

# BIONOR

FOURTH QUARTER AND FULL YEAR 2015 RESULTS



Q4 2015

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12 FEBRUARY 2015



# AGENDA

- CLINICAL AND OPERATIONAL HIGHLIGHTS
- REDUC RESULTS
- STRATEGY AND LONG-TERM CAPITAL NEED
- FINANCIAL REVIEW AND 2016 OUTLOOK



## HIGHLIGHTS Q4 2015

- Successful completion of the HIV 'Shock & Kill' trial REDUC with Vacc-4x and romidepsin, which met its endpoints by demonstrating control of viral load and a reduction of the latent HIV reservoir
- Submission of a clinical trial application (CTA) to the Danish Medicines Agency requesting approval to initiate BIOSKILL in Denmark
- At a Capital Markets Day in Oslo 7 October, the company presented its revised company strategy and development plans for advancing toward a functional cure for HIV
- Strategic augmentation of its Clinical Advisory Board to emphasize the company's focus on functional HIV cure
- 11 February 2016, the company's shareholders approved the completion of a private placement raising NOK 45 million in gross proceeds, which is expected to fund the company through the first half of 2016, and a subsequent repair offering for existing shareholders
- 1 February 2016, Bionor was granted up to NOK 9.2 million from Research Council of Norway to further advance Vacc-4x in a combination treatment regimen.



## REDUC HIGHLIGHTS

**The HIV 'Shock & Kill' trial REDUC Part B successfully demonstrated control of viral load after administration of Vacc-4x and romidepsin, and met its primary endpoint by reducing latent HIV reservoir**

- Viral load remained below the level of quantification in 11 out of 17 patients on cART despite reservoir reactivation
  - Only four patients had measurable but low HIV in the blood after only one of the three romidepsin infusions, and only 21-59 copies/ml
  - Only two patients had detectable viral load after each of the three romidepsin infusions
- The latent HIV reservoir was significantly reduced by 40% measured by Total HIV DNA ( $p=0.012$ ,  $n=16$ ) and HIV quantitative viral outgrowth assay ( $p=0.019$ ,  $n=6$ )
- The combination of Vacc-4x and romidepsin was safe and well tolerated



# **BIONOR IS WELL POSITIONED TO ADVANCE VACC-4X TO EXPECTED MAJOR VALUE INFLECTION POINTS AND POSSIBLE PARTNERING**

FIRST MOVER POTENTIAL

CONVINCING CLINICAL DATA AND CLEAR DEVELOPMENT STRATEGY

FULL PROPRIETARY RIGHTS TO VACC-4X PRODUCT CANDIDATES

TARGETING GLOBAL HIV MARKET WITH SIGNIFICANT COMMERCIAL POTENTIAL

STRONG BOARD & MANAGEMENT

INTERNATIONAL CLINICAL ADVISORY BOARD WITH WORLD-LEADING KOLs

# ANTICIPATED OUTLINE FOR ADVANCING A FUNCTIONAL CURE FOR HIV

A functional cure for HIV requires a combination of agents

Phase II trial with a triple regimen



**SUCCESSFUL COMPLETION OF REDUC**  
*'Shock & Kill' proof of principle*

**BIOSKILL** to confirm 'Shock & Kill'  
Exploratory studies testing agent combinations

Pivotal Phase III trials for registration of final drug

★  
BIOSKILL STARTUP

EXPLORATORY STUDIES

★  
BIOSKILL FINAL RESULTS

Phase II  
Vacc-4x + LRA\*+IRA\*

Phase III  
Vacc-4x + LRA+IRA

2016	2017	2018	2019	2020+
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\* LRA: Latency Reversing Agent; IRA: Immune Regulating Agent



# FEB 2016 PRIVATE PLACEMENT AND LONG-TERM CAPITAL NEED

## Private placement of NOK 45 million – Approved at EGM 11 February 2016

- Proceeds from the private placement are expected to provide financial resources to prepare the company for BIOSKILL and related clinical activities, and for working capital and other general corporate purposes, including for fulfilling the company's outstanding contractual obligations and existing payment obligations
- Repair Offering for existing shareholders 16 February – 1 March 2016

## Long-term capital need

- The company is planning to conduct an equity offering during the first half of 2016, before initiation of the BIOSKILL clinical trial and related clinical activities
- The company's capital need is estimated to approximately NOK 375-425 million, from third quarter 2016 to first quarter 2019, equivalent to the period from initiation of BIOSKILL clinical trial until 6-9 months after the expected announcement of final results of BIOSKILL clinical trial



## ALLOCATION OF LONG-TERM CAPITAL NEED (2016-2019)

The estimated total capital need from third quarter 2016 through first quarter 2019 is based on the below mentioned clinical trials and activities:

- The BIOSKILL Phase II clinical trial with Vacc-4x administered with an adjuvant (GM-CSF) and given prior to a latency reversing agent (romidepsin).
- A Phase II randomized, double-blind clinical trial to document the effect of GM-CSF on Vacc-4x immunogenicity
- An exploratory Phase I/II clinical trial to evaluate an immune regulating agent in combination with Vacc-4x
- An exploratory Phase I/II clinical trial to evaluate a latency reversing agent with a more convenient route of administration than what is currently possible with romidepsin
- Making a liquid formulation of Vacc-4x, which is currently presented as a powder for injection, available in a pre-filled syringe prior to initiation of a Phase III program
- Strengthening of the internal clinical development organization
- The remainder for working capital and other general corporate purposes.

