

#### Press Release, 20 October 2008

# **Medivir, Interim Report, 1 January – 30 September 2008**

- Net sales were SEK 31.9 (80.8) m. In May, Medivir signed an additional agreement with Tibotec Pharmaceuticals Ltd. on hepatitis C, triggering a SEK 46.2 m (EUR 5 m) payment. This amount has been allocated over the assessed agreement term, with SEK 9.6 m recognized as revenue.
- The loss after tax amounted to SEK -102.4 (-138.1) m.
- Earnings per share were SEK -4.91 (-8.23).
- Cash flow from operating activities was SEK -30.4 (-129.6) m.
- Liquid assets as of 30 September were SEK 295.7 (264.0) m.

# CEO's statement—comments on the third quarter

In September, we reported the most important clinical results yet for TMC435350, our hepatitis C project conducted together with Tibotec. The results are from the two first dose groups which are completed and analyzed in the ongoing phase IIa study. These results will be presented at the annual meeting of the AASLD (American Association for the Study of Liver Diseases) in early-November.

The results can be summarized as follows:

- TMC435350 had a dose-dependent antiviral activity at doses of 25 mg and 75 mg once daily, both with and without simultaneous SoC (standard of care, peginterferon alpha-2a and ribavirin) treatment.
- The group that received four weeks' treatment at 75 mg per day of TMC435350 with simultaneous SoC showed undetectable plasma viral load levels (<10 IU/ml) in eight of the nine subjects, corresponding to 89% of RVR (rapid antiviral response). The ninth patient was below the lower limit of quantification (< 25 IU/ml). This activity data was measured on day 28, the final day of treatment with TMC435350, whereupon patients continued with SoC.
- No serious or severe adverse events relating to TMC435350 were observed.

Based on these results together with previously reported clinical and preclinical results, we continue building a strong base for the continued documentation of TMC435350 as a once daily therapy for hepatitis C with a potentially unique profile.

On 1 October, we filed an NDA with the FDA (US regulator, the Food & Drug Administration) for Lipsovir<sup>®</sup>, a topical product for the prevention and treatment of cold sores. The process of entering partnerships is ongoing, and our objective is to enter one or more agreements to commercialize Lipsovir<sup>®</sup> globally.

Lars Adlersson CEO

Huddinge, Sweden, 20 October 2008

# Significant events in the third quarter 2008

# Pharmaceutical compound TMC435350 well tolerated and demonstrates potent antiviral activity in hepatitis C patients

TMC435350 is a protease inhibitor being jointly developed in partnership by Medivir and Tibotec for treating hepatitis C virus infections (HCV). The compound is now in the concluding stage of clinical phase IIa trials. Preparations for the coming phase IIb are ongoing.

#### Phase I

The phase I trials conducted in 2007 covered 52 healthy volunteers and 6 patients with hepatitis C infections. The six patients that had previously not responded to therapy with other pharmaceuticals were dosed for five days with TMC435350, at 200 mg once daily. The treatment resulted in a sharp reduction in viral load of 3.9 log10 units/ml (99.98% reduction). This potent and rapid decline in viral load was observed in all patients, with both HCV of genotype 1a and 1b. TMC435350 was well tolerated by healthy volunteers and hepatitis C patients, with no serious adverse events observed.

#### Phase IIa

The phase IIa trial is a randomized, double-blind, placebo-controlled trial with TMC435350 administered orally with increasing doses.

This trial involves 96 previously untreated (naive) patients and 34 patients that had previously not responded to treatment with other pharmaceuticals, all with chronic hepatitis C genotype 1 infections.

Patients receive either TMC435350 or placebo, one tablet daily for 28 days, together with Standard of Care treatment (SoC), peginterferon alpha-2a (Pegasys®) and ribavirin (Copegus®) administered for 24 or 48 weeks, depending on therapy response. Patients are then monitored for a further 24 weeks after SoC concludes to evaluate how many are cured, i.e. no longer have quantifiable levels of hepatitis C virus.

The first two dosage groups (25 mg and 75 mg) included 50 patients. Half of these patients were dosed with TMC435350 or placebo for the first week, followed by TMC435350 or placebo plus SoC for three weeks. The other half was treated with TMC435350 or placebo plus SoC for four weeks. Subsequently, all patients were administered SoC only. After four weeks, hepatitis C plasma viral loads were measured, with the activity measured as a rapid viral response, RVR, defined as viral load of less than 10 IU/ml.

