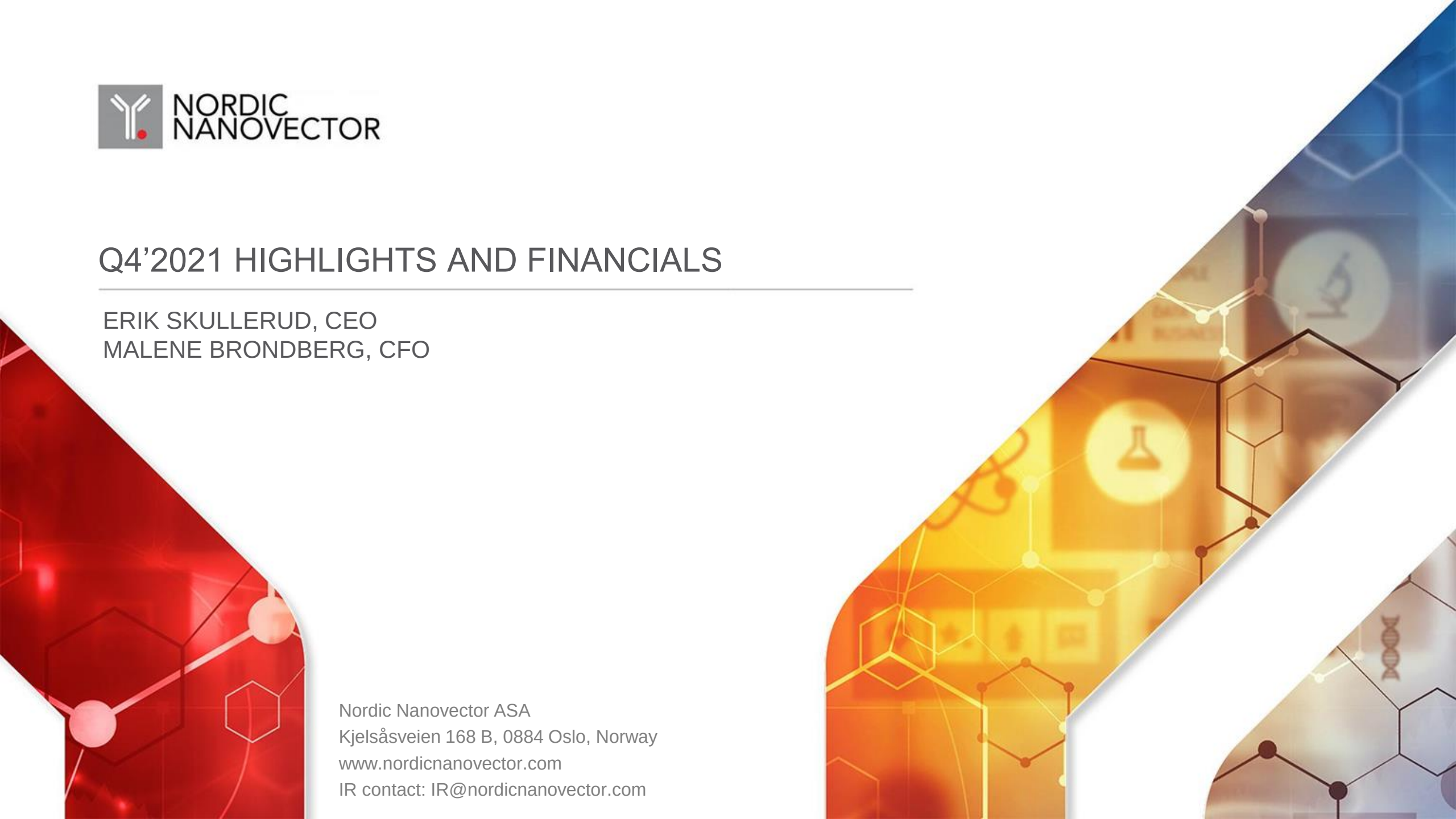
# Q4’2021 HIGHLIGHTS AND FINANCIALS

ERIK SKULLERUD, CEO
MALENE BRONDBERG, CFO



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# Agenda

1. **Quarterly business update**

Erik Skullerud, Chief Executive Officer

2. **Financial review**

Malene Brondberg, Chief Financial Officer



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# Positioning Nordic Nanovector for success – key achievements

- **106** of a targeted 120 **evaluable patients enrolled** into the pivotal **PARADIGME** Phase 2b **trial** for **Betalutin®** (28 Feb 2022)
  - Preliminary three-month data readout from PARADIGME expected to be reported during H2'2022
  - Timeline revised (Jan 2022) owing to ongoing impact on patient recruitment from the SARS-CoV-2 omicron variant
- **~NOK 250 million gross** (~USD 28.4 million) **raised from** a private placement of **new shares** (Jan 2022)
- **New members** to the **management team** – **Pierre Dodion** as **CMO** and **Sandra Jonsson** as **COO**
- **R&D Day Nov 2021 showcased** the **Company's vision** and **strategy** for **creating value from Betalutin®** and **leveraging** its **deep expertise** and **experience** in **CD37 biology**
- Announced (Nov 2021) **support** for **The Health Policy Partnership's initiative** to improve patient access to novel radioimmunotherapies
- **Entered research collaboration** with the **University of Pennsylvania** to **generate** a **novel CD37-targeting CAR-T cell therapy**



