

MEDIVIR, INTERIM REPORT, 1 January – 30 September 2004

- Medivir's major and rapid advances within hepatitis C research have resulted in one protease project reaching its preclinical optimization phase.
- In August, Medivir and Novartis resolved the partly overlapping patent issue on ME-609 (herpes) in the US.
- The collaboration between Medivir and Biovitrum in the diabetes segment, which began in July, is now fully up and running.
- Medivir's new rights issue was fully subscribed in June, raising the company SEK 322.5 m before deducting issue costs.
- Net sales amounted to SEK 18.4 m in the period (148.2 inc. CCS, 63.1 exc. CCS).
- The loss after tax was SEK -131.6 m (previous year: a profit of SEK 2.3 m for the group included gains from the divestiture of CCS, and SEK -0.9 m for the research operations also included these gains). Earnings per share were SEK -12.25 (0.27).

FOR MORE INFORMATION, PLEASE CONTACT

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FORTHCOMING FINANCIAL INFORMATION

The Financial Statement will be published on 18 February 2005

The Three-month Interim Report will be published on 21 April 2005

The Annual General Meeting will be held on 21 April 2005, from 3 p.m.

Medivir's financial reports are available from its Website, www.medivir.se from these dates, under the 'Financial Information' heading.

The Medivir Group

Medivir is an innovative, specialist research corporation that develops drugs with the objective of becoming a sustaining and profitable pharmaceuticals corporation. Medivir is located in Huddinge, Sweden and near Cambridge, UK.

Medivir's research is oriented on developing new drug compounds based on polymerases and proteases as target enzymes. The group consists of Medivir AB, its subsidiary Medivir UK Ltd. and Medivir Personal AB. As of 30 September 2004, the group had 125 employees. Medivir was listed on the Stockholm Exchange O-list in 1996. Medivir's research portfolio includes projects against HIV, jaundice, shingles, cold sores, osteoporosis, RA (rheumatoid arthritis), asthma and MS (multiple sclerosis). Medivir has five projects in clinical development phases, each with a unique clinical profile. The company's broad-based preclinical research portfolio houses six defined projects and nearly ten activities in various preclinical phases.

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INFECTIOUS DISEASES

Valomaciclovir (Previously RP-606); Phase II Concluded, Proceeding to Phase III

Data from a phase IIb trial on the **shingles** indication suggests that valomaciclovir is more effective than current therapies in terms of alleviation of the chronic pain (PHN, post-herpetic neuralgia) after acute shingles infection.

During the summer, Medivir's partner—Reliant—concluded its efforts on upscaling, tablet formulation and pharmacological trials ahead of forthcoming registration studies.

Discussions are currently underway with the FDA regarding the design of further trials to demonstrate a palpable effect on PHN optimally. The design of forthcoming trials is crucial, because a significant difference in efficacy against PHN over and above extant drugs might imply an opportunity to position valomaciclovir as first line therapy for treating shingles.

On a suitable occasion, Medivir and Reliant intend to reach an agreement with partners outside their respective market territories (the Nordic region and North America), whereupon Medivir is entitled to have 50% or more of revenues on these markets. Reliant is funding, and is responsible for, ongoing clinical development, application for market registration in North America and Europe and marketing in North America.

ME-609: Phase II Concluded, Proceeding to Phase III

Data from a phase IIb trial on the **labial herpes** indication (cold sores) suggests that with early treatment start, ME-609 may prevent the incidence of lesions and cold sores. These results suggest an opportunity to differentiate ME-609 from extant drugs for treating cold sores.

Preparations for phase III trials are underway, including upscaling, production of the substance for clinical trials and discussions regarding trial structure with the FDA.

In August, Medivir and Novartis resolved the issue of partly overlapping patents in the US. A two-way, no-fee licensing agreement will confer Medivir with the exclusive rights to topical combination products (such as creams) containing the virus inhibitor acyclovir or Medivir's proprietary virus inhibitor omaciclovir. Novartis will receive a non-exclusive license to certain combination products containing compounds such as penciclovir. Medivir will retain exclusive rights to its formulation patents. As in Europe, patent protection in the US extends to 2016.

