



## **MEDIVIR INTERIM REPORT 1 JANUARY 2000 – 30 SEPTEMBER 2000**

- The integration of Medivir UK is complete and the new preclinical organisation operational.
- Phase II trials with cold sore preparation ME-609 are now complete with 417 patients. Analysis of coded data has commenced with the goal of reporting the results by the end of the year.
- Reformulation of MIV-150 now completed. Phase I trials continue as planned.
- CCS acquired a range of optical products from Astra Zeneca during October and signed an agreement relating to contract manufacture of Nezeril.
- Profit after financial items amounted to SEK –53. 4 (25.5) million. Net sales amounted to SEK 78.6 (152.6) million.
- CCS increased sales by 11.5% to SEK 57.6 (51.6) million, while also increasing net sales to SEK 13.3 (7.8) million, a rise of 70.5% compared with the corresponding period last year.

### **Integration of Medivir UK is completed**

On 27 March 2000 Medivir reached agreement with Peptide Therapeutics Group plc in relation to acquisition of Peptide's pharmaceutical development operations, now denoted Medivir UK. During the April-August period, the two research organisations have been integrated and created a unified research organisation with a strong project focus.

Medivir UK, localised in Cambridge, England has developed unique patent-pending technologies which significantly expedite preclinical development. This substantially reinforces Medivir's prioritised preclinical research, *inter alia* the development of protease inhibitors. Over and above the patented technologies, the acquisition also brings to Medivir promising research projects for the treatment of autoimmune disorders and osteoporosis. Both of these important therapeutic areas are in great need of new and improved therapies. The Medivir UK acquisition establishes Medivir as an even more internationally competitive European pharmaceuticals company with 125 researchers (of which 50 are contracted externally through university collaborations), patent pending technologies and an expansive project portfolio. In parallel with the acquisition Medivir has additionally expanded its collaborative research with EU-projects where Medivir participates to develop polymerase inhibitors.

### **Development of the shingles antiviral MIV-606 proceeds as planned**

The clinical Phase II study with anti-shingles agent MIV-606 was finalised in December 1999 and analysed during the early part of the year 2000. The study demonstrated that MIV-606 has good efficacy and is at least as good as acyclovir, the currently most used drug against shingles, notwithstanding a substantially lower dose. The study provided further confirmation that MIV-606 has a good safety profile. The now completed Phase II study provides Medivir with high quality documentation as a prelude to coming Phase III trials. The Phase III trials are under preparation simultaneously with activities in relation to the outlicensing of MIV-606.

**The Phase II study with herpes cream ME-609 is now completed.**

The extensive North American Phase II studies embracing 417 patients have now been completed. Analysis of the coded data has commenced with the goal of reporting the results by the end of the year.

AstraZeneca has an option on Me609 when the Phase II study is finalised, which may trigger a minor milestone payment from AstraZeneca. Upon launching of a product Medivir will obtain royalties on sales. CCS is responsible for development of the cream base and will manufacture products arising from this collaboration.

**Reformulation of anti-HIV agent MIV-150**

Additional formulation work to enhance bioavailability and associated studies were commenced during the quarter and have now been completed. The Phase I trials continue as planned together with Chiron and a Phase II study is planned to begin in 2001.

**The MIV-310 project against multiresistant HIV**

As previously announced, Medivir has decided to reopen the clinical development of MIV-310. A new Phase II study is required to ascertain whether MIV-310 is efficacious in patients with multiresistant HIV. Discussions are underway with the appropriate authorities and clinical investigators in relation to the planned Phase II study. It is likely this will mean rescheduling the start of Phase II to the first half of 2001.

**The HBV antiviral MIV-210**

Development of Medivir's compound MIV-210 (FLG), a nucleoside analog against hepatitis B virus (HBV) with enhanced bioavailability, is nearing the commencement of Phase I studies. *In vitro*, MIV-210 displays good activity in the inhibition of HBV replication and has also shown activity against lamivudine-resistant HBV strains. Resistance development is also a growing problem with HBV. Toxicology evaluation is currently underway, as is manufacture of drug for the coming Phase I trials. The goal is to commence these trials before the end of the year.

**CCS continues to develop positively**

CCS' positive sales development continued during the third quarter. The moisturising cream Karbasal, launched during summer 1999, displays the most robust growth and in a short time has captured a market share of around 10%. CCS' other pharmaceuticals also continue to develop positively.

