

# FOURTH QUARTER 2018 REPORT

**Ultimovacs** 



## Year-to-date of 2018 – at a glance...

- Encouraging signs of clinical effect based on results across the three completed clinical trials (prostate cancer, non-small cell lung cancer and malignant melanoma).
- In the US based phase I trial study in malignant melanoma, in which UV1 is given in combination with a PD-1 checkpoint inhibitor, the first three patients have been included. There have been no observed safety issues related to UV1 for the first patient and no observed safety issues related to UV1 for patients 2 and 3 when they have had four doses of UV1. All patients shall receive 8 doses of UV1. When patients 2 and 3 have completed 5 doses of UV1 (expected by mid-February 2019) without serious safety issues related to UV1, the study will open for general inclusion of the remaining patients.
- In July, Ultimovacs took over the immunotherapy technology business of the Swedish company Immuneed AB. The complementary technologies of the two companies provide a unique platform for development of novel vaccine solutions for treatment and possibly prevention of cancer.
- To finance the activities towards a prospective registration of UV1 and the preclinical development of a new vaccine solution, Ultimovacs prepares for a possible IPO on the Oslo Stock Exchange.

## **CEO's corner**

The main purpose of Ultimovacs at the present stage is to document the possible clinical usefulness of our cancer vaccine UV1. The company has now generated the knowledge needed to reach a decision on attempting to register UV1.

The main reason for starting on the final step towards possible filing for registration in 2023 is that we believe our vaccine is well positioned to play a major role in future cancer treatment and possibly



prevention. Manipulating the immune system to kill cancer cells and clear tumors will save many lives that earlier cancer treatments could not. It is important to remember that no matter how you manipulate the immune system, the effect of the treatment



comes from cells in the immune system that are able to recognize and kill the cancer cells.

The vast majority of immunotherapy treatments used today rely on these cells being made spontaneously by the immune system. These treatments make it possible for immune cells to do their job by removing some of the obstacles preventing them from attacking the tumor. If patients do not have enough cells with the capability to kill the cancer cells, the present therapies simply cannot work. Our vaccine can supply these patients with activated cells able to fire up the immune system against the tumor. How do we know this? We know this because we have documented it in the trials we already have done. This, and the changes we see in some patients, is the very reason why we think it is right to take the big leap and document the effect of the vaccine in a large, randomized trial.

If we succeed and are allowed to use the vaccine as a regular cancer treatment, we will continue to document the effect of the universal cancer vaccine in many different types of cancer and in different stages of disease, right up to where we possibly can prevent cancer from occurring in persons with very high risk. This will also be the future for cancer treatments in general. New technology will make it possible to diagnose cancer much earlier than we do now. The biology will be very different in a small, newly established tumor as compared to an older tumor with metastasis (i.e disease spread to other organs). What they will have in common is the possibility to be killed by an activated immune system. It is likely that a small "inexperienced" tumor is easier to eliminate than the tumors we are treating today. The best might be to make the immune system fit and ready to attack **if** the cancer appears. We will try to make our vaccine do that.

Oslo, 31 January 2019 Øyvind Kongstun Arnesen, CEO



## **Background**

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 for use as monotherapy, and as a platform for 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 and the USA.

Ultimovacs was established in 2011. The company and its proprietary technology is based on pre-clinical and clinical research on immunotherapies conducted at the Oslo University Hospital. The company is privately held, mainly by Norwegian private investors/family offices.

Ultimovacs is located at the Oslo Cancer Cluster Innovation Park in Oslo, Norway, and is an active member of Oslo Cancer Cluster.

Treatment in three Phase I studies have been completed at the Oslo University Hospital. The patients have been followed up for survival, immune response and new anti-cancer treatment. Fifty-two (52) patients have been enrolled in these studies.

- Prostate cancer (22 patients)
   Patients with advanced prostate cancer without lung and/or liver metastases were enrolled. These patients had started CAB treatment (GnRH-agonist combined with anti-androgen) prior to UV1 treatment.
- Non-small cell lung cancer (NSCLC, 18 patients)
  In the lung study stage 3b/4 NSCLC patients were enrolled, who previously had been treated with palliative radiotherapy and/or at least two courses of chemotherapy. These patients were not to be in progression, confirmed by CT, at least 4 weeks prior to UV1 treatment.
- Malignant Melanoma UV1 in combination with ipilimumab (12 patients)
   The malignant melanoma trial included patients with unresectable or metastatic disease when enrolled, and were eligible for ipilimumab. Ipilimumab is an agent stimulating immune cell generation and is an approved drug for treatment of malignant melanoma.

