

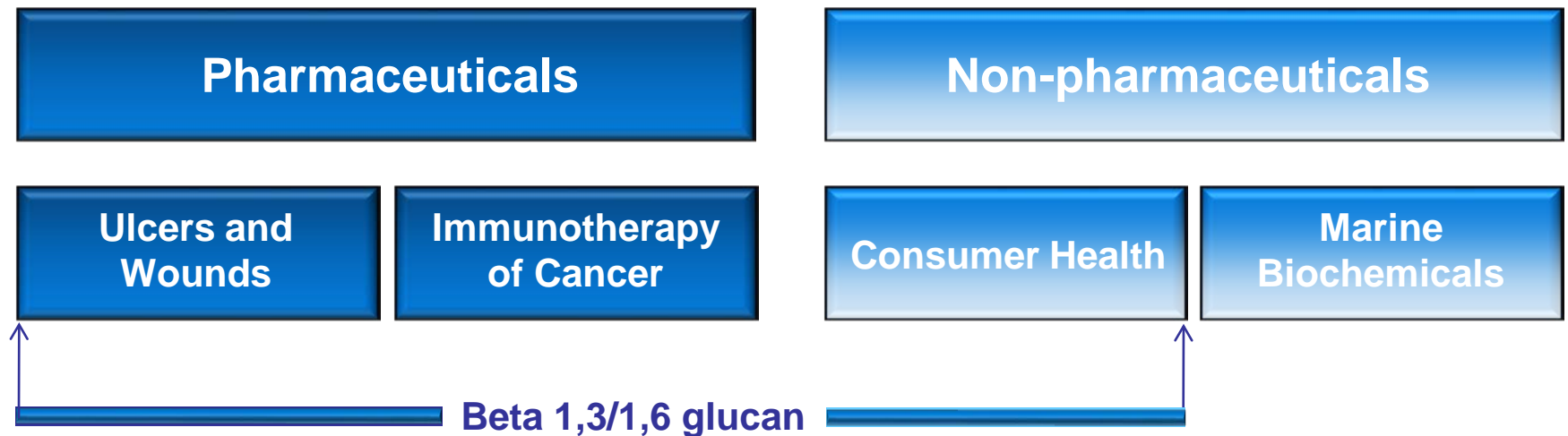


## **Second quarter and first half year 2009**

CEO Lars Viksmoen  
CFO Jørn Lunde  
MD Jan Buch Andersen

August 11, 2009

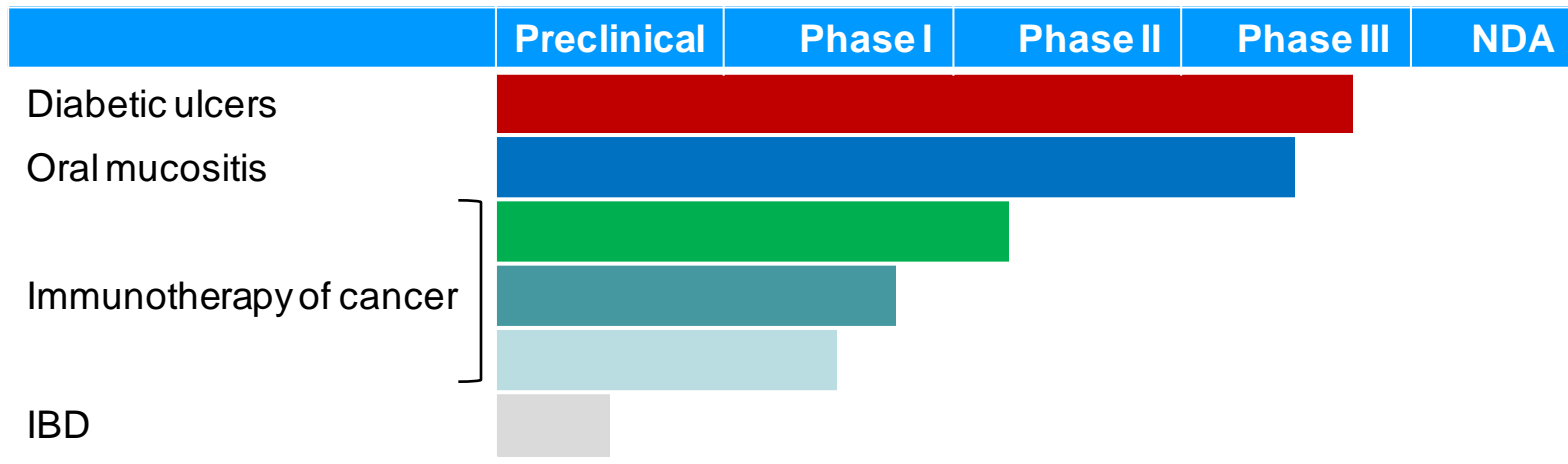
# Biotec Pharmacon overview



Pharmaceutical R&D

Commercial non-pharma production, marketing and sales

# SBG - Clinical development portfolio



- Addressing unresolved medical problems in major disease areas
- No well established therapies, few new product candidates in development
- Commercial aspects of SBG:
  - Innovative products - attractive pricing,
