



***Activating the immune system to fight cancer***

***Fourth quarter 2019 presentation***

*14 February 2020*

*Øyvind Kongstun Arnesen, CEO  
Jens Bjørheim, CMO  
Hans Vassgård Eid, CFO*

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# Significant expansion of the UV1 development program in Q4 2019

## The INITIUM trial is progressing according to plan

- ▶ Randomized phase II trial in malignant melanoma
- ▶ 154 patients
- ▶ First patient expected Q1 2020

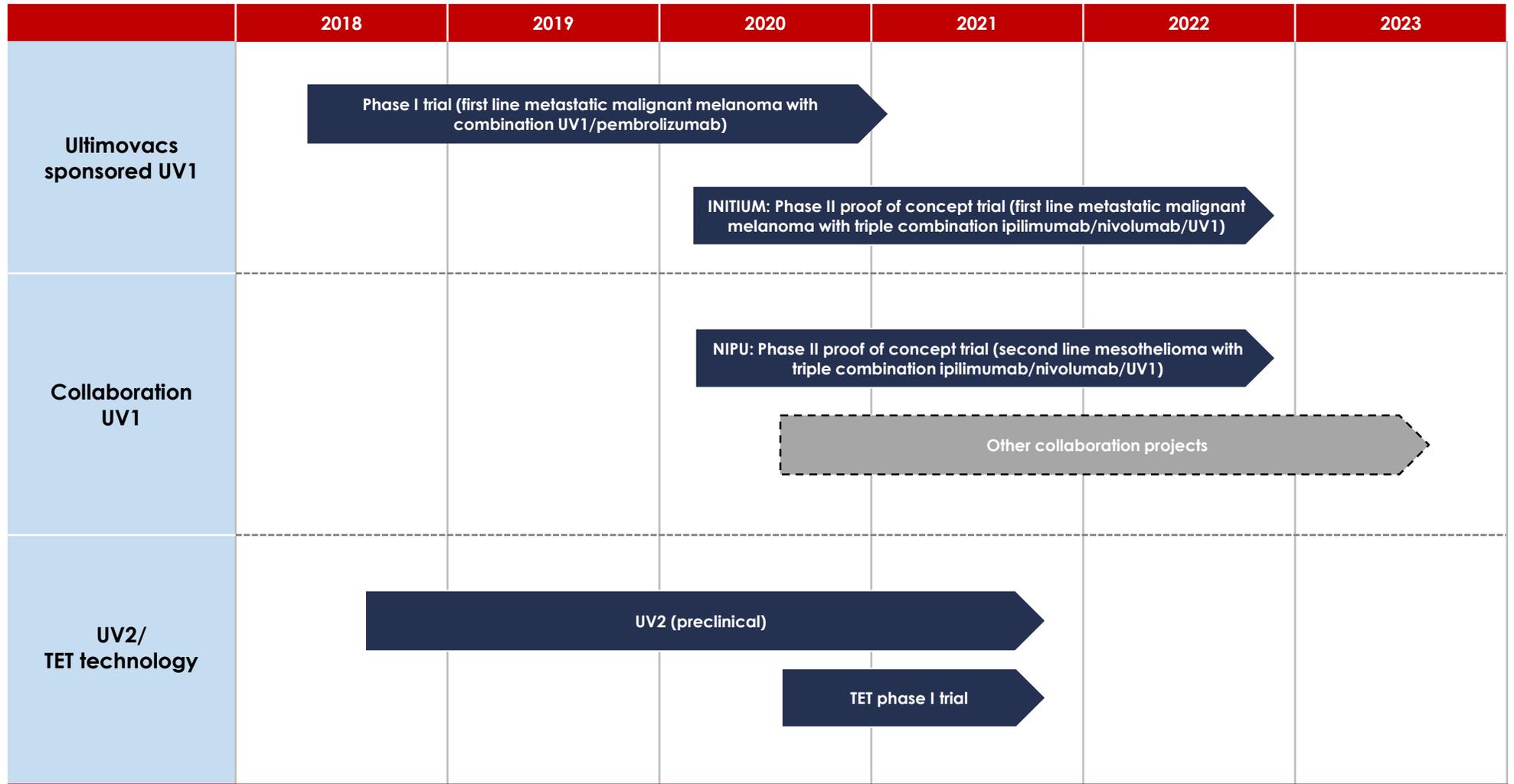
## UV1 will also be tested in the NIPU trial

- ▶ Randomized phase II trial in mesothelioma
- ▶ 118 patients
- ▶ Sponsored by Oslo University Hospital and supported by Ultimovacs and Bristol-Myers Squibb (BMS)
- ▶ First patient expected Q1 2020

## Major expansion of the UV1 development program achieved

- ▶ Two large randomized, fully funded phase II trials in different cancer types.
- ▶ 272 patients in total.
- ▶ Will enhance opportunities for successful clinical results and support that UV1 may be broadly applicable across cancer types.