Safety and tolerability were primary endpoints in all three studies, while immune response towards any of the UV1 peptides and efficacy were secondary endpoints.

Three different dose levels of UV1 were investigated in the prostate cancer and NSCLC studies (100, 300 and 700  $\mu$ g). In the malignant melanoma study, 300  $\mu$ g UV1 was



given in combination with ipilimumab. The UV1 doses have been given with GM-CSF as an adjuvant treatment.

Data from the three studies showed that UV1 is generally well tolerated. There were no dose limiting toxicities.

UV1 induced an immune response (hTERT specific T-cells) in 82% of patients across the three studies (range 67-91%).

When combining UV1 with ipilimumab, a CTLA-4 checkpoint inhibitor, 91% of malignant melanoma patients developed an immune response. The responses appeared earlier, required fewer vaccinations, and were stronger and more long lasting compared to vaccination with UV1 alone. These data are compatible with a mechanism of action where blocking CTLA-4 checkpoints induce additional expansion of UV1 specific T cells induced by UV1 vaccination.

The three completed trials show clinical outcomes that Ultimovacs sees as a strong basis for the next development phase towards registration of UV1;

- Prostate cancer: 73% of patients were alive after 3 years
- Non-small cell lung cancer (NSCLC): Median progression free survival (mPFS)
  was reached at 12 months and median overall survival was reached at 28
  months
- Malignant melanoma: Median progression free survival (mPFS) was reached at
   6.5 months and 67% of patients were alive after 3 years

All patients are followed for overall survival up to ten years and overall survival status will be updated regularly.

Ultimovacs believes that the effect of the UV1 vaccine will be most beneficial when combined with agents improving immune cells' ability to attack tumor cells.

Ultimovacs is currently the sponsor of one ongoing clinical study which is run in the US. In this phase 1 study the safety and tolerability of treatment with the combination of pembrolizumab (PD1 inhibitor) and UV1 in 20 patients with metastatic malignant melanoma is investigated.

Ultimovacs is currently planning for a randomized registration trial with the combination treatment of pembrolizumab and UV1 in patients with metastatic malignant melanoma.



## **Key Operational Highlights Q4 2018**

#### R&D - Update from clinical trials

- In the US based phase I trial study in malignant melanoma, UV1 is given in combination with the PD-1 checkpoint inhibitor pembrolizumab.
   Pembrolizumab is a therapy improving immune cells' ability to attack tumor cells. The first three patients have been included in this trial. There have been no observed safety issues related to UV1 for the first patient and no observed safety issues related to UV1 for patients 2 and 3 when they have had four doses of UV1.
- All patients in this trial shall receive 8 doses of UV1. When patients 2 and 3 have completed 5 doses of UV1 (expected by mid-February 2019) without serious safety issues related to UV1, the study will open for general inclusion of the remaining patients.

#### 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 favorable terms. The Company's ability to obtain such additional capital or financing will depend in part upon prevailing market conditions as well as conditions of its business and its operating results, and those factors may affect its efforts to arrange



additional financing on satisfactory terms. The Board of Directors works continuously to secure the business operation's need for financing.

Ultimovacs' financial risk exposures are described in more detail in the 2017 IFRS financial statement. No significant changes have occurred that affect these reported risks.



#### **Outlook**

In the phase I study in malignant melanoma where UV1 is combined with pembrolizumab (PD1 inhibitor), Ultimovacs aims to have all 20 patients recruited by Q2 2019, and all safety data available shortly thereafter.

Ultimovacs intends to apply for conditional approval for UV1 in combinations with anti-PD-1 based on data from a planned pivotal phase II study investigating UV1 in combination with anti-PD-1 in malignant melanoma. This study is intended to be initiated in Q1 2020, with readout of primary endpoints approximately 3 years after study start (PFS) and 4 years after study start (OS). Study objectives include to obtain efficacy and safety data on the combination therapy. The experimental objective across all Ultimovacs studies is to establish a relevant biobank of patient material for characterization of the immunological response and changes in the tumor milieu promoted by UV1 vaccination.

Ultimovacs actively seeks to broaden its pipeline of drug/technology candidates. The R&D activities focus 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.

