

### Dear shareholders and stakeholders,

Medivir is making progress and changing; we are launching our first proprietary product in 2010. The pure-play research enterprise we once were is starting to become a pharmaceutical company. Our business goal is to be a profitable pharmaceutical company within five years, with its main focus in infectious diseases. We are now actively addressing new markets, and from this point forwards, Medivir will also be visible for consumers through the launch of our labial herpes pharmaceutical, Xerclear™.

Our Annual Report is one of our key communication channels. This year we have chosen to base it on three key concepts: Core, Competence and Cure, with information on our core business, our competence and the segments where we have ambitions to bring relief, cures and greater well-being to the patient. This is followed by the Report of the Directors.

Here's wishing you an enjoyable read and welcome to Medivir's Annual Report for 2009.

Yours sincerely,

Rein Piir
Chief Financial Officer and
Vice President, Investor Relations



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This translation of "Medivirs Årsredovisning 2009" is provided as a courtesy to our Englishspeaking investors and shareholders. The Swedish version is the authentic text upon which the Audit Report is based.



Medivir's core competence consists of its knowledge of the enzymes polymerase and protease. In over 20 years of pharmaceutical development, Medivir has carved out a competitive position in these segments. We have invested in competence, accumulated experience, built unique compound libraries and developed competitive CDs (candidate drugs) which make us an attractive collaboration partner for the large pharmaceutical companies. Our pharmaceutical research is based on our competence in preventing and inhibiting the activity of polymerases and proteases with our focus on infectious diseases – over 70% of our projects are in these segments. We have a long history of producing experimental drugs against diseases including HIV, herpes and hepatitis. Right now, Medivir and our collaboration partners have very high expectations of our hepatitis C project, TMC435.

# Competence

There are few research companies that could launch a pharmaceutical on the market they have developed themselves, as Medivir has. This involves a long development chain, through preclinical and clinical development phases, which must be successful, before launching a finished pharmaceutical is possible. And there can be no shortcuts. Medivir now has the competence to go all the way − we've done it with Xerclear™ and we can do it again. The company harbors a dedication and competence that extends across all the skills segments necessary for pharmaceutical development. From preclinical research and patents to clinical development and market launch. This makes us unique among companies of our size.



The hypothesis Medivir formulated a number of years ago, that labial herpes can be prevented if outbreaks were treated in a new way, has been corroborated. In 2010, we are launching our first pharmaceutical, Xerclear<sup>™</sup>, whose efficacy in clinical trials has been demonstrated as superior to all competitors on the market. Our core competence in polymerases and proteases have given us the possibility to extend our focus to diseases that are more serious and harder to treat. We have a raft of attractive and promising projects in development, including two in the hepatitis C segment. With our experience and ambition in pharmaceutical development we can bring relief, cures and greater well-being to the patient.



## A very exciting future

"The driving force in my career has been to develop technologies and products that help secure a positive change in how patients are diagnosed and treated. The products Medivir has in development are well on the way to attaining medical significant results in clinical trials against infectious diseases that currently lack satisfactory treatment."

Ron Long has worked in the pharmaceutical industry through most of his career, holding a range of positions in large corporations like Wellcome and Amersham plc, and smaller enterprises like Kudos Pharmaceuticals. He has been, and remains, a director of several biotechnology companies within and outside Sweden.

"These experiences of small and large companies are invaluable for the tasks we are now facing. My ambition, and that of the Board, is for Medivir to evolve from being a research and development enterprise into a profitable pharmaceutical company with proprietary products and its own marketing organization. Medivir's HCV project TMC435, in partnership with Tibotec/Johnson & Johnson, is progressing as planned, and when it reaches the market, has the potential to transform Medivir completely. The current focus is on launching Xerclear™ across the Nordic region with our own resources, and through partners in Europe and the US. The product will be branded Xerese™ and launched by Meda AB in the US. We have the potential to be one of few biotech companies to succeed in developing an international business on geographical markets outside the Nordic region," adds Mr. Long.

## Sticking with our basic idea

Medivir is now a well-established research company. Our goal has previously been to develop high-quality pharmaceutical compounds that we can license to large pharmaceutical companies for onward development, and we've been good at this. But we're raising our ambitions and aiming to bring more of our products all the way to the market.

Our priority is to develop drugs against infectious diseases, with a sustained emphasis on antiviral compounds.

Our business goal is to be a profitable, medium-sized pharmaceutical company in high growth within five years. We will continue to rely on the specialist know-how we possess in our research and development team. And we will supplement this by building a strong commercial organization, whose mission is to outlicense and inlicense products, and to acquire products that enable us to achieve our long-term goal.

The core of Medivir's business is our world-leading knowledge in polymerases, proteases and infectious diseases. Through innovation and effective teamwork, these



skills have enabled us to create a stable and expanding project portfolio of high-quality new candidate drugs. We will be developing them towards market launch with the support of strong collaboration partners like Tibotec/Johnson & Johnson and through our own marketing resources, as is the case with our first product Xerclear™ on the Nordic market. In the future, we also want to inlicense products, especially in segments where we think our development team can help onward clinical development already started by others.

#### High quality is standard

Marketing products itself is new to Medivir but not for the people that work in the commercial team we're building.

We intend to maintain the same high standard across our sales and marketing resources as in our research and development work. We started building a marketing organization in 2008, and have continued its development ahead of the launch of Xerclear™. Medivir is now well prepared for market launch, which will be conducted via partners worldwide, and through our own



resources in the Nordic region. We're also actively screening new products and product opportunities, and in this way, we expect to be able to expand our product portfolio as early as in 2010.

We also started reviewing our project portfolio in 2009, which is expected to result in a more focused R&D portfolio, where a number of current projects that do not fit our new strategy will be outlicensed or discontinued. This review was concluded in the first quarter of 2010.

There are a number of projects lying outside our focus on infectious diseases, which we will continue to run until a suitable point for entering partnerships. Future research and development projects will be evaluated on the basis of how well they fit our strategy, and the time and cost involved in going all the way to market launch. Going forward, this means fewer projects with a more concentrated allocation of resources.



#### Setting our sights on the future

Medivir enjoyed a very satisfactory 2009.

Xerclear™ secured market approval in Europe and the US and is well positioned for launch in 2010. We made major advances in our existing infectious diseases portfolio in partnership with Tibotec/Johnson & Johnson, and look forward to the clinical results from phase IIb trials on TMC435 (HCV) in 2010.



We also saw good results from phase IIb trials on MIV-606 (shingles) in partnership with Epiphany Biosciences, and made major advances in our cathepsin K and S projects.

So we can build on our successes, over time, our intention is to invest in new projects in infectious diseases, such as hepatitis C. We also need to invest in Xerclear™ to be able to exploit the product's competitive advantages. Will also be examining which types of product we can inlicense to supplement and develop our project portfolio, first and foremost on the Nordic market. In the coming five-year period, it may also be necessary to secure funds to expand our geographical base outside our Nordic home market.

We have a highly ambitious scientific and commercial agenda, and from a solid starting-point, we have the vision of an exciting future, which will also create longterm shareholder value.

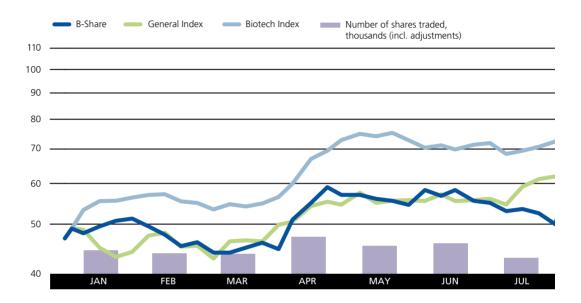
Ron Long

Chief Executive Officer

Huddinge, Sweden, January 2010

## High returns for our shareholders

2009 was an eventful year for Medivir, characterized by success and maturity. We secured our first product approval, made notable advances in our project portfolio and raised awareness of Medivir among new investors in Europe and the US. Interest in, and understanding of, our projects in hepatitis C especially, and then primarily TMC435, was one reason for positive share price performance in the year. Our 71% share price increase provided our shareholders with high returns. We intend to keep developing Medivir, and thus create more shareholder value.



### Q1

- Ron Long appointed Medivir's new CEO.
- MIV-710 against bone disorders like osteoporosis designated as a CD.
- Cost rationalization with savings package introduced.
- The objective is to downscale the cost base by 20% to SEK 150 m.
- Epiphany Biosciences reports its intention to file an application with the FDA to conduct clinical trials on Medivir's licensed compound valomaciclovir (MIV-606) on MS patients.

### Q2

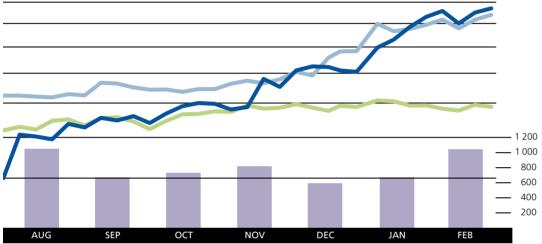
- Positive results from phase IIa studies on TMC435 for treating hepatitis C presented at the EASL (European Association for the Study of the Liver) meeting in Copenhagen, Denmark.
- Number of board members reduced to five.

"Whenever people agree with me I always feel I must be wrong".

Oscar Wilde



Medivir presented its operations at several investor seminars in the year. One main focus was on a series of road shows, mainly in the US. Medivir's hepatitis C projects are attracting substantial interest from US investors, creating new opportunities for us as a company.



Medivir is actively monitored by analysts at most Nordic banks. Most of them write regular research and update notes on Medivir and our projects. In the year, a number of US analysts actively monitored TMC435, our hepatitis C project in clinical phase IIb trials.

Q3

- The FDA, the US pharmaceutical regulator, approves Lipsovir<sup>®</sup> for marketing and sale in the US.
- Medivir extends its portfolio in bone disorders by designating another CD: MIV-711.
- Medivir presents how Lipsovir® prevents
  the incidence of ulcerative lesions in patients
  with recurrent labial herpes at the ICAAC
  (Interscience Conference on Antimicrobial
  Agents and Chemotherapy).
- Medivir presents data relating to its CDs for bone disorders at the ASBMR (American Society for Bone and Mineral Research) meeting in Denver, US.

### Q4

- European pharmaceutical regulators approve Medivir's application for the market registration of Lipsovir® in 14 European countries. In Europe, the product will be branded Xerclear™.
- New positive phase IIb results on TMC435 for treating hepatitis C patients that have not previously responded to treatment presented at the AASLD (American Association for the Study of Liver Diseases) conference in Boston, US.
- Medivir's collaboration partner Epiphany Biosciences reports positive results from phase IIb trials on valomaciclovir (MIV-606) in shingles patients.
- Xerclear<sup>™</sup> approved as an OTC pharmaceutical in Sweden and will be available at pharmacies from the first quarter of 2010.



Medivir has received very favourable publicity during the year.



### The core of Medivir

In over 20 years as an active company, Medivir's portfolio has been dominated by antiviral projects based on polymerases as the target for pharmaceutical treatment in therapy areas like HIV, herpes and hepatitis. About 10 years ago, we extended our sphere of operations to also cover proteases. This gave us the possibility of accessing new therapy areas, while also deepening our knowledge of the antiviral segment.