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# Nearing the completion of PARADIGME recruitment

- **During Q4**, we continued to **drive PARADIGME recruitment** with the implementation of **targeted initiatives** to **boost enrolment** and **mitigate COVID restrictions**

- In **Jan 2022**, the company **revised** the **timeline** for the **preliminary data readout** following a **review of the rate of patient recruitment** and discussions with its **clinical advisors** that also considered the **continuing impact from the COVID pandemic**

- As of 28 Feb 2022, **106** of a targeted **120 evaluable patients** have been enrolled (total PARADIGME trial)

**Preliminary 3-month data readout now expected during H2'2022**

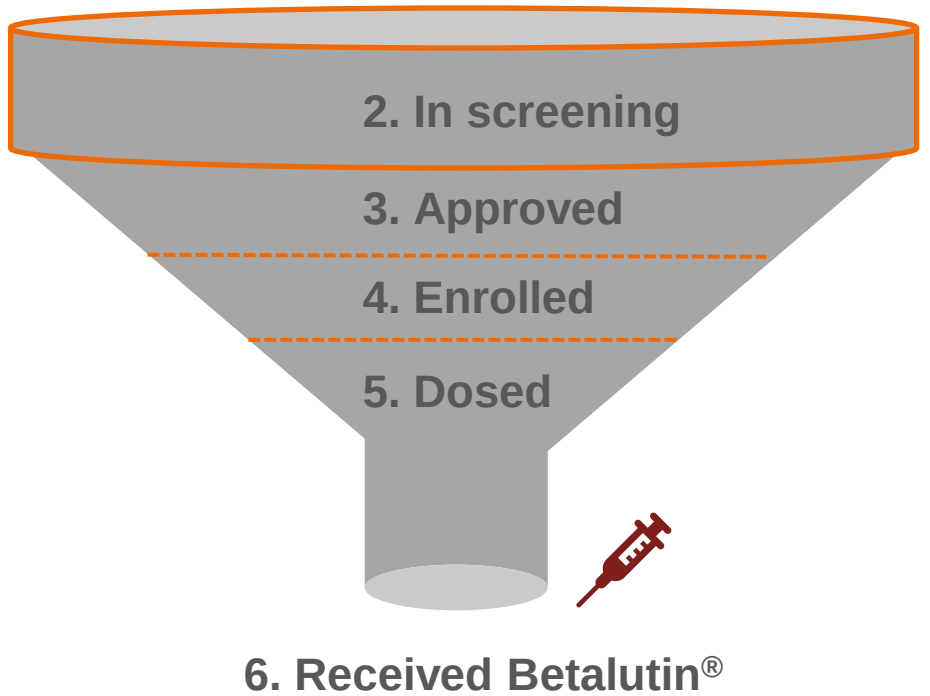
# We remain disciplined in our PARADIGME recruitment

## Targeted initiatives to boost enrolment

- Centres focus planning
- Tailored Centre-by-Centre plan
- Trialbee in selected countries (US, Israel, Spain)
- Investigator meetings
- Face-to-Face meetings where possible
- Additional clinical scientist – MD

Key enrolment countries:
US/CAN, UK, Ireland, France, Spain

## Patient enrolment steps – leading indicators



# Advancing our Betalutin® strategy and operations

**Activities:**

**Regulatory Affairs**

- We continue to **engage with FDA**:
  1. First on **confirmatory Phase 3 design**, building on successful ARCHER outcome
  2. Later in the year, on **CMC** and **clinical pharmacology requirements**
- If positive results, **we have** a **clear regulatory strategy** to **gain rapid approval**
  - **BLA filing for Accelerated Approval** based on **PARADIGME data** and **start** of **confirmatory Phase 3 trial**
  - Seek **Priority Review** from **FDA** to **reduce review time from 12 to 8 months**
  - **Orphan Drug Designation** for **3L FL granted** in **US** and **EU** / **Fast-track designation granted** in the **US**

**Manufacturing**

- Continue **preparing** for a **successful outcome** to **PARADIGME** by **qualifying** our **manufacturing process** to **support** a **regulatory filing**

**Partnership for growth**

- Executing our **business development** and **partnering strategy** to **realise** the **full potential** of **Betalutin®** in NHL



BLA – Biologics License Application; 3L – 3rd line; FL – Follicular Lymphoma; NHL – Non-Hodgkin Lymphoma

