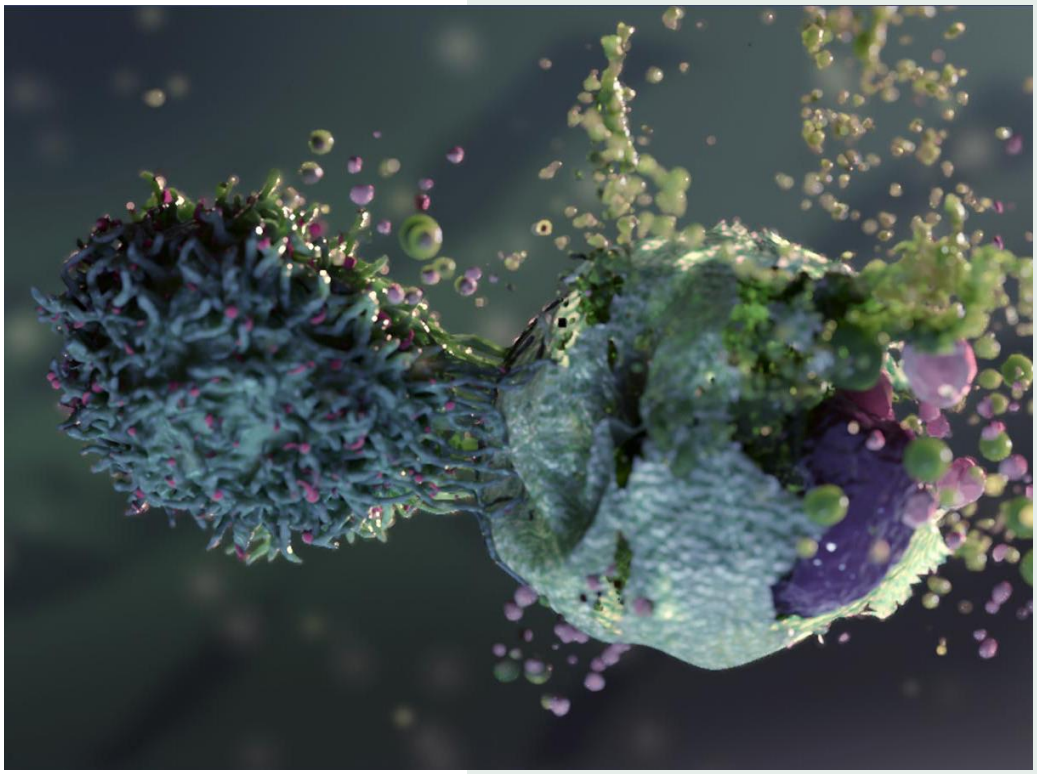
# 2022

# Fourth Quarter Report

## Ultimovacs ASA



ultimovacs

# Introduction

Ultimovacs is a clinical-stage biotech company developing novel immunotherapies against cancer. Lead product, UV1, is a cancer vaccine aiming to enhance the efficacy and durability of immune-oncology therapy when combined with checkpoint inhibitors. UV1 triggers an immune response against telomerase, which is present in 85-90% of cancer types in all stages of tumor growth. UV1 is off-the-shelf, easy to use, with broad applicability across cancer indications.

The Company is advancing a broad clinical development program with five Phase II randomized, comparative clinical trials, where the universal cancer vaccine UV1 is combined with different checkpoint inhibitors.

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

# Fourth Quarter 2022 Highlights

- Ultimovacs is on track to Phase II clinical trial readout; topline results continue to be expected during the first half of 2023 from the first two randomized Phase II clinical trials, INITIUM in malignant melanoma and NIPU in metastatic pleural mesothelioma.
- The INITIUM and NIPU trials are evaluating whether UV1, used in combination with checkpoint inhibitors, can improve outcomes in patients with malignant melanoma and metastatic pleural mesothelioma. Both studies have completed enrollment. Last patient enrolled in NIPU was announced 23 January 2023 (*post period event*)
- Enrollment in the Phase I TENDU trial is complete, as announced 14 December 2022. The study is evaluating the safety and tolerability of the first product candidate from Ultimovacs' second technology platform, TET. Readout is expected during H2 2023.
- Ultimovacs expects the time the current cash resources will support operations to be extended until mid-2024, based on current programs.

# CEO Statement

The fourth quarter of 2022 was very productive for Ultimovacs. We continued to prepare for topline results, expected during the first half of 2023, from the first two Phase II randomized clinical trials with UV1; INITIUM in metastatic malignant melanoma and NIPU in metastatic pleural mesothelioma. The results from these two trials represent potentially transformative milestones for Ultimovacs and cancer patients with unmet medical needs and will provide important guidance for the regulatory pathway for UV1.

As UV1 is a universal cancer vaccine, the Phase II clinical program explores the impact of UV1 in different cancer types and in combination with different checkpoint inhibitors. As part of this Q4 2022 reporting, Ultimovacs has updated the guidance for the readout timelines for the investigator-sponsored studies. We expect to receive data from the study in head and neck cancer, FOCUS, during the first half of 2024; and from the study in in ovarian cancer, DOVACC, during the second half of 2024. For the study in non-small cell lung cancer, LUNGVAC, we expect the readout during the second half of 2025. During the fourth quarter, we also completed enrollment in the TENDU study in prostate cancer, the 'first-in-human' clinical trial based on our technology platform, TET. The results from this study, expected in the second half of 2023, will be important for planning of the further development of this novel vaccine adjuvant technology.

