# Q1’2020 REPORT HIGHLIGHTS AND FINANCIALS

MAY 26TH, 2020

LARS NIEBA, INTERIM CEO
MALENE BRONDBERG, CFO
MARCO RENOLDI, MD, COO

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# Management Team with international experience

**LARS NIEBA**
Interim Chief Executive Officer
& Chief Technology Officer

Roche · Bayer · cytos biotechnology

**DOMINIC SMETHURST, MD**
Interim Chief Medical Officer

TUSK · AMGEN · AstraZeneca

**MARCO RENOLDI, MD**
Chief Operating Officer

NOVARTIS · PHARMACIA · AMGEN

**ROSEMARIE CORRIGAN**
Chief Quality Officer

ThromboGenics · NORGINE · Stiefel a GSK company

**MALENE BRONDBERG**
Chief Financial Officer

ABG SUNDAL COLLIER

**JOSTEIN DAHLE, PhD**
Co-Founder, Chief Scientific Officer

Oslo University Hospital · Norwegian Radium Hospital

**GABRIELE ELBL**
Vice President Global
Regulatory Affairs

morphosys · SANOFI · EUROPEAN MEDICINES AGENCY



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# Q1’ 20 highlights

- Dr Lars Nieba appointed as interim Chief Executive Officer
- Dr Dominic Smethurst appointed as interim Chief Medical Officer
- Pivotal Phase 2b PARADIGME trial with Betalutin® in 3rd-line follicular lymphoma (FL) progressing
  - COVID-19 has had a negative impact on PARADIGME during H1’2020
  - 51 patients enrolled as of May 25th, 2020
- Initiated strategic review with focus on advancing PARADIGME and extending cash runway into 2021



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# Events after Q1’20

- Strategic review completed: Clinical development strategy revised, and cost-saving initiatives implemented
- FDA meeting sought to discuss PARADIGME protocol amendments designed to enlarge eligible patient population and increase rate of enrolment
  - PARADIGME timelines under review
- Planned restructuring completed
  - Malene Brondberg appointed as Chief Financial Officer
  - Corporate and personnel reorganisation implemented
  - Headcount reduced by approx. 20%
  - Cost savings of approx. NOK 35 million in connection with the restructuring on an annual basis
- Betalutin® recommended for Orphan Drug Designation for Marginal Zone Lymphoma (MZL) in EU

# STRATEGIC REVIEW - FOCUS ON ADVANCING PARADIGME AND EXTENDING CASH RUNWAY

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# Revised clinical development strategy to capture significant value from Betalutin® in NHL

## Core Focus

### PARADIGME

**Single-agent Betalutin® 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
  - Orphan Drug Designation recommended reflecting unmet need
  - Possibility to augment patient flow into PARADIGME leveraging existing infrastructure

## Under Review

### Archer-1

**Betalutin® + 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® in DLBCL**

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

**Goal: Develop differentiated target product profile for Betalutin® to meet requirements of NHL patients, KOLs, regulatory and reimbursement agencies**



NHL – Non-Hodgkin's Lymphoma; R/R – relapsed/refractory; KOLs – Key opinion leaders

# Revised development plans

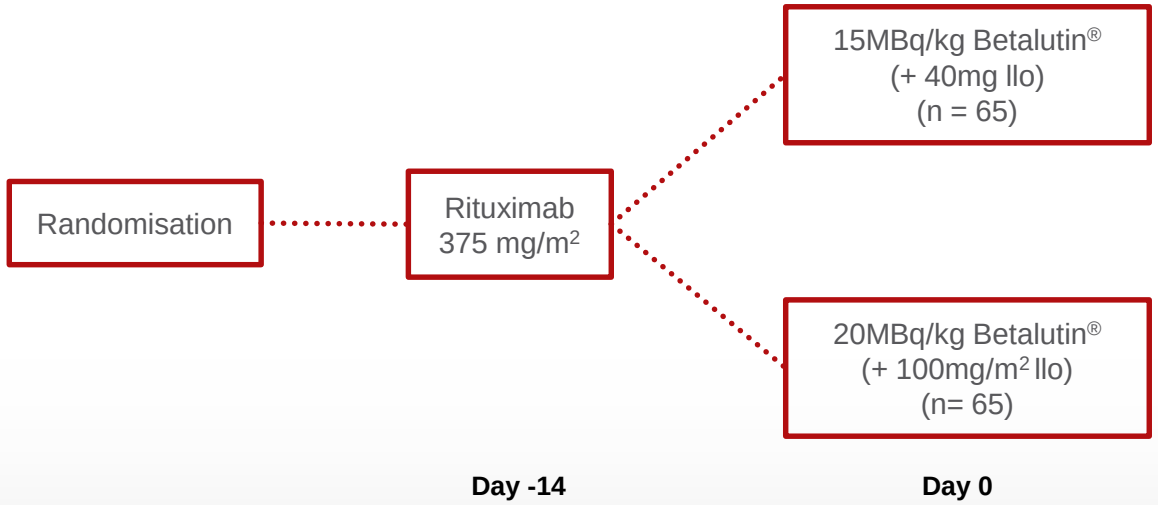
- Focus exclusively on PARADIGME
  - Pause enrolment into Archer-1 & LYMRIT 37-05 following completion of current cohorts
  - Pause all pre-clinical and research initiatives (Alpha37) after IND submission
- Formal meeting request filed with US FDA
  - Seek expansion of inclusion criteria to increase the pool of eligible patients
- Improve execution of PARADIGME
- Align CMC activities with clinical timelines
- Target top-line PARADIGME data in 2021
- Submit BLA in US based on results, if positive