# Manufacturing initiatives to ensure readiness and growth

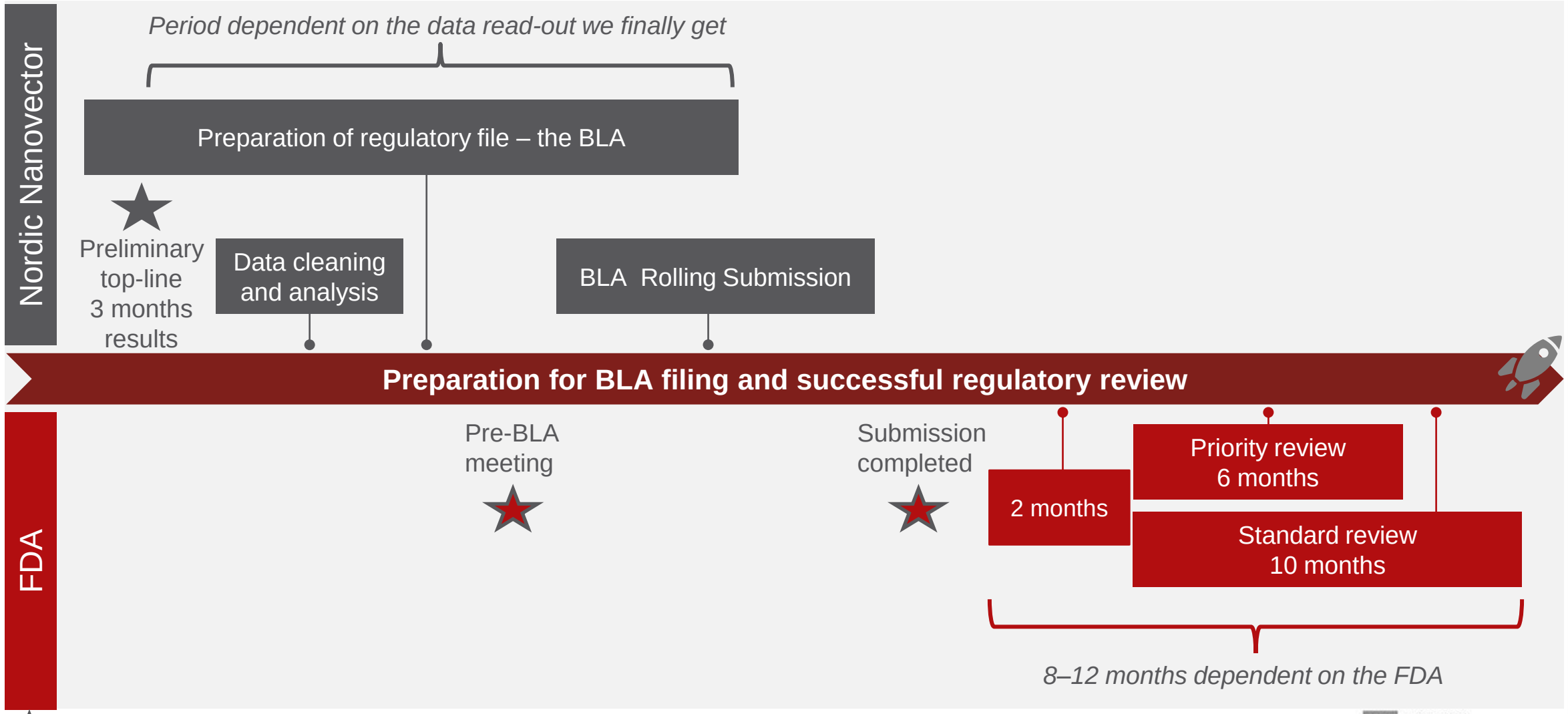
## We remain on target with the qualification of our manufacturing process to support the Betalutin® BLA filing

| Process Performance Qualification | BLA preparation | Set-up commercial supply chain | Launch | Cost of Goods (COGs) reduction |
|---|---|---|---|---|
| • Requirement to **demonstrate & validate robustness** of the **entire production process** in a **GMP facility** | • Prepare **process documentation** for **submission**<br>• Prepare **partners** and **facilities** for **pre-approval inspection** | • Define, **validate** and **implement** all **manufacturing/ business processes** to **enable supply** in all countries<br>• Define **stock policy**/ have the right **planning systems in place** | • Be ready at the time of approval for an immediate launch | • Focus on improving the efficiency and effectiveness of the entire supply chain to further increase robustness and reduce costs |
| ✓ On track | ✓ On track | ✓ On track | ✓ Started | ✓ Conceptual stage |



