Interim report, 18 August 2009

Meda AB (publ) – Interim report, January–June 2009

- The Group's net sales reached SEK 6,901 million (5,159), a 34% increase compared to the previous year.

- EBITDA rose 26% to SEK 2,349 million (1,871), thus yielding a 34.0% margin (36.3).

- Operating profit climbed to SEK 1,641 million (1,350).

- Profit after tax increased to SEK 867 million (624).

- Earnings per share reached SEK 2.87 (2.31).

- Cash earnings per share rose to SEK 4.97 (2.80).

HIGHLIGHTS

FDA approved Onsolis

- The US Food and Drug Administration (FDA) approved Onsolis (fentanyl). This new, patented drug is designed to treat breakthrough pain in cancer patients.
- Onsolis's unique treatment method enables fast and accurate dosage of fentanyl, the active substance.
- The US market launch will start in Q4 2009.

Successful US launch of Astepro

- Astepro's share of total azelastine prescribed rose to 30% during Q2.
- A formal FDA response to Meda's new registration application for a higher dose of Astepro is expected in September 2009. This product has the potential to be the first approved once-daily nasal antihistamine in the US.

SALES

January–June

Net sales for January–June rose 34% to SEK 6,901 million (5,159). Currency effects regarding like-for-like sales had a positive SEK 860 million impact on sales compared to the previous year. Sales of the most important products in H1 were:

Astepro (allergic and non-allergic rhinitis treatment) had US sales during the period of SEK 169 million after the product was progressively launched during H1.

Astelin (allergic and non-allergic rhinitis treatment) totaled SEK 821 million (771). In the US, sales in local currency were down 22% to USD 89 million (114)—mainly due to the launch of the new Astepro product.

Tambocor (cardiac arrhythmia treatment) reached SEK 484 million (473), a 2% increase on the previous year. Sales in local currency fell somewhat, primarily following the previous year's price decrease in France.

Betadine (infection treatment) rose 15% to SEK 469 million (408). Sales grew in the major south-European markets except for Spain, where sales in local currency decreased.

Minitran (angina prevention) reached SEK 277 million (266).

Aldara (actinic keratosis treatment) displayed ongoing robust growth in the European market. Sales totaled SEK 248 million (195), a 27% increase compared to 2008.

Soma (muscle relaxant) amounted to SEK 240 million (140). Sales in local currency rose by 29%.

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Optivar (allergic conjunctivitis treatment) reached SEK 247 million (194). In the US, sales in local currency were down 1%.

Zamadol (moderate to severe pain treatment) increased 4% to SEK 197 million (189). Meda retained its position from 2008 in local currency despite falling price levels in several European markets.

Novopulmon (budesonide Novolizer, asthma treatment) climbed 21% to SEK 108 million (89).

April–June

Net sales for April–June rose 34% to SEK 3,464 million (2,589). Currency effects regarding like-for-like sales had a positive SEK 429 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) US sales during the period were SEK 123 million. Astepro's proportion of total azelastine prescribed rose to about 30% in Q2.

Astelin (allergic and non-allergic rhinitis treatment) totaled SEK 383 million (366). In the US, sales in local currency were down 25% and reached USD 43 million (57).

Tambocor (cardiac arrhythmia treatment) amounted to SEK 248 million (243), a 2% increase on the previous year.

Betadine (infection treatment) rose 14% to SEK 240 million (211).

Minitran (angina prevention) reached SEK 138 million (138).

Aldara (actinic keratosis treatment) totaled SEK 127 million (105), a 21% increase on the previous year.

Soma (muscle relaxant) amounted to SEK 120 million (74). Sales in local currency were up 22%.

Optivar (allergic conjunctivitis treatment) reached SEK 145 million (114). In the US, sales in local currency increased 2%.

Zamadol (moderate to severe pain treatment) increased 3% to SEK 100 million (97).

Novopulmon (budesonide Novolizer, asthma treatment) climbed 15% to SEK 47 million (41).