As communicated with the Q3 2022 reporting, the biomarker analysis from the Phase I study with UV1 and pembrolizumab in malignant melanoma indicated that UV1 induced increased efficacy also in patients less likely to respond to monotherapy checkpoint inhibition. This encouraging signal in a universal, off-the-shelf cancer vaccine, strengthens the hypothesis that UV1 can represent a valuable addition to current cancer treatment regimes. This opportunity includes a possible expansion of the number of patients that may benefit from immunotherapy treatment combinations. We believe UV1 can potentially play an essential role in treating cancer patients and provide increased treatment access - a key topic on the global healthcare agenda.

We appreciate an increased interest in cancer vaccines in general from the medical, corporate and investment communities. These are truly exciting times for Ultimovacs and the cancer vaccine space, more broadly. UV1 is the result of 30 years of research and more than a thousand cancer patients have contributed to where we are today. I want to express my gratitude to our dedicated Ultimovacs team, our clinical and research collaborators around the world, our business partners, investors, and all the patients who have participated in our clinical trials and follow our progress. Your support inspires us every day. We look forward to taking the next steps with you to develop universal vaccines that improve treatment outcomes for people with cancer.

*Carlos de Sousa, Chief Executive Officer*

# Fourth Quarter 2022: Summary

## Operational update

- On 5 October 2022, Ultimovacs announced positive three-year results of 71% overall survival rate in Cohort 1 of the Phase I UV1-103 trial in metastatic malignant melanoma. *(Also reported in the Q3 2022 report)*
- On 18 October 2022, Ultimovacs ASA announced multiple biomarker analyses data from the Phase I UV1-103 malignant melanoma trial. These analyses support the promising efficacy signals, including enhanced efficacy in 'hard-to-treat' patients. *(Also reported in the Q3 2022 report)*
- On 25 October, Ultimovacs announced that the first patient had been randomized in the Phase II LUNGVAC Trial. *(Also reported in the Q3 2022 report)*
- On 14 December 2022, Ultimovacs announced that the last patient was enrolled in the Phase I TENDU trial in prostate cancer, the first in-human study based on the Company's novel TET platform. After a six months follow-up period, readout is expected during H2 2023.
- On 20 December, Ultimovacs announced that as of January 1st, 2023, UV1 would be combined with the PD-1 checkpoint inhibitor cemiplimab, instead of pembrolizumab, in the LUNGVAC trial, following the decision of change of reimbursement of PD-1 checkpoint inhibitor from the Norwegian health authorities.
- On 23 January 2023, Ultimovacs announced that patient enrollment was completed in the NIPU Phase II clinical trial in metastatic pleural mesothelioma *(post period event)*

## Clinical program - enrollment, as of 15 February 2023, updated quarterly

- **INITIUM Phase II trial (malignant melanoma):** The enrollment of patients was completed in June 2022 with a total of 156 patients. Enrollment has started in the single arm supplementary study (not to be included in the INITIUM topline readout).
- **NIPU Phase II trial (metastatic pleural mesothelioma):** The enrollment of patients was completed in January 2023 with a total of 118 patients.
- **FOCUS Phase II trial (head and neck cancer):** 50 out of 75 patients have been enrolled to date, up from 41 as of the previous quarterly report.
- **DOVACC Phase II trial (ovarian cancer):** 17 out of 184 patients have been enrolled to date, up from 7 as of the previous quarterly report.
- **LUNGVAC Phase II trial (non-small cell lung cancer):** 2 out of 138 patients have been enrolled and treated with cemiplimab, since January 1st. In addition, 3 patients have been treated with pembrolizumab (prior to the change in reimbursement by Norwegian health authorities). These 3 patients will be maintained as a separate sub-group in the trial.
- **TENDU Phase I trial (prostate cancer):** The enrollment of patients was completed in mid-December with a total of 12 patients.

## UV1 Phase II clinical program - expected timeline topline readouts

As previously communicated, Ultimovacs provides an update of the guidance on clinical timelines with the Q4 2022 reporting:

- INITIUM (malignant melanoma): H1 2023 (no change from previous statements)
- NIPU (metastatic pleural mesothelioma): H1 2023 (no change from previous statements)
- FOCUS (head and neck cancer): H1 2024 (previously communicated: In 2023)
- DOVACC (ovarian cancer): H2 2024 (previously communicated: In 2023)
- LUNGVAC (non-small cell lung cancer): H2 2025 (previously communicated: End of 2024)

The updated guidance in the last two UV1 Phase II studies is due to extended time to obtain approvals from local authorities and ethical committees during the pandemic, and the change of reimbursement regime for checkpoint inhibitor in LUNGVAC. The Company expects to provide the next update to the guidance for expected timeline for clinical readouts with the Q4 2023 report.

## Scientific publications and presentations

- On 18 October 2022, Ultimovacs ASA announced biomarker data from the Phase I UV1-103 melanoma trial, presented at the 19th International Congress of the Society for Melanoma Research (SMR) in Edinburgh, UK. The data support strong clinical responses from UV1 in combination with pembrolizumab, also in patients considered less likely to respond to monotherapy checkpoint inhibition. (*Also reported in the Q3 2022 report)*
- On 27-30 October 2022, the lead investigator of the DOVACC Phase II clinical trial, Mansoor Mirza from Copenhagen University Hospital, presented a trial-in-progress poster, giving an overview of the DOVACC trial at the European Society of Gynaecological Oncology (ESGO) 2022 Congress in Berlin, Germany. (*Also reported in the Q3 2022 report)*
- On 26 January 2023, *Current Opinion in Oncology* published the article 'Therapeutic cancer vaccination against telomerase: clinical developments in melanoma' by Espen Ellingsen, Jens Bjørheim and Gustav Gaudernack. *(Post period event)*

## Financial update

- Total operating expenses amounted to **MNOK 72.3** in Q4-22, and **MNOK 183.6** in FY22. Total loss was **MNOK 70.5** in Q4-22 and **MNOK 167.8** in FY22.
- Net negative cash flow from operations was **MNOK 50.0** in Q4-22, and net decrease in cash and cash equivalents, not including currency effects, was **MNOK 42.1** during Q4-22. Cash and cash equivalents amounted to **MNOK 425.3** as per 31 December 2022.
- On 16 November 2022, 130,700 options granted under Ultimovacs' option program were exercised at an average strike price of NOK 31.39 per share. Subsequently, the Company's share capital was increased by NOK 13,070 by issuing 130,700 new shares, giving a total of 34,396,461 shares issued as of 31 December 2022, each share of par value NOK 0.10.