  - Underdeveloped market - high growth potential,
  - Hospital products - easier market access

# Key financials

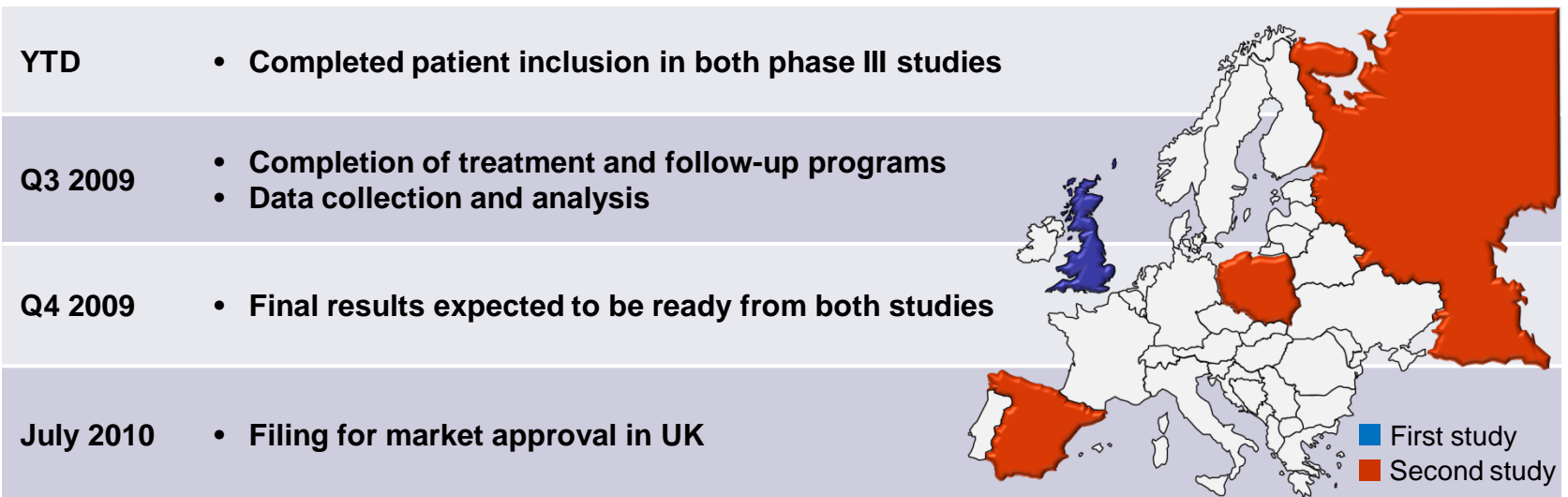
NOKm	Q209	Q2 08	H1 09	H1 08	2008	Q1 09
Revenue	11.4	14.3	23.7	26.2	51.7	12.3
EBITDA, non-pharma	0.2	-1.1	-0.6	-3.8	-5.6	-0.8
EBITDA, pharma R&D	-20.1	-10.0	-36.0	-21.0	-72.0	-15.9
EBITDA, unallocated	-0.9	-3.5	-1.1	-5.1	-10.3	-0.2
EBITDA, total	-20.8	-14.6	-37.7	-29.9	-87.9	-16.9
Net result for the period	-20.6	-12.3	-36.8	-26.9	-52.2	-16.1
Cash flow from operating activities	-26.7	-13.1	-43.1	-21.6	-65.7	-16.4