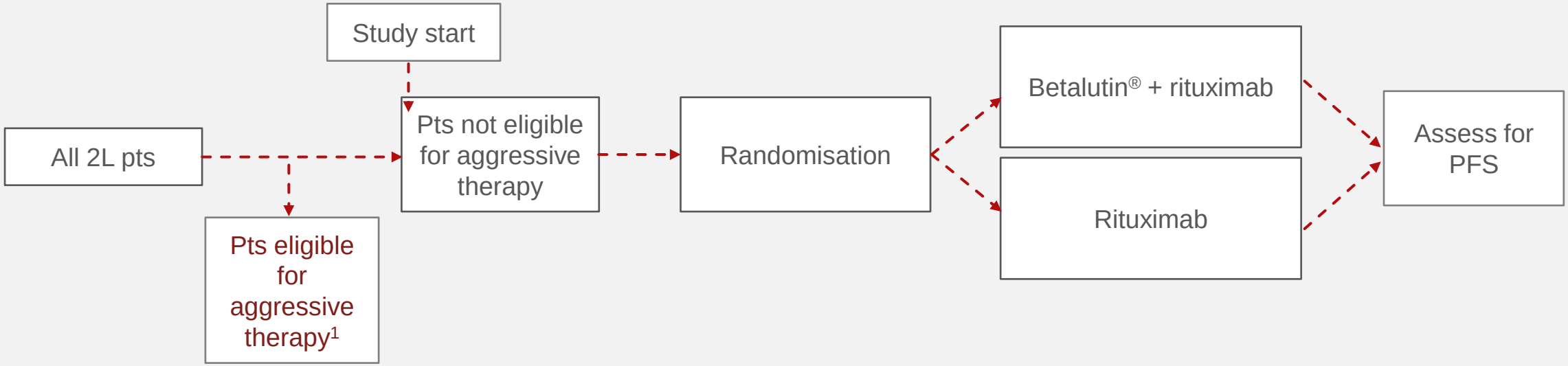
GMP – Good Manufacturing Practice

# Betalutin® top-line results expected H2'2022 – key anticipated events



# Close contact with regulatory agencies to finalise design of confirmatory Phase 3 study

**Preliminary study design to assess Betalutin® + rituximab combination in 2L FL patients not eligible for aggressive therapy:**




- Would also serve as confirmatory, randomised trial as part of a possible post approval commitment in 3L FL

[1] (R)-CHOP, bendamustine, R-bendamustine, Obinutuzumab - bendamustine, RFCM, rituximab lenalidomide

2L – 2nd line follicular lymphoma; Pts – Patient; PFS – progression-free survival

# Our focus on NHL given its high unmet medical need

**We are committed to develop and deliver the therapeutic potential of Betalutin® and other innovative CD37-targeted immunotherapies to address major unmet medical needs**

- **NHL** is a **common cancer**, impacting more than **150,000* new patients every year**
- **Unmet need** in **NHL** is still **high** in **both aggressive** and **indolent sub-types**, **in particular** in the **relapsed** setting, despite more therapies being recently available
- **Betalutin®'s clinical development** is **most advanced** in the **treatment of R/R FL**
  - **40-60%** indolent **NHL patients treated** with **rituximab-containing regimen** (standard of care) are **refractory** or develop **resistance within 5 years**
  - **Elderly R/R FL patients** may **not tolerate** – due to age or co-morbidities – **chemotherapy** or other **novel agents** (targeted and cell therapies) which, while effective, are associated with a **high side-effect burden**

**Betalutin®** is in a **unique position** to meet the clear need for a **chemo-free**, **effective** yet **tolerable treatment** and its **convenient administration** schedule has **QoL advantages in particular** for **frail patients**



* Number of Diagnosed Incident Cases of NHL in the key 7 markets; QoL – Quality of Life

# LYMRIT 37-01 – Part A (Phase 1/2a study in 74 patients): Promising safety and efficacy in R/R FL and MZL[1]

## Compelling response rate in FL and MZL patients from a single administration

| | ORR | CR |
|---|---|---|
| All patients (n=74) | 61% | 30% |
| All FL patients (n=57) | 65% | 30% |
| **FL with ≥2 prior therapies (n=37)** | **70%** | **32%** |
| RTX-refractory FL (n = 26) | 58% | 19% |
| **RTX-refractory FL, ≥2 prior therapies (n = 21)** | **67%** | **24%** |

| | ORR | CR |
|---|---|---|
| MZL* (n=9)* | 78% | 44% |

## Betalutin® is well tolerated

- Most common grade 3/4 AEs were transient and reversible neutropenia and thrombocytopenia
- Serious AEs occurred in 14 patients (19%)
- No cases of febrile neutropenia, low incidence of platelet transfusion and no study related deaths

**Patients closest to the 'PARADIGME' population**

## mDoR and mPFS

- Elderly (median 68 years), heavily pre-treated with advanced disease
- Median DoR: 13.6 months for all responders (n=45), 32.0 months for complete responders (n=22) with median follow-up for responders of 30 months
- Median PFS: 8.8 months overall (n=74), 9 months in patients with FL (n=57)

[1]Kolstad *et al. Blood Advances*, vol. 4, issue 17, 2020 (FL data); Kolstad A, *et al.* Abstract 2879, ASH 2018 (MZL data)
MZL – Marginal zone lymphoma; AE – Adverse Event; CR – Complete Response; DoR – Duration of Response; ORR – Overall Response Rate; PFS – Progression Free Survival; RTX – Rituximab