## **Key financials Q4 2018**

- Preparations for IPO/listing on Oslo Børs (Oslo Stock Exchange) are in process –
  the aim is to complete an IPO during the first half of 2019. The main purpose of
  the IPO is to ensure financing of operations and core development projects
  until potential filing for Marketing Authorization of UV1.
- Significant increase in net loss in Q4-18 compared to Q4-17 primarily due to increased activity level of R&D activities (including manufacturing), higher headcount and more use of external advisors.

NOK (000) Upgudited	Q4-18	Q4-17	FY18	FY17
NOK (000) Unaudited	Q4-10	Q4-17	FIIO	FII/
Total revenues	-	-	-	-
Total operating expenses	13 472	7 887	56 532	33 391
Operating profit (loss)	(13 472)	(7 887)	(56 532)	(33 391)
Profit (loss) for the peiod	(12 704)	(7 624)	(55 289)	(32 830)
Diluted and undiluted earnings / (loss) per share (NOK)	(20)	(13)	(89)	(62)
Net increase/(decrease) in cash and cash equivalents	(8 132)	119 488	(54 246)	96 806
Cash and cash equivalents at end of period	115 540	169 808	115 540	169 808



#### **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 Q4-18 (MNOK 7.1) compared to the same period in 2017 (MNOK 4.3), primarily as a result of a higher headcount (4.5 additional FTEs), of which 1 FTE (2 employees) in the Swedish company, as well as an increase in the share-based compensation scheme liability of MNOK 1.9 compared to MNOK 1.1 in the Q4-17 period. Payroll and payroll related expenses YTD-18 was MNOK 27.1 (MNOK 18.2 in YTD-17).

Other operating expenses amounted to MNOK 6.2 in Q4-18 (MNOK 3.4 in Q4-17), of which MNOK 4.5 related to external R&D expenses. During 2017, Ultimovacs started preparations for a potential listing of the Company on Oslo Børs (Oslo Stock Exchange). Significant effort and simultaneous workstreams have commenced during YTD-18 in order to meet listing criteria and prepare the Company for a potential listing in H1-19. Several corporate, legal and financial advisors have been involved in the process in YTD-18. Other operating expenses in YTD-18 was MNOK 28.9 (MNOK 14.7 in YTD-17).

Loss for the period in Q4-18 amounted to MNOK 12.7 (vs. a loss of MNOK 7.6 in Q4-

17), and MNOK 55.3 in YTD-18 (MNOK 32.8 in YTD-17).

#### **Financial position**

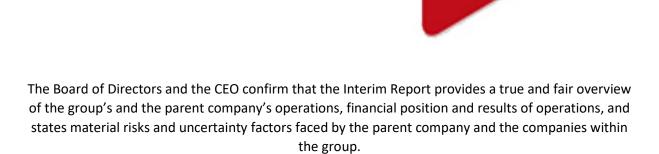
Total assets per 31 December 2018 was MNOK 189.9, an increase of MNOK 11.0 from 31 December 2017 as result of the purchase of TET Pharma AB with newly issued shares, partly offset by the operating loss.

Total liabilities as of 31 December 2018 amounted to MNOK 30.0, and total equity equaled MNOK 159.9.

#### Cash flow

The net decrease in cash and cash equivalents in Q4-18 of MNOK 8.1 was a result of operating activities. In the same period in FY17, the cash position increased by MNOK 119.5 due to the share issue, however net change in cash and cash equivalents excluding net cash flow from financing activities decreased by MNOK 4.0 in Q4-17.

Total net decrease in cash and cash equivalents in the YTD-18 period was MNOK 54.2, a result of operating activities and the purchase of TET Pharma AB for MNOK 4.6 in cash in addition to shares in Ultimovacs AS. In YTD17, the increase was MNOK 96.8, and a decrease of MNOK 26.7 if excluding net cash flow from the share issue. Total cash and cash equivalents per 31 December 2018 amount to MNOK 115.5.