The inclement summer weather slowed the market for retail goods at pharmacies and led to weak sales of CCS' sun screens and skin care products. The poor sales at pharmacies during the period were offset by the introduction of new retail goods in the CCS product range.

CCS' British subsidiary showed a strong sales development and improved profitability. A major contribution to this positive development was an expanded distribution of CCS foot care product range. During the period, Boots, a market-leading chain selling pharmaceuticals and retail goods has launched the range in its 1100 stores. CCS (UK) previously only distributed direct to chiropodists.

During August, construction of a 2700 square metre extension to the existing factory premises was commenced. CCS signed an agreement with ACO Hud during the second quarter in relation to transfer of pharmaceutical and skin care product manufacturing to CCS' production facility in Borlänge, Sweden. The extensions will contribute to continued production rationalisation at CCS and will assist in meeting the substantially increased production volumes under the agreement.

During October CCS signed two agreements with AstraZeneca in which CCS acquires a range of optical products. These products currently have a turnover of around SEK 18 million. Production will be integrated at CCS' production facility at the beginning of 2002. CCS has also signed an agreement in relation to the contract manufacture of Nezeril, similarly starting in

2002. This contract manufacture will increase CCS' annual production volume by 0.4 million units.

### **The Medivir Group's income and expenses**

The Group's net sales amounted to SEK 78 586 (152 626) thousand and operating costs amounted to SEK -144 306 (-131 601) thousand. These costs include amortised goodwill of SEK -1 693 (-1 270) thousand. Net financial items increased to SEK 10 682 (3 401) thousand. Profit after financial items was SEK -53 401 (25 514) thousand and profit per share was SEK -7.16 (3.85).

Net sales for Medivir AB was SEK 19 307 (99 792) thousand. This decrease reflects the USD 12.6 million, which Medivir received during the period January-September 1999 as license income for HIV antiviral MIV-150. Operating costs decreased to SEK -74 967 (-84 967) and operating profit amounted to SEK -55 503 (15 489) thousand. Profit after financial items was SEK -45 253 (18 771).

Net sales for Medivir UK during the period April-September was SEK 0 thousand. Operating profit during this period amounted to SEK -21 081 thousand and profit after financial items was SEK -21 064 thousand.

Net sales for CCS AB for the period increased to SEK 57 607 (51 653) thousand. Operating profit amounted to SEK 13 265 (7 815) and profit after financial items increased to SEK 13 736 (7 922) thousand. Of CCS' net sales, contract manufacture contributes SEK 25 (26) % and export sales contribute SEK 22 (22) %.

A significant component of the sales increase reflects the successful launch of skin care cream Karbasal and the improvements in profit margin arising from rationalised production and improved purchasing agreements.

Net sales for CCS UK was SEK 3 693 (2 405) thousand and the operating profit amounted to SEK 459 (27) thousand. Profit after financial items was SEK 463 (29) thousand.

### **Financial position**

The Group's liquid assets including short-term placements amounted to SEK 381 260 thousand (SEK 147 625 thousand as at 31 December 1999). There were no interest bearing liabilities at 30 September 2000 or 31 December 1999. Shareholders' equity amounted to SEK 523 572 thousand (SEK 238 478 thousand as at 31 December 1999), due to the new share issue during the period (SEK 296 million), a new share option programme (SEK 0.6 million), a directed non-cash share issue in relation to acquisition of Medivir UK (SEK 27.5 million) and conversion of part of the 1996 Medivir option programme (SEK 14.4 million). The Group's equity ratio amounted to 92.0 per cent, compared with 85.7 per cent as at 31 December 1999.

### **Investments**

The Group's gross investments in fixed tangible assets during the period amounted to SEK 23 874 (6 347) thousand. The investments principally relate to completion of the premises for combinatorial chemistry and high throughput screening (HTS) and associated research equipment in Medivir AB. At CCS, the investments relate to extension of existing production facilities and production equipment.

## Forecast

The forecast issued in the 1999 year-end financial statement is superceded by the Medivir UK acquisition, which increases total research expenses by SEK 35-45 million. As previously advised, moving the start of Phase II for MIV-150 to next year also leads to rescheduling of the associated milestone payment and a further negative impact on this year's figures. The net financial items improved by around SEK 9 million as a result of the new share issue. The financial result for the year is dependent upon the outlicensing activities currently underway and therefore no forecast for the year is provided.

