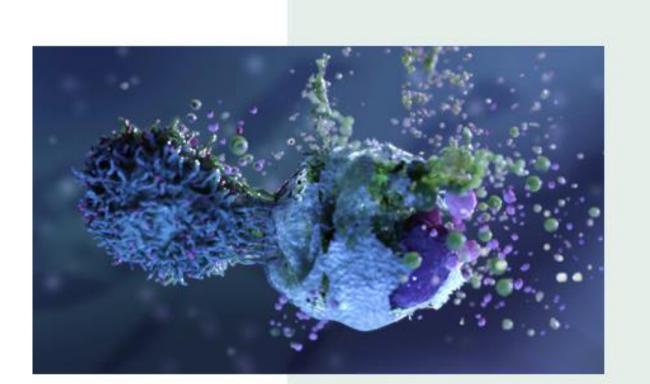
# **2023** Second Quarter Report Ultimovacs ASA







# Introduction

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

Ultimovacs is advancing a broad clinical development program with five Phase II randomized clinical trials, in which the universal cancer vaccine UV1 is combined with different checkpoint inhibitors. More than 670 patients in the U.S., Europe, and Australia will be enrolled in the program. The first three randomized Phase II studies in malignant melanoma (INITIUM), pleural mesothelioma (NIPU), and head and neck squamous cell carcinoma (FOCUS) have completed enrollment.

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

# Second Quarter 2023 Highlights

- The INITIUM study completed enrollment of 156 patients with malignant melanoma in July 2022. The study will provide randomized data on the benefit of UV1 vaccination as add-on to standard ipilimumab and nivolumab treatment. On 25 April, the Company announced that, based on historical reference trials, it is taking longer than anticipated for the study participants to experience disease progression. To date, the patients in the INITIUM study have been followed between 13 and 38 months. Patient follow-up continues until cancer progression has been verified in 70 patients, which has not yet occurred, as of August 21, 2023. Topline results are now expected in the first half of 2024. With continued slow progression in the number of endpoint events, Ultimovacs will explore alternative approaches for data readout acceptable to regulatory authorities. The revised time to readout has minor cost implications for the Company.
- The NIPU study completed the enrollment of 118 patients with pleural mesothelioma in January 2023. The study will provide randomized data on the benefit of UV1 vaccination as add-on to ipilimumab and nivolumab treatment. On 7 June, Ultimovacs announced topline results from the NIPU trial. While the primary Progression Free Survival (PFS) endpoint was not met based on an independent central analysis, a significant positive PFS outcome was observed based on an on-site analysis at all five study centers. In addition, an encouraging Overall Survival (OS) benefit trend was observed in the UV1 arm compared to the control arm. Detailed, updated data from the study, including a longer-term follow-up on OS, will be



presented by the study's principal investigator at an international medical conference during the fall this year.

- On 3 August 2023, the Company announced that the Phase II FOCUS study reached an important milestone by completing enrollment of all 75 patients with head and neck cancer (*post-period event*). The study will provide randomized data on the benefit of UV1 vaccination as add-on to standard pembrolizumab treatment. The topline readout, including PFS and OS, will be disclosed after 12 months minimum follow up, expected during H2 2024.
- Long-term follow-up of the ongoing Phase I trial UV1-103, evaluating the Company's lead candidate UV1 in patients with malignant melanoma, remains encouraging as reported in the 3-year survival update. On 19 June 2023, the Company announced that all patients in cohort 2 who were alive after 2 years remained alive after 3 years. Across both cohorts, 67% of the patients were still alive after 3 years.
- On 28 June 2023, Ultimovacs announced the publication of clinical and biomarker analyses of the UV1-103 Phase I trial in the Clinical Cancer Research, a renowned peer-reviewed journal by the American Association for Cancer Research. The article expands upon the clinical data presented in October 2022, highlighting the promising efficacy and safety of UV1 and pembrolizumab also in patients considered less likely to respond to monotherapy checkpoint inhibition.
- In June 2023, Ultimovacs' Chief Scientific Officer Gustav Gaudernack was awarded the Norwegian Tech Awards' Honorary Prize as an outstanding pioneer in the fight against cancer.
- Ultimovacs received Intention to Grant from the European patent office (17729078.0) in April 2023, and a Decision to Grant from the Japanese patent office (PN822210JP) in July 2023 (*post-period event*). The patents are the European and Japanese counterpart of the US patent No. 11419927 which was granted in August 2022. These patents protect UV1 cancer vaccine-checkpoint inhibitor combinations until at least 2037, and covers UV1 combined with CTLA-4, PD-1 or PD-L1 checkpoint inhibitors.
- In total, more than 300 cancer patients have now received treatment with UV1 in Phase I and Phase II trials. To date, no safety concerns have been reported with the use of UV1.
- In Q4 2023, Ultimovacs plans to host a presentation of the TET technology platform along with the release of safety and immune response findings from the Phase I TENDU study.

