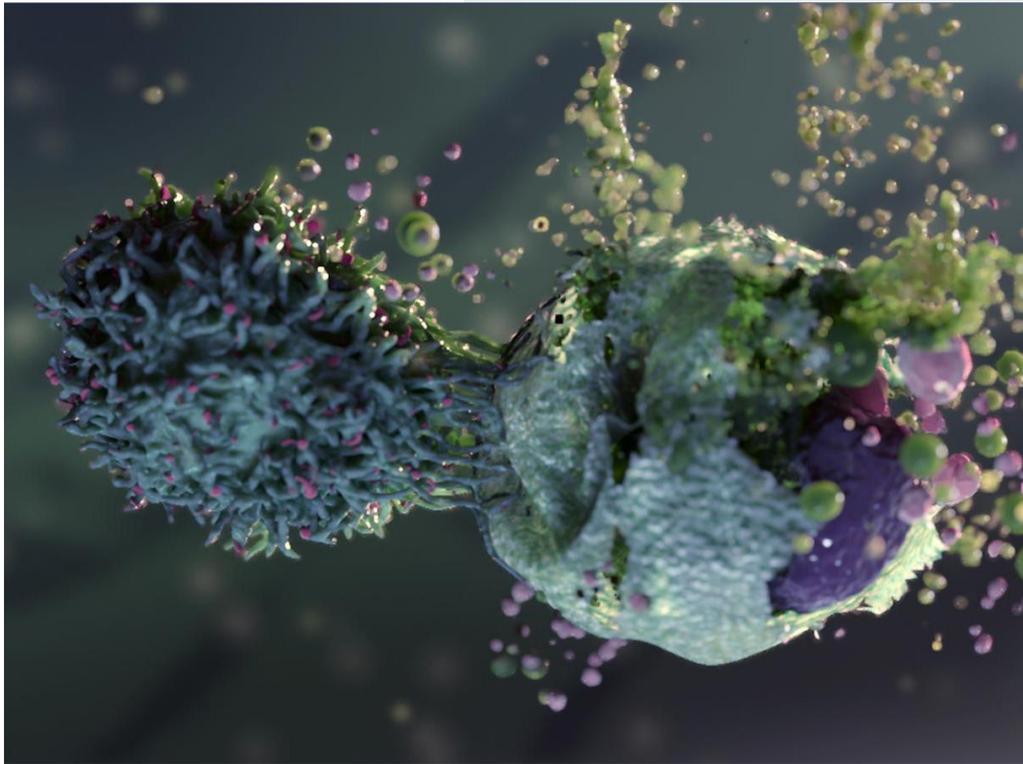


# 2022

## Third Quarter Report

*Ultimovacs ASA*



## Third Quarter 2022 Highlights

- Ultimovacs is getting close to key value inflection points: Readouts from the first two UV1 phase II studies, INITIUM and NIPU, are expected during the first half of 2023
- Good patient enrollment continues in Ultimovacs' phase II program, including the recruitment of the first patients in LUNGVAC, the fifth randomized phase II clinical trial with UV1 in combination with checkpoint inhibitors
- New data from our phase I study UV1-103 in malignant melanoma, with the combination of UV1 and pembrolizumab, showed an encouraging 71% overall survival rate after three years in cohort 1, on top of the good safety and 33% complete response rate data previously announced for all 30 patients in the study
- 'Hard-to-treat patients' appear to have much to gain as multiple biomarker analyses of the biological samples from the UV1-103 study support the promising efficacy signals
- Financially, Ultimovacs' shareholder base and funding remain strong, with an expected financial runway until first half of 2024 based on current programs.

## CEO's Statement

The third quarter of 2022 has been eventful for the Ultimovacs team. We are preparing for next year's important milestones, the topline readouts from Ultimovacs' phase II key comparative trials. The fifth randomized phase II clinical trial started enrolling patients, and we shared positive new 3-year clinical data and biomarker analyses from the UV1-103 study in malignant melanoma. And elsewhere in pharma, two large innovative companies signaled just how commercially important cancer vaccines are likely to be for them this decade.



During the first half of 2023, Ultimovacs and everyone tracking the company will be looking out for the topline readouts from the two key phase II clinical trials of our universal cancer vaccine UV1, INITIUM in malignant melanoma and NIPU in mesothelioma. Readouts from the two trials, each of which assess directly the impact of UV1 on widely-used checkpoint inhibitor treatments, represent key potential value inflection points in the growth of the company.

In October, Ultimovacs reported that the first patient with non-small cell lung cancer was randomized in LUNGVAC - the fifth phase II clinical trial of UV1 in combination with checkpoint inhibitors. This is another important milestone in our ambitious phase II clinical program, treating more than 650 patients in five cancer indications with UV1 in combination with different checkpoint inhibitors.

The phase I clinical trial UV1-103 treating malignant melanoma patients with UV1 in combination with pembrolizumab, continued to deliver strong data. Ultimovacs has previously reported good safety and an encouraging 33% complete response rate across both cohorts in the study. Recently released three-year survival data from cohort one showed a positive 71% overall survival rate. For reference, historical data on the treatment of malignant melanoma with pembrolizumab showed a 51% three-years overall survival rate.

The UV1-103 study also generated promising biomarker data supporting a positive contribution from UV1 and a defined active role attributable to the cancer vaccine when used in combination with checkpoint inhibitors. Pembrolizumab is known to exert stronger effects on patients with higher PD-L1 expression and less strong on patients with low PD-L1 expression, so-called “hard-to-treat patients”. When pembrolizumab was combined with UV1, patients exhibited clinical responses independent of the PD-L1 expression levels. Thus, UV1 appeared to level the odds for patients, changing the range of tumors that appear to respond to treatment and raising the potential number of patients that might be effectively treated. All five biomarkers we assessed reinforced that range-expanding trend.

This encouraging data indicates that UV1 has the potential to extend the use of immunotherapy to broader patient populations in multiple cancer types with unmet needs, underserved by existing therapies. The lead investigator of the UV1-103 trial, MD Yousef Zakharia, shared these data in a plenary presentation to the melanoma community in Edinburgh last month, during the annual International Society of Melanoma Research Conference.

