



# ultimovacs

**Activating the immune system to fight cancer**

**Third quarter 2020 presentation**

12 November 2020

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## Highlights Q3 2020

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- ▶ The Phase II INITIUM trial (metastatic malignant melanoma): **twelve** patients enrolled (vs. three after Q2 2020)
- ▶ The Phase II NIPU trial (mesothelioma): **six** patients enrolled (vs. four after Q2 2020)
- ▶ The Covid-19 pandemic has so far had limited impact regarding site openings and patient inclusion. The longer-term effect on the biotech industry and the general ability to conduct clinical trials is still uncertain.

## Highlights Q3 2020 (cont.)

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- ▶ Positive signals of clinical efficacy in two Phase I trials:
  - ▶ In the fully enrolled US-based Phase I trial in malignant melanoma where UV1 is combined with pembrolizumab, 12-month overall survival (OS) in the first cohort of 20 patients was announced in September 2020
  - ▶ Five-year overall survival data from the Phase I trial evaluating UV1 as maintenance therapy in patients with non-small cell lung cancer was reported in October 2020
- ▶ The observed safety profile of UV1 continues to be favorable across all trials

## Highlights Q3 2020 (cont.)

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- ▶ A third Phase II clinical trial was announced in May 2020:
  - ▶ Collaboration with a non-specified large pharma company and a leading European oncology clinical trial group
  - ▶ UV1 will be evaluated in a new indication and a new combination
  - ▶ Finalization of the agreement and announcement of the collaboration is expected to be disclosed in Q4 2020
- ▶ The regulatory approval is now in place to start the Phase I TENDU trial. This trial will investigate a prostate cancer specific vaccine based on the TET technology. First patient is expected in Q1 2021

# Broad Development Pipeline

Platform / candidate	Indication	Clinical trial information	Preclinical	Phase I	Phase II	Phase III	Partner / Collaboration
UV1	Prostate	Conducted at OUS, 22 patients. Completed in 2015					
	Non-small cell lung cancer (NSCLC)	Conducted at OUS, 18 patients. Completed in 2016					
	Metastatic malignant melanoma	Conducted at OUS, 12 patients. UV1 in combination with Ipilimumab. Completed in 2016					
	Metastatic malignant melanoma	First line phase I trial with combination UV1/pembrolizumab). 30 patients, enrolment completed in Aug-20					
	Metastatic malignant melanoma	<b>INITIUM:</b> Phase II proof of concept trial (first line metastatic malignant melanoma with triple combination ipilimumab/nivolumab/UV1) 154 patients					
	Mesothelioma	<b>NIPU:</b> Phase II proof of concept trial (second line mesothelioma with triple combination ipilimumab/nivolumab/UV1) 118 patients					Bristol Myers Squibb and Oslo University Hospital (OUS)
	Undisclosed	Phase II trial – new combination in new indication					To be disclosed
TET	Prostate	<b>Project TENDU:</b> phase I study to assess the safety of the TET platform.					
	Various	First-in-class cancer vaccine solutions based on the TET-platform technology					