#### **Clinical trials enrollment updates**

#### UV1 Phase II program

- **INITIUM (malignant melanoma):** The enrollment of 156 patients was completed in July 2022. Enrollment is ongoing in the single arm supplementary study (not to be included in the INITIUM topline readout).
- NIPU (metastatic pleural mesothelioma): The enrollment of 118 patients was completed in January 2023.
- **FOCUS (head and neck cancer):** The enrollment of 75 patients was completed in August 2023, up from 61 as of the previous quarterly report.
- **DOVACC (ovarian cancer):** 37 out of 184 patients have been enrolled to date, up from 24 as of the previous quarterly report.

• LUNGVAC (non-small cell lung cancer): 11 out of 138 patients have been enrolled to date, up from 7 as of the previous quarterly report.

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**TENDU Phase I trial (prostate cancer) based on the TET technology platform:** The enrollment of 12 patients was completed in mid-December 2022.

#### **Financial update**

- Ultimovacs expects that the current cash resources will support operations to H2 2024, based on current programs and plans, i.e. through the reporting of overall survival data in NIPU and the topline readouts in INITIUM and FOCUS. The extension of the timeline for INITIUM topline readout has minor cost implications for Ultimovacs.
- Total operating expenses amounted to **MNOK 50.6** in Q2 2023, and **MNOK 101.4** YTD. Total loss was **MNOK 43.4** for the period and **MNOK 77.5** YTD.
- Net negative cash flow from operations was MNOK 71.0 in Q2 2023, and net decrease in cash and cash equivalents, not including currency effects, was MNOK 68.1 during Q2 2023. Cash and cash equivalents amounted to MNOK 344.1 as per 30 June 2023.
- On 21 April 2023, a total of 160,000 options for shares in the Company were distributed amongst the employees. The number of options granted corresponds to 0.47% of the outstanding number of shares in the Company. Following the award of the new share options, a total of 2,298,885 share options have been granted, corresponding to 6.68% of the outstanding number of shares in the Company. (Also reported in the Q1 2023 report)

NOK (000) Unaudited	Q2-23	Q2-22	YTD-23	YTD-22	FY22
Total revenues		-			
Total operating expenses	50 641	35 421	101 404	67 321	183 631
Operating profit (loss)	(50 641)	(35 421)	(101 404)	(67 321)	(183 631)
Profit (loss) for the period	(43 375)	(22 376)	(77 486)	(58 976)	(167 792)
Diluted and undiluted earnings / (loss) per share (NOK)	(1.3)	(0.7)	(2.3)	(1.7)	(4.9)
Net increase / (decrease) in cash and cash equivalents	(68 100)	(31 837)	(102 052)	(76 344)	(155 426)
Cash and cash equivalents at end of period	344 104	486 338	425 309	486 338	425 309
	NOK/EUR - 11.7	7040			
Cash and cash equivalents at end of period - EUR (000)	29 401				

#### **Key financials**



# **CEO Statement**

In the past quarter, Ultimovacs' unwavering dedication to advancing cancer treatments with our therapeutic cancer vaccine UV1, has led to significant progress in our broad Phase II development strategy, enabling us to maximize the value we can provide to both cancer patients and our shareholders. Additionally, we have achieved important corporate and scientific milestones, including expanding our patent portfolio and publishing key Phase I data in a recognized scientific journal.



The first three Phase II trials, INITIUM, NIPU, and FOCUS, have successfully completed enrollment. We anticipate receiving data on the clinical efficacy of UV1 across these three randomized trials in different indications within the next 2-16 months, representing significant value inflection points over the coming year. The insight from these studies will enable us to define the right path forward for UV1 and underscore its powerful potential as a universal cancer vaccine when combined with other immunotherapies.

In the INITIUM trial in malignant melanoma, we have reached a noteworthy milestone as all patients in the study have been followed for over 12 months. As of today, the pre-defined endpoint of verified cancer progression or death in 70 patients has not yet been reached. Assuming the current trend persists, we will explore potential alternatives for data readout to be discussed with regulatory authorities. We appreciate the encouraging observation of slower disease progression for the patients, and we eagerly await the data that will contribute to our comprehension of UV1's role in these positive clinical outcomes.

This quarter also brought us the topline results in the NIPU trial in pleural mesothelioma, a hardto-treat cancer with a high mortality rate and few therapeutic options. While the progressionfree survival (PFS) was not met in the analysis by central review, we remain highly encouraged by the positive trends observed in overall survival (OS) in the UV1 arm as compared to the control arm. The benefit to patient survival is a cornerstone in any cancer trial and guides the continual development of novel cancer treatments. We are looking forward to the comprehensive data presentation this fall to determine the path forward for UV1 in mesothelioma.

Finally, we are immensely proud that the brilliant mind behind our cancer vaccine UV1, our Chief Scientific Officer Gustav Gaudernack, was honored with the prestigious Norwegian Tech Awards' Honorary Prize for his outstanding contributions to the fight against cancer. Gustav's long-term commitment within the field of immunotherapy is exceptional, and the recognition was truly well deserved.