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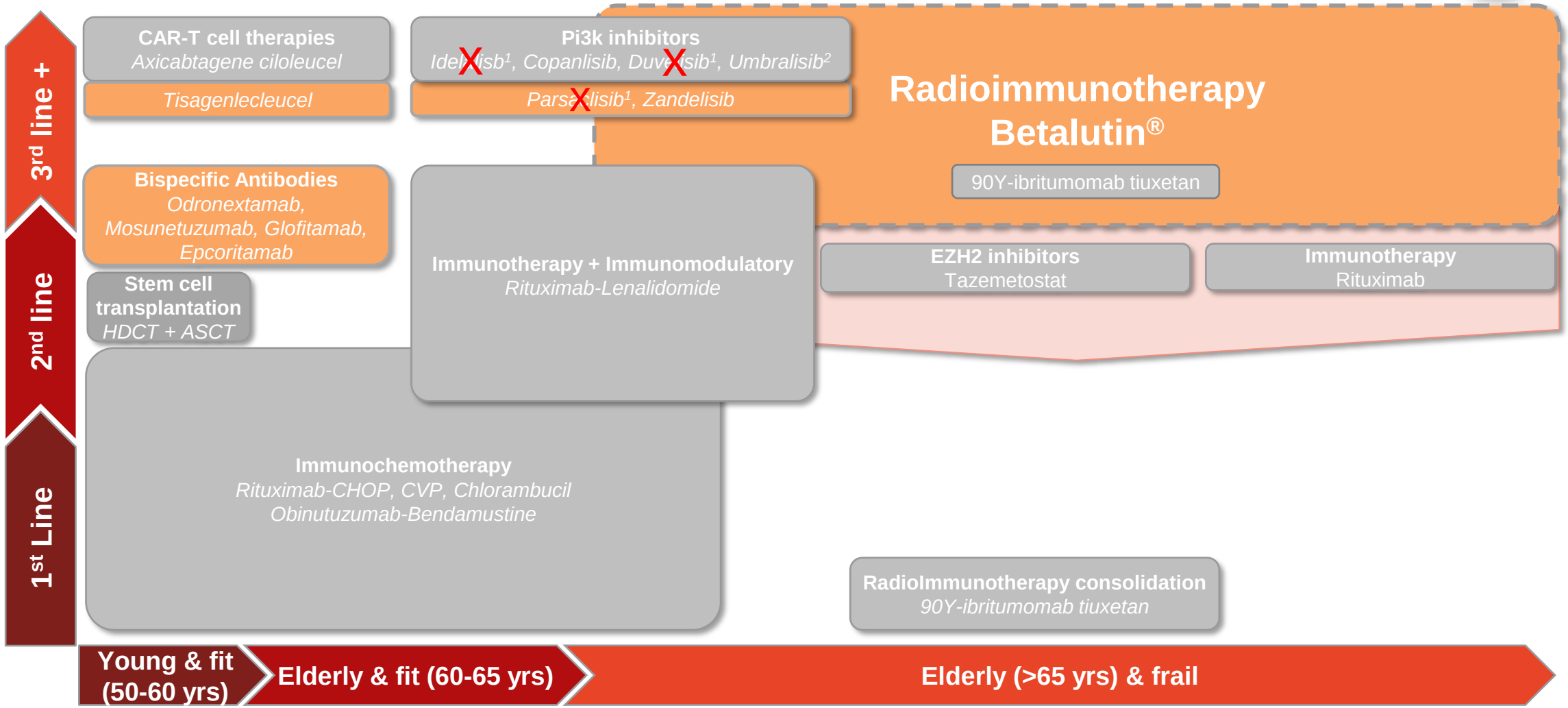
# Betalutin® ready to address unmet medical need in R/R FL – heightened by decreased presence of Pi3k inhibitors




[1] Withdrawn Dec 21'– Feb 22' [2] Safety concerns Feb 22'

Management of 3L FL patients is dependent on many factors, including patient age, performance status and co-morbidities, goals of therapy, number, type and response to prior therapies

# Reduced threat from Pi3k inhibitors – increased noise from Bispecific antibodies and CAR-T

## CAR-T

- Safety: **Cytokine release syndrome**, **neurotoxicity**
- Administration schedule: Infusion of re-engineered T cells several weeks following apheresis
- Administration: **Limited number** of **administration sites**; access restrictions due to **high cost of therapy**
- Response rate: 70-90% ORR
- Uptake in FL: Modest

## Bispecific antibodies

- Safety: **Cytopenia**, **cytokine release syndrome**
- Administration schedule: **Repeated i.v. infusions**
- Response rate: 70-90% ORR
- Expected launch: 2023 for 1st bispecific antibodies

**Evolving Competitive Landscape**

## Pi3k inhibitors

**Withdrawals & safety concerns Q4'21-Q1'22**

- Safety: **High burden** of **side-effects** incl. infections
- Administration schedule: **Repeated** & **inconvenient**
- Response rate: 40-60% ORR
- Uptake in market: Modest



CAR – Chimeric Antigen Receptor

# Aspiring to evolve the Betalutin® positioning narrative by embedding Archer-1 data & upcoming Phase 3 study

**PARADIGME**

**The convenience of a single agent, one-time treatment in late lines of therapy**

- **Betalutin®** can **elicit a precise** and **powerful response,** even **when other regimens have become ineffective**
  - **Betalutin®** is a durable **effective treatment** for **R/R FL**
  - **One-time administration + manageable toxicity + simplicity for patients** and **physicians**

*Betalutin®'s gentle safety profile makes it especially suitable for elderly & frail patients*

**Archer-1 & Phase 3**

**The powerful synergy of combination with rituximab in earlier lines of therapy**

- **Betalutin® resensitises tumour cells to rituximab in patients** who have become **resistant** or **refractory to CD20-targeted regimens**
  - **Betalutin® in combination with rituximab** represents a **powerful, chemo-free alternative** to more toxic options **for 2L FL patients** and **beyond**



