Interim report – November 3, 2009

Meda AB (publ) - Interim report, January–September 2009

- The Group's net sales reached SEK 9,918 million (7,515), a 32% increase compared to the previous year.

- EBITDA rose 28% to SEK 3,356 million (2,616), yielding a 33.8% margin (34.8).

- Operating profit climbed to SEK 2,275 million (1,826).

- Profit after tax increased to SEK 1,205 million (808).

- Earnings per share reached SEK 3.99 (2.99).

- Cash earnings per share rose to SEK 6.88 (5.19).

- Forecast for full-year 2009

  "The Meda Group expects to reach sales of about SEK 13,000 million and an EBITDA of about SEK 4,200 million for the full-year 2009."

Meda is a leading international specialty pharma company that focuses on marketing and pharmaceutical development in the late clinical phase. Meda is fully represented in Europe and the US through its subsidiaries in more than 40 countries. Meda AB's shares are listed under Large Cap on the Nasdaq OMX Nordic exchange in Stockholm. Its headquarters are located in Solna, Sweden.

HIGHLIGHTS

Positive sales trend for Astepro (0.1%) continues

- The positive sales trend for Astepro (0.1%) that was launched during Q1 continues. Astepro's proportion of total azelastine prescribed rose to about 33% in Q3.

FDA approves Astepro (0.15%) Once-Daily — market launch started

- The US Food and Drug Administration (FDA) approved a higher dose of Astepro (0.15%).
- Astepro (0.15%) is the first nasal antihistamine in the US that is approved for once-daily treatment of seasonal allergies.
- Launch on the US market began in October 2009.

FDA approves Onsolis — launch begins

- The FDA approved Onsolis (fentanyl). This new patented drug is indicated for the management of breakthrough pain in cancer patients.
- The launch of Onsolis began in mid-October 2009.

SALES

January–September

Net sales for January-September rose 32% to SEK 9,918 million (7,515). Currency effects regarding like-for-like sales had a positive SEK 1,063 million impact on sales compared to the previous year. Sales of the most important products during the period were:

Astepro (allergic and non-allergic rhinitis treatment) had US sales during the period of SEK 244 million.

Astelin (allergic and non-allergic rhinitis treatment) totaled SEK 1,082 million (1,049). In the US, sales in local currency were down 21% and reached USD 122 (155), primarily due to the launch of the new Astepro product.

Tambocor (cardiac arrhythmia treatment) reached SEK 712 million (670), a 6% increase on the previous year. Despite increased sales in Q3, total sales in local currency for the year fell somewhat, primarily following the previous year's price decrease in France.

Betadine (antiseptic treatment) rose 14% to SEK 696 million (609). Sales grew in the major south-European markets except for Spain, where sales in local currency decreased.

Minitran (angina prevention) reached SEK 388 million (380).

Aldara (actinic keratosis treatment) displayed ongoing robust growth. Sales totaled SEK 359 million (290), a 24% increase compared to 2008.

Soma (muscle relaxant) amounted to SEK 346 million (218). Sales in local currency were up 25%.

Optivar (allergic conjunctivitis treatment) reached SEK 323 million (260). In the US, sales in local currency increased 2%.

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Zamadol (moderate to severe pain treatment) increased 4% to SEK 293 million (282). Meda retained its position from 2008 in local currency in several European markets despite falling price levels.

Novopulmon (budesonide Novolizer, asthma treatment) climbed 23% to SEK 154 million (125).

July–September

Net sales for July-September rose 28% to SEK 3,017 million (2,356). Currency effects regarding like-for-like sales had a positive SEK 203 million impact on sales compared to the previous year. Sales of the most important products during the period were:

Astepro (allergic and non-allergic rhinitis treatment) had US sales during the period of SEK 75 million. Astepro's proportion of total azelastine prescribed rose to about 33% in Q3.

Astelin (allergic and non-allergic rhinitis treatment) totaled SEK 261 million (278). In the US, sales in local currency were down 20% and reached USD 33 million (41), primarily due to the launch of the new Astepro product.

Tambocor (cardiac arrhythmia treatment) amounted to SEK 228 million (197), a 16% increase on the previous year.