As we move forward, we remain steadfast in our goal of advancing science and delivering innovative treatments to patients battling cancer with the dedication of our talented team and the support of our shareholders and stakeholders. We thank you for your ongoing support, and we are looking forward to sharing important milestones during the next months.

Carlos de Sousa, Chief Executive Officer



# **Operational Review**

#### Lead product candidate: UV1

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

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

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

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 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 670 patients 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. No safety concerns have been reported with the use of UV1 to date.

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

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**

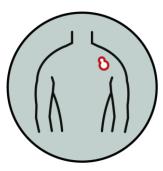
On December 2021, Ultimovacs announced that UV1 has received Orphan Drug designation from the U.S. FDA for the treatment of malignant melanoma stage IIB-IV. UV1, as add-on therapy to checkpoint inhibitors ipilimumab and nivolumab, is currently being studied as first-line treatment for unresectable or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

#### **UV1 clinical program**

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

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

The first patient received treatment in the INITIUM trial in June 2020, and the last patient was enrolled in July 2022. The study is being conducted at 39 hospitals across the U.S., UK, Belgium, and Norway.



The initial study design called for enrollment of 154 patients. Two additional patients were enrolled bringing the total number of patients in the study to 156.

Half of the 156 patients enrolled in the trial have been dosed with UV1 plus the PD-1 checkpoint inhibitor nivolumab and the CTLA-4 checkpoint inhibitor ipilimumab, while the other half received nivolumab and ipilimumab. Analysis of data from the study follows after disease progression or death has been observed in 70 patients, which has not yet occurred as per Q2 2023 reporting. Top line results are now expected during the first half of 2024. Assuming the current trend of continued slow progression in the number of endpoint events persists, Ultimovacs will explore potential alternatives for data readout acceptable to regulatory authorities.

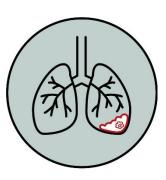


The primary endpoint in the study is progression-free survival. Secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR) and safety.

In September 2022, Ultimovacs initiated a supplementary study to the INITIUM trial with 20 patients in a single-arm study. The objective of the study is to provide insight into the mode of action of the UV1 vaccine with extensive research activities parallel to the clinical observation of the patients. All patients will receive experimental treatment, i.e., the triple combination of UV1, ipilimumab and nivolumab. Data collected from the supplementary study will not be part of the primary and secondary endpoint analyses of INITIUM and will not affect the timeline for topline read-out.

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

NIPU is an investigator-initiated randomized, comparative, multicenter Phase II trial in which the cancer vaccine UV1 will be evaluated in combination with the checkpoint inhibitors ipilimumab and nivolumab as second-line treatment of patients with metastatic pleural mesothelioma, a hard-to-treat cancer with a high mortality rate and few therapeutic options for second line patients. 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 supported the trial.



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

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

The readout of the primary endpoint of progression-free survival was reported in June 2023, following disease progression or death had been observed in 69 patients. According to a central review conducted by a blinded, independent clinical research organization, the study did not meet the primary PFS endpoint. However, an investigator assessment of the primary endpoint, a pre-defined sensitivity analysis conducted by specialized radiologists across the study locations in Australia, Spain, Denmark, Sweden, and Norway, showed a statistically significant favorable PFS benefit for the UV1 arm patients.

While progression-free survival, which measures the time from treatment initiation until disease progression or death, can serve as an indicator of clinical benefit, overall survival (OS), which measures the duration of patient survival from the time of treatment initiation, stands as a universally accepted direct measure of clinical benefit.

Importantly, a clinically relevant trend was observed in overall survival in the UV1 arm over the control arm in the NIPU study at the time of the topline readout. The data needs to mature further before a conclusion can be reached. Updated, detailed data from the NIPU trial is expected to be presented at an international medical conference this fall, as well as in a publication in a peer-reviewed journal.

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

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

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

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

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

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

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





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enroll patients with high-grade BRCA-negative ovarian cancer after partial or complete response following the second round of chemotherapy. MD Manzoor Raza Mirza is the principal investigator for the trial, which is sponsored by NSGO-CTU.

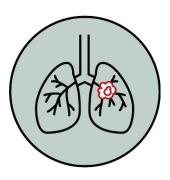
The first patient received treatment in the DOVACC trial in December 2021. A total of 37 out of 184 patients have been enrolled in DOVACC. The trial will be conducted at more than 40 hospitals in more than 10 European countries. Ultimovacs will provide the UV1 vaccine and AstraZeneca will provide durvalumab and olaparib for the study.

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

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

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

The LUNGVAC trial is an investigator-initiated, randomized, comparative Phase II clinical trial in which the cancer vaccine UV1 will be evaluated in combination with the checkpoint inhibitor cemiplimab as first-line treatment of NSCLC patients with advanced or metastatic disease. The trial will enroll previously untreated patients with adenocarcinoma or squamous NSCLC, where tumor biopsies show a PD-L1-expression score equal to or above 50%. These subgroups represent approximately 30% of all advanced and metastatic NSCLC patients. Professor Odd Terje Brustugun is the



principal investigator for the trial which is sponsored by Drammen Hospital in Vestre Viken Hospital Trust, Norway.