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PROFIT

Operating profit

Operating expenses for Q2 amounted to SEK 1,457 million, 4% less than in the previous quarter. This is largely attributable to lower marketing costs (since a large part of the Astepro launch costs were incurred in Q1) and to somewhat lower administrative expenses.

Operating profit for January–June reached SEK 1,641 million (1,350), corresponding to a 22% increase.

EBITDA for the same period was SEK 2,349 million (1,871), yielding a 34.0% margin (36.3).

Operating profit for April–June reached SEK 884 million (689), corresponding to a 28% increase.

EBITDA for the same period was SEK 1,239 million (946), yielding a 35.8% margin (36.5).

Financial items

The Group's net financial items for January–June were SEK –344 million (–412). Higher interest-bearing liabilities compared to the same period the previous year were chiefly compensated for by lower market interest rates. The average interest rate on 30 June 2009 was 4.0% (5.7).

The Group's profit after net financial items for January–June rose to SEK 1,297 million (938).

The Group's net financial items for April–June were SEK –168 million (–199).

Group profit after net financial items for the same period thereby totaled SEK 716 million (490).

Net profit and earnings per share

Net profit for January–June rose 39% to SEK 867 million (624).

Group tax expense for H1 amounted to SEK 430 million (314), equivalent to a tax rate of 33.2% (33.5).

Basic earnings per share for January–June were SEK 2.87 (2.31).

Net profit for April–June rose 47% to SEK 482 million (329).

Group tax expense for April–June amounted to SEK 234 million (161), equivalent to a tax rate of 32.7% (32.9).

Basic earnings per share for April–June were SEK 1.60 (1.22).

CASH FLOW

Cash flow from operating activities, before changes in working capital, for January–June rose to SEK 1,557 million (1,123). Implemented restructuring measures had an adverse effect of SEK –92 million on cash flow. Cash flow from change in working capital was SEK –6 million (–311). Cash flow from operating activities for January–June thereby rose to SEK 1,551 million (812).

Cash flow from operating activities for April–June climbed to SEK 802 million (416).

Cash flow from investing activities amounted to SEK –147 million (–344) for January–June. In January Meda paid the remaining purchase consideration of EUR 10 million for the product portfolio acquired from Roche in 2008.

Cash flow from financing activities amounted to SEK –1,390 million (–501) for H1. Dividend of SEK 227 million was paid to Meda's shareholders in May.

At the end of June, Group cash and cash equivalents were SEK 214 million, compared to SEK 198 million at the start of 2009.

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Cash earnings per share for January–June rose 78% to SEK 4.97 (2.80).

Cash earnings per share for April–June climbed 84% to SEK 2.52 (1.37).

FINANCING

On 30 June equity stood at SEK 13,723 million, compared to SEK 13,290 million at the year's start, which corresponds to SEK 45.4 (44.0) per share. The equity/assets ratio rose to 39.1% from 37.1% at the start of the year. The translation difference in equity for January–June amounted to SEK –239 million (–359).

The Group's net debt totaled SEK 14,945 million on 30 June, compared to SEK 16,129 million at the year's start. The SEK 1,184 million reduction in net debt is attributable to the Group's strong cash flow.

In Q2 Meda refinanced a SEK 2,000 million credit facility in the bank market. This facility is back-up for Meda's commercial paper program. The refinancing took place at competitive rates and the maturity of the facility was extended by 18 months.

PARENT COMPANY

Meda AB markets and sells pharmaceuticals and healthcare products. The company also has interests in subsidiaries that operate in most European markets, the US, and the Middle East.

Net sales for January–June totaled SEK 1,824 million (1,160), of which intra-Group sales represented SEK 1,408 million (839).

Profit before appropriations and tax reached SEK 3,093 million (–39).

Net financial items were SEK 2,496 million (–277), which includes dividend of SEK 2,715 million (24) from subsidiaries.

Cash and cash equivalents amounted to SEK 3 million, compared to SEK 3 million at year-end 2008.

