



## Q3'2020 REPORT HIGHLIGHTS AND FINANCIALS

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NOVEMBER 19<sup>TH</sup>, 2020

LARS NIEBA, INTERIM CEO  
MALENE BRONDBERG, CFO

Nordic Nanovector ASA  
Kjelsåsveien 168 B, 0884 Oslo, Norway  
[www.nordicnanovector.com](http://www.nordicnanovector.com)  
IR contact: [IR@nordicnanovector.com](mailto:IR@nordicnanovector.com)

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# Q3'2020 highlights

- Positive outcome from PARADIGME Interim Analysis
  - IRC\* recommendation to focus on single arm investigating the “40/15” dosing regimen
- Approval of protocol amendments to PARADIGME proceeding as planned and completed in best-recruiting countries
  - Designed to enlarge eligible patient population and increase rate of enrolment
- Pivotal Phase 2b PARADIGME trial with Betalutin<sup>®</sup> progressing in 3<sup>rd</sup>-line Follicular Lymphoma (FL)
  - 59 patients enrolled as of 18<sup>th</sup> November 2020
  - COVID-19 continues to have a negative impact on recruitment
- Private placement successfully completed in September raising approx. MNOK 231 (gross)
  - Extends cash runway into Q3'2021
- Dr Christine Wilkinson Blanc appointed Chief Medical Officer
  - 25+ years' clinical development experience in oncology/haematology with pharma and biotechs

# Events after Q3'2020

- Second cohort fully enrolled into Archer-1 Phase 1 safety trial of Betalutin<sup>®</sup> plus rituximab in 2L R/R FL
  - Final 2 patients enrolled
  - Preliminary data readout expected in H1'2021
  - Trial to be paused pending analysis of data and evaluation of plans for further development
- Results of preclinical studies demonstrating Betalutin<sup>®</sup> reverses tumour resistance to rituximab in NHL disease models published in *Journal of Nuclear Medicine*
  - Adds to evidence supporting potential of Betalutin<sup>®</sup> and rituximab combination in NHL



## FOCUS ON ADVANCING PARADIGME

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# Revised clinical development strategy to capture significant value from Betalutin<sup>®</sup> in NHL

## Core Focus

### PARADIGME

#### Single-agent Betalutin<sup>®</sup> in 3L R/R FL

- Targeting 3L R/R FL as first-to-market indication
- Evaluating optimal strategy to advance into earlier lines
- Evaluating opportunity to investigate in R/R MZL based on:
  - Promising response in LYMRIT 37-01
  - Clear unmet need reflected in Fast-track (US) and Orphan Drug (EU) designations
  - Possibility to augment patient flow into PARADIGME leveraging existing infrastructure

## To be paused after completing ongoing cohorts

### Archer-1

#### Betalutin<sup>®</sup> + RTX in 2L R/R FL

- Good initial efficacy, but recruitment is very slow
- Need to consider future positioning and optimal strategy

### LYMRIT 37-05

#### Single-agent Betalutin<sup>®</sup> in DLBCL

- Recruitment is very slow
- DLBCL remains an important indication – need to evaluate optimal development strategy

- All pre-clinical and research initiatives (**Alpha37**) to be paused after IND submission

# Positive outcome of Interim Analysis

- Recommendation by IRC to focus on “40/15” dosing arm
- Comprehensive review of interim data by Independent Review Committee
- Both arms were well-tolerated, demonstrated a manageable safety profile and activity (CR, PR and SD)
- “40/15” arm demonstrated more consistent and favourable clinical responses across all sub-groups
- “100/20” arm to be discontinued – dosed patients to be monitored for the remainder of the trial
- Evaluating options to reduce patient numbers required for completing PARADIGME based on a single-arm design

# Impact of COVID-19

- The impact of the COVID-19 pandemic has negatively affected recruitment into all non-COVID related clinical trials, particularly those involving vulnerable patients
- PARADIGME target patient population is at high-risk for COVID-19
  - Restrictions on movement during lockdown prevented follow-up visits and data collection on existing patients, and dosing of newly enrolled patients
- Recent emergence of second wave has led to restrictions that may outweigh the actions taken
  - Getting more difficult to screen and enrol patients (e.g. re-prioritisation of hospital activities, healthcare staff or patients being affected by the virus, or supply issues due to restriction of movement)
  - Uncertainty around lockdown and continued restrictions in Q4 and into 2021 may lead to further delays to completing enrolment