In parallel with preparatory efforts ahead of forthcoming registration studies, Medivir has pursued contacts with potential partners in order to find a partnership model for the remaining development and future marketing.

Alovudine (previously MIV-310); Phase II Continues

Data from a concluded phase IIa trial suggests that as a supplement to current therapy, alovudine confers extremely good efficacy against multiresistant strains of **HIV**. These trial results suggest an opportunity to differentiate alovudine distinctly from extant HIV drugs.

Medivir's partner, Boehringer Ingelheim, is currently undertaking a further large phase IIa study to determine an optimal dose for ongoing development efforts. Long-term toxicological studies continue in parallel. Boehringer Ingelheim is funding, and is responsible for, onward clinical development, retaining global rights outside the Nordic market.

MIV-210; Phase I Concluded

In vitro trials show that MIV-210 enjoys extremely good efficacy against multiresistant strains of **HIV**. These trial results suggest an opportunity to differentiate MIV-210 distinctly from extant HIV drugs.

At present, Medivir's partner—GlaxoSmithKline—is evaluating the substance's long-term toxicological profile to assess the future clinical dose. GlaxoSmithKline is funding, and is responsible for, onward clinical development, and is retaining global rights outside the Nordic market.

MIV-150; Phase I

Preclinical data shows that MIV-150 has a pronounced effect against **HIV**. Medivir has outlicensed MIV-150 to the Population Council, a New York-based non-profit organization. The Population Council is responsible for development and funding of forthcoming clinical trials. Medivir has voluntarily donated the rights for topical use in a vaginal microbicide in developing countries. Medivir has retained rights to sales in other countries, and an option to receive exclusive rights on the Nordic market. MIV-150 has concluded phase I with oral dosage.

Medivir and the Population Council presented the results of preclinical trials of a combination of MIV-150 and Carraguard against HIV at the international congress Microbicides 2004 in London in late March. This type of combination product may be a vital tool in the struggle against the increasing spread of HIV.

MV026048; in Preclinical Development Phase

MV026048 is an NNRTI polymerase inhibitor for treating **HIV**. In November 2003, Medivir took back development responsibility from Roche, which has an advisory role on this project. Efforts are focused on preclinical safety studies and evaluation of the clinical development program.

MIV-170; in Preclinical Optimization Phase

MIV-170 is an NNRTI polymerase inhibitor, specifically intended for therapy for the growing multiresistant HIV patient population. Two highly active inhibitors have been identified, which are now being evaluated in a number of test models to document their effect against the multiresistant virus, and their safety.

HCV Polymerase; Preclinical Optimization Phase

In November 2003, Medivir entered a collaborative agreement with Roche to jointly develop a drug against chronic **HCV (hepatitis C virus)**. Medivir will receive research contributions, milestone payments and royalty revenues within the auspices of this collaboration, while Medivir also retains rights to the Nordic markets.

This collaboration is based on development of new, what are termed ribonucleoside analogues that inhibit hepatitis C polymerase, thereby preventing virus replication. Promising substances have been identified. Synthesis efforts are based on extensive shared know-how regarding how these nucleoside analogues should be developed to block HCV replication, and on Roche's extensive knowledge in the hepatitis C segment. This jointly pursued research continues to progress positively.

HCV Protease; in Preclinical Optimization Phase

In a very short time, Medivir has developed several new types of highly potent inhibitor of viral **hepatitis C** protease in house. This enzyme is essential to the virus's capacity to replicate. The substances produced effectively impair virus replication in a cell-based *in vitro* model, which closely predicts efficacy on HCV-infected individuals. Extensive patent efforts have been completed and the project advanced to its preclinical optimization phase in the period.

In recent years, the HCV segment has attracted extensive research interest from many corporations, with major initiatives undertaken to bring new compounds to clinical development.

AUTOIMMUNE DISORDERS

Cathepsin S; in Preclinical Development

The cathepsin S project (protease inhibitor) is intended for the treatment of **autoimmune disorders**. This project is being pursued jointly with Peptimmune of the US, against RA (rheumatoid arthritis) and MS (multiple sclerosis) with other potential indications including chronic pain.

A CD was selected in late March, the project is now in the regulated preclinical development phase and the goal is to file an IND (Investigational New Drug) application and proceed to clinical trials.