Betadine (antiseptic treatment) rose 13% to SEK 227 million (201). All southern European markets increased their sales in local currency during Q3.

Minitran (angina prevention) reached SEK 111 million (114). Sales in Italy declined due to the authorities' requirement to lower prices.

Aldara (actinic keratosis treatment) totaled SEK 111 million (95), a 17% increase on the previous year.

Soma (muscle relaxant) amounted to SEK 106 million (78). Sales in local currency were up 18%.

Optivar (allergic conjunctivitis treatment) reached SEK 76 million (66). In the US, sales in local currency increased 9%.

Zamadol (moderate to severe pain treatment) increased 3% to SEK 96 million (93).

Novopulmon (budesonide Novolizer, asthma treatment) climbed 28% to SEK 46 million (36).

PROFIT

Operating profit

Operating expenses for Q3 amounted to SEK 1,323 million, 9% down from the previous quarter. This is largely attributable to launch costs for Astepro incurred in Q2 and to a somewhat lower level of activity on the market during the summer months. A non-recurring expense of EUR 6 million in settlement to 3M, a contract manufacturer, impacted operating expenses for Q3. The settlement means that Meda will not take over a substance factory as previously agreed, and the long-term supply of certain key substances is guaranteed.

Operating profit for January–September reached SEK 2,275 million (1,826), corresponding to a 25% increase.

EBITDA for the same period was SEK 3,356 million (2,616), yielding a 33.8% margin (34.8).

Operating profit for July–September reached SEK 634 million (476), corresponding to a 33% increase.

EBITDA for the same period was SEK 1,007 million (745), yielding a 33.4% margin (31.6).

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Financial items

The Group's net financial items for January–September were SEK -485 million (–613). On average higher interest-bearing liabilities compared to the same period last year were chiefly compensated for by lower market interest rates. The average interest rate on September 30, 2009 was 3.5% (5.9).

The Group's profit after net financial items for January–September rose to SEK 1,790 million (1,213).

The Group's net financial items for July–September were SEK –141 million (–201).

Group profit after net financial items for the same period totaled SEK 493 million (275).

Net profit and earnings per share

Net profit for January–September rose 49% to SEK 1,205 million (808).

Group tax expense for January–September amounted to SEK 586 million (405), equivalent to a tax rate of 32.7% (33.4).

Earnings per share for January–September reached SEK 3.99 (2.99).

Net profit for July–September rose 84% to SEK 338 million (184).

Group tax expense for July–September amounted to SEK 156 million (91), equivalent to a tax rate of 31.6% (33.1).

Earnings per share for Q3 rose 65% to SEK 1.12 (0.68).

CASH FLOW

Cash flow from operating activities, before changes in working capital, for January–September rose to SEK 2,263 million (1,528). Implemented restructuring measures had an adverse effect of SEK –107 million on cash flow. Cash flow from changes in working capital was SEK –100 million (–46). Cash flow from operating activities for January–September thereby rose to SEK 2,163 million (1,482).

For Q3, cash flow from operating activities declined to SEK 613 million (670). This is due to a sharp reduction in working capital during Q3 previous year.

Cash flow from investing activities amounted to SEK –457 million (–2,991) for January–September. In January, Meda paid the remaining purchase consideration of SEK 107 million for the product portfolio acquired from Roche in 2008. In conjunction with the FDA's approval of Onsolis in July, a milestone of SEK 208 million was paid to BioDelivery Sciences Inc., Meda's US development partner.

Cash flow from financing activities amounted to SEK –1,833 million (1,647) for January–September. Dividend of SEK 227 million was paid to Meda's shareholders in May.

Cash earnings per share for January–September rose 33% to SEK 6.88 (5.19).

Cash earnings per share for July–September totaled SEK 1.91 (2.39).

FINANCING

On 30 September equity stood at SEK 13,186 million, compared to SEK 13,290 million at the year's start, which corresponds to SEK 43.6 (44.0) per share. The equity/assets ratio rose to 39.7% from 37.1% at the start of the year. The translation difference in equity due to currency effects for January-September amounted to SEK –1,370 million (–613).

