

# Third quarter 2009

*Presentation 3 November 2009*

*CEO Morten Jurs and CFO Synne H Røine*



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# Q3 highlights

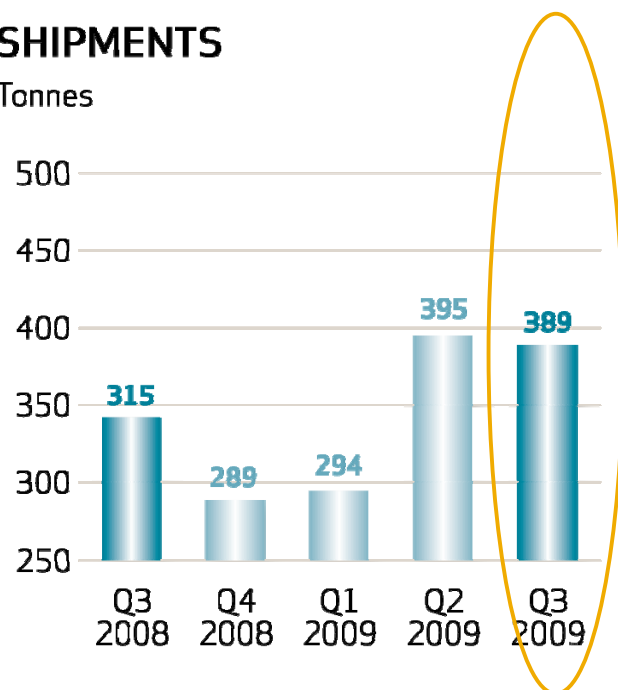
- **Production started in Kalundborg**
  - *enabling future growth potential with double capacity*
- **No generic entrance in the EU**
  - *IBSA Italian application for marketing authorisation rejected*
- **The strong operational performance continues**
  - *396 tonnes produced and 389 tonnes shipped*
  - *revenue growth in all regions*
  - *continued growth in EBITDA*
- **Strong operational cash flow and improved financial position**
  - *NOK 164.8 million from operating activities*
  - *Kalundborg capital expenditures near completion*



# The strong operational performance continues

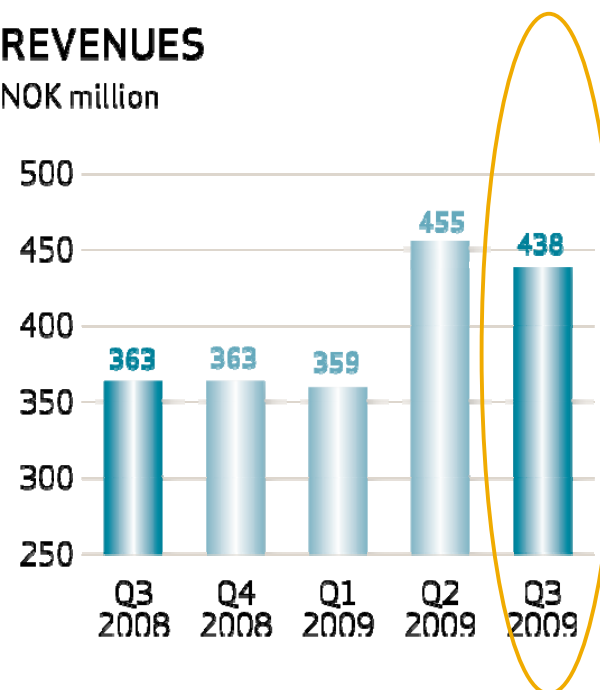
## SHIPMENTS

Tonnes



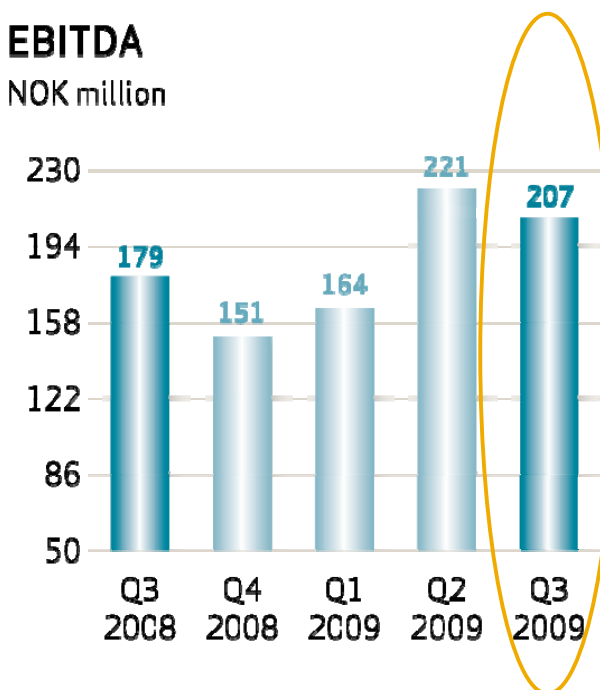
## REVENUES

NOK million



## EBITDA

NOK million



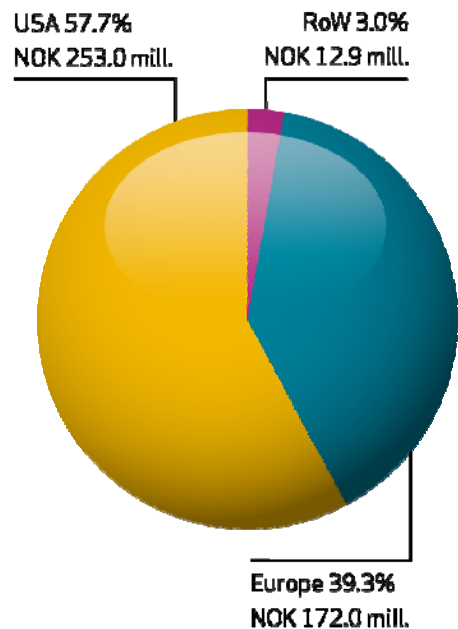
# Market development



## Revenues by geography:

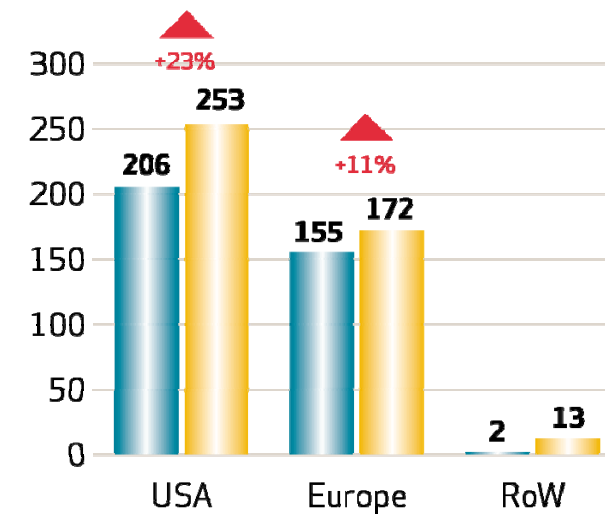
# Increased sales income in all geographical segments