The LUNGVAC study will be conducted at approximately 10 clinical centers in Norway. The first patient received treatment in the LUNGVAC trial in October 2022. In December 2022, the Norwegian health authorities changed the reimbursement in the indication from pembrolizumab to cemiplimab. Following this decision, the LUNGVAC study changed the PD-1 inhibitor in the study from pembrolizumab to cemiplimab. 11 out of 138 patients have been enrolled in the study since the change to cemiplimab on 1 January 2023. The three patients enrolled prior to 1 January 2023 will continue treatment with pembrolizumab and will be maintained as a separate sub-group in the trial.

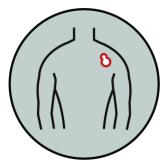
Half of the patients in the trial will be treated with UV1 + cemiplimab and the other half will be treated with cemiplimab monotherapy.

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

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

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



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

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

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

After the study ended at two years follow up, the protocol was amended to allow extended follow-up of patients for up to five years to evaluate overall survival. Three patients in cohort 1 chose not to be followed up further after two years, changing the number of participating patients in cohort 1 from 20 to 17.

The patient population in the UV1-103 trial is the same as in the UV1 Phase II trial INITIUM.

#### The UV1-103 trial – biomarker analyses

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

Clinical analyses from the UV1-103 study indicate efficacy of the UV1-pembrolizumab combination in patients with low levels of PD-L1 (<1%). Low PD-L1 levels are a key predictive biomarker associated with lower efficacy for pembrolizumab and other anti-PD-1 therapies,



in some tumor types. The analyses showed robust responses in patients treated with the combination of UV1 and pembrolizumab, regardless of patients' PD-L1 status.

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

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

In addition to the sub-analysis of PD-L1 status, the study also evaluated four other key biomarkers that, in other historical studies, have indicated how responsive patients may be to pembrolizumab monotherapy: baseline tumor mutational burden (TMB), predicted neoantigens, interferon gamma (IFN-gamma) gene signature, and levels of tumor infiltrating lymphocytes (TILs). In the UV1-103 study, objective responses were observed also in patients with low TMB, in patients with low neoantigen tumors, and in patients with tumors which were not enriched for IFN-gamma. These patient groups 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 9.5 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 inducing T cell responses against cancer-specific peptides. The platform can generate multiple first-in-class cancer vaccine candidates that harness pre-existing



antibody responses against tetanus induced by standard tetanus vaccination. TET vaccine candidates can be tailored to many types of cancer, and potentially to infectious diseases.

#### The TENDU Phase I clinical trial

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

The TENDU trial is being conducted at Oslo University Hospital. The first patient was treated in February 2021, and the last patient was enrolled in December 2022. A total of 12 patients have been enrolled. Three different doses of TENDU have been investigated: 40mcg (3 patients), 400mcg (3 patients) and 6 patients received the highest dose (960mcg). All patients are followed up for 6 months after their last treatment. So far, the TENDU treatment has been shown to be safe and well tolerated. Readout of safety and immune responses is expected during second half of 2023.





#### **Patents and IP**

On 13 April 2023, Ultimovacs announced that the Company has received a Notice of Intention to Grant from the European Patent Office (EPO) concerning its European Patent application 17729078.0 on the use of vaccine-checkpoint inhibitor combinations to treat cancer. Subject to grant formalities including translations and fee disbursement, the European patent will issue with a patent term to June 2037. When granted, the European patent and its counterpart in the U.S. add substantially to the strong intellectual property base Ultimovacs is building around UV1 combination therapies. Supplementary Patent Certificates around UV1-combination therapies have the potential to further extend protection beyond 2037.

In July 2023, Ultimovacs received a Decision to Grant from the Japanese patent office concerning its Japanese patent application PN822210JP (*post-period event*). These patents are the European and Japanese counterparts of the U.S. patent No. 11419927 which was granted in April 2022. The Company has similar patent applications pending in other territories worldwide, including Japan, Canada and Australia. They cover synergistic cancer treatments that include the UV1 peptide vaccine in combination with an anti-CTLA-4, anti-PD-1 or anti-PD-L1 antibody checkpoint inhibitor. The primary patents of many of the current CTLA-4 and PD-1/PD-L1 checkpoint inhibitors face expiry over the course of the next several years. (also reported in the Q1 2023 report)

#### **Organization and board**

On 20 April 2023, 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 2024: Jónas Einarsson (chair), Kari Grønås, Eva Dugstad, Leiv Askvig, Ketil Fjerdingen, Henrik Schüssler, Haakon Stenrød and Aitana Peire.

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), Hans Peter Bøhn, Jakob Iqbal (*also reported in the Q1 2023 report*).