As Ultimovacs continued to share the progress of UV1 with clinical, research and business colleagues, we could not ignore the unprecedented momentum that cancer vaccines have gained recently across the industry. Merck took up the development and commercialization options in its personalized cancer vaccines agreement with Moderna while BioNTech’s founders signaled that cancer vaccines could be available before the end of the decade.

Our growing understanding of how UV1 works has resulted from highly collaborative efforts involving researchers and oncologists around the world, supported by our business partners, investors and dedicated team. In the current financial climate, we are pleased that the company has an expected cash runway to the first half of 2024, beyond key value inflection points. I sincerely thank all who have come with Ultimovacs on its journey thus far and look forward to making the transition with you as our remarkable company approaches its next crucial and potentially transformative phase.

*Carlos de Sousa, Chief Executive Officer*

## Third 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 UV1-103 trial in metastatic malignant melanoma. (*post period event*)
- On 18 October 2022, Ultimovacs ASA announced multiple biomarker analyses data from the phase I UV1-103 malignant melanoma trial. The analyses of biological samples from the UV1-103 study support the promising efficacy signals, including enhanced efficacy in 'hard-to-treat patients' (*post period event*)
- On 25 October, Ultimovacs announced that the first patient had been randomized in the phase II LUNGVAC Trial. (*post period event*)
- On 22 August 2022, Ultimovacs received a Notice of Allowance from the United States Patent and Trademarks Office (USPTO) concerning its US patent application covering methods for eliciting a T cell immune response with the UV1 universal cancer vaccine.

### Clinical trial enrollment updates

- **INITIUM trial (malignant melanoma):** Recruitment was completed in June 2022 with a total of 156 patients. Enrollment has started in the single arm supplementary study.
- **NIPU trial (mesothelioma):** 108 out of 118 patients have been enrolled to date, up from 92 as of the previous quarterly report.
- **FOCUS trial (head and neck cancer):** 41 out of 75 patients have been enrolled to date, up from 27 as of the previous quarterly report.
- **DOVACC trial (ovarian cancer):** 7 out of 184 patients have been enrolled to date, up from 6 as of the previous quarterly report. During the last quarter, more hospitals in more countries have been activated.
- **LUNGVAC trial (non-small cell lung cancer):** The first out of 138 patients was enrolled in October 2022, and a total of 3 patients have been enrolled to date.
- **TENDU trial (prostate cancer):** 10 out of 12 patients have been enrolled to date, up from 9 as of the previous quarterly report. The three main dosing cohorts are fully enrolled, and no safety concerns or dose-limiting toxicities have been observed.

## Scientific publications and presentations

- On 18 October 2022, Ultimovacs ASA announced data from its phase I UV1-103 melanoma trial which were [presented](#) at the 19th International Congress of the Society for Melanoma Research (SMR) in Edinburgh, UK. *(post period event)*
- On 12 September 2022, Ultimovacs ASA announced the [publication](#) of data from the phase I melanoma trial combining UV1 with ipilimumab in *Journal of Translational Medicine*.
- 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.

## Financial

- Total operating expenses amounted to **MNOK 44.1** in Q3-22, and **MNOK 111.4** YTD. Total loss was **MNOK 38.3** for the period and **MNOK 97.3** YTD.
- Net negative cash flow from operations was **MNOK 32.3** in Q3-22, and net decrease in cash and cash equivalents, not including currency effects, was **MNOK 29.7** during Q3-22. Cash and cash equivalents amounted to **MNOK 469.1** as per 30 September 2022.
- On 5 September 2022, 44,000 options, granted under Ultimovacs' option program, were exercised at a strike price of NOK 31.25 per share. Subsequently, the Company's share capital was increased by NOK 4,400 by issuing 44,000 new shares, totaling 34,265,761 shares as per 30 September 2022, each share of par value NOK 0.10.

### Key financials

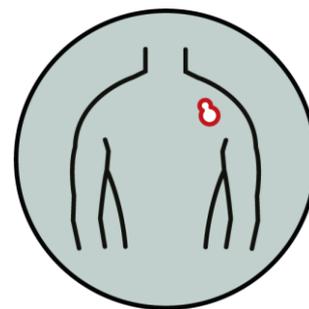
<b>NOK (000) Unaudited</b>	<b>Q3-22</b>	<b>Q3-21</b>	<b>YTD-22</b>	<b>YTD-21</b>	<b>FY21</b>
Total revenues	-	-	-	-	-
Total operating expenses	44 055	42 517	111 376	112 903	163 832
<b>Operating profit (loss)</b>	<b>(44 055)</b>	<b>(42 517)</b>	<b>(111 376)</b>	<b>(112 903)</b>	<b>(163 832)</b>
<b>Profit (loss) for the period</b>	<b>(38 303)</b>	<b>(43 308)</b>	<b>(97 279)</b>	<b>(113 570)</b>	<b>(164 722)</b>
Diluted and undiluted earnings / (loss) per share (NOK)	(1.1)	(1.4)	(2.8)	(3.5)	(5.1)
Net increase / (decrease) in cash and cash equivalents	(29 726)	(32 880)	(113 289)	(90 751)	137 106
<b>Cash and cash equivalents at end of period</b>	<b>469 063</b>	<b>347 804</b>	<b>469 063</b>	<b>347 804</b>	<b>574 168</b>
	NOK/EUR - 10.58				
<b>Cash and cash equivalents at end of period - EUR (000)</b>	<b>44 319</b>				

## Operational Review

### Clinical trial update (as per reporting date, unless otherwise specified)

#### ***The INITIUM trial***

The first INITIUM patient was treated at the Oslo University Hospital (OUS) in June 2020, and the last patient was enrolled 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. The readout of the primary endpoint of progression-free survival is expected in H1-2023. Topline progression-free survival results will be disclosed after progression of cancer or death has been observed in a total of 70 patients.