A cathepsin S follow-up project was initiated in the spring and is making rapid progress thanks to cumulative experience on the project. This will ensure that the project gains access to new potential CDs with differing biological and physical chemistry characteristics for onward screening in the extensive autoimmune deficiency segment.

OTHER THERAPY AREAS

Cathepsin K; in Late Preclinical Optimization Phase

Cathepsin K is a protease whose activity results in skeletal deterioration. **Osteoporosis** (brittle bones) arises coincident with increased Cathepsin K activity or an imbalance between skeletal formation and resorption.

Disease models demonstrate that the pathological deterioration of skeletal tissue can be radically reduced if Cathepsin K activity is inhibited. Medivir's inhibitor has demonstrated vigorous efficacy in a human cell-based model of skeletal resorption (breakdown).

This project is currently making brisk progress in its optimization phase. The ambition is to select a CD on this project at the next stage, for onward development towards clinical trials.

EARLY-PHASE ACTIVITIES

Medivir has nearly ten activities in phases before preclinical optimization, in segments such as HIV-NNRTI, HIV-NRTI, COPD and diabetes.

In July, Medivir and Biovitrum signed up for a research collaboration within type 2 diabetes; the collaboration began in the period, and is now fully underway. The intention of this agreement is to utilize both participants' strengths to develop a CD for treating type 2 diabetes. With its know-how within proteases and its technologies, Medivir will complement Biovitrum's current research in this segment. In the COPD area Medivir collaborates with the Chinese company Hengrui. Several early-phase activities are made with prominent university groups.

MEDIVIR'S CONSOLIDATED TURNOVER AND COSTS

The Group

Consolidated net sales in 1 January - 30 September 2004 amounted to SEK 18.4 (148.2) m, and operating costs were SEK -155.0 (-214.0) m, which include goodwill amortization of SEK -1.3 (-2.1) m. The net financial position was SEK 4.2 m (previous year: SEK 64.9 m including the divestiture of CCS), while the profit after financial items was SEK -131.6 (2.3) m.

The consolidated figures for January - September 2003 include the CCS group's turnover and costs until 30 June 2003 inclusive. The CCS group was divested on 1 July 2003, and the gains from this transaction are accounted in the Income Statement for 2003 under the 'profit from financial investments' item.

Medivir's Research Operations

The net sales of Medivir's research operations, encompassing Medivir AB and Medivir UK Ltd., were SEK 18.4 (63.1) m in the period, which primarily comprises remuneration from Roche for its research into HCV polymerase. The previous year's net sales largely comprise the outlicensing of MIV-210 to GlaxoSmithKline. Operating costs amounted to SEK -154.9 (-141.2) m, divided between external costs of SEK -74.6 (-62.8) m, personnel costs of SEK -68.5 (-67.2) m and depreciation and amortization (including goodwill amortization) of SEK -11.9 (-12.5) m. Operating profit was SEK -135.8 (-78.6) m, while profit after financial items was SEK -131.6 (-0.9) m.

Medivir AB, Corporate Identity No. 556238-4361, Parent Company

Medivir AB's business comprises research operations and group-wide administrative functions. In the period, parent company net sales amounted to SEK 16.9 (66.5) m and operating costs to SEK -139.8 (-124.7) m with these costs including SEK -43.8 (-31.6) m of remuneration to Medivir UK of Cambridge for contracted preclinical research. Profit after financial items, and profit after tax, were SEK -126.5 m (previous year: SEK 20.4 m including the divestiture of CCS).

The profit figure includes covering a loss in Medivir UK of SEK 9.0 m. Liquid assets were SEK 421.4 (269.8) m, with investments in the period, primarily in research equipment, of SEK 8.1 (4.3) m.

Financial Position

As of 30 September, consolidated liquid assets including short-term investments stood at SEK 423.6 (270.8) m, with the increase in liquid assets due to the new rights issue consummated in the second quarter, which raised SEK 322.5 m before issue costs. The market value of listed equities, accounted under 'financial fixed assets' of SEK 5.4 (9.6) m, is additional. Listed equities with a book value of SEK 1.3 m were divested in September for SEK 3.9 m.