# The Board of Directors and CEO of Ultimovacs AS Oslo, 31 January 2019

Jonas Einarsson	Bjørn Rune Gjelsten	Ole Kristian Hjelstuen
Chairman of the Board	Board member	Board member
Henrik Schüssler	Ketil Fjerdingen	Leiv Askvig
Board member	Board member	Board member
Kristin L. A. Wilhelmsen Board member		Øyvind Kongstun Arnesen CEO



#### Interim condensed consolidated statement of comprehensive income

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NOK (000) Unaudited	Note	Q4-18	Q4-17	FY18	FY17
Other operating income		-	-	-	-
Total revenues		-	-	-	-
Payroll and payroll related expenses	3, 5	7 137	4 310	27 074	18 158
Depreciation and amortization		129	141	601	534
Other operating expenses	4, 5	6 205	3 436	28 857	14 700
Total operating expenses		13 472	7 887	56 532	33 391
Operating profit (loss)		(13 472)	(7 887)	(56 532)	(33 391)
Financial income		827	314	1 376	631
Financial expenses		58	51	134	70
Net financial items		768	263	1 243	561
Profit (loss) before tax		(12 704)	(7 624)	(55 289)	(32 830)
Income tax		-	-	-	-
Profit (loss) for the peiod		(12 704)	(7 624)	(55 289)	(32 830)
Other comprehensive income - Translation differences		2 894	-	2 894	-
Total comprehensive income (loss) for the period		(9 810)	(7 624)	(52 395)	(32 830)
Diluted and undiluted earnings/(loss) pr share (NOK)	6	(20)	(13)	(89)	(62)

#### Interim condensed consolidated statement of financial position

NOK (000) Upgudited	Note	31 Dec 2018	31 Dec 2017
NOK (000) Unaudited	Note	2010	2017
ASSETS			
Goodwill	2, 11	10 981	-
Licenses	2, 11	53 307	-
Patents		3 111	3 378
Property, plant and equipment		736	558
Total non-current assets		68 136	3 935
Receivables and prepayments	7	6 184	5 082
Bank deposits		115 540	169 808
Current assets		121 724	174 890
TOTAL ASSETS		189 860	178 825
EQUITY			
Share capital		641	606
Share premium		314 256	268 475
Total paid-in equity		314 897	269 082
Accumulated losses		(157 890)	(102 601)
Translation differences		2 894	-
TOTAL EQUITY	6, 9	159 900	166 480
LIABILITIES			
Deferred tax	2, 11	10 981	-
Non-current liabilities		10 981	-
Accounts payable		2 978	3 033
Other current liabilities		16 000	9 312
Current liabilities	8	18 978	12 345
TOTAL LIABILITIES		29 959	12 345
TOTAL EQUITY AND LIABILITIES		189 860	178 825
			-



#### Interim condensed consolidated statement of cash flow

NOK (000) Unaudited	Q4-18	Q4-17	FY18	FY17
Loss before tax	(12 704)	(7 624)	(55 289)	(32 830)
Non-cash adjustments	-			
Depreciation and amortization	129	141	601	534
Interest received incl. investing activities	(1 246)	(312)	(1 247)	(564)
Net foreign exchange differences	48	50	10	2
Working capital adjustments:				
Changes in prepayments and other receivables	(1 029)	(943)	(1 102)	95
Changes in payables and other current liabilities	5 512	4 375	6 633	5 538
Net cash flow from operating activities	(9 290)	(4 314)	(50 395)	(27 226)
Purchase of property, plant and equipment	(88)	-	(513)	(21)
Acquisition of subsidiary	-	-	(4 586)	-
Interest received	1 246	312	1 247	564
Net cash flow used in investing activities	1 158	312	(3 851)	542
Proceeds from issuance of equity	-	125 919	-	125 919
Share issue cost	-	(2 430)	-	(2 430)
Net cash flow from financing activities	-	123 489	-	123 489
Net change in cash and cash equivalents	(8 132)	119 488	(54 246)	96 806
Effect of change in exchange rate	(62)	(50)	(22)	(2)
Cash and cash equivalents at beginning of period	123 734	50 370	169 808	73 004
Cash and cash equivalents at end of period	115 540	169 808	115 540	169 808

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

NOK (000) Unaudited	Share Capital	Share Premium	Accum. losses	Total equity
Balance at 1 January 2017	511	145 081	(69 771)	75 821
Loss for the period	-	-	(32 830)	(32 830)
Issue of ordinary shares	95	125 824	-	125 919
Share issue costs	-	(2 430)	-	(2 430)
Translation differences	-	-	-	-
Balance at 31 Dec 2017	606	268 475	(102 601)	166 480
Balance at 1 January 2018	606	268 475	(102 601)	166 480
Loss for the period	-	-	(55 289)	(55 289)
Issue of ordinary shares	35	45 781	-	45 815
Share issue costs	-	-	-	-
Translation differences			2 894	2 894
Balance at 31 Dec 2018	641	314 256	(154 996)	159 900



#### **Notes**

#### 1. General information

Ultimovacs AS (the Company or Ultimovacs) and its subsidiary (together the Group) is a pharmaceutical Group developing novel immunotherapies against cancer. The Company is a limited liability company and is privately held, mainly by Norwegian private investors/family offices.

