posters and presentations

- Data from the TENDU-101 study in patients relapsed following primary radical prostatectomy (NCT04701021) was presented in a poster at the 2024 American Association for Cancer Research (AACR), on April 5-10, 2024, in San Diego, CA.
- Data from the Phase II clinical trial INITIUM (NCT04382664) was presented in a poster session at the 2024 ASCO Annual Meeting, on June 1, 2024, in Chicago, IL & online. The poster presentation featured key findings and analyses after a minimum 18-month follow-up of the patients in the trial.



## Outlook

Ultimovacs' off-the-shelf therapeutic cancer vaccine UV1 triggers immune responses against telomerase, which is present in 85-90% of all cancer indications at all tumor stages. The essentially universal nature of the target supports a clinical development strategy designed to assess UV1's potential across multiple cancer types and treatment combinations.

Ultimovacs benefits from an extensive international collaboration with medical experts and academic research groups in cooperation with leading pharmaceutical companies. UV1 is being investigated in five randomized Phase II trials enrolling more than 670 patients in the US, Australia and Europe, to assess the efficacy and safety with UV1 added to different checkpoint inhibitors as treatment to a range of cancer types.

The clinical trial results are central to the data-driven clinical strategy, potentially establishing UV1's path to commercialization as an add-on therapy with checkpoint inhibitors for selected cancer indications. A successful outcome in a randomized controlled Phase II trial indicates a promising treatment that warrants further evaluation in Phase III trials to establish its efficacy, safety, and overall benefit compared to existing treatments.

While the results from the INITIUM trial in malignant melanoma and the FOCUS trial in head and neck cancer were disappointing, the NIPU trial in mesothelioma has shown a clinically meaningful improvement in overall survival for the patients treated with the UV1 vaccine in addition to ipilimumab and nivolumab. Ultimovacs anticipates the results from the DOVACC trial in ovarian cancer in H1 2025.

Ultimovacs has been granted patents in key markets covering the UV1 composition and its use in combination with anti-CTLA-4 and/or anti-PD(L)-1 checkpoint inhibitors. A commercial-scale manufacturing process has been developed in collaboration with reputable manufacturers.

Furthermore, Ultimovacs is developing a novel conjugation technology, initially formed to support the expansion of our vaccine pipeline. With the objective of driving value and future pipeline growth, this flexible conjugation technology has the potential to be broadly applicable to a variety of therapeutic modalities, such as innovative drug conjugates with favorable pharmacological properties, and in multiple disease areas.

Following the recent cash preservation initiatives, Ultimovacs expects that the current financial resources will sustain operations to Q4 2025 based on current programs and plans.

## Risks and uncertainties

As a clinical-stage biotechnology company, Ultimovacs is exposed to the same generic risks as other companies within this sector. The Company has not generated any revenues historically and is not expected to do so in the short term, unless a potential partnering agreement for UV1 provides early revenues. The Group's development, results of operations and operational progress have been, and will continue to be, affected by a range of factors, many of which are beyond the Group's control.

### Operational risks

Research and development up to approved registration is subject to considerable risk and is a capital-intensive process. The Company's cancer vaccine candidates and technology platforms are dependent on research and development and may be delayed and/or incur higher costs than currently expected.

### Product risk

Ultimovacs' product and technology candidates may not meet the anticipated efficacy requirements or safety standards, resulting in discontinuation of the development.

### Legislative and regulatory environment

Operations may be impacted negatively by changes or decisions regarding laws and regulations. Several regulatory factors have influenced and will likely continue to influence the Group's results of operations. The Group operates in a heavily regulated market and regulatory changes may affect the Group's ability to commence and perform clinical studies, include patients in clinical trials, protect intellectual property rights and obtain patents, obtain marketing authorization(s), market and sell potential products, operate within certain geographical areas/markets, produce the relevant products, in-license and out-license products and technology, etc.