# Full focus on improved trial execution

- Approval of protocol amendments to PARADIGME proceeding as planned and completed in best-recruiting countries
  - Significantly enlarges eligible patient population, allowing inclusion of FL patients:
    - who have had ASCT – frequently used for treating R/R FL in some countries\*
    - with a lower platelet count at baseline
  - Enrolment to continue under existing protocol until amendments approved
- Enhanced working relationship with CRO and interactions with study investigators
  - Implemented improved patient referral networks
- These actions are expected to improve the rate of patient enrolment
- Targeting three-month data readout in H2'2021



## BETALUTIN<sup>®</sup> - FURTHER OPPORTUNITIES IN NHL

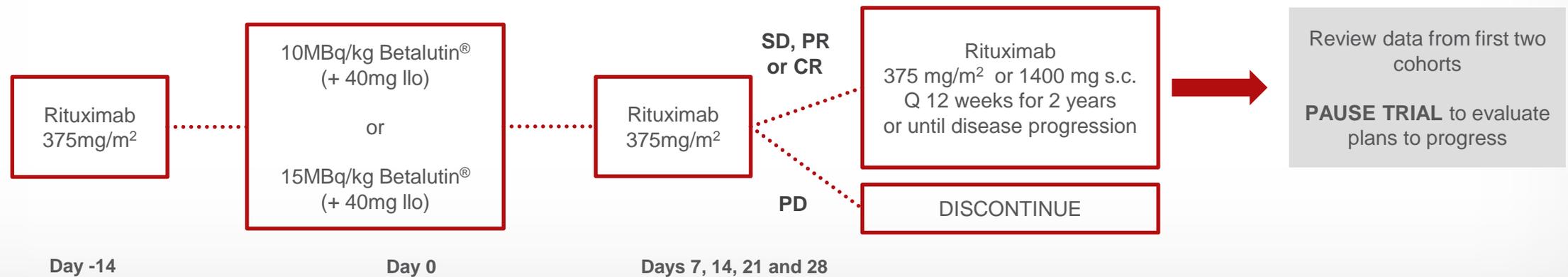
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# Archer-1: Betalutin<sup>®</sup> + rituximab in R/R FL

Patient enrolment into both safety cohorts is completed

- **Patient population:** Patients with FL (grade I-III A)  $\geq 1$  prior regimens
- **Primary objective:** To evaluate the safety and tolerability of Betalutin<sup>®</sup> in combination with RTX
- **Secondary objective:** To evaluate the preliminary anti-tumour activity of combination treatment



- Final 2 patients enrolled into second safety cohort
- Preliminary data readout expected in H1'2021