Ultimovacs is located 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 2017 financial statements. These condensed interim financial statements should therefore be read in conjunction with the financial statements. The Group has implemented IFRS 15 *Revenue from Contracts with Customers in 2018*; however, this did not have any impact as the Group is not generating revenues.

The consolidated financial statements comprise the financial statements of the Ultimovacs AS and its newly acquired 100% owned subsidiary Ultimovacs AB as at 31 December 2018. Note that as the Group just comprised of Ultimovacs AS prior to the acquisition, historical comparative figures in this report are therefore of Ultimovacs AS only.

These interim financial statements were approved for issue by the Board of Directors on 31 January 2019.

#### Consolidation

The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases.

When the Group loses control over a subsidiary, it derecognizes the assets and liabilities of the subsidiary, and any related non-controlling interests and other components of equity. Any resulting gain or loss is recognized in profit or loss. Any interest retained in the former subsidiary is measured at fair value when control is lost. When a foreign operation is disposed of in its entirety or partially such that control, significant influence or joint control is lost, the cumulative amount in the translation reserve related to that foreign operation is reclassified to profit or loss as part of the gain



or loss on disposal. If the Group disposes of part of its interest in a subsidiary but retains control, then the relevant proportion of the cumulative amount is reattributed to non-controlling interests.

#### **Foreign Operations and currency**

The Group's interim financial statements are presented in NOK, which is the Groups's functional currency.

Transactions in foreign currencies are initially recorded by the companies in the Group in its respective functional currency spot rate at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date. Differences arising on settlement or translation of monetary items are recognized in the statement of profit and loss and other comprehensive income.

Intra-group balances and transactions, and any unrealized income and expenses arising from intra-group transactions, are eliminated. Unrealized losses are eliminated in the same way as unrealized gains, but only to the extent that there is no evidence of impairment.

The assets and liabilities of foreign operations, including goodwill and fair value adjustments arising on acquisition, are translated into NOK at the exchange rates at the reporting date. The income and expenses of foreign operations are translated into NOK at the average exchange rates within each respective month of the date of the transactions. Exchange differences on intra-group items are recognized in profit or loss of the respective company and Group accounts.

Foreign currency differences are recognized in other comprehensive income (OCI) and accumulated in the translation reserve.

#### **Business combination**

The Group accounts for business combinations using the acquisition method when control is transferred to the Group. The consideration transferred in the acquisition is generally measured at fair value, as are the identifiable net assets acquired. Any goodwill that arises is tested annually for impairment. Any gain on a bargain purchase is recognized in profit or loss immediately. Transaction costs are expensed as incurred, except if related to the issue of debt or equity securities.

At each reporting date, the Group reviews the carrying amounts of its non-financial assets to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated.

Goodwill is tested annually for impairment, as well as when there is any indication that the goodwill may be impaired. For impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or cash generating units (CGU). Goodwill arising from a business combination is allocated to CGUs or groups of CGUs that are expected to benefit from the synergies of the combination. An impairment loss is recognized in the income statement when the carrying amount



of CGU, including the goodwill, exceeds the recoverable amount of the CGU. Recoverable amount of the CGU is the higher of the CGU's fair value less cost to sell and value in use.

#### **Intangible assets**

Intangible assets are reviewed for impairment whenever there is any indication that these assets may be impaired. If any such indication exists, the recoverable amount (i.e. the higher of the fair value less cost to sell and value in use) of the asset is estimated to determine the amount of impairment loss.

For the purpose of impairment testing of these assets, recoverable amount is determined on an individual asset basis unless the asset does not generate cash flows that are largely independent of those from other assets. If this is the case, recoverable amount is determined for the CGU to which the asset belongs to.

#### **Deferred tax**

Deferred tax liabilities are recognized on taxable temporary differences arising on investments in subsidiaries.

#### **IFRS 16 Leases**

The Group has analyzed the potential impact of implementing IFRS 16 Leases. The standard will require the Group to recognize a liability to make lease payment (lease liability) and an asset representing the right to use the underlying assets during the lease term (the right-of-use asset) and separately recognize the interest expense on the lease liability and the depreciation expense of the right-to-use asset. As lessee the Group can chose to apply the standard either using a full retrospective or a modified retrospective approach and this is currently being evaluated by the Group. The Group does currently not expect that the new standard will significantly impact the Group's Statement of profit and loss and other comprehensive income or statement of financial position, but will require more extensive note disclosures. The newly acquired subsidiary Ultimovacs AB will not be affected by the implementation of this standard as the company has no material long term contracts.