### Revenues split by market Q3 2009



### Revenue growth Q3 2008 > 2009

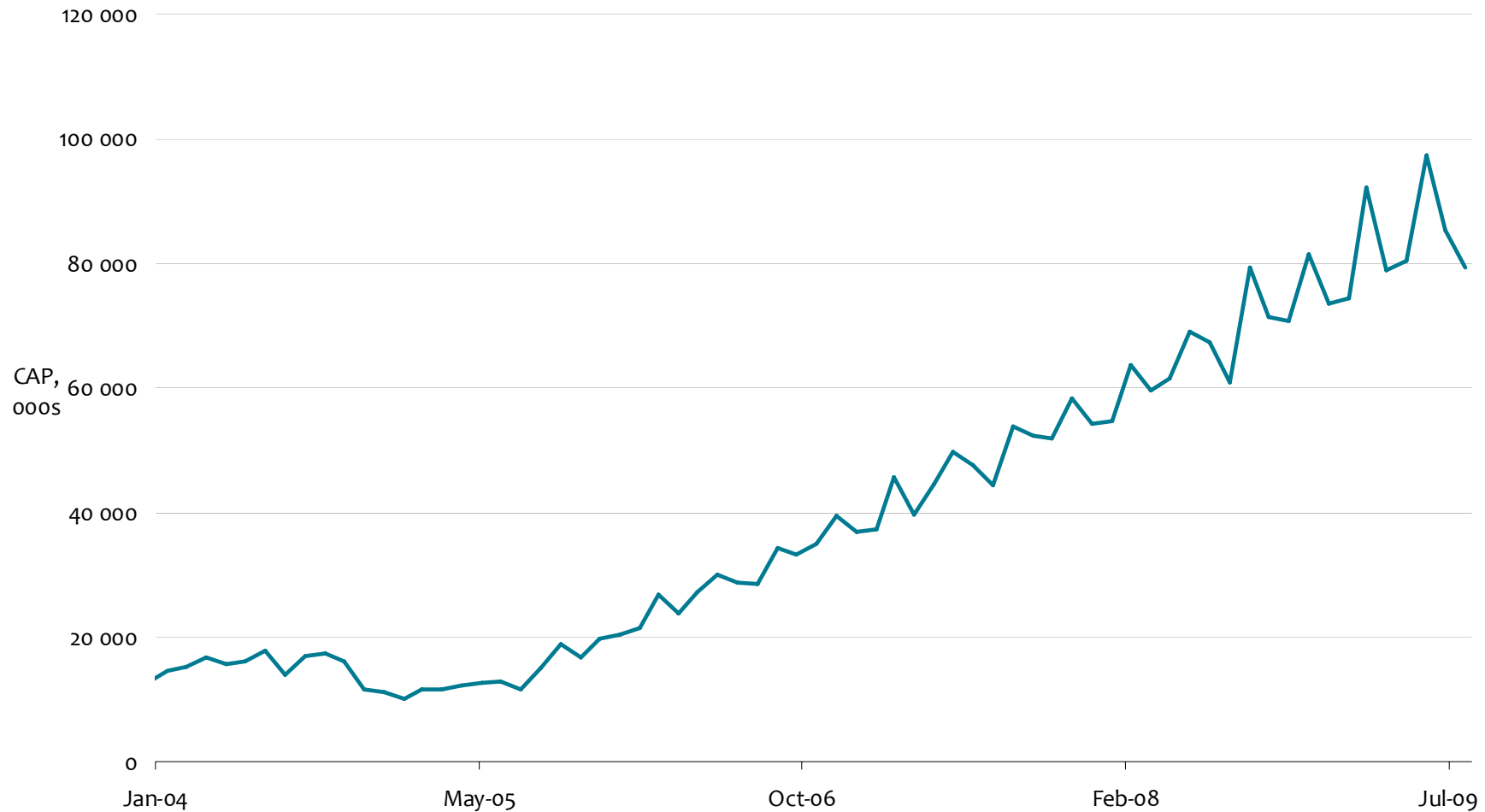
NOK million      → Q3 2008      → Q3 2009



*End-user sales volume:*

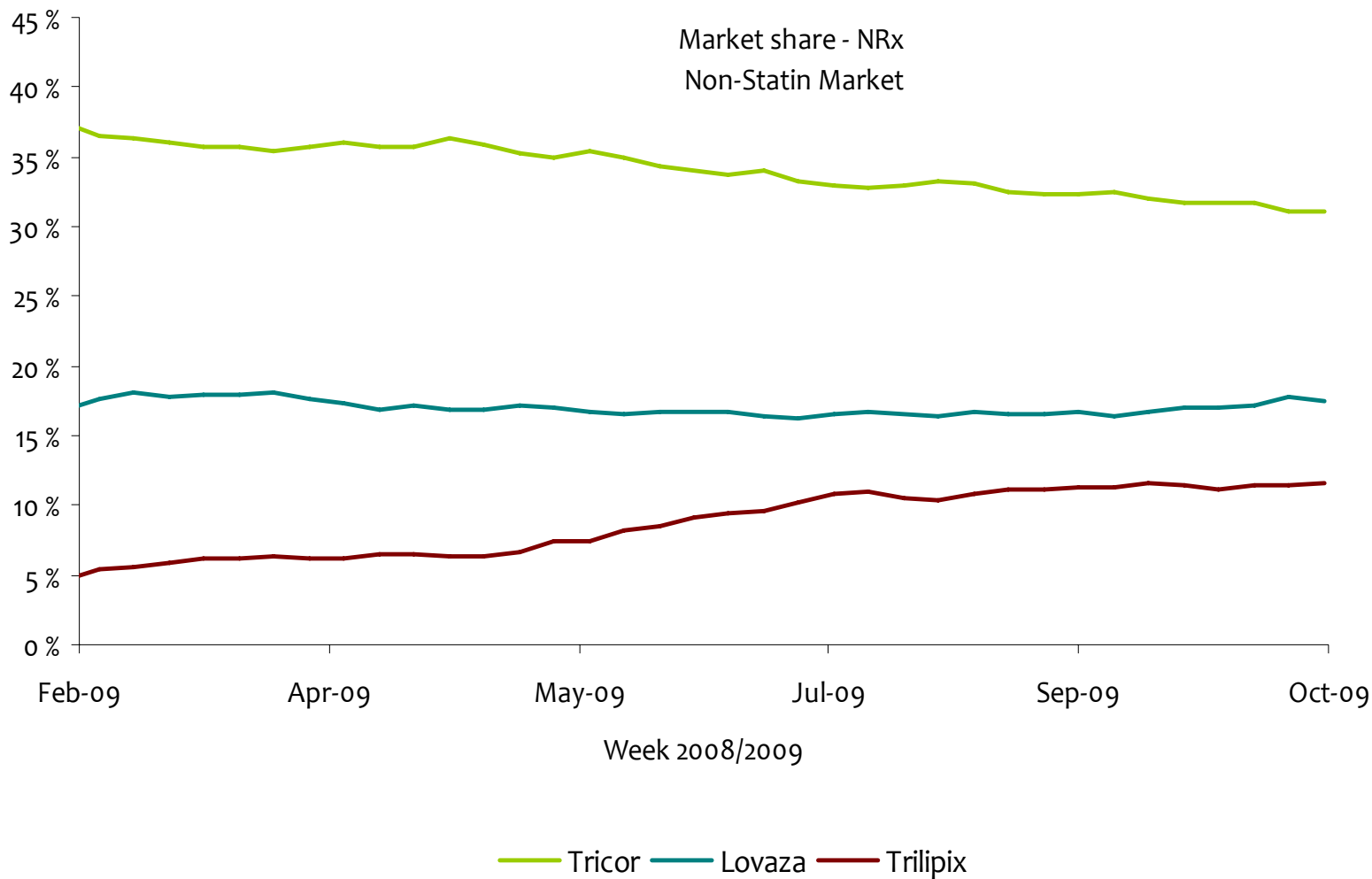
# Steady momentum towards blockbuster

IMS sales, 8 major markets



Market share – NRx:

# Maintaining market share in competitive market



# Prescription growth in the US market: Underlying growth

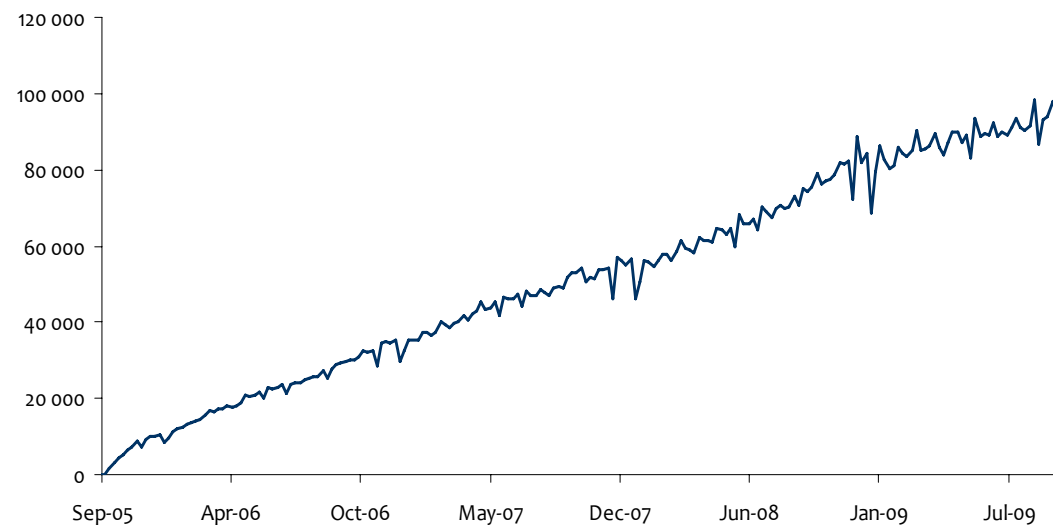
Omacor/Lovaza: Sales development since launch

— NRx



Omacor/Lovaza: Sales development since launch

— TRx



- **New prescriptions (NRx)**

- Q3 volume growth of 32% (year-on-year)

- **Total prescriptions (TRx)**

- Q3 volume growth of 36% (year-on-year)