Results from the two first dose groups in the phase IIa trial and preclinical results will be published at the AASLD meeting on 3 - 4 November 2008.

#### Results from the first two dose groups show:

- Dose-dependent antiviral activity at doses of 25 mg and 75 mg once daily.
- No serious or severe adverse events related to TMC435350 were observed.
- In the group receiving four weeks' treatment with TMC435350 at 75 mg/day + SoC, plasma viral load in all patients reduced sharply and was undetectable (<10 IU/ml) in 8 of 9 subjects, corresponding to an RVR of 89%. The viral load in the ninth patient was below limit of quantification (<25 IU/ml). Patients continue with SoC for 20 weeks until the next evaluation.

• Steady-state plasma levels of TMC435350 were achieved after three days' dosing. Plasma levels immediately before the next dose (trough level) were 10-30 times higher than the expected effective dose level (EC<sub>50</sub> in replicon test—preclinical model). This data confirms that TMC435350 has a good clinical dose margin.

#### Phase II trial on MIV-606 continues after interim analysis

US corporation Epiphany Biosciences is managing and conducting the clinical development of valomaciclovir (MIV-606). In September, Epiphany announced that its current phase IIb shingles trial is continuing after interim data analysis. The study is scheduled for completion in the first half of 2009.

# Significant events after the end of the period

## NDA for Lipsovir® filed with the FDA

Results from the phase III program which were presented during spring demonstrated the possibility of preventing the incidence of cold sores through early treatment onset, which has not been demonstrated by available products. Thus Lipsovir® offers patients with recurrent cold sores an improved treatment alternative compared to current therapy.

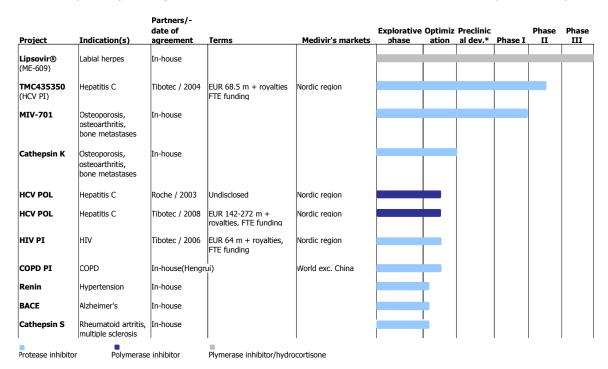
On 1 October, Medivir filed an NDA with the US regulatory agency, the FDA for Lipsovir®, a topical product for preventing and treating cold sores. Lipsovir® is a patented combination of hydrocortisone (anti-inflammatory agent) and acyclovir (antiviral agent) in a proprietary cream base developed by Medivir.

Preparatory work for filing an NDA also in Europe is in its final stage. The process of entering partnerships is ongoing, with the objective of entering one or more agreements to commercialize Lipsovir<sup>®</sup> globally.

### **Prioritized project portfolio**

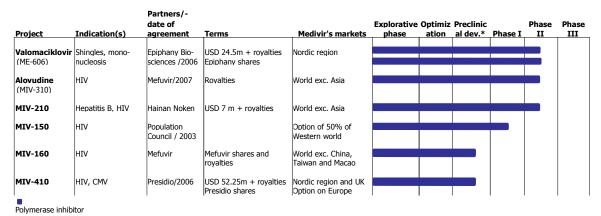
Medivir's prioritized clinical projects currently comprise Lipsovir® against labial herpes, TMC435350 against hepatitis C and MIV-701 against bone degradation diseases. The prioritized preclinical projects are Cathepsin K (bone degradation diseases), BACE (Alzheimer's disease), HIV-PI and HCV polymerase (hepatitis C).

In addition to Medivir's prioritized projects, there are a number of protease-based projects, which Medivir has not assigned full resources to at present. These projects include projects against COPD (chronic obstructive pulmonary disease), a project against hypertension (renin inhibitors) and Cathepsin S (focusing on autoimmune disorders such as RA, MS and chronic pain control).



#### **Polymerase-based projects**

Medivir HIV Franchise AB administers the polymerase-based projects against HIV, HBV, shingles and glandular fever.