#### 3. Personnel expenses

#### **Personnel expenses**

NOK (000)	Q4-18	Q4-17	FY18	FY17
Salaries and bonuses	5 511	3 718	18 751	13 396
Social security tax	856	593	2 904	2 139
Pension expenses	439	240	1 448	899
Share-based compensation	1 867	1 059	5 416	3 199
Other personnel expenses	181	49	415	138
Government grants	(1 718)	(1 349)	(1 860)	(1 613)
Total personnel expenses	7 137	4 310	27 074	18 158
Number of FTEs at end of period	14	10	14	10

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

Note that the remuneration to the Board of Directors have historically been paid and fully recognized in the P&L in March/April each year, including FY18. From FY18, the remuneration to the Board for FY19 has in addition been accrued monthly from April in order to distribute this cost more correctly throughout the year. Remuneration to the Board of Directors will therefore be higher in FY18 compared to prior years as both the remuneration payment in March (MNOK 1.1) and monthly accrual for the payment in FY19 (totaling MNOK 1.1) have been recognized in the P&L. The remuneration to the Board is included in Salaries and bonuses.

#### 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)	Q4-18	Q4-17	FY18	FY17
External R&D expenses	4 516	4 964	16 957	12 829
Clinical studies	2 273	2 235	7 876	3 826
Manufacturing costs	1 500	2 803	6 793	8 329
Other R&D expenses	743	(74)	2 289	674
Rent, office and infrastructure	800	446	2 729	1 856
IP expenses	571	378	2 444	1 240
Accounting, audit, legal, consulting	2 277	198	6 654	397
Other operating expenses	1 615	731	4 000	2 589
Government grants	(3 573)	(3 281)	(3 927)	(4 212)
Total operating expenses	6 205	3 436	28 857	14 700



#### 5. Government grants

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

#### **Government grants**

NOK (000)	Q4-18	Q4-17	FY18	FY17
Skattefunn from The Research Council of Norway	4 946	4 182	4 946	4 182
BIA grants from The Research Council of Norway	-	47	496	1 243
Innovation Norway	-	400	-	400
Eurostars	285	-	285	-
Other grants	60	-	60	-
Total government grants	5 291	4 629	5 787	5 825

Refer to note 3 and 4 for information regarding the reduction-amount the government grants has on 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)	Q4-18	Q4-17	FY18	FY17
Loss for the period	(12 704)	(7 624)	(55 289)	(32 830)
Average number of share during the period	640 816	574 410	623 488	526 786
Earnings/loss per share (NOK)	(20)	(13)	(89)	(62)

As the Company has currently no issuable ordinary shares, diluted and basic (undiluted) earnings per share is the same.

#### 7. Current assets

#### **Receivables and prepayments**

NOK (000)	31 Dec 2018	31 Dec 2017
Government grants	5 231	4 229
Prepayments	595	421
Other receivables	357	431
Total receivables and prepayments	6 184	5 082



#### 8. Current liabilities

#### **Current liabilities**

NOK (000)	31 Dec 2018	31 Dec 2017
Accounts payable	2 978	3 033
Public duties payable	1 712	1 347
Share-based compensation liability	10 207	4 791
Other current liabilities	4 082	3 173
Total current liabilities	18 978	12 345

#### 9. Shareholder information

The share capital as at 31 December 2018 was NOK 640.816, all as ordinary shares with equal voting rights and a nominal value of NOK 1. The acquisition of TET Pharma AB in July 2018 was paid partly in newly issued shares, where the number of shares increased from 606.160 pre-transaction to 640.816.

