

# FIRST QUARTER 2020 REPORT Ultimovacs ASA





# First Quarter 2020 – at a glance...

# **Operational**

- Despite the temporary halt in clinical trial activities at several hospitals caused by the covid-19 situation, the first site in the INITIUM trial has recently opened for patient inclusion. In total, an opening of 35-40 sites are planned for this trial. Several additional sites are expected to open in Norway and the US during Q2-20. The INITIUM trial is a randomized phase II trial for investigation of UV1 as treatment for first-line patients with metastatic malignant melanoma.
- Similarly, the first out of totally six planned sites in the NIPU trial has also opened for patient inclusion. The NIPU trial is a randomized, multi-center phase II trial where UV1 is investigated as second-line treatment in mesothelioma.
- In the US based phase I trial in malignant melanoma, in which UV1 is given in combination with a PD-1 checkpoint inhibitor, eight of the planned 10 patients in cohort 2 (dose finding GM-CSF) have been included as per the reporting date of the Q1-20 report. Four of these patients have been included in the period of covid-19 related lockdown in the US. No unexpected safety issues have been observed to date.

## Presented in the Q4-19 report as subsequent events:

- As previously reported, long-term results from a clinical study with UV1 in combination with ipilimumab in patients with malignant melanoma were presented at the 2020 ASCO-SITC Clinical Immuno-Oncology Symposium in Orlando, Florida. Overall survival was 50% after 4 years (6 out of 12 patients alive).
- Ultimovacs has appointed Carlos de Sousa as new Chief Executive Officer. He will join Ultimovacs on 1 June 2020. Until then, Øyvind Kongstun Arnesen will continue in his position as CEO.

### **Financial**

- Total operating expenses amounted to MNOK 31.3 in Q1-20.
- Cash flow from operations was MNOK -32.4 in Q1-20. Total cash and cash equivalents was reduced by MNOK 31.5 during Q1-20, amounting to MNOK 367.7 as per 31 March 2020.

### **Key financials**

NOK (000) Unaudited	Q1-20	Q1-19	FY19
Total revenues	-	-	-
Total operating expenses	31 259	14 970	66 217
Operating profit (loss)	(31 259)	(14 970)	(66 217)
Profit (loss) for the period	(30 337)	(14 723)	(61 166)
Diluted and undiluted earnings / (loss) per share (NOK)	(1.1)	(0.9)	(2.7)
Net increase / (decrease) in cash and cash equivalents	(31 494)	(16 110)	284 332
Cash and cash equivalents at end of period	367 686	99 352	399 607



# **CEO's corner**

## **Key success factors in Ultimovacs**

I would like to use this last opportunity to sum up what Ultimovacs has achieved in my time as CEO and to look ahead. For a company to develop a new technology, three components are needed: The right technology, the right people and (the right) money. I would like to elaborate on how these key components have been developed and put to work in Ultimovacs.



#### Technology

To develop UV1 and the TET-technology ("UV2") into medical treatments is to document that the solutions can benefit patients, have acceptable side effects and can be manufactured in a process meeting defined quality standards.

Both UV1 and the TET technology are in many ways technology platforms more than drugs. Both are applicable to most cancer types and there is a good biologic rationale that they also can be combined with most other cancer treatments to take advantage of complementary mode of actions. We often refer to our technologies as 'universal' because they can potentially be used across most cancer indications and in many different combinations with our cancer treatments.

To develop this type of technology platforms is much more complex than to develop a drug that is specific for one cancer type. The reason is that technology platforms create much broader opportunities. Finding out in which cancer types we should do our clinical trials have been and still is one of Ultimovacs most important tasks. We need to do clinical trials that have a good chance of positive outcome, within reasonable time and cost, combining with other cancer treatments where there is a reason to believe in synergy, together with partners that can perform the trial and gives good business development opportunities if the results are positive. Ultimovacs have two of these trials in place, and we are planning for more.

The reward for complexity in development is clearly the number of opportunities for business. UV1 can benefit patients in several drug combinations and in many different cancer types, just like checkpoint inhibitors do.

When I leave the company, I know that we will soon know if UV1 can benefit patients in at least two randomized trials. We have also established a commercial scale production process and we will continue to document that this process meets the defined quality standards.

#### People

Ultimovacs has been able to build a solid team of people with the right competencies and right personalities. When discussing with possible employees I always say that I do not want "the sharpest brains that will work 110%". I want people that are competent in their field, live normal lives, have a high degree of social intelligence and have their focus on the task of the company and not on their personal career. We value disagreements when the agenda for the discussion is to find the best



solution and nothing else. That means that understanding and accepting that your idea was not as good as the one of your colleagues is necessary and a sign of personal integrity. The team we have built in Ultimovacs is the best I have ever worked in, and I am truly sorry it is necessary to leave this team.

#### (the right) Money

Ultimovacs is today a result and a consequence of what our main shareholders have wanted Ultimovacs to be. They have been loyal to the company both with their investments but also in their contributions in their board participation and mentorship for the administration. From the start, I was told that the purpose of the company is to find out if UV1 could benefit patients. When we know this, we can build up the business part to create an income.