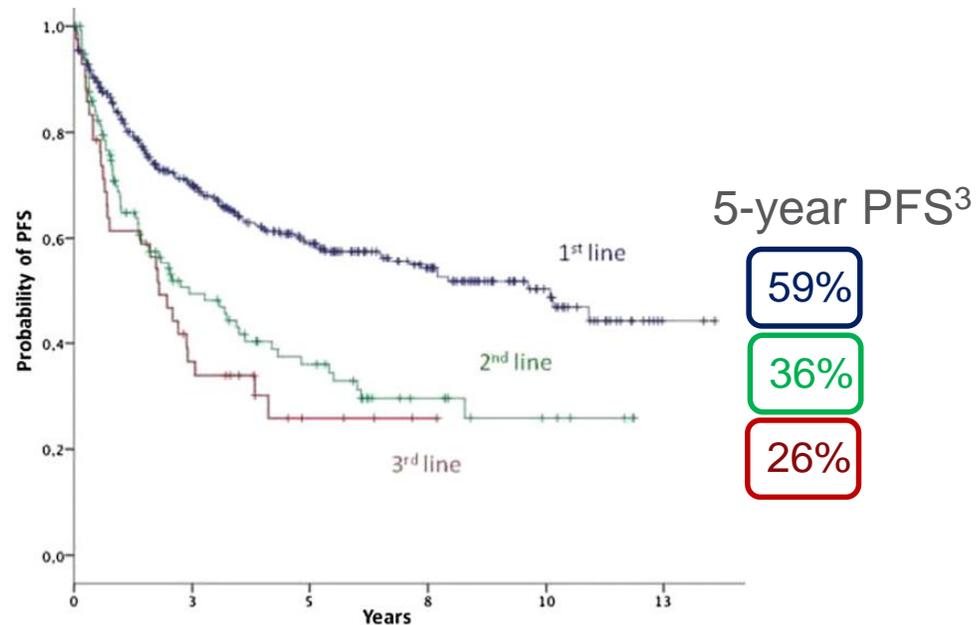
## BETALUTIN® POTENTIAL TO ADDRESS UNMET NEED IN FL

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# NHL – the need for new treatment options

- 40-60% indolent NHL patients treated with RTX-containing regimen are either refractory (10%) or develop resistance within 5 years
- R/R patients may not tolerate chemotherapy because of age or co-morbidities
- The need: Alternative target to CD20 + “chemo-free” regimens with gentle side-effect profile



FL: 5-year overall survival for RTX-refractory patients vs all: 58%<sup>1</sup> vs 88%<sup>2</sup>

MZL: patients with refractory or relapsed MZL have poor outcomes with current approaches<sup>4</sup>

~40% of DLBCL patients relapse following 1L RTX-chemo; 60-70% of these patients fail or unsuitable for subsequent high-dose chemo + SCT

<sup>1</sup>Abdollahi S et al, Blood 2008:112

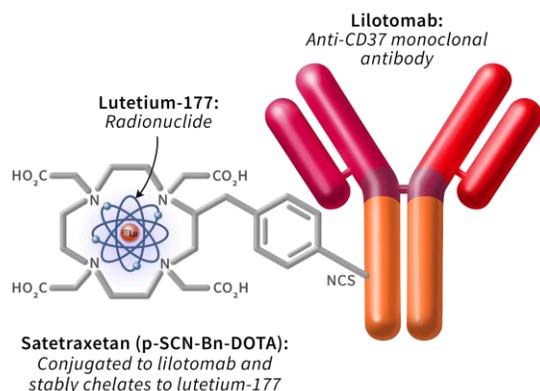
<sup>2</sup>seer.cancer.gov (2019)

<sup>3</sup>Rivas-Delgado A et al. EHA 2017; abstract 405

<sup>4</sup>Current Treatment Options in Marginal Zone Lymphoma, The American Journal of Hematology/Oncology, vol. 13, no. 5, 2017

# Betalutin<sup>®</sup> has a compelling, unique and differentiated value proposition for NHL patients

Betalutin<sup>®</sup>: A novel CD37-targeting radioimmunotherapy



- CD37 is highly expressed in B-NHL<sup>1</sup>
- <sup>177</sup>Lu: a low energy  $\beta$ -emitter with a half-life of 6.7 days
- Mechanism of action:
  - Internalization and cell death
  - Crossfire effect targets cells with variable CD37 expression and poorly-vascularized tumour regions