# Ultimovacs – Development Plan



# Highlights – Q4 2019: Clinical trial update

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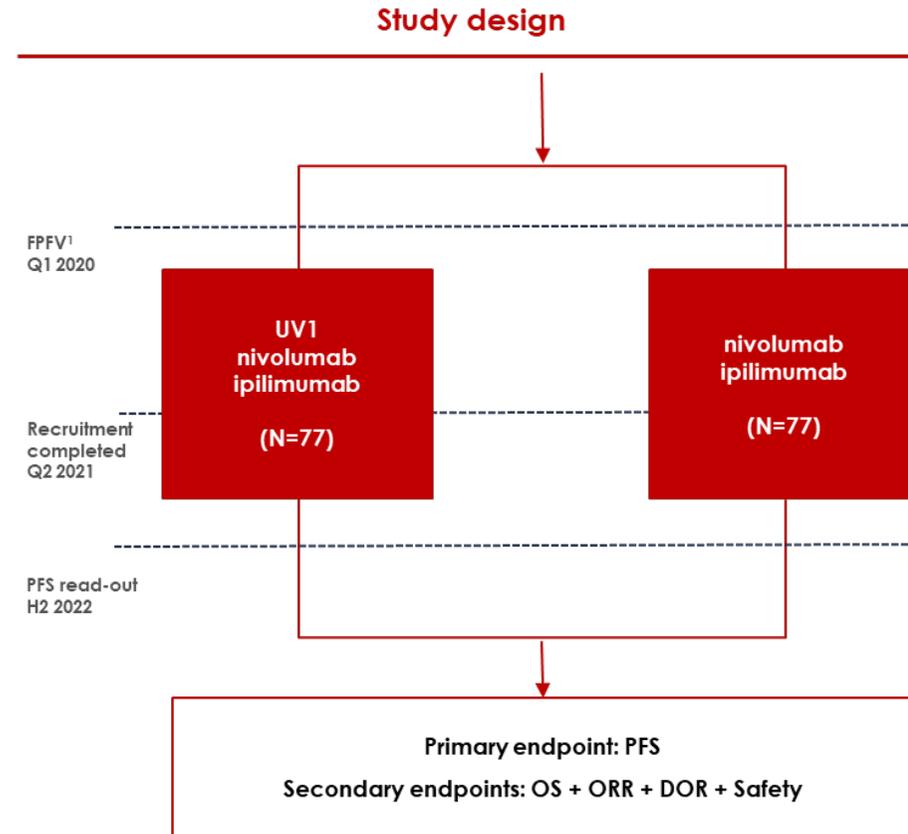
## Ongoing US based phase I trial study in malignant melanoma

- ▶ UV1 is given in combination with the PD-1 checkpoint inhibitor pembrolizumab
- ▶ All 20 of the initially planned patients have been successfully included (**cohort 1 – safety pembrolizumab/UV1**)
  - ▶ No unexpected safety issues related to UV1 have been observed to date
  - ▶ 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
  - ▶ 3 of these 10 additional patients have been enrolled to date – the remaining patients are expected to be fully enrolled during 2020
  - ▶ 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