**Key financials**

| NOK (000) Unaudited | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|
| **Total revenues** | **-** | **-** | **-** | **-** |
| Total operating expenses | 72 255 | 50 930 | 183 631 | 163 832 |
| **Operating profit (loss)** | **(72 255)** | **(50 930)** | **(183 631)** | **(163 832)** |
| **Profit (loss) for the period** | **(70 513)** | **(51 152)** | **(167 792)** | **(164 722)** |
| Diluted and undiluted earnings / (loss) per share (NOK) | (2.1) | (1.5) | (4.9) | (5.1) |
| Net increase / (decrease) in cash and cash equivalents | (42 137) | 227 856 | (155 426) | 137 106 |
| **Cash and cash equivalents at end of period** | **425 309** | **574 168** | **425 309** | **574 168** |
| | NOK/EUR - 10.51 | | | |
| **Cash and cash equivalents at end of period** - EUR (000) | ***40 452*** | | | |

# Operational Review

## Lead product candidate: UV1

The Company's lead product candidate is UV1, a second-generation peptide-based cancer vaccine inducing a specific T cell response against the universal cancer antigen telomerase (hTERT), which is expressed at a high level in 85-90% of human tumors.

UV1's mode of action is to make the immune system produce CD4 T cells (i.e., T helper cells) that recognize cancer cells expressing telomerase. UV1 does not interfere with the activity of telomerase; no material safety issues have been observed to date.

UV1 expands T-cells that identify fragments of telomerase presented in the context of HLA molecules on cells in the tumor. This triggers an immune response towards the cancer. UV1 may potentially be applied universally across cancer types, in different stages of disease and in combination with different cancer treatments. The vaccine is easy to use and does not require sophisticated infrastructure in hospital. UV1 is manufactured as an off-the-shelf product with a long shelf life.

UV1 is being developed as a therapeutic cancer vaccine and a platform for other immuno-oncology drugs which require an ongoing T cell response for their mode of action. Longer-term, it would be attractive to investigate the use of UV1 in adjuvant and neo-adjuvant treatment.

Treatment with UV1 has been assessed in three 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 further 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 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. The Phase II program will enroll more than 650 patients at approximately 100 hospitals in Europe, the US and Australia.

UV1 is a patented, proprietary technology owned by Ultimovacs.

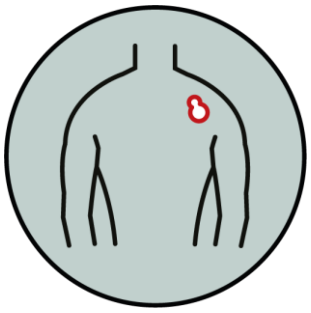
## Regulatory designations

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

## UV1 clinical program

**The INITIUM Phase II trial in metastatic malignant melanoma**
INITIUM is an Ultimovacs-sponsored randomized, 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 metastatic malignant melanoma.



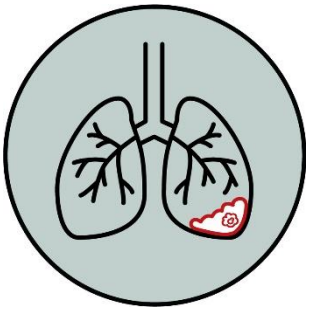
The first INITIUM patient was treated at the Oslo University Hospital (OUS) in June 2020, and the last patient was enrolled in the study in July 2022. The initial study design called for enrollment of 154 patients. Two additional patients were enrolled bringing the total number of patients in the study to 156. A total of 39 hospitals are participating in this trial being run in the US, UK, Belgium and Norway. Dr. Karl Lewis, University of Colorado Hospital (U.S.), is the International Coordinating Investigator of the INITIUM trial.

Half 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. The readout of the primary endpoint of progression-free survival is expected in H1 2023, after progression of cancer or death has been observed in 70 patients. Secondary endpoints will include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety. The objective of the study is to achieve a clinically meaningful progression-free survival (PFS) benefit in patients with metastatic malignant melanoma.

With the INITIUM enrollment completed, Ultimovacs is running a supplementary study to the INITIUM trial with 20 patients in a single arm. Patient enrollment in the supplementary study started in September 2022. The objective of the study is to provide further characterization of the manner in which an immune response specific to the UV1 vaccine translates into anti-tumor activity and clinical benefit for patients. These patients will receive experimental treatment, i.e. the triple combination of UV1, ipilimumab and nivolumab. Data collected from the patients in 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.

**The NIPU Phase II trial in metastatic pleural mesothelioma**

NIPU is a randomized, multi-center Phase II trial in which the universal cancer vaccine, UV1, will be evaluated in combination with the checkpoint inhibitors ipilimumab and nivolumab as second-line treatment in metastatic pleural mesothelioma. Prof. MD PhD Åslaug Helland is the principal investigator for the trial, which is sponsored by Oslo University Hospital (OUS). Bristol-Myers Squibb and Ultimovacs have entered into agreements with OUS to support the preparations and execution of the trial.