## Key Benefits

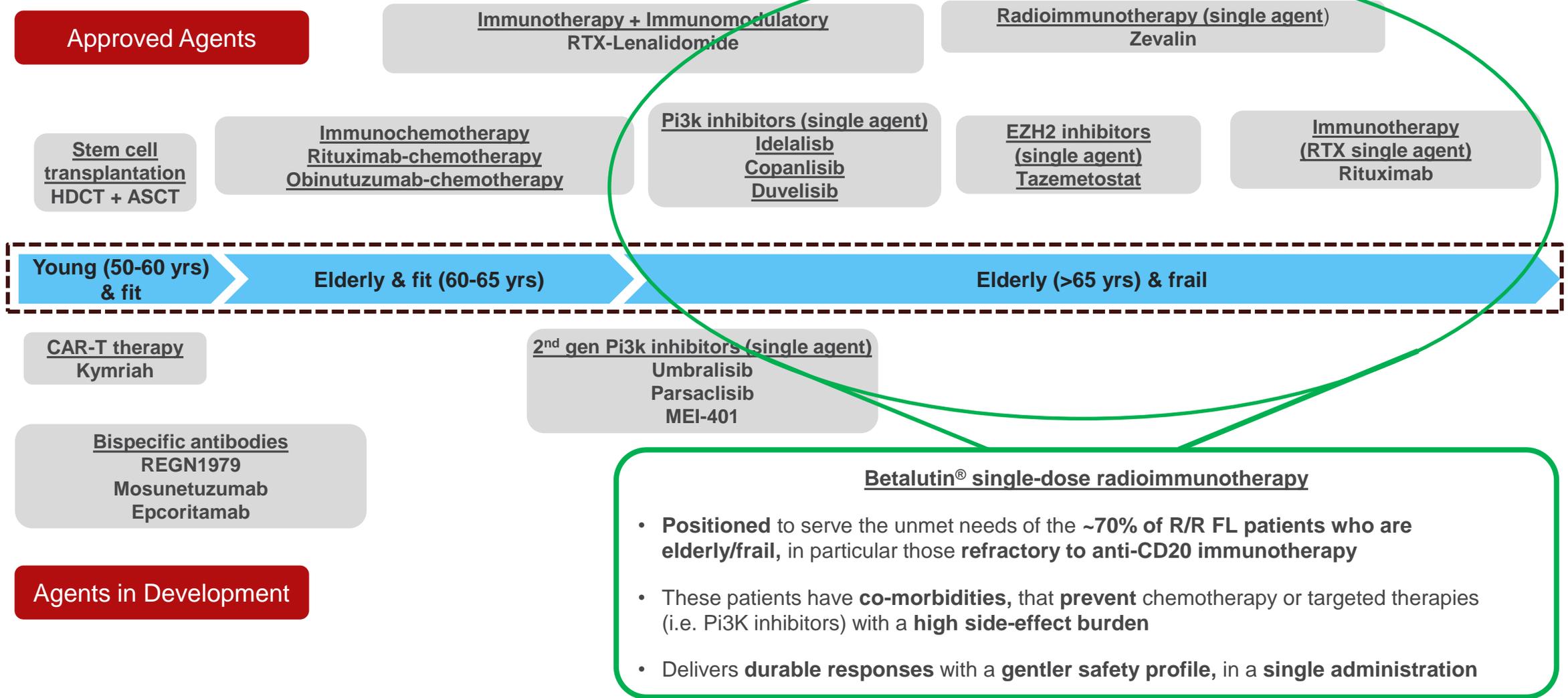
Single-dose treatment

Durable responses in elderly and heavily pre-treated NHL patients

Predictable and manageable side-effect burden

Alternative target to CD20: suitable for rituximab refractory patients

# Betalutin<sup>®</sup> profile positions it as treatment of choice for the ~70% of 3L+ FL patients who are elderly/frail



# 2020 highlights growing interest in radiopharmaceuticals

- Nordic Nanovector is well positioned to expand awareness of the benefits of radiopharmaceuticals
- Novartis confirms commitment to build on its late-stage radio-ligand portfolio
  - Lutathera in Phase 3 for Gastroenteropancreatic neuroendocrine tumors (GEP-NET)
  - <sup>177</sup>Lu-PSMA-617 in Phase 3 for Metastatic Castration-resistant Prostate Cancer (mCRPC)
- Fusion Pharmaceuticals nets \$197.6M through IPO on Nasdaq in June
  - Announces collaboration with AstraZeneca to develop and commercialize next-generation radiopharmaceuticals and combination therapies in November (targeted alpha therapies)
- POINT Biopharma raises \$20M Series A financing in August to develop Lutetium-177 conjugated radiopharmaceuticals for cancer
- RayzeBio Inc. raises \$45M Series A financing in October to develop Actinium-225 conjugated radiopharmaceuticals