# Highlights – Q4 2019: Clinical trial update (cont.)

## The INITIUM trial (randomized phase II trial in malignant melanoma)

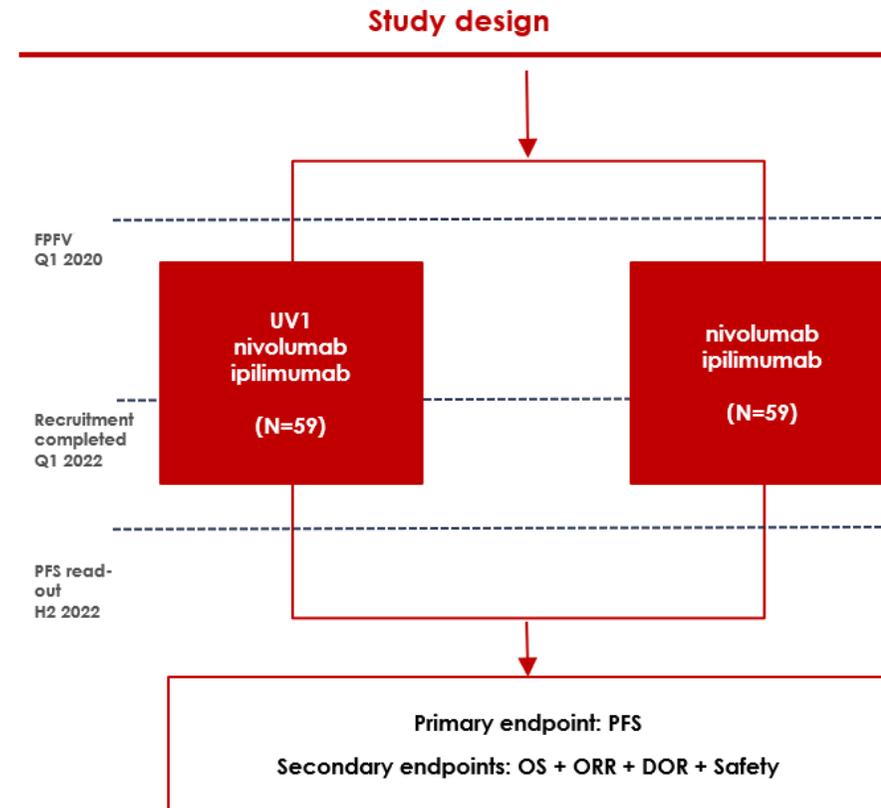
- ▶ UV1 will be given in combination with the CTLA-4 checkpoint inhibitor ipilimumab and the PD-1 checkpoint inhibitor nivolumab
- ▶ 154 patients, first patient expected Q1 2020
- ▶ The trial will be run in the US and Europe (including Norway)
- ▶ Independent Data Monitoring Committee (IDMC) established
  - Jeffrey Weber (NYU Langone Health, NY, USA)
  - James Larkin (Royal Marsden, London, England)
  - Caroline Robert (Gustave Roussy Cancer Campus, Grand Paris, France)
  - Kevin Carroll (KJC Statistics Ltd)



# Highlights – Q4 2019: Clinical trial update (cont.)

## The NIPU trial (randomized phase II trial in malignant pleural mesothelioma)

- ▶ UV1 will be given in combination with the CTLA-4 checkpoint inhibitor ipilimumab and the PD-1 checkpoint inhibitor nivolumab
- ▶ 118 patients, first patient expected Q1 2020
- ▶ The trial will be run in the Scandinavian countries and Australia
- ▶ Malignant pleural mesothelioma (MPM) is heavily linked to asbestos exposure (up to 10-50 years prior to symptoms)
- ▶ MPM is the most common type of mesothelioma with a high unmet medical need. mOS is appr. 1 year
- ▶ 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



# Highlights – Q4 2019: Results from the completed trials – in follow-up phase

Clinical trial	Overall Survival (OS) <sup>1</sup>					Median OS (months)	mPFS <sup>2</sup> (months)
	Year 1	Year 2	Year 3	Year 4	Year 5		
Prostate (n=22)	95 %	86 %	73 %	55 %	50 %	Will be more than 60 months	n.a. <sup>3</sup>
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	6.7 <sup>4</sup>

- Note that some patients have received other treatments upon progression and this is likely to affect survival
- Median Progression-Free Survival
- 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 (Prostate-specific antigen) levels.
- mPFS updated after database revision (previously reported as 6.5 months)

▶ Most recent overall survival data:

- ▶ Prostate cancer – 5 years – publication in progress
- ▶ NSCLC – 4 years – presented at SITC November 2019
- ▶ Malignant melanoma – 4 years – presented at ASCO-SITC February 2020

# Highlights – Q4 2019: Results from the completed trials – in follow-up phase (cont.)

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- ▶ Malignant melanoma – 4 years – presented at ASCO-SITC February 2020
  - ▶ UV1 given in combination with ipilimumab, 12 patients
  - ▶ Treatment was generally well-tolerated
  - ▶ Immune responses occurred very early and 10/11 (91%) showed an immune response
  - ▶ ORR (objective response rate) of 44% based on 9 evaluable patients: One CR (complete response) and three PR (partial responses)
  - ▶ Median progression free survival (mPFS) was 6.7 months
  - ▶ Overall survival at 3 and 4 years was 67% and 50%, respectively
    - ▶ The results compare favorably to the ipilimumab monotherapy phase IV study at the Oslo University Hospital (the 'IPI4 study') which had 4-year overall survival of 27.5%
    - ▶ 69 patients in the IPI4 study, same investigators, same time period, similar inclusion criteria