IND – Investigational New Drug; FDA – Food and Drug Administration; BLA – Biologics License Application

# Resources prioritised towards PARADIGME

- **Patient population**: 130 3L FL patients who are refractory to anti-CD20 therapy
- **Primary endpoint**: Overall response rate (ORR)
- **Secondary endpoints**: Duration of response (DoR), Progression free survival (PFS), Overall survival (OS), Quality of life (QoL)




- 51 patients have been enrolled (as of May 25th, 2020)
- 95 sites in 24 countries open for enrolment



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# Improved trial execution

- Actions taken
  - Enhanced working relationship with CRO and interactions with study investigators
  - Implemented better patient referral networks
- Impact of actions blunted by COVID-19, which has adversely effected PARADIGME
  - Target patient population is at high risk (>70 years of age, fragile)
  - Restricted movement has prevented follow-up visits and data collection on existing patients, and dosing of newly enrolled patients
  - Hospital resources for clinical trials re-prioritised
- Easing of COVID-19 lockdown enabling cancer clinical trials to restart
  - Remain in close contact with investigators – increased enthusiasm for trial and potential of Betalutin®



CRO – Clinical Research Organisation; KPIs – Key Performance Indicators

# Improving the PARADIGME protocol

- Meeting with FDA
  - “Briefing Book” submitted
  - Seek expansion of inclusion criteria to increase the pool of eligible patients

- PARADIGME protocol amendments to be filed after review of feedback
  - FDA response expected late Q2/Q3
  - Following FDA response, estimate 2-3 months to gain approval for protocol amendments with regulators in all 24 countries
  - Working closely with CRO to maximise enrolment once the new protocol is approved

# COST-SAVING INITIATIVES AND CORPORATE REORGANISATION

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# Cost-saving initiatives implemented

- Headcount reduced by approx. 20%
- Consolidated number of leadership functions
- Ongoing focus on core clinical and CMC activities
  - Spending on CMC aligned with progress with PARADIGME
- Members of the Board of Directors will voluntarily reduce their fee by 20% for board year 2019/2020

- Financial impact of changes will materialise gradually
  - Cost savings of approx. NOK 35 million in connection with the restructuring on an annual basis
  - Q2 results will reflect costs associated with these organisational changes
  - Management will continue to seek further efficiencies

# Organisational changes

- The restructuring efforts have affected approx. 30% of our team
- Changes to the management team
  - New interim CEO (Lars Nieba) and interim CMO (Dominic Smethurst)
  - New CFO (Malene Brondberg) with expanded role incorporating finance, HR and IR/communications
- Focus on organisational efficiency – consolidation of certain staff functions
  - Expand roles of certain key individuals – move talented people into new functional roles
- Increased involvement by Chairman and other members of the board
  - Chairman will work closely with the CEO
  - Clinical Strategy Committee is involved in revised clinical strategy