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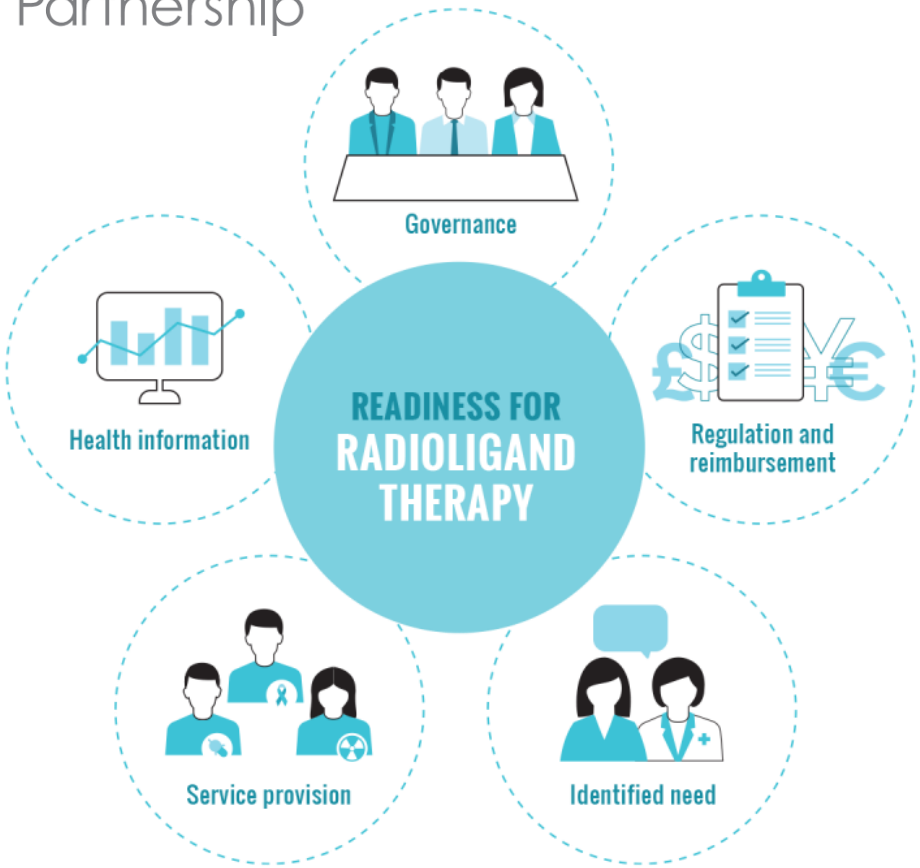
# We are supporting the Health Policy Partnership improving readiness for radioligand therapy

The Health Policy Partnership




www.radioligandtherapy.com

- **Independent government affairs initiative** led by **The Health Policy Partnership (HPP) –** a specialist health policy research organisation
- HPP has assembled the **Radioligand Therapy Readiness Assessment Framework**
  - Bringing expertise from an international panel of nuclear medicine, oncology/haematology experts and patient advocacy organization representatives
- The **framework**, **adaptable to any country/health system**, has initially been applied to **US** and **UK**, aiming to **expand** to **Germany, Japan, South Korea** and **China** in 2022
  - to assess health system readiness for the use of radioligand therapy
  - to identify policy changes that could facilitate appropriate integration of radioligand therapy



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# Advancing a promising pipeline of CD37-targeted immunotherapies

| Project | Targeted indication | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|---|---|---|
| **Betalutin®** | 3L FL | | | LYMRIT 37-01 / PARADIGME | | |
| **Betalutin®** | 2L FL | | | ARCHER-1 | Confirmatory Phase 3 | |
| **Betalutin®** | R/R DLBCL, SCT ineligible | | | LYMRIT 37-05 | | |
| **Humalutin®** | NHL | | | | | |
| **Alpha37** | CLL (NHL) | | | oranomed | | |
| **Humanized CD37 Ab** | NHL, Autoimmune diseases | | | | | |
| **CD37 CAR-T** | NHL | | Penn | | | |



CLL – Chronic Lymphocytic Leukaemia; DLBCL – Diffuse Large B-Cell Lymphoma; SCT – Stem Cell Transplant

# Innovation is the lifeblood of our current and future success

We focus our innovation across areas with **high unmet medical need**

We aim to **expand our cancer expertise** and offerings through **research and partnerships**, and to **extend** our **existing portfolio of products** to **new indications** and **therapeutic areas**

## Pipeline activities continue to advance

### Humalutin®

- Preclinical paper describing Humalutin® in combination with the PARP inhibitor Olaparib, submitted

### Alpha37 programme

- Abstract approved for presentation at AACR, 8-13 April 2022
- Feedback pending from FDA regarding analytical method for Alpha37 (Type B meeting), Q1'2022

### Humanized anti-CD37 antibody programme

- Two patent applications submitted, Oct 2021
- Antibody lead identification, on-going

### CAR-T programme

- Project initiation, Jan 2022



AACR – American Association of Clinical Research; PARP – poly adenosine diphosphate-ribose polymerase