Investments in intellectual property rights during January–June were SEK 204 million (194), and investments in property, plant, and equipment totaled SEK 0 million (0).

Financial non-current assets stood at SEK 20,901 million, compared to SEK 20,853 million at year-end 2008.

AGREEMENTS AND KEY EVENTS

- **ENHANCED PRODUCT PORTFOLIO IN DERMATOLOGY**

Meda signed a long-term license agreement with Valeant, a US pharma company, for marketing a patented combination of the active ingredients clindamycin and tretinoin and for a product containing tretinoin as sole active ingredient. Both products are currently in the registration phase.

The agreement covers all of Europe and strengthens Meda's position in dermatology, a key therapy area. The products are for acne treatment and the European market is estimated to be around SEK 1,500 million.

Meda will pay Valeant a "up-front" payment of about SEK 20 million, and single-digit royalties on sales. Meda will own the selected brands, and the gross margin is estimated to be over 70%. The license agreements are dependent on signing manufacturing agreements.

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AGREEMENTS AND KEY EVENTS AFTER THE REPORTING DATE

- **FDA APPROVED ONSOLIS**

The US Food and Drug Administration (FDA) approved Onsolis (fentanyl). This new and patented drug is designed to treat breakthrough pain in cancer patients. Onsolis has a unique administration method that allows rapid, reliable dosage of fentanyl, the active substance. The product consists of a thin soluble disc that contains fentanyl and is applied to the inside of the cheek. The product is unique and marks an important step toward better pain treatment cancer patients.

Onsolis is another key addition to Meda's product range in the US. Preparations for the US market launch in Q4 are in progress. Meda paid a USD 26.8 million milestone payment on receipt of the FDA's approval.

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

- **EDLUAR BEING LAUNCHED IN THE US**

The FDA approved Edluar (for temporary sleep disorders) in March 2009. The US launch starts in mid-August, which is somewhat ahead of schedule.

- **PRODUCT DEVELOPMENT OF SOMA SUSTAINED RELEASE UNDER EVALUATION**

Meda's product development of SOMA (muscle relaxant) in a sustained release formulation for the US market did not achieve the desired effect in recently completed phase III trials. Evaluation is ongoing.

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).

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.

REPORTS IN 2009

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

Stockholm, 18 August 2009

Bert-Åke Eriksson
Board chairman

Peter Claesson
Board member

Marianne Hamilton
Board member

Tuve Johannesson
Board member

Carola Lemne
Board member

Anders Lönner
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REVIEW REPORT

We have reviewed the interim report for the period January 1 – June 30, 2009 for Meda. The Board of Directors and the CEO are responsible for the preparation and presentation of this interim financial information in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim financial information based on our review.

We conducted our review in accordance with the Standard on Review Engagements SÖG 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Standards on Auditing in Sweden RS and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying interim financial information is not, in all material respects, in accordance with IAS 34 and the Annual Accounts Act, regarding the Group, and with the Annual Accounts Act, regarding the Parent Company.

Stockholm August 18, 2009

PricewaterhouseCoopers AB

Göran Tidström
Authorized public accountant
Partner in charge

Mikael Winkvist
Authorized public accountant

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Group consolidated income statement