The Group's net debt totaled SEK 14,195 million on 30 September, compared to SEK 16,129 million at the year's start. The SEK 1,934 million reduction in net debt is primarily attributable to the Group's cash flow.

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PARENT COMPANY

Net sales for January–September reached SEK 2,801 million (1,732), of which intra-Group sales represented SEK 2,231 million (1,382).

Profit before appropriations and tax reached SEK 3,232 million (–44).

Net financial items were SEK 2,420 million (–430), which includes dividend of SEK 2,723 million (24) from subsidiaries.

Investments in intellectual property rights during January–September were SEK 457 million (1,057), and investments in property, plant, and equipment totaled SEK 0 million (0).

Financial non-current assets stood at SEK 20,271 million, compared to SEK 20,853 million at year-end 2008.

AGREEMENTS AND KEY EVENTS

- **FDA APPROVES THE FIRST ONCE-DAILY NASAL ANTIHISTAMINE — LAUNCH STARTED**

The US Food and Drug Administration (FDA) approved Astepro (azelastine) nasal spray 0.15% for treatment of the symptoms of seasonal and perennial allergic rhinitis.. This new product is the first nasal antihistamine approved for once-daily treatment of seasonal allergies (Astepro Once-Daily). Astepro Once-Daily contains azelastine, a leading antihistamine for nasal treatment of allergic rhinitis in the US.

The FDA approval is mainly due to results from seven double-blind placebo-controlled phase-III studies and a 12-month safety study. In total, more than 2,300 patients with allergic rhinitis from seasonal and perennial allergic rhinitis participated in these clinical trials.

US market launch started in October 2009.

- **FDA APPROVES ONSOLIS — LAUNCH STARTED**

The FDA approved Onsolis (fentanyl). This new and patented product is indicated for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Onsolis uses a unique delivery system designed to give rapid and reliable delivery of fentanyl. The product consists of a small dissolvable disc for application of fentanyl to the buccal (inner lining of cheek) membranes. The product is unique and offers an important step to a better pain treatment of cancer patients.

Meda developed a Risk Evaluation and Mitigation Strategy (REMS) for Onsolis in close cooperation with BioDelivery Sciences Inc, Meda's development partner. The FDA approved this REMS.

Meda paid a USD 26.8 million milestone payment in conjunction with the FDA's approval.

The launch of Onsolis on the US market began in mid-October 2009.

The registration work on obtaining approval for Onsolis in other key markets is proceeding as planned.

- **EXPANDED RIGHTS FOR AZELASTINE AND FLUTICASONE COMBINATION PRODUCT**

Meda and Cipla Ltd, a leading pharma company in India, have expanded the existing long term collaboration agreement for the combination of azelastine and fluticasone. Azelastine is an antihistamine and fluticasone a corticosteroid; both are indicated for nasal treatment of allergic rhinitis. As mono substances (in the antihistamine and corticosteroid markets respectively) they have leading positions in the U.S. In the future, a combination of azelastine and fluticasone in a nasal formulation, may give patients with allergic rhinitis a more effective treatment than current therapies.

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In collaboration with Cipla, Meda has been developing this combination for the North American markets during the past years. The product is currently in phase III and the remaining clinical studies are expected to be completed during the second half of 2010. Meda and Cipla have now agreed to extend the collaboration to include other key markets such as Europe, Japan, Brazil, South Korea and Australia.

This product could become the first combination of an antihistamine and corticosteroid in a nasal formulation, which would strengthen Meda's position in the allergy area.

Meda will pay Cipla 5 MUSD upon regulatory approval in the first market and up to 10 MUSD as other milestone payments. Cipla will manufacture the product.

AGREEMENTS AND KEY EVENTS AFTER THE REPORTING DATE

- **RETIGABINE FILINGS SUBMITTED IN THE US AND EUROPE**

Meda's partner, Valeant Pharmaceuticals, announced on November 2 that both the New Drug Application (NDA) and the Marketing Authorisation Application (MAA) were submitted for retigabine on October 30, 2009.

Retigabine is a novel method for affecting potassium channels in the central nervous system. It has been documented for the treatment of epilepsy and has a different mechanism of action than current anti-epileptic drugs.