# Phase III – diabetic foot ulcer

## Two pivotal studies



Blue area = periods of patient inclusion, black areas = periods of study completion and reporting



# Preparing for filing of Market Authorisation Application (MAA)

- **Contracted regulatory CRO to assist in development of a well-documented application file**
  - Chosen global CRO in line with plans for later applications in the US and other markets
- **Decided on process for filing of MAA in Europe**
  - Will apply in EU/EAA under a Decentralized Procedure with UK as Reference Member State (RMS)
  - Benefits compared to a alternative filing application procedures
- **Allocated slot in July 2010 for submission of MAA in UK**
  - Received confirmation from UK Regulatory Agency (MHRA) in early July

# Alternative MAA filing procedures

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## 1. Decentralised procedure

- + Flexibility regarding which countries to include
- + Flexibility regarding selection of RMS
- + Delayed payment scheme for SME-companies
- Somewhat more costly

## 2. Centralised procedure

- All or nothing
- Limited flexibility

## 3. Local approval followed by mutual recognition procedure

- Low agency priority
- Less predictable with regards to timing

# Preparation of MAA

## - A challenging task for a small company

- **General information**

- Summary of Product Characteristics
- Patient Information Leaflet and Labeling
- Pharmacovigilance System
- Risk Management Plan
- Pediatric Investigation Plan
- Environmental Assessment

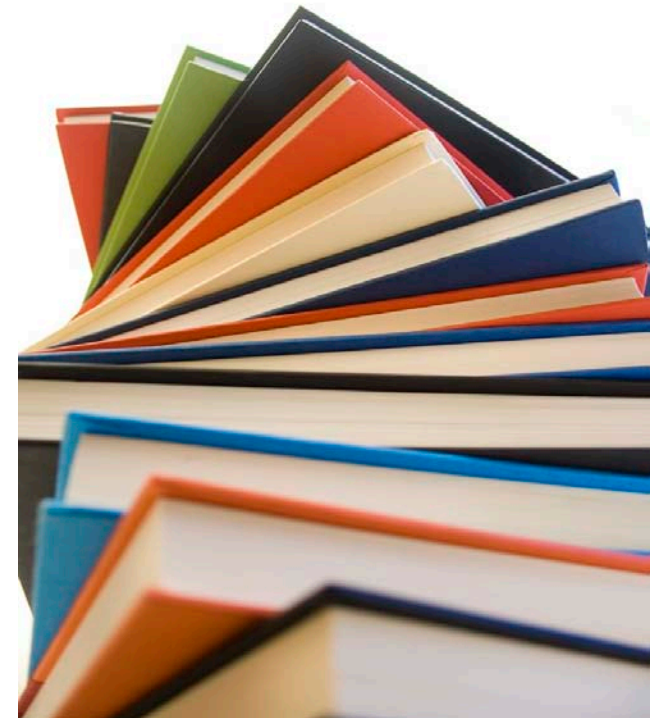
- **Data and complete reports**

- Product, manufacturing and control
- Pre-clinical data on pharmacology, pharmacokinetic & toxicology
- Clinical

- **Summaries and expert reports**

**Approx. 15.000 pages**

- **Electronic file**
- **Hard copies**





# Addressing major unmet medical needs

## Sizeable markets\*:

250+ million adult diabetics, growing at ~2.5% p.a.