## CEO's corner in the Q4 2019 report: 'UV1 – a Universal cancer vaccine'

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- ▶ Being Universal
- ▶ Easy to combine with other immunotherapies
- ▶ Simple to manufacture and use
- ▶ Can be developed to prevent cancer

# Key financials

## Key financials per Q4-2019 - Ultimovacs Group

NOK (000)	Q4-18	Q4-19	FY18	FY19
<b>Total revenues</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Payroll and payroll related expenses	7 141	8 686	27 078	20 160
External R&D and IPR expenses (incl. grants)	1 514	16 598	15 474	32 938
Other operating expenses (incl. depreciation)	4 808	2 550	13 971	13 119
<b>Total operating expenses</b>	<b>13 463</b>	<b>27 833</b>	<b>56 522</b>	<b>66 217</b>
<b>Operating profit (loss)</b>	<b>-13 463</b>	<b>-27 833</b>	<b>-56 522</b>	<b>-66 217</b>
Net financial items	768	2 470	1 243	5 051
<b>Profit (loss) before tax</b>	<b>-12 694</b>	<b>-25 363</b>	<b>-55 280</b>	<b>-61 166</b>
				0
Net increase/(decrease) in cash and cash eq.	-8 126	-12 440	-54 240	284 332
<b>Cash and cash equivalents at end of period</b>	<b>115 540</b>	<b>399 607</b>	<b>115 540</b>	<b>399 607</b>
Number of FTEs at end of period	14	17	14	17

### Cash

- ▶ FY19 includes increase in cash from share issue/IPO (net MNOK 344.6). Without this element, net decrease in cash would have been MNOK 60.1

### Comments:

#### Payroll expenses

- ▶ Higher cost in Q4-19 than Q3-18 due to 3 more FTEs
- ▶ Lower costs in FY19 compared to FY18 primarily due to the MNOK 10.2 reversal of share-based payment liability in FY19

#### External R&D and IPR expenses

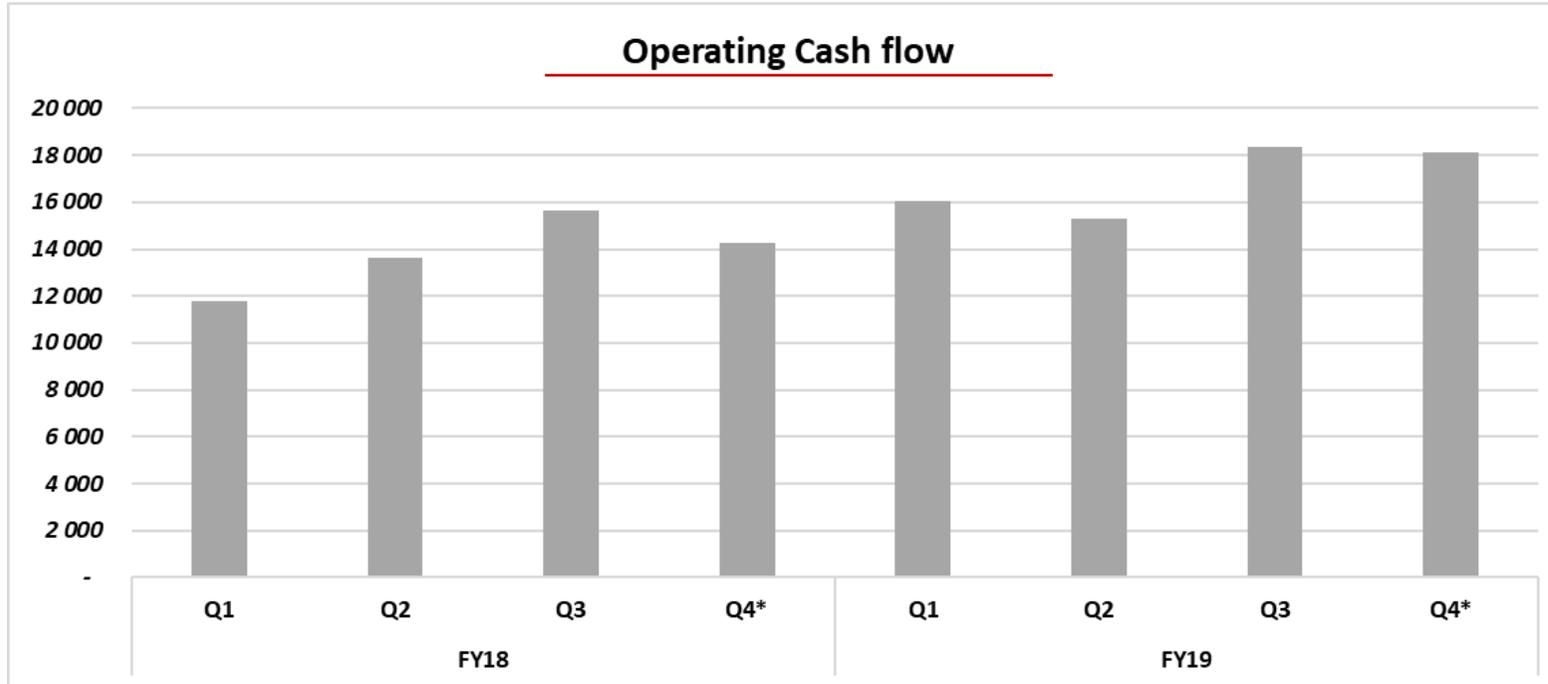
- ▶ Higher costs in Q4/FY19 due to more patients in the ongoing trial, high CMC activity and other R&D