Completed

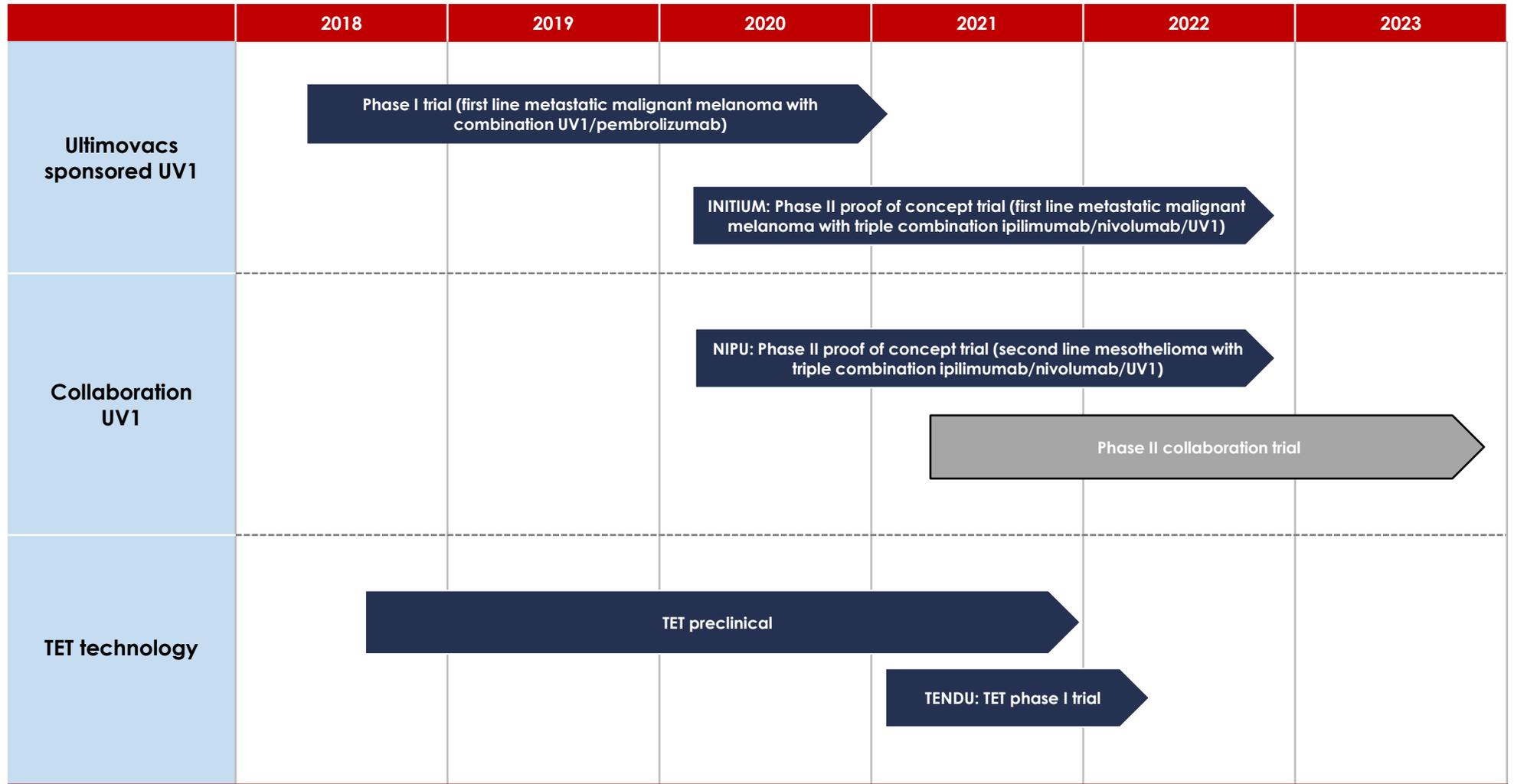
Ongoing

## A third Phase II clinical trial – non-disclosed indication

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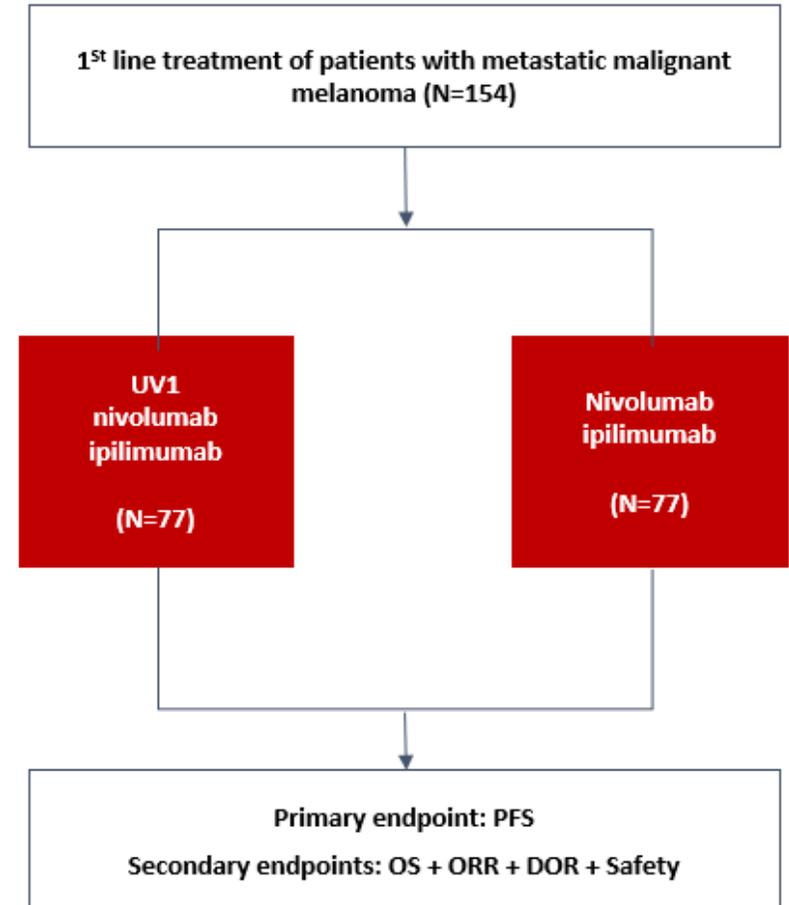
- ▶ In May 2020, Ultimovacs announced the collaboration with a leading large pharma company and a European oncology clinical trial group to evaluate the Company's universal cancer vaccine, UV1, in an additional randomized, multi-center Phase II clinical trial.
- ▶ This third Phase II clinical trial will evaluate UV1 in a new cancer indication in combination with indication-specific standard of care cancer therapies different from those to be tested in the INITIUM and NIPU trials.