Our research and development focus is on specific protein molecules rather than therapy areas, where we prioritize pharmaceuticals against infectious diseases caused by virus. Our first product launch, of Xerclear™ against labial herpes, is in 2010.

We have three projects in partnership with Tibotec, part of the Johnson & Johnson group, of which two are hepatitis C projects that are in, and close to, clinical

development. All projects are based on our competence in developing antiviral pharmaceuticals.

Thanks to our growing knowledge of proteases, we also have exciting projects outside our traditional focus in our own project portfolio. If and when they proceed to clinical trials, they may generate major potential values for our own business and our shareholders.



## Medivir sustaining its focus on polymerases and proteases

A human cell contains thousands of different proteins, which are necessary for various processes in our cells. Polymerases and proteases are enzymes that regulate the production, and for proteases, also the activation and metabolism, of proteins. Many diseases arise when an imbalance in enzymatic processes occurs.

Polymerases join small building-blocks (nucleotides) into long chains, which comprise genes in viruses and humans. Proteases cut polypeptide chains (amino acids) into shorter peptides/proteins. Although building and breaking down peptides may not sound so serious, polymerases and proteases are involved in some of the most serious diseases of our era – HIV, hepatitis C, cancer, osteoporosis and Alzheimer's disease to name but a few.

By inhibiting polymerases and proteases, it is possible to cure and/or treat diseases. Our competence and our research focus lies in regulating these enzymatic processes. Over the years, Medivir has created a highly competitive compound library and accumulated substantial knowledge of inhibitor compounds, and patented compounds and technologies for pharmaceutical development targeting these enzymes.

Polymerases are important targets for pharmaceutical development, especially in infectious diseases. Viruses and bacteria each contain one to three polymerases. The diseases where polymerases are involved are among the most common disease groups in the world. We have very high hopes of being able to deliver improved pharmaceuticals to the market. We are in the frontline of knowledge of polymerases, and we have projects against diseases like HIV, hepatitis B and hepatitis C, and shingles in our portfolio. There are no sufficiently functional pharmaceuticals against these infectious diseases on the market at present.

Proteases are involved in, and can give rise to, a range of different diseases. Each protease can have several different target proteins that they divide into various sections, resulting in increased or decreased

activity of a physiological process. Activating proteases or increasing protease activity can cause diseases, or play an important role in a certain type of disease. Moreover, each protease is divided into different tissues, which are often unique.

Most known viruses include at least one protease and all bacteria and parasites have several different proteases. Until now, Medivir's competence in proteases has spawned projects against HIV, hepatitis C, and bone disorders like osteoarthritis and osteoporosis, as well as Alzheimer's disease.

## A look at Medivir's project portfolio

All Medivir's projects are polymerase or protease inhibitors with their main focus currently in infectious diseases caused by viruses. The project that has come furthest is that previously known as Lipsovir<sup>®</sup>, our combination preparation of acyclovir and hydrocortisone against labial herpes. This project is in its launch phase in the US and Europe. In Europe, the launch will be branded Xerclear™ and in the US, Xerese™.

We have two projects in hepatitis C. The protease inhibitor TMC435 is well advanced, and is in phase IIb studies in partnership with Tibotec/Johnson & Johnson. For a detailed description, see the Report of the Directors.

| Prioritized projects      | Phase                    | Therapy area  | Target enzyme                         | Partnership                  |  |  |  |
|---------------------------|--------------------------|---|---------------------------------------|------------------------------|--|--|--|
| Xerclear™                 | Market launch            | Labial herpes                                       | Polymerase and hydrocortisone         | In-house                     |  |  |  |
| TMC435 (HCV-PI)           | Clinical phase IIb       | Hepatitis C   | Protease                              | Tibotec/J&J                  |  |  |  |
| HCV POL                   | Preclinical development  | Hepatitis C   | Polymerase                            | Tibotec                      |  |  |  |
| MIV-710 (Cath K)          | Preclinical development  | Osteoporosis, osteoarthritis, bone metastases       |                                       |                              |  |  |  |
| MIV-711 (Cath K)          | Preclinical development  | Osteoporosis, osteoarthritis, bone metastases       | · · · · · · · · · · · · · · · · · · · |                              |  |  |  |
| HIV PI                    | Preclinical optimization | HIV   | Protease                              | Tibotec/J&J                  |  |  |  |
| BACE                      | Preclinical optimization | Alzheimer's disease                                 | Protease                              | In-house                     |  |  |  |
| Cathepsin S               | Preclinical optimization | Neuralgia, rheumatoid arthritis, multiple sclerosis |                                       | In-house                     |  |  |  |
| COPD PI                   | Preclinical optimization | COPD  |                                       | In-house                     |  |  |  |
| Renin                     | Preclinical optimization | Hypertension  | In-house                              |                              |  |  |  |
| Polymerase-based projects | Phase                    | Therapy area  |                                       | Partnership                  |  |  |  |
| Valomaciclovir (MIV-606)  | Clinical phase IIb       | Shingles, glandular fever                           |                                       | Epiphany<br>Biosciences/2006 |  |  |  |
| Alovudine (MIV-310)       | Clinical phase IIb       | HIV   |                                       | Mefuvir/2007                 |  |  |  |
| Lagociclovir (MIV-210)    | Clinical phase IIb       | Hepatitis B, HIV                                    | , HIV Hainan Nok                      |                              |  |  |  |
| MIV-150                   | Clinical phase I         | HIV   | Population Council/2003               |                              |  |  |  |
| MIV-160                   | Preclinical optimization | HIV   |                                       | Mefuvir/2007                 |  |  |  |
| MIV-410                   | Preclinical optimization | HIV, CMV  | Presidio/2006                         |                              |  |  |  |

#### Preclinical research phases

Explorative phase - identifying active hit compounds.

**Lead identification** – identifying feasible compounds with drugable potential

**Optimization phase** – this stage is focused on producing the optimal compound/compound class possessing pharmaceutical potential. Towards the end of this phase, CDs (candidate drugs) are designated.

**IND** – late preclinical development – the final working phase before designated CDs enter clinical studies. This phase is authority regulated and includes extensive safety studies, pharmacokinetics, metabolism studies and is when the first kilogram-scale amounts of the active compound are produced. Applications for regulatory approval for clinical trials of designated CDs are also filed.

#### Clinical development phases

**Phase I** – trials of the CD on healthy volunteers, usually involving 20 to 50 individuals. Phase I is divided into two parts. In phase Ia, a single dose of increasing strength, then repeat doses, are administered to healthy volunteers. Sometimes, phase Ib studies are conducted, on a small group of patients for a short period.

**Phase II** – the first trials on patients suffering from the target disorder. Studies usually encompass 100 to 500 patients, with efficacy and safety assessed. Phase II is also divided into two parts. Phase IIa is intended to demonstrate that the course of the disease can genuinely be influenced. Phase IIb demonstrates the efficacy of various doses on the course of the disease.

**Phase III** – comparative trials on a large sample of patients to measure efficacy in relation to other treatments, if any exist, as well as safety.

**NDA** – New Drug Application, which often requires Phase III trials as documentation.

## Broad-based knowledge creates opportunities

In the multidimensional universe of molecules forming the basis of all pharmaceutical development, it is vital to make your own space in the chemical design of molecules. The big challenge lies in finding your own niche that no-one has discovered yet. Most companies work according to the same principles and look for similar opportunities. You need to be able to patent your own inventions so the investments you make can be protected and generate returns for shareholders.

"At Medivir we work very consciously with patents to create as much space as possible. We've also ensured that that we build competence at all links of the pharmaceutical development chain, and have specialized in two enzymes, polymerase and protease," comments Patent Attorney Iain Morrison.

At Medivir, the patent engineer is part of the project organization right from the start, alongside all those involved in the various stages of pharmaceutical development such as chemistry and biology.

"The project organization's working method is our big strength. We integrate different competences and everyone helps shed light on the project from different A molecule close to competitors' segments has a lower technical risk. But when there are a lot of products with a similar profile, the commercial risk immediately becomes greater.

"Often, there are broad patents that prevent us from working where we want to be. If we want to beneftit from what our competitors have already done, we have to navigate through this patchwork of patents. This is very demanding on our flexibility and speed, which we're good at."

# Combete

perspectives – medical, technical and commercial. As the Patent Attorney, I work on ensuring the patentability of what we're doing. We need patents so we can make major investment decisions for onward development, and so we can work in peace."

Creating your own chemical space close to a target enzyme's field of work, i.e. the pharmacophore, in a dimension where a competitor is already active in chemical synthesis, sets major demands on creativity.

"We need to know whether there's anyone that could prevent us working where we want to. We can't look too far from the pharmacophore because of the risk of ending up in something that doesn't work. This is a constant balance between risks and opportunities," adds Jain Morrison.



## Interaction between chemistry, biology and patents

Developing pharmaceuticals requires co-operation. Pharmaceutical development at Medivir involves a close interaction between chemistry, biology, pharmacokinetics, drug design and patents. The chemist is responsible for how the molecule will look, the biologist demonstrates that it works in the biological model, and the patent engineer pilots the project to a patent approval.

Developing a new pharmaceutical is a stepby-step process involving many specialists at each stage. Preclinical research phases start with building infrastructure and identifying active prototype compounds. Then, feasible compounds with drugable characteristics are identified.

"When you move into a new segment, there are a lot of infrastructures that need to be built, such as assays for therapeutic effect. A lot of assays in vitro and in cell cultures are required to demonstrate that the desired inhibition of your target enzyme has a biological and/or antiviral effect, and a large number of biological evaluations and tests

are performed. Pharmacokinetic assays are also needed to ensure that the compound enters the body, and to study how it is metabolized and excreted so that adverse events can be avoided. This kind of evaluation tool must be in place throughout the development period so that we can adapt molecules as work progresses. Accordingly, the biologist and pharmacokineticist play a very important role in identifying potential compounds," continues Iain Morrison.

New candidate drugs

The next research stage is to produce the most optimal compound that can be designated as a CD (candidate drug). At this stage, activities include studies of how a pharmaceutical is absorbed and metabolized in the body (pharmacokinetics) and its effect (pharmacology).

"Having projects in different development phases is one of our strengths. It makes us less sensitive to potential setbacks when we have to stop, move back and start again. We were able to designate two new CDs in our Cathepsin K program against bone disorders, MIV-710 and MIV-711 in 2009."

After designating a CD, the preclinical development phase begins. This involves major safety trials in assays where we examine how the pharmaceutical is absorbed and metabolized in the body, its effect and potential adverse events. This phase is fully regulated by the authorities, and if everything goes well, we apply for approval to start the first trials on humans with the designated CD.

"The chemist decides how the molecule will look and the biologist ensures that the compound has good efficacy and pharmaDetermining a molecule's appearance, ensuring good pharmacokinetics and evaluating its commercial potential is work that is done between three functions in Medivir: chemistry, biology and patents.





"Eternity is really long, especially near the end".

Woody Allen



"Only dead fish swim with the current."

Russian proverb

cokinetics. If molecules are changed by metabolism, this has an impact on how the pharmaceutical behaves in the body. Accordingly, a close interaction between biology and chemistry is important in pharmaceutical development."