### Competitive environment

Competitive cancer treatments and new/alternative therapies, either within immunoncology or within the broader space of oncology, may affect the Group's ability to commence and complete clinical trials, as well as the opportunity to apply for marketing authorization, and may influence future sales if marketing authorization is obtained. Competing pharmaceuticals 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. The amount and magnitude of clinical trials within different oncology areas in which the Group operates may influence the access to patients for clinical trials.

## Financial risks

The primary financial risks are financing risk and foreign exchange risks.

### Financing

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 Group monitors the liquidity risk through monthly rolling consolidated forecasts for result and cash flow, and the Board of Directors works continuously to secure the business operation's need for financing. The financing risk is higher after the negative results from the INITIUM trial.

### Foreign exchange rate exposure

Ultimovacs will conduct a large share of its clinical studies and other R&D activities outside of Norway and is therefore exposed to fluctuations in the exchange rate between NOK and several currencies, mainly EUR and USD. Further, production is conducted in France and Italy, and production costs are, therefore, exposed to the fluctuations of EUR against NOK. In addition, the Company has investment in foreign operations, whose net assets are exposed to currency translation risk. Operational currency exposure is constantly monitored and assessed. The Group has converted cash to EUR and entered into EUR swaps to mitigate the foreign exchange risk and to get a better predictability regarding future costs.

### Interest rate risk

The Group has no interest-bearing debt. Bank deposits are exposed to market fluctuations in interest rates, which impact the financial income.

Ultimovacs' financial risk exposures are described in more detail in note 17 in this financial statement.

## 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 Q2 2024 (**MNOK 13.7**) compared to the same period in FY 2023 (MNOK 4.4), primarily as a result of a reversal of a social security tax accrual related to share options in Q2 2023. Regular salaries not including option expenses were, however, slightly lower in Q2 2024 compared to Q2 2023 as one more full-time equivalent (FTE) was employed in Q2 2023 compared to Q2 2024.

In YTD 2024 the payroll and payroll related expenses were lower (**MNOK 11.3**) than in YTD 2023 (MNOK 25.4), primarily due to differences in reversals of a social security tax accrual related to share options. Due to the significant drop in the company share price in Q1 2024, the social security tax accrual related to share options, which fluctuates with the Company share price, was fully reversed, resulting in a positive accounting effect of MNOK 21.0 in YTD 2024. This accounting element explains most of the difference in these two YTD periods.

Other operating expenses (**MNOK 30.9** in Q2 2024 vs. MNOK 45.6 in Q2 2023) are primarily comprised of R&D related expenses. These expenses, including IP and external R&D expenses, offset by government grants, amounted to **MNOK 26.7** in Q2 2024 vs. MNOK 40.9 in Q2 2023. The main contributors to R&D expenses so far in FY 2024 are the INITIUM and DOVACC trials, and chemistry, manufacturing and controls (CMC) activities.

Net financial items amounted to **MNOK 0.6** in Q2 2024, compared to MNOK 7.3 in Q2 2023. 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 Q2 2024, the net financial income is comprised primarily of MNOK 1.9 in interest from bank deposits offset by MNOK 1.3 in net currency losses.

Total loss for the Q2 2024 period amounted to **MNOK 44.8**, compared to MNOK 43.4 in Q2 2023. Total loss YTD-24 amounted to **MNOK 67.5** compared to a loss of MNOK 77.5 YTD-23.

### Financial position

Total assets per 30 June 2024 were **MNOK 252.8**, a decrease of MNOK 96.2 from 31 December 2023, primarily as a consequence of negative operational cashflow.

Total liabilities as of 30 June 2024 amounted to **MNOK 35.4**, of which MNOK 12.6 are non-current. 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 3.0, and **tNOK 7** of 'Current liabilities' are related to the fair value of these EUR swap contracts by the end of the quarter.