- ▶ In the collaboration, Ultimovacs will supply UV1 and the large pharma company will supply its proprietary cancer treatment to the clinical trial group which will sponsor the trial.
- ▶ **Finalization of the agreement and announcement of the collaboration is expected to be disclosed in Q4 2020**
- ▶ **The first patient is expected to be enrolled in the study during 1H 2021 with the read-out of primary endpoints anticipated during 2023**

# Ultimovacs – Extensive Development Plan



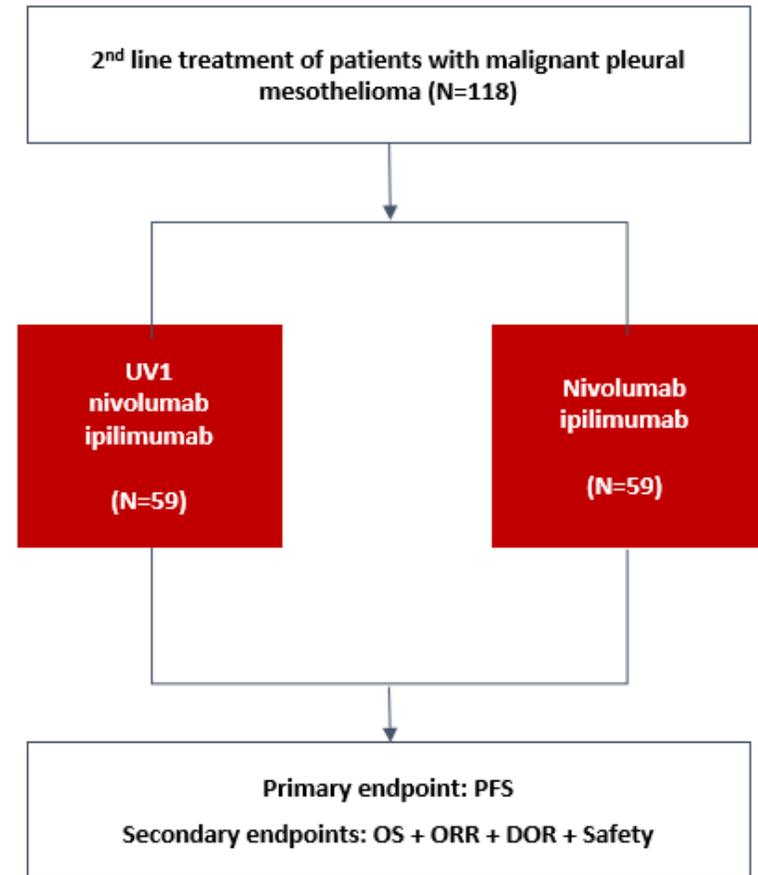
# The INITIUM trial (randomized phase II trial in malignant melanoma)