For a detailed description of all projects, go to Medivir's website <u>www.medivir.se</u> under Research & Development.

# **Consolidated earnings and financial position**

## Turnover and earnings, 1 January - 30 September 2008

Net sales were SEK 31.9 (80.8) m for the period. In May, Medivir signed an agreement with Tibotec Pharmaceuticals Ltd. on hepatitis C, triggering a one-off payment of SEK 46.2 m (EUR 5 m). This payment has been allocated over the assessed agreement term, and SEK 9.6 m of revenue has been recognized. Turnover in the period also included remuneration of SEK 19.9 m for research collaboration on HIV protease inhibitors and hepatitis C from Tibotec Pharmaceuticals Ltd.

In the corresponding period of the previous year, turnover was SEK 80.8 m, largely comprising research collaboration of SEK 25.6 m, an allocated one-off payment of SEK 9.2 m on HIV protease inhibitors and a milestone payment of SEK 22.6 m on HCV protease inhibitors from Tibotec Pharmaceuticals Ltd. Turnover also included a SEK 17.7 m milestone payment on the MIV-606 shingles project from Epiphany Biosciences.

Operating costs were SEK -147.9 (-225.5) m, comprising external costs of SEK -68.0 (-133.1) m, personnel costs of SEK -72.2 (-71.4) m, depreciation and amortization of SEK -7.7 (-8.0) m and impairment losses of SEK -0.0 (-13.0) m. The reduced operating costs mainly related to lower costs for the Lipsovir and MIV-701 projects, because clinical trials were conducted in the corresponding period of the previous year. Impairment losses in the previous period were on the balance sheet item 'non-current assets held for sale' of Medivir UK.

The operating loss was SEK -113.7 (-143.7) m. The profit gains are mainly a consequence of lower operating costs. Profit from financial investments was SEK 10.4 (6.1) m. The increase in profits from financial investments is due mainly to rising interest rates. The net loss for the period was SEK -102.4 (-138.1) m.

## Turnover and earnings, 1 July - 30 September 2008

Net sales were SEK 17.2 (14.1) m in the period. Turnover consisted of an allocated up-front payment of SEK 5.8 m at signing on hepatitis C from Tibotec Pharmaceuticals Ltd. and SEK 9.9 m of remuneration from research collaboration on HIV protease inhibitors and hepatitis C from Tibotec Pharmaceuticals Ltd. Turnover in the corresponding period of the previous year was SEK 14.1 m, mainly consisting of SEK 8.6 m from research collaboration from Tibotec Pharmaceuticals Ltd. on HIV protease inhibitors and share-based remuneration of SEK 4.8 m on antiviral compounds alovudine (MIV-310) and PPI-801/802 (MIV-410) from Presidio Pharmaceuticals Inc.

Operating costs were SEK -47.8 (-55.4) m, comprising external costs of SEK -22.0 (-32.6) m, personnel costs of SEK -23.3 (-20.0) m and depreciation and amortization of SEK -2.5 (-2.8) m. The reduced operating costs in the period are mainly attributable to reduced costs for the projects Lipsovir<sup>®</sup> and MIV-701. The operating loss was SEK -29.3 (-40.9) m, the net financial position was SEK 3.3 (1.3) m and profit after financial items was SEK -26.0 (-39.6) m. The net loss was SEK -25.2 (-40.1) m. The profit gains are mainly a result of lower operating costs.

## **Cash flow and financial position**

Cash flow from operating activities was SEK -30.4 (-129.6) m, an increase of SEK 99.2 m. In year-on-year terms, cash flow from operating activities was positively affected by changes in working capital, mainly from reduced current receivables. Cash flow from financing activity was SEK 0.0 (208.7) m. In the first quarter of the previous period, a new share issue raised SEK 214.9 m net of issue costs.

Liquid assets including short-term investments with a maximum maturity of three months were SEK 295.7 (264.0) m.

## Investments, depreciation, amortization and impairment losses

Gross investments in tangible and intangible fixed assets were SEK 3.1 (12.3) m in the period, in research equipment and existing research premises. Medivir's future investments comprise the acquisition of additional research equipment and rebuilding of existing research premises. Depreciation and amortization in the period reduced profit by SEK -7.7 (-8.0) m and impairment losses reduced it by SEK 0.0 (13.0) m. In the corresponding period of the previous year, impairment losses related to the 'non-current assets held for sale' balance sheet item of Medivir UK.