As of 30 September, interest-bearing liabilities were SEK 30.9 (3.3) m. Shareholders' equity stood at SEK 459.2 (320.4) m. The consolidated equity ratio was 87.5 (93.4)%.

Investments

Gross investments in consolidated tangible fixed assets amounted to SEK 44.7 (8.0) m in the period, of which SEK 30.6 m in new research premises for Medivir UK, SEK 2.3 m for construction in progress at Medivir AB's existing research premises, with the remainder relating to the acquisition of research equipment within Medivir AB and Medivir UK Ltd.

Medivir's planned future investments primarily comprise the acquisition of further research equipment and investments as a consequence of Medivir UK's relocation to new premises in Chesterford in late-September 2004. The total investments in the new premises in Chesterford are estimated at some SEK 48 m. In the period, Medivir AB drew down a SEK 27.5 m loan to finance the new UK premises. The costs for rent and operation of the new premises are estimated at just below previous cost of premises.

The Share

The AGM of 22 April approved the execution of a new issue with preferential rights for existing shareholders. The transaction offered the right to subscribe for one new class B share for SEK 75 for every two class A and/or class B shares held, raising SEK 322.5 m for Medivir.

In February, Medivir issued 9,765 new class B shares through outstanding staff stock options; in June, the number of class B shares increased by a further 4,299,682 through the aforementioned new rights issue. In September, 2,849 class B shares were issued through outstanding staff stock options. The total number of outstanding shares is thus 12,901,896, comprising 660,000 class A and 12,241,896 class B shares. Previous staff stock option plans from 2000, 2001 and 2002 have been recalculated due to the consummated new rights issue. This implies that in total, the number of outstanding options is 647,545, and upon full conversion, the total number of shares would be 13,593,196.

Accounting Principles

This Interim Report has been prepared pursuant to the Swedish Annual Accounts Act and RR's (*Redovisningsrådet*, the Swedish Financial Accounting Standards Council) recommendation RR 20 Interim Reports. The accounting and valuation principles are consistent with RR recommendations and statements.

From 1 January 2004, Medivir is applying RR's recommendation RR 29 Employee Benefits. Medivir AB's ITP (supplementary pensions for salaried employees) are insured with Alecta, and should be regarded as a defined-benefit pension plan, pursuant to statement URA 42 from the RR Emerging Issues Task Force. Because Alecta is unable to provide sufficient information at present, the plan is accounted as a defined-contribution plan. The group's other pension plans are defined contribution. Accordingly, the application of RR 29 has not implied any change to Medivir's accounting of pension commitments compared to its Annual Report 2003.

Overheads associated with the new rights issue impacted both the parent company's and consolidated restricted equity.

In its Annual Report for 2003, Medivir reviewed the accounting principles it observes, how its efforts are proceeding for adaptation to the IFRS (International Financial Reporting Standards) that all quoted corporations will observe from 2005 onwards, and their implications for Medivir.

The accounting principles and calculation methods in this report are unchanged from the Annual Report for 2003. At present, Medivir is examining the potential discrepancies that may arise coincident with the corporation transferring to IFRS.

Outlook

Medivir's ability to produce new CDs, to enter partnerships on its projects, and to bring its clinical development projects to market launches and sales, is decisive to its future. Existing and new partnerships may exert a major influence on Medivir's revenues and cash position, although scheduling revenue flows is impossible. Medivir's estimated research costs are SEK 175 m for 2004. As stated in the new rights issue prospectus, some additional initiatives on the cathepsin in S and K research programs will be undertaken in the remainder of the year to precipitate development towards clinical trials.

Medivir
The Board

Huddinge, Sweden, 26 October 2004.

Audit Report

We have performed a summary review of this Interim Report pursuant to the relevant recommendation issued by FAR (the Institute for the Accountancy Profession in Sweden). A summary review is far more limited than a full audit. Nothing has arisen to suggest that this Interim Report does not satisfy the stipulations of the Swedish Stock Exchange and Annual Accounts Acts.

Liselott Stenudd
Authorised Public Accountant

Peter Clemedtson
Authorised Public Accountant

Stockholm, Sweden, 26 October 2004.