Total equity equaled **MNOK 217.5** as of 30 June 2024. Total equity has, since year-end 2023, been decreased by the period's operating loss and currency translation, amounting to **MNOK 68.5**, and has in addition been increased by the recognition of share-based payments/stock options of **MNOK 6.6**.

## Cash flow

The total net decrease in cash and cash equivalents in Q2 2024, not including currency effects, was **MNOK 49.2**, which is primarily related to net negative cash-flow from operations amounting to **MNOK 50.5**.

Total cash and cash equivalents were **MNOK 170.4** per 30 June 2024, of which MNOK 19.9 (**MEUR 1.7**) is held on EUR account.

## Key financials

<b>NOK (000) Unaudited</b>	<b>Q2-24</b>	<b>Q2-23</b>	<b>YTD-24</b>	<b>YTD-23</b>	<b>FY23</b>
<b>Total revenues</b>	-	-	-	-	-
Total operating expenses	45 322	50 641	73 969	101 404	215 736
<b>Operating profit (loss)</b>	<b>(45 322)</b>	<b>(50 641)</b>	<b>(73 969)</b>	<b>(101 404)</b>	<b>(215 736)</b>
<b>Profit (loss) for the period</b>	<b>(44 767)</b>	<b>(43 375)</b>	<b>(67 519)</b>	<b>(77 486)</b>	<b>(189 239)</b>
Diluted and undiluted earnings / (loss) per share (NOK)	(1.3)	(1.3)	(2.0)	(2.3)	(5.5)
Net increase / (decrease) in cash and cash equivalents	(49 180)	(67 185)	(92 840)	(101 137)	(177 640)
<b>Cash and cash equivalents at end of period</b>	<b>170 403</b>	<b>344 104</b>	<b>170 403</b>	<b>344 104</b>	<b>266 559</b>
NOK/EUR - 11.3965					
<b>Cash and cash equivalents at end of period - EUR (000)</b>	<b>14 952</b>				

## Responsibility Statement

We confirm, to the best of our knowledge, that the unaudited condensed interim financial statement for the six months ended 30 June 2024 has been prepared in accordance with IAS 34 – Interim Financial Reporting, and gives a true and fair view of the Group’s assets, liabilities, financial position and profit or loss as a whole. We also confirm, to the best of our knowledge, that the interim management report includes a fair review of important events that have occurred during the first six months of the financial year and their impact on the condensed set of financial statements, a description of the principal risks and uncertainties for the remaining six months of the financial year, and major related party transactions.

### The Board of Directors and CEO of Ultimovacs ASA

Oslo, 20 August 2024

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Jónas Einarsson  
Chairman of the Board  
(Sign.)

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Kari Grønås  
Board member  
(Sign.)

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Henrik Schüssler  
Board member  
(Sign.)

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Carlos de Sousa  
CEO  
(Sign.)

## Interim condensed consolidated statement of comprehensive income

<b>NOK (000) Unaudited</b>	<b>Note</b>	<b>Q2-24</b>	<b>Q2-23</b>	<b>YTD-24</b>	<b>YTD-23</b>	<b>FY23</b>
Other operating income		-	-	-	-	-
<b>Total revenues</b>		-	-	-	-	-
Payroll and payroll related expenses	3, 5	13 708	4 359	11 283	25 361	75 130
Depreciation and amortization		713	691	1 427	1 391	2 768
Other operating expenses	4, 5	30 901	45 591	61 260	74 652	137 837
<b>Total operating expenses</b>		<b>45 322</b>	<b>50 641</b>	<b>73 969</b>	<b>101 404</b>	<b>215 736</b>
<b>Operating profit (loss)</b>		<b>(45 322)</b>	<b>(50 641)</b>	<b>(73 969)</b>	<b>(101 404)</b>	<b>(215 736)</b>
Financial income		822	8 326	7 080	25 511	29 640
Financial expenses		267	1 059	630	1 593	3 143
<b>Net financial items</b>		<b>555</b>	<b>7 266</b>	<b>6 450</b>	<b>23 918</b>	<b>26 497</b>
<b>Profit (loss) before tax</b>		<b>(44 767)</b>	<b>(43 375)</b>	<b>(67 519)</b>	<b>(77 486)</b>	<b>(189 239)</b>
Income tax		-	-	-	-	-
<b>Profit (loss) for the period</b>		<b>(44 767)</b>	<b>(43 375)</b>	<b>(67 519)</b>	<b>(77 486)</b>	<b>(189 239)</b>
Other comprehensive income (loss) - Currency translation		(443)	(308)	(1 013)	3 392	4 724
<b>Total comprehensive income (loss) for the period</b>		<b>(45 210)</b>	<b>(43 683)</b>	<b>(68 532)</b>	<b>(74 094)</b>	<b>(184 515)</b>
Diluted and undiluted earnings/(loss) per share(NOK)	6	(1.3)	(1.3)	(2.0)	(2.3)	(5.5)