1 in 6 diabetics develop an ulcer at some stage

## Serious condition\*:

15%-25% of diabetics with foot ulcer require amputation

85% of diabetics' leg amputations are preceded by ulcers

70% of all leg amputations happen to diabetics

People with diabetes are 25 times more likely to amputate a leg

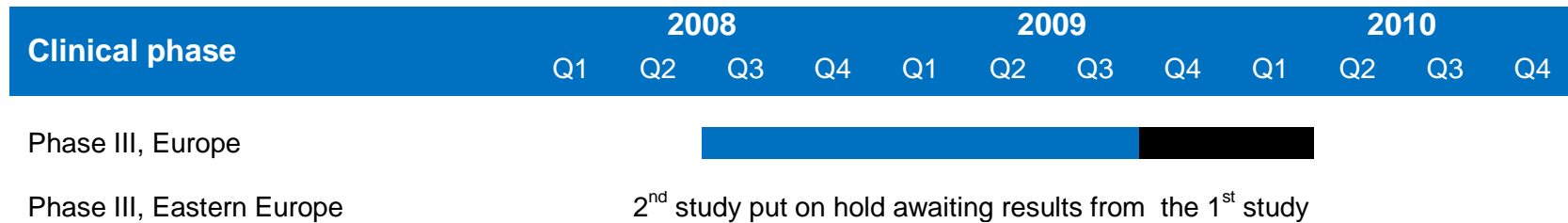
## Therapies:

No standard drug treatment, only hygiene/general wound care

## SBG approach:

SBG reactivates skin immune cells and enhances the body's own wound healing capabilities

# Oral Mucositis – Clinical Program



*Blue area represent periods of patient inclusion, black areas represent periods of study completion and reporting*

- **Patient enrolment nearing completion**

- Sample size increased from 120 to 130 patients due to withdrawals
- 124 patients included to date, at ~20 centres in three countries in Europe
- Interim study based on first 92 patients prompted no changes to sample size

- **Study results expected in Q1 2010**

- Possible 2<sup>nd</sup> study and timing of filing pending these results

# Pipeline – immunotherapy of cancer

- Phase I/II studies with SBG in combinations with mAbs for;
    - **Neuroblastoma**
    - **Non-Hodgkins' lymphoma**
    - **Breast cancer**
- } **Patient enrolment:  
Completed in all  
three studies**
- Two patients still being treated in the neuroblastoma study (MSKCC), awaiting report on final data
  - Primary end-points in all studies to demonstrate safety; no significant adverse effects reported
  - Decision on further progress following final results from MSKCC study

# Maximising shareholder value: Awaiting data before entering partnership(s)

- **Decided to await the results of the ongoing phase III program**
  - A commercial decision based on risk/reward assessments;
    - Pharma & Big Biotech – mitigation of risk in times of financial constrain
    - Pharma & Big Biotech – escalated need for new products
    - Confirmed results & established road through filing – triggers “actions”
- **Continuing to widen the network among potential partners within dermatology, therapy and supportive care of cancer, cancer and immunotherapy**
  - Participated in 8 partnering events globally so far this year
  - Established >100 company contacts and entered into >20 confidentiality agreements
  - Confirmed presentations on at least 6 international conferences in the second half 2009

# Immunocorp Consumer Health

## nbg<sup>®</sup> 24:7 series - dietary supplements and skin creams

**Revenue decrease of -34% in Q2'09 and -26% in H1'09, but improved results due to reduced sales and marketing costs**

### Norway:

- Significantly lower marketing efforts - explains both slight revenue decline and improved results
- Sales mix: ~40% skin care and ~60% dietary supplements
- Expect product launches and possibly also international sales agreements to trigger growth in H2'09

### US:

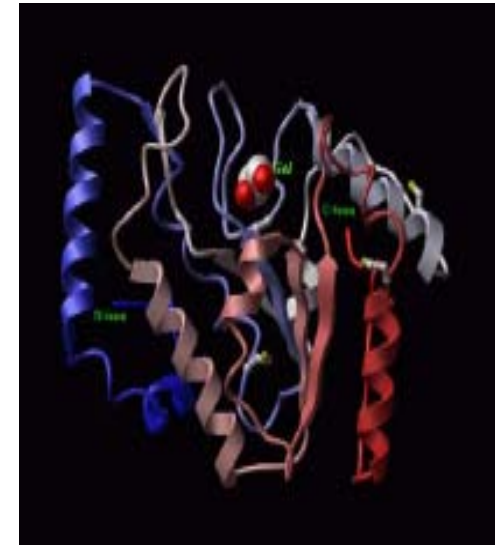
- Revenue decline in skincare, due to low consumer spending and reduced marketing and direct mail
- Improved result due to the cost reductions
- Sales mix: ~35% skin care and ~65% dietary supplements
- Expects continued slow demand