SEK million	January–June			April-June			January-December
	2009	2008	Change	2009	2008	Change	2008
Net sales	6,901	5,159	34%	3,464	2,589	34%	10,675
Cost of sales	-2,291	-1,681		-1,123	-842		-3,572
Gross profit	**4,610**	**3,478**	**33%**	**2,341**	**1,747**	**34%**	**7,103**
Selling expenses	-1,574	-1,088		-765	-544		-2,434
Medicine and business development expenses[1)]	-1,040	-787		-523	-395		-1,688
Administrative expenses	-355	-253		-169	-119		-679
Operating profit (EBIT)	**1,641**	**1,350**	**22%**	**884**	**689**	**28%**	**2,302**
Net financial items	-344	-412		-168	-199		-884
Profit before tax (EBT)	**1,297**	**938**	**38%**	**716**	**490**	**46%**	**1,418**
Tax	-430	-314		-234	-161		-464
Net income	**867**	**624**	**39%**	**482**	**329**	**47%**	**954**
[1)]Of which depreciation and amortization of product rights	-641	-477		-321	-236		-1,029
EBITDA	**2,349**	**1,871**		**1,239**	**946**		**3,425**
Amortization, product rights	-641	-477		-321	-236		-1,029
Depreciation and amortization, other	-67	-44		-34	-21		-94
Operating profit (EBIT)	**1,641**	**1,350**		**884**	**689**		**2,302**
EBITDA (excluding restructuring costs)	**2,349**	**1,871**	**26%**	**1,239**	**946**	**31%**	**3,640**
Key ratios related to earnings							
Operating margin, %	23.8	26.2		25.5	26.6		21.6
Profit margin, %	18.8	18.2		20.7	18.9		13.3
EBITDA, %	34.0	36.3		35.8	36.5		32.1
EBITDA, % (excluding restructuring costs)	34.0	36.3		**35.8**	**36.5**		**34.1**
Return on capital employed, rolling 12 months, %	9.9	11.4					8.7
Return on equity, rolling 12 months, %	10.3	12.9					8.4

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Group statement of comprehensive income

SEK million	January-June		April–June		January-December
	2009	2008	2009	2008	2008
Net income	**867**	**624**	**482**	**329**	**954**
Translation difference	-239	-359	-611	108	2,418
Net investment hedge, after tax	36	-16	147	-24	-588
Cash flow hedges, after tax	-3	47	-	45	-135
Other comprehensive income for the period, net of tax	**-206**	**-328**	**-464**	**129**	**1,695**
Total comprehensive income	**661**	**296**	**18**	**458**	**2,649**

Share data

	January–June		April–June		January-December
	2009	2008	2009	2008	2008
Earnings per share[1]					
Basic earnings per share, SEK	2.87	2.31	1.60	1.22	3.49
Diluted earnings per share, SEK	2.87	2.31	1.60	1.22	3.49
Average number of shares[1]					
basic (thousands)	302,243	270,380	302,243	270,380	273,601
diluted (thousands)	302,243	270,380	302,243	270,380	273,601
Number of shares on closing day					
basic (thousands)	302,243	259,065	302,243	259,065	302,243
diluted (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 June 2009	30 June 2008	31 December 2008
ASSETS			
Non-current assets			
- Property, plant, and equipment	918	759	935
- Intangible assets[1]	29,000	23,610	29,609
- Other non-current assets	918	605	949
Non-current assets	**30,836**	**24,974**	**31,493**
Current assets			
- Inventory	1,764	1,176	1,736
- Current receivables	2,280	2,004	2,388
- Cash and cash equivalents	214	204	198
Current assets	4,258	3,384	4,322
Total assets	**35,094**	**28,358**	**35,815**
EQUITY AND LIABILITIES			
Equity	**13,723**	**9,469**	**13,290**
Non-current liabilities			
- Borrowings	10,733	10,685	12,673
- Pension obligations	935	809	942
- Deferred tax liabilities	2,549	2,091	2,451
- Other liabilities, non-interest-bearing	486	280	507
Non-current liabilities	**14,703**	**13,865**	**16,573**
Current liabilities			
- Borrowings	3,520	2,735	2,753
- Short-term, non-interest-bearing	3,148	2,289	3,199
Current liabilities	**6,668**	**5,024**	**5,952**
Total equity and liabilities	**35,094**	**28,358**	**35,815**
Key ratios related to balance sheet			
Net debt	14,945	13,973	16,129
Net debt/equity ratio, times	1.1	1.5	1.2
Equity/assets ratio, %	39.1	33.4	37.1
Equity per share, SEK (at end of period)	45.4	36.55	44.0
[1]Of which goodwill	14,044	11,406	14,256