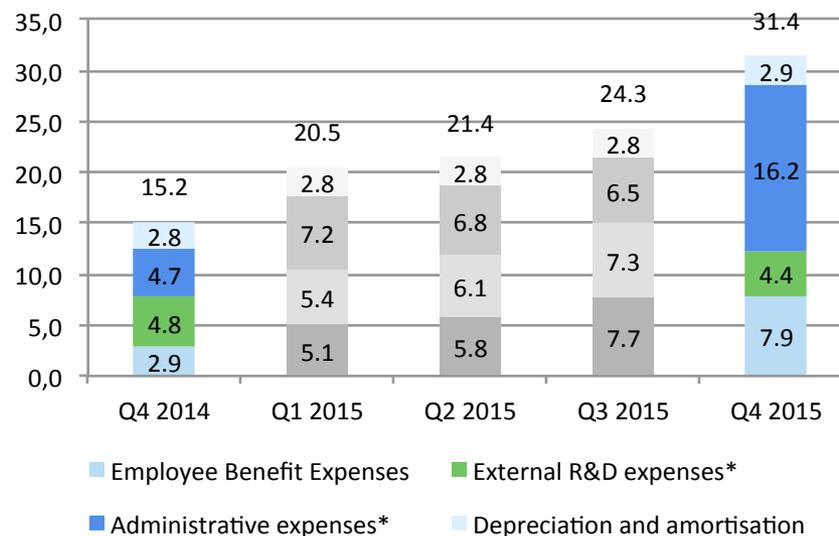
# FINANCIAL REVIEW



# INCOME STATEMENT

- Q4 Employee Benefit Expenses amounted to NOK 7.9 million (Q4 2014: NOK 2.9 million)
  - Hiring of new Executive Management
- Q4 Other operating expenses was NOK 20.6 million (Q4 2014: NOK 9.5 million)
  - Company infrastructure
  - Fee unrealized equity raise
- FY Employee Benefit Expenses amounted to NOK 26.5 million (FY 2014: NOK 13.8 million)
- FY Other operating expenses was NOK 59.8 million (FY 2014: NOK 45.1 million)

## TOTAL OPERATING EXPENSES NOK million



\*) External R&D expenses + Administrative expenses  
= Other operating expenses

## CORE COST BASE AND FINANCIAL OUTLOOK 2016

In NOK millions	Q4 2015	Q4 2014	FY 2015	FY 2014
Employee Benefit Expenses	7.9	2.9	26.5	13.8
+ Other operating expenses	20.6	9.5	59.8	45.1
- External R&D expenses	4.4	4.8	23.1	30.2
<b>Core cost base</b>	<b>24.1</b>	<b>7.6</b>	<b>63.1</b>	<b>28.6</b>

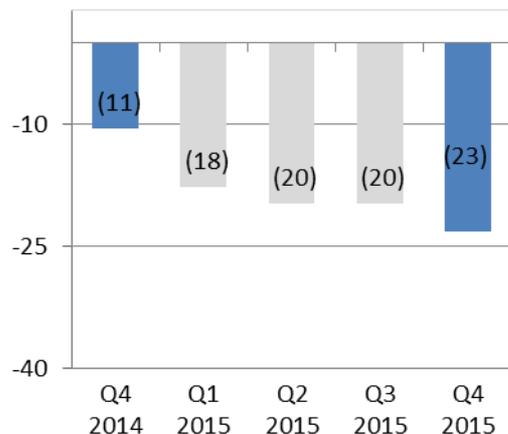
- Monitoring of financial performance and basis for financial outlook
- Costs required to run the company, excluding External R&D expenses, which can vary over time
- **For the full year 2015, Bionor met its financial guidance for 2015 of a Core cost base in the range of NOK 55 - 63 million. The Core cost base amounted to NOK 63.1 million**
  - Increase in Core cost base compared to 2014 related to invigoration of company strategy, management and infrastructure to maintain first mover potential to advance toward a possible functional HIV cure, and costs related to preparation of an unrealized equity raise in 2015
- **For the full year 2016, Bionor expects the Core cost base to be in the range of NOK 58 - 66 million**

Due to rounding differences certain summations might not add up. Please refer to note 4 on page 14 in the Q4 2015 Interim Financial Report for further specification of external R&D expenses

# CASH FLOW AND NET CASH

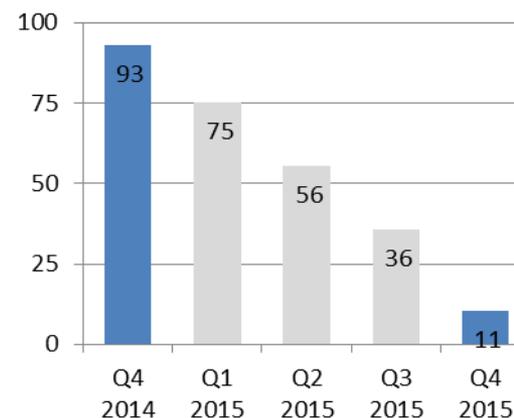
## CASH FLOW FROM OPERATING ACTIVITIES

NOK million



## NET CASH

NOK million



- Cash flow from operating activities was NOK -23.3 million (Q4 2014: NOK -10.6 million)
- Net cash flow was NOK -25.2 million (Q4 2014: NOK -10.6 million)

- Cash at hand at period end NOK 10.6 million (Period end 2014: NOK 93.1 million)
- Capital raise of gross NOK 45 million in February 2016



# Q&A

## **Further information**

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