And this is where the third part of this interaction enters the picture: patents. The chemist needs help in prioritizing which of the molecules may provide commercial opportunities. The patent attorney must participate and control this so that we don't work on a molecule that a competitor has already patented, or doesn't have what is necessary to secure a patent."

#### Proprietary competence on preclinical projects

Medivir has the competence to handle all the important preclinical stages in-house. The company harbors competence and technology to find new ways of reaching the target molecule and moving forwards on paths where competitors may have failed.

"The latter applies to compounds such as TMC435 against hepatitis C. Pharmaceutical company Boehringer Ingelheim's anti-hepatitis C compound did not behave as expected and was shelved, which we noted in 2003. This provided us with useful information, which with our extensive knowledge of proteases, we were able to benefit from on our project. With our knowledge and technologies, we have produced a series of molecules of which TMC435, now in clinical phase IIb trials, is one. TMC435 is a highly potent and competitive compound against hepatitis C. It has been developed in collaboration with Tibotec, our partner in the Johnson & Johnson group. TMC435 has progressed from preclinical research to clinical development in a very short time," adds Iain Morrison.

#### Clinical development

When the regulators have approved a CD for clinical trials, the project enters clinical phase I.

Generally, the first real trials on humans are conducted within the auspices of phase I. Phase I trials are usually performed on between 20 and 40 healthy volunteers. Phase

I trials, which have two parts, phase Ia and phase Ib, ensure the safety and tolerability of the compound, and designate doses for ongoing clinical trials.

If the project makes it to further trials, phase II starts, which also has two parts. Patients affected by the disease the pharmaceutical is intended for are now included. Between 100 and 500 people are involved, and the trials measure efficacy and safety. Phase IIa demonstrates whether the course of the disease can really be influenced and phase IIb includes extended trials over the longer term to demonstrate intended treatment efficacy in relation to other therapies.

"TMC435 is currently in phase IIb trials with various dose and patient groups involving nearly 1,000 patients."

The final clinical development phase is phase III, involving comparative studies on a large number of patients. This also measures efficacy in relation to other therapy. Documentation from trials, assuming positive results, then forms the basis for a registration application for a new pharmaceutical, an NDA (New Drug Application).

This stage of pharmaceutical development is very extensive and requires enormous human and financial resources. A large, strong and experienced partner like Johnson & Johnson is necessary in the development of TMC435 to conduct and fund ongoing and future trials.

Medivir controlled and performed its own extensive phase III trials for the development of Xerclear™ against labial herpes.

"This was possible for us, a small company, for several reasons. We contracted an extensive network of consultants to help us. The product is part of our specialist competence and intended for topical application, which needs less documentation in clinical trials than tablets administered orally, for example. The treatment period is short, five days in an outbreak of labial herpes. Our own phase III trial, the largest of its class in the topical treatment of cold sores, really succeeded in demonstrating our competence and the effectiveness of our business focus, producing pharmaceuticals against infectious diseases caused by viruses.

## A risk-balanced portfolio is important to Medivir's business model

Developing new pharmaceuticals is a high-risk business. Generally, only a few ideas become a reality and reach the market. For every approved pharmaceutical there are hundreds of projects that fail somewhere on the way from idea to market registration.

"As a development company, we focus on those of our compounds that can reach the market. We have a strong ambition to succeed while also being realists, highly conscious of the risks involved in producing new pharmaceuticals. You have to dare to invest and adopt a long-term perspective – the lead-times in the development chain are substantial. The prime factors in pharmaceutical development are competence, quality and time, which require financial resources. The big challenge facing a small company is to manage these effectively to achieve your final objective," comments Chief Financial Officer Rein Piir.

Another dimension is to manage the mandate granted by shareholders; to create high returns and trust among investors optimally, even on markets that are new to the company.

"Our focus is on development projects in polymerase and protease inhibitors primarily for treating infectious diseases caused by viruses. This is where the base of our knowledge lies, which we are fine-tuning in project terms so our business becomes even more focused."

With our greatest experience in infectious diseases, our pharmaceutical development should be results oriented, emphasize benefits and be competitive. It should be stable enough to provide our shareholders with a return on their investment, which means some greater risk-taking in different phases of the company's development.

Medivir's development projects in proteases, including cathepsin K against bone disorders, cathepsin S against neuropathic pain and BACE against Alzheimer's disease, have higher risks than its core business of infectious diseases

"Despite this we see the possibilities and can take a chance. If we are successful in producing an effective CD in Alzheimer's disease, for example, the rewards could be enormous," continues Rein Piir.

Launching your own product through your marketing organization is a new challenge for Medivir, which will involve a greater market presence in the Nordic region, Europe and the US in 2010.

Eva Arlander heads up this organization, which is now about to launch Xerclear™, a pharmaceutical against labial herpes:

"Having your own product raises interest in the company from investors and competitors. We can show our partners and competitors that we've got the power to deliver what we said we would. We took the risk and went all the way – from the hypothesis and molecule to the patient's lips. We dared and we succeeded!"



## Our dedication and drive lies in finding cures

Any research and development company that produces compounds for pharmaceuticals has the goal of delivering relief, and if possible, curing patients. But getting from an idea to reality can take a long time. Success rates vary sharply depending on the chosen therapy area.

Researching and developing pharmaceuticals is always associated with risk, but without any risk-taking in the sector, we wouldn't have access to most of the pharmaceuticals that currently relieve disease and cure patients all over the world. The natural counterpoint to this risk is the possibility of succeeding, and thus being able to offer new and better pharmaceutical alternatives. Simultaneously, substantial values are created, which become shareholders' rewards for their risk-taking.

The goal for everyone is to succeed, and thus deliver improved patient care. As a company, we have to strike a balance between risks and opportunities the whole time if we are to achieve success. Then, it's about repeating successes.

In the following pages we have chosen to illustrate three projects in our project portfolio which are having, and will have, a big impact on Medivir. However, one of these lies outside our core segment, but we illustrate how we can apply our knowledge of proteases in an indication other than infectious diseases.

#### **Labial herpes**

Right from the start, we viewed our own labial herpes pharmaceutical, Xerclear™, as a project with somewhat lower-than-average risk for antiviral compounds. This is because Xerclear™ is a combination product of two well-known and widely used compounds with low adverse event profiles. The risk of this project lay in our ability to be able to prove our hypothesis, that the combination prevents the incidence of labial herpes. With the benefit of hindsight, we can say that we succeeded. Xerclear™ will be launched on the market in 2010, and we will be able to expose it to patients and doctors. Xerclear™ is the first pharmaceutical that we have produced

ourselves. There are very few research companies that have had the privilege of doing this.

We are really proud that we have the right competence and have been given the resources we needed from our shareholders to achieve this.

#### **Hepatitis C**

TMC435 is intended to treat infections caused by the hepatitis C virus (HCV). This project is being run in partnership with Tibotec/Johnson & Johnson in the US, and at present, is our strongest candidate for another new pharmaceutical. We succeeded in producing an experimental drug, which proved to be highly effective and safe in clinical phase I and IIa trials. Several phase IIb trials are now ongoing, and right now, we have high hopes of producing a pharmaceutical with the possibility of a single daily dose and that cures patients with HCV to a greater extent than current pharmaceuticals.

#### Alzheimer's disease

higher risk than our core seg-

ment of antiviral pharma-

ceuticals, for example.

BACE is a protease involved in Alzheimer's disease. This project, outside our core segment of infectious diseases, is a very hot research segment, where BACE inhibitors have the potential to become the optimal therapy against Alzheimer's disease. Current pharmaceuticals only relieve the symptoms and do not affect the course of the disease. BACE is a project in the CNS (central nervous system) therapy area, generally associated with much



A lot of unseen work goes into pharmaceutical packaging. Its colour and design has to be neat, attractive and accessible to work on all markets where the product is sold.

The product name, Xerclear™, is intended to convey the pharmaceutical's three strengths: a proprietary cream base developed by Medivir whose active ingredients inhibit viruses and reduce inflammation.



Packaging text has to be approved by the pharmaceutical regulators in every country. It will be translated and modified for each market.

Product volume has to be stated on the packaging. There are two versions of Xerclear<sup>™</sup>, a 2g tube for OTC sale and a 5g tube available on prescription on most markets.

The Patient Information Leaflet states the pharmaceutical's content, dose, effect and any adverse events observed, as well as potential reactions when combined with other pharmaceuticals. This text is printed in language versions for each market.

Medivir's marketing liability includes follow-ups and safety checks, termed pharmacovigilance, how patients perceive the pharmaceutical and report potential adverse events. Packaging must state a contact address.

## From molecule to the patient's lips – the journey to the market continues

In autumn 2009, pharmaceutical regulators in the US and Europe approved the first pharmaceutical Medivir had developed itself, a highly competitive labial herpes product.

"This has been a fantastic journey. Now we're proudly closing on in our really big goal – market launch," says Eva Arlander, Marketing Director and Head of Medivir's labial herpes project, with the previous working title Lipsovir\*.

#### A unique and highly competitive label

Our product has labels that distinguish it clearly from competitors in the US and Europe. The label approved by the FDA, the US pharmaceutical regulator reads as follows: 'Acyclovir and Hydrocortisone Cream is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and adolescents (12 years of age and older)".

"This means that our patented combination of antiinflammatory hydrocortisone and antiviral acyclovir is approved for early treatment of recurrent labial herpes to reduce the risk of cold sores and shorten healing times for those cold sores that cannot be avoided. This is a clear and competitive label, which gives a distinct competitive edge. No other product has the corresponding label and none of our competitors have been able to demonstrate that they prevent the incidence of cold sores given early treatment onset in clinical trials (phase III) with statistically significant results. For patients, it is important that this type of pharmaceutical is easily available because treatment with Xerclear™ should begin immediately the first symptoms occur. Being available over the counter means it is easily obtainable, and in most European countries, Xerclear™ will be sold over the counter.

But initially, it will be available on prescription in some countries.

In the US, this preparation, like competing products, will require a prescription.

#### **Building for the future**

To evolve from a research enterprise to a profitable pharmaceutical company involves familiarity with a raft of new activities and regulatory structures.

"We've built a new organization, created new services, undergone restructuring and accumulated more knowledge about launching pharmaceuticals. Now we have a marketing organization for our own product, Xerclear™, and other potential products."

Medivir always consciously retains sales and marketing rights in the Nordic region for its proprietary projects. If and when such projects reach the market, the ambition is to sell them itself.

## One product is on the market, so now we're focusing on the next goal ...

After Xerclear™ reaches the market, TMC435 against hepatitis C (HCV) is the most advanced of Medivir's projects. This project is now in extensive clinical phase IIb trials and the compound has proven to be highly effective, and thus probably, very competitive.

"Our protease inhibitor against the hepatitis C virus maintained its positive progress in the year and is now in several major, global phase IIb trials. The project is a high priority for our partner Tibotec/Johnson & Johnson, and we all have high expectations of its ongoing development towards the market," says Bertil Samuelsson, Medivir's Vice President of Discovery Research.

Although hepatitis C infection can be cured, current therapies are demanding and very long term, about one year for the most common hepatitis C infection in the West, caused by genotype 1. The therapy involves a lot of troublesome adverse events, and there is a high risk that patients abandon their ordination before treatment is complete.