- ▶ UV1 will be given in combination with the CTLA-4 checkpoint inhibitor ipilimumab and the PD-1 checkpoint inhibitor nivolumab
- ▶ 154 patients in total
- ▶ The trial will be run in the US and Europe (including Norway)
- ▶ Appr. 40 sites (hospitals)
- ▶ Sites are opened both in Europe and the US and further sites are continuously being opened
- ▶ **Twelve patients enrolled as of 11 November 2020** (vs. three after Q2 2020)



# 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 in total
- ▶ Lead investigator is Dr. Åslaug Helland at Oslo University Hospital, Norway
- ▶ The trial will be run at 7 sites (hospitals) in the Scandinavian countries, Spain and Australia.
- ▶ Until now, recruitment has only taken place in Norway – three other countries are opening for recruitment now
- ▶ **Six patients enrolled as of 11 November 2020** (vs. four after Q2 2020)



# Ongoing US based phase I trial study in malignant melanoma

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- ▶ UV1 is given in combination with the PD-1 checkpoint inhibitor pembrolizumab
- ▶ The trial is fully enrolled (as previously reported)
- ▶ Positive topline results from the first cohort of 20 patients
  - ▶ **12-months overall survival (OS) rate of 85%**
  - ▶ **Median Progression-Free Survival (mPFS) not reached at 12 months**
  - ▶ An appropriate historical comparison demonstrated a 68% OS and a mPFS of 11.6 months (results from the cohort in the KEYNOTE006 trial in which patients with advanced melanoma without prior treatment history were treated with pembrolizumab only)
- ▶ During Q3 2021, all patients in cohort 1 will have 2-years observation time and all patients in cohort 2 will have 1-year observation time.
- ▶ No unexpected safety issues related to UV1 have been observed to date

# Results from the completed trials in follow-up phase – Five-year overall survival data from the Phase I trial NSCLC

Clinical trial <sup>4</sup>	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 %	61.8	n.a. <sup>3</sup>
NSCLC (n=18)	72 %	50 %	44 %	39 %	33 %	28.2	10.7
Malignant Melanoma (n=12)	75 %	75 %	67 %	50 %	Q1-21	Will be more than 48 months	6.7

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

## Most recent update on overall survival data:

► **5-year overall survival (OS) of 33% in the NSCLC trial**

► How is this compared to historical controls? At the time the study was conducted, no checkpoint inhibitors were available. Patients that had received two or more lines of chemotherapy had an expected survival rate of less than 5%

## **TENDU Phase I clinical trial**

- ▶ The regulatory approval is now in place to start the Phase I TENDU trial. This trial will investigate a prostate cancer specific vaccine based on the TET technology. First patient is expected in Q1 2021
- ▶ The TENDU trial will be conducted at Oslo University Hospital
- ▶ 9-12 patients will be enrolled
- ▶ This Phase I trial will provide valuable safety information toward the further development of new vaccine solutions based on the TET technology

## **Development of new vaccines based on the TET technology platform**

- ▶ Pending confirmation of the safety of the TET technology and results from ongoing and further pre-clinical development of the TET platform, the ambition is to identify new cancer vaccine candidates to move into clinical development
- ▶ Ultimovacs is in the process of developing an improved manufacturing process for vaccines based on the TET core molecule which will enable new vaccine candidates to move into clinical development
- ▶ The TENDU project provides us an opportunity to do early testing of the safety and immune activation of the TET technology while we continue to optimize the core TET molecule and production process
- ▶ The outcome of all these activities will support the decision of which drug candidates to move into clinical development in the future

## Financial position

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- ▶ Total cash end of Q3 2020 amounted to MNOK 453.5
- ▶ As expected, the negative cash-flow from operations has increased significantly in YTD-20, due to the ramp-up of the R&D activities with the initiation the Phase II trials
- ▶ However, the increase in R&D costs in Q3/H2 2020 is lower than previously guided due to slight delays of initial costs in clinical trials
- ▶ A further increase in R&D costs should be expected in the next quarters with the increase in patient inclusion in ongoing studies and start-up of the new Phase II trial and the TENDU Phase I trial
- ▶ Based on current development plan and timeline, the existing funding is expected to last through the read-out of primary endpoints in the Phase II trials in 2022 and 2023