## Consolidated Income Statement

Summary, (SEK 000)

	2000 Jan-Sept	1999 Jan-Sept	1998 Jan-Sept	1999 Jan-Dec
<b>Turnover etc.</b>				
Net sales	78 586	152 626	52 374	189 400
Change in inventories	1 325	327	40	1 275
Other turnover	312	761	59	806
<b>Total turnover</b>	<b>80 223</b>	<b>153 714</b>	<b>52 473</b>	<b>191 481</b>
<b>Operating costs</b>				
Raw materials & supplies	-63 480	-73 587	-30 642	-92 756
Personnel costs	-47 412	-29 676	-25 440	-44 245
Depreciation	-9 853	-6 611	-5 463	-8 814
<b>Total operating costs</b>	<b>-144 306</b>	<b>-131 601</b>	<b>-82 987</b>	<b>-175 102</b>
<b>Operating profit</b>	<b>-64 083</b>	<b>22 113</b>	<b>-30 514</b>	<b>16 379</b>
<b>Profit from financial investments</b>				
Profit from other securities and receivables	291	0	158	226
Other interest income, etc	10 478	3 448	5 717	4 739
Interest expenses, etc	-87	-47	-19	-36
<b>Total profit from financial investments</b>	<b>10 682</b>	<b>3 401</b>	<b>5 856</b>	<b>4 929</b>
<b>Profit after financial items</b>	<b>-53 401</b>	<b>25 514</b>	<b>-24 658</b>	<b>21 308</b>
Taxes*	0	0	0	164
<b>Net profit for the period</b>	<b>-53 401</b>	<b>25 514</b>	<b>-24 658</b>	<b>21 472</b>

\* No tax liability was posted for 1999 for Medivir AB as the previous year's results showed a tax deficit.

**Consolidated Balance Sheet**  
Summary (SEK 000)

	<b>2000</b> <b>30 Sept</b>	<b>1999</b> <b>30 Sept</b>	<b>1998</b> <b>30 Sept</b>	<b>1999</b> <b>31 dec</b>
<b>Assets</b>				
<b>Fixed assets</b>				
Intangible fixed assets	42 304	26 905	28 595	26 481
Tangible fixed assets	80 572	51 251	47 903	51 225
Financial fixed assets	3 133	3 133	5 257	3 133
<b>Total fixed assets</b>	<b>126 009</b>	<b>81 289</b>	<b>81 755</b>	<b>80 839</b>
<b>Currents assets</b>				
Inventories	40 343	35 147	11 690	36 094
Current receivables	21 478	14 104	19 473	13 583
Cash & bank balance & other short term investments	381 260	144 960	141 830	147 625
<b>Total current assets</b>	<b>443 081</b>	<b>194 211</b>	<b>172 993</b>	<b>197 302</b>
<b>Total assets</b>	<b>569 090</b>	<b>275 500</b>	<b>254 748</b>	<b>278 141</b>
<b>Liabilities and shareholders' equity</b>				
Shareholders' equity	523 572	242 519	224 570	238 478
Provisions	6 245	6 498	6 752	6 245
Long term liabilities	0	0	0	0
Current liabilities	39 273	26 483	23 426	33 418
<b>Total liabilities and share- holders' equity</b>	<b>569 090</b>	<b>275 500</b>	<b>254 748</b>	<b>278 141</b>

**Consolidated Income Statement**

Summary, (SEK 000)

	<b>2000</b>	<b>1999</b>	<b>1998</b>
	<b>July-Sept</b>	<b>July-Sept</b>	<b>July-Sept</b>
<b>Turnover etc.</b>			
Net sales	23 866	42 124	15 916
Change in inventories	1 240	-451	-170
Other turnover	292	334	18
<b>Total turnover</b>	<b>25 398</b>	<b>42 007</b>	<b>15 764</b>
<b>Operating costs</b>			
Raw materials and supplies	-5 507	-6 583	-6 263
Other external costs	-23 426	-27 565	-11 144
Personnel costs	-17 512	-9 666	-7 865
Depreciation	-3 919	-2 233	-1 881
<b>Total operating costs</b>	<b>-50 364</b>	<b>-46 047</b>	<b>-27 153</b>
<b>Operating profit</b>	<b>-24 966</b>	<b>-4 040</b>	<b>-11 389</b>
<b>Profit from financial investments</b>			
Profit from other securities and receivables	35	0	158
Other interest income, etc	5 429	1 087	1 575
Interest expenses, etc	-5	-3	-15
<b>Total profit from financial investments</b>	<b>5 459</b>	<b>1 084</b>	<b>1 718</b>
<b>Profit after financial items</b>	<b>-19 507</b>	<b>-2 956</b>	<b>-9 671</b>
Taxes	0	0	0
<b>Net profit for the period</b>	<b>-19 507</b>	<b>-2 956</b>	<b>-9 671</b>