Ultimovacs is at this turning point now. We have good signals that UV1 will benefit patients. In 2022 we will know if these signals of clinical efficacy hold what they promise. Ultimovacs needs to prepare for positive results by preparing for sale of rights to our technology, most likely through strong industrial partnerships. This means that it is also time to change CEO. Carlos de Sousa will take over my role from June 1st. He has the competence, experience and personality to take Ultimovacs into the exciting period that lies ahead. Please welcome him! I wish Carlos and the rest of the team the best of luck – to the benefit of cancer patients and shareholders.

Øyvind Kongstun Arnesen, CEO



# **Key Operational Highlights Q1 2020**

# **Clinical trial update**

• Implications of the covid-19 situation

Mid-March 2020, the covid-19 related lockdown strongly influenced clinical trial activities at hospitals in all relevant territories. In order to secure control of the pandemic, hospitals temporarily halted clinical trial activities. This also impacted preparations of new trials. After a few weeks of lock-down, regular trial activities are gradually resumed in most countries. Shortterm, the lock-down has influenced the start-up of Ultimovacs' new phase II trials. Long-term, the impact on the study progress is yet uncertain. Ultimovacs is actively working with its clinical trial partners to ensure activation of sites and patient enrolment as close to initial plans as possible.

### • The INITIUM trial

Despite the temporary halt in clinical trial activities at several hospitals caused by covid-19 situation, the first INITIUM trial site has recently opened for patient inclusion. In total, an opening of 35-40 sites are planned for this trial. Several additional sites are expected to open in Norway and the US during Q2-20. The preparations to start the randomized phase II trial in malignant melanoma were delayed due to the covid-19 situation and the implications for clinical trial activities at several hospitals. The initial



plan was inclusion of the first patient in Q1-20. After a few weeks of reduced activity level at hospitals, several sites are now resuming their trial activities.

The INITIUM trial is a Ultimovacs-sponsored randomized phase II trial for patients with metastatic malignant melanoma. Patients will be given UV1 in combination with ipilimumab (CTLA-4 checkpoint inhibitor) and nivolumab (PD-1 checkpoint inhibitor). The trial will be run in the US and Europe (including Norway). In total, 154 patients will be enrolled, where 77 patients will receive nivolumab and ipilimumab and the other 77 patients will receive nivolumab, ipilimumab and UV1. Planned readout of the primary endpoint progression-free survival is H2-2022. This date is subject to change as the impact of the covid-19 situation is yet uncertain.

Malignant melanoma is a type of skin cancer that develops when melanocytes (the cells that give the skin its tan or brown color) start to grow out of control. Malignant melanoma is less common than other types of skin cancers. Malignant melanoma is, however, more dangerous because it is much more likely to spread to other parts of the body if not diagnosed and treated at an early stage. Malignant melanoma can develop anywhere on the skin, but it is more likely to start on the trunk (chest and back) in men and on the legs in women. The neck and face are other common sites.



• The NIPU trial

The first out of totally six planned sites in the NIPU trial has also opened for patient inclusion. Initially, the first patient in this trial was expected to be recruited during the first quarter of 2020. Due to the Covid-19 situation, preparations for clinical trials were halted at the relevant hospitals.

The NIPU trial is a randomized, multi-center phase II trial where the universal cancer vaccine UV1 is investigated 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. A total of 118 patients will be included in the NIPU study. Half of the patients will be treated with the combination of UV1, with ipilimumab (CTLA-4 checkpoint inhibitor) and nivolumab (PD-1 checkpoint inhibitor), whereas the other half will receive nivolumab and ipilimumab only. The study is planned to be conducted at six hospitals in four countries (Norway, Sweden, Denmark and Australia). The study sites are planned to be Oslo University Hospital in Norway, Karolinska University Hospital and Skåne University Hospital Lund in Sweden, Copenhagen University Hospital and Aalborg University Hospital in Denmark and University of Western Australia in Perth, Australia.

The objective of the study is to induce 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 primary endpoint of the trial is progression-free survival (PFS) and the PFS read-out is planned for H2-2022. This date is subject to change as the impact of the covid-19 situation is yet uncertain.

MPM is a rare malignant tumor originating from the cells lining the mesothelial surface in the lungs. MPM is the most common type of mesothelioma and is a disease with a high unmet medical need with a median overall survival of approximately 1 year. It is a fatal form of thoracic cancer that is diagnosed in more than 30,000 and kills over 25,000 people per year. Most patients are treated with palliative chemotherapy. Patients with disease progression after first-line therapy have few therapeutic options. Asbestos exposure is heavily linked to the development of the disease. It may take 10 - 50 years for symptoms of mesothelioma to manifest after initial asbestos exposure. Even though the use of asbestos to a large extent is banned today, new incidences of mesothelioma will continue to be a medical challenge for decades.

Ongoing phase I trial in malignant melanoma
 In this study, where UV1 is given in combination with a PD-1
 checkpoint inhibitor, all 20 of the initially planned patients have been
 successfully included (cohort 1 – safety pembrolizumab/UV1).

In September 2020, all patients in cohort 1 will have 1-year observation time. Safety and efficacy data from this cohort will be presented at an international medical conference.





A group of 10 patients (cohort 2 – dose finding GM-CSF) will be added in order to investigate an increased dosage of the adjuvant GM-CSF. 8 of the 10 additional patients in cohort 2 have been enrolled as of 13 May 2020. Four of these patients have been included in the period of covid-19 related lockdown in the US. The remaining patients are expected to be fully enrolled during 2020.