# Biotec Marine Biochemicals

## Enzymes for genetic R&D and diagnostics

- Revenue increase of 31% in Q2'09 and 70% in H1'09
- Positive contribution to operating profit from Q2'09
- Higher deliveries of both SAP and Cod-UNG
- Strengthened business focus:
  - All marine enzyme activities organized in new separate company – **Biotec Marine Biochemicals AS**
  - **Jan Buch Andersen** hired as Managing Director
    - >15 years of experience from molecular biology and companies like Invitrogen and Roche Diagnostics
- Targets continued strong growth internationally in the years to come
- Revenue of NOK 15 million and EBITDA-margin of ~40% expected for 2009



Molecular structure of Atlantic Cod-UNG

# Biotec Marine Biochemicals (BMB)

Constantly expanding market

**Total market expanding – new applications being introduced at a rapid rate**

## Research Applications:

- **PCR** – research tool for “any” genetic research project – ie constant introduction of new methods
- **Extraction of DNA/RNA or Protein** – numerous extraction platforms and home brew
- **New technologies** – High Throughput Sequencing, Microarrays, Genotyping etc.

## Diagnostic Applications:

- **Rapid rate for introduction of new tests** (eg. H1N1 – numerous tests already available)
- **Personalised medicine** – instead of just diagnosing a disease the many tests are intended to be used to monitor Minimal Residual Disease during treatment as a tool to optimise disease treatment – ie. many tests instead of just one per patient
- **Need for more extraction capacity** – with more tests a growing need for approved extraction systems
- **General advantage with Nucleic Acid Testing** – increased sensitivity, actual data, treatment decisions

# Biotec Marine Biochemicals (BMB)

## Unique product properties

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### Activity at low temperature:

- **Perform reaction at temperature not interfering with later process stages** – many protocols involve temperature shifts so our product can be used in a very conserved way

### Inactivation at relatively low temperature:

- **Inactivation irreversible** – “normal” enzymes not always 100% inactivated
- **Inactivation at non-interfering temperature** – Inactivation takes place at temperatures non-interfering with subsequent PCR reactions
- **Heat inactivation an excellent alternative to extraction** – In multienzyme reactions previous activity must be eliminated before next step. Heat-inactivation = no loss of precious DNA/RNA.

**More unique properties being introduced shortly !**



# Biotec Marine Biochemicals (BMB)

## Increasing sales activities

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**Biotec Marine Biochemicals expects to double sales from 2009-2012**

**How?**

### **Increase in sales activities**

- Implementation of direct sales activities (B2B)
- Increased presence in front of customers (conferences, exhibitions etc.)
- Optimization of sales channels to reach more customers (web, distributors, direct sales – B2B or B2C)
- Branding of BMB as a high quality supplier of unique products

### **Introducing of a range of new products**

- Some new products are ready for introduction this fiscal year
- New product development based on market needs
- Utilize access to unique product opportunities – Unique "Arctic" properties

# Ambitious, but realistic goals

## Why is this doable?

- **Increased customer knowledge**

- Very few people know us (<40 companies), and current sales has been obtained with very few customers (<10)
- We have very few references in the scientific literature, but many coming

- **Increasing product portfolio**

- Products have numerous and universal applications in molecular biology
- Products are well protected with in-house IP
- Current sales has been obtained with only 3 products
- More products are ready for launch
- Strong platform for discovery of new product opportunities

### **Most importantly:**

**Biotec Marine Biochemicals is now a dedicated and focused company with a scope of exploiting the market potential outlined – bringing the company to a new level**