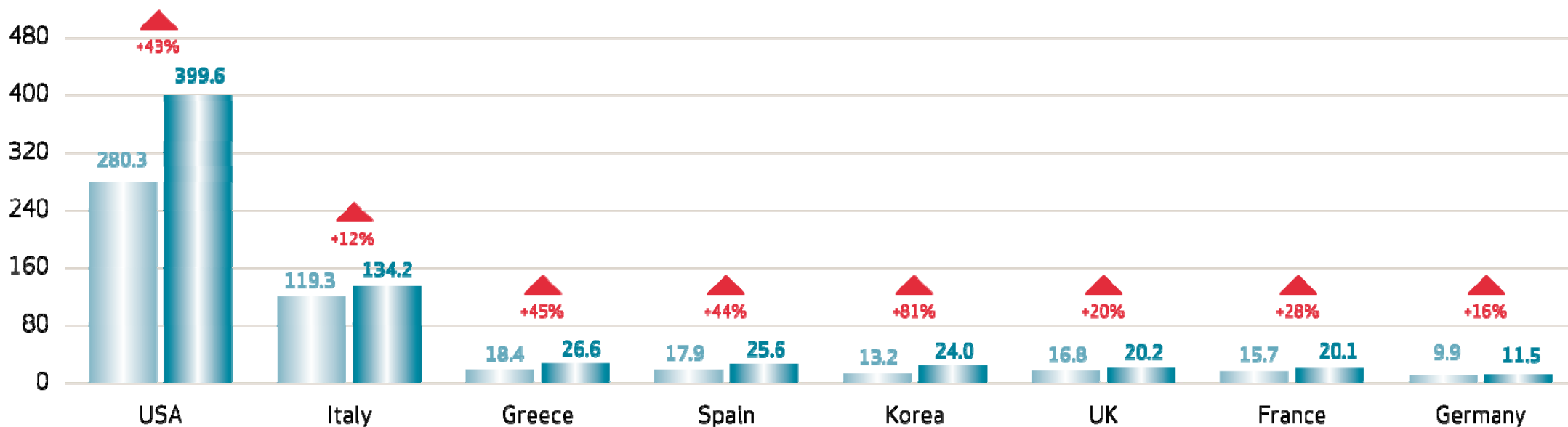
End-user sales by August 2009:

# Substantial volume growth in all markets

## End-user sales by major markets at 31 August\*

Volume sold in tonnes

→ YTD 2008 → YTD 2009

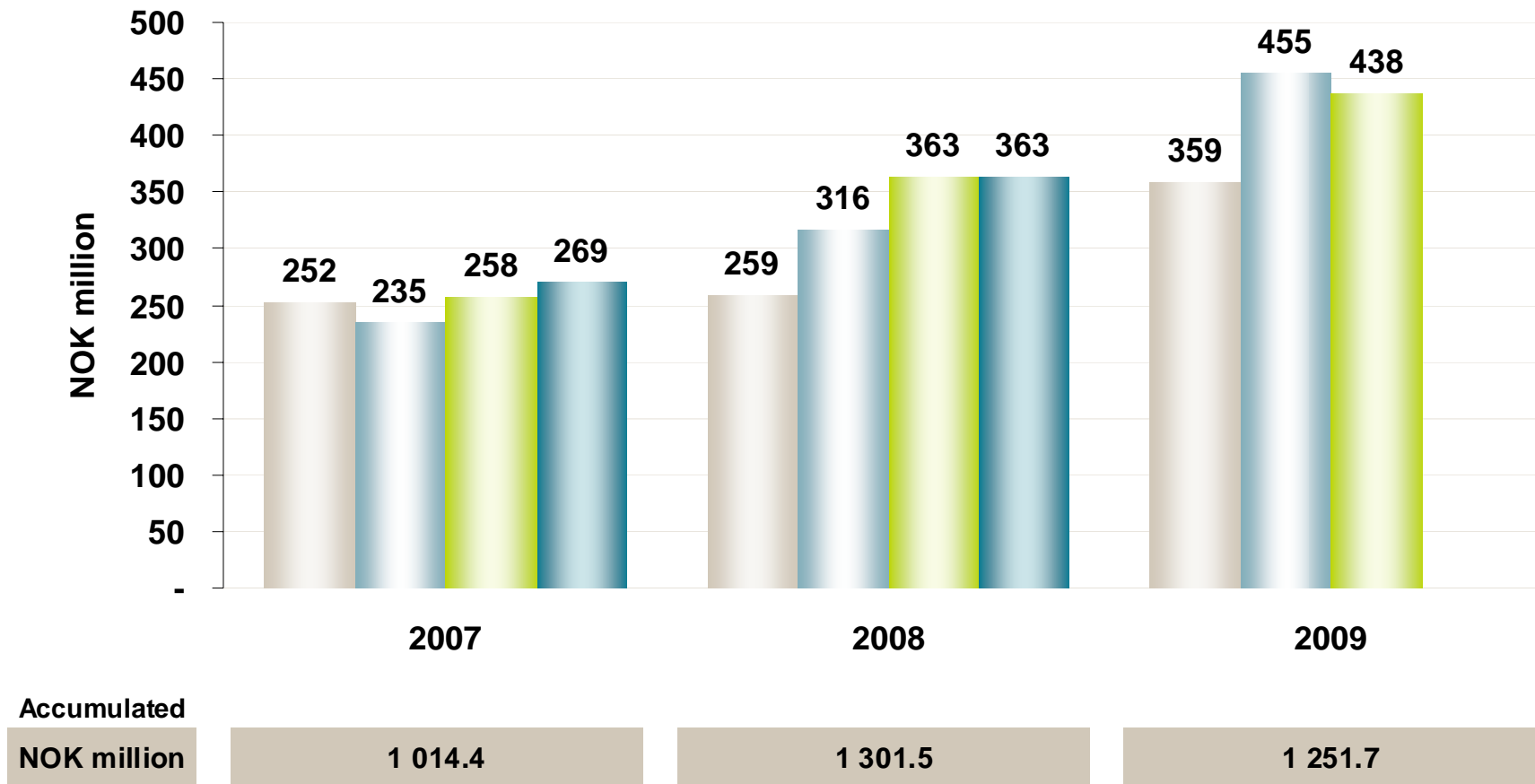


\* Source: IMS Health

# Financial review

*Income statement:*

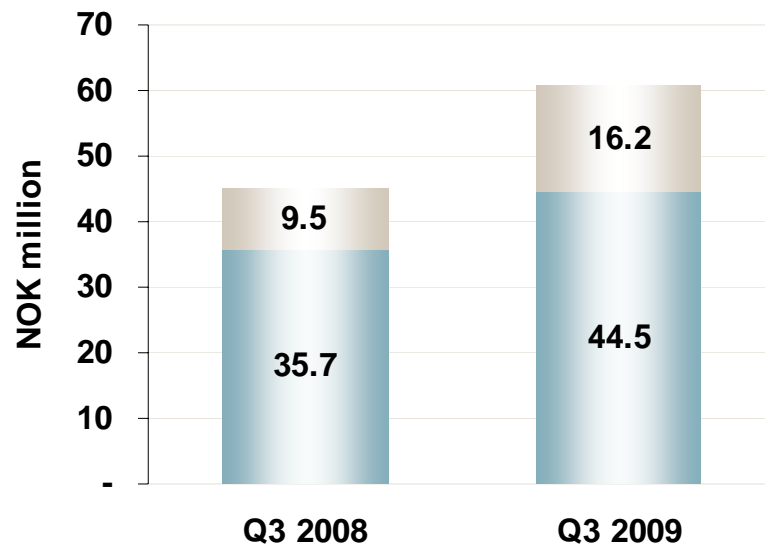
# Revenues up 21 per cent from Q3 2008



Income statement:

# Employee benefit and other operating expenses

Employee benefit expenses



NOK million

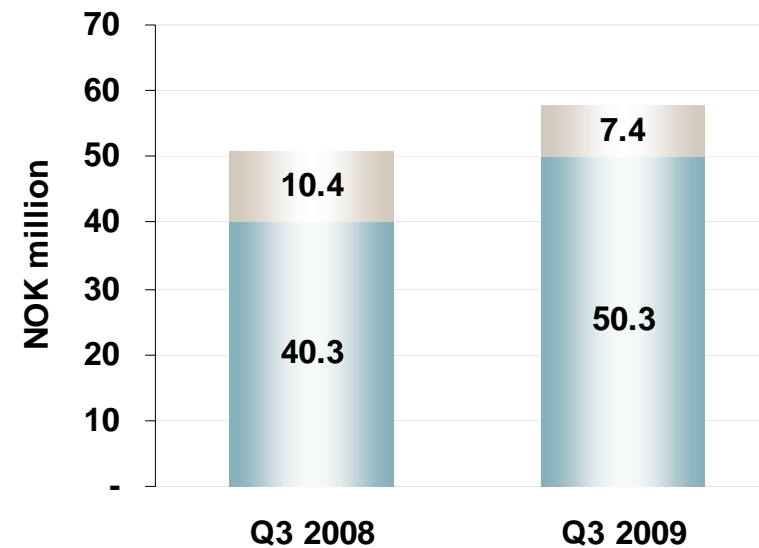
45.1

60.6

■ Denmark

■ Norway

Other operating expenses

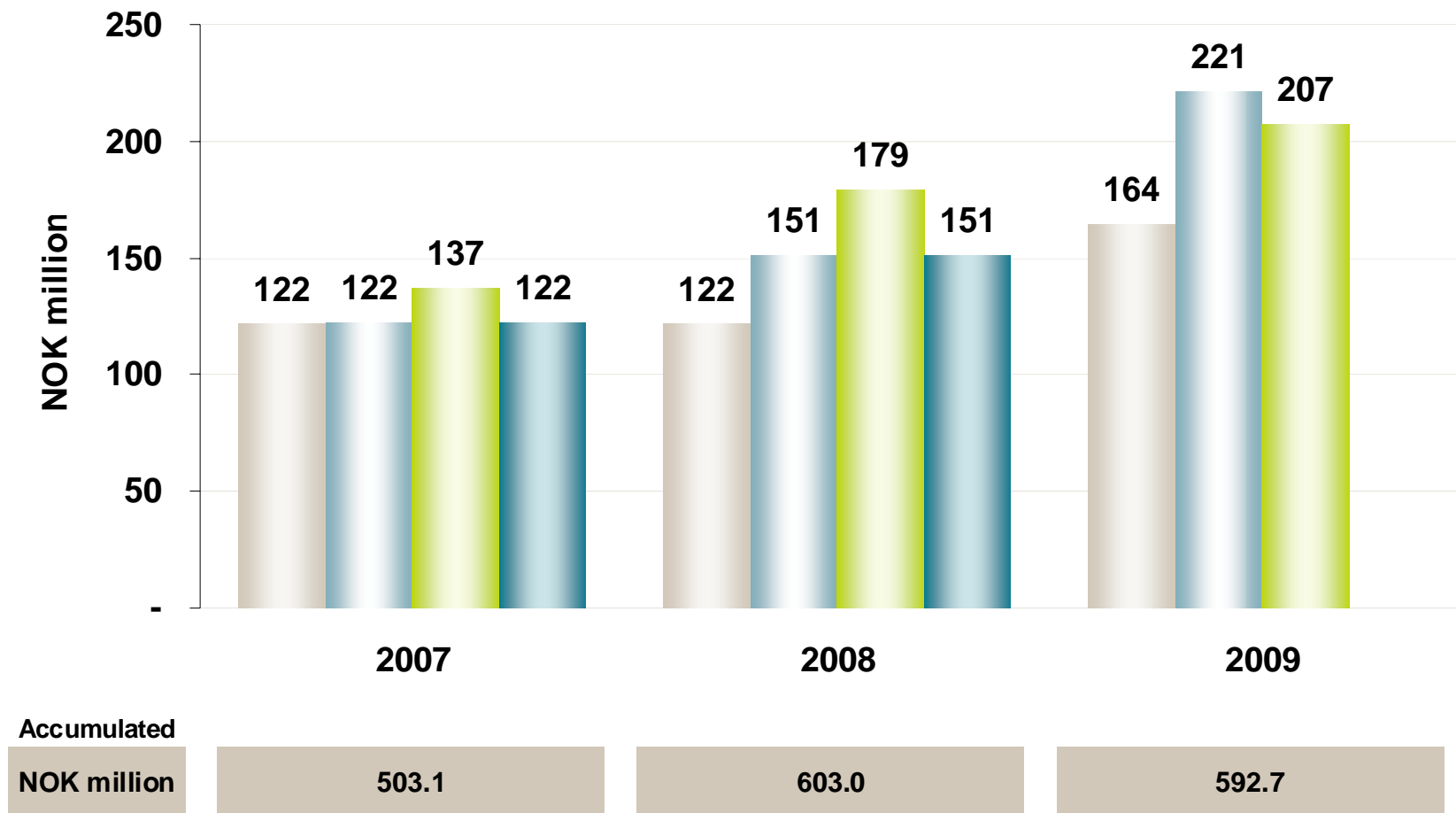


50.7

57.7

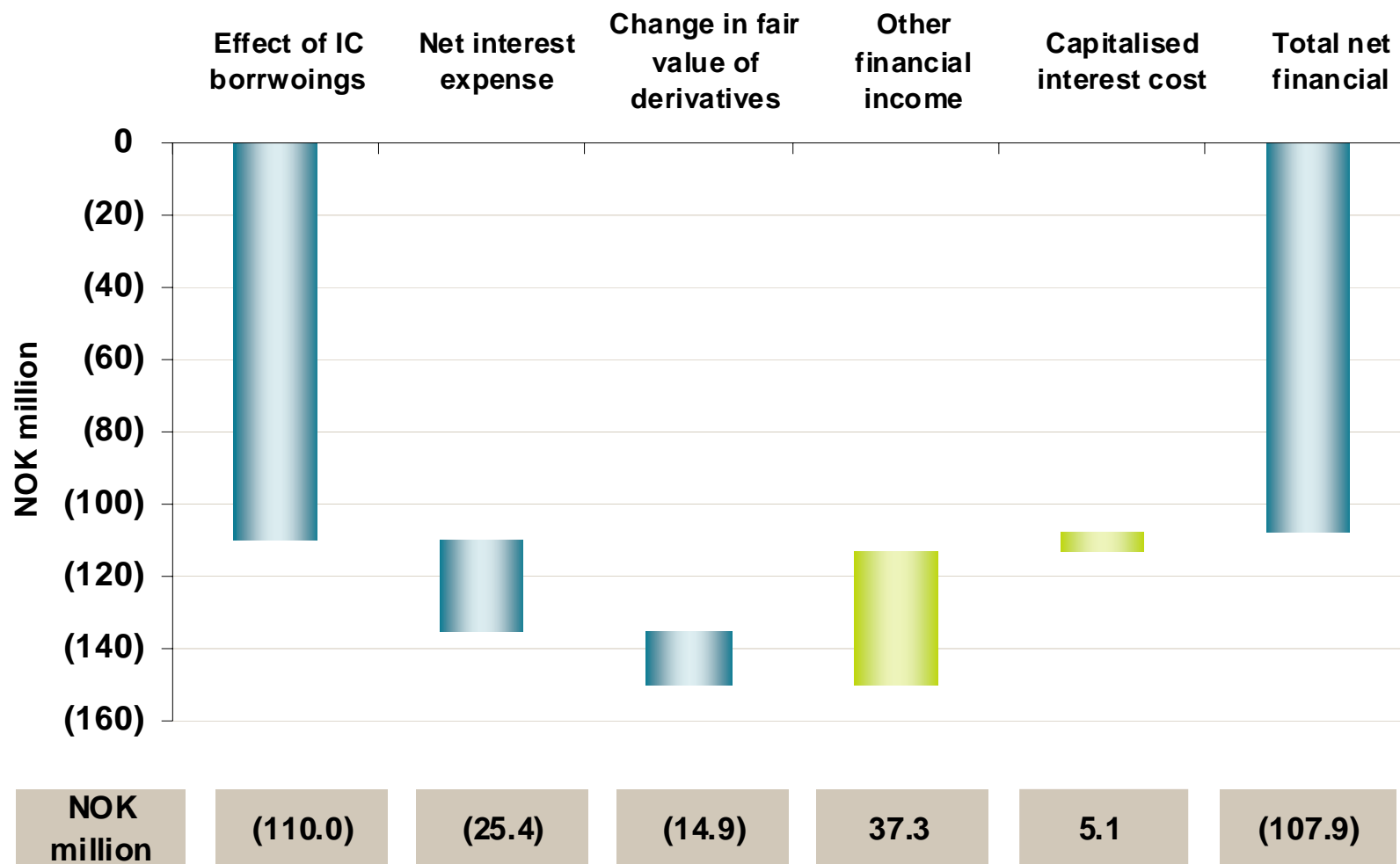
Income statement:

# EBITDA per Q3 2009 in line with total 2008 level



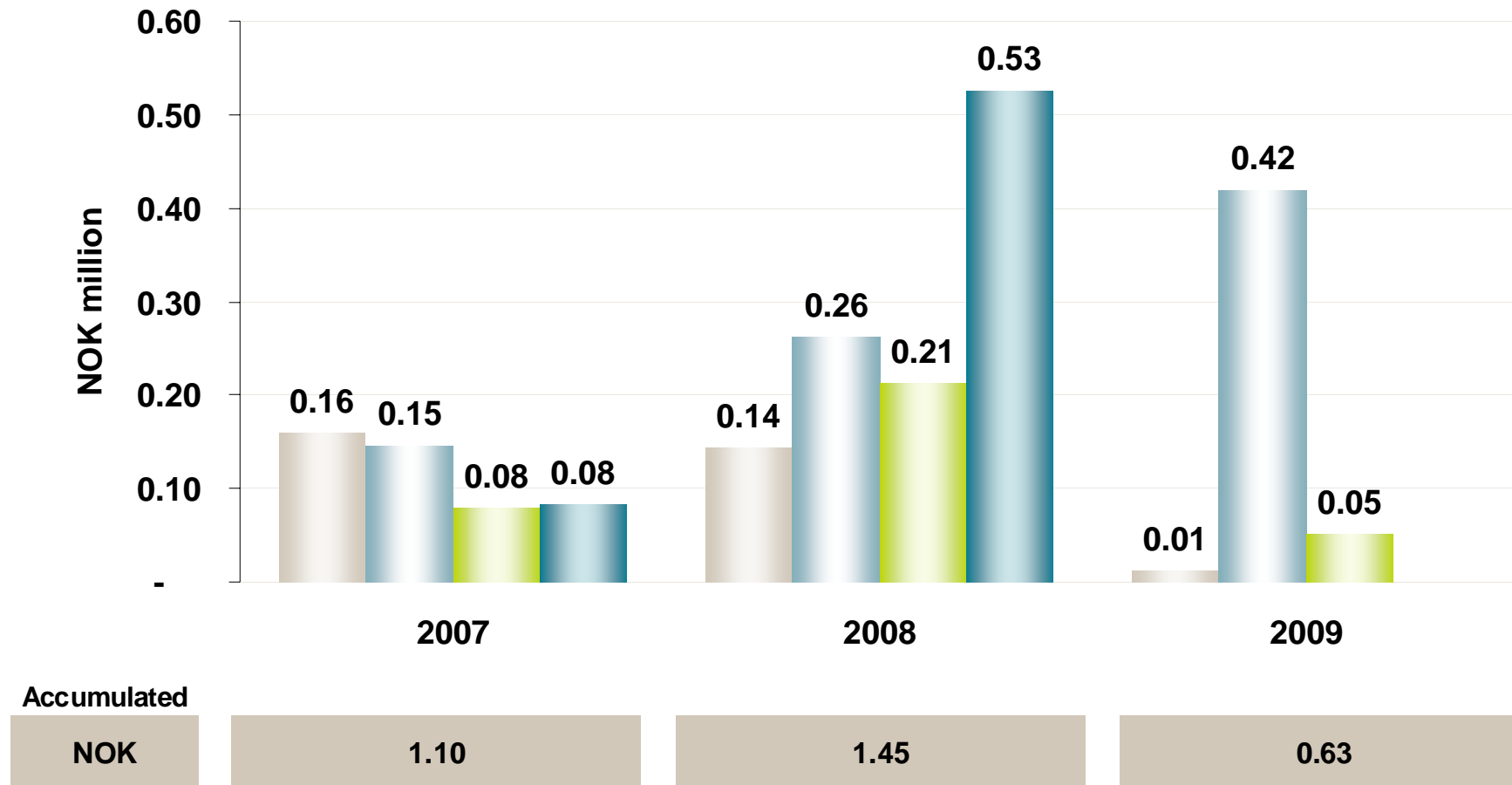
Income statement:

# Net financial items



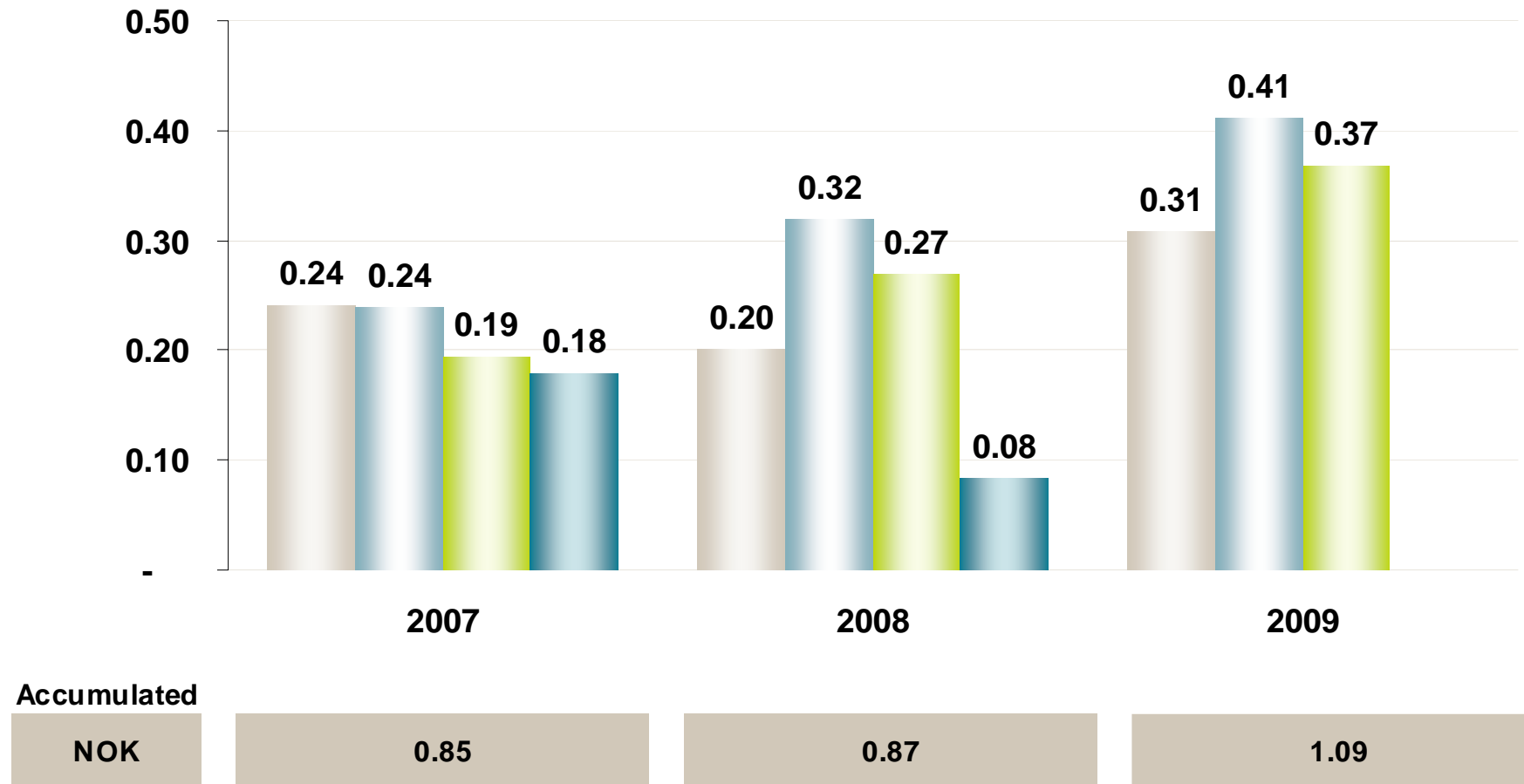
*Earnings per share:*

# Impacted by unrealised effects of IC borrowings



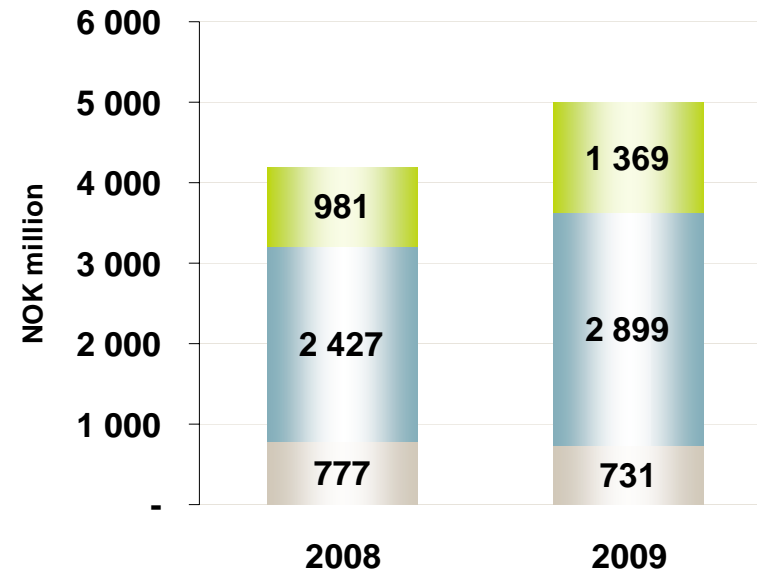
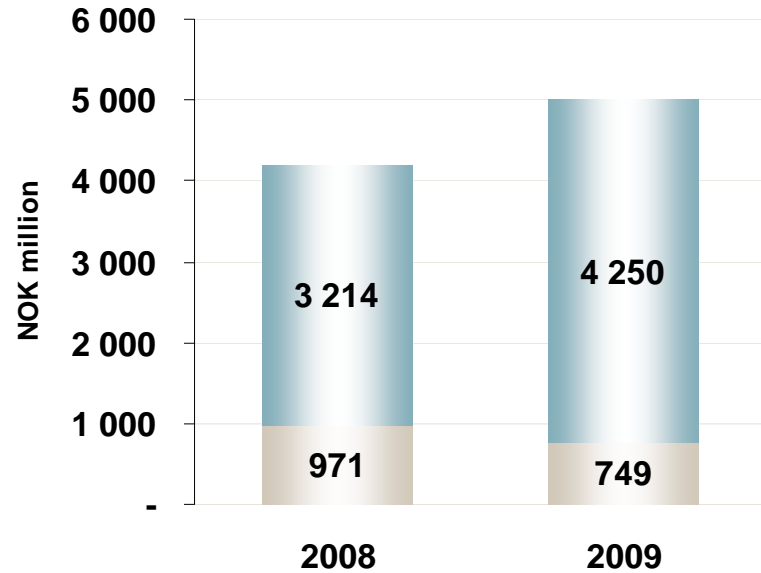
Earnings per share:

# Adjusted for IC borrowings effects and amortisation



Financial position:

# Total assets at 30 September



NOK million	2008	2009
Total assets	4185.0	4998.8

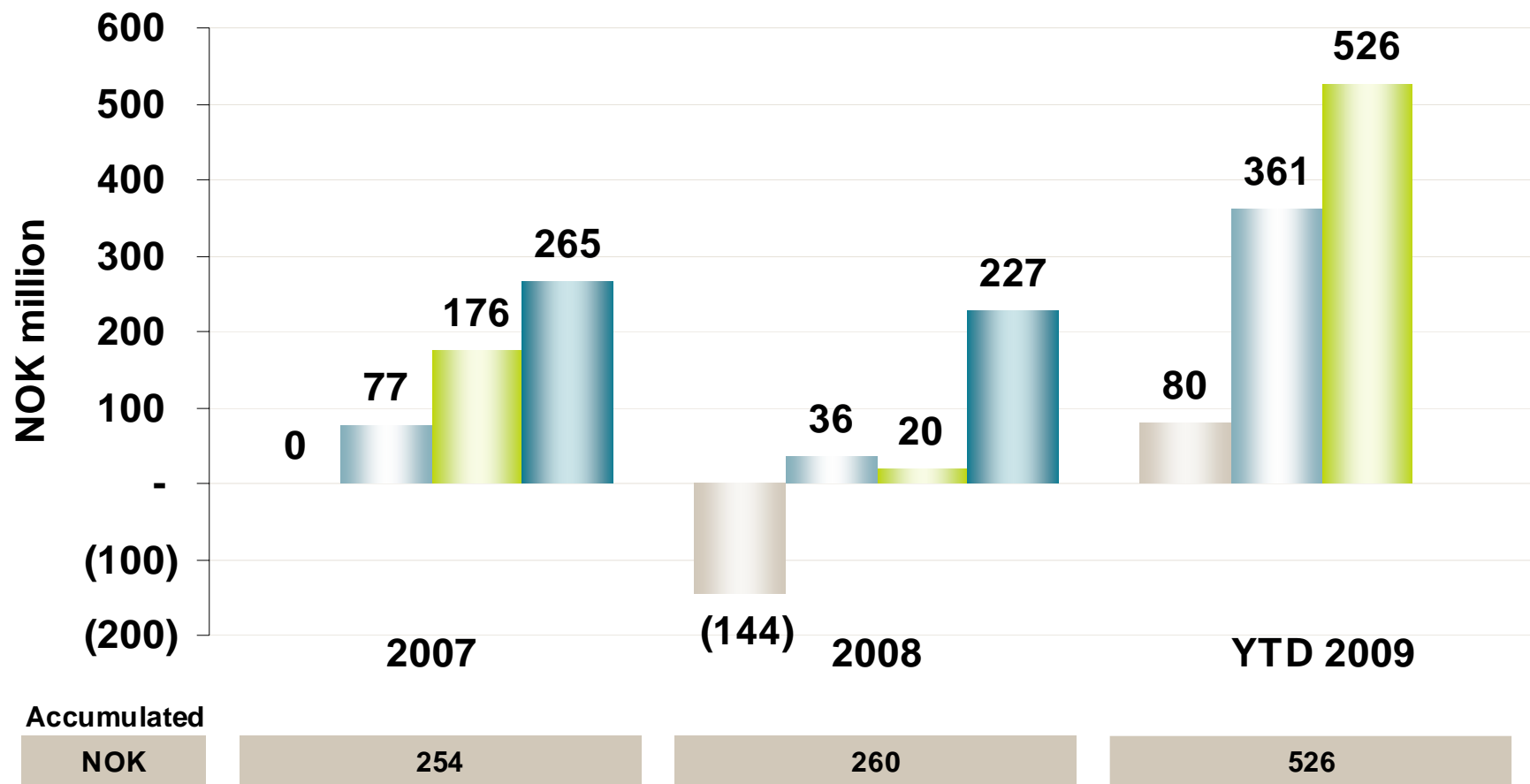
NOK million	2008	2009
Total liabilities and equity	4185.0	4998.8

■ Current assets    ■ Non Current assets

■ Current liability    ■ Non current liability  
■ Total equity

Cash flow statement:

# Strong operational cash flow



A woman wearing a yellow hard hat, safety glasses, and a red uniform is standing in a pharmaceutical production facility. She is holding a blue cup and looking towards the camera. The background shows a complex network of stainless steel pipes, valves, and machinery. The scene is brightly lit, and the overall atmosphere is professional and industrial.

# Operational review

## Production

The logo for PRONOVA BIOPHARMA features a yellow sphere above the word "PRONOVA" in a bold, blue, sans-serif font. Below "PRONOVA" is the word "BIOPHARMA" in a smaller, blue, sans-serif font.

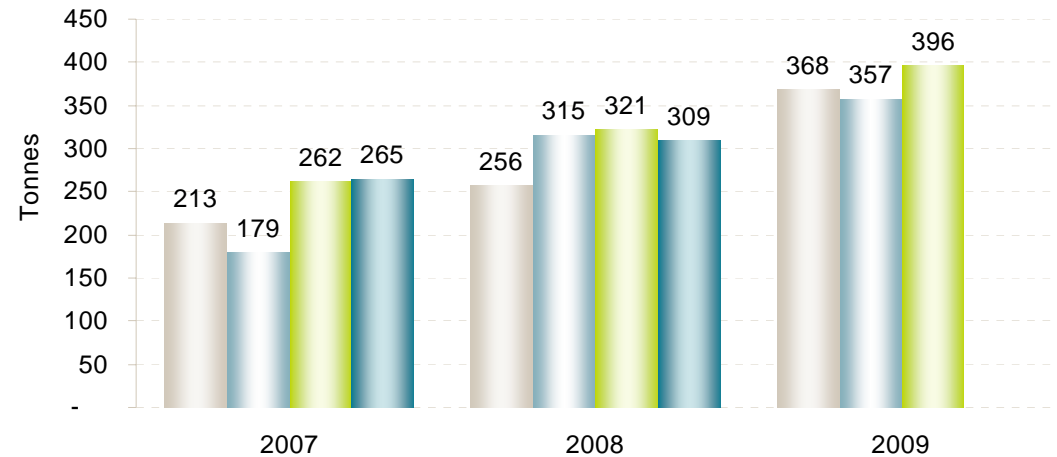
**PRONOVA**  
BIOPHARMA

*Record high production:*

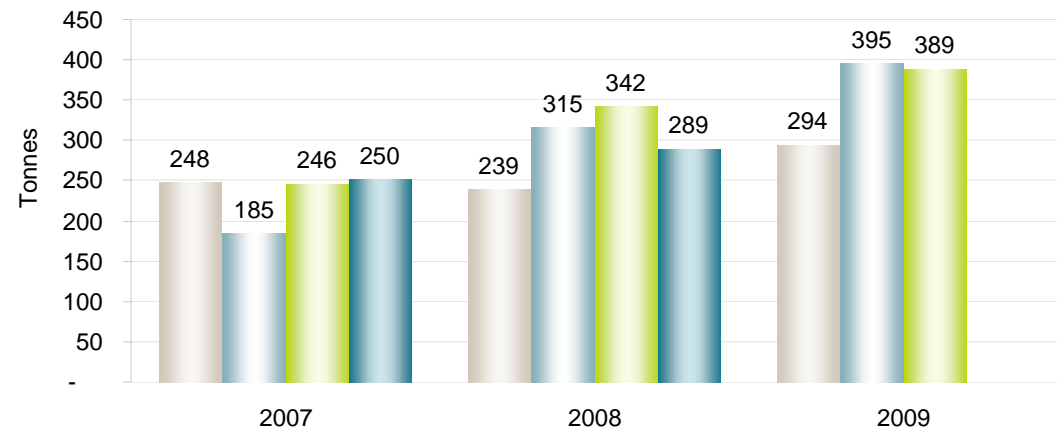
# Effect of dual sites materialising

- **396 tonnes produced**
  - *high level of in-sourcing*
  - *optimising production from two plants*
- **389 tonnes shipped**
  - *shipments according to plan*
  - *maintained strong partner demand*
- **Inventory of finished goods**
  - *80 -100 tonnes by year end*
  - *inventory build-up started late in Q3*