# Outlook

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

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

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

- NIPU (metastatic pleural mesothelioma): The primary endpoint of progression-free survival was reported in June 2023. Detailed, updated results including overall survival will be presented at an upcoming international medical conference during H2 2023
- INITIUM (metastatic malignant melanoma): H1 2024. Assuming the current trend of continued slow progression in number of endpoint events persists, Ultimovacs will explore potential alternatives for data readout acceptable to regulatory authorities.
- FOCUS (head and neck cancer): H2 2024
- DOVACC (ovarian cancer): H2 2024 (to be updated with the Q4 2023 reporting)
- LUNGVAC (non-small cell lung cancer): H2 2025 (to be updated with the Q4 2023 reporting)

Ultimovacs expects that the current cash resources will support operations to H2 2024, based on current programs and plans, i.e., through the reporting of overall survival data in NIPU and the topline readouts in INITIUM and FOCUS. The extension of timeline for INITIUM topline readout has minor cost implications for Ultimovacs.

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



clinical trials would reinforce the significant potential of UV1 to improve the treatment of cancer.

Ultimovacs is also seeking to broaden its pipeline of drug candidates. The Company's research activities are currently focused on the development of new first-in-class cancer vaccine solutions, building on Ultimovacs' base technology, the TET-platform, and the development of new molecules and technologies based on biobank material from the ongoing and planned clinical studies conducted with UV1. Pending final confirmation of the safety of the TET technology through the Phase I TENDU trial and further preclinical development, Ultimovacs' ambition is to apply the TET technology to identify new cancer vaccine program candidates and to advance them into clinical development.

# **Risks and uncertainties**

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

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

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



# **Financial review**

**Financial results** 

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

Total payroll and payroll related expenses were lower in Q2 2023 (**MNOK 4.4**) compared to the same period in FY 2022 (MNOK 14.3). Regular salaries not including option expenses were higher in Q2 2023 compared to Q2 2022 as the second quarter in 2023 had one more full-time equivalent (FTE) employed compared to Q2 2022. However, option expenses and the social security tax accrual related to share options, which fluctuates with the company share price, was MNOK 12.9 lower in Q2 2023 compared to Q2 2022, explaining most of the difference these two quarters.

Other operating expenses (**MNOK 45.6** in Q2 2023 vs. MNOK 20.4 in Q2 2022) are primarily comprised of R&D related expenses. These expenses, including IP and external R&D expenses, offset by government grants, amounted to **MNOK 41.0** in Q2 2023 vs. MNOK 16.3 in Q2 2022. The main contributors to the increase in R&D expenses so far in FY 2023 were the INITIUM and NIPU trials, and chemistry, manufacturing and controls (CMC) activities.

Net financial items amounted to **MNOK 7.3** in Q2 2023, compared to MNOK 13.0) in Q2 2022. Financial items are primarily comprised of currency fluctuations from EUR at bank and the value of EUR currency future contracts swapped on a quarterly basis, in addition to interest gain from cash at bank accounts. In Q2 2023, the net financial income is mainly comprised of MNOK 3.4 in interest from bank and MNOK 4.5 in currency gain from the EUR currency future contracts.

Total loss for the Q2-23 period amounted to **MNOK 43.4**, compared to MNOK 22.4 in Q2-22. Total loss YTD-22 amounted to **MNOK 77.5** compared to a loss of MNOK 59.0 YTD-22.

#### **Financial position**

Total assets per 30 June 2023 were **MNOK 437.1**, a decrease of MNOK 72.6 from 31 December 2022, primarily as a consequence of negative operational cashflow.

Total liabilities as of 31 December 2022 amounted to **MNOK 53.9**, of which MNOK 14.1 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 12.2, and **MNOK 1.2** of 'Current liabilities' are related to the fair value of these EUR swap contracts by the end of the quarter.

Total equity equaled **MNOK 383.2** as of 30 June 2023. Total equity has, since year-end 2022, been decreased by the period's operating loss and currency translation, amounting to **MNOK** 



**74.1**, and has in addition been increased by the recognition of share-based payments/stock options of **MNOK 7.9**.

#### **Cash flow**

The total net decrease in cash and cash equivalents in Q2 2023, not including currency effects, was **MNOK 68.1**, which is primarily related to net negative cash-flow from operations amounting to **MNOK 71.0**.

Total cash and cash equivalents were **MNOK 344.1** per 30 June 2023, of which MNOK 1.3 (**MEUR 0.1**) is held on EUR account.

#### **Key financials**

NOK (000) Unaudited	Q2-23	Q2-22	YTD-23	YTD-22	FY22
Total revenues	-	-	-	-	-
Total operating expenses	50 641	35 421	101 404	67 321	183 631
Operating profit (loss)	(50 641)	(35 421)	(101 404)	(67 321)	(183 631)
Profit (loss) for the period	(43 375)	(22 376)	(77 486)	(58 976)	(167 792)
Diluted and undiluted earnings / (loss) per share (NOK)	(1.3)	(0.7)	(2.3)	(1.7)	(4.9)
Net increase / (decrease) in cash and cash equivalents	(68 100)	(31 837)	(102 052)	(76 344)	(155 426)
Cash and cash equivalents at end of period	344 104	486 338	425 309	486 338	425 309
	NOK/EUR - 11.7	040			
Cash and cash equivalents at end of period - EUR (000)	29 401				

## **Responsibility Statement**

We confirm, to the best of our knowledge, that the unaudited condensed interim financial statement for the six months ended 30 June 2023 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, 21 August 2023

Jónas Einarsson Chairman of the Board (Sign.)