# Key financials

## Key financials per Q3-2020 - Ultimovacs Group

NOK (000)	Q3-19	Q3-20	YTD-19	YTD-20	FY19
<b>Total revenues</b>	0	0	0	0	0
Payroll and payroll related expenses	8 653	13 115	11 474	36 327	20 160
External R&D and IPR expenses (incl. grants)	6 766	15 307	16 341	53 334	32 938
Other operating expenses (incl. depreciation)	3 898	2 695	10 569	8 897	13 119
<b>Total operating expenses</b>	<b>19 317</b>	<b>31 116</b>	<b>38 384</b>	<b>98 558</b>	<b>66 217</b>
<b>Operating profit (loss)</b>	<b>-19 317</b>	<b>-31 116</b>	<b>-38 384</b>	<b>-98 558</b>	<b>-66 217</b>
Net financial items	2 082	391	2 581	2 587	5 051
<b>Profit (loss) before tax</b>	<b>-17 235</b>	<b>-30 725</b>	<b>-35 803</b>	<b>-95 971</b>	<b>-61 166</b>
Net increase/(decrease) in cash and cash eq.	-33 858	-29 186	296 772	54 582	284 332
<b>Cash and cash equivalents at end of period</b>	<b>412 025</b>	<b>453 523</b>	<b>412 025</b>	<b>453 523</b>	<b>399 607</b>
Number of FTEs at end of period	17	19			17

### Cash flow

- ▶ YTD-20 includes increase in cash from share issue of net MNOK 152.9, and YTD-19 includes cash from IPO of net MNOK 344.5

### Comments:

#### Payroll expenses

- ▶ Higher cost in Q3/YTD-20 than same periods previous year due to:
  - ▶ 2 more FTEs in 2020 and higher share-option costs
  - ▶ severance pay liability of MNOK 5.0 recognised in the P&L related to the resignation of the former CEO (YTD)
  - ▶ liability of MNOK 10.2 related to employees' synthetic shares was reversed in June 2019 (YTD)