Between 42 and 46% of patients undergoing treatment respond to current therapy, while the rest are forced to wait for future treatment methods.

In just a few years, two of the first generation of new pharmaceuticals are expected to be approved. These will increase the share of cured patients and improve the situation facing those patient groups that have not previously responded to therapy. After another year or so, TMC435, a second-generation pharmaceutical, may reach the market.

"Our compound is highly competitive and has exceptional potential to transform current standard of care fundamentally."

2008. As new treatments emerge, and thus more patients can and want to receive treatment, this market will expand. And the better the acceptance of these new treatments by patients that have been diagnosed and are waiting for treatment, the higher the rate of increase. Many observers estimate that the market for hepatitis C pharmaceuticals may be worth some USD 8-10 bn by

2013 and USD 14-16 bn by around 2016-2018.

The value of the market

for hepatitis C pharma-

ceuticals has been esti-



According to the WHO (World Health Organization) some 3% of the global population suffers from chronic hepatitis C infection. This is some 170 million people. Every year, 3-4 million people are infected.

Of the 170 million people infected worldwide, nearly a quarter have had their diagnosis confirmed, and of these, only 20% are being treated.

Over 20 years can pass from infection to the first symptoms expressing, and the first signs are often bad liver values. The disease is transmitted via the blood and many people are still infected through drug abuse, by sharing hypodermic needles with a carrier, or in blood transfusions of unchecked or infected blood in countries with inadequate processing.

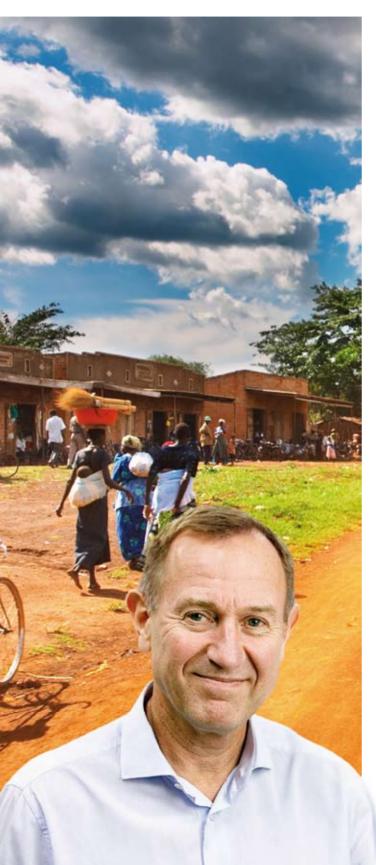
The infection becomes chronic in 80% of carriers. In 20% of carriers, the immune

system manages to eliminate the virus, and they recover without treatment.

The most common type of hepatitis C in the West, called genotype 1, represents some 70-75% of all cases. Some 2-4% of chronic HCV carriers get cancer of the liver, and over one-third of all liver transplants in the developed world are due to hepatitis C.

The disease operates in silence. The virus multiplies in liver cells and a slow deterioration of liver function occurs. This is often not apparent before it has gone so far that it almost cannot be remedied. The virus is aggressive, exceptionally infectious and mutates very quickly.

## ... to improve the lives of hepatitis C patients



Medivir has two points of attack against hepatitis C. Both are being developed in partnership with Tibotec/Johnson & Johnson. The first is protease inhibitor TMC435 and the second is an inhibitor of the polymerase NS5B, what is known as a nucleoside analogue. In combination with each other, it is likely that these compounds could significantly improve the frequency of cured patients, while simultaneously enhancing quality of life for many others.

Medivir has far-reaching commitments in the HCV segment.

"Our knowledge of polymerases and proteases is at its best advantage in this segment. We are one of the leading players in developing new hepatitis C pharmaceuticals," adds Bertil Samuelsson.

Standard of care (SoC) for hepatitis C, a combination of interferon alpha and ribavirin, has existed for over ten years. Intensive research is ongoing to produce new pharmaceuticals that directly inhibit the virus's ability to multiply, and in combination with each other, would be more potent against the virus, while simultaneously reducing the risk of developing resistance. Two of these new CDs, known collectively as STAT-Cs (specifically targeted antiviral therapy for HCV) are in clinical phase III trials. A number of clinical compounds are also in phases I and II.

TMC435, Medivir's protease inhibitor, is in clinical phase IIb, where there are several phase IIb trials involving over 900 patients. In these trials, TMC435 is being administered in combination with ribavirin and interferon.

The nucleoside program in partnership with Tibotec is in late preclinical development, and a CD was designated in December 2008.

"In preclinical trials, TMC435 has been demonstrated as suitable for use in combination therapy with other antivirals (STAT-Cs). In the longer term, the goal is for a combination of two or three STAT-Cs to replace current SoC, which would mean avoiding the adverse events associated with ribavirin and interferon."

Nucleosides, which inhibit the HCV polymerase NS5B, are less potent than protease inhibitors but have a high genetic barrier to resistance development, which is a major advantage. They also appear to retain their

activity against resistant mutants of the virus, which can be selected from protease inhibitors and that are active against the different genotypes of HCV present today.

"By adding a nucleoside analogue to a basic therapy containing a potent protease inhibitors like TMC435, you might be able to increase the share of patients cured and shorten therapy times. This is a fully feasible scenario that could bring a major financial gain for society generally and the patient," continues Bertil Samuelsson.

#### Combinations are the future

Thanks to the development of new antiviral pharmaceuticals, hepatitis C treatment will look different in the

future. The first new type of therapy that will reach the market in the next few years will be a combination of SoC and a STAT-C, probably a protease inhibitor.

"The next compound produced will be administered as an adjuvant to current SoC, usually termed quad therapy. In parallel with quad, there will be experimentation with two or three antivirals, STAT-Cs, with either ribavirin or interferon, or both, removed from therapy completely. This means the future of both Medivir's experimental drugs looks very promising. Our hope is that TMC435 will be part of all leading emergent combinations. It has the right safety characteristics and antiviral potency for this."

## Sustained very positive progress for TMC435

In the year, Medivir presented data from phase IIa trials, which showed TMC435 as having highly potent antiviral efficacy even at low doses. TMC435 was administered over four weeks, and several phase IIb trials are currently ongoing with TMC435 being administered in different doses and for longer periods.

Data from phase IIa trials showed that a maximum single daily dose of 150 mg had a very potent antiviral effect.

"You won't need to think about exactly when in the day, or whether or not to take a tablet with a meal. These are a few of the positive characteristics of TMC435. The dose will be low and precise timing will be less important. And treatment will still be effective," notes Bertil Samuelsson.

Current SoC against genotype 1 hepatitis C is a combination of ribavirin and interferon. This treatment continues for almost a year, for 48 weeks. Many patients are so badly affected by adverse events from this treatment that, unfortunately, they discontinue therapy before it is complete.

Of those genotype 1 hepatitis C patients that start therapy, only 42-46% are cured.

"With TMC435, it will be possible to reduce the total therapy period. We have observed few clinical adverse events in our trials apart from those related to SoC. For patient safety, all new pharmaceuticals have to be administered in combination with SoC. What we've observed includes influenza symptoms, which we recognize from interferon, and anemia from the ribavirin, both to the same extent as SoC."



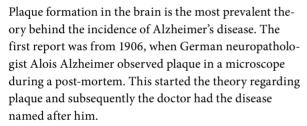
Current phase IIb trials include patients that have not previously responded to therapy and those that have responded to therapy but not completed previous treatment. Results from the trials will be available in 2010.

## The fight against Alzheimer's takes

## stamina and small designed molecules

Scientists have been searching for a key to unlock the riddle of Alzheimer's disease for over 100 years, to develop a pharmaceutical that inhibits the course of this disease. This is an exceptional challenge, associated with high risk.

BACE is a project outside our core segment, that illustrates how we can apply our knowledge of proteases in an indication other than infectious diseases.



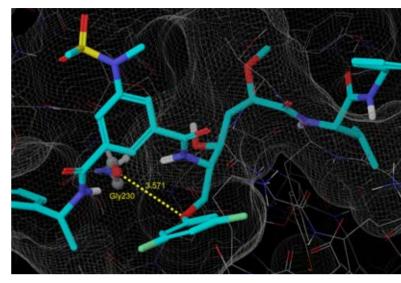
"It was first established that plaque consists of amyloid peptides (linked amino acids), called A-beta, in 1984," says Erik Lindström, Project Manager of BACE, Medivir's protease inhibitor project against Alzheimer's disease.

#### Proteases must be stopped

A-beta is formed with the aid of proteases, proteins that cut and cleave other proteins like scissors.

"There is a large protein, APP, in the nerve cells of the brain that sits in the cell membrane. It can be cut in different ways, but if the protease BACE cleaves it, A-beta peptides are formed. BACE stands for Beta-site APP Cleaving Enzyme and is an enzyme we are aiming to inhibit. BACE is also located in the cell membrane where it attacks APP. There is another protease, gamma secretase, that also goes in and cleaves APP at another site. Both are necessary to form plaque, so the idea is that if we can block either of their advances, we can also prevent pathological plaque formation."

However, developing pharmaceuticals that can cross the blood-brain barrier is exceptionally complex.



"The brain is very well protected. The small capillaries that supply the brain with oxygen and nutrients don't just let anything in and the molecules that cross this barrier must be small."

#### Knowledge and experience

Medivir has access to the full battery of in silico, in vitro cellular and in vivo assays, either in our laboratory or in partnership with foreign CROs (contract research organizations).

We have long-term experience of developing inhibitors for this type of protease, called aspartyl protease, and already have potent compounds that inhibit the enzyme and block its activity. We also have a crystal structure of protease, and are very familiar with how our inhibitors bind to the protease.

#### **Competitive landscape**

A number of trials are ongoing in clinical development focusing on Alzheimer's disease. Two trials on antibodies against the A-beta peptide are in phase III, and there are three gamma secretase inhibitors in different clinical trials. The most advanced is in phase III, with expected delivery of final data in 2011-2012. Medivir's BACE inhibitor is in preclinical optimization, with the goal of designating a pre-candidate in 2010.

### Corporate Governance Report

Medivir AB (publ) was founded in 1988 and has been quoted on Nasdaq OMX Stockholm since 1996. Medivir adopted the revised Swedish Code of Corporate Governance ("the Code") on 1 July 2008, as part of Nasdaq OMX Stockholm's regulatory structure. Medivir had no instances of non-compliance with the code in 2009. Pursuant to the Swedish Corporate Governance Board's adoption guidelines, this

Corporate Governance Report includes a separate section on how internal controls of financial reporting are organized.

The Report is not part of the formal Annual Report documentation, and has not been reviewed by the company's auditor. The figure to the right illustrates Medivir's corporate governance model, and the operations of its central bodies.

Internal regulatory structures and policies that affect corporate governance

#### **Articles of Association**

- Board of Directors' Rules of Procedure and CEO's Instructions
- Remuneration Guidelines for Senior Executives
- Rules of Procedure for Board Committees
- Finance Policy
- IT Policy
- Accounting Handbook
- HR Handbook

### External regulatory structures that affect corporate governance

- Swedish Companies Act
- The Swedish Book-keeping Act
- Swedish Annual Accounts Act
- Nasdaq OMX Stockholm's Listing Agreement
- Swedish Code of Corporate Governance

#### The share and shareholders

Medivir's class B share was floated on Nasdaq OMX Stockholm in 1996. The high-vote class A share is not listed. All shares possess equal rights to participation in Medivir's assets and profits. Class A shares confer ten votes and class B shares confer one vote. Medivir's share capital was Sek 104.2 (104.2) m at year-end, divided between 20,843,547 (20,843,547) shares. The closing price at year-end was Sek 80.50 (46.90) per share, equating to market capitalization of Sek 1,678 (980) m.