Henrik Schüssler Board member (Sign.)

Aitana Peire Board member (Sign.) Kari Grønås Board member (Sign.)

Ketil Fjerdingen Board member (Sign.)

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

Leiv Askvig Board member (Sign.)

Carlos de Sousa CEO (Sign.)



#### Interim condensed consolidated statement of comprehensive income

NOK (000) Unaudited	Note	Q2-23	Q2-22	YTD-23	YTD-22	FY22
Other operating income		-	-	-	-	-
Total revenues		-	-	-	-	-
Payroll and payroll related expenses	3, 5	4 359	14 340	25 361	25 724	71 466
Depreciation and amortization		691	646	1 391	1 275	2 648
Other operating expenses	4, 5	45 591	20 436	74 652	40 322	109 517
Total operating expenses		50 641	35 421	101 404	67 321	183 631
Operating profit (loss)		(50 641)	(35 421)	(101 404)	(67 321)	(183 631)
Financial income		8 326	13 663	25 511	14 889	17 375
Financial expenses		1 059	618	1 593	6 543	1 536
Net financial items		7 266	13 045	23 918	8 346	15 839
Profit (loss) before tax		(43 375)	(22 376)	(77 486)	(58 976)	(167 792)
Income tax		-	-	-	-	-
Profit (loss) for the period		(43 375)	(22 376)	(77 486)	(58 976)	(167 792)
Other comprehensive income (loss) - Currency tr	anslation	(308)	2 734	3 392	(187)	(1 889)
Total comprehensive income (loss) for the	period	(43 683)	(19 642)	(74 094)	(59 163)	(169 681)
Diluted and undiluted earnings/(loss) pr share (N	ОК) 6	(1.3)	(0.7)	(2.3)	(1.7)	(4.9)

#### Interim condensed consolidated statement of financial position

NOK (000) Unaudited	Note	30 Jun 2023	30 Jun 2022	31 Dec 2022
ASSETS				
Goodw ill		11 358	10 999	10 701
Licenses		55 137	53 395	51 944
Patents		5 407	6 162	5 784
Property, plant and equipment		172	314	220
Right to use asset	11	4 502	1 736	5 444
Total non-current assets		76 577	72 606	74 093
Receivables and prepayments	7	16 378	20 309	10 270
Bank deposits		344 104	486 338	425 309
Current assets		360 482	506 647	435 579
TOTAL ASSETS		437 059	579 253	509 672
EQUITY				
Share capital		3 440	3 422	3 440
Share premium		1 076 308	1 070 841	1 076 308
Total paid-in equity		1 079 747	1 074 264	1 079 747
Accumulated losses		(749 599)	(563 297)	(672 113)
Other equity		48 665	32 146	40 752
Translation differences		4 356	2 665	964
TOTAL EQUITY	6, 9	383 169	545 778	449 350
LIABILITIES				
Lease liability	11	2 763	714	3 713
Deferred tax		11 358	10 999	10 701
Non-current liabilities		14 122	11 713	14 414
Accounts payable		14 021	6 038	7 655
Lease liability	11	1 852	1 114	1 767
Other current liabilities		23 895	14 609	36 485
Current liabilities	8	39 768	21 761	45 907
TOTAL LIABILITIES		53 890	33 475	60 321
TOTAL EQUITY AND LIABILITIES		437 059	579 253	509 672

#### Interim condensed consolidated statement of changes in equity

NOK (000) Unaudited	Share Capital	Share Premium	Accum. Iosses	Other equity	Transl. differenc.	Total equity
Balance at 1 Jan 2022	3 422	1 070 841	(504 321)	20 358	2 853	593 152
Loss for the period	-	-	(58 976)	-	-	(58 976)
Issue of ordinary shares	-	-	-	-	-	-
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	11 788	-	11 788
Translation differences	-	-	-	-	(187)	(187)
Balance at 30 Jun 2022	3 422	1 070 841	(563 297)	32 146	2 665	545 778
Balance at 1 Jan 2023	3 440	1 076 308	(672 113)	40 752	964	449 350
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
Balance at 31 Jun 2023	3 440	1 076 308	(749 599)	48 665	4 356	383 169