No unexpected safety issues related to UV1 have been observed to date in this trial.

For Ultimovacs, this trial gives supporting data for future filing applications. The progress of this trial does not dictate timelines for the randomized phase II trials.

Follow up trials (also presented in the Q4-19 report as a subsequent event)
 The three completed phase I trials have been reviewed by FDA (U.S. Food and Drug
 Administration) and founded the basis for starting clinical research in the US in malignant
 melanoma. Ultimovacs sees the outcome of these trials as a strong basis for the further
 development of UV1.

Overall Survival (OS) <sup>1</sup>				Median OS	mPFS <sup>2</sup>		
Clinical trial⁵	Year 1	Year 2	Year 3	Year 4	Year 5	(months)	(months)
Prostate (n=22)	95 %	86 %	73 %	55 %	50 %	Will be more than 60 months	n.a.³
NSCLC (n=18)	72 %	50 %	44 %	39 %	H2-20	28.2	12.3
Malignant Melanoma (n=12)	75 %	75 %	67 %	50 %	Q1-21	Will be more than 48 months	6.74

1. Note that some patients have received other treatments upon progression and this is likely to affect survival

2. Median Progression-Free Survival

3. PFS (Progression-Free Survival) not possible to measure in the prostate cancer trial. Instead, patients are followed on PSA measurements. As of today, 8 patients have normalized PSA levels. (For definition of PSA, please see Glossary at the end of this report)

4. mPFS updated after database revision (previously reported as 6.5 months)

5. Prostate: (EudraCT No. 2012-002411-26) NSCLC: (EudraCT No. 2012-001852-20) MM: (EudraCT No. 2013-005582-39 )

During the fourth quarter of 2019, Ultimovacs obtained new data on overall survival in the malignant melanoma trial, where 4-year overall survival is 50%. The results were presented in more detail in the Q4-19 report.

### Publications and presentations (also presented in the Q4-19 report as a subsequent event)

 Abstract presentation: As previously reported, Ultimovacs presented the abstract 'A Phase I/IIa Clinical Trial Investigating the Therapeutic Cancer Vaccine UV1 in Combination with Ipilimumab in Patients with Malignant Melanoma: 4-year Survival Update' on 7 February 2020 at the ASCO-SITC Clinical Immuno-Oncology Symposium. 4-year survival outcome of the clinical trial (UV1 + ipilibumab combination) conducted at the Oslo University Hospital in malignant melanoma was presented (please see previous section for results). The ASCO-SITC Clinical Immuno-Oncology Symposium is a three-day meeting focused on clinical and translational research in immunooncology and the implications for clinical care.



#### **Organization** (also presented in the Q4-19 report as a subsequent event)

• As presented in a separate stock exchange announcement on 13 February 2020, Ultimovacs has appointed Carlos de Sousa as new Chief Executive Officer. Dr. de Sousa will join Ultimovacs on 1 June 2020. Until then, Øyvind Kongstun Arnesen will continue in his position as CEO.

Dr. de Sousa joins Ultimovacs as a seasoned industry executive with 30 years of experience ranging from leadership positions at international pharmaceutical companies such as Pfizer, Novartis and Nycomed/Takeda, to executive management roles at several innovative biotech companies. During his work with these biotech companies, he achieved several rounds of successful capital increases and fund-raising efforts, supported the up-listing to the main market of Nasdaq Stockholm, and enabled the advance of early to mid-stage product development pipelines. Over the course of his career, Dr. de Sousa has built extensive experience in business development, licensing agreements and strategic partnerships and brings to Ultimovacs the benefit of a broad and international industry network. His most recent position was President and Chief Executive Officer of the Swedish immuno-oncology company, Immunicum AB. Dr. de Sousa is a Medical Doctor by training, having earned his degree at School of Medicine, University of Lisbon and holds an Executive MBA from the Stern School of Business, New York University.



# 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 pre-clinical and clinical research on immunotherapies conducted at the Oslo University Hospital. Ultimovacs is located at the Oslo Cancer Cluster Innovation Park in Oslo, Norway, and is an active member of Oslo Cancer Cluster. Ultimovacs is performing a broad clinical development program with clinical trials in Europe, Australia and the USA.

The lead product candidate is UV1, a peptide-based vaccine inducing a specific T cell response against the universal cancer antigen telomerase (hTERT), expressed at a high level in over 85% of human tumors. The vaccine's mode of action is to make the immune system produce CD4 T cells (i.e. T helper cells), recognizing cancer cells expressing telomerase (hTERT). 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 requires no sophisticated infrastructure in hospitals. UV1 is manufactured as an off-the-shelf product with long shelf life.

UV1 is being developed as a therapeutic cancer vaccine and a platform for other immuno-oncology drugs which require an ongoing T cell response for their mode of action. Longer-term, a vaccine like UV1 is attractive to investigate in early stage tumors and also in preventing tumors from starting to grow.

UV1 treatment in three Phase I studies (metastatic prostate cancer, metastatic non-small cell lung cancer and metastatic malignant melanoma) with a total of 52 patients enrolled have been completed at the Oslo University Hospital.

The three completed trials show clinical outcomes that Ultimovacs sees as a strong basis for the further clinical development of UV1, both with respect to safety and signals of clinical effect.