# Recent business development activity strengthening our pipeline

Penn
University of Pennsylvania

| CAR-T cell therapy collaboration with University of Pennsylvania |
| --- |
| • An **immunotherapy** that involves **modifying** a **patient's own immune cells** (T cells) to **target** a **specific tumour-associated protein** so they **attack** and **kill cancer cells** |
| • **CAR-T** has already shown **strong promise in NHL**, including **FL** and **DLBCL**, e.g. Yescarta, Kymriah, Breyanzi |
| • The Perelman School of Medicine at the **University of Pennsylvania** are **world-leaders** in **CAR-T research**, and developed the **first approved CAR-T therapy**, Kymriah, **in collaboration** with **Novartis** |
| • New research **collaboration aims** to **generate** a **CD37-targeting CAR-T cell** approach as a potential **treatment** for **patients** with **B-cell malignancies**<br>✓ **Will combine Nordic Nanovector's CD37 expertise with Penn's CAR-T expertise** |
| • **Nordic Nanovector** has **option to license exclusive worldwide rights** to any **CD37-targeting CAR-T cell therapy** that results from the collaboration for further development |



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# Evaluating options to maximise the value of our portfolio

**Strategic partnering options for advancing the treatment of patients with haematological cancers and immunological diseases**

| Launch flagship asset | Expand clinical development | Enrich pipeline further |
|---|---|---|
| • Explore partnership opportunities for Betalutin® launch across geographic regions | • Move Alpha37 and Humalutin® into clinical development | • Accelerate preclinical projects with partner(s)<br>• Scout for new discovery RIT collaborations to broaden pipeline |



RIT – radioimmunotherapy

# Agenda

1. **Quarterly business update**

Erik Skullerud, Chief Executive Officer

2. **Financial review**

Malene Brondberg, Chief Financial Officer



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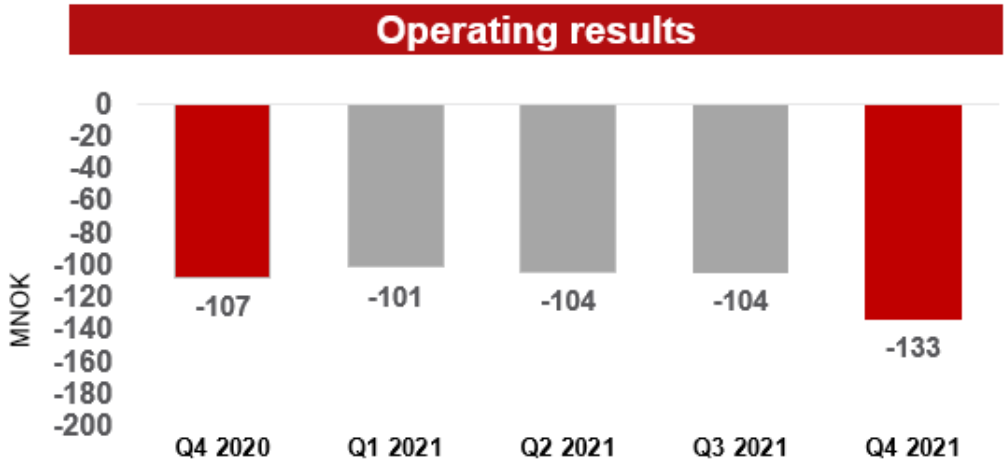
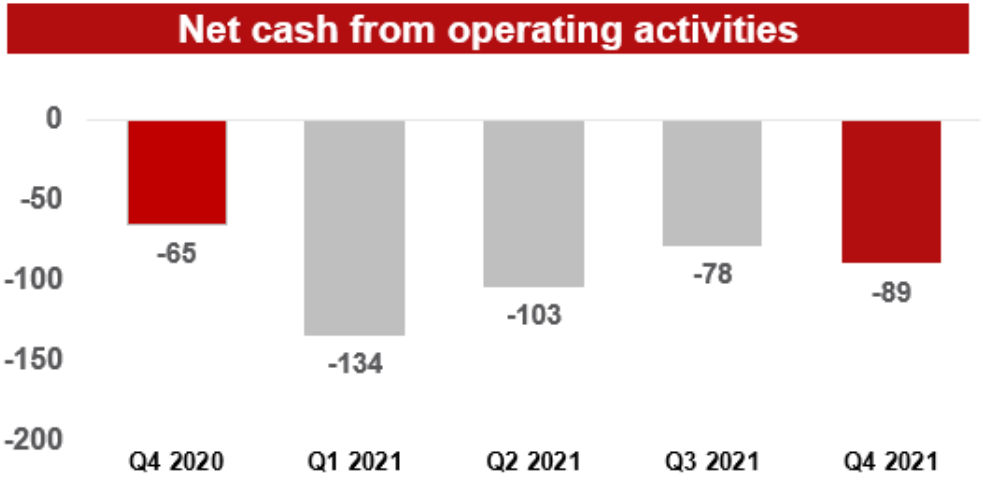
# Costs remain tightly focused on delivering Betalutin® to market