#### Interim condensed consolidated statement of cash flow

NOK (000) Unaudited	Q2-23	Q2-22	YTD-23	YTD-22	FY22
Loss before tax	(44 290)	(22 376)	(78 401)	(58 976)	(167 792)
Non-cash adjustments			-		
Depreciation and amortization	691	646	1 391	1 275	2 648
Interest received incl. investing activities	(3 428)	(1 679)	(6 635)	(2 904)	(8 887)
Net foreign exchange differences	(3 938)	(11 460)	(17 491)	(5 618)	(7 176)
Other finance expense	100	26	208	56	105
Share option expenses	3 702	8 840	7 912	11 788	20 395
Working capital adjustments:			-		
Changes in prepayments and other receivables	(5 042)	(1 289)	(7 192)	(2 370)	(1 859)
Changes in payables and other current liabilities	(18 788)	(5 680)	(7 381)	(21 402)	(5 129)
Net cash flow from operating activities	(70 991)	(32 971)	(107 589)	(78 150)	(167 695)
Purchase of property, plant and equipment	-	(87)	(25)	(195)	(195)
Interest received	3 428	1 679	6 635	2 904	8 887
Net cash flow used in investing activities	3 428	1 592	6 610	2 709	8 691
Proceeds from issuance of equity	-	-	-	-	5 484
Share issue cost	-	-	-	-	-
Interest paid	(100)	(26)	(208)	(56)	(105)
Payment of lease liability	(437)	(431)	(866)	(846)	(1 802)
Net cash flow from financing activities	(537)	(457)	(1 074)	(903)	3 577
Net change in cash and cash equivalents	(68 100)	(31 837)	(102 052)	(76 344)	(155 426)
Effect of change in exchange rate	6 676	(5 532)	20 846	(11 487)	6 567
Cash and cash equivalents at beginning of period	405 528	523 706	425 309	574 168	574 168
Cash and cash equivalents at end of period	344 104	486 338	344 104	486 338	425 309



# **Notes**

#### **1.** General information

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

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

#### 2. Basis for preparations and accounting principles

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

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

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

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

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

These interim financial statements were approved for issue by the Board of Directors on 21 August 2023. The figures in the statements have not been audited.



**FY22** 

95 175

66 772

19 899

8 504

3 571

4 221

9 246 5 020

(7717)

109 517

(618)

40 322

#### **Personnel expenses** 3.

#### **Personnel expenses**

NOK (000)	Q2-23	Q2-22	YTD-23	YTD-22	FY22
Salaries	8 128	6 816	19 895	17 538	38 215
Social security tax	1 803	1 469	3 691	3 170	9 142
Social security tax related to options	(9 724)	(1 945)	(7 584)	(6 915)	2 016
Pension expenses	938	642	1 782	1 422	2 818
Share-based compensation	3 702	8 840	7 912	11 788	20 395
Other personnel expenses	(61)	173	92	376	702
Government grants	(427)	(1 656)	(427)	(1 656)	(1 822)
Total personnel expenses	4 359	14 340	25 361	25 724	71 466
Number of FTEs at end of period	24	23	24	23	23

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

#### 4. **Operating expenses**

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

Operating expenses				
NOK (000)	Q2-23	Q2-22	YTD-23	YTD-22
External R&D expenses	40 711	15 639	63 112	30 039
Clinical studies	17 924	10 377	28 075	19 856
Manufacturing costs	20 360	2 985	29 529	6 148
Other R&D expenses	2 427	2 277	5 508	4 035
IP expenses	874	1 251	2 180	1 576
Rent, office and infrastructure	1 110	1 118	2 651	2 148
Accounting, audit, legal, consulting	2 511	1 823	4 159	4 722
Other operating expenses	1 026	1 222	3 191	2 455

Government grants

Total other operating expenses

(641)

45 591

(618)

20 436

(641)

74 652



#### 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)	Q2-23	Q1-22	YTD-23	YTD-22	FY22
Skattefunn from The Research Council of Norw ay (RCN)	-	-	-		4 750
Innovation Norw ay	-	-	-		-
Innovation Project grant from the RCN	1 068	2 076	1 068	2 076	4 194
Other grants	-	198	-	198	594
Total government grants	1 068	2 274	1 068	2 274	9 538

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

#### 6. Earnings per share

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

#### Earnings per share

NOK (000)	Q2-23	Q2-22	YTD-23	YTD-22	FY22
Loss for the period	(43 375)	(22 376)	(77 486)	(58 976)	(167 792)
Average number of shares during the period ('000)	34 396	34 222	34 396	34 222	34 247
Earnings/loss per share (NOK)	(1.3)	(0.7)	(2.3)	(1.7)	(4.9)

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

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



#### 7. Current assets

#### **Receivables and prepayments**

	30 Jun	30 Jun	31 Dec
NOK (000)	2023	2022	2022
Government grants	4 750	4 750	4 990
Prepayments	1 799	1 458	2 916
Financial instruments	-	10 611	1 083
Other receivables	9 829	3 490	1 280
Total receivables and prepayments	16 378	20 309	10 270

### 8. Current liabilities

#### **Current liabilities**

NOK (000)	30 Jun 2023	30 Jun 2022	31 Dec 2022
Accounts payable	14 021	6 038	7 655
Public duties payable	3 975	1 974	3 698
Public duties payable related to options	7 320	5 973	14 904
Lease liability	1 852	1 114	1 767
Financial instruments	1 158	-	-
Other current liabilities	11 442	6 662	17 883
Total current liabilities	39 768	21 761	45 907