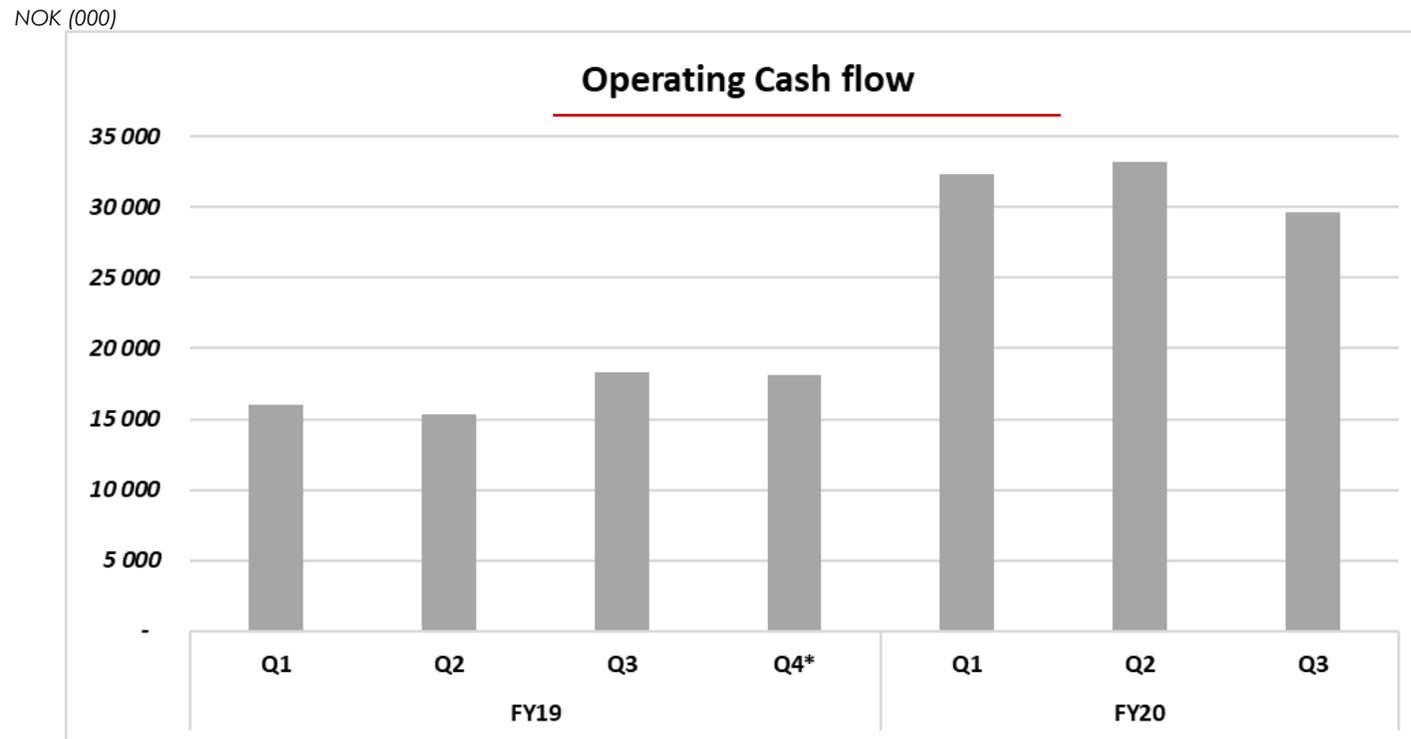
#### External R&D and IPR expenses

- ▶ Higher R&D costs in Q3/YTD-20 primarily due to the start-up of the NIPU and INITIUM clinical trials
  - ▶ Start-up fees
  - ▶ Site set-up / openings and patient inclusion

#### Other operating expenses

- ▶ Approximately at the same level as the same quarter in the previous year, with the exception of the IPO related costs recognized in 2019

# Key financials – operating cash flow



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

## Comments:

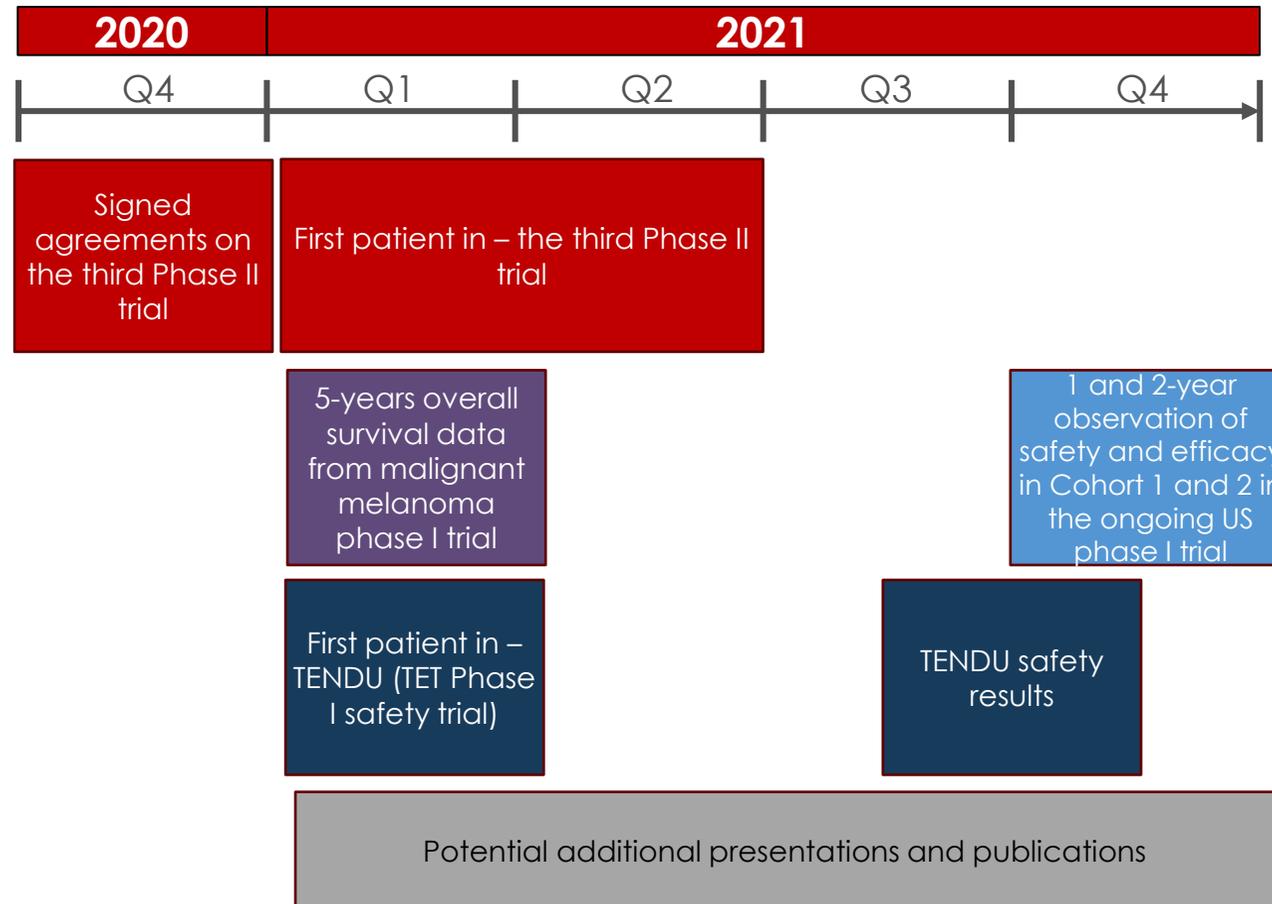
- ▶ Following relatively stable operating cash flow per quarter, the negative cash flow has increased significantly in 2020 due to higher R&D activities (as planned)
- ▶ A further increase in operating costs related to R&D should be expected in Q4-20 and into 2021
- ▶ Increase of personnel expenses during this period due to number of FTEs going from 15 in early 2019 to 19 per Q3-20
- ▶ Cash flows related to the 2019 IPO and the 2020 share issue are not included in the operating cash-flow