# **Financial Figures**

## **Second quarter and first half year 2009**

# Financial Highlights

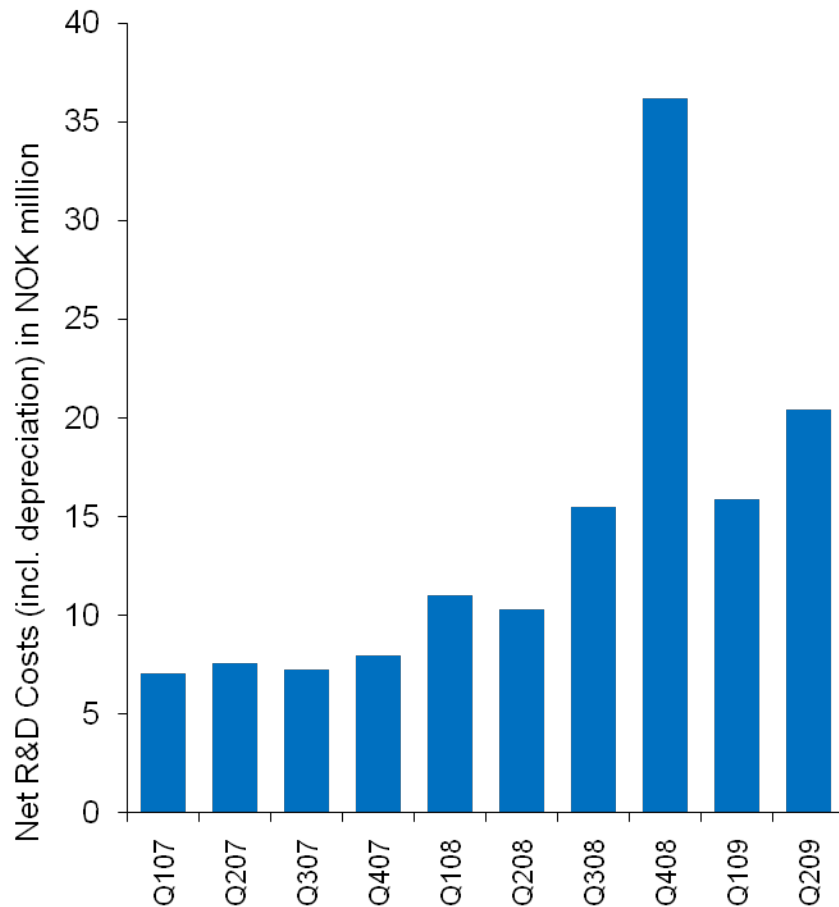
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EBITDA, total	-20.8	-14.6	-37.7	-29.9	-87.9	-16.9
EBIT	-21.6	-15.4	-39.2	-31.5	-91.3	-17.6
Net financials	1.0	2.0	2.5	3.9	8.3	1.5
Profit before tax, continued operations	-20.6	-13.4	-36.8	-27.7	-83.0	-16.1
Net profit, continued operations	-20.6	-13.4	-36.8	-27.7	-78.8	-16.1
Net profit, discontinued operations	-	1.0	-	0.7	26.6	-
Net result for the period	-20.6	-12.3	-36.8	-26.9	-52.2	-16.1

# Non-pharmaceuticals

	Q2'09	Q2'08	Growth	H1'09	H1'08	Growth	2008	Q4'08
Consumer Health	6.8	10.4	-34%	15.4	20.8	-26%	38.9	8.5
Marine Biochemicals	4.4	3.4	31%	7.8	4.6	70%	11.6	3.4
Other	0.1	0.6	-79%	0.5	0.6	-23%	1.1	0.4
Revenue non-pharma	11.4	14.3	-21%	23.7	26.2	-9%	51.7	12.3
Other OPEX (net)	-11.2	-15.4		-24.3	-30.0		-57.3	-13.1
EBITDA	0.2	-1.1		-0.6	-3.8		-5.6	-0.8
Depreciation	-0.5	-0.5		-0.9	-1.0		-2.0	-0.5
EBIT	-0.3	-1.6		-1.5	-4.8		-7.7	-1.3