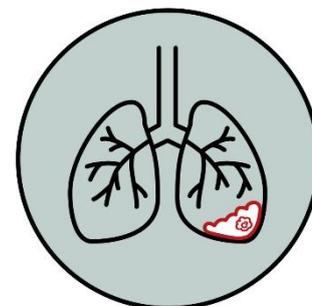


INITIUM is an Ultimovacs-sponsored randomized phase II trial for first-line treatment of patients with metastatic malignant melanoma. A total of 39 hospitals are participating in this trial being run in the US and Europe, including Norway. Half the 156 patients recruited to the trial have been dosed with UV1 plus the PD-1 checkpoint inhibitor nivolumab and the CTLA-4 checkpoint inhibitor ipilimumab, while the other half received nivolumab and ipilimumab. Dr. Karl Lewis, University of Colorado Hospital (U.S.), is the International Coordinating Investigator of the INITIUM trial.

With the INITIUM enrollment completed, Ultimovacs is running a supplementary study to the INITIUM trial, and patient enrollment 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. The supplementary study will include 20 patients in a single arm. 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 trial***

The first patient in the NIPU trial was treated at the Oslo University Hospital in June 2020, and a total of 108 out of 118 patients have been enrolled compared to 92 patients in the previous quarterly report. The study is being conducted in five countries (Norway, Sweden, Denmark, Spain, and Australia). The readout of the primary endpoint of progression-free survival is expected in H1-2023.

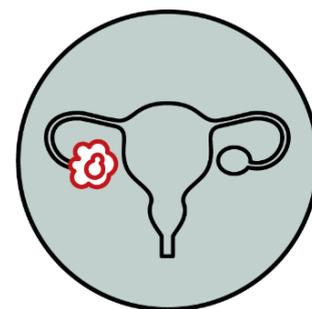


NIPU is a randomized, multi-center phase II trial in which the universal cancer vaccine, UV1, will be evaluated in combination with the checkpoint inhibitors ipilimumab and nivolumab as second-line treatment in mesothelioma. Oslo University Hospital is the sponsor of the NIPU study. Bristol-Myers Squibb and Ultimovacs have entered into agreements with OUS to support the preparations and execution of the trial. NIPU will include 118 patients; half will be treated with the combination of UV1, ipilimumab and nivolumab and half will

receive nivolumab and ipilimumab only. The objective of the study is to achieve a clinically meaningful progression-free survival (PFS) benefit in patients with malignant pleural mesothelioma (MPM) after progression on first-line standard platinum doublet chemotherapy.

### ***The DOVACC trial***

Enrollment began in December 2021. A total of 7 out of 184 patients have been enrolled in DOVACC, compared to 6 patients in the previous quarterly report. Multinational, multicenter 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. During the last quarter, more hospitals in more countries have been activated.



DOVACC (**D**urvalumab **O**laparib **V**ACCine) is a multicenter, multinational, 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. The trial is sponsored by the NSGO, the leading gynecological oncology research society in the Nordic and Baltic regions. Ultimovacs will provide the UV1 vaccine and AstraZeneca will provide durvalumab and olaparib for the study.

The trial is designed to evaluate UV1 in combination with AstraZeneca's durvalumab, a PD-L1 checkpoint inhibitor and its PARP inhibitor, olaparib, the maintenance therapy for BRCA-mutated, advanced ovarian cancer. The trial will be conducted at more than 40 hospitals in more than 10 European countries. Top line data on the primary endpoint has been expected in 2023. Ultimovacs will provide an update on expected timeline for topline readout for DOVACC with the Q4 2022 report.

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. 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. Under the terms of the collaboration, Ultimovacs will provide its UV1 vaccine and AstraZeneca will provide the PD-L1 and PARP inhibitors for the study.

### ***The FOCUS trial***

The first patient in the FOCUS trial was treated in August 2021 and 41 out of 75 patients have been enrolled compared to 27 patients in the previous quarterly report. The FOCUS trial (**F**irst-line metastatic **O**r recurrent HNSCC/**C**heckpoint inhibitor **UV1** **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. FOCUS is led by principal investigator Prof. Mascha Binder, Medical Director and Head of the Immunological Tumor Group at University Medicine Halle, Germany, a renowned oncology clinician and researcher specializing in the analysis of immuno-oncology treatments and their interaction with tumor tissues.

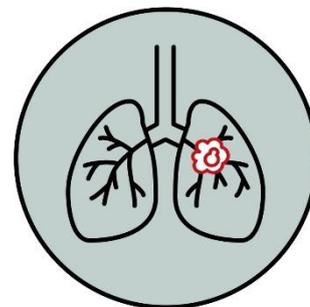


The trial will evaluate the addition of UV1 to a standard of care treatment with PD-1 checkpoint inhibitor pembrolizumab as compared to pembrolizumab monotherapy. A total of 75 patients indicated for treatment with pembrolizumab will be enrolled in FOCUS, randomized 2-to-1 so that 50 patients will receive UV1 and pembrolizumab and 25 patients will receive pembrolizumab alone. The primary endpoint of the study is the progression-free survival rate at 6 months.

Topline readout is expected in 2023. Ultimovacs will review the guidance and will provide an update on expected timeline for topline readout for FOCUS with the Q4 2022 report.

### ***The LUNGVAC trial***

The first patient in the LUNGVAC trial was enrolled in October 2022 and 3 out of 138 patients have been included so far. The LUNGVAC trial is a phase II multi-center, randomized, open-label trial assessing the safety and efficacy of UV1 in combination with pembrolizumab versus pembrolizumab alone in NSCLC patients with advanced or metastatic disease. The trial will treat patients with PD-L1-expressing tumors classified within the adenocarcinoma or squamous subgroups of NSCLC, where at least half of their tumor cells express the PD-L1 antigen and who have not previously received pembrolizumab treatment. These subgroups represent approximately 30% of all advanced and metastatic NSCLC patients. The primary endpoint of the trial will be progression-free survival. Secondary endpoints will include response rate and overall survival.

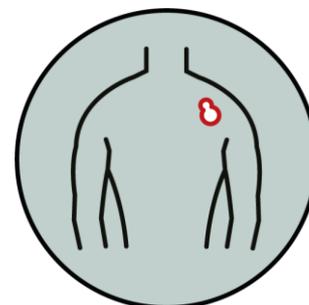


Professor Odd Terje Brustugun is the principal investigator for the trial, which is sponsored by Drammen Hospital, a leading oncology research center in Norway. The trial will enroll 138 patients and will be conducted at approximately 10 clinical centers in Norway.