## Interim condensed consolidated statement of financial position

<b>NOK (000) Unaudited</b>	<b>Note</b>	<b>30 Jun 2024</b>	<b>30 Jun 2023</b>	<b>31 Dec 2023</b>
<b>ASSETS</b>				
Goodwill		11 453	11 358	11 653
Licenses		55 599	55 137	56 566
Patents		4 653	5 407	5 030
Property, plant and equipment		77	172	114
Right to use asset	11	2 904	4 502	3 561
<b>Total non-current assets</b>		<b>74 685</b>	<b>76 577</b>	<b>76 923</b>
Receivables and prepayments	7	7 728	16 378	5 557
Bank deposits		170 403	344 104	266 559
<b>Current assets</b>		<b>178 130</b>	<b>360 482</b>	<b>272 117</b>
<b>TOTAL ASSETS</b>		<b>252 815</b>	<b>437 059</b>	<b>349 039</b>
<b>EQUITY</b>				
Share capital		3 441	3 440	3 441
Share premium		1 076 607	1 076 308	1 076 607
<b>Total paid-in equity</b>		<b>1 080 047</b>	<b>1 079 747</b>	<b>1 080 047</b>
Accumulated losses		(928 872)	(749 599)	(861 352)
Other equity		61 613	48 665	55 009
Translation differences		4 674	4 356	5 687
<b>TOTAL EQUITY</b>	6, 9	<b>217 463</b>	<b>383 169</b>	<b>279 391</b>
<b>LIABILITIES</b>				
Lease liability	11	1 170	2 763	1 886
Deferred tax		11 453	11 358	11 653
<b>Non-current liabilities</b>		<b>12 623</b>	<b>14 122</b>	<b>13 539</b>
Accounts payable		8 677	14 021	11 169
Lease liability	11	1 841	1 852	1 827
Other current liabilities		12 211	23 895	43 113
<b>Current liabilities</b>	8	<b>22 729</b>	<b>39 768</b>	<b>56 109</b>
<b>TOTAL LIABILITIES</b>		<b>35 352</b>	<b>53 890</b>	<b>69 648</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>252 815</b>	<b>437 059</b>	<b>349 039</b>