The first patient in the NIPU trial was treated at the Oslo University Hospital in June 2020, and the last patient was enrolled in January 2023. The study is being conducted in 118 patients in five countries (Norway, Sweden, Denmark, Spain, and Australia). Half of the patients in the trial has been treated with the combination of UV1, ipilimumab and nivolumab and the other half have been treated with ipilimumab and nivolumab. The readout of the primary endpoint of progression-free survival is expected in H1 2023, after progression of cancer or death has been observed in 69 patients. Secondary endpoints will include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety. The objective of the study is to achieve a clinically meaningful progression-free survival (PFS) benefit in patients with metastatic pleural mesothelioma after progression on first-line standard platinum doublet chemotherapy.

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

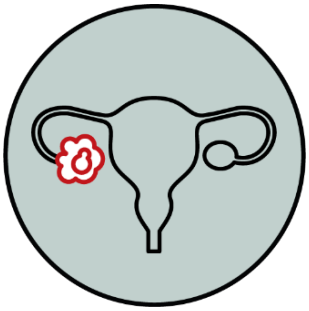
The FOCUS trial (**F**irst-line metastatic **O**r recurrent HNSCC/**C**heckpoint inhibitor **U**V1 **S**tudy) is an investigator-sponsored, randomized Phase II clinical trial. It will enroll patients with recurrent or metastatic PD-L1 positive head and neck squamous cell carcinoma at 10 sites across Germany. Prof. Mascha Binder is the principal investigator for the trial, which is sponsored by University Medicine Halle in Germany.

The trial will evaluate the addition of UV1 to standard of care treatment of PD-1 checkpoint inhibitor pembrolizumab as compared to pembrolizumab monotherapy. A total of 75 patients indicated for treatment with pembrolizumab will be enrolled in FOCUS, randomized 2-to-1 so that 50 patients will receive UV1 and pembrolizumab and 25 patients will receive pembrolizumab alone.

The first patient in the FOCUS trial was treated in August 2021 and 50 out of 75 patients have been enrolled. 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 enrolled. Secondary endpoints will include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety.

Topline readout is expected in H1 2024.

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



DOVACC (**D**urvalumab **O**laparib **VACC**ine) is a multicenter, randomized 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), AstraZeneca and Ultimovacs. 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 trial is designed to evaluate UV1 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. 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.

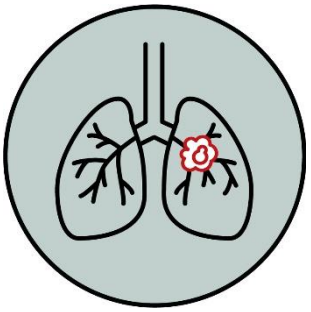
Enrollment began in December 2021. A total of 17 out of 184 patients have been enrolled in DOVACC. Multi-national, multi-center clinical trials such as DOVACC engage a large number of specialists and are administratively complex to organize. Treating a patient requires approval from a national drug authority and, subsequently, approval from an ethical committee at the individual hospital or treatment center.

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 that 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 data on the primary endpoint are expected in H2 2024.

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

The LUNGVAC trial is a Phase II multi-center, randomized, open-label trial assessing the safety and efficacy of UV1 in combination with cemiplimab versus cemiplimab alone in NSCLC patients with advanced or metastatic disease.



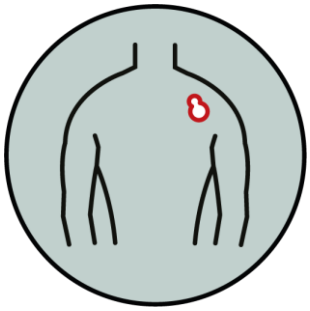
The trial will enroll previously untreated patients with adenocarcinoma or squamous NSCLC, where tumor biopsies show a PD-L1-expression score above 50%. These subgroups represent approximately 30% of all advanced and metastatic NSCLC patients.

Professor Odd Terje Brustugun is the principal investigator for the trial which is sponsored by Drammen Hospital in Vestre Viken Hospital Trust, Norway. The trial will enroll 138 patients and will be conducted at approximately 10 clinical centers in Norway. The trial will evaluate the addition of UV1 to standard of care treatment with PD-1 checkpoint inhibitor cemiplimab as compared to cemiplimab monotherapy. Half of the patients in the trial will be treated with UV1 + cemiplimab and the other half will be treated with cemiplimab monotherapy.

The first patient in the LUNGVAC trial was enrolled 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. 2 out of 138 patients have been enrolled in the study after the change to cemiplimab 1 January 2023. The three patients enrolled prior to 1 January 2023, will continue treatment with pembrolizumab.

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 readout is expected in H2 2025.

**The UV1-103 Phase I trial in metastatic malignant melanoma**



This US-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 metastatic malignant melanoma. The first cohort of 20 patients were enrolled by September 2019. The second cohort of 10 additional patients were enrolled by August 2020. In addition to UV1, the first cohort received 37.5 mcg of the adjuvant GM-CSF and the second cohort received the standard 75 mcg dose.

UV1 has demonstrated a good safety profile, and no unexpected safety issues related to UV1 have been observed in this trial. At the end of the study, the clinical results for the 30 patients in cohort 1 and cohort 2 combined 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%
- Overall survival rate after 24 months: 73%
- Overall survival rate after 36 months (cohort one): 71%

After the study ended at two years follow up, the protocol was amended to follow patients for overall survival for up to five years. Three patients in cohort 1 did not consent to further follow up, changing the number of participating patients in cohort 1 from 20 to 17, after two years. At the three years cut-off date for patients in the first cohort, the three-year overall survival rate was a positive 71% (12 out of 17 patients).