Topline readout is expected by the end of 2024. Ultimovacs will review the guidance and will provide an update on expected timeline for topline readout for LUNGVAC with the Q4 2022 report.

### ***The UV1-103 trial***

This US-based phase I clinical trial is evaluating the Company's lead candidate, 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 ten 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%

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 of the patients, all 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***

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. 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 tumor infiltrating lymphocytes prior to treatment.

The analyses of each of these five biomarkers signal efficacy in patients treated with UV1 in combination with pembrolizumab, regardless of tumor phenotype. 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.

#### ***Other 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 the phase I clinical trials showed that UV1 was generally well tolerated and there were no dose limiting toxicities. UV1 immune monitoring data from the first three phase I studies showed a robust immune response induction with dynamic T cell responses lasting up to 7.5 years.

The observed clinical outcomes from the 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. Malignant melanoma is the lead indication currently in phase II development (INITIUM).

#### ***Data reported from the UV1-ipi study:***

- Median overall survival (mOS): 66.3 months
- Median progression free survival (mPFS): 6.7 months
- Objective response rate (ORR): 33%

### ***The TET-platform and the TENDU clinical trial***

In addition to its universal vaccine, UV1, Ultimovacs is developing a vaccine adjuvant technology platform, TET (Tetanus-Epitope Targeting). The patent protected TET-platform combines antigens and vaccine adjuvant in the same molecule. This allows a beneficial safety profile and simplifies administration, offering a promising approach to strengthen and increase 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.

In 2021, Ultimovacs started the TENDU trial, its first phase I trial to test the TET technology in patients with the main objective to assess the safety of 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 and will enroll up to 12 patients in total. The first patient was treated in February 2021, and ten patients have been enrolled to date. Enrollment of the first cohort (three patients dosed at 40 mcg) was completed during the second quarter of 2021, the second cohort (three patients dosed at 400 mcg) was completed during the fourth quarter of 2021 and the third cohort (three patients dosed at 960 mcg) was completed during the second quarter of 2022. The Drug Safety Monitoring Board found no safety concerns related to the nine treated patients. Ultimovacs will include up to three additional patients at the highest dose level of 960 mcg. A total of 10 patients have been enrolled to date.

## **Intellectual property rights**

### ***Patents***

On 22 August 2022, Ultimovacs received a Notice of Allowance from the United States Patent and Trademarks Office (USPTO) concerning its US patent application covering methods for eliciting a T cell immune response with the UV1 universal cancer vaccine. Subject to grant formalities, the company expects that the patent will issue with a term to at least 15 February 2031. Ultimovacs has similar patent applications pending or granted in other territories worldwide, including Europe, Japan and China.

## Scientific publications and presentations

On 18 October 2022, Ultimovacs ASA announced data from its phase I melanoma trial on [presented](#) at the 19th International Congress of the Society for Melanoma Research (SMR) in Edinburgh, UK. Biomarker data support strong clinical responses from UV1 in combination with pembrolizumab, also in patients considered less likely to respond to monotherapy checkpoint inhibition. *(post period event)*

On 12 September 2022, Ultimovacs ASA announced the [publication](#) of data from the UV1 phase I malignant melanoma trial combining UV1 with ipilimumab in *Journal of Translational Medicine*. Clinical responses were observed in patients with favored and less favored baseline characteristics, as well as T cell activation observed post-treatment in tumors of responding patients

On 27-30 October 2022, the lead investigator of the DOVACC phase II clinical trial, Mansoor Mirza from Copenhagen University Hospital, presented a poster named 'A randomised clinical Trial Investigating olaparib, durvalumab and an anticancer vaccine, UV1 as maintenance therapy in patients with recurrent ovarian cancer' giving an overview of the DOVACC trial at the European Society of Gynaecological Oncology (ESGO) 2022 Congress in Berlin, Germany. *(Also reported in the Q2-22 report)*

## 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 in 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.

The FDA Fast Track process is designed to facilitate the development and expedite the review of drugs that meet urgent needs in serious medical conditions. Fast Track designation enables early and frequent communication with the FDA to support the drug's development, as well as entitlement to a Rolling Review of the Biologic License Application. Drugs with Fast Track designation may also be considered for Accelerated Approval and Priority Review provided certain criteria are met.

### ***Orphan Drug Designation***

On December 2021, Ultimovacs announced that UV1 has received Orphan Drug designation from the U.S. FDA in 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.

The FDA Office of Orphan Products Development (OOPD) supports and advances the development and evaluation of new treatments for rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug designation provides certain benefits, including seven-year market exclusivity upon regulatory approval, if received, exemption from FDA application fees and tax credits for qualified clinical trials.

## Background

Ultimovacs (the 'Company') is a pharmaceutical company developing novel immunotherapies against cancer. The Company was established in 2011 and is listed on the Oslo Stock Exchange. The Company's proprietary technology is based on preclinical and clinical research on immunotherapies conducted at Oslo University Hospital. Ultimovacs is advancing a broad clinical development program with clinical trials in Europe, Australia, and the U.S.

### *UV1 – lead product candidate*

The Company's lead product candidate is UV1, a next generation peptide-based cancer vaccine inducing a specific T cell response against the universal cancer antigen telomerase (hTERT), 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 telomerase. 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 immunology 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 the 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. 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 pembrolizumab (PD-1 checkpoint inhibitor) in 30 patients with metastatic malignant melanoma.

### *UV1 phase II clinical development program*

Ultimovacs has an extensive development program for UV1 with five phase II studies in five different indications including more than 650 patients:

- **INITIUM (156 patients):** Ultimovacs sponsored trial in malignant melanoma in which UV1 is combined with nivolumab and ipilimumab. Patient enrollment was completed in July 2022.
- **NIPU (118 patients):** trial in mesothelioma, UV1 in combination with nivolumab and ipilimumab. Oslo University Hospital is the sponsor of the NIPU study. Bristol-Myers Squibb and Ultimovacs have entered into agreements with Oslo University Hospital to support the execution of the trial.
- **DOVACC (184 patients):** trial in collaboration with the Nordic Society of Gynaecological Oncology Clinical Trial Unit, the European Network of Gynaecological Oncological Trial Groups and AstraZeneca. UV1 is tested in combination with AstraZeneca's durvalumab and olaparib (PARP inhibitor) in patients with relapsed ovarian cancer.