GlaxoSmithKline, the pharmaceutical company, signed a worldwide collaboration agreement with Valeant Pharmaceuticals for the retigabine substance. Meda is entitled to receive substantial royalties and certain milestone payments for the substance.

- **NEW DRUG APPLICATION SUBMITTED FOR ONSOLIS IN CANADA**

The registration file for Onsolis (fentanyl buccal soluble film) has been submitted to the Canadian regulatory authority; Health Canada. If approved, it may become the first available fentanyl product approved for breakthrough pain in opioid tolerant patients with cancer in Canada. A decision by Health Canada is expected during 2010.

Canada represents an important market for Onsolis. The product will be commercialized by the joint venture between Meda and Valeant (Meda Valeant Pharma Canada Inc.).

FORECAST

In its 2008 year-end report and the Q1 2009 interim report, Meda set a profitability target of an EBITDA margin exceeding 30% for the full-year 2009.

This forecast is given for full-year 2009:

"The Meda Group expects to achieve sales of about SEK 13,000 million and an EBITDA of about SEK 4,200 million for full-year 2009."

RISKS AND UNCERTAINTIES

The Meda Group's operations are exposed to financial risks. Meda's 2008 annual report describes the company's management of these risks (pp 60-61). Several other factors, which Meda cannot fully control, affect the Group's operations. Factors judged particularly significant to Meda's future growth are: competitors and pricing, actions by authorities, partnerships, market assessments, clinical trials, key individuals and recruitment, product liability, patents, and trademarks. The annual report for 2008 describes these types of risks (pp 112–114).

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ACCOUNTING POLICIES

Group

Meda complies with the EU-approved IFRS standards and their interpretations (IFRIC). This interim report was prepared as per IAS 34 Interim financial reporting. New accounting standards applied since 1 January 2009:

The amended IAS 1, Presentation of financial statements. This amendment brings a new structure to financial reporting; the company is required to prepare a statement of comprehensive income, including all changes in assets and liabilities that are not due to transactions with the company's owners. Changes previously recognized directly in equity are now recognized in the Group's statement of comprehensive income. Meda has chosen to present the Group's report on comprehensive income as a separate table.

IFRS 8 Operating segments. This standard replaces the previous IAS 14 Segment reporting. IFRS 8 does not change the definitions of Meda's segments.

In other respects, the Group's accounting policies and calculation methods remain unchanged from the 2008 annual report.

2009 YEAR-END REPORT

The 2009 year-end report will be presented on February 16, 2010.

The board of directors and CEO hereby confirm that this interim report (1) provides a true and fair view of the parent company's and Group's operations, position and performance, and (2) describes material risks and uncertainties faced by the parent company and Group companies.

Stockholm, November 3, 2009

Bert-Åke Eriksson
Board chairman

Peter Claesson
Board member

Marianne Hamilton
Board member

Tuve Johannesson
Board member

Carola Lemne
Board member

Anders Lönner
CEO

Anders Waldenström
Board member

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The company's auditors did not review this interim report.

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Group consolidated income statement

SEK million	January–September			July-September			January–December
	2009	2008	Change	2009	2008	Change	2008
Net sales	9 918	7 515	32%	3 017	2 356	28%	10 675
Cost of sales	-3 351	**-2 498**		-1 060	-817		-3 572
Gross profit	**6 568**	**5 017**	**31%**	**1 958**	**1 539**	**27%**	**7 103**
Selling expenses	-2 163	-1 605		-589	-517		-2 434
Medical and business development expenses[1)]	-1 608	-1 195		-568	-408		-1 688
Administrative expenses	-521	-391		-166	-138		-679
Operating profit (EBIT)	**2 275**	**1 826**	**25%**	**634**	**476**	**33%**	**2 302**
Net financial items	-485	-613		-141	-201		-884
Profit before tax (EBT)	**1 790**	**1 213**	**48%**	**493**	**275**	**79%**	**1 418**
Tax	-586	-405		-156	-91		-464
Net profit	**1 205**	**808**	**49%**	**338**	**184**	**84%**	**954**
[1)]Of which depreciation and amortization of product rights	-982	-723		-341	-246		-1 029
EBITDA	**3 356**	**2 616**		**1 007**	**745**		**3 425**
Amortization, product rights	-982	-723		-341	-246		-1 029
Depreciation and amortization, other	-99	-67		-32	-23		-94
Operating profit (EBIT)	**2 275**	**1 826**		**634**	**476**		**2 302**
EBITDA (excluding restructuring costs)	**3 356**	**2 616**	**28%**	**1 007**	**745**	**35%**	**3 640**
Key ratios related to earnings							
Operating margin, %	22.9	24.3		21.0	20.2		21.6
Profit margin, %	18.0	16.1		16.3	11.7		13.3
EBITDA, %	33.8	34.8		33.4	31.6		32.1
EBITDA, % (excluding restructuring costs)	33.8	34.8		33.4	31.6		34.1
Return on capital employed, rolling 12 months, %	10.2	9.2					8.7
Return on equity, rolling 12 months, %	11.5	9.5					8.4