Ultimovacs is currently the sponsor of one ongoing clinical study which is run in the US. In this phase I study the safety and tolerability of treatment with the combination of pembrolizumab (PD-1 checkpoint inhibitor) and UV1 in 30 patients with metastatic malignant melanoma is investigated.

Ultimovacs is sponsor of a randomized phase II trial named INITIUM where UV1 will be combined with nivolumab (PD-1 checkpoint inhibitor) plus ipilimumab (CTLA-4 checkpoint inhibitor) in metastatic malignant melanoma. Study objectives include obtaining efficacy and safety data on the combination therapy.

UV1 will also be investigated in a randomized, multi-center phase II trial in mesothelioma. The trial, named NIPU, investigates the efficacy and safety of UV1 in combination with the checkpoint inhibitors nivolumab and ipilimumab as second-line treatment in mesothelioma.



# Outlook

Ultimovacs' vaccine technology is universal in the sense that it may have effect across most types of cancer and may be used in combination with different types of cancer treatment. The cancer vaccine is expected to generate immune responses across major population sub-groups (i.e. be independent of HLA type). The vaccine is simple to manufacture and requires no sophisticated infrastructure in use. If the further clinical development/testing of Ultimovacs' cancer vaccine demonstrates that the vaccine gives clinical benefit to cancer patients, the potential will consequently be very high.

The phase I study in malignant melanoma, where UV1 is combined with pembrolizumab, is expected to be fully recruited during 2020 and to give valuable information regarding UV1 safety and GM-CSF safety and dosing.

In 2020, two randomized phase II trials will start where UV1 will be tested in two different cancer types. Ultimovacs is the sponsor in one of these trials. Prior to the outbreak of the COVID-19 pandemic, both trials had expected readout of the primary endpoint progression-free survival during the second half of 2022. These dates are subject to change as the impact of the covid-19 situation is yet uncertain. The two trials will include a total of 272 patients. Main study objectives are efficacy and safety data on the combination therapies.

Ultimovacs continuously has or seek discussions to enter into cooperation projects with academic institutions and pharmaceutical companies in order to document the effect and safety of UV1 in other cancer types and in combinations with different cancer treatments.

Ultimovacs also seeks to broaden its pipeline of drug/technology candidates. The R&D activities are currently focused on development of a new first-in-class cancer vaccine solution building on technology of Ultimovacs and the acquired TET-platform, and on development of new molecules and technologies based on biobank material from the ongoing and planned clinical studies conducted with UV1.

Ultimovacs is making development choices based on the knowledge that UV1 is a universal vaccine in several dimensions; the vaccine can potentially play a role across most cancer types, in most patients, in different stages of cancer and in combination with other cancer treatments. Thus, with positive results from future randomized, clinical trials, the development potential is significant.



# **Risks and uncertainties**

Ultimovacs is a research and development company that is still in its early stages. The Company has not generated any revenues historically and is not expected to do so in the short 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 investment in foreign operations, whose net assets are exposed to currency translation risk. Adequate sources of funding may not be available when needed or may not be available on favourable 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 seem to be protected from operational and financial consequences. The final impact of the pandemic is currently difficult to assess. For a biotech company like Ultimovacs, some of the possible implications of the COVID-19 pandemic will be:

- The initiation, patient inclusion and conduct of clinical trials may be affected
- The supply chain (manufacturing and/or logistics) for the investigational products may be interrupted
- The pandemic, together with changes in the oil price, has caused significant fluctuations in currency exchange rates (NOK/EUR and NOK/USD), which may potentially increase R&D costs

Ultimovacs' financial risk exposures are described in more detail in the Annual Report 2019. 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.

Payroll and payroll related expenses increased in Q1-20 (MNOK 10.0) compared to the same period in 2019 (MNOK 7.5), due to three more FTEs in this period compared to the same period in 2019.

Other operating expenses primarily comprise R&D related expenses. These expenses, including IP and external R&D expenses, offset by government grants, amounted to MNOK 18.1 in Q1-20, and MNOK 4.7 in Q1-19. With the initiation of two phase II trials in Q1-20, the R&D costs have been and are expected to be at a higher level than in prior periods. Other operating expenses were higher in Q1-20 (MNOK 20.7) compared to Q1-19 (MNOK 7.0) due to higher R&D expenses.

Total loss for the Q1-20 period amounted to MNOK 30.3 vs. a loss of MNOK 14.7 in Q1-19.

## **Financial position**

Total assets per 31 March 2020 were MNOK 453.3, a decrease of MNOK 24.7 from 31 December 2019. Total liabilities as of 31 March 2020 amounted to MNOK 33.7.

Total equity equalled MNOK 419.6 as of 31 March 2020. The reduction of MNOK 25.1 from 31 December 2019 is a result of the period's operating loss and translation differences amounting to MNOK 25.9, and in addition the increase by the recognition of share-based payments/stock options of MNOK 0.9.

### **Cash flow**

Total net decrease in cash and cash equivalents in Q1-20 was MNOK 31.5, primarily a result of the decrease of MNOK 32.3 related to operations. Total cash and cash equivalents per 31 March 2020 amounts to MNOK 367.7.