## Shareholders' equity, share data and stock options

The share capital at the end of the period was SEK 104.2 (103.3) m and shareholders' equity was SEK 283.4 (266.0) m. The number of shares was 20,843,547 (20,659,449), of which 660,000 (660,000) were class A and 20,183,547 (19,999,449) class B shares with a quotient value of SEK 5. There were 970,000 outstanding options at the end of the period, corresponding to 1,102,300 class B shares. No options were converted or expired in the period. The number of outstanding options could increase shareholders' equity by SEK 82.9 m and upon full conversion, the total number of shares could amount to 21,945,847.

The equity ratio at the end of the period was 74.2 (76.7)%. Earnings per share, based on a weighted average number of outstanding shares, was SEK -4.91 (-8.23) and shareholders' equity per share was SEK 13.60 (12.87).

#### **Employees**

Medivir had 103 (99) employees at the end of the period, 48 (44)% of which were women.

#### Parent company

Medivir AB (publ), corporate identity no. 556238-4361, is the parent company of the group. The group's operations are mainly conducted in the parent company, and consist of research operations and administrative functions. Parent company net sales for the period were SEK 31.9 (80.8) m. Operating costs were SEK -145.5 (-198.3) m, divided between external costs of SEK -65.7 (-123.2) m, personnel costs of SEK -72.1 (-67.1) m and depreciation and amortization of SEK -7.7 (-8.0) m. The operating loss was SEK -112.8 (-117.3) m and the loss after financial items was SEK -102.9 (-137.1) m. The loss after financial items included a cost for covering the deficits of Medivir UK Ltd. of SEK -0.5 (-26.8) m. Gross investments in tangible fixed assets were SEK 3.1 (16.3) m in the period. Liquid assets including short-term investments with a maximum maturity of three months amounted to SEK 294.8 (259.5) m.

#### **Nomination Committee 2008-2009**

Pursuant to a resolution by the Annual General Meeting (AGM), the Nomination Committee for 2008-2009 will consist of representatives of at least the three largest shareholders at the end of the third quarter 2008, as well as the Chairman of the Board. Work on appointing a new Nomination Committee is underway and the results will be announced via the company's website.

### **Outlook including significant risks and uncertainty factors**

Medivir's ability to produce new CDs, to enter partnerships on its projects and to bring its development projects to market launch and sale, is decisive to its future. The progress of existing partnerships and securing new partnerships will exert a major influence on Medivir's revenues and cash position.

There are many risk factors to consider for Medivir as a company in the research and development process. Medivir has several projects in, or close to, clinical phases and many collaboration partners to develop compounds and conduct clinical trials. This diversifies risks, both financial and operational.

Because no significant change to significant risks and uncertainty factors occurred in the quarter, the reader is referred to the Report of the Directors in the Annual Report 2007.

Anders Vedin Chairman

Björn C Andersson Board member Lars-Göran Andrén Board member

Anna Malm Bernsten Board member Magnus Falk Board member Donna Janson Board member

Ingemar Kihlström Board member Ron Long *Board member*  Göran Pettersson Board member