- **FOCUS (75 patients):** trial in collaboration with the Immunological Tumor Group at University Medicine Halle, Germany, where UV1 is tested in combination with pembrolizumab in head and neck cancer patients.
- **LUNGVAC (138 patients):** trial in non-small cell lung cancer where UV1 will be investigated in combination with pembrolizumab. Drammen Hospital is the sponsor of the study.

#### ***TET technology platform***

In addition, the Company is expanding its pipeline using its novel TET technology platform that can generate multiple vaccine candidates designed to achieve increased T cell responses to a broad range of target antigens. **TENDU** (up to 12 patients) is a phase I trial conducted at the Oslo University Hospital, testing the TET technology incorporating prostate cancer specific antigens.

## Outlook

Ultimovacs' UV1 vaccine technology is universal in the sense that it 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., independent 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 of the universal cancer vaccine, UV1. The main study objectives are efficacy and safety data on combination therapies.

Topline data readouts of the primary endpoints of the INITIUM and NIPU trials are expected during the first half of 2023. Further, Ultimovacs has guided that the readouts of topline results in the DOVACC and FOCUS trials are expected to take place in 2023 and have done so since the trials began. Topline results for LUNGVAC are expected by the end of 2024. Once each of the three trials DOVACC, FOCUS and LUNGVAC has progressed sufficiently to provide a reliable trajectory beyond initiation, Ultimovacs will review guidance and expects to give an update with the Q4 2022 report.

The Company will continue to actively monitor the impact of the COVID-19 pandemic on patient enrollment for the clinical trials and continues to implement activities to minimize the impact.

With current funding, plans and expectations, Ultimovacs has an estimated financial runway to the first part of 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 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 on 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 in identifying new cancer vaccine program candidates to move into clinical development.

## Risks and uncertainties

Ultimovacs is a research and development company. The Company has not generated revenues historically and is not expected to do so in the near term. 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 pharmaceuticals can capture market shares or reach the market faster than Ultimovacs. If competing projects have a better product profile (e.g., better efficacy and/or less side effects), the future value of Ultimovacs' product offerings may be lower than expected. The 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.

The coronavirus pandemic has a profound impact on the global economy and no industry is protected from operational and financial consequences. For a biotech company like Ultimovacs, some of the possible implications of the COVID-19 pandemic may affect:

- The initiation, patient inclusion and conduct of clinical trials
- Disruption of the supply chain (manufacturing and/or logistics) for the investigational products
- Fluctuations in currency exchange rates, (NOK/EUR and NOK/USD), which may increase R&D costs

Although the pandemic has continued to impact patient enrollment during the quarter, Ultimovacs remains optimistic regarding progress in the Company's broad clinical program. The effect of the pandemic on the biotech industry and the conduct of clinical trials going forward, remains uncertain. Ultimovacs will continue to provide enrollment updates in each quarterly report.

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.

Total payroll and payroll related expenses were significantly lower in Q3-22 (**MNOK 14.1**) compared to the same period in FY21 (MNOK 23.3). Regular salaries not including option expenses were higher in Q3-22 as there were two more FTEs in this quarter compared to Q3-21. However, option expenses and the social security tax accrual related to share options, which fluctuates with the company share price, was MNOK 13.3 higher in Q3-21 compared to Q3-22, explaining most of the difference these two quarters. Total personnel expenses YTD-22 were **MNOK 39.8** compared to MNOK 50.0 in YTD-21.

Other operating expenses (**MNOK 29.3** in Q3-22 vs. MNOK 18.6 in Q3-21) primarily comprise R&D related expenses. These expenses, including IP and external R&D expenses, offset by government grants, amounted to **MNOK 24.7** in Q3-22 vs. MNOK 16.0 in Q3-21. The Q3-22 expenses were higher primarily due to milestone payments in FOCUS and INITIUM, as well as significant CMC expenses this quarter. Total other operating expenses YTD-22 (**MNOK 69.6**) were slightly lower compared to YTD-21 (MNOK 60.8)

Net financial items amounted to **MNOK 5.8** in Q3-22, compared to MNOK (0.8) in Q3-21. Financial items primarily comprise currency fluctuations from EUR at bank and the value of EUR currency future contracts swapped on a quarterly basis, in addition to interest gain from cash at bank accounts. In Q3-22, the financial income comprise MNOK 1.7 in interest from bank, MNOK 0.9 in currency gain from cash in EUR bank account and MNOK 3.2 in currency gain from the EUR currency future contracts.

Total loss for the Q3-22 period amounted to **MNOK 38.3**, compared to MNOK 43.3 in Q3-21. Total loss YTD-22 amounted to **MNOK 97.3** compared to a loss of MNOK 113.6 YTD-21.

### Financial position

Total assets per 30 September 2022 were **MNOK 549.6**, a decrease of MNOK 105.9 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 15.8, and **MNOK 2.2** 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 30 September 2022 amounted to **MNOK 36.5**, of which MNOK 11.9 are non-current.

Total equity equaled **MNOK 513.1** as of 30 September 2022. A capital increase in September, related to the exercise of 44,000 options granted under Ultimovacs' option program, resulted in gross proceeds of **MNOK 1.4**. Subsequently, the Company's share capital was increased by NOK 4,400 by issuing 44,000 new shares, totaling 34,265,761 shares as per 30 September 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 97.6**, and in addition been increased by the recognition of share-based payments/stock options of **MNOK 16.1**.

## Cash flow

The total net decrease in cash and cash equivalents in Q3-22, not including currency effects, was **MNOK 29.7**, which is primarily related to net negative cash-flow from operations amounting to **MNOK 32.3**. Total cash and cash equivalents were **MNOK 469.1** per 30 September 2022, of which MNOK 43.8 (**MEUR 4.1**) is held on EUR account.