*The UV1-103 trial – biomarker analyses*

The analyses of five different biomarkers in the UV1-103 trial 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, underserved by existing therapies. The potential value of expanding the number of patients that can benefit from UV1 can 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 the 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 observed in patients with low TMB, in patients with low neoantigen tumors, and in patients with tumors which were not enriched for IFN-gamma. These patients have tumors which 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 7.5 years.

The observed clinical outcomes from these three completed trials served as a strong basis for the further clinical development of UV1, both 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 induce 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. Readout of safety and immune responses is expected during H2-2023.

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 is expected during H2 2023.

# 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 a sophisticated hospital infrastructure to be administered. If the ongoing clinical development and testing of Ultimovacs' cancer vaccine demonstrates that UV1 gives 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 650 patients in total, representing a strong potential platform for Ultimovacs to move toward a possible registration path of the universal cancer vaccine, UV1. The main study objectives are efficacy and safety data on combination therapies.

With the Q4 2022 report, Ultimovacs updated the guidance for expected timeline readout from the UV1 Phase II clinical program as follows:

- INITIUM (malignant melanoma): H1 2023
- NIPU (metastatic pleural mesothelioma): H1 2023
- FOCUS (head and neck cancer): H1 2024
- DOVACC (ovarian cancer): H2 2024
- LUNGVAC (non-small cell lung cancer): H2 2025

Ultimovacs will provide an update to the guidance for expected timelines for topline readouts with the Q4 2023 reporting.

Based on current funding, plans and expectations, Ultimovacs current cash balance is expected to support operations to mid-2024.

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 reinforce the significant development potential of UV1.

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 to move 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 approved registration, 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. The 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 2021. 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. In FY22, the Company recognized government grants of **MNOK 9.5** compared to MNOK 14.6 in FY21, which have been deducted from payroll expenses and other operating expenses. The grants are primarily received during the year following the accounting year when the grants are booked in the P&L.

Total payroll and payroll related expenses were significantly higher in Q4-22 (**MNOK 31.6**) compared to the same period in FY21 (MNOK 11.9). Regular salaries not including option expenses were approximately at the same level as both quarters had the same numbers of full-time equivalents (FTEs). However, option expenses and the social security tax accrual related to share options, which fluctuates with the company share price, was MNOK 16.9 higher in Q4-22 compared to Q4-21, explaining most of the difference these two quarters.

Total personnel expenses in FY22 were **MNOK 71.5** compared to MNOK 61.9 in FY21. The FY22 increase was primarily due to two more FTEs employed in the company during FY22 compared to FY21, explaining MNOK 4.2 of the difference. In addition, MNOK 2.3 of the increase is due to higher expenses related to the share-based compensation option program, as well as an increase in social security costs as options were exercised during the year.

Other operating expenses (**MNOK 39.9** in Q4-22 vs. MNOK 38.4 in Q4-21) are primarily comprised of R&D related expenses. These expenses, including IP and external R&D expenses, offset by government grants, amounted to **MNOK 35.3** in Q4-22 vs. MNOK 35.5 in Q4-21.

Total other operating expenses in FY22 **(MNOK 109.5)** were higher compared to FY21 (MNOK 99.2), which are primarily comprised of R&D expenses, MNOK 91.0 in FY22 and MNOK 88.2 in FY21. The main contributors to the R&D expenses in FY22 were the INITIUM trial and chemistry, manufacturing and controls (CMC) activities, as well as the investigator-initiated trials.

Net financial items amounted to **MNOK 1.7** in Q4-22, compared to MNOK (0.2) in Q4-21. 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 Q4-22, the financial income is comprised of MNOK 4.3 in interest from bank, MNOK 0.6 in currency loss from cash in EUR bank account and MNOK 2.1 in currency loss from the EUR currency future contracts.

In FY22, the net financial income of **MNOK 15.8** is comprised of MNOK 8.9 in interest from bank, MNOK 2.1 in currency gain from cash in EUR bank account and MNOK 5.1 in currency gain from the EUR currency future contracts.

Total loss for the Q4-22 period amounted to **MNOK 70.5**, compared to MNOK 51.2 in Q4-21. Total loss in FY22 amounted to **MNOK 167.8** compared to a loss of MNOK 164.7 in FY21.

## Financial position

Total assets per 31 December 2022 were **MNOK 509.7**, a decrease of MNOK 145.9 from 31 December 2021, 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 15.0, and **MNOK 1.1** in 'Receivables and prepayments' are related to the fair value of these EUR swap contracts by the end of the quarter.

Total liabilities as of 31 December 2022 amounted to **MNOK 60.3**, of which MNOK 14.4 are non-current.

Total equity equaled **MNOK 449.4** as of 31 December 2022. Capital increases in September (44,000 shares) and November (130,700 shares), related to the exercise of a total of 174,700 options granted under Ultimovacs' option program, resulted in gross proceeds of **MNOK 5.5**. Subsequently, the Company's share capital was in 2022, increased by NOK 17,470 by issuing 174,700 new shares, totaling 34,396,461 shares as per 31 December 2022, each share of par value NOK 0.10.

Further, total equity has, since year-end 2021, been decreased by the period's operating loss and currency translation, amounting to **MNOK 169.7**, and in addition has been increased by the recognition of share-based payments/stock options of **MNOK 20.4**.

## Cash flow

The total net decrease in cash and cash equivalents in Q4-22, not including currency effects, was **MNOK 42.1**, which is primarily related to net negative cash-flow from operations amounting to **MNOK 50.0.**

The total net decrease in cash and cash equivalents in FY22, not including currency effects, was **MNOK 155.4**, which is primarily related to net negative cash-flow from operations amounting to **MNOK 167.7,** offset by interest income of MNOK 8.7 and two share issues related to share option exercises, raising net proceeds of MNOK 5.5. Total cash and cash equivalents were **MNOK 425.3** per 31 December 2022, of which MNOK 19.7 (**MEUR 1.9**) is held on EUR account.