#### **Key financials**

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NOK (000) Unaudited	Q1-20	Q1-19	FY19
Total revenues	-	-	-
Total operating expenses	31 259	14 970	66 217
Operating profit (loss)	(31 259)	(14 970)	(66 217)
Profit (loss) for the period	(30 337)	(14 723)	(61 166)
Diluted and undiluted earnings / (loss) per share (NOK)	(1.1)	(0.9)	(2.7)
Net increase / (decrease) in cash and cash equivalents	(31 494)	(16 110)	284 332
Cash and cash equivalents at end of period	367 686	99 352	399 607



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

Oslo, 13 May 2020

Jónas Einarsson Chair of the Board Kari Grønås Board member Eva S. Dugstad Board member

Henrik Schüssler Board member Ketil Fjerdingen Board member

Leiv Askvig Board member

Øyvind Kongstun Arnesen CEO

Kristin L. A. Wilhelmsen Board member





#### Interim condensed consolidated statement of comprehensive income

NOK (000) Unaudited	Note	Q1-20	Q1-19	FY19
Other operating income		-	-	-
Total revenues		-	-	-
Payroll and payroll related expenses	3, 5	10 015	7 538	20 160
Depreciation and amortization		586	398	2 063
Other operating expenses	4, 5	20 658	7 034	43 995
Total operating expenses		31 259	14 970	66 217
Operating profit (loss)		(31 259)	(14 970)	(66 217)
Financial income		1 519	351	5 631
Financial expenses		597	104	580
Net financial items		922	247	5 051
Profit (loss) before tax		(30 337)	(14 723)	(61 166)
Income tax		-	-	-
Profit (loss) for the period		(30 337)	(14 723)	(61 166)
Other comprehensive income (loss) - Translation differences		4 430	(2 321)	(672)
Total comprehensive income (loss) for the period		(25 907)	(17 044)	(61 838)
Diluted and undiluted earnings/(loss) pr share (NOK)	6	(1.1)	(0.9)	(2.7)

### Interim condensed consolidated statement of financial position

NOK (000) Unaudited	Note	31 Mar 2020	31 Mar 2019	31 Dec 2019
ASSETS				
Goodwill		11 749	10 515	10 851
Licenses		57 033	51 043	52 675
Patents		2 778	3 044	2 844
Property, plant and equipment		614	759	536
Right to use asset	2, 11	3 785	3 879	3 523
Total non-current assets		75 959	69 240	70 430
Receivables and prepayments	7	9 649	6 587	8 004
Bank deposits		367 686	99 352	399 607
Current assets		377 334	105 939	407 611
TOTAL ASSETS		453 293	175 180	478 041
EQUITY				
Share capital		2 786	641	2 786
Share premium		656 692	314 256	656 692
Total paid-in equity		659 478	314 897	659 478
Accumulated losses		(249 384)	(172 604)	(219 047)
Other equity		2 838	-	1 985
Translation differences		6 645	567	2 216
TOTAL EQUITY	6, 9	419 578	142 860	444 633
LIABILITIES				
Lease liability	2, 11	2 406	2 948	2 301
Deferred tax	2	11 749	10 515	10 851
Non-current liabilities		14 154	13 463	13 152
Accounts payable		10 483	2 437	11 768
Lease liability		1 500	957	1 325
Other current liabilities		7 578	15 463	7 164
Current liabilities	8	19 561	18 857	20 257
TOTAL LIABILITIES		33 716	32 320	33 409
TOTAL EQUITY AND LIABILITIES		453 293	175 180	478 041

#### Interim condensed consolidated statement of cash flow

NOK (000) Unaudited	Q1-20	Q1-19	FY19
Loss before tax	(30 337)	(14 723)	(61 166)
Non-cash adjustments			
Depreciation and amortization	586	398	2 063
Interest received incl. investing activities	(1 500)	(330)	(4 490)
Net foreign exchange differences	515	21	224
Other finance expense	63	58	258
Share option expenses	852	-	1 985
Working capital adjustments:			
Changes in prepayments and other receivables	(1 644)	(404)	(1 820)
Changes in payables and other current liabilities	(870)	(1 075)	(42)
Net cash flow from operating activities	(32 336)	(16 055)	(62 989)
Purchase of property, plant and equipment	(182)	(109)	(172)
Acquisition of subsidiary	-	-	-
Interest received	1 500	330	4 490
Net cash flow used in investing activities	1 318	221	4 318
Proceeds from issuance of equity	-	-	370 000
Share issue cost	-	-	(25 418)
Interest paid	-	-	(258)
Payment of lease liability	(461)	(276)	(1 321)
Net cash flow from financing activities	(461)	(276)	343 002
Net change in cash and cash equivalents	(31 479)	(16 110)	284 332
Effect of change in exchange rate	(443)	(78)	(265)
Cash and cash equivalents at beginning of period	399 607	115 540	115 540
Cash and cash equivalents at end of period	367 686	99 352	399 607

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

NOK (000) Unaudited	Share Capital	Share Premium	Accum.	Other equity	Transl. differenc.	Total equity
Balance at 1 Jan 2019	641	314 256	(157 881)		2 888	159 904
Loss for the period	-	-	(14 723)	-	-	(14 723)
Issue of ordinary shares			-	-	-	-
Share issue costs	-		-	-	-	-
Recognition of share-based payments	-	-	-	-	-	-
Translation differences			-	-	(2 321)	(2 321)
Balance at 31 Mar 2019	641	314 256	(172 604)	-	567	142 860
Balance at 1 Jan 2020	2 786	656 692	(219 047)	1 985	2 216	444 633
Loss for the period	-	-	(30 337)		-	(30 337)
Issue of ordinary shares	-	-	-	-	-	-
Share issue costs	-	-	-	-	-	-
Recognition of share-based payments	-	-	-	852	-	852
Translation differences			-	-	4 430	4 430
Balance at 31 Mar 2020	2 786	656 692	(249 384)	2 838	6 645	419 578



# Notes

# **1.** General information

Ultimovacs ASA (the Company or Ultimovacs) and its subsidiary (together the Group) is a pharmaceutical 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 2019 financial statements. These condensed interim financial statements should therefore be read in conjunction with the 2019 financial statements.