#### Medivir's corporate governance model



At year-end there were 5,207 (4,868) shareholders, of which 4,395 (4,012) had holdings of 1,000 shares or less.

Bo Öberg was the largest shareholder in terms of voting rights, followed by Staffan Rasjö and Nils-Gunnar Johansson. 84.4 (82.4)% of shareholders held 1,000 shares or less and the ten largest shareholders held 54.1 (48.5)% of the total number of shares and 60.7 (61.2)% of the votes. The share of foreign shareholders was 23.4 (27.6)% of total equity.

For more information on ownership structure, see The Medivir share on page 38.

#### **Annual General Meeting**

Shareholders exercise control over the company at the Annual General Meeting (AGM). The AGM is held within six months of the end of the financial year. At the AGM, shareholders resolve issues including election of the Board of Directors, and where appropriate auditors, how to appoint the Nomination Committee and discharging the Board of Directors and CEO from liability for the past year. The AGM also considers adoption of the Income Statement and Balance Sheet, fees to the Board of Directors and Auditors and remuneration guidelines for the CEO and other senior executives. The minutes from the AGM 2008 and 2009 are available at the company's website.

The AGM 2010 will be held on 29 April. Minutes from the AGM will be uploaded to Medivir's website, www.medivir.se.

#### **Nomination Committee**

The procedures of the Nomination Committee adopted at the AGM 2009 require the Chairman of the Board to contact at least three of the largest shareholders as of the end of the third quarter of the year. These shareholders are each requested to appoint a representative to the Nomination Committee, which should also include the Chairman of the Board. If any of these shareholders waives their right to appoint a representative, this right transfers to that shareholder with the largest shareholding after the aforementioned shareholders. The Nomination Committee appoints a Chairman to lead its work internally.

The Nomination Committee prepares proposals for electing and remunerating the Board of Directors, Chairman, and where appropriate, Auditors, and the method for appointing the Nomination Committee and its Chairman to be submitted to the AGM for resolution.

The Nomination Committee's proposals for 2010 will be published at the latest coincident with the invitation

to the AGM 2010. Shareholders were able to submit proposals to the Nomination Committee by 31 December 2009 by means including e-mail to valberedning@medivir.se. The name of the shareholders representatives on the Nomination Committee should be published as soon as they are appointed. The Nomination Committee for the AGM 2010 consists of Eva Gottfridsdotter-Nilsson (representing Länsförsäkringar Fonder, 4.2% of the votes\*), Frank Larsson (representing Handelsbanken Fonder, 4.4% of the votes\*), Bo Öberg (representing class A shareholders, 26% of the votes\*) and Göran Pettersson, Chairman of Medivir's Board, as published in the prescribed manner. The mandate term runs until the composition of the next Nomination Committee has been published.

Since its appointment in autumn 2009, the Nomination Committee has met on three occasions where all members attended, apart from on one occasion. On this occasion, the member was able to study the decisions

#### Board members' attendance in 2009

|                    |          |                | Remuneration  |           |                 |  |
|--------------------|----------|----------------|---------------|-----------|-----------------|--|
| Name               | Function | Board meetings | R&D Committee | Committee | Audit Committee |  |
| Björn C Andersson  | Member   | 100%           |               |           | 100%            |  |
| Ingemar Kihlström  | Member   | 100%           | 100%          | 100%      |                 |  |
| Ron Long           | Member   | 100%           | 100%          |           |                 |  |
| Anna Malm Bernsten | Member   | 100%           |               |           | 100%            |  |
| Göran Pettersson   | Chairman | 100%           |               | 100%      |                 |  |

#### Composition of the Board of Directors, May 2009 - April 2010

| Name               | Remuneration<br>Committee | Audit Committee | R&D Committee | the company's<br>management and<br>major shareholders |
|--------------------|---------------------------|-----------------|---------------|---|
| Björn C Andersson  |                           | Chairman        |               | No  |
| Ingemar Kihlström  | Chairman                  |                 | Member        | No  |
| Ron Long*          |                           |                 | Chairman      | Yes   |
| Anna Malm Bernsten |                           | Member          |               | No  |
| Göran Pettersson   | Member                    |                 |               | No  |

<sup>\*</sup> Ron Long is an employee of the company and holds 10,975 class B shares with total voting power of 0.04%.

#### Directors' fees for the period May 2009-April 2010 (SEK)

| Name                | Function | Directors' fees | Committee fee | Total     |  |
|---------------------|----------|-----------------|---------------|-----------|--|
| Björn C Andersson   | Member   | 185,000         | 80,000        | 265,000   |  |
| Ingemar Kihlström*  | Member   | 185,000         | 90,000        | 275,000   |  |
| Ron Long**          | Member   | 0               | 0             | 0         |  |
| Anna Malm Bernsten* | Member   | 185,000         | 65,000        | 250,000   |  |
| Göran Pettersson    | Chairman | 435,000         | 50,000        | 485,000   |  |
| Total               |          | 990,000         | 285,000       | 1,275,000 |  |

<sup>\*</sup> In addition, consulting fees of SEK 25,000 were paid to Anna Malm Bernsten and consulting fees of SEK 60.000 were paid to Ingemar Kihström.

Affiliation to

<sup>\*</sup> Record date 31 December 2009

<sup>\*\*</sup> Ron Long was appointed as CEO on 1 February 2009 and thus has not drawn Directors' fees.

### Board of Directors

#### GÖRAN PETTERSSON

Göran is also a member of Medivir's Remuneration Committee. He was born in 1945 and elected to Medivir's Board in 2008. Göran is a pharmacist and market economist (IHM) and possesses long-term experience of the pharmaceutical industry in Sweden and foreign countries. He has been a self-employed life sciences consultant since 2000, and previously held senior positions with the Astra group, KabiVitrum, Pharmacia/PharmaciaUpJohn and Meda. Göran holds several directorships in other companies and is Chairman of OxyPharma AB and Vivoxid Oy and a Board member of Diamyd Medical AB, Pfizer Sweden's pension fund and Recipharm AB. Medivir shareholding: 3,600 class B.



#### BIÖRN C ANDERSSON

Born in 1946, has been a Board member since 2008 and is Chairman of Medivir's Audit Committee. He is a Licentiate of Economics and former employee of Handelsbanken, where he was Deputy CEO and Head of Handelsbanken Markets, then Head of Handelsbanken Asset Management. Björn is Chairman of Euroben Life & Pension, Nordben Life, NAXS Nordic Access Buyout Fund AB and a Board member of Bliwa Livförsäkring.

Medivir shareholding: 0.

#### INGEMAR KIHLSTRÖM

Born in 1952. Board member since 2008 and Chairman of Medivir's Remuneration Committee and a member of its R&D Committee. Ingemar is an Associate Professor at the University of Uppsala, and is a self-employed consultant in the life sciences sector. He possesses broad experience of pharmaceuticals and business development, from the pharmaceutical industry and financial sector. Ingemar previously held senior positions with Pharmacia, Aros Securities and ABG Sundal Collier. He has several directorships in Scandinavia, including chairmanships of Artimplant AB, Creative Antibiotics AB, Hammercap AB and RecoPharma AB, and is Deputy Chairman of Diagenic ASA.

Medivir shareholding: 2,180 class B.





#### **RON LONG**

Born in 1947, Board member since 2007 and Chairman of Medivir's R&D Committee. Contributes a broad network across Europe. B.A. from Reading University. Chairman of Procognia Israel, several senior executive positions in Sky Medical Technology (GB), Aeomica Medical Technologies (GB), PepTonic Medical AB and EuroDiagnostica AB. Previous experience including positions in the Wellcome Foundation plc, Amersham Pharmacia and directorships of Biacore AB. Medivir shareholding: 10,975 class B.



#### ANNA MALM BERNSTEN

Anna is also a member of Medivir's Audit Committee. She was born in 1961, and has been a member of Medivir's Board since 2006. Anna holds a B.Sc. (Eng.) and possesses broad experience of life sciences. She was previously employed by Medivir, and is a self-employed leadership and business development consultant. Apart from senior executive experience at GE Healthcare Life Sciences, Pharmacia, Assa Abloy, Medivir and Baxter Medical, she was also CEO and President of Carmeda AB. Anna is a Board member of Fagerhult AB and Artimplant AB.

Medivir shareholding: 0.



#### **AUDITORS**

PricewaterhouseCoopers AB for 2008 to 2012.
The Senior Auditor is Authorized Public Accountant Claes Dahlén.
Board members of Medivir UK Ltd.: Bertil Samuelsson and Bo Öberg.
Board members of Medivir HIV Franchise AB: Bo Öberg and Rein Piir.
Board members of Medivir Personal AB: Bo Öberg, Christina Kassberg and Rein Piir.

subsequently and approve them. The Chairman of the Board reported to the Nomination Committee on the annual appraisal process for the Board of Directors, Board members and CEO to the Nomination Committee, and also informed them of the outcome of this appraisal.

The Nomination Committee is proposing at the Annual General Meeting 2010 that a Board of Directors is appointed through the re-election of its five members, namely Göran Pettersson (Chairman of the Board), Björn C. Andersson, Anna Malm Bernsten, Ingemar Kihlström and Ron Long (CEO).

#### **Board of Directors**

The over-arching task of the Board of Directors is to manage the company's affairs on behalf of the share-holders in the best way possible. The Board of Directors possesses substantial skills and experience in pharmaceutical industry, finance and strategy.

The Board of Directors evaluates the group's financial situation and appraises its executive management on an ongoing basis. The Board considers matters including the group's strategic orientation and organization, and decides on significant investments and commitments.

The Board adopts Rules of Procedure including the CEO's Instructions annually, which formalize matters including the division of responsibilities between the Board of Directors and the CEO. The Rules of Procedure also formalize how Board activities are divided between Board members, how often the Board should meet and how work should be delegated to Board committees.

At each Board meeting, Board members receive a written agenda and comprehensive supporting documentation. Current business conditions, the group's results of operations and financial position and the outlook for the remainder of the year are reviewed at each scheduled Board meeting.

The Chairman of the Board leads the Board's work, represents the company on ownership issues and is responsible for appraising the Board's activities. The Chairman is also responsible for maintaining ongoing contacts with the group management, and for the Board performing its duties. Board members are presented on pages 20-21.

#### The work of the Board in 2009

The Board of Directors elected its officers on 23 April 2009, held 6 meetings where minutes were taken in 2009 and was quorate on all occasions. Medivir's General Counsel, who is not a Board member, is Board Secretary. Other Medivir employees also participated at Board

meetings, to submit reports. In the year, the Board of Directors mainly considered issues regarding strategy, research and development, partnerships, significant investments, financing, quarterly reports, the Financial Statement and Annual Report.