**Key financials**

| NOK (000) Unaudited | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|
| **Total revenues** | - | - | - | - |
| Total operating expenses | 72 255 | 50 930 | 183 631 | 163 832 |
| **Operating profit (loss)** | **(72 255)** | **(50 930)** | **(183 631)** | **(163 832)** |
| **Profit (loss) for the period** | **(70 513)** | **(51 152)** | **(167 792)** | **(164 722)** |
| Diluted and undiluted earnings / (loss) per share (NOK) | (2.1) | (1.5) | (4.9) | (5.1) |
| Net increase / (decrease) in cash and cash equivalents | (42 137) | 227 856 | (155 426) | 137 106 |
| **Cash and cash equivalents at end of period** | **425 309** | **574 168** | **425 309** | **574 168** |
| | NOK/EUR - 10.51 | | | |
| **Cash and cash equivalents at end of period** - EUR (000) | ***40 452*** | | | |

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

Oslo, 15 February 2023

Jónas Einarsson
Chairman of the Board
(Sign.)

Kari Grønås
Board member
(Sign.)

Eva S. Dugstad
Board member
(Sign.)

Henrik Schüssler
Board member
(Sign.)

Ketil Fjerdingen
Board member
(Sign.)

Leiv Askvig
Board member
(Sign.)

Aitana Peire
Board member
(Sign.)

Haakon Stenrød
Board member
(Sign.)

Carlos de Sousa
CEO
(Sign.)

## Interim condensed consolidated statement of comprehensive income

| NOK (000) Unaudited | Note | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|---|
| Other operating income | | - | - | - | - |
| **Total revenues** | | - | - | - | - |
| Payroll and payroll related expenses | 3, 5 | 31 630 | 11 885 | 71 466 | 61 916 |
| Depreciation and amortization | | 694 | 623 | 2 648 | 2 703 |
| Other operating expenses | 4, 5 | 39 930 | 38 422 | 109 517 | 99 213 |
| **Total operating expenses** | | **72 255** | **50 930** | **183 631** | **163 832** |
| **Operating profit (loss)** | | **(72 255)** | **(50 930)** | **(183 631)** | **(163 832)** |
| Financial income | | 2 013 | 5 188 | 17 375 | 13 383 |
| Financial expenses | | 271 | 5 410 | 1 536 | 14 272 |
| **Net financial items** | | **1 742** | **(222)** | **15 839** | **(890)** |
| **Profit (loss) before tax** | | **(70 513)** | **(51 152)** | **(167 792)** | **(164 722)** |
| Income tax | | - | - | - | - |
| **Profit (loss) for the period** | | **(70 513)** | **(51 152)** | **(167 792)** | **(164 722)** |
| Other comprehensive income (loss) - Currency translation | | (1 600) | (1 426) | (1 889) | (3 953) |
| **Total comprehensive income (loss) for the period** | | **(72 113)** | **(52 578)** | **(169 681)** | **(168 676)** |
| Diluted and undiluted earnings/(loss) pr share (NOK) | 6 | (2.1) | (1.5) | (4.9) | (5.1) |

## Interim condensed consolidated statement of financial position

| NOK (000) Unaudited | Note | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|---|
| **ASSETS** | | | |
| Goodwill | | 10 701 | 11 031 |
| Licenses | | 51 944 | 53 549 |
| Patents | | 5 784 | 6 539 |
| Property, plant and equipment | | 220 | 212 |
| Right to use asset | 11 | 5 444 | 1 951 |
| **Total non-current assets** | | **74 093** | **73 282** |
| Receivables and prepayments | 7 | 10 270 | 8 087 |
| Bank deposits | | 425 309 | 574 168 |
| **Current assets** | | **435 579** | **582 255** |
| **TOTAL ASSETS** | | **509 672** | **655 537** |
| | | | |
| **EQUITY** | | | |
| Share capital | | 3 440 | 3 422 |
| Share premium | | 1 076 308 | 1 070 841 |
| **Total paid-in equity** | | **1 079 747** | **1 074 264** |
| Accumulated losses | | (672 113) | (504 321) |
| Other equity | | 40 752 | 20 358 |
| Translation differences | | 964 | 2 853 |
| **TOTAL EQUITY** | 6, 9 | **449 350** | **593 152** |
| **LIABILITIES** | | | |
| Lease liability | 11 | 3 713 | 457 |
| Deferred tax | | 10 701 | 11 031 |
| **Non-current liabilities** | | **14 414** | **11 488** |
| Accounts payable | | 7 655 | 22 555 |
| Lease liability | 11 | 1 767 | 1 628 |
| Other current liabilities | | 36 485 | 26 714 |
| **Current liabilities** | 8 | **45 907** | **50 897** |
| **TOTAL LIABILITIES** | | **60 321** | **62 384** |
| **TOTAL EQUITY AND LIABILITIES** | | **509 672** | **655 537** |