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 13 May 2020.



# 3. Personnel expenses

#### **Personnel expenses**

NOK (000)	Q1-20	Q1-19	FY19
Salaries and bonuses	7 670	6 010	24 545
Social security tax	966	886	4 076
Pension expenses	493	572	1 798
Share-based compensation	852	-	(8 222)
Other personnel expenses	32	70	437
Government grants	1	-	(2 476)
Total personnel expenses	10 015	7 538	20 160
Number of FTEs at end of period	19	16	17

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

# 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)	Q1-20	Q1-19	FY19
External R&D expenses	17 687	4 314	35 528
Clinical studies	14 818	2 527	24 042
Manufacturing costs	1 888	1 214	5 640
Other R&D expenses	982	572	5 847
Rent, office and infrastructure	618	550	2 712
IP expenses	402	352	2 333
Accounting, audit, legal, consulting	895	919	3 658
Other operating expenses	1 056	899	5 066
Government grants	0	-	(5 302)
Total operating expenses	20 658	7 034	43 995



### 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)	Q1-20	Q1-19	FY19
Skattefunn from The Research Council of Norway	-	-	5 277
Eurostars	2	-	2 344
Other grants	-	-	157
Total government grants	2	-	7 778

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 for the year divided by the weighted average number of ordinary shares outstanding.

#### Earnings per share

NOK (000)	Q1-20	Q1-19	FY19
Loss for the period	(30 337)	(14 723)	(61 166)
Average number of shares during the period ('000)	27 860	16 020	22 927
Earnings/loss per share (NOK)	(1.1)	(0.9)	(2.7)

In the annual general meeting on 21 May 2019, a split of the shares was resolved so that one share with a nominal value of NOK 1 was split into 25 shares with a nominal value of NOK 0.10. The Q1-19 figures in the overview above takes into account the share split in order to be comparable with the number of shares post-split.

When the Company was listed on the Oslo Stock exchange on 3 June 2019, 11,840,000 new shares were issued, increasing the total number of shares to 27,860,400.

In addition to the above, in accordance with the board's proposal, the general meeting approved the establishment of a new share option program. This program commenced on the day of listing, 3 June 2019, where 557,500 options, each giving a right to acquire one share, where allocated to the Group's employees. The share options issued 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.

See note 10 for more information regarding the option program.

# 7. Current assets

# **Receivables and prepayments**

	31 Mar	31 Mar	31 Dec
NOK (000)	2020	2019	2019
Government grants	5 434	4 946	5 797
Prepayments	832	760	435
Other receivables	3 383	882	1 772
Total receivables and prepayments	9 649	6 587	8 004

# 8. Current liabilities

#### **Current liabilities**

	31 Mar	31 Mar	31 Dec
NOK (000)	2020	2019	2019
Accounts payable	10 483	2 437	11 768
Public duties payable	1 644	1 327	2 495
Share-based compensation liability	-	10 207	-
Lease liability	1 500	957	1 325
Other current liabilities	5 934	3 929	4 669
Total current liabilities	19 561	18 857	20 257



# 9. Shareholder information

The share capital as at 31 March 2020 was NOK 2,786,040, with 27,860,400 ordinary shares, all with equal voting rights and a nominal value of NOK 0.1. Ultimovacs ASA has appr. 3,000 shareholders as of 31 March 2020, and the 20 largest shareholders as of this date are listed below:

#### Share register as per 31 March 2020

	# of	
Shareholder	shares	Share-%
Gjelsten Holding AS	5 747 599	20.6 %
Canica AS	2 232 663	8.0 %
Inven2 AS	1 866 658	6.7 %
Watrium AS	1 620 925	5.8 %
Radiumhospitalets Forskningsstiftelse	1 395 875	5.0 %
Langøya Invest AS	1 226 325	4.4 %
Helene Sundt AS	782 132	2.8 %
CGS Holding AS	782 132	2.8 %
Sundt AS	617 150	2.2 %
Danske Invest Norge Vekst	600 000	2.2 %
Verdipapirfondet KLP AksjeNorge	591 635	2.1 %
SEB Prime Solutions Sissener Canopus	500 000	1.8 %
Prieta AS	485 175	1.7 %
Brown Brothers Harriman (Lux.) SCA (Nominee)	458 657	1.6 %
Verdipapirfondet Nordea Avkastning	441 450	1.6 %
JP Morgan Chase Bank, N.A., London (Nominee)	429 417	1.5 %
Swedbank AB (Nominee)	382 427	1.4 %
Kommunal Landspensjonskasse	372 510	1.3 %
Månebakken AS	349 000	1.3 %
Verdipapirfondet Nordea Kapital	269 660	1.0 %
20 Largest shareholders	21 151 390	<b>75.9%</b>
Other shareholders	6 709 010	24.1%
Total	27 860 400	100.0%

On 5 August 2019, FIL Limited ('FIL') announced that the number of shares and right to shares in Ultimovacs ASA that were attributable to FIL had crossed above the threshold of 5% in Ultimovacs ASA due to purchase of shares. FIL is a privately-owned group comprising of two divisions, Fidelity International and Eight Roads.