#### Directors' fees 2009

The AGM on 23 April 2009 resolved on maximum Directors' fees of Sek 2,620,000 payable for the period until the next AGM, divided as follows. Directors' fees of Sek 435,000 payable to the Chairman of the Board and Sek 185,000 to each of those Board members entitled to fees. For work on the Audit Committee, a fee of Sek 80,000 is payable to the Chairman of the Committee, and Sek 65,000 to each of the Committee's members. For work on the Remuneration Committee, a fee of Sek 65,000 is payable to the Chairman of the Committee and Sek 50,000 to each of the Committee's members. For work on the R&D Committee, a fee of Sek 65,000 is payable to the Chairman of the Committee and Sek 50,000 to each of the Committee and Sek 50,000 to each of the Committee's members.

#### **Board Committees**

There are three consultative committees within the Board: the Remuneration Committee, the Audit Committee and the R&D Committee.

#### **Remuneration Committee**

The Remuneration Committee is appointed by the Board of Directors and has a maximum of four members. The members are Ingemar Kihlström (Chairman) and Göran Pettersson. The Committee is advisory and does not have the right to take decisions. This Committee submits proposals to the Board regarding:

- (i) the CEO's salary and other employment terms,
- (ii) salaries and employment terms for other senior executives, and
- (iii) evaluation and proposals regarding incentive schemes.

In 2009, the Remuneration Committee held three meetings where minutes were taken, where all members attended. In addition, the Committee held a number of consultations by telephone and e-mail. At the AGM, the Board presents proposed guidelines for determining salary and other remuneration for the CEO and other members of the company's management, for the approval of the shareholders.

#### **Audit Committee**

The Audit Committee is appointed by the Board and has a maximum of four members. The members are Björn C

Andersson (Chairman) and Anna Malm Bernsten. The Committee is advisory and does not have the right to take decisions.

The primary task of the Committee is to support the Board in its work on the company's risk management, control and internal controls, and to quality-assure financial reporting. The Committee considers significant accounting issues affecting the group, and meets the company's auditors on an ongoing basis. The Committee evaluates audit work, supports the Nomination Committee in considering proposed auditors and their remuneration, and approves the supplementary services the company may purchase from external auditors. The Chairman of the Audit Committee is responsible for the whole Board being kept informed regarding audit work, and where necessary, submits matters for decision to the Board.

In 2009, the Audit Committee considered the company's risk analysis, finance policy and significant audit matters. The Committee also studied and discussed the risk analysis and audit plan the auditors prepared as a basis for the statutory audit process. All of the Committee's members are independent of the company's major shareholders. In 2009, the Audit Committee held three meetings where minutes were taken, where all members attended. The Auditors and Chief Financial Officer also attended all meetings, and the Chairman of the Board attended two meetings.

#### **R&D Committee**

The R&D Committee is appointed by the Board and has a maximum of four members. The members are Ron Long (Chairman) and Ingemar Kihlström. The Committee is advisory and does not have the right to take decisions. This Committee's main tasks are, in consultation with Medivir's management team, to:

- (a) participate in preparing the principles for managing and prioritizing, and systems for monitoring, R&D activities.
- (b) review and provide the Board with decision-support data regarding the strategic focus of R&D operations and (c) periodically screen the research portfolio and participate in structuring proposals for overall priorities ahead of budget decisions and major updates.
- (d) conduct a review of the project portfolio twice yearly.At each meeting, Medivir's project teams will update the prepared review templates for each research project.(e) prepare written feedback to project managers regarding decisions on project priorities and allocation of resources. The management team is responsible for com-

municating the background to decisions. In addition, and on demand from the management team, the R&D Committee should

- -approve project start-ups coincident with the start of lead optimization
- -take decisions on the appointment of project managers -be advisory to the management team regarding complex scientific matters.

In 2009, the R&D committee held one meeting where minutes were taken.

#### Management

The Chief Executive Officer leads the company's operations pursuant to instructions adopted by the Board of Directors. The CEO is responsible for keeping the Chairman and other Board members continuously informed on the company's progress, both financially and operationally, and for the required information being available to Board members.

Medivir's management has seven members including the CEO. The management has a broad composition of individuals with in-depth, thorough experience of the research and development, marketing and sale of pharmaceuticals. Management also possesses the necessary skills in accounting and finance, legal issues and corporate communications.

#### Remuneration guidelines for senior executives

The AGM 2009 resolved that the compensation package offered by Medivir will follow market norms and enable skilled senior executives to be hired and retained. Remuneration to senior executives will consist of basic salary, potential performance-related pay, stock options in the stock option plans resolved by AGMs, pension and other benefits. Basic salaries relate to individual responsibilities and experience. Performance-related pay - which at present, and where appropriate, is payable as a discretionary individual bonus - Is a maximum of 50% of basic salary. The CEO's pension scheme will conform to the ITP (supplementary pensions for salaried employees) scheme, and approximately 15% of basic pay excluding bonus and benefits. The pension plans of other senior executives will conform to the ITP scheme, and the relevant individual plan in the UK corresponds to legislated contributions, plus 6% of basic pay excluding bonus and benefits. The Board of Directors is entitled to diverge from the above guidelines if the Board considers that there are special circumstances in an individual case that justify this. For more detail on remuneration, see Note 4 on pages 50-52.

#### **Auditing**

Auditing firm PricewaterhouseCoopers AB, which has been Medivir's auditor since 1988, was elected at the AGM 2008 for a mandate term of four years. PricewaterhouseCoopers then appointed Authorized Public Accountant Claes Dahlén as Senior Auditor. PricewaterhouseCoopers audits all group companies.

On assignment from the Board, the Auditor conducts a summary review of all interim financial statements pursuant to the applicable standard for limited reviews (SÖG) 2410 "Limited review of interim financial information conducted by the company's appointed auditor". Other statutory audits of the Annual Accounts, Consolidated Accounts and accounting records and the Board of Directors' and CEO's administration is conducted pursuant to applicable Swedish RS Auditing Standards. Audits of management, internal processes and control systems are conducted in the fourth quarter. The conclusions of this audit are reported to the Audit Committee, and for the fourth quarter, also directly to the Board of Directors. During the year, the Auditors attended three meetings with the Audit Committee and one meeting with the Board of Directors.

Apart from auditing, Medivir also consulted PricewaterhouseCoopers on tax issues and a range of accounting and finance matters. Pricewaterhouse-Coopers is accountable for verifying its independence ahead of decisions to also offer independent advisory services to Medivir apart from its auditing assignment. Information on audit fees is stated in Note 3 on page 50.

#### **Internal Audit**

The company has a simple legal and operational structure and formulated controlling and internal control systems. The Board of Directors and Audit Committee monitors the company's evaluation of internal controls through means including contacts with the company's Auditors. Against the above background, the Board of Directors has chosen not to conduct a dedicated internal audit process.

## Board of Directors' report for the financial year 2009 on the organization of internal control of financial reporting

Pursuant to the Swedish Annual Accounts Act and the Swedish Code of Corporate Governance Medivir's Board of Directors is responsible for internal controls. This report has been prepared pursuant to section 3.7.2 of the Swedish Code of Corporate Governance, with supplementary instructions from the Swedish Corporate Governance Board. This report has not been reviewed by the company's auditors.

The over-arching purpose of internal controls is to provide reasonable assurance that the company's operational strategies and goals are monitored and that shareholders' investments are protected. Additionally, internal controls should provide reasonable assurance that external financial reporting is reliable and prepared in accordance with generally accepted accounting practice, that applicable laws and ordinances are observed, and that the requirements of listed companies are observed.

The internal control environment at Medivir conforms to the international Internal Control – Integrated Framework structure, "COSO", having the following five main elements: control environment, risk assessment, control activities, information and communication and monitoring.

#### Control environment

Primarily, the control environment is the culture the Board of Directors and management communicate and operate from. The Board has overall responsibility for internal controls of financial reporting. The Board has adopted written Rules of Procedure that clarify the Board's responsibilities and formalize the internal division of responsibilities of its Committees. Additionally, the Board of Directors has appointed an Audit Committee whose primary task is to safeguard financial reporting and internal controls, and maintain expedient relations with the company's Auditors. Medivir's internal control activities are intended to ensure that the group realizes the objectives of financial reporting.

Medivir's financial reporting conforms to applicable laws and ordinances for companies listed on the Stockholm Stock Exchange. Apart from external laws and ordinances, financial reporting is also subject to fundamental policies and guidelines including a finance policy, certification and authorization instructions as well as purchasing and investment policies.

Financial reports are prepared monthly and quarterly for the group, parent company, subsidiaries and for Functions and projects. Forecasts, extensive analysis and comment, with purposes including quality-assuring financial reporting are prepared coincident with reporting. Medivir has prepared an accounting handbook comprising internal instructions and directions. There are also checklists for significant routines and processes. Internal instructions and routines are subject to continuous enhancement.

#### Risk assessment

Effective risk assessment integrates Medivir's business opportunities and results with the requirements of

shareholders and other stakeholders for stable, long-term value growth and control. Developing a new pharmaceutical to approved registration and launch is a highly capital intensive and risky process. The likelihood of reaching the market increases as the project moves through the development chain, which also affects costs, which rise steeply in later clinical phases.

Medivir is exposed to a range of risks, both operational and financial, including risks of misstatements in financial reporting. The company has an established risk management process for operational and financial risks. The company has identified, mapped and documented all significant operational risks and classified them systematically in terms of the likelihood and consequences of these risks for operations. The risk assessment and classification has been presented to, and is endorsed by, the Audit Committee and Board of Directors. Based on the outcome of internal and external risk assessment, the Committee continually discusses the focus and scope of the audit with the company's Auditors.

Financial risks such as liquidity risk, currency risk, interest risk and credit risk have been identified. They are mainly managed by the accounting and finance function pursuant to the group's finance policy. For a detailed review, see Note 8 on pages 53-56.

#### Control activities

The primary purpose of control activities is to prevent, discover and rectify misstatements in financial reporting. Processes and activities have been structured to manage and address significant risks related to financial reporting.

These activities include analytical updates and comparisons of the progress of profits or items, reconciling accounts and balances, and approval of all business transactions and collaboration agreements, powers of attorney and certification instructions, as well as accounting and valuation policies. Access to ERP systems is limited by authority, responsibility and role.

There is an established controller function that conducts control activities at all levels of the company. This function analyses and monitors budget variances, prepares forecasts, investigates significant fluctuations over periods and also reports within the company, which minimizes the risk of misstatements in financial reporting.

#### Information and communication

Medivir has information and communication pathways intended to promote the completeness and accuracy of financial reporting. The Board of Directors approves the group's annual report and financial statement, and

assigns the CEO to issue quarterly reports pursuant to the Board's Rules of Procedure. All financial reports are transmitted to Nasdaq OMX Stockholm first. They are also distributed to all shareholders that have not declined the opportunity of receiving this information. External information is also communicated continuously via Medivir's website (www.medivir.se), where quarterly reports, financial statements, annual reports, press releases and news are uploaded in chronological order. Information from press and analysts' conferences is also uploaded to the website.

The Board receives regular financial reports regarding the group's position and progress of profits. Meetings are held within the company at management level, and at the level individual function managers and project managers consider appropriate. The intranet is a prime internal communication channel, where policies, guidelines and information is uploaded and informative meetings for all staff are held on an ongoing basis.