### Key financials

<b>NOK (000) Unaudited</b>	<b>Q3-22</b>	<b>Q3-21</b>	<b>YTD-22</b>	<b>YTD-21</b>	<b>FY21</b>
<b>Total revenues</b>	-	-	-	-	-
Total operating expenses	44 055	42 517	111 376	112 903	163 832
<b>Operating profit (loss)</b>	<b>(44 055)</b>	<b>(42 517)</b>	<b>(111 376)</b>	<b>(112 903)</b>	<b>(163 832)</b>
<b>Profit (loss) for the period</b>	<b>(38 303)</b>	<b>(43 308)</b>	<b>(97 279)</b>	<b>(113 570)</b>	<b>(164 722)</b>
Diluted and undiluted earnings / (loss) per share (NOK)	(1.1)	(1.4)	(2.8)	(3.5)	(5.1)
Net increase / (decrease) in cash and cash equivalents	(29 726)	(32 880)	(113 289)	(90 751)	137 106
<b>Cash and cash equivalents at end of period</b>	<b>469 063</b>	<b>347 804</b>	<b>469 063</b>	<b>347 804</b>	<b>574 168</b>
	NOK/EUR - 10.58				
<b>Cash and cash equivalents at end of period - EUR (000)</b>	<b>44 319</b>				

## The Board of Directors and CEO of Ultimovacs ASA

Oslo, 9 November 2022

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Jónas Einarsson  
Chairman of the Board

(Sign.)

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Kari Grønås  
Board member

(Sign.)

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Eva S. Dugstad  
Board member

(Sign.)

---

Henrik Schüssler  
Board member

(Sign.)

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Ketil Fjerdingsén  
Board member

(Sign.)

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Leiv Askvig  
Board member

(Sign.)

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Aitana Peire  
Board member

(Sign.)

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Haakon Stenrød  
Board member

(Sign.)

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Carlos de Sousa  
CEO

(Sign.)

## Interim condensed consolidated statement of comprehensive income

NOK (000) Unaudited	Note	Q3-22	Q3-21	YTD-22	YTD-21	FY21
Other operating income		-	-	-	-	-
<b>Total revenues</b>		-	-	-	-	-
Payroll and payroll related expenses	3, 5	14 112	23 314	39 836	50 031	61 916
Depreciation and amortization		678	634	1 954	2 080	2 703
Other operating expenses	4, 5	29 264	18 568	69 586	60 792	99 213
<b>Total operating expenses</b>		<b>44 055</b>	<b>42 517</b>	<b>111 376</b>	<b>112 903</b>	<b>163 832</b>
<b>Operating profit (loss)</b>		<b>(44 055)</b>	<b>(42 517)</b>	<b>(111 376)</b>	<b>(112 903)</b>	<b>(163 832)</b>
Financial income		6 158	3 644	15 362	8 195	13 383
Financial expenses		406	4 435	1 265	8 863	14 272
<b>Net financial items</b>		<b>5 752</b>	<b>(791)</b>	<b>14 097</b>	<b>(668)</b>	<b>(890)</b>
<b>Profit (loss) before tax</b>		<b>(38 303)</b>	<b>(43 308)</b>	<b>(97 279)</b>	<b>(113 570)</b>	<b>(164 722)</b>
Income tax		-	-	-	-	-
<b>Profit (loss) for the period</b>		<b>(38 303)</b>	<b>(43 308)</b>	<b>(97 279)</b>	<b>(113 570)</b>	<b>(164 722)</b>
Other comprehensive income (loss) - Currency translation		(102)	(458)	(289)	(2 527)	(3 953)
<b>Total comprehensive income (loss) for the period</b>		<b>(38 405)</b>	<b>(43 766)</b>	<b>(97 568)</b>	<b>(116 098)</b>	<b>(168 676)</b>
Diluted and undiluted earnings/(loss) pr share (NOK)	6	(1.1)	(1.4)	(2.8)	(3.5)	(5.1)

## Interim condensed consolidated statement of financial position

NOK (000) Unaudited	Note	30 Sep 2022	30 Sep 2021	31 Dec 2021
<b>ASSETS</b>				
Goodwill		10 993	11 316	11 031
Licenses		53 362	54 934	53 549
Patents		5 973	6 727	6 539
Property, plant and equipment		265	174	212
Right to use asset	11	1 729	2 338	1 951
<b>Total non-current assets</b>		<b>72 322</b>	<b>75 489</b>	<b>73 282</b>
Receivables and prepayments	7	8 206	3 237	8 087
Bank deposits		469 063	347 804	574 168
<b>Current assets</b>		<b>477 269</b>	<b>351 042</b>	<b>582 255</b>
<b>TOTAL ASSETS</b>		<b>549 592</b>	<b>426 531</b>	<b>655 537</b>
<b>EQUITY</b>				
Share capital		3 427	3 200	3 422
Share premium		1 072 212	810 140	1 070 841
<b>Total paid-in equity</b>		<b>1 075 639</b>	<b>813 341</b>	<b>1 074 264</b>
Accumulated losses		(601 600)	(453 169)	(504 321)
Other equity		36 449	17 344	20 358
Translation differences		2 564	4 279	2 853
<b>TOTAL EQUITY</b>	6, 9	<b>513 051</b>	<b>381 794</b>	<b>593 152</b>
<b>LIABILITIES</b>				
Lease liability	11	935	873	457
Deferred tax		10 993	11 316	11 031
<b>Non-current liabilities</b>		<b>11 928</b>	<b>12 189</b>	<b>11 488</b>
Accounts payable		10 527	4 853	22 555
Lease liability	11	861	1 610	1 628
Other current liabilities		13 224	26 084	26 714
<b>Current liabilities</b>	8	<b>24 613</b>	<b>32 548</b>	<b>50 897</b>
<b>TOTAL LIABILITIES</b>		<b>36 541</b>	<b>44 737</b>	<b>62 384</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>549 592</b>	<b>426 531</b>	<b>655 537</b>