#### Other operating expenses

- ▶ Higher costs in Q4-18 than Q4-19 due to IPO preparations

# Key financials – operating cash flow

NOK (000)



\* Each of Q4-18/19 are adjusted (increased) with MNOK 5 due to exclude the receipt of public grants from Skattefunn. No other adjustments made.

## Comments:

- ▶ Relatively stable operating cash flow per quarter, primarily affected by R&D activities
- ▶ Increase of personnel expenses during this period due to number of FTEs going from 10 to 17
- ▶ Operating cash outflows expected to increase significantly during FY20 with the commencement of planned projects/activities
- ▶ Cash flow related to the IPO is not included in operating cash-flow

# Key financials – quarterly overview

## Key financials per Q4-2019 - Ultimovacs Group

NOK (000)	Q1-18	Q2-18	Q3-18	Q4-18	Q1-19	Q2-19	Q3-19	Q4-19	FY18	FY19
<b>Total revenues</b>	<b>0</b>									
Payroll and payroll related expenses	6 355	4 128	9 454	7 141	7 538	-4 717	8 653	8 686	27 078	20 160
External R&D and IPR expenses (incl. grants)	2 453	6 943	4 564	1 514	4 665	4 909	6 766	16 598	15 474	32 938
Other operating expenses (incl. depreciation)	2 158	3 837	3 168	4 808	2 766	3 905	3 898	2 550	13 971	13 119
<b>Total operating expenses</b>	<b>10 967</b>	<b>14 908</b>	<b>17 185</b>	<b>13 463</b>	<b>14 970</b>	<b>4 096</b>	<b>19 317</b>	<b>27 833</b>	<b>56 522</b>	<b>66 217</b>
<b>Operating profit (loss)</b>	<b>-10 967</b>	<b>-14 908</b>	<b>-17 185</b>	<b>-13 463</b>	<b>-14 970</b>	<b>-4 096</b>	<b>-19 317</b>	<b>-27 833</b>	<b>-56 522</b>	<b>-66 217</b>
Net financial items	47	143	284	768	247	252	2 082	2 470	1 243	5 051
<b>Profit (loss) before tax</b>	<b>-10 919</b>	<b>-14 765</b>	<b>-16 901</b>	<b>-12 694</b>	<b>-14 723</b>	<b>-3 844</b>	<b>-17 235</b>	<b>-25 363</b>	<b>-55 280</b>	<b>-61 166</b>
Net increase/(decrease) in cash and cash eq.	-12 096	-13 648	-20 370	-8 126	-16 110	346 740	-33 858	-12 440	-54 240	284 332
<b>Cash and cash equivalents at end of period</b>	<b>157 760</b>	<b>144 144</b>	<b>123 734</b>	<b>115 540</b>	<b>99 352</b>	<b>446 041</b>	<b>412 025</b>	<b>399 607</b>	<b>115 540</b>	<b>399 607</b>
Number of FTEs at end of period	10	11	14	14	16	17	17	17	14	17

# For questions

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**Øyvind Kongstun Arnesen, CEO**

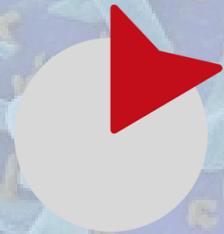
E-mail: [oyvind.arnesen@ultimovacs.com](mailto:oyvind.arnesen@ultimovacs.com)

Phone: +47 469 33810

**Hans Vassgård Eid, CFO**

E-mail: [hans.eid@ultimovacs.com](mailto:hans.eid@ultimovacs.com)

Phone: +47 469 19822



**ultimovacs**

**Q&A**