### 10. Shared-based payments

#### Share option program

A new share equity settled option program was introduced in June 2019 and the Board is authorized to increase the Group's share capital in connection with the share incentive arrangement by up to NOK 55 000 (550 000 share options) until the next ordinary General Assembly in 2021.

The share option program is groupwide and includes all employees in the Group. A total of 557,500 options for shares in the Company have been distributed amongst the employees, of which 362,500 options are allocated to the management team. The number of options currently granted corresponds to 2.0% of the outstanding number of shares in the Company. Each option gives the right to acquire one share in the Company and are 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. Vesting normally requires the option holder still to be an employee in the Company. The exercise price is NOK 31.25 per share which is equal to the IPO price at listing on Oslo Børs on 3 June 2019. Options that are not exercised within 5 years from the date of grant will lapse and become void.

#### Allocation of options to Management Team

Name	Position	Number of options
Øyvind Kongstun Arnesen	Chief Executive Officer	72 000
Hans Vassgård Eid	Chief Financial Officer	62 500
Jens Egil Torbjørn Bjørheim	Chief Medical Officer	53 000
Audun Tornes	Chief Operating Officer	38 000
Gudrun Trøite	Director Regulatory Affairs and QA	38 000
Ingunn Hagen Westgaard	Head of Research	38 000
Øivind Foss	Head of Clinical Operations	38 000
Gunilla Ekström	Managing Director Ultimovacs AB	23 000

### Assumptions, costs and social security provisions:

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.

The exercise price is set out in the Ultimovacs Award Agreements with each employee and is stated in the Norwegian Krone. The current price of the underlying shares used in the model is the last available closing price of Ultimovacs at grant date.

The risk-free interest rate used in the B&S Model is equal to the rates of the government bond issues of the country in whose currency the exercise price is expressed, with the term equal to the expected term of the option being valued. Since the exercise price is expressed in Norwegian Krone, the "Norges Bank Statskasseveksler" and "Obligasjoner"-rate is used as input. The interest rates used for the options with term structures outside of the quoted terms of Norges Banks interest rates are calculated with the use of a linear interpolation between the two closest quoted rates.

A dividend parameter is not included in the calculations.

The B&S Model assumes that the time from grant until expiry gives the time parameter in the model. This assumption is based on the options being free from restraints and that the owner of the options holds the right to sell the option in the market at any time. As this is not the case for most employee share options, IFRS-2 Appendix B §B16-18, states that a shorter time period can be used as the expected lifetime of the options in some cases. Half a year after vesting date is therefore assumed to be the estimated end-of-lifetime of each option in the model. However, exercise patterns will be monitored, and expected option lifetime will be updated if needed for future grants.



For valuation purposes, expected future volatility of 58.46%, 59.02% and 69.25% has been applied for the three tranches with vesting after 1, 2 and 3 years respectively. As Ultimovacs has not been listed on a stock exchange long enough to have a sufficient share price history to calculate the shares' volatility, comparable firms' share price volatility have been used to estimate the expected volatility.

#### Movement of share options

	Number of share option	Weighted average strike
Outstanding at opening balance 01.01.2020	557 500	31.25
Granted	-	-
Exercised	-	-
Forfeited	-	-
Outstanding at closing balance 31.03.2020	557 500	31.25
Vested at closing balance	-	-

Equity-settled share-based payments are measured at the fair value of the equity instruments at the grant date. For equity-settled share-based payment transactions, the liability needs to be remeasured at the end of each reporting period up to the date of settlement, with any changes in fair value recognised in the profit or loss with a corresponding adjustment to equity. This requires a reassessment of the estimates used at the end of each reporting period.

The total expense recognized for the option program in Q1-20 is MNOK 0.7, including social security accruals of MNOK (0.1). No new options have been granted in Q1-20.