#### Monitoring

The Board of Directors considers all the group's quarterly reports, financial statements and annual reports before publication. The Board receives regular financial reports on the group's position and profits, and the group's financial situation is considered at every Board meeting.

The Board's monitoring of internal control of financial reporting is mainly conducted through the Audit Committee. Medivir's Auditors conduct their audit process pursuant to the audit plan and monitor parts of internal controls within the auspices of the statutory audit annually. After the audit is completed, observations are reported continuously back to the Audit Committee. The auditors also attend one Board meeting each year, where they report their observations on the audit for the year and operational routines. The practice on this occasion is to reserve time for special discussions where the CEO or other employees are not present.

The company has a simple legal and operational structure and formulated controlling and internal control systems. Against the above background, the Board of Directors has chosen not to operate a dedicated internal audit process. The Board and Audit Committee evaluate and monitor the issue of the potential creation of an internal audit function on a continuous basis.

## Management



#### **RON LONG**

Born in 1947. B.A. from Reading University. CEO and President since 2009. Previous experience includes positions in the Wellcome Foundation plc, Amersham Pharmacia AB, Kudos Pharmaceuticals and directorships of Biacore AB and Asterand plc. Medivir shareholding: 10,975 class B.

#### **EVA ARLANDER**

Born in 1964. Pharmacist, Ph.D. in Medical Science. Vice President of Medivir Pharma. Marketing Director and Project Manager of Xerclear. Medivir employee since 2004. Previous positions include Project Manager and Manager of AstraZeneca's clinical research operation. Medivir shareholding: 0.

Stock options\* 2005–2010: 2,500. Stock options\* 2007–2012: 12,000.



#### REIN PIIR

Born in 1958. B.Sc. (Econ.) Chief Financial Officer/ Vice President of Investor Relations. Medivir employee since 2000. Previously senior positions include Healthcare & Research at D. Carnegie AB and Research & Strategy at SPP. Medivir shareholding: 0. Stock options\* 2005–2010: 7,000.

Stock options\* 2007–2012: 20,000.





#### IAIN MORRISON

Born in 1960, LL.B. & B.Sc. (Hons.) Vice President of Legal Affairs. Corporate and patent lawyer. Medivir employee since 1993. Previously attorney and patent attorney at established law firms in Australia and Sweden.

Medivir shareholding: 0.
Stock options\* 2005–2010: 2,500.
Stock options\* 2007–2012: 6,000.



#### CHRISTINA KASSBERG

Born in 1968. B.Sc. (Econ.) Vice President of Business Control and Administration. Medivir employee since 2000. Previously Controller of Medivir AB, Accounting Manager at Skandia Link Multifond and Auditor at Öhrlings PricewaterhouseCoopers.

Medivir shareholding (family): 4,104 class B.

Stock options\* 2005–2010: 2,000.

Stock options\*2007–2012: 20,000.

#### BERTIL SAMUELSSON

Born in 1950. Ph.D., Professor. Vice President of Discovery Research. Medivir employee since 1999. Previous positions include Head of Medicinal Chemistry at AstraZeneca, Mölndal, Sweden. Medivir shareholding (family): 40,460 class B.

Stock options\* 2005–2010: 7,500. Stock options\* 2007–2012: 22,000.



#### PAUL WALLACE

Born in 1962. Ph.D., University of Cambridge. Vice President of Business Development. Medivir employee since 2000. Previously Business Development Manager at Peptide Therapeutics plc and Director of Research at Eclagen, both in the UK. Medivir shareholding: 0.

Stock options\* 2005–2010: 7,500.

Stock options\* 2007–2012: 22,000.

<sup>\*</sup> For the terms governing the rights to acquire shares, see 'The Medivir Share' on page 39.

## Glossary

#### Alzheimer's disease

A form of dementia named after the German neuropathologist and psychiatrist Alois Alzheimer.

#### Antiviral

Inhibition of virus growth.

#### CD (candidate drug)

Compound designated to proceed into clinical studies. Medivir uses the same criteria as the big pharmaceutical companies.

#### Clinical studies

Studies of experimental drug on humans.

#### CMV-Cytomegalovirus

A herpesvirus giving severe infections in persons with deficient immune defence.

#### **Compound library**

A collection of chemical compounds which can be screened for inhibition of different enzymes.

#### COPD

Chronic obstructive pulmonary disease.

#### CRO (Clinical Research Organization)

A company that conducts clinical studies on a contract basis.

#### Enzyme

A protein molecule, typically a very large one, that catalyses chemical reactions in living cells. These reactions occur rapidly and with great precision without the enzyme itself being consumed. Polymerases and proteases are enzymes.

#### Genotype

An individual's precise genetic characteristics (genome), usually in the form of DNA. Genotype 1a is the most common in North America, and 1b in Europe.

#### **Hepatitis B**

Jaundice caused by human Hepatitis B virus (HBV).

#### **Hepatitis C**

Jaundice caused by human Hepatitis C virus (HCV).

#### HIV (Human immunodeficiency virus)

Causes deficiencies in the immune system and gives rise to AIDS.

#### IAS (International

Accounting Standards) See 'IFRS'.

#### IFRS (International Financial Reporting Standards)

New accounting rules adopted by the EU. Intended to facilitate comparisons between Annual Reports in different European countries. Listed companies must comply with IFRS since 1 January 2005.

#### Interferon

Human protein with antiviral effect.

#### Labial herpes/cold sores

Caused by herpes simplex virus type 1 (HSV-1) and transmitted via saliva/oral contact. There are two types of herpes simplex virus, type 1 and 2 (HSV-2). HSV-2 is normally sexually transmitted, but it can also cause labial herpes. The infection becomes latent and the virus can be reactivated.

#### Milestone payments

Payments upon attaining contracted achievements.

#### Mononucleosis

A human disease caused by Epstein-Barr virus, from the family of herpes virus. The disease is transmitted via saliva, sexually and via blood transfusions.

#### MS (Multiple Sclerosis)

Disease of the central nervous system.

#### Neuropathic pain

Nerve pain arising as a direct consequence of lesions or disease that affects the somatosensory system. There is a distinction between peripheral and central pain.

#### **Nucleoside analogue**

A structural modification of the nucleosides used as building blocks for genes.

#### Option

Right to buy shares at some time in the future.

#### Osteoarthritis

Chronic degenerative arthritic disease.

#### Osteoporosis

Brittle bones.

#### **Pharmacokinetics**

The study of a drug's metabolism in the human body (absorption, distribution, conversion and secretion).

#### **Polymerase**

A type of enzyme that replicates genes, for example, of a virus.

#### Preclinical research

Research into a pharmaceutical compound prior to studies on humans (clinical studies).

#### Pre-emption

If a holder of class A shares wishes to sell these shares, they must be offered to other holders of class A shares first.

#### Proof-of-principle

Preclinical or early stage clinical drug development studies on a compound to examine it's potential to modulate a physiologically relevant mechanism and to detect and monitor a signal or biomarker for it's pharmacodynamic effect.

#### **Protease**

An enzyme able to break proteins down into smaller units.

#### Rheumatoid arthritis

Chronic, painful and disabling collagen disease affecting joints.

#### Resistance

Reduced efficacy of a compound that normally suppresses a virus or other microorganism.

#### Ribavirin

A nucleoside analogue which inhibits virus replication through cellular interaction.

#### Royalty

Payment, often calculated as a percentage of product (drug) sales.

#### Share issue

Provision of new shares to raise capital.

#### Shingles

Painful disease with vesicles on the skin caused by a herpes virus, the varicella- zoster virus (VZV). This virus remains latent within the body after chickenpox infection, and may re-activate many years later, causing shingles.

#### VZV (Varicella-zoster virus)

A herpes virus that causes chickenpox, usually in children, and which remainsin ganglia throughout life. It may re-activate later and if so, give rise to shingles.

#### Wild-type virus

A virus which has not developed resistance to any drug.

## Report of the Directors

The Board of Directors and Chief Executive Officer of Medivir AB (publ), corporate identity number 556238-4361, with registered office in Huddinge, Sweden, hereby submit the Annual Report for the operations of the group and parent company for the financial year 2009. The group comprises parent company Medivir AB (publ) and wholly owned subsidiaries Medivir UK Ltd., Medivir HIV Franchise AB and Medivir Personal AB.

Medivir has been quoted on Nasdaq OMX Stockholm since 1996. For more information, go to www.medivir.se.

#### **Operations**

Medivir's pharmaceutical development is based on in-depth knowledge of inhibiting the activity of polymerases and proteases in the course of diseases. We have created a competitive position in these segments through the long-term, goal-oriented accumulation of specialist techniques, knowledge and experience. We have built unique compound libraries and developed competitive candidate drugs that have made us an attractive collaboration partner for the large pharmaceutical companies.

#### **Business focus**

Our primary business focus is within infectious diseases, where most of our projects are positioned.

Our project portfolio also has projects targeting other major indications as a result of our broad knowledge of inhibiting the activity of proteases, where they play a key role in disease mechanisms.

The project that has advanced furthest in development is the cold sore pharmaceutical Medivir has developed itself, formerly called Lipsovir®. Following the FDA and EMEA approval in 2009 this product is now in its launch phase and will reach the market in 2010.

Medivir's greatest commitments in infectious diseases are its projects in the hepatitis C segment. These projects address the hepatitis C virus using two different approaches, protease and polymerase inhibition, putting Medivir in the global development front line of developing new pharmaceuticals for this indication. We have several partnerships with established pharmaceutical companies and smaller biotechnology enterprises on clinical and preclinical projects.

Medivir's business goal is to be a leading, profitable pharmaceutical company with its primary focus in infectious diseases within five years. The first phase of this process is to launch our cold sore pharmaceutical as an Rx product under the Xerclear™ brand ourselves in the Nordic region and to receive royalties on sales by future partners in the rest of Europe and the US.

#### Significant events in 2009

In February an organizational review was initiated whose goal was to downscale our fixed cost base. The overall aim was to continue to run and develop projects effectively within the framework of a lower fixed cost base. The implementation of this overhaul was concluded in late-spring 2009. This also liberated the financial resources needed to prepare for the launch of Xerclear<sup>TM</sup>.

CHRISTINA KASSBERG Vice President, Business Control Phone +46 (0)8 546 831 69 christina.kassberg@medivir.se In 2008, Medivir filed NDAs in the US and the EU for the cold sore pharmaceutical Lipsovir®, developed by Medivir. In autumn 2009, this product was approved for marketing and sale in the US and 14 European countries. Medivir will be launching the product itself in the Nordic region under the Xerclear™ brand, starting with the prescription pack in March 2010. For other European countries, the goal is to enter partnerships on Xerclear™ so that product launch is possible in the second half-year 2010. In the US, the product will be launched via partners under the brand Xerese™. This launch is expected during the second half-year 2010.

In partnership with Tibotec, a Johnson & Johnson group company, Medivir presented several positive results on TMC435 in the year, a protease inhibitor under development for treating hepatitis C virus infections (HCV).

The interim results presented are from phase IIa trials, which commenced in 2008. They show that a single daily dose of TMC435 over four weeks as an adjuvant to existing standard of care (SoC) has very potent antiviral efficacy, i.e. reduces virus levels effectively. It is well tolerated and safe at the doses evaluated. The subsequent, very large-scale phase IIb trials were designed on the basis of these clinical results and previously conducted trials.