## Interim condensed consolidated statement of cash flow

<b>NOK (000) Unaudited</b>	<b>Q2-24</b>	<b>Q2-23</b>	<b>YTD-24</b>	<b>YTD-23</b>	<b>FY23</b>
<b>Loss before tax</b>	<b>(44 767)</b>	<b>(43 375)</b>	<b>(67 519)</b>	<b>(77 486)</b>	<b>(189 239)</b>
<b>Non-cash adjustments</b>					
Depreciation and amortization	713	691	1 427	1 391	2 768
Interest received incl. investing activities	(1 949)	(3 428)	(5 060)	(6 635)	(14 127)
Net foreign exchange differences	1 322	(3 938)	(1 582)	(17 491)	(12 750)
Other finance expense	71	100	151	208	380
Share option expenses	3 467	3 702	6 604	7 912	14 256
<b>Working capital adjustments:</b>					
Changes in prepayments and other receivables	3 073	(5 042)	(2 170)	(7 192)	3 629
Changes in payables and other current liabilities	(12 416)	(18 788)	(28 515)	(7 381)	5 256
<b>Net cash flow from operating activities</b>	<b>(50 485)</b>	<b>(70 076)</b>	<b>(96 664)</b>	<b>(106 674)</b>	<b>(189 827)</b>
Purchase of property, plant and equipment	-	-	(17)	(25)	(25)
Interest received	1 941	3 428	5 034	6 635	14 059
<b>Net cash flow used in investing activities</b>	<b>1 941</b>	<b>3 428</b>	<b>5 017</b>	<b>6 610</b>	<b>14 034</b>
Proceeds from issuance of equity	-	-	-	-	300
Interest paid	(70)	(100)	(149)	(208)	(380)
Payment of lease liability	(567)	(437)	(1 043)	(866)	(1 767)
<b>Net cash flow from financing activities</b>	<b>(637)</b>	<b>(537)</b>	<b>(1 193)</b>	<b>(1 074)</b>	<b>(1 847)</b>
Net change in cash and cash equivalents	(49 180)	(67 185)	(92 840)	(101 137)	(177 640)
Effect of change in exchange rate	(378)	5 761	(3 316)	19 931	18 889
<b>Cash and cash equivalents at beginning of period</b>	<b>219 962</b>	<b>405 528</b>	<b>266 559</b>	<b>425 309</b>	<b>425 309</b>
<b>Cash and cash equivalents at end of period</b>	<b>170 403</b>	<b>344 104</b>	<b>170 403</b>	<b>344 104</b>	<b>266 559</b>

## Interim condensed consolidated statement of changes in equity

<b>NOK (000) Unaudited</b>	<b>Share Capital</b>	<b>Share Premium</b>	<b>Accum. losses</b>	<b>Other equity</b>	<b>Transl. differenc.</b>	<b>Total equity</b>
<b>Balance at 1 Jan 2023</b>	<b>3 440</b>	<b>1 076 308</b>	<b>(672 113)</b>	<b>40 752</b>	<b>964</b>	<b>449 350</b>
Loss for the period	-	-	(77 486)	-	-	(77 486)
Issue of ordinary shares	-	-	-	-	-	-
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	7 912	-	7 912
Translation differences	-	-	-	-	3 392	3 392
<b>Balance at 30 Jun 2023</b>	<b>3 440</b>	<b>1 076 308</b>	<b>(749 599)</b>	<b>48 665</b>	<b>4 356</b>	<b>383 169</b>
<b>Balance at 1 Jan 2024</b>	<b>3 441</b>	<b>1 076 607</b>	<b>(861 352)</b>	<b>55 009</b>	<b>5 687</b>	<b>279 391</b>
Loss for the period	-	-	(67 519)	-	-	(67 519)
Issue of ordinary shares	-	-	-	-	-	-
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	6 604	-	6 604
Translation differences	-	-	-	-	(1 013)	(1 013)
<b>Balance at 30 Jun 2024</b>	<b>3 441</b>	<b>1 076 607</b>	<b>(928 872)</b>	<b>61 613</b>	<b>4 674</b>	<b>217 463</b>



## 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 2023 financial statements. These condensed interim financial statements should therefore be read in conjunction with the 2023 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 August 20, 2024. The figures in the statements have not been audited.