Bo Öberg Board member Lars Adlersson Chief Executive Officer

Huddinge, Sweden, 20 October 2008

CONSOLIDATED INCOME STATEMENT	2008	2007	2007
(SEK m)	Jan-Sep	Jan-Sep	Jan-Dec
Turnover, etc.			
Net sales	31.9	80.8	249.6
Other revenue	2.3	1.0	3.8
Total	34.2	81.8	253.5
Operating costs	00.0	400.4	400.4
Other external costs	-68.0	-133.1	-168.1
Personnel costs	-72.2	-71.4	-99.0
Depreciation and amortization	-7.7	-8.0	-10.8
Impairment loss	0.0	-13.0	-12.9
Total	-147.9	-225.5	-290.8
Operating profit	-113.7	-143.7	-37.3
Profit from financial investments	10.4	6.1	8.5
Profit after financial items	-103.3	-137.6	-28.8
Tax	0.8	-0.5	-0.5
Net profit	-102.4	-138.1	-29.3
Basic and diluted earnings per share, SEK	-4.91	-8.23	-1.74
Average number of shares, 000	20,844	16,781	16,873
Number of shares at end of period, 000	20,844	20,659	20,844
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CONSOLIDATED INCOME STATEMENT, Q3	2008	2007
(SEK m)	Jul-Sep	Jul-Sep
Turnover, etc.		
Net sales	17.2	14.1
Other revenue	1.3	0.4
Total	18.5	14.5
Operating costs		
Other external costs	-22.0	-32.6
Personnel costs	-23.3	-20.0
Depreciation and amortization	-2.5	-2.8
Total	-47.8	-55.4
Operating profit	-29.3	-40.9
	0.0	4.0
Profit from financial investments	3.3	1.3
Profit after financial items	-26.0	-39.6
Tax	0.8	-0.5
Net profit	-25.2	-40.1
Basic and diluted earnings per share, SEK	-1.21	-3.88
Average number of shares, 000	20,844	10,340
Number of shares at end of period, 000	20,844	20,659
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CONSOLIDATED BALANCE SHEET			
SUMMARY (SEK m)	2008	2007	2007
	30 Sep	30 Sep	30 Dec
Assets			
Intangible fixed assets	0.6	1.0	0.9
Tangible fixed assets	31.6	38.1	35.9
Financial fixed assets	18.8	18.8	18.8
Fixed assets held for sale	0.0	0.0	0.0
Current receivables	35.4	24.5	73.9
Short-term investments	224.8	244.3	311.5
Cash and bank balances	70.9	19.7	17.8
Total assets	382.1	346.6	458.9
Liabilities and shareholders' equity			
Shareholders' equity	283.4	266.0	384.0
Current liabilities, non interest-bearing	98.7	80.6	74.9
Total liabilities and shareholders' equity	382.1	346.6	458.9
STATEMENT OF CHANGES TO			
SHAREHOLDERS' EQUITY	2008	2007	2007
(SEK m)	30 Sep	30 Sep	30 Dec
Opening balance	384.0	186.3	186.3
Exchange rate difference	0.1	0.8	0.7
Net profit	-102.4	-138.1	-29.3
New share issue	0.0	215.6	224.2
Staff stock option plans: value of employee service	1.7	1.4	2.1
Closing balance	283.4	266.0	384.0

CONSOLIDATED CASH FLOW STATEMENT	2008	2007	2007
SUMMARY (SEK m)	Jan-Sep	Jan-Sep	Jan-Dec
Cash flow from operating activities before changes in working capital	-92.7	-133.2	-16.4
Changes in working capital	62.3	3.6	-54.1
Cash flow from operating activities	-30.4	-129.6	-70.5
Investment activity Acquisition/divestment of fixed assets Cash flow from investment activity	-2.9 - <b>2.9</b>	-10.2 -10.2	-12.4 <b>-12.4</b>
Financing activity			
New share issue	0.0	215.6	224.2
Amortization/change in loans	0.0	-6.9	-6.9
Cash flow from financing activity	0.0	208.7	217.3
Cash flow for the period			
Liquid assets, opening balance	329.3	195.1	195.1
Change in liquid assets	-33.4	68.9	134.4
Exchange rate difference in liquid assets	-0.2	0.0	-0.2
Liquid assets, closing balance	295.7	264.0	329.3

KEY FIGURES, SHARE DATA, OPTIONS	2008	2007	2007
	Jan-Sep	Jan-Sep	Jan-Dec
Return on:			
- equity, %	-30.7	-61.1	-10.3
- capital employed, %	-30.9	-59.8	-9.9
- total capital, %	-24.5	-43.4	-7.6
Number of shares at beginning of period, 000	20,844	12,903	12,903
Issues	0	7,757	7,941
Number of shares at end of period, 000	20,844	20,659	20,844
- of which class A shares	660	660	660
- of which class B shares	20,184	19,999	20,184
Average number of shares, 000	20,844	16,781	16,873
Outstanding warrants, 000	970	1,146	970
- entitlement to class B shares at conversion, 000	1,102	1,349	1,102
Share capital at end of period, SEK m	104.2	103.3	104.2
Shareholders' equity at end of period, SEK m	283.4	266.0	384.0
Basic and diluted earnings per share, SEK	-4.91	-8.23	-1.74
Shareholders' equity per share, SEK	13.60	12.87	18.42
Net worth per share, SEK	13.60	12.87	18.42
Cash flow per share after investments, SEK	-1.61	-8.33	-4.91
Equity ratio, %	74.2	76.7	83.7