Ultimovacs AS had 41 shareholders as at 31 December 2018, and the 20 largest shareholders are listed below:

#### **Share register**

	# of	
Shareholder	shares	Share-%
Gjelsten Holding AS	195 418	30,5%
Inven2 AS	80 871	12,6%
Canica AS	55 886	8,7%
Radiumhospitalets Forskningsstiftelse	55 835	8,7%
Langøya Invest AS	36 253	5,7%
Imuneed AB	34 656	5,4%
Watrium AS	32 837	5,1%
Sundt AS	24 686	3,9%
Prieta AS	19 407	3,0%
CGS Holding AS	14 575	2,3%
Helene Sundt AS	14 575	2,3%
Wiarom AS	10 000	1,6%
Annemvax AS	9 876	1,5%
Holmetjern Invest AS	9 142	1,4%
Månebakken AS	7 560	1,2%
Vitmed AS	6 400	1,0%
K-TO AS	4 767	0,7%
Asteroidebakken AS	3 780	0,6%
Aeolus AS	3 500	0,5%
Jakob Hatteland Holding AS	2 500	0,4%
20 Largest shareholders	622 524	97,1%
Other shareholders (21)	18 292	2,9%
Total	640 816	100,0%



#### 10. Shared-based payments

At the Annual General Meeting in April 2016 the Board was authorized to introduce a new incentive scheme for employees (Phantom stock plan), based on the value development of the Company's shares. All employees have been granted a certain number of phantom shares, which are not physically held by the owner. Employees are entitled, upon exercise, to receive a cash amount corresponding to the increase in the value of the underlying share in the period from the option was assigned to the exercise. According to the agreement, the Board of Directors of the Company may, at its discretion and subject to applicable authorizations from the general meeting, elect to settle any compensation-amounts payable in shares rather than cash payments. The Board of Directors has made a decision to propose to the General Assembly a new option program to be initiated as soon as the Company is listed on the Stock Exchange. The intention of the Board is to settle in cash and terminate the Phantom stock plan simultaneously. The compensation scheme has therefore been treated as a cash-settled share-based payment.

Due to the planned listing on the Oslo Stock exchange in H1-19, the compensation is expected to be settled in cash to the phantom-shareholders shortly after the listing, and the compensation-liability is therefore classified as a short-term liability in the interim condensed statement of financial position.

The fair value of the phantom shares are based on a Black Scholes model, with an exercise price for all allocated and non-allocated phantom shares of NOK 1.133, vesting period until 31 March 2019, a volatility of 60-70%, risk free rate of 1.1% and an estimated share price based on the latest shares issues with an increase based on estimated share price at the time of the IPO.

#### 11. Business combinations and intangible assets

#### **Acquisition of Tet Pharma AB**

On 11 July 2018, Ultimovacs AS completed the acquisition of Tet Pharma AB, the immunotherapy technology business of Immuneed AB. The acquired business is now established as a fully-owned Swedish subsidiary of Ultimovacs, based in Uppsala, Sweden, and has been renamed to Ultimovacs AB.

Based on an exclusive license agreement with the Leiden University Medical Centre, Immuneed has developed the proprietary and patent-protected Tetanus-Epitope Targeting-platform (the 'TET-platform') that Ultimovacs believes can attractively complement the vaccine technology of Ultimovacs. Ultimovacs considers the TET-platform technology as a promising and general strategy to strengthen and increase T cell responses against cancer peptides.

In parallel with the continued development of the therapeutic cancer vaccine UV1, Ultimovacs will therefore pursue the development of a new first-in-class cancer vaccine solution based on the proprietary TET-platform technology.

Following the acquisition of the business from Immuneed AB, Ultimovacs AB currently has two employees, bringing the total number of employees in Ultimovacs Group by the end of 2018 to 16 (totaling 14 FTEs).

Ultimovacs AB is consolidated into Ultimovacs' consolidated financial statements from 11 July 2018. From 11 July to 31 December 2018, Ultimovacs AB had no revenues, and a negative loss before tax for



the period of MNOK 2.2. The company had not revenues or costs prior to the acquisition on 11 July 2018.

Total transactions costs related to the acquisition amounts to MNOK 2.6.

The purchase price was partly paid in cash and partly in shares in Ultimovacs AS. SEK 5,000,000 (corresponding to NOK 4,631,500) was paid in cash. Additionally, Ultimovacs AS issued 34,656 new shares to Immuneed AB. In the previous share issue in Ultimovacs AS (October 2017), the subscription price per share was NOK 1,322. Based on this valuation, the value of the newly issued shares corresponds to NOK 45,815,232, bringing the total purchase price to NOK 50,446,732. Based on the preliminary purchase price allocation (PPA), the gross purchase price is tNOK 50,447. Book value of the equity is tNOK 46, which gives an excess value of tNOK 50,401. All the excess value identified in the PPA process has been allocated to the patented TET-technology which is available through an exclusive license, classified as an intangible asset in the balance sheet. The intangible asset will be tested for impairment loss whenever circumstances indicate that an intangible asset's carrying amount may not be recoverable, or at least once a year. When it is assessed that the probability of expected future economic benefits using reasonable and supportable assumptions, amortization of the intangible asset shall begin by the straight-line method over the estimated useful life of the asset.