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

<b>NOK (000) Unaudited</b>	<b>Share Capital</b>	<b>Share Premium</b>	<b>Accum. losses</b>	<b>Other equity</b>	<b>Transl. differenc.</b>	<b>Total equity</b>
<b>Balance at 1 Jan 2021</b>	<b>3 197</b>	<b>809 214</b>	<b>(339 599)</b>	<b>8 762</b>	<b>6 806</b>	<b>488 380</b>
Loss for the period	-	-	(113 570)	-	-	(113 570)
Issue of ordinary shares	3	927	-	-	-	930
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	8 582	-	8 582
Translation differences	-	-	-	-	(2 527)	(2 527)
<b>Balance at 30 Sep 2021</b>	<b>3 200</b>	<b>810 140</b>	<b>(453 169)</b>	<b>17 344</b>	<b>4 279</b>	<b>381 794</b>
<b>Balance at 1 Jan 2022</b>	<b>3 422</b>	<b>1 070 841</b>	<b>(504 321)</b>	<b>20 358</b>	<b>2 853</b>	<b>593 152</b>
Loss for the period	-	-	(97 279)	-	-	(97 279)
Issue of ordinary shares	4	1 371	-	-	-	1 375
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	16 092	-	16 092
Translation differences	-	-	-	-	(289)	(289)
<b>Balance at 30 Sep 2022</b>	<b>3 427</b>	<b>1 072 212</b>	<b>(601 600)</b>	<b>36 449</b>	<b>2 564</b>	<b>513 051</b>

**Interim condensed consolidated statement of cash flow**

<b>NOK (000) Unaudited</b>	<b>Q3-22</b>	<b>Q3-21</b>	<b>YTD-22</b>	<b>YTD-21</b>	<b>FY21</b>
<b>Loss before tax</b>	<b>(38 303)</b>	<b>(43 308)</b>	<b>(97 279)</b>	<b>(113 570)</b>	<b>(164 722)</b>
<b>Non-cash adjustments</b>					
Depreciation and amortization	678	634	1 954	2 080	2 703
Interest received incl. investing activities	(1 680)	(300)	(4 584)	(1 750)	(3 062)
Net foreign exchange differences	(4 098)	1 002	(9 716)	2 168	3 619
Other finance expense	26	41	82	144	179
Share option expenses	4 303	3 014	16 092	8 582	11 595
<b>Working capital adjustments:</b>					
Changes in prepayments and other receivables	3 681	4 348	1 310	5 200	351
Changes in payables and other current liabilities	3 104	1 835	(25 517)	5 177	23 509
<b>Net cash flow from operating activities</b>	<b>(32 289)</b>	<b>(32 733)</b>	<b>(117 659)</b>	<b>(91 969)</b>	<b>(125 828)</b>
Purchase of property, plant and equipment	-	-	(195)	-	(85)
Interest received	1 680	300	4 584	1 750	3 062
<b>Net cash flow used in investing activities</b>	<b>1 680</b>	<b>300</b>	<b>4 389</b>	<b>1 750</b>	<b>2 977</b>
Proceeds from issuance of equity	1 375	-	1 375	930	272 864
Share issue cost	-	-	-	-	(11 012)
Interest paid	26	-	(30)	-	(179)
Payment of lease liability	(518)	(447)	(1 364)	(1 461)	(1 716)
<b>Net cash flow from financing activities</b>	<b>883</b>	<b>(447)</b>	<b>(20)</b>	<b>(532)</b>	<b>259 957</b>
Net change in cash and cash equivalents	(29 726)	(32 880)	(113 289)	(90 751)	137 106
Effect of change in exchange rate	12 452	(1 114)	8 184	(2 371)	(3 863)
<b>Cash and cash equivalents at beginning of period</b>	<b>486 338</b>	<b>381 799</b>	<b>574 168</b>	<b>440 925</b>	<b>440 925</b>
<b>Cash and cash equivalents at end of period</b>	<b>469 063</b>	<b>347 804</b>	<b>469 063</b>	<b>347 804</b>	<b>574 168</b>

## Notes

### 1. General information

Ultimovacs ASA (the Company or Ultimovacs) and its subsidiary (together the Group) is a 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 the Ultimovacs ASA and its 100% owned subsidiary Ultimovacs AB as at the reporting date.

These interim financial statements were approved for issue by the Board of Directors on 9 November 2022. The figures in the statements have not been audited.

### 3. Personnel expenses

#### Personnel expenses

NOK (000)	Q3-22	Q3-21	YTD-22	YTD-21	FY21
Salaries	10 243	6 761	27 781	24 446	34 543
Social security tax	2 886	1 646	6 056	4 929	6 686
Social security tax related to options	(2 187)	12 419	(9 102)	13 002	8 557
Pension expenses	741	593	2 163	1 870	2 690
Share-based compensation	4 303	3 014	16 092	8 582	11 595
Other personnel expenses	109	(59)	486	121	318
Government grants	(1 983)	(1 060)	(3 639)	(2 919)	(2 472)
<b>Total personnel expenses</b>	<b>14 112</b>	<b>23 314</b>	<b>39 836</b>	<b>50 031</b>	<b>61 916</b>
Number of FTEs at end of period	23	21	23	21	24

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 is in a development phase, and the majority of the Group's costs are related to R&D. These costs are expensed in the statement of comprehensive income.

#### Operating expenses

NOK (000)	Q3-22	Q3-21	YTD-22	YTD-21	FY21
External R&D expenses	24 176	17 151	54 216	56 201	96 735
Clinical studies	10 349	7 018	30 205	28 215	56 675
Manufacturing costs	11 750	2 235	17 899	12 795	21 455
Other R&D expenses	2 077	7 899	6 112	15 192	18 605
IP expenses	857	822	2 433	2 513	3 540
Rent, office and infrastructure	921	797	3 069	2 742	3 645
Accounting, audit, legal, consulting	2 699	1 224	7 421	3 755	5 061
Other operating expenses	902	515	3 357	1 663	2 338
Government grants	(291)	(1 942)	(909)	(6 083)	(12 106)
<b>Total other operating expenses</b>	<b>29 264</b>	<b>18 568</b>	<b>69 586</b>	<b>60 792</b>	<b>99 213</b>

## 5. Government grants

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

### Government grants

NOK (000)	Q3-22	Q3-21	YTD-22	YTD-21	FY21
Skattefunn from the Research Council of Norway (RCN)	-	-	-	-	4 750
Eurostars	-	262	-	524	786
Innovation Norway	-	-	-	3 000	3 000
Innovation Project grant from the RCN	2 076	2 472	4 152	4 944	5 241
Other grants	198	267	396	534	802
<b>Total government grants</b>	<b>2 274</b>	<b>3 001</b>	<b>4 548</b>	<b>9 002</b>	<b>14 578</b>

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

## 6. Earnings per share

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

### Earnings per share

NOK (000)	Q3-22	Q3-21	YTD-22	YTD-21	FY21
Loss for the period	(38 303)	(43 308)	(97 279)	(113 570)	(164 722)
Average number of shares during the period ('000)	34 236	32 003	34 227	31 997	32 373
<b>Earnings/loss per share (NOK)</b>	<b>(1.1)</b>	<b>(1.4)</b>	<b>(2.8)</b>	<b>(3.5)</b>	<b>(5.1)</b>

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 is therefore the same.