# R&D Cost Development

## Increasing with breadth of phase III program

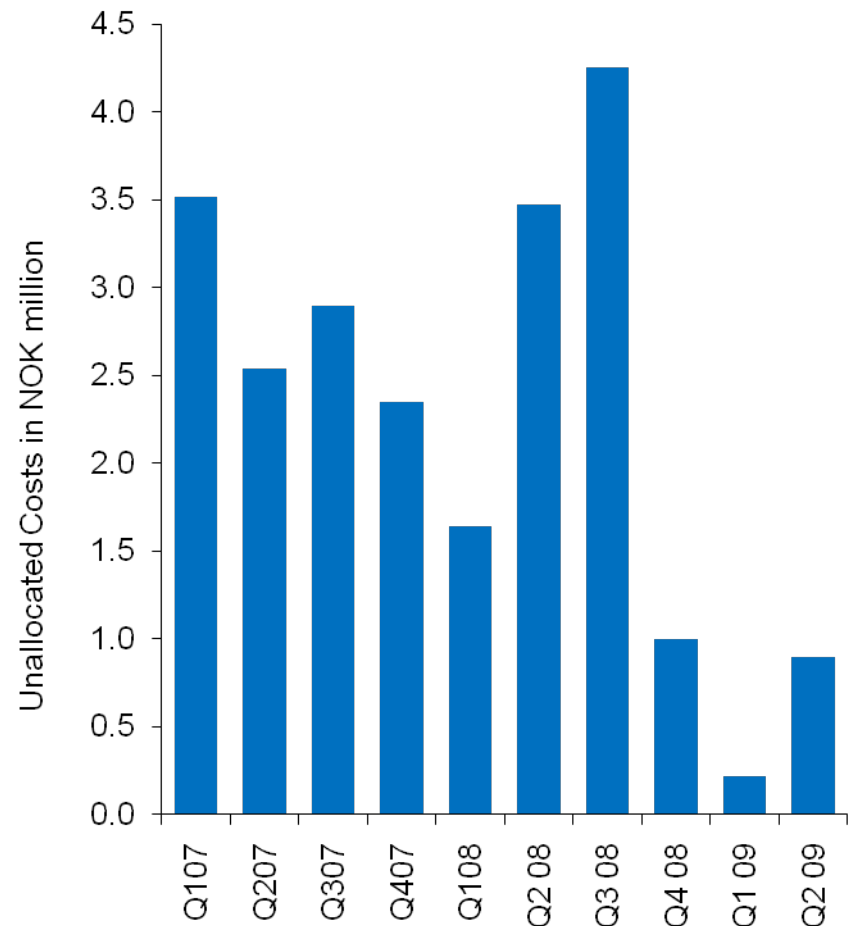


- **Q2'09 cost level in line with company expectations**
  - Below estimates in Q1'09 due to positive currency effects
- **FY'09 estimate for R&D remains unchanged at NOK 85-90 million**
  - Up from NOK 72 million in 2008

# Unallocated Costs

Less complex patent case = lower costs

- **Relatively low cost level until court case**
  - Favourable ruling in January dismissed 12 of 14 claims from US competitor
  - Only claims under two patents and defamation claims proceed to court
  - Court case scheduled to start 14 September, 2009