PARENT COMPANY INCOME STATEMENT	2008	2007	2007
(SEK m)	Jan-Sep	Jan-Sep	Jan-Dec
Turnover, etc.			
Net sales	31.9	80.8	254.3
Other revenue	0.8	0.2	2.4
Total	32.7	81.0	256.7
Operating costs			
Other external costs	-65.7	-123.2	-168.4
Personnel costs	-72.1	-67.1	-94.7
Depreciation and amortization	-7.7	-8.0	-10.8
Total	-145.5	-198.3	-273.8
Operating profit	-112.8	-117.3	-17.1
Profit from financial investments	9.9	-19.8	-10.1
Profit after financial items	-102.9	-137.1	-27.2
Net profit	-102.9	-137.1	-27.2

PARENT COMPANY BALANCE SHEET	2008	2007	2007
SUMMARY (SEK m)	30 Sep	30 Sep	30 Dec
Assets			
Intangible fixed assets	0.6	1.0	0.9
Tangible fixed assets	31.5	38.1	35.9
Financial fixed assets	19.0	20.4	19.0
Current receivables	30.5	17.5	69.5
Short-term investments	224.8	244.3	311.5
Cash and bank balances	70.0	15.2	14.5
Total assets	376.4	336.5	451.3
Liabilities and shareholders' equity			
Shareholders' equity	283.1	265.0	384.2
Long-term liabilities, non interest-bearing	1.3	0.0	0.6
Current liabilities, non interest-bearing	92.0	71.5	66.5
Total liabilities and shareholders' equity	376.4	336.5	451.3

# **Accounting policies**

#### Group

Medivir prepares its consolidated accounts pursuant to IFRS, as endorsed by the EU. These are the same principles as applied in the Annual Report for 2007. Apart from the stated IFRS, the group also observes RR's (Redovisningsrådet, the Swedish Financial Accounting Standards Council) recommendations RR 30:06 (Supplementary Accounting Regulations for Groups) and RR 31 (Interim Reporting for Groups) and applicable RR Emerging Issues Task Force statements. The Interim Report has been prepared pursuant to IAS 34 Interim Financial Reporting.

#### **Parent company**

In its accounting, as previously, Medivir AB applies the principles applicable to legal entities that prepare consolidated accounts and are listed on a stock exchange. Briefly, this implies the continued application of RR's recommendations to the extent they are applicable to a group parent company. Thus Medivir AB observes RR 32:06 'Accounting for Legal Entities'.

# **Review report**

We have conducted a limited review of the Financial Statement for Medivir AB (publ) for the period 1 January – 30 September 2008. The preparation and presentation of these interim financial statements pursuant to IAS 34 and the Swedish Annual Accounts Act are the responsibility of the Board of Directors and Chief Executive Officer. Our responsibility is to report our conclusions concerning these interim financial statements on the basis of our limited review.

We have conducted our limited review pursuant to the Standard for Limited Review (SÖG) 2410 "Limited review of interim financial information conducted by the company's appointed auditor". A limited review consists of making inquiries, primarily to individuals responsible for financial and accounting matters, as well as performing analytical procedures and taking other limited review measures. A limited review has a different focus and significantly less scope than an audit according to RS Auditing Standards in Sweden and generally accepted auditing practice. The review procedures undertaken in a limited review do not enable us to obtain a level of assurance where we would be aware of all important circumstances that would have been identified had an audit been conducted. Therefore, a conclusion reported on the basis of a limited review does not have the level of certainty of a conclusion reported on the basis of an audit.

Based on our limited review, no circumstances have come to our attention that would give us reason to believe that the interim financial statements have not been prepared pursuant to IAS 34 and the Swedish Annual Accounts Act for the group, and pursuant to the Swedish Annual Accounts Act for the parent company, in all material respects.

PricewaterhouseCoopers AB

Claes Dahlén Authorized Public Accountant

Stockholm, Sweden, 20 October 2008

## For more information, please contact:

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## Forthcoming financial information:

The Annual Financial Statement will be published on 17 February 2009.

The Three-month Interim Report will be published on 23 April 2009.

The AGM will be held on 23 April 2009.

The Reports will be available at Medivir's Website, <u>www.medivir.se</u> from these dates under the 'Investor/Media' heading.