## Interim condensed consolidated statement of changes in equity

| NOK (000) Unaudited | Share Capital | Share Premium | Accum. losses | Other equity | Transl. differenc. | Total equity |
|---|---|---|---|---|---|---|
| **Balance at 1 Jan 2021** | **3 197** | **809 214** | **(339 599)** | **8 762** | **6 806** | **488 380** |
| Loss for the period | - | - | (164 722) | - | - | (164 722) |
| Issue of ordinary shares | 225 | 272 640 | - | - | - | 272 864 |
| Share issue costs | - | (11 012) | - | - | - | (11 012) |
| Recognition of share-based payments | - | - | - | 11 595 | - | 11 595 |
| Translation differences | - | - | - | - | (3 953) | (3 953) |
| **Balance at 31 Dec 2021** | **3 422** | **1 070 841** | **(504 321)** | **20 358** | **2 853** | **593 152** |
| | | | | | | |
| **Balance at 1 Jan 2022** | **3 422** | **1 070 841** | **(504 321)** | **20 358** | **2 853** | **593 152** |
| Loss for the period | - | - | (167 792) | - | - | (167 792) |
| Issue of ordinary shares | 17 | 5 466 | - | - | - | 5 484 |
| Share issue costs | - | - | - | - | - | - |
| Recognition of share-based payments | - | - | - | 20 395 | - | 20 395 |
| Translation differences | - | - | - | - | (1 889) | (1 889) |
| **Balance at 31 Dec 2022** | **3 440** | **1 076 308** | **(672 113)** | **40 752** | **964** | **449 350** |

## Interim condensed consolidated statement of cash flow

| NOK (000) Unaudited | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|
| **Loss before tax** | **(70 513)** | **(51 152)** | **(167 792)** | **(164 722)** |
| **Non-cash adjustments** | | | | |
| Depreciation and amortization | 694 | 623 | 2 648 | 2 703 |
| Interest received incl. investing activities | (4 302) | (1 312) | (8 887) | (3 062) |
| Net foreign exchange differences | 2 540 | 1 451 | (7 176) | 3 619 |
| Other finance expense | 22 | 35 | 105 | 179 |
| Share option expenses | 4 303 | 3 014 | 20 395 | 11 595 |
| **Working capital adjustments:** | | | | |
| Changes in prepayments and other receivables | (3 169) | (6 499) | (1 859) | 351 |
| Changes in payables and other current liabilities | 20 389 | 19 980 | (5 129) | 23 509 |
| **Net cash flow from operating activities** | **(50 036)** | **(33 859)** | **(167 695)** | **(125 828)** |
| Purchase of property, plant and equipment | - | (85) | (195) | (85) |
| Interest received | 4 302 | 1 312 | 8 887 | 3 062 |
| **Net cash flow used in investing activities** | **4 302** | **1 227** | **8 691** | **2 977** |
| Proceeds from issuance of equity | 4 109 | 271 935 | 5 484 | 272 864 |
| Share issue cost | - | (11 012) | - | (11 012) |
| Interest paid | (22) | - | (105) | (179) |
| Payment of lease liability | (490) | (434) | (1 802) | (1 716) |
| **Net cash flow from financing activities** | **3 597** | **260 489** | **3 577** | **259 957** |
| Net change in cash and cash equivalents | (42 137) | 227 856 | (155 426) | 137 106 |
| Effect of change in exchange rate | (1 617) | (1 493) | 6 567 | (3 863) |
| **Cash and cash equivalents at beginning of period** | **469 063** | **347 804** | **574 168** | **440 925** |
| **Cash and cash equivalents at end of period** | **425 309** | **574 168** | **425 309** | **574 168** |

# 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 Oslo Cancer 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 2021 financial statements. These condensed interim financial statements should therefore be read in conjunction with the 2021 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 15 February 2023. The figures in the statements have not been audited.

## 3. Personnel expenses

**Personnel expenses**

| NOK (000) | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|
| Salaries | 10 434 | 10 097 | 38 215 | 34 543 |
| Social security tax | 3 086 | 1 756 | 9 142 | 6 686 |
| Social security tax related to options | 11 117 | (4 445) | 2 016 | 8 557 |
| Pension expenses | 655 | 821 | 2 818 | 2 690 |
| Share-based compensation | 4 303 | 3 014 | 20 395 | 11 595 |
| Other personnel expenses | 217 | 196 | 702 | 318 |
| Government grants | 1 818 | 447 | (1 822) | (2 472) |
| **Total personnel expenses** | **31 630** | **11 885** | **71 466** | **61 916** |

On 21 April 2022, the Annual General Meeting approved revised remuneration guidelines. In accordance with the revised guidelines, the Board of Directors has decided to extend the duration of all options under the share option program from 5 years to 7 years. Due to this life extension, the unamortized value of the options has increased, resulting in an increased IFRS cost related to the options going forward, as well as a one-off cost of MNOK 4.5 booked in Q2-22 in accordance with IFRS 2.

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) | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|
| External R&D expenses | 40 959 | 40 533 | 95 175 | 96 735 |
| Clinical studies | 34 176 | 28 460 | 66 772 | 56 675 |
| Manufacturing costs | 4 392 | 7 218 | 19 899 | 21455 |
| Other R&D expenses | 2 392 | 4 855 | 8 504 | 18 605 |
| IP expenses | 1 138 | 1 027 | 3 571 | 3 540 |
| Rent, office and infrastructure | 1 152 | 903 | 4 221 | 3 645 |
| Accounting, audit, legal, consulting | 1 825 | 1 306 | 9 246 | 5 061 |
| Other operating expenses | 1 664 | 675 | 5 020 | 2 338 |
| Government grants | (6 808) | (6 022) | (7 717) | (12 106) |
| **Total other operating expenses** | **39 930** | **38 422** | **109 517** | **99 213** |

## 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) | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|
| Skattefunn from the Research Council of Norway (RCN) | 4 750 | 4 750 | 4 750 | 4 750 |
| Eurostars | - | 262 | - | 786 |
| Innovation Norway | - | - | - | 3 000 |
| Innovation Project grant from the RCN | 42 | 296 | 4 194 | 5 241 |
| Other grants | 198 | 267 | 594 | 802 |
| **Total government grants** | **4 990** | **5 576** | **9 538** | **14 578** |