Production by quarter



Shipments by quarter



*New plant in Kalundborg:*

# Double capacity supports further growth

- **Plant completed and validated**
  - *GMP certification achieved late September*
  - *official opening 1 October*
- **Production started**
  - *plant fully operational*
  - *first batches of intermediates produced*
- **On track to start commercial shipments in 2010**
  - *regulatory approval EU : Expected Q1 2010*
  - *regulatory approval US: Expected H2 2010*
- **Two plants gives operational flexibility**



Operational review  
**Intellectual property**

**PRONova**  
BIOPHARMA

# Intellectual property update

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- **IBSA's application for marketing authorisation of a generic product in Italy has been rejected by AIFA**
  - *the decision has been appealed*
- **Litigation processes against ANDA filers progressing according to agreed schedule**
  - *parties have agreed on time schedule which set the trial at March/April 2011*
  - *the parties are preparing for discovery phase*
- **Nullity action in the District Court of Milan**
  - *hearing held 28 October 2009*
  - *submission of the parties' final briefs and final replies in early 2010*
- **No generic entrance to date in Europe post patent expiry**

A scientist wearing glasses and a white lab coat is shown in profile, looking at a computer monitor. The background is a laboratory with various pieces of equipment, including a large machine with a control panel and a computer monitor. The scene is brightly lit, and the overall atmosphere is professional and focused.

Operational review  
**Research and development**

**PRONOVA**  
BIOPHARMA

# Programme highlights

## ● VITAL

- letter of intent was signed in September for the VITAL study
- largest primary prevention trial preformed
- first patient in Q1 2010

## ● GISSI-HF study

- encouraging subgroups results presented at the ESC 2009 in Barcelona
- Omacor/Seacor significantly reduced death or hospitalization for ventricular arrhythmias
- Pronova expects to conclude in Q1 2010 on utilization of the HF-data

## ● Fixed dose combination

- 1 g Omacor and 20 mg simvastatin tested in bioequivalence studies with promising results
- Sigma-Tau (Defiante) consulted regulatory agencies in Europe with positive feedback
- expected launch of the product in 2010/2011

## ● Alginate capsule technology

- preparing for clinical trials in 2009/2010
- expected regulatory filing late 2010

## ● PRB programme

- R&D initiatives on several PRB candidates have increased
- preparing to advance into clinical Phase I during 2010



# Outlook



# Revenue outlook

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- **Contractual price adjustments to some major partners will impact 2010 revenues**
- **Revenues per shipped volumes in 2010 is expected to be in the range 0.95 - 1.00 during 2010**
- **Negative impact partly offset by reduced material costs**

## Revenue outlook:

# Elements impacting price to major partners

- **Contractual agreement to some major partners include adjustments for:**
  - *CPI*
  - *crude fish-oil prices*
- **Annual adjustments of next year prices**
  - *adjustments dependent on current year elements*
- **Prices still to be decided, but main direction is outlined**

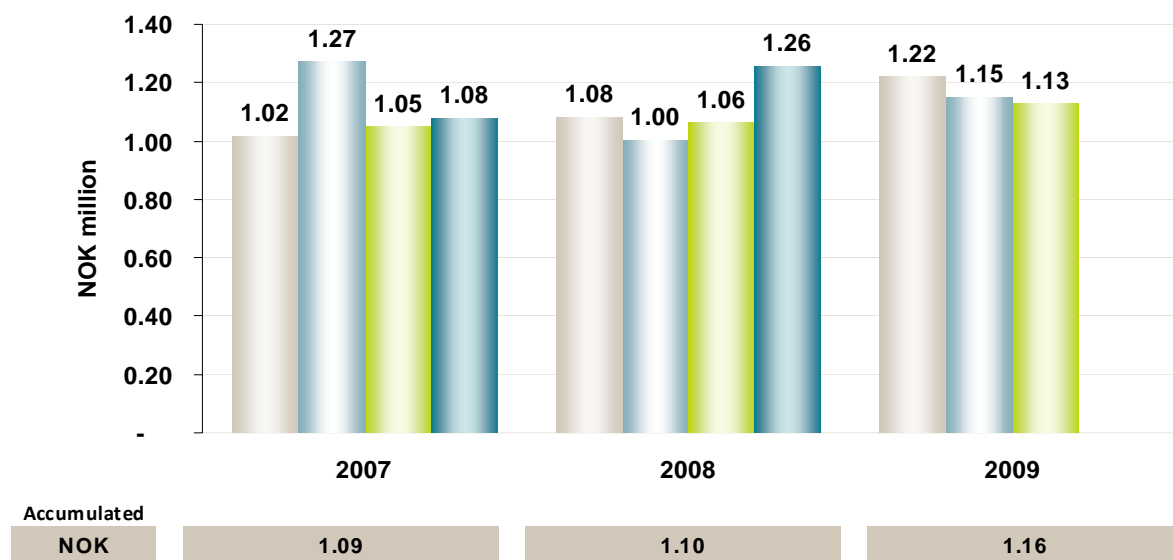
	2009	2010	2011e*
Adjustments (CPI + fish oil)	+	-	+

*\*Assumption based on fish-oil price late in October 2009*

# Revenue outlook

- **Revenues per shipped volumes impacted by:**

- *prices (implied royalty rates to partners)*
- *partners' inventory build-up / build-down versus royalty received on end-user sales*
- *geographical mix (different implied royalty rates to partners)*
- *level of sampling (sample price is lower than supply price)*
- *level of by-product sales*
- *foreign exchange fluctuations*



# Outlook

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- **Production on track to meet the target of 1550 - 1600 tonnes for 2009**
  - *80-100 tonnes inventory by year-end*
- **Well positioned to utilise growth potential**
  - *double capacity with Kalundborg coming on stream*
  - *increasing end-user demand in all markets*
- **Partner demand expected to be around 1 800 – 2 000 tonnes in 2010**
  - *dependent on potential generic competition in Europe and developments in end-user sales*
- **Focus to increase future market potential**
  - *continued growth in existing markets*
  - *successful launches in new markets*
  - *development of new indications*
  - *new formulations and new products*

# Q & A

# Additional information



# Condensed consolidated income statement

(All amounts in NOK 1000)	Q3 2009	Q3 2008	YTD 2009	YTD 2008	FY 2008
Total revenues	437 916	363 301	1 251 722	938 514	1 301 500
Change in inventories	10 945	17 918	38 777	16 805	44 812
Cost of materials	(123 073)	(106 243)	(368 721)	(224 250)	(340 339)
Employee benefits expense	(60 649)	(45 125)	(169 098)	(139 864)	(204 086)
Depreciation of property, plant and equipment and write downs	(49 536)	(18 962)	(91 693)	(57 270)	(76 160)
Amortisation of intangible assets	(22 471)	(23 812)	(67 374)	(71 407)	(95 290)
Other operating expenses	(57 685)	(50 741)	(160 059)	(139 395)	(198 880)
Total operating expenses	(302 470)	(226 965)	(818 169)	(615 381)	(869 943)
Operating profit	135 446	136 336	433 554	323 133	431 557
Net financial items	(107 913)	(46 962)	(222 353)	(65 096)	37 332
Profit before tax	27 533	89 374	211 201	258 037	468 889
Income tax expense	(12 250)	(25 611)	(66 501)	(71 948)	(124 756)
Net profit for the period	15 284	63 763	144 700	186 089	344 133
Earnings per share (in NOK) - basic and diluted	0.05	0.21	0.48	0.62	1.14
EBITDA	207 454	179 110	592 621	451 810	603 007
EBITDA margin	47.4 %	49.3 %	47.3 %	48.1 %	46.3 %

## Consolidated statement of financial position:

# Total assets

(All amounts in NOK 1000)