CONSOLIDATED INCOME STATEMENT, AGGREGATE

Summary, SEK m

	2004 Jan-Sep	2003 Jan-Sep	2002 Jan-Sep	2003 Jan-Dec
Turnover, etc.				
Net sales	18.4	148.2	208.7	149.0
Change in inventories and other revenues	0.8	3.2	1.5	3.6
Total	19.2	151.4	210.2	152.6
Operating costs				
Raw materials and consumables	0.0	-33.7	-50.2	-33.7
Other external costs	-74.6	-76.7	-90.4	-101.8
Personnel costs	-68.5	-87.1	-81.1	-109.0
Depreciation	-11.9	-16.5	-17.9	-20.4
Total operating costs	-155.0	-214.0	-239.6	-264.9
Operating profit	-135.8	-62.6	-29.4	-112.3
Profit from financial investments	4.2	64.9	2.7	69.6
Profit after financial items	-131.6	2.3	-26.7	-42.7
Tax*	0.0	0.0	0.0	2.4
Net profit	-131.6	2.3	-26.7	-40.3
Earnings per share, SEK	-12.25	0.27	-3.16	-4.69
Average number of shares, 000	10 746	8 590	8 439	8 590
Number of shares, closing balance, 000	12 902	8 590	8 590	8 590

* The positive tax amount is mainly attributable to Medivir UK's tax credits, a consequence of UK fiscal legislative support for research. The Group has estimated accrued tax-deductible losses of at least SEK 400 m until 2003 inclusive.

CONSOLIDATED INCOME STATEMENT, QUARTERLY

Summary, SEK m

	2004 July-Sep	2003 July-Sep	2002 July-Sep
Turnover, etc.			
Net sales	5.9	9.6	43.1
Change in inventories and other revenues	0.2	0.8	-0.4
Total	6.1	10.4	42.7
Operating costs			
Raw materials and consumables	0.0	0.0	-15.4
Other external costs	-23.5	-17.0	-27.9
Personnel costs	-20.8	-18.4	-25.4
Depreciation	-4.0	-4.0	-6.0
Total operating costs	-48.3	-39.4	-74.7
Operating profit	-42.2	-29.0	-31.9
Profit from financial investments	3.1	64.6	1.0
Profit after financial items	-39.1	35.6	-31.0
Tax	0.0	0.0	0.0
Net profit	-39.1	35.6	-31.0

CONSOLIDATED BALANCE SHEET

Summary, SEK m

	2004 30 Sep	2003 30 Sep	2002 30 Sep	2003 31 Dec
Assets				
Fixed assets				
Intangible fixed assets	9.4	11.1	38.0	10.7
Tangible fixed assets	74.6	40.9	105.6	40.2
Financial fixed assets	1.8	3.2	3.1	3.1
Total fixed assets	85.8	55.2	146.7	54.0
Current assets				
Inventories	0.0	5.4	42.4	0.0
Current receivables	15.6	11.5	52.6	14.5
Short-term investments	358.0	264.8	130.2	229.0
Cash and bank balances	65.6	6.0	26.1	10.2
Total current assets	439.2	287.7	251.3	253.7
Total assets	525.0	342.9	398.0	307.7
Liabilities and shareholders' equity				
Restricted equity	863.3	585.3	588.5	552.1
Accumulated deficit	-404.1	-264.9	-234.8	-274.2
Total shareholders' equity	459.2	320.4	353.7	277.8
Provisions	0.0	0.0	4.5	0.0
Long-term liabilities, interest-bearing	21.8	3.3	2.4	3.4
Current liabilities, interest-bearing	9.2	0.0	0.0	0.0
Current liabilities, non interest-bearing	34.8	19.2	37.4	26.5
Total liabilities and shareholders' equity	525.0	342.9	398.0	307.7
Assets pledged				
Pledged current investments	13.8	0.0	3.0	0.0

Change in shareholders' equity (SEK m)

	2004 Jan-Sep	2003 Jan-Sep	2002 Jan-Sep
Balance sheet, 31 Dec 2003	277.8	320.0	361.2
New rights issue	313.6		20.5
Exchange rate differences	-0.6	-1.9	-1.3
Net profit	-131.6	2.3	-26.7
Balance sheet, 30 September 2004	459.2	320.4	353.7