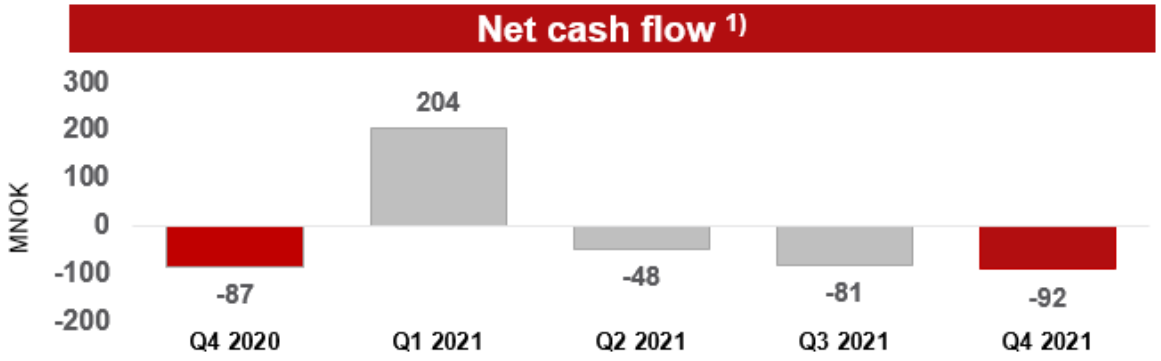


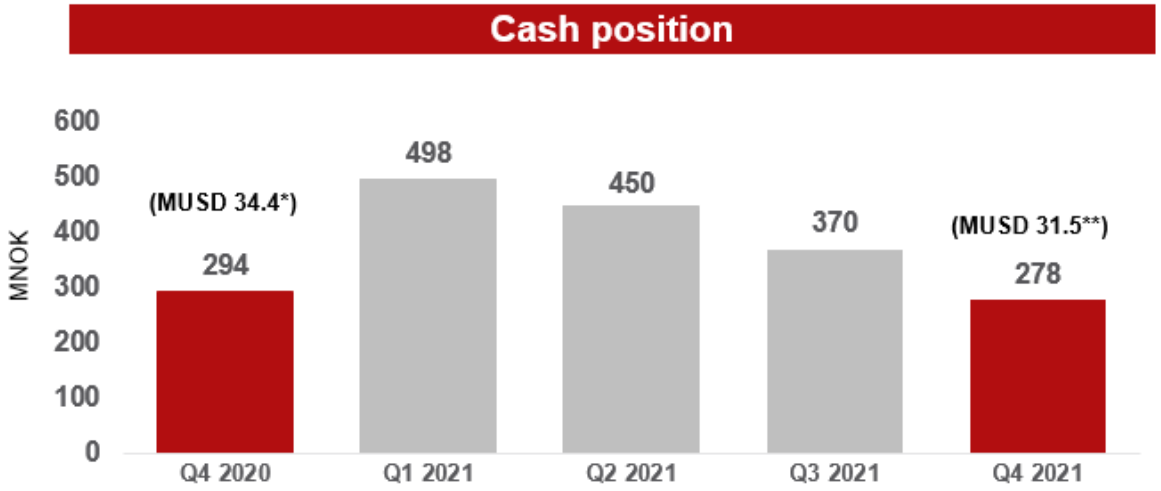

- Operating results NOK -133.1 million (Q4 20: NOK -106.8 million)




- Net cash from operating activities NOK -88.7 million (Q4 20: NOK -65.2 million)

# Cash runway into H1’2023




- Net cash from operating activities of NOK -88.7 million (Q4 20: NOK -65.2 million)
- Net cash flow from investing activities of NOK 0.9 million (Q4 20: NOK 1.4 million)
- Net cash flow from financing activities of NOK -2.9 million (Q4 20: NOK -19.3 million)
- Effects of exchange rate changes on cash and cash equivalents NOK -1.1 million (Q4 20: NOK 3.6 million)
- Cash and cash equivalents amounted to NOK 278 million end of December 2021
- 19 January NOK 250 million gross proceeds raised via Private Placement. Repair issue is currently running until 11 March 2022

* USD/NOK 8.54
** USD/NOK 8.84

1) Net cash flow from operating, investing and financing activities plus/minus currency effect

# Agenda

1. **Quarterly business update**

Erik Skullerud, Chief Executive Officer

2. **Financial review**

Malene Brondberg, Chief Financial Officer



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# FOCUSED ON CREATING VALUE

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# Nordic Nanovector – Investment highlights

**We develop innovative targeted therapies using our proprietary CD37 platform designed to advance the treatment of patients with haematological cancers and immunological diseases, starting with Betalutin®**

## Betalutin® – a targeted radioimmunotherapy designed for treating NHL

- Promising Phase 1/2 data from one-time administration in R/R iNHL
- Pivotal Phase 2b trial (PARADIGME) in 3L FL – preliminary data read-out expected H2'2022
- Fast track (US) & Orphan designation (US, EU)

## Betalutin® is a wholly owned asset; clear plan to bring it to market

- Robust market research and stakeholder feedback highlights attractive commercial opportunity and route to patients
- Phased execution of manufacturing and distribution strategies
- Opportunistic business development strategy

## Targeted anti-CD37 immunotherapies provide multiple pipeline opportunities

- Broad R&D expertise and robust IP portfolio and know-how
- Risk diversification, with many shots on goals
- Newsflow opportunities

## World-class management team

- Extensive R&D, clinical & commercial experience from global pharma and biotech

## Cash into H1'2023

- Expected to be sufficient to reach preliminary data read-out for PARADIGME



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# Financial calendar*

| | |
|---|---|
| **Q1’2022 results** | **13 May 2022** |
| **Q2’2022 results** | **20 July 2022** |
| **Q3’2022 results** | **10 November 2022** |

*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



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# THANK YOU

## QUESTIONS?

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