### 3. Personnel expenses

#### Personnel expenses

NOK (000)	Q2-24	Q2-23	YTD-24	YTD-23	FY23
Salaries	7 738	8 128	20 181	19 895	43 514
Social security tax	1 762	1 803	3 751	3 691	8 787
Social security tax related to options	2	(9 724)	(21 006)	(7 584)	6 104
Pension expenses	936	938	1 943	1 782	3 586
Share-based compensation	3 467	3 702	6 604	7 912	14 256
Other personnel expenses	(25)	(61)	(18)	92	427
Government grants	(172)	(427)	(172)	(427)	(1 544)
<b>Total personnel expenses</b>	<b>13 708</b>	<b>4 359</b>	<b>11 283</b>	<b>25 361</b>	<b>75 130</b>
Number of FTEs at end of period	23	24	23	24	25

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)	Q2-24	Q2-23	YTD-24	YTD-23	FY23
External R&D expenses	26 271	40 711	47 900	63 112	123 834
Clinical studies	16 917	17 924	29 415	28 075	70 922
Manufacturing costs	8 101	20 360	14 783	29 529	39 256
Other R&D expenses	1253	2 427	3 703	5 508	13 656
IP expenses	953	874	3 912	2 180	6 031
Rent, office and infrastructure	1 056	1 110	2 572	2 651	4 874
Accounting, audit, legal, consulting	2 404	2 511	5 022	4 159	6 476
Other operating expenses	735	1 026	2 369	3 191	5 284
Government grants	(517)	(641)	(517)	(641)	(8 663)
<b>Total other operating expenses</b>	<b>30 901</b>	<b>45 591</b>	<b>61 260</b>	<b>74 652</b>	<b>137 837</b>

## 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)	Q2-24	Q2-23	YTD-24	YTD-23	FY23
Skattefunn from The Research Council of Norway (RCN)	-	-	-	-	2 047
Innovation Norway	-	-	-	-	5 073
Innovation Project grant from the RCN	689	1 068	689	1 068	3 088
Other grants	-	-	-	-	-
<b>Total government grants</b>	<b>689</b>	<b>1 068</b>	<b>689</b>	<b>1 068</b>	<b>10 207</b>

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)	Q2-24	Q2-23	YTD-24	YTD-23	FY23
Loss for the period	(44 767)	(43 375)	(67 519)	(77 486)	(189 239)
Average number of shares during the period ('000)	34 406	34 396	34 406	34 396	34 398
<b>Earnings/loss per share (NOK)</b>	<b>(1.3)</b>	<b>(1.3)</b>	<b>(2.0)</b>	<b>(2.3)</b>	<b>(5.5)</b>

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

<b>NOK (000)</b>	<b>30 June 2024</b>	<b>30 June 2023</b>	<b>31 Dec 2023</b>
Government grants	2 047	4 750	2 998
Prepayments	843	1 799	1 463
Other receivables	4 839	9 829	1 096
<b>Total receivables and prepayments</b>	<b>7 728</b>	<b>16 378</b>	<b>5 557</b>

## 8. Current liabilities

### Current liabilities

<b>NOK (000)</b>	<b>30 June 2024</b>	<b>30 June 2023</b>	<b>31 Dec 2023</b>
Accounts payable	8 677	14 021	11 169
Public duties payable	3 579	3 975	4 914
Public duties payable related to options	2	7 320	21 008
Lease liability	1 841	1 852	1 827
Financial instruments	7	1 158	4 886
Other current liabilities	8 624	11 442	12 306
<b>Total current liabilities</b>	<b>22 729</b>	<b>39 768</b>	<b>56 109</b>

## 9. Shareholder information

The share capital as of June 30, 2024, was NOK 3,440,606.1, with 34,406,061 ordinary shares, all with equal voting rights and a nominal value of NOK 0.10 per share. As of June 30, 2024, Ultimovacs ASA has around 8,000 shareholders and the 20 largest shareholders as of this date are listed below:

### Share register as per 30 June 2024

Shareholder	# of shares	Share-%
Gjelsten Holding AS	6 495 866	18.9 %
Radforsk Investeringsstiftelse	1 519 263	4.4 %
Inven2 AS	1 265 139	3.7 %
Folketrygdfondet	912 225	2.7 %
Prieta AS	533 988	1.6 %
Farstad, Ove Steinar	510 000	1.5 %
J.P. Morgan Securities PLC	490 158	1.4 %
Rongevær, Otto	434 461	1.3 %
Nordnet Livsforsikring AS	427 464	1.2 %
Langøya Invest AS	400 000	1.2 %
Vinje, Siggurd Heggstad	382 500	1.1 %
Utmost PanEurope Dac	323 517	0.9 %
Tran, Tuan Ba	313 263	0.9 %
Bye, Robin Trulssen	305 000	0.9 %
Lefdalsnes, Johan Gunnar Godø	292 080	0.8 %
Nymo, Robin Harald	277 000	0.8 %
Nordnet Bank AB	267 352	0.8 %
The Bank Of New York Mellon	266 496	0.8 %
Verdipapirfondet Nordea Avkastning	263 622	0.8 %
Dybvad-Roll, Peter	255 447	0.7 %
<b>20 Largest shareholders</b>	<b>15 934 841</b>	<b>46.3%</b>
Other shareholders	18 471 220	53.7%
<b>Total</b>	<b>34 406 061</b>	<b>100.0%</b>

## 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 18 April 2024, the Board was authorized to increase the Company's share capital in connection with the share incentive arrangement by up to NOK 344,060.6. The authorization is valid until the next ordinary General Meeting in 2025.

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. Options that are not exercised within 7 years from the date of grant will lapse and become void.

The exercise price was NOK 31.25 for the options granted in 2019 and NOK 39.15 for the options granted in 2020. In June 2024, the board of directors of Ultimovacs ASA decided to revise the terms of parts of the share option program. The terms of the already issued share options to the employees who were made redundant during the downsizing process, i.e. employees that were not served notice of termination during April 2024, were adjusted as follows:

- The strike price was adjusted for the following subset of the currently non-exercised options; 100% of the options issued in 2023 (i.e., 98,500 options with a previous strike price of NOK 128.61 per share), 100% of the options issued in 2022 (i.e., 303,500 options with a previous strike price of NOK 83.46 per share), and 50% of the options issued in 2021 (i.e., 185,825 options with a previous strike price of NOK 61.99 per share).
- For these options, the new strike price is NOK 8.18 per share, which was equal to the volume weighted average share price the last five trading days prior to the date of this decision, June 24th, 2024.

The Ultimovacs Employee Share Options' fair value is calculated according to the IFRS-2 regulations. Please see the Annual Report for more information regarding the calculation of the fair value and which parameters are used in the model.

Equity-settled share-based payments are measured at the fair value of the equity instruments at the grant date. Please see the Annual Report for more information regarding the accounting method of the options.

### Movement of share options

	Number of share options	Weighted Average strike
<b>Outstanding at opening balance 1 January 2024</b>	<b>2 289 285</b>	<b>59.82</b>
Granted	-	-
Exercised	-	-
Forfeited	(8 500)	103.38
<b>Outstanding at closing balance 30 June 2024</b>	<b>2 297 785</b>	<b>59.22</b>
Vested at closing balance	1 929 285	40.88

A total of 2,287,785 share options are granted per 30 June 2024, corresponding to 6.68% of the outstanding number of shares in the Company.

The total IFRS cost recognized for the option program in Q2 2024 is MNOK 3.5, and the accruals for social security tax related to the options is tNOK 2. YTD 2024, the total IFRS costs are MNOK 6.6, and the reversal of social security accruals is MNOK 21.0.

## 11. IFRS 16 – rental contracts

The agreements classified as operating leases are the rental agreement for office premises in Oslo with 2 years left of the rental contract as of 31 December 2023, and four car-leasing contracts. The weighted average discount rate applied is 8.3%. Please see the 2023 Annual report for more information.