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

## 7. Current assets

### Receivables and prepayments

<b>NOK (000)</b>	<b>30 Sep 2022</b>	<b>30 Sep 2021</b>	<b>31 Dec 2021</b>
Government grants	-	-	5 314
Prepayments	1 001	981	878
Financial instruments	2 189	-	759
Other receivables	5 016	2 256	1 135
<b>Total receivables and prepayments</b>	<b>8 206</b>	<b>3 237</b>	<b>8 087</b>

## 8. Current liabilities

### Current liabilities

<b>NOK (000)</b>	<b>30 Sep 2022</b>	<b>30 Sep 2021</b>	<b>31 Dec 2021</b>
Accounts payable	10 527	4 853	22 555
Public duties payable	1 974	694	2 506
Public duties payable related to options	3 787	17 333	12 888
Lease liability	861	1 610	1 628
Financial instruments	-	1 649	-
Other current liabilities	7 464	6 408	11 320
<b>Total current liabilities</b>	<b>24 613</b>	<b>32 548</b>	<b>50 897</b>

## 9. Shareholder information

The share capital as of 30 September 2022 was NOK 3,426,576.1, with 34,265,761 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 30 September 2022 and the 20 largest shareholders as of this date are listed below:

### Share register as per 30 September 2022

Shareholder	# of shares	Share-%
Gjelsten Holding AS	6 495 866	19.0 %
Canica AS	2 705 957	7.9 %
Watrium AS	1 780 575	5.2 %
Inven2 AS	1 555 492	4.5 %
Radforsk Investeringsstiftelse	1 506 913	4.4 %
Folketrygdfondet	1 501 571	4.4 %
Langøya Invest AS	1 389 006	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	736 440	2.1 %
Stavanger Forvaltning AS	596 999	1.7 %
Prieta AS	533 988	1.6 %
Verdipapirfondet Nordea Avkastning	483 573	1.4 %
SEB Prime Solutions Sissener Canopus	400 000	1.2 %
Verdipapirfondet KLP Aksjenorge	348 416	1.0 %
Sw edbank AB	259 839	0.8 %
Wiarom AS	250 000	0.7 %
Torstein Tvenge	250 000	0.7 %
Verdipapirfondet Nordea Kapital	246 178	0.7 %
<b>20 Largest shareholders</b>	<b>23 692 068</b>	<b>69.1%</b>
Other shareholders	10 573 693	30.9%
<b>Total</b>	<b>34 265 761</b>	<b>100.0%</b>

## 10. Share-based payments

### Share option program

The share option program was introduced in June 2019. 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.

The share option program is groupwide and includes all employees in the Group. After the distribution of 480,000 new options on 21 April 2022 and the exercise of 44,000 shares in September 2022, a total of 2,269,585 share options are granted, corresponding to 6.62% 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 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
<b>Outstanding at closing balance 31 December 2021</b>	<b>1 833 585</b>	<b>44.77</b>
Granted	480 000	83.46
Exercised	44 000	31.25
Forfeited	-	-
<b>Outstanding at closing balance 30 September 2022</b>	<b>2 269 585</b>	<b>53.21</b>
Vested at closing balance	991 154	39.53

On the basis of the approval by the General Meeting on 21 April 2022, the Board of Directors resolved to issue a total of 480,000 options that were distributed amongst the employees on 21 April 2022. The number of new options granted corresponded to 1.40% of the outstanding number of shares in the Company. On 5 September, 44,000 options were exercised at a strike price of NOK 31.25 per share.

The total IFRS cost recognized for the option program in Q3-22 is MNOK 4.3, and the reversal in accruals for social security tax related to the options are MNOK 2.2. Total IFRS costs in YTD-22 is MNOK 16.1, and a reversal of MNOK 9.1 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 1 year left in the rental contract as of 1 January 2022, and four car-leasing contracts also classified as operating leases. The weighted average discount applied is 6.0%. 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 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 pharmaceutical 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 telomerase (hTERT), an enzyme that extends the telomeres of chromosomes. Telomerase is expressed at a high level in over 80% of human tumors. UV1 uses telomerase (hTERT) as an immune therapy target.
Tetanus	Tetanus (Norwegian: “Stivkrampe”) 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
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.)
mPFS	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.)
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	<p>A serious adverse event (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose</p> <ol style="list-style-type: none"> <li>1. results in death,</li> <li>2. is life-threatening</li> <li>3. requires inpatient hospitalization or causes prolongation of existing hospitalization</li> <li>4. results in persistent or significant disability/incapacity</li> <li>5. is a congenital anomaly/birth defect, or</li> <li>6. requires intervention to prevent permanent impairment or damage.</li> </ol> <p>The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. Adverse events are further defined as "Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment."</p>
PSA	Prostate-specific antigen (PSA) is an enzyme (protein) important for reproduction. PSA is present in small quantities in the serum of men with healthy prostates but is often elevated in the presence of prostate cancer or other prostate disorders.

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## Contact us



Ultimovacs ASA  
Ullernchausséen 64  
0379 Oslo  
Norway



[ir@ultimovacs.com](mailto:ir@ultimovacs.com)



+47 413 80 080

## About Ultimovacs

Ultimovacs was established in 2011 and is a public limited liability company listed on the Oslo Stock Exchange in Norway. The Company and its proprietary technology is 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.

Ultimovacs 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 over 80% 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 can generate multiple vaccine candidates designed to achieve increased T cell responses to a broad range of target antigens.