Deferred taxes of tNOK 10,383 have been calculated on the excess values utilizing the tax rate in Sweden of 20.6%. Goodwill related to the step up of deferred tax amounts to tNOK 10,383. The goodwill comprises the value of expected synergies arising from the acquisition, assembled workforce and deferred tax on excess values.

The valuation date for the preliminary purchase price allocation is 11 July 2018, which also is the date of the transaction. The PPA is preliminary, as we have not yet obtained all of the information related to the fair value of the acquired assets and liabilities related to the acquisition to finalize the purchase price allocation. Accordingly, these preliminary estimates may be subject to change during the measurement period, which is up to one year from the acquisition date. The preliminary purchase price allocation has identified the following fair values of identifiable assets and liabilities in Ultimovacs AB as at the date of the acquisition:

(000)	SEK	NOK
Goodwill related to step up/deferred tax	11 320	10 383
Intangible asset (licensed technology)	54 950	50 401
Total non-current assets	66 270	60 783
Cash and cash equivalents	50	46
Total current assets	50	46
TOTAL ASSETS	66 320	60 829
Deferred tax	(11 320)	(10 383)
TOTAL LIABILITIES	(11 320)	(10 383)
TOTAL CONSIDERATION (PURCHASE PRICE)	55 000	50 447

Note that the SEK-amounts in the above table have been converted to NOK using the currency rate as at the valuation date (transaction date), while the amounts in the balance sheet are converted with the exchange rate per reporting date. The amounts in the above table will therefore not reconcile with the balance sheet. The difference is reported as other comprehensive income (loss) in the P&L.



#### 12. IFRS 16 – rental contracts

The only significant agreement classified as operating lease is the rental agreement for office and lab premises in Oslo. The net present value of future minimum rents related to non-cancellable leases for these premises is estimated to be MNOK 3.8 as per 31 December 2018. If IFRS 16 had been implemented before 1 January 2019, this amount would have been capitalized as a liability and asset in the balance sheet. If IFRS 16 had been implemented in FY18, the effects on the P&L would have been immaterial, as depreciation and interest cost would have been approximately the same amount as total the rental costs recognized in FY18. IFRS 16 is effective for annual periods beginning 1 January 2019.

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

No significant events 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. PD1 / PDL1 inhibitors (Keytruda and Opdivo) and CTLA4
	inhibitors (Yervoy – ipilimumab) are examples of Checkpoint inhibitors.
	There are many others in development.
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 CTLA4 to bind
	to B7. Ipilimumab (Ipi/Yervoy) was the first checkpoint inhibitor to reach
DD 1 / DD 11	the market.
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.
Checkpoint inhibitors	
Yervoy (Ipilimumab)	Anti-CTLA-4 checkpoint inhibitor from BMS (Bristol-Myers Squibb)
Opdivo (Nivolumab)	Anti-PD-1 checkpoint inhibitor from BMS (Bristol-Myers Squibb)
Keytruda (Pembrolizumab)	Anti-PD-1 checkpoint inhibitor from Merck
Tecentriq (Atezolizumab)	Anti-PD-L1 checkpoint inhibitor from Roche
Bavencio (Avelumab)	Anti-PD-L1 checkpoint inhibitor from Merck (Germany)/Pfizer/Eli Lilly
Imfinzi (Durvalumab)	Anti-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	
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.)	
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 amount of immune cells, mainly dermal dendritic cells.  Epidermis  Dermis  Subcutaneous-tissue	
Biopsy	A piece of tissue, normal or pathological removed from the body for the purpose of examination.	
lgE	Immunoglobulin E (IgE) are antibodies produced by the immune system. If you have an allergy, your immune system overreacts to an allergen (what you are allergic to) by producing IgE. These antibodies travel to cells that release chemicals, causing an allergic reaction when an allergen enters 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
	6. requires intervention to prevent permanent impairment or damage.
	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	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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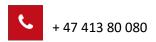
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### **About Ultimovacs**

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 and the USA.

Ultimovacs was established in 2011. The company and its proprietary technology is based on preclinical and clinical research on immunotherapies conducted at the Oslo University Hospital. The company is privately held, mainly by Norwegian private investors/family offices.

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.