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Group statement of comprehensive income

SEK million	January–September		July–September		January–December
	2009	2008	2009	2008	2008
Net income	**1 205**	**808**	**338**	**184**	**954**
Translation difference	-1 370	613	-1 131	976	2 418
Net investment hedge, after tax	268	-198	232	-182	-588
Cash flow hedges, after tax	21	17	24	-30	-135
Other comprehensive income for the period, net of tax	**-1 081**	**432**	**-875**	**764**	**1 695**
Total comprehensive income	**124**	**1 240**	**-537**	**948**	**2 649**

Share data

	January–September		July–September		January–December
	2009	2008	2009	2008	2008
Earnings per share[1]					
Earnings per share before dilution, SEK	3.99	2.99	1.12	0.68	3.49
Earnings per share after dilution, SEK	3.99	2.99	1.12	0.68	3.49
Average number of shares[1]					
before dilution (thousands)	302 243	270 380	302 243	270 380	273 601
after dilution (thousands)	302 243	270 380	302 243	270 380	273 601
Number of shares on closing day					
before dilution (thousands)	302 243	259 065	302 243	259 065	302 243
after dilution (thousands)	302 243	259 065	302 243	259 065	302 243

1) Recalculated to consider the bonus issue element in the 2008 new share issue.

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Group consolidated balance sheet

SEK million	30 September 2009	30 September 2008	31 December 2008
ASSETS			
Non-current assets			
- Property, plant, and equipment	865	844	935
- Intangible assets[1)]	27 652	26 913	29 609
- Other non-current assets	832	781	949
Non-current assets	**29 349**	**28 538**	**31 493**
Current assets			
- Inventories	1 679	1 449	1 736
- Current receivables	2 118	2 116	2 388
- Cash and cash equivalents	68	396	198
Current assets	**3 864**	**3 961**	**4 322**
Total assets	**33 213**	**32 499**	**35 815**
EQUITY AND LIABILITIES			
Equity	**13 186**	**10 413**	**13 290**
Non-current liabilities			
- Borrowings	9 005	13 186	12 673
- Pension obligations	874	853	942
- Deferred tax liabilities	2 425	2 379	2 451
- Other liabilities, non-interest-bearing	427	287	507
Non-current liabilities	**12 731**	**16 705**	**16 573**
Current liabilities			
- Borrowings	4 406	2 788	2 753
- Short-term, non-interest-bearing	2 890	2 593	3 199
Current liabilities	**7 296**	**5 381**	**5 952**
Total equity and liabilities	**33 213**	**32 499**	**35 815**
Key ratios affecting balance sheet			
Net debt	14 195	16 390	16 129
Net debt/equity ratio, times	1.1	1.6	1.2
Equity/assets ratio, %	39.7	32.0	37.1
Equity per share, SEK (at end of period)	43.6	40.2	44.0
[1)] Of which goodwill	13 174	12 964	14 256

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Group consolidated cash flow statement