# Key financials – quarterly overview

## Key financials per Q3-2020 - Ultimovacs Group

NOK (000)	Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20	Q3-20	FY19
<b>Total revenues</b>	<b>0</b>							
Payroll and payroll related expenses	7 538	-4 717	8 653	8 686	10 015	13 197	13 115	20 160
External R&D and IPR expenses (incl. grants)	4 665	4 909	6 766	16 598	18 089	19 938	15 307	32 938
Other operating expenses (incl. depreciation)	2 766	3 905	3 898	2 550	3 155	3 048	2 695	13 119
<b>Total operating expenses</b>	<b>14 970</b>	<b>4 096</b>	<b>19 317</b>	<b>27 833</b>	<b>31 259</b>	<b>36 183</b>	<b>31 116</b>	<b>66 217</b>
<b>Operating profit (loss)</b>	<b>-14 970</b>	<b>-4 096</b>	<b>-19 317</b>	<b>-27 833</b>	<b>-31 259</b>	<b>-36 183</b>	<b>-31 116</b>	<b>-66 217</b>
Net financial items	247	252	2 082	2 470	922	1 274	391	5 051
<b>Profit (loss) before tax</b>	<b>-14 723</b>	<b>-3 844</b>	<b>-17 235</b>	<b>-25 363</b>	<b>-30 337</b>	<b>-34 909</b>	<b>-30 725</b>	<b>-61 166</b>
Net increase/(decrease) in cash and cash equivalents	-16 110	346 740	-33 858	-12 440	-31 479	115 247	-29 186	284 332
<b>Cash and cash equivalents at end of period</b>	<b>99 352</b>	<b>446 041</b>	<b>412 025</b>	<b>399 607</b>	<b>367 686</b>	<b>483 159</b>	<b>453 523</b>	<b>399 607</b>
Number of FTEs at end of period	16	17	17	17	19	19	19	17

# Expected newsflow 2020-2021



# Key take-aways

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- ▶ **Universal vaccine technology** (UV1 and TET) broadly applicable in different cancer types and in different therapeutic combinations
- ▶ **Good safety profile** and early positive signals of clinical efficacy
- ▶ **Broad Phase II development program** – 3 trials with more than 400 patients (on top of the 82 patients in Phase I)
- ▶ **Validation through collaboration with large pharma companies and oncology specialist groups**
- ▶ **Strong shareholder base and good cash position** with funding through read-out of Phase II primary endpoints
- ▶ **Experienced team** with strong execution skills and good track-record
- ▶ **Multiple near-term milestones** and news flow