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Group consolidated cash flow statement

SEK million	January–June		April-June		January–December
	2009	2008	2009	2008	2008
Cash flow from operating activities					
Profit after financial items	1,297	938	716	490	1,418
Adjustments for items not included in cash flow	613	485	310	244	1,108
Net change in pensions	-	2	-7	1	-18
Net change in other provisions	-110	-102	-26	-32	31
Income taxes paid	-243	-200	-203	-171	-536
Cash flow from operating activities before changes in working capital	**1,557**	**1,123**	**790**	**532**	**2,003**
Cash flow from changes in working capital					
Inventory	-20	-21	-37	-1	-154
Receivables	108	-260	196	-86	-73
Liabilities	-94	-30	-147	-29	174
Cash flow from operating activities	**1,551**	**812**	**802**	**416**	**1,950**
Cash flow from investing activities	-147	-344	-31	-237	-4,102
Cash flow from financing activities	-1,390	-501	-854	-130	2,083
Cash flow for the period	**14**	**-33**	**-83**	**49**	**-69**
Cash and cash equivalents at period's start	198	242	299	156	242
Exchange rate difference for cash and cash equivalents	2	-5	-2	-1	25
Cash and cash equivalents at period's end	**214**	**204**	**214**	**204**	**198**
Key ratios related to cash flow					
Free cash flow, MSEK[1]	1,502	757	763	370	1,839
Cash earnings per share, SEK[2]	4.97	2.80	2.52	1.37	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 June 2009	30 June 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	661	296	2,649
Closing balance, equity	**13,723**	**9,469**	**13,290**

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Information on geographic markets

SEK million	January–June		April-June		January–December
	2009	2008	2009	2008	2008
External net sales					
Northern Europe	834	762	396	381	1,642
Central and eastern Europe	1,932	1,166	962	589	2,439
Western Europe	2,188	1,714	1,118	876	3,469
US	1,487	1,112	764	550	2,244
Export markets	326	246	158	122	571
Unallocated sales	134	159	66	71	310
	6,901	**5,159**	**3,464**	**2,589**	**10,675**
EBITDA					
Northern Europe	347	269	171	135	531
Central and eastern Europe	759	462	400	237	910
Western Europe	961	737	509	386	1,353
US	625	592	358	301	1,103
Export markets	118	76	52	39	191
Unallocated sales	-461	-265	-251	-152	-663
	2,349	**1,871**	**1,239**	**946**	**3,425**

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Income statement for the parent company

SEK million	January–June 2009	January–June 2008
Net sales	1,824	1,160
Cost of sales	-806	-556
Gross profit	**1,018**	**604**
Other operating income	77	53
Selling expenses	-98	-87
Medicine and business development expenses	-373	-271
Administrative expenses	-76	-61
Operating profit (EBIT)	**548**	**238**
Net financial items	2,496[1)]	-277
Profit/loss before tax (EBT)	**3,044**	**-39**
Appropriations and tax	-331	62
Net income	**2,713**	**23**

[1]Net financial items includes income from subsidiaries of SEK 2,715 million.

Balance sheet for the parent company

SEK million	30 June 2009	31 December 2008
ASSETS		
Non-current assets		
- Intangible	7,114	7,202
- Property, plant, and equipment	1	1
- Financial	20,901	20,853
Total non-current assets	**28,016**	**28,056**
Current assets		
- Inventory	172	157
- Current receivables	918	1,020
- Cash and bank balances	3	3
Total current assets	**1,093**	**1,180**
Total assets	**29,109**	**29,236**
EQUITY AND LIABILITIES		
Restricted equity	3,477	3,477
Non-restricted equity	8,003	5,521
Total equity	**11,480**	**8,998**
Untaxed reserves	1,460	1,129
Provisions	60	66
Non-current liabilities	10,267	12,076
Current liabilities	5,842	6,967
Total equity and liabilities	**29,109**	**29,236**

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