SEK million	January-September		July-September		January–December
	2009	2008	2009	2008	2008
Cash flow from operating activities					
Profit after financial items	1 790	1 213	493	275	1 418
Adjustments for items not included in cash flow	988	793	375	308	1 108
Net change in pensions	-8	-	-8	-2	-18
Net change in other provisions	-122	-138	-12	-36	31
Income taxes paid	-385	-340	-142	-140	-536
Cash flow from operating activities before changes in working capital	**2 263**	**1 528**	**707**	**405**	**2 003**
Cash flow from changes in working capital					
Inventories	-82	-27	-62	-6	-154
Receivables	137	75	29	335	-73
Liabilities	-155	-94	-61	-64	174
Cash flow from operating activities	**2 163**	**1 482**	**613**	**670**	**1 950**
Cash flow from investing activities	-457	-2 991	-310	-2 647	-4 102
Cash flow from financing activities	-1 833	1 647	-446	2 148	2 083
Cash flow for the period	**-127**	**138**	**-144**	**171**	**-69**
Cash and cash equivalents at period's start	198	242	214	204	242
Exchange rate difference for cash and cash equivalents	-3	16	-3	21	25
Cash and cash equivalents at end of period	**68**	**396**	**68**	**396**	**198**
Key ratios affecting cash flow					
Free cash flow, MSEK[1)]	2 081	1 404	579	647	1 839
Cash earnings per share, SEK[2)]	6.88	5.19	1.91	2.39	6.72

[1)] Cash flow from operating activities less investments in property, plant, and equipment
[2)] Calculated on diluted average number of shares

Group change in equity

SEK million	30 September 2009	30 September 2008	31 December 2008
Opening balance, equity	**13 290**	**9 364**	**9 364**
Dividend	-227	-194	-194
New share issue, preferential	-1	-	1 471
Subscription, through exercised rights	-	3	-
Total comprehensive income	124	1 240	2 649
Closing balance, equity	**13 186**	**10 413**	**13 290**

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Information on geographic markets

SEK million	January-September		July-September		January–December
	2009	2008	2009	2008	2008
External net sales					
Northern Europe	1 233	1 130	399	368	1 550
Central and eastern Europe	2 784	1 724	852	558	2 531
Western Europe	3 184	2 505	996	791	3 469
US	2 057	1 555	570	443	2 244
Export markets	482	376	156	130	571
Unallocated sales	178	225	44	66	310
	9 918	**7 515**	**3 017**	**2 356**	**10 675**
EBITDA					
Northern Europe	513	400	166	140	517
Central and eastern Europe	1 067	689	308	218	924
Western Europe	1 411	1 049	450	312	1 353
US	916	783	291	191	1 103
Export markets	179	126	61	50	191
Unallocated sales	-730	-431	-269	-166	-663
	3 356	**2 616**	**1 007**	**745**	**3 425**

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Income statement for the parent company

SEK million	January-September	
	2009	2008
Net sales	2 801	1 732
Cost of sales	-1 176	**-820**
Gross profit	**1 625**	**912**
Other operating income	123	104
Selling expenses	-165	-129
Medicine and business development expenses	-653	-408
Administrative expenses	-118	-93
Operating profit (EBIT)	**812**	**386**
Net financial items	**2 420**[1)]	**-430**
Profit/loss before tax (EBT)	**3 232**	**-44**
Appropriations and tax	**-510**	**70**
Net income	**2 722**	**26**

[1]Net financial items include income from subsidiaries of SEK 2,723 million

Balance sheet for the parent company

SEK million	30 September 2009	31 December 2008
ASSETS		
Non-current assets		
- Intangible	7 218	7 202
- Property, plant, and equipment	1	1
- Financial	20 271	20 853
Total non-current assets	**27 490**	**28 056**
Current assets		
- Inventory	197	157
- Current receivables	839	1 020
- Cash and bank balances	17	3
Total current assets	**1 053**	**1 180**
Total assets	**28 543**	**29 236**
EQUITY AND LIABILITIES		
Restricted equity	3 477	3 477
Non-restricted equity	8 037	5 521
Total equity	**11 514**	**8 998**
Untaxed reserves	1 639	1 129
Provisions	58	66
Non-current liabilities	8 747	12 076
Current liabilities	6 585	6 967
Total equity and liabilities	**28 543**	**29 236**

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