# For questions

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**Carlos de Sousa, CEO**

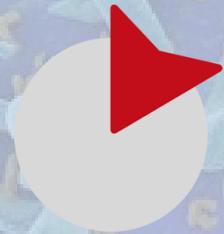
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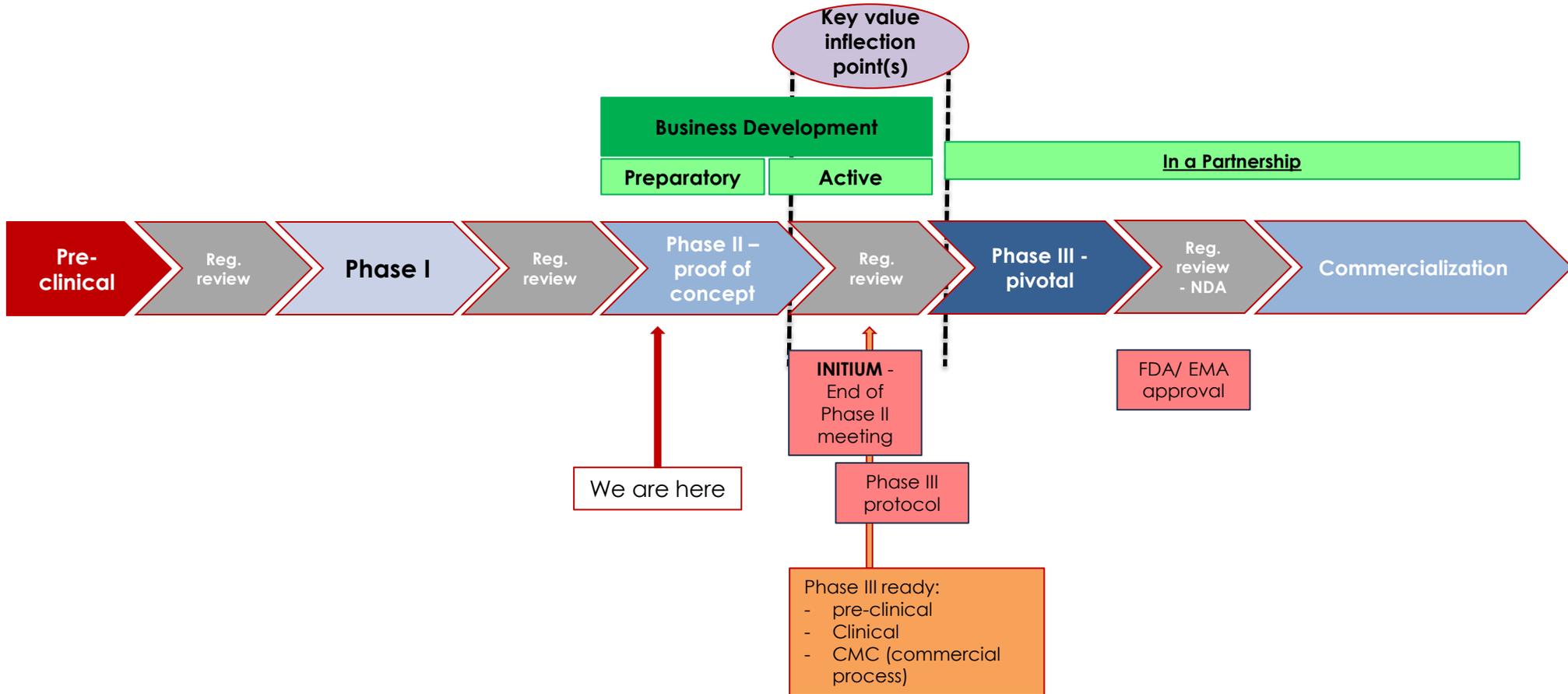
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**Q&A**

# Regulatory Pathway and Partnering Activities – UV1



# Regulatory Pathway and Partnering Activities – UV1