**Group Cash Flow Analysis**  
Summary (SEK 000)

	<b>Jan-Sept 2000</b>	<b>Jan-Sept 1999</b>	<b>Jan-Sept 1998</b>	<b>Jan-Dec 1999</b>
<b>Operations</b>				
Operating profit after financial items	-53 401	25 514	-24 658	21 308
Adjustment for non-cash flow items:				
Depreciation	9 853	6 611	5 463	8 814
Exchange rate fluctuation	-877	0	0	0
Capital gains(-) /loss(+) on divested fixed assets	-100	-8	0	-12
Tax paid	-733	0	0	9
<b>Cash flow from operations before changes in working capital</b>	<b>-45 258</b>	<b>32 117</b>	<b>-19 195</b>	<b>30 119</b>
Changes in working capital	-7 472	-14 390	-3 661	-7 971
<b>Cash flow from operations</b>	<b>-52 730</b>	<b>17 727</b>	<b>-22 856</b>	<b>22 148</b>
<b>Investment activities</b>				
Acquisition of fixed assets	-23 874	-6 347	-11 506	-8 194
Acquisition of financial assets	-873	0	0	0
Divestiture of fixed assets	140	246	0	337
<b>Cash flow from investment activities</b>	<b>-24 607</b>	<b>-6 101</b>	<b>-11 506</b>	<b>-7 857</b>
<b>Financing activities</b>				
Cash flow from financial activity	310 972	0	2 055	0
<b>Cash flow from financing activities</b>	<b>310 972</b>	<b>0</b>	<b>2 055</b>	<b>0</b>
<b>Cash flow for the period</b>				
Liquid assets* brought forward	147 625	133 334	174 137	133 334
Change in liquid assets	233 635	11 626	-32 307	14 291
<b>Liquid assets, closing balance*</b>	<b>381 260</b>	<b>144 960</b>	<b>141 830</b>	<b>147 625</b>

\* Liquid assets relates to bank deposits and short term placements.

## Financial Ratios

	2000 Jan-Sept	1999 Jan-Sept	1998 Jan-Sept	1999 Jan-Dec
Return on:				
- equity, %	-14.0	11.3	-10.4	9.6
- capital employed, %	-14.0	11.3	-10.4	9.5
- total capital, %	-12.6	10.0	-9.3	8.3
Average number of shares, thousands*	7 459	6 626	6 596	6 626
Number of shares at the end of the period, thousands*	8 262	6 655	6 596	6 655
Earnings per share, SEK*	-7.16	3.85	-3.74	3.24
Shareholders' equity per share, SEK*	63.37	36.44	34.05	35.83
Cash flow per share, SEK*	31.3	1.75	-4.9	2.16
Earnings per share, SEK**	-6.74	3.87	-3.36	3.33
Shareholders' equity per share, SEK**	67.48	42.30	40.07	41.79
Equity ratio, %	92.0	88.0	88.2	85.7

\* Adjusted for bonus issues and split.

\*\* Adjusted for bonus issues and split after full exercise of outstanding warrants.

Huddinge 25 October 2000

MEDIVIR AB (publ)

Medivir's auditors have not subjected this report to an in-depth examination.

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The Financial Statement for 2000 will be published on 15 February 2001.

The Annual General Meeting will be held on 28 March 2001.

The Interim Report for the first quarter will be published on 10 May 2001.

At this date the report will be on our web-site [www.medivir.se](http://www.medivir.se)

*Medivir is a research and development company, which develops new and improved pharmaceuticals for the treatment of infection and associated diseases. Through its subsidiary CCS, Medivir develops, manufactures and markets body care products and pharmaceuticals. The Group has been listed on the O list of the Stockholm Stock Exchange since November 1996 and consists of the parent company Medivir AB, wholly owned British subsidiary, Medivir UK Ltd, wholly owned subsidiary CCS AB and CCS' British subsidiary CCS (UK) Ltd.*