# Cash Flow

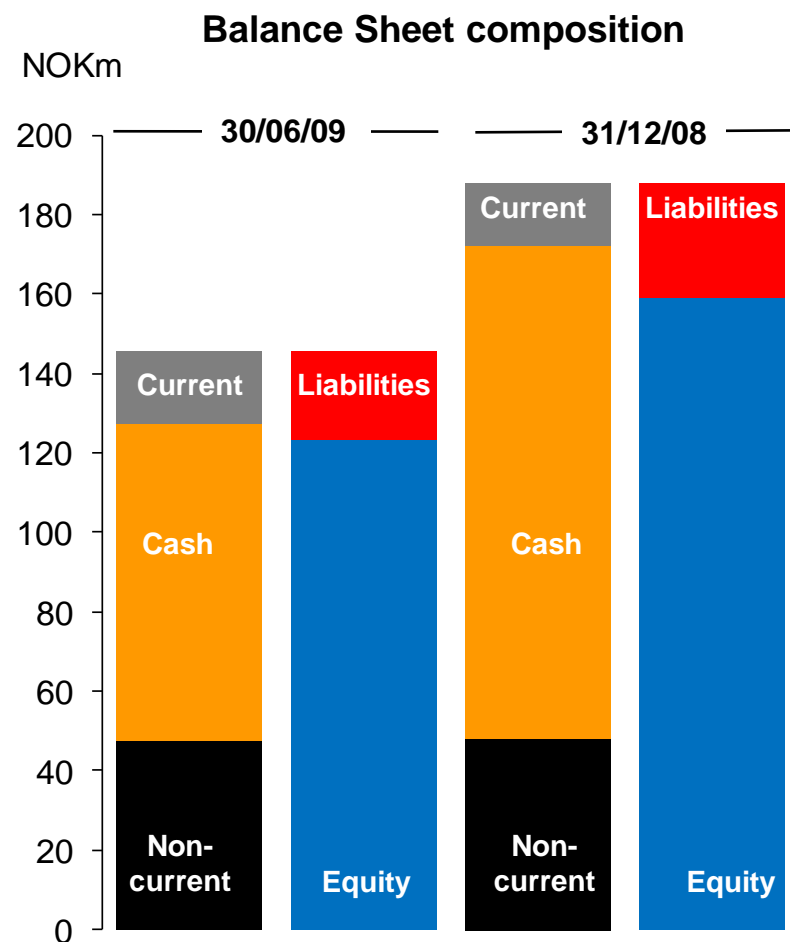
NOK ('000)	Q2 09	Q2 08	H1'09	H1'08	2008	Q1 09
CFI from operating activities	-26,715	-13,111	-43,086	-21,572	-65 657	-16 371
CF from investing activities	-1,553	-1,077	-1,520	-1,478	36 491	33
CF from financing activities	-	-	-	-	-45	0
Cash flow in the period	-28,268	-14,188	-44,606	-23,050	-29 211	-16 338
Currency conversion differences	-98	-4	-202	-194	683	-104
Cash and cash equivalents, beginning of period	108,148	142,648	124,589	151,700	149 641	124 589
Cash and cash equivalents, end of period	79,782	128,456	79,782	128,456	121 113	108 148



# Consolidated Balance Sheet

## Condensed figures

(NOK '000)	30.06.09	31.12.08
Non-current assets	47 719	47 818
Cash and cash eq.	79 782	124 589
Other current assets	18 044	15 349
Total current assets	97 826	139 938
<b>Assets</b>	<b>145 545</b>	<b>187 757</b>
Equity	123 152	159 264
Liabilities	22 393	28 493
<b>Equity &amp; Liabilities</b>	<b>145 545</b>	<b>187 757</b>
Equity Ratio	85%	85%



# Summary

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- On track to file for market authorization application (MAA) with SBG for diabetic foot ulcer in UK in July 2010
- UK to act as reference member state in decentralised procedure in EU/EAA
- Maximising shareholder value - awaiting study results before entering partnership(s)
- Progressing as planned with first phase III study with SBG for oral mucositis – no adjustment of sample size after interim analysis
- Awaiting final results from MSKCC before deciding on the road ahead for the immunotherapy of cancer portfolio
- Overall improved results in non-pharma

# Outlook

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- Q3'09:** Completing treatment/follow-up of diabetic foot ulcer patients
- Q4'09:** Results from both phase III studies for diabetic foot ulcer  
Completing treatment and follow-up of oral mucositis patients  
Ruling in the Biothera patent case
- Q1'10:** Results from first phase III study for oral mucositis
- July 2010:** Filing for MAA in Europe for diabetic foot ulcer

**FY'09 cost estimate for R&D remains unchanged at NOK 85-90 million**

**Process in place to increase financial flexibility and secure funding through 2010**

**Continue working to secure value-enhancing partnership deals**