CONSOLIDATED CASH FLOW STATEMENT

Summary, SEK m

	2004 Jan-Sep	2003 Jan-Sep	2002 Jan-Sep	2003 Jan-Dec
Ongoing operations				
Operating profit after financial items	-131.6	2.3	-26.7	-42.7
Estimated subsidiary tax credit	0.0	0.0	0.0	2.4
<i>Adjustment for items not included in cash flow:</i>				
Divestment of subsidiaries	0.0	-53.7	0.0	-53.7
Depreciation and write-downs	11.9	16.5	17.9	20.4
Capital gain/loss on divestment of fixed assets and exchange rate difference	-3.6	-2.1	-0.4	-2.5
Received/paid tax	-1.0	0.8	-1.8	3.2
Cash flow from ongoing operations before change in working capital	-124.3	-36.2	-11.0	-72.9
Change in working capital	8.4	-1.8	-23.3	5.5
Cash flow from ongoing operations	-115.9	-38.0	-34.3	-67.4
Investment activity				
Acquisition/divestment of tangible fixed assets	-44.7	-7.8	-10.7	-10.0
Acquisition of intangible fixed assets	0.0	0.0	-3.4	0.0
Divestment of subsidiaries	0.0	114.1	0.0	114.1
Divestment of financial fixed assets	3.9	0.0	0.0	0.0
Reduction in long-term receivables	0.0	59.5	0.0	59.5
Cash flow from investment activity	-40.8	165.8	-14.1	163.6
Financing activity				
New rights issue	313.6	0.0	20.5	0.0
Increase (+) / decrease (-) in long-term liabilities	0.0	-0.8	1.5	0.0
Loans raised	27.6	0.0	0.0	0.0
Amortisation	0.0	0.0	0.0	-0.8
Cash flow from financing activity	341.2	-0.8	22.0	-0.8
Cash flow for the period				
Liquid assets, opening balance*	239.2	143.9	182.7	143.9
Change in liquid assets	184.4	127.0	-26.4	95.4
Exchange rate difference, liquid assets	0.0	-0.1	-0.1	-0.1
Liquid assets, closing balance*	423.6	270.8	156.2	239.2

* Liquid assets comprise cash and bank balances, plus short-term investments. The market value of listed equities, of SEK 5.4 m (SEK 10.4 m at year-end 2003) is additional to the above. As collateral for the SEK 27.5 m loan it has raised, Medivir AB has pledged short-term investments of SEK 13.8 m.

KEY FIGURES

	2004 Jan-Sep	2003 Jan-Sep	2002 Jan-Sep	2003 Jan-Dec
Return on:				
- equity, %	-35.72	0.71	-7.46	-13.49
- capital employed, %	-34.51	0.88	-7.34	-13.91
- total capital, %	-31.59	0.80	-6.52	-12.43
Average number of shares, 000	10 746	8 590	8 439	8 590
Number of shares, closing balance, 000	12 902	8 590	8 590	8 590
Outstanding warrants, 000	647.5	513.4	313.4	449.9
Earnings per share, SEK	-12.25	0.27	-3.16	-4.69
Shareholders' equity per share, SEK	35.59	37.30	41.18	32.35
Cash flow per share after investments, SEK	-14.59	14.86	-5.75	11.20
Earnings per share, SEK* **	-11.34	0.44	-2.89	-4.27
Shareholders' equity per share, SEK* **	39.07	42.42	45.62	36.33
Equity ratio, %	87.47	93.44	88.86	90.30

For forecast year-2004 earnings per share, please refer to the "Outlook" heading in the section on Medivir's consolidated turnover and costs.

* After full utilization of outstanding warrants.

RR's (the Swedish Financial Accounting Standards Council) instruction No. 18 stipulates that any potential ordinary shares do not give rise to any dilution effect when their conversion into ordinary shares results in increased EPS, which would occur upon the conversion of Medivir's outstanding warrants. Thus, the above should not be considered a calculation of dilution effects but a theoretical calculation on profit and shareholders' equity per share, after the full exercise of outstanding warrants.

** As the new rights issue was completed in June 2004 the earlier option plans 2000, 2001 and 2002 were recounted. The warrants from these programs confer conversion of 1.10 shares per warrant and the exercise price has been recounted.