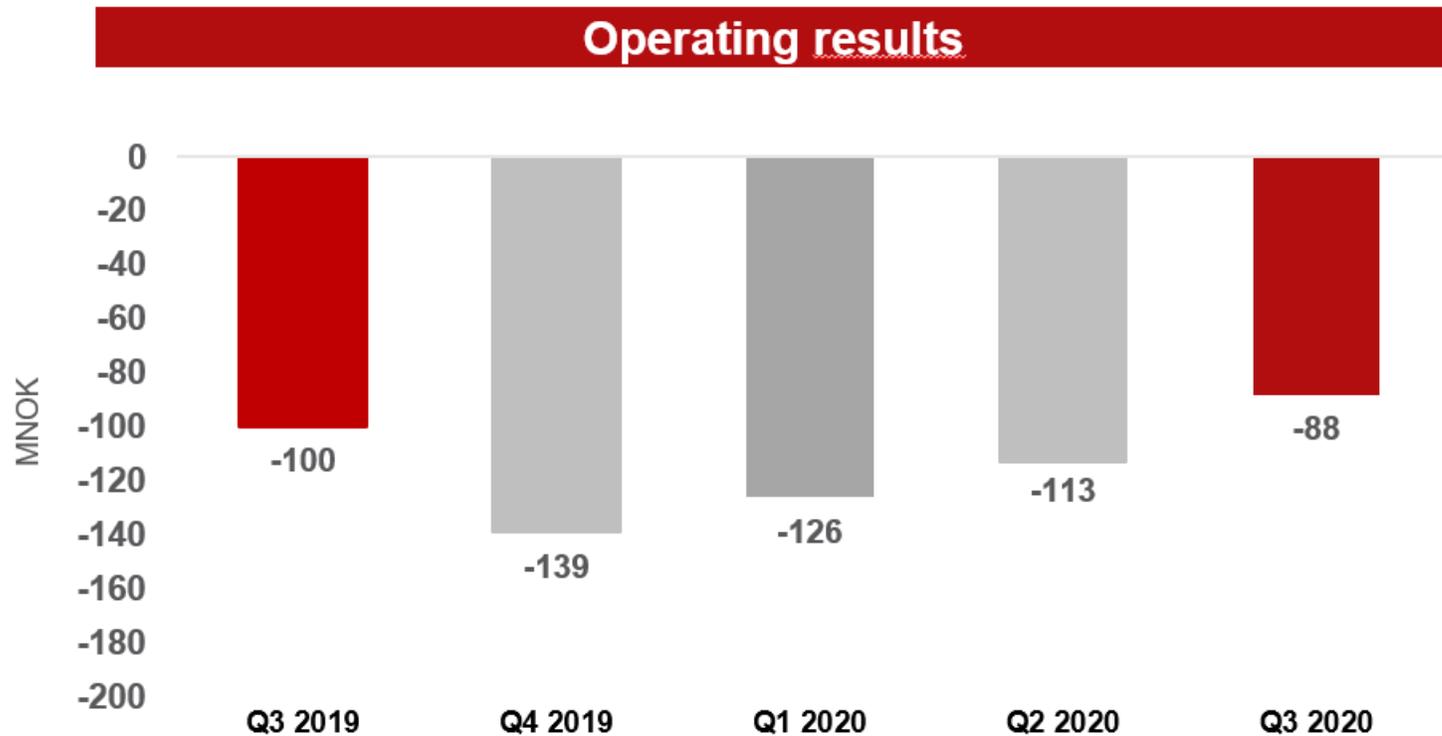


## FINANCIAL RESULTS FOR Q3'2020

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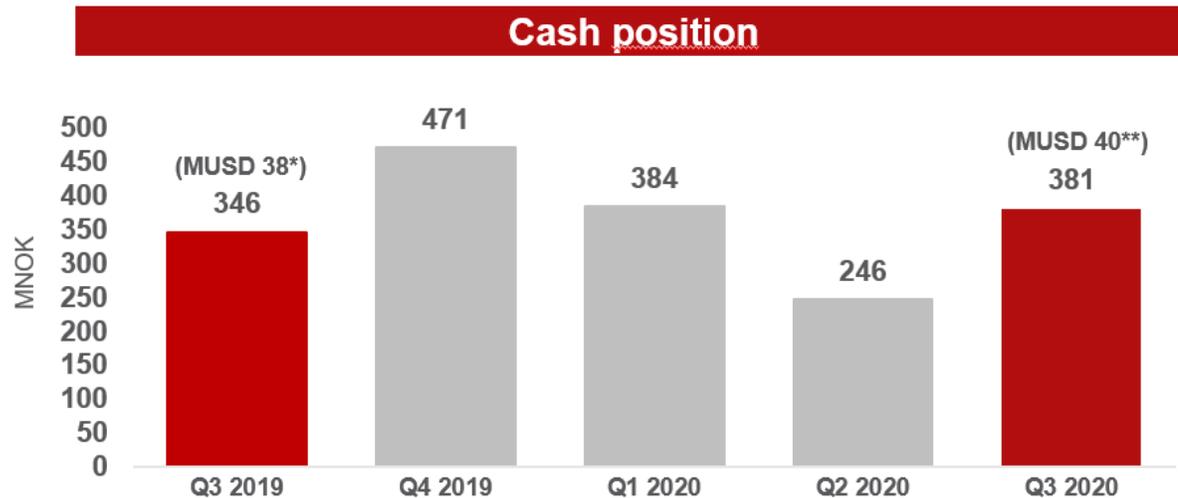
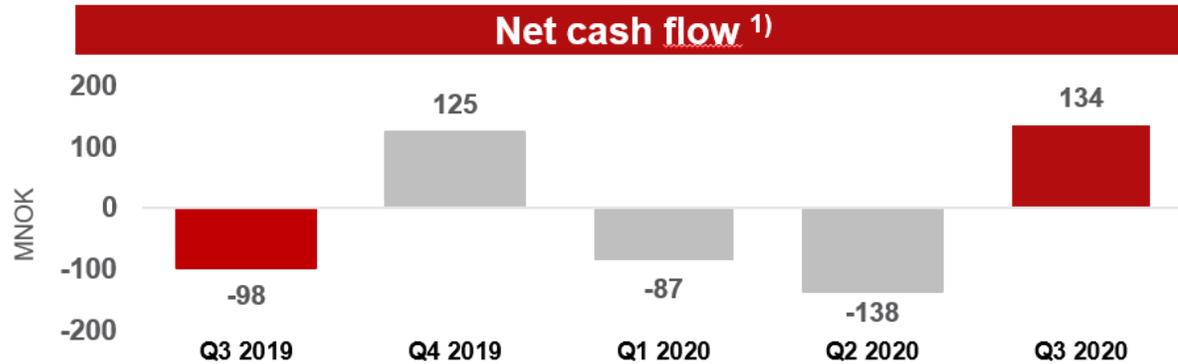
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# Investing in Betalutin<sup>®</sup>



- Operating results MNOK -88.1 (Q2'2020: MNOK -113.4)
- Visible impact of restructuring of approx. MNOK 6
- Operational expenditure will continue to be focused on the activities needed to complete PARADIGME and prepare for filing

# Cash runway extended into Q3'2021



- Net cash from operating activities of MNOK -93.8 (Q4: MNOK -116.0)
- Cash and cash equivalents amounted to MNOK 380.7 end of September 2020
  - includes MNOK 231 (gross) raised in a Private Placement in Q3'2020

# We are focused on PARADIGME

- Goal to complete PARADIGME as quickly as possible
- Recommendation from IRC on Interim Analysis has provided clarity on advancing PARADIGME
  - Betalutin<sup>®</sup>'s manageable safety profile confirmed
- Approval of PARADIGME amendments proceeding as planned and completed in best-recruiting countries
- Enhanced partnership with CRO to implement other initiatives to speed up enrolment
- Targeting readout of 3-month top-line data from PARADIGME in H2'2021
- Our confidence in potential of Betalutin<sup>®</sup> to fulfil important unmet needs in NHL remains unchanged

# Financial calendar

**Q4 and FY 2020 results**

**February 2021**

**Q1 2021 results**

**May 2021**

**Q2 2021 results**

**August 2021**

Dates subject to change. The time and location of the presentations will be announced in due time.

- A two-week quiet period takes place ahead of full year and quarterly results
- Please send Investor Relations enquiries to [ir@nordicnanovector.com](mailto:ir@nordicnanovector.com)

## *Questions*

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