30.09.2009

30.09.2008

31.12.2008

### ASSETS

#### Non-current assets

Property, plant and equipment

2 813 345

1 759 212

2 564 590

Goodwill

633 453

633 453

633 453

Other intangible assets

731 503

809 759

792 080

Deferred tax assets

34 544

11 497

87 778

Other financial assets

37 337

-

-

Total non-current assets

4 250 182

3 213 921

4 077 901

#### Current assets

Inventories

323 140

392 477

394 625

Trade and other receivables

230 585

421 965

346 828

Other financial assets

24 213

18 792

-

Cash and cash equivalents

170 631

137 381

76 776

Total current assets

748 569

970 615

818 229

Total assets

4 998 751

4 184 536

4 896 130

# Consolidated statement of financial position :

## Total equity and liabilities

(All amounts in NOK 1000)	30.09.2009	30.09.2008	31.12.2008
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	6 017	6 017	6 017
Share premium reserve	579 665	579 665	579 665
Retained earnings	729 806	427 192	585 106
Reserves	53 993	(31 875)	(172 424)
<b>Total equity</b>	<b>1 369 481</b>	<b>980 999</b>	<b>998 364</b>
<b>Non-current liabilities</b>			
Deferred tax liabilities	234 814	224 657	253 242
Borrowings	2 419 344	1 910 715	2 079 774
Deferred revenues	206 656	219 033	210 161
Retirement benefit obligation	22 280	21 520	23 114
Other financial liabilities	15 453	50 669	242 405
<b>Total non-current liabilities</b>	<b>2 898 547</b>	<b>2 426 594</b>	<b>2 808 696</b>
<b>Current liabilities</b>			
Trade and other payables	147 517	316 744	425 785
Borrowings	205 227	175 000	206 089
Other financial liabilities	51 692	22 451	177 224
Current tax liabilities	183 371	139 629	119 341
Deferred revenues	17 646	19 827	23 489
Other liabilities	103 190	85 733	118 404
Provisions	22 079	17 559	18 738
<b>Total current liabilities</b>	<b>730 723</b>	<b>776 943</b>	<b>1 089 070</b>
<b>Total liabilities</b>	<b>3 629 270</b>	<b>3 203 537</b>	<b>3 897 766</b>
<b>Total equity and liabilities</b>	<b>4 998 751</b>	<b>4 184 536</b>	<b>4 896 130</b>

# Consolidated statement of comprehensive income

(All amounts in NOK 1000)	Q3 2009	Q3 2008	YTD 2009	YTD 2009	FY 2008
Net profit for the period	15 284	63 763	144 700	186 089	344 134
<b>Other comprehensive income</b>					
Exchange differences arising on translation of foreign operations	(25 722)	16 907	(75 489)	16 907	87 244
Cash flow hedges	158 515	(144 721)	419 314	(104 876)	(397 774)
Income tax relating to cash flow hedges	(44 384)	40 522	(117 408)	29 365	111 377
Other comprehensive income for the period (net of tax)	88 409	(87 292)	226 417	(58 604)	(199 153)
Total comprehensive income for the period	103 693	(23 529)	371 117	127 485	144 981

# Consolidated statement of changes in equity

(All amounts in NOK million)	Share capital	Share premium	Retained earnings	Reserves	Total equity
Balance at 1 January 2009	6.0	579.7	585.1	(172.4)	<b>998.4</b>
Total comprehensive income 1.1 - 30.09	-	-	144.7	226.4	<b>371.1</b>
Balance at 30 September 2009	6.0	579.7	729.8	54.0	<b>1 369.5</b>
Balance at 1 January 2008	6.0	579.7	241.1	26.7	<b>853.5</b>
Total comprehensive income 1.1 - 30.09	-	-	186.1	(58.6)	<b>127.5</b>
Balance at 30 September 2008	6.0	579.7	427.2	(31.9)	<b>981.0</b>
Balance at 1 January 2008	6.0	579.7	241.1	26.7	<b>853.5</b>
Total comprehensive income 1.1 - 31.12	-	-	344.1	(199.2)	<b>145.0</b>
Loss on sales of treasury shares	-	-	(0.1)	-	<b>(0.1)</b>
Balance at 31 December 2008	6.0	579.7	585.1	(172.4)	<b>998.4</b>

# Consolidated cash flow statement

(All amounts in NOK 1000)	Q3 2009	Q3 2008	YTD 2009	YTD 2008	FY 2008
<b>Cash flow from operating activities</b>					
Profit before tax	27 534	89 374	211 201	258 035	468 889
Unrealised group internal currency loss(+)/gains(-)	110 024	-	186 267	-	(208 328)
Taxes paid in the period	(656)	-	(83 823)	(47 060)	(81 108)
Depreciation and amortisation and write downs	72 007	42 774	159 067	128 677	171 450
Loss on disposal of property plant and equipment	-	-	-	-	971
Expensed borrowing costs	392	-	1 177	-	2 317
Pension costs, without cash effect	570	634	(834)	(2 009)	(415)
Currency effects	8 505	(9 258)	31 523	(10 227)	(26 308)
Changes in inventories	43 465	(1 169)	71 485	(235 157)	(237 305)
Changes in trade receivables	507	(54 569)	142 044	(98 462)	(120 892)
Changes in trade payables	(57 482)	(44 775)	(118 235)	78 458	100 575
Changes in other current assets/liabilities	(40 030)	(39 557)	(73 748)	(52 498)	189 676
<b>Net cash from operating activities</b>	<b>164 836</b>	<b>(16 545)</b>	<b>526 124</b>	<b>19 758</b>	<b>259 522</b>
<b>Cash flow from investing activities</b>					
Payments for property, plant and equipment	(177 359)	(380 717)	(773 189)	(940 655)	(1 371 239)
<b>Net cash from investing activities</b>	<b>(177 359)</b>	<b>(380 717)</b>	<b>(773 189)</b>	<b>(940 655)</b>	<b>(1 371 239)</b>
<b>Cash flow from financing activities</b>					
Proceeds from new long-term borrowings	-	418 036	450 000	848 819	1 050 000
Repayment of long term debt	(1 292)	-	(104 033)	(75 000)	(150 000)
Net payment relating to treasury shares	-	-	-	-	(132)
<b>Net cash from financing activities</b>	<b>(1 292)</b>	<b>418 036</b>	<b>345 967</b>	<b>773 819</b>	<b>899 868</b>
<b>Effect of currency translation of bank deposits, cash and</b>	<b>(2 009)</b>	<b>-</b>	<b>(5 046)</b>	<b>-</b>	<b>4 167</b>
<b>Net change in bank deposits, cash and cash equivalents</b>	<b>(15 824)</b>	<b>20 774</b>	<b>93 855</b>	<b>(147 078)</b>	<b>(211 849)</b>
Bank deposits, cash and cash equivalents at beginning of period	186 456	116 606	76 776	284 458	284 458
Bank deposits, cash and cash equivalents at end of period	170 631	137 380	170 631	137 380	76 776

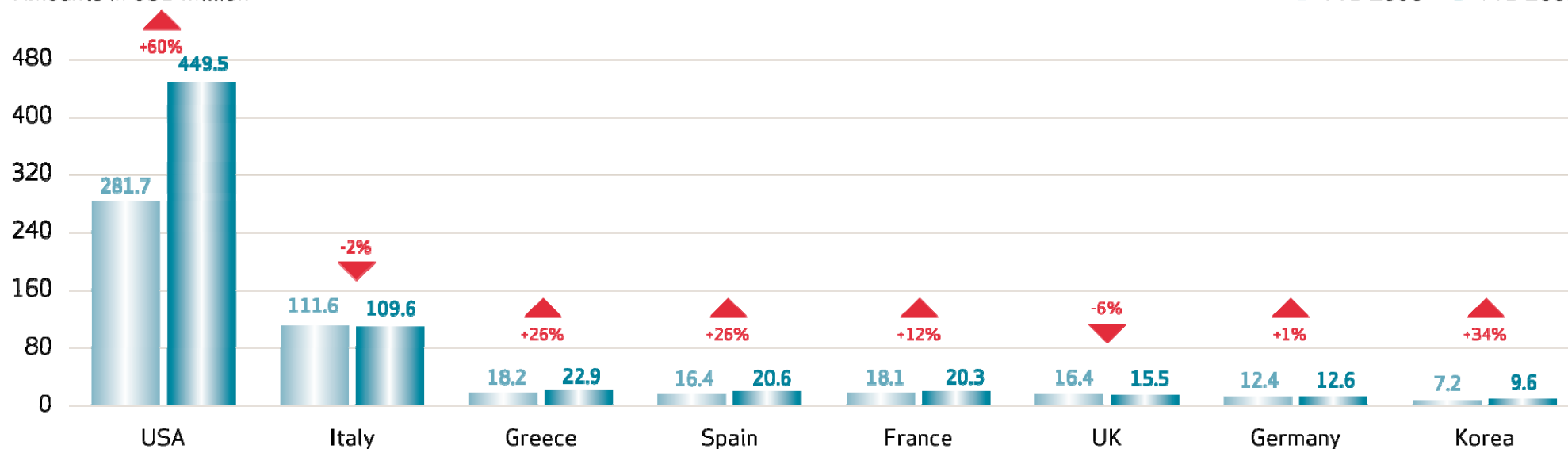
3 November 2009

# End-user sales by major markets, USD

## End-user sales by major markets at 31 August\*

Amounts in USD million

→ YTD 2008 → YTD 2009



\* Source: IMS Health

Market share - NRx & TRx  
Non-Statins Market