# **11.** IFRS 16 – rental contracts

The Group implemented IFRS 16 in 2019 with the modified retrospective approach. The most significant agreement classified as operating lease is the rental agreement for office premises in Oslo with 3 years left in the rental contract as of 1 January 2020. In addition, there are four car-leasing contracts also classified as operating leases. With the transition to IFRS 16, the Group has recognized these contracts as a right-of-use assets of MNOK 4.6, and lease liabilities of MNOK 4.6 as of 1 January 2019. The weighted average discount applied at 1 January 2019 was 6.0%. Please see the 2019 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.
Immune response	The activity of the immune system against foreign substances (antigens).
Adjuvant	A medical substance used to enhance the effect of another medical
	substance.
GM-CSF	"Granulocyte-macrophage colony-stimulating factor". Ultimovacs uses GM-
	CSF as adjuvant together with UV1 to strengthen the ability of UV1 to
	stimulate the immune system.
Immune checkpoint	Medicines that "takes the brakes off the immune system". The immune
inhibitors	system has brakes necessary to balance a normal immune response. The
	downside to these brakes is that it makes it easier for a tumor to grow
	because the immune system becomes less able to fight the tumor. By
	"blocking the brakes", the immune system becomes more potent in killing
	tumor cells. PD-1 / PDL-1 inhibitors (Keytruda and Opdivo) and CTLA-4
	inhibitors (Yervoy – ipilimumab) are examples of Checkpoint inhibitors.
	There are many others in development.
CILA-4	A protein found on 1 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 CI LA-4 is bound to another protein called B7, it helps
	keep I cells from multiplying and killing other cells, including cancer cells.
	Ipilimumab works by making it difficult for the CILA-4 to bind to B7.
	philmumab (ipi/ vervoy) was the first checkpoint inhibitor to reach the
	Markel.
	normal immune response. The balance is needed to avoid collateral damage
	of normal cells. When PD-1 is bound to another protein called PD-11 it
	balos keen T cells from killing other cells including cancer cells. Some
	anticancer drugs called immune checknoint inhibitors are used to block PD-
	1 or PD-I1 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
	eukarvotic 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 85% of human
	tumors. UV1 uses telomerase (hTERT) as an immune therapy target.
Checkpoint inhibitors	
Yervoy (ipilimumab)	CTLA-4 checkpoint inhibitor from BMS (Bristol-Myers Squibb)
Opdivo (nivolumab)	PD-1 checkpoint inhibitor from BMS (Bristol-Myers Squibb)
Keytruda	PD-1 checkpoint inhibitor from Merck
(pembrolizumab)	
Tecentriq	PD-L1 checkpoint inhibitor from Roche
(atezolizumab)	



Bavencio (avelumab)	PD-L1 checkpoint inhibitor from Merck (Germany)/Pfizer/Eli Lilly	
Imfinzi (durvalumab)	PD-L1 checkpoint 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	Overall 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	
DEC	One way to see now 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	
	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 un by	
intraderinar	antigen presenting cells (dendritic cells) LIV1 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 amount of immune cells, mainly dermal dendritic cells.	
	17777	
	Epidermis	
	Epidermis — Dermis —	
	Epidermis	
	Epidermis Dermis Subcutaneous	
	Epidermis Dermis Subcutaneous- tissue	
	Epidermis Dermis Subcutaneous- tissue	
Biopsy	Epidermis Dermis Subcutaneous- tissue	
Biopsy	Epidermis Dermis Subcutaneous tissue A piece of tissue, normal or pathological removed from the body for the purpose of examination	
Biopsy	Epidermis Dermis Subcutaneous tissue A piece of tissue, normal or pathological removed from the body for the purpose of examination.	
Biopsy	Epidermis       Epidermis         Dermis       Subcutaneous         Subcutaneous       Epidermis         Immunoglobulin E (IgE) are antibodies produced by the immune         system       If you have an allergy, your immune system overreacts to an	
Biopsy	Epidermis       Epidermis         Dermis       Subcutaneous         Subcutaneous       Epidermis         Suppose of examination.       Epidermis         Immunoglobulin E (IgE) are antibodies produced by the immune       Epidermis         System. If you have an allergy, your immune system overreacts to an allergen (what you are	
Biopsy IgE	Epidermis       Epidermis         Dermis       Epidermis         Subcutaneous       Epidermis         Subcutan	
Biopsy	Epidermis	
Biopsy IgE	Epidermis       Epidermis         Dermis       Epidermis         Subcutaneous       Epidermis         Subcutan	



Metastasis/	The development of malignant growths at a distance from a primary
	site of cancer/
Metastatic cancer	Metastatic cancer is cancer that spreads from its site of origin to
	another part of the body.
SAE	A serious adverse event (SAE) in human drug trials is defined as any
	untoward medical occurrence that at any dose
	1. results in death,
	2. is life-threatening
	<ol> <li>requires inpatient hospitalization or causes prolongation of existing hospitalization</li> </ol>
	4. results in persistent or significant disability/incapacity,
	5. is a congenital anomaly/birth defect, or
	<ol> <li>requires intervention to prevent permanent impairment or damage.</li> </ol>
	The term "life-threatening" in the definition of "serious" refers to an
	event in which the patient was at risk of death at the time of the event;
	it does not refer to an event which hypothetically might have caused
	death if it were more severe. Adverse events are further defined as
	"Any untoward medical occurrence in a patient or clinical investigation
	subject administered a pharmaceutical product and which does not
	necessarily have to have a causal relationship with this treatment."
PSA	Prostate-specific antigen (PSA) is an enzyme (protein) important for
	reproduction. PSA is present in small quantities in the serum of men
	with healthy prostates, but is often elevated in the presence of
	prostate cancer or other prostate disorders.



# Disclaimer

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# **About Ultimovacs**

Ultimovacs is a pharmaceutical company developing novel immunotherapies against cancer. The lead product candidate is UV1, a peptide-based vaccine inducing a specific T cell response against the universal cancer antigen telomerase. UV1 is being developed as a therapeutic cancer vaccine which may serve as a platform for use in combination with other immuno-oncology drugs which require an ongoing T cell response for their mode of action. Ultimovacs is performing a broad clinical development program with clinical trials in Europe, Australia and the USA.

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 pre-clinical 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.