#### 9. Shareholder information

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

#### Share register as per 30 June 2023

	# of	
Shareholder	shares	Share-%
Gjelsten Holding AS	6 495 866	18.9 %
Canica AS	2 705 957	7.9 %
Watrium AS	1 780 575	5.2 %
Folketrygdfondet	1 520 000	4.4 %
Radforsk Investeringsstiftelse	1 519 263	4.4 %
Inven2 AS	1 424 127	4.1 %
Langøya Invest AS	1 396 006	4.1 %
Helene Sundt AS	965 802	2.8 %
CGS Holding AS	882 132	2.6 %
Sundt AS	803 321	2.3 %
Danske Invest Norge Vekst	719 549	2.1 %
Stavanger Forvaltning AS	578 104	1.7 %
Prieta AS	533 988	1.6 %
Verdipapirfondet Nordea Avkastning	451 573	1.3 %
SEB Prime Solutions Sissener Canopus	369 717	1.1 %
Wiarom AS	250 000	0.7 %
Myrlid AS	250 000	0.7 %
Verdipapirfondet Nordea Kapital	246 178	0.7 %
Gade, Leif Johan	226 500	0.7 %
Sw edbank AB	226 124	0.7 %
20 Largest shareholders	23 344 782	<b>67.9%</b>
Other shareholders	11 051 679	32.1%
Total	34 396 461	100.0%

#### **10.** Share-based payments

#### Share option program

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

Each option gives the right to acquire one share in the Company and is granted without consideration. Pursuant to the vesting schedule, 25% of the options will vest one year after the day of grant, 25% of the options will vest two years after the day of grant and the remaining 50% will vest three years after



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

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

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

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

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

#### **Movement of share options**

The total IFRS cost recognized for the option program in Q2 2023 is MNOK 3.7, and the reversal in accruals for social security tax related to the options is MNOK 9.7. YTD 2023, the total IFRS costs are MNOK 7.9, and the reversal of in social security accruals is MNOK 7.6.



#### **11.** IFRS 16 – rental contracts

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

#### 12. Events after the balance sheet date

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



# Glossary

Words/terms	Description
General/basic terms	
UV1	UV1 is Ultimovacs' synthetic peptide vaccine
Peptides	Peptides are short or long-chains of amino acids, and amino acids are the
	building blocks of protein.
Adjuvant	A medical substance used to enhance the effect of another medical
	substance.
GM-CSF	"Granulocyte-macrophage colony-stimulating factor". Ultimovacs uses GM-
	CSF as adjuvant together with UV1 to strengthen the ability of UV1 to
	stimulate the immune system.
Immune checkpoint	Medicines that "takes the brakes off the immune system". The immune
inhibitors	system has brakes necessary to balance a normal immune response. The
	downside to these brakes is that it makes it easier for a tumor to grow because
	the immune system becomes less able to fight the tumor. By "blocking the brokes" the immune system becomes more potent in killing tumor calls.
	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).
inimune response	The activity of the initiale system against foreign substances (antigens).
Investigational New	The United States Food and Drug Administration's Investigational New Drug
Drug (IND)	(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 (Merck & Co. Inc.)
Durvalumab	PD-L1 checkpoint inhibitor from AstraZeneca
Cemiplimab	PD-L1 checkpoint inhibitor from Regeneron Pharmaceuticals
Olaparib	PARP inhibitor from AstraZeneca
Clinical trial terms	
CR	Complete response (The disappearance of all signs of cancer in response to
	treatment. Also called complete remission.)
PR	Partial response (A decrease in the size of a tumor, or in the extent of cancer
	in the body, in response to treatment. Also called partial remission.)
SD	Stable disease (Cancer that is neither decreasing nor increasing in extent or
	severity.)
PD	Progressive disease (Cancer that is growing, spreading, or getting worse.)
ORR	Objective response rate = CR + PR
DOR	Duration of response (The length of time that a tumor continues to respond
	to treatment without the cancer growing or spreading.)
OS	Overall survival (The length of time from either the date of diagnosis or the
	start of treatment for a disease, such as cancer, that patients diagnosed with
	the disease are still alive. In a clinical trial, measuring the overall survival is
	one way to see how well a new treatment works.)
PFS	Progression-free survival (The length of time during and after the treatment
	of a disease, such as cancer, that a patient lives with the disease but it does
	not get worse. In a clinical trial, measuring the progression-free survival is one
	way to see how well a new treatment works.)
mOS	Median overall survival means (The length of time during and after the
	treatment of a disease, such as cancer, that half of the patients in a group of
	patients diagnosed with the disease are still alive.)
mPFS	Median progression-free survival (The length of time during and after
	the treatment of a disease, such as cancer, that a patient lives with the
	disease but it does not get worse. In a clinical trial, measuring the
	progression-free survival is one way to see how well a new treatment
	works.)
Medical terms	
Intradermal	In order to initiate an immune response, a vaccine must be taken up by
	antigen presenting cells (dendritic cells). UV1 is administered via the
	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.
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	<ul> <li>A serious adverse event (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose</li> <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> </ul>
	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.



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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 the Oslo Cancer Cluster and the Life Science Cluster.