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) | Q4-22 | Q4-21 | FY22 | FY21 |
|---|---|---|---|---|
| Loss for the period | (70 513) | (51 152) | (167 792) | (164 722) |
| Average number of shares during the period ('000) | 34 309 | 33 502 | 34 247 | 32 373 |
| **Earnings/loss per share (NOK)** | **(2.1)** | **(1.5)** | **(4.9)** | **(5.1)** |

The share options issued to employees as a part of the employee incentive 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**

| NOK (000) | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|
| Government grants | 4 990 | 5 314 |
| Prepayments | 2 916 | 878 |
| Financial instruments | 1 083 | 759 |
| Other receivables | 1 280 | 1 135 |
| **Total receivables and prepayments** | **10 270** | **8 087** |

## 8. Current liabilities

**Current liabilities**

| NOK (000) | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|
| Accounts payable | 7 655 | 22 555 |
| Public duties payable | 3 698 | 2 506 |
| Public duties payable related to options | 14 904 | 12 888 |
| Lease liability | 1 767 | 1 628 |
| Other current liabilities | 17 883 | 11 320 |
| **Total current liabilities** | **45 907** | **50 897** |

## 9. Shareholder information

The share capital as of 31 December 2022 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. Ultimovacs ASA has approximately 5,000 shareholders as of 31 December 2022 and the 20 largest shareholders as of this date are listed below:

**Share register as per 31 December 2022**

| Shareholder | # of shares | Share-% |
|---|---|---|
| Gjelsten Holding AS | 6 495 866 | 18.9 % |
| Canica AS | 2 705 957 | 7.9 % |
| Watrium AS | 1 780 575 | 5.2 % |
| Inven2 AS | 1 555 492 | 4.5 % |
| Folketrygdfondet | 1 515 813 | 4.4 % |
| Radforsk Investeringsstiftelse | 1 512 163 | 4.4 % |
| Langøya Invest AS | 1 389 006 | 4.0 % |
| Helene Sundt AS | 965 802 | 2.8 % |
| CGS Holding AS | 882 132 | 2.6 % |
| Sundt AS | 803 321 | 2.3 % |
| Danske Invest Norge Vekst | 736 440 | 2.1 % |
| Stavanger Forvaltning AS | 590 000 | 1.7 % |
| Prieta AS | 533 988 | 1.6 % |
| Verdipapirfondet Nordea Avkastning | 480 573 | 1.4 % |
| SEB Prime Solutions Sissener Canopus | 400 000 | 1.2 % |
| Verdipapirfondet KLP Aksjenorge | 348 416 | 1.0 % |
| Swedbank AB | 252 814 | 0.7 % |
| Wiarom AS | 250 000 | 0.7 % |
| Verdipapirfondet Nordea Kapital | 246 178 | 0.7 % |
| Gade, Leif Johan | 225 052 | 0.7 % |
| **20 Largest shareholders** | **23 669 588** | ***68.8%*** |
| Other shareholders | 10 726 873 | *31.2%* |
| **Total** | **34 396 461** | ***100.0%*** |

## 10. Share-based payments

**Share option program**

The share option program was introduced in June 2019. The share option program is groupwide and includes all employees in the Group. At the Annual General Meeting held on 21 April 2022, the Board was authorized to increase the Company's share capital in connection with the share incentive arrangement by up to NOK 342,217.61. The authorization is valid until the next ordinary General Meeting in 2023.

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 for all options granted in 2019 was NOK 31.25, NOK 39.15 for the options granted in 2020, NOK 61.99 for the options granted in 2021 and NOK 83.46 for the options granted in 2022. 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.

**Movement of share options**

| | Number of share options | Weighted average strike |
|---|---|---|
| **Outstanding at closing balance 31 December 2021** | **1 833 585** | **44.77** |
| Granted | 480 000 | 83.46 |
| Exercised | 174 700 | 31.39 |
| Forfeited | - | - |
| **Outstanding at closing balance 31 December 2022** | **2 138 885** | **54.55** |
| Vested at closing balance | 860 454 | 40.76 |

After the distribution of 480,000 new options on 21 April 2022 and the exercise of 174,700 shares during 2022, a total of 2,138,885 share options are granted per 31 December 2022, corresponding to 6.22% of the outstanding number of shares in the Company.

The total IFRS cost recognized for the option program in Q4-22 is MNOK 4.3, and MNOK 11.1 in social security tax accruals related to the options. Total IFRS costs in FY22 is MNOK 20.4, and MNOK 2.0 in social security accruals.

## 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 2021 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 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. PD-1 / PDL-1 inhibitors (e.g., pembrolizumab, cemiplimab and nivolumab) and CTLA-4 inhibitors (e.g. ipilimumab). There are many others in development. |
| 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 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 |

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| | 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 |
| Durvalumab | PD-L1 checkpoint inhibitor from AstraZeneca |
| Cemiplimab | PD-L1 checkpoint inhibitor from Regeneron |
| 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 intradermal route, i.e., injection in the dermis, one of the layers of the skin. |

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| | 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. |
| IgE | Immunoglobulin E (IgE) are antibodies produced by the immune system. With an allergy, the individual's immune system overreacts to an allergen (what they are allergic to) by producing IgE. These antibodies travel to cells that release chemicals, causing an allergic reaction when an allergen enters the body. |
| 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 | A serious adverse event (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose<br>1. results in death,<br>2. is life-threatening<br>3. requires inpatient hospitalization or causes prolongation of existing hospitalization<br>4. results in persistent or significant disability/incapacity<br>5. is a congenital anomaly/birth defect, or<br>6. requires intervention to prevent permanent impairment or damage.<br><br>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

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## 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 Oslo Cancer Cluster.

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