# FINANCIAL RESULTS FOR Q1’2020

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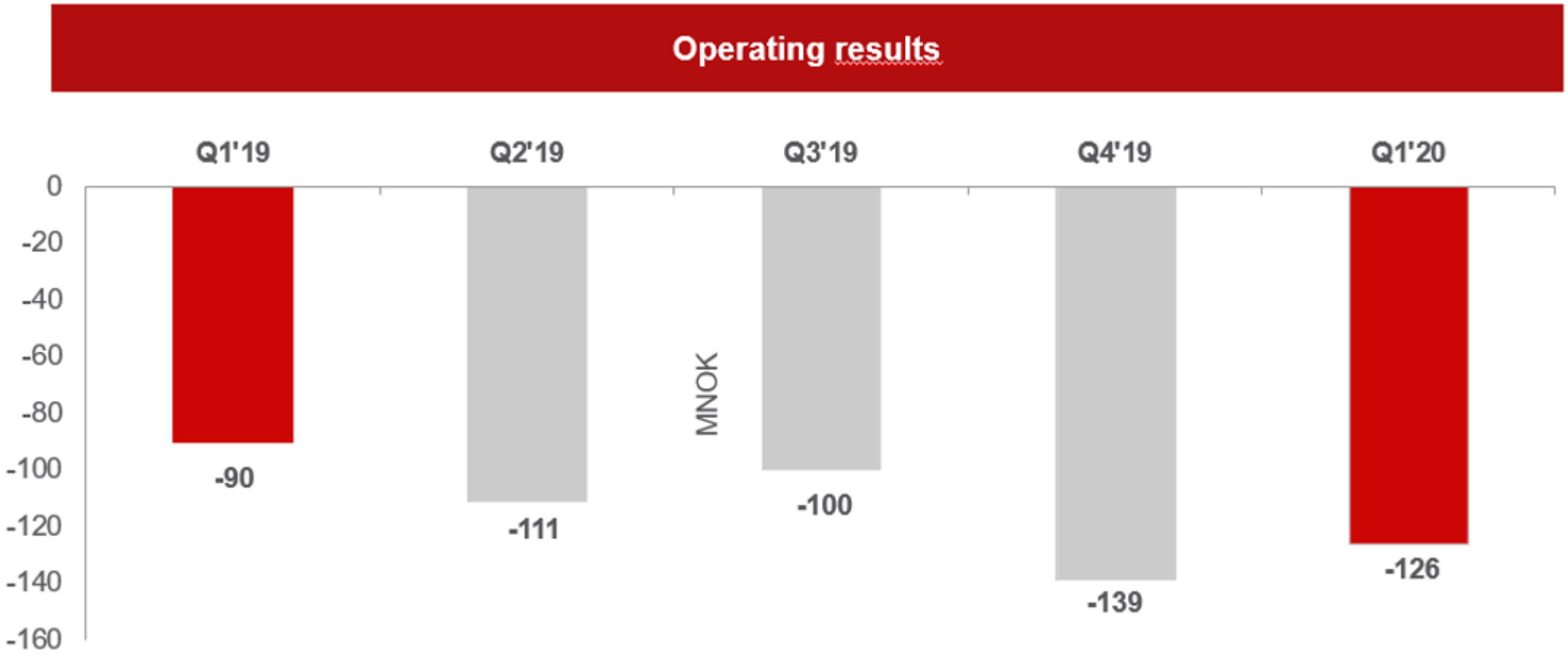
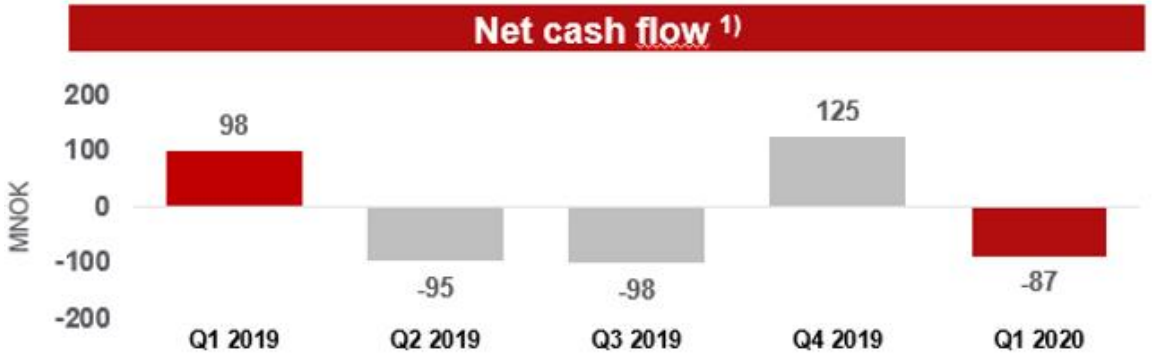
# Investing in Betalutin®



# Cash runway extended into 2021





- Net cash from operating activities of NOK -116.0 million (Q4: MNOK -100.5)
- Cash and cash equivalents amounted to NOK 384.3 million end of March 2020
- We have executed the restructuring plans announced on April 1st and implemented several cost-saving initiatives to extend our cash runway into 2021
- We will continue to review other cost lines during Q2'2020. Overall, we expect these lower operating costs will materialise during the second half of the year



* USD/NOK 8.76
** USD/NOK 10.49

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

# We are focused on PARADIGME

- We continue to target the readout of top-line data from PARADIGME in 2021
- Current COVID-19 situation has prompted review of enrolment timeline for PARADIGME, which previously was guided for H2’2020
- We expect to provide updated timelines for PARADIGME once we have received all relevant regulatory feedback from FDA and when we have more clarity on the impact of COVID-19
- PARADIGME – Reconfirming top-line data in 2021 (despite headwinds from COVID-19)
  - FDA meeting to discuss proposed protocol amendments
  - Seek approval for protocol amendments from authorities in all 24 countries
  - Evaluate opportunity and clinical development strategy in R/R MZL
  - Submit BLA in US based on results, if positive
- Our confidence in potential of Betalutin® to fulfil important unmet needs in NHL remains unchanged

# Financial calendar

| | |
|---|---|
| **AGM** | **10 June 2020** |
| **Oslo Q2 2020 results** | **27 August 2020** |
| **Oslo Q3 2020 results** | **19 November 2020** |

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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# *Questions*