## 12. Events after the balance sheet date

In August 2024, Ultimovacs reported topline results from the Phase II FOCUS trial in head and neck cancer. The trial did not meet the primary endpoint of improved progression-free survival (PFS). The data did not show improvement in overall survival.

## Glossary

Words/terms	Description
General/basic terms	
UV1	UV1 is Ultimovacs' off-the-shelf synthetic peptide vaccine
Peptides	Peptides are short or long-chains of amino acids, and amino acids are the building blocks of proteins.
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.
Universal target	A cancer target relevant across individual tumors within the same patient, across patients with the same tumor type, and across patients with different tumor types.
Shared antigen	An antigen (target for the immune system) relevant across different patients with the same tumor type.
Immune checkpoint inhibitors	Medicines that "takes the brakes off the immune system". The immune 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. Examples of immune checkpoint inhibitors include PD-1 / PDL-1 inhibitors (e.g., pembrolizumab, cemiplimab and nivolumab) and CTLA-4 inhibitors (e.g., ipilimumab). There are many others in development.
HLA	Human leukocyte antigens (HLA) are molecules on the surface of cells that present peptide antigens to T cells allowing them to distinguish healthy cells from cancerous or infected cells.
Immune response	The activity of the immune system against foreign substances (antigens).
Investigational New Drug (IND)	The United States Food and Drug Administration's Investigational New Drug (IND) program is the means by which a biopharmaceutical company obtains permission to start human clinical trials and to ship 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 balance a normal immune response. The balance is needed to avoid collateral damage to 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 half of the patients have progressed disease or died.)
Medical terms	
Intradermal	In order to initiate an immune response, a vaccine antigen is usually taken up by antigen presenting cells (dendritic cells). UV1 is administered via the 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 / Metastatic cancer	The development of malignant growths at a distance from a primary site of cancer / Metastatic cancer is cancer that spreads from its site of origin to another part of the body.
SAE	<p>A serious adverse event (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose</p> <ol style="list-style-type: none"> <li>1. results in death,</li> <li>2. is life-threatening</li> <li>3. requires inpatient hospitalization or causes prolongation of existing hospitalization</li> <li>4. results in persistent or significant disability/incapacity</li> <li>5. is a congenital anomaly/birth defect, or</li> <li>6. requires intervention to prevent permanent impairment or damage.</li> </ol> <p>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.”</p>
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 report has been prepared by Ultimovacs ASA ('Ultimovacs' or the 'Company').

The report 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 report has not been reviewed or approved by any regulatory authority or stock exchange.

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## About Ultimovacs

Ultimovacs is a clinical-stage biotechnology company developing novel immunotherapies against cancer. The product candidate UV1 is an off-the-shelf therapeutic cancer vaccine designed to enhance the benefits of immunotherapy and improve cancer treatment efficacy for patients. UV1 triggers an immune response against the shared cancer antigen telomerase, a target present in 85-90% of all cancer indications across disease stages.

Ultimovacs is investigating the safety and efficacy of UV1 in a wide-ranging clinical development program including various cancer indications and different immunotherapy combinations. The ongoing Phase II program comprises five randomized clinical trials in melanoma, mesothelioma, head and neck cancer, ovarian cancer, and non-small cell lung cancer. More than 750 patients in the U.S., Europe, and Australia are being enrolled in all Phase I and Phase II trials in the current program.

Furthermore, Ultimovacs is developing a novel conjugation technology, initially formed to support the expansion of our vaccine pipeline. With the objective of driving value and future pipeline growth, this flexible conjugation technology has the potential to be broadly applicable to a variety of therapeutic modalities, such as innovative drug conjugates with favorable pharmacological properties, and in multiple disease areas.

Ultimovacs was established in 2011 and is a public limited liability company listed on the Euronext Oslo Stock Exchange in Norway. Ultimovacs is headquartered at the Oslo Cancer Cluster Innovation Park in Oslo, Norway, and also has an office in Uppsala, Sweden.