Three major clinical phase IIb trials started in 2009, which when completed, will have involved nearly 1,000 patients. Two of the trials were conducted mainly in North America and Europe, while the third is ongoing in Japan.

An overarching portfolio review was initiated in the autumn in order to prioritize and run future projects in a more focused and resource optimal manner. This applies to explorative activities, which have not yet been assigned full project resources and projects conducted and funded by Medivir or partners. The ambition is also to exploit existing explorative activities in infectious diseases, in hepatitis C and elsewhere. This review is scheduled for completion before the end of the first quarter 2010 and will result in a portfolio with greater emphasis on infectious diseases.

As a result of the successful designation of CDs in bone disorders, MIV-710 and MIV-711 (cathepsin K), resources were freed up in Medivir's preclinical organization in the autumn. The two main preclinical projects in the year apart from cathepsin K were cathepsin S, primarily targeting neuropathic pain, and BACE, an Alzheimer's disease project.



#### Patents and patent filings

Broad patent protection is the foundation of all new pharmaceuticals and their commercial possibilities. Patent activities are a fundamental and integrated part of Medivir's early preclinical activities. At the close of 2009, Medivir had 65 patent families, including those filed by collaboration partners and that may generate royalties in the future for Medivir. A patent family is the collection of national

or regional patents and patent applications that cover a single invention or group of related inventions.

In 25 of these 65 families, the official examination process has progressed to the point that at least one US or EU patent has been granted. Including these approved US/EU patents, Medivir or collaboration partners had 444 granted patents in force at vear-end.

| Project     | Patent No     | Normal expiry | AU | BR | CA | CN | EU  | IL | IN | KR | JP | мх | MY | RU | TH | TW | US | ZA | Expiry of further<br>patent families |
|-------------|---------------|---------------|----|----|----|----|-----|----|----|----|----|----|----|----|----|----|----|----|--------------------------------------|
| Xerclear™   | WO96/24355    | 2/2016        |    | )  |    |    | 19  |    |    |    |    |    |    | )  |    |    |    |    | 2029                                 |
|             | WO00/29027    | 12/2019       |    |    |    |    | 20  |    |    |    |    |    |    | )  |    |    |    |    | 2023                                 |
| TMC 435     | WO07/014926   | 07/2026       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    | 2028                                 |
| TIVIC 435   | WO05/073195   | 01/2025       |    |    |    |    | 35  |    |    |    |    |    |    |    |    |    |    |    | 2028                                 |
| HCV POL     | WO08/043704   | 10/2027       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    | 2029                                 |
| BACE        | Not published | 10/2029       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    | 2030                                 |
| MIV-710     | WO09/000877   | 06/2028       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    |                                      |
| MIV-711     | Not published | 09/2028       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    |                                      |
| HIV-PI      | WO06/084688   | 02/2026       |    |    |    |    | 12  |    |    |    |    |    |    |    |    |    |    |    | 2029                                 |
| MMP12       | WO07068474    | 11/2026       |    |    |    |    | All |    |    |    |    |    | )  |    |    |    |    |    |                                      |
| Cathepsin S | Not published | 12/2029       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    | 2030                                 |
| Renin       | Not published | 08/2029       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    |                                      |
| MIV-606     | WO97/30051    | 02/2017       |    |    |    |    | 25  |    |    |    |    |    |    |    |    |    |    |    | 2028                                 |
| MIV-210     | WO99/09031    | 08/2018       |    |    |    |    | 20  |    |    |    |    |    |    |    |    |    |    |    |                                      |
| MIV-150     | WO99/36406    | 01/2019       |    |    |    |    | 23  |    |    |    |    |    |    |    |    |    |    |    |                                      |
| MIV-160     | WO02/70516    | 3/2022        |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    |                                      |
| MIV-170     | WO05/66131    | 12/2024       |    |    |    |    | All |    |    |    |    |    |    |    | )  |    |    |    |                                      |
| MIV-410     | WO07/006707   | 07/2026       | Ó  | Ŏ  | Ŏ  | Ŏ  | All |    | O  | Ŏ  |    |    |    | Ó  | )  |    |    |    |                                      |
| MIV-310     | WO07/129274   | 05/2027       |    |    |    |    | All |    |    |    |    |    |    |    |    |    |    |    |                                      |

Patent granted
Patent allowed by patent examiner, grant formalities not completed
Patent pending, await examination at the Patent Office

#### Normal expiry

- Since 1995, almost all countries specify a patent life of 20 years from the international application date
- Older US patents have a life of 17 years from grant, which could lead to substantially different lives in different countries. An example is MIV-310, where Medivir's US patent claiming the use of alovudine in the treatment of HIV is due to expire in March 2019, almost ten years after the expiry of the remaining patents
- Europe additionally allows up to five year's extension of pharmaceutical patents, where the European marketing authorization was granted more than 5 years from the patent application date. The projects where European extension is relevant (extended expiry in brackets) are: MIV-606 (2/2022), MIV-210 (8/2023), MIV-150 (1/2024), and MIV-160 (3/2027). In the case of Xerclear  $^{\text{TM}}$ Medivir is in the process of filing the formal "Supplementary Protection Certificate" papers in he EU countries where both patents and marketing authorizations have already been granted, inter alia Britain Germany and Sweden
- Many countries have an additional form of market exclusivity for pharmaceuticals, called "data exclusivity". This prevents generic pharmaceutical applications "ANDA" being approved based on an original product for a defined number of years, namely 10 years in Europe, 2.5 - 5 years in the US and 6 years in China. This exclusivity is independent of patents and as it is based on the launch date, the exclusivity may extend longer than the patent life. For example in Europe, MIV-310 will gain 10 years protection from generic pharmaceutical applications notwithstanding that the European patent has expired.

#### Country codes

- AU Australia, BR Brazil, CA Canada, CN China/Hong Kong, IL Israel, IN India, KR South Korea, JP Japan, MX Mexico, MY Malaysia, RU Russia, TH Thailand, TW Taiwan, US USA, ZA South Africa. WO is an international (PCT) patent
- EU At present, a European patent can cover all countries in the EU and a number of other European countries such as Switzerland, Iceland, Croatia. Turkey, and soon, Norway. Medivir always validates granted European patents, at least in the key pharmaceutical markets of Germany, the UK, France, Italy, Spain, Switzerland and Sweden. The figure in this column is the total number of European countries where the patent is pending or has been validated.

#### Additional patent families

- Wherever possible, Medivir ensures that its patent applications include product claims (also known as "composition of matter") and therapeutic method claims. Product claims are preferred in pharmaceutical contexts as they give control over product pricing, notwithstanding that further uses for a product may be discovered in the future
- Medivir practices patent portfolio management and files successive generations of patents to in-house and CRO developments such as formulations, synthesis methods and synergistic combinations. Although such patent families can seldom totally prevent generic competition after the basic product patent has expired, they do serve a role in ensuring continued royalty income from Medivir's partners even after the introduction of generic competition. This extended royalty period is indicated in this column.

#### **Project portfolio**

Medivir's research and development projects focus on two drug targets, polymerase and protease. Indications where Medivir has run projects based on protease inhibition, itself or via partners, include hepatitis C, HIV, osteoporosis, skeletal metastases, neuropathic pain and Alzheimer's disease.

Developing pharmaceuticals based on polymerase inhibition is well suited to infectious diseases like hepatitis B and C, HIV, herpes and shingles. In its projects based on polymerase inhibition for HIV, Medivir decided several years ago to cease working actively and outlicense these projects within the auspices of Medivir HIV Franchise AB. These projects are also being evaluated in the ongoing portfolio review and those that are considered to have good commercial prospects will be consolidated into the single portfolio and the rest will be discontinued completely.

At year-end 2009, Medivir's project portfolio included 15 projects, one of which, Xerclear<sup>TM</sup>, is in its launch phase. Five projects are in clinical development phases of which four projects are in phase II and one in phase I. Two projects are in the regulated preclinical development phase and seven are in the preclinical phase.

At present, nine of Medivir's projects are being conducted in collaboration with partners.

#### Summarized progress by project

The projects that Medivir ran actively in the year, either in-house or via partners, are reviewed below.

#### Xerclear™

*Indication:* Labial herpes (cold sores) caused by the herpes simplex virus. The herpes virus mainly is mainly passed on via direct contact during a cold sore episode. The virus remains dormant in the body and the illness can recur year after year. Common colds, stress and exposure to the sun are some of the factors that can trigger a herpes outbreak.

**Medivir's compound/pharmaceutical:** is a patented combination of hydrocortisone (anti-inflammatory) and acyclovir (antiviral) in a novel proprietary formulation.

**Progress in the year:** in autumn 2008, Medivir submitted NDAs to regulatory authorities in the US and 14 European countries. The pharmaceutical was approved for market registration and sale by the US and European regulatory authorities in autumn 2009. The remaining phase in the process before product launch in the 14 European countries is a national phase, selecting product packaging and legal status (prescription or OTC). This process is scheduled for completion in spring 2010.

In the year, Medivir prepared for its own launch of Xerclear<sup>TM</sup> in the Nordic region. The objective is to complete this in spring 2010. Work on entering partnerships for product launch and sale in the US are ongoing, with the objective being completion before the end of the first quarter of 2010. Partnership discussions for the remaining non-Nordic European countries are also ongoing.

Competitors: there are a number of is established products in the US and EU, although their market profiles differ. In Europe, most products are OTC pharmaceuticals like Anti, Vectavir and Zovirax. Famvir and Zovirax are available on prescription in many EU countries such as Sweden and Denmark. In the US, all antiviral herpes pharmaceuticals require prescription. Xerclear™ has a competitive label "Treatment of early signs and symptoms of recurrent herpes labialis (cold sores) to reduce the progression of cold sore episodes

to ulcerative lesions in immunocompetent adults and adolescents (12 years of age and older)" giving Medivir's product a clear competitive edge in the US and Europe.

#### TMC435 – hepatitis C

Indication: hepatitis C

**Medivir's compound/pharmaceutical:** TMC clinical development is being run by Tibotec/Johnson & Johnson in partnership with Medivir and is a protease inhibitor in clinical phase IIb administered as an adjuvant to existing SoC with interferon and ribavirin. Existing SoC alone cures around 40% of patients with HCV genotype 1, the most common genotype in the West and the hardest to cure. By adding a protease inhibitor, the expectation is that it will be possible to increase the proportion of cured patients markedly, with a shorter therapy period than the current 48 weeks.

**Progress in the year:** phase IIa data show that TMC435 in combination with SoC reduces virus levels very significantly when treating patients for one month, using only a single daily tablet and at a low dose. Based on this promising data from phase IIa trials in different dose groups, Medivir's partner Tibotec started several phase IIb trials in the spring and late-autumn. These phase IIb trials will involve several patient groups, previously treated and treatment-naïve patients in different dose groups, with differing therapy periods of TMC435. Overall, these phase IIb trials will enroll nearly 1,000 patients. All patients will have concluded therapy in 2010.

Competitors: TMC435 is the only second-generation protease inhibitor in phase IIb trials, with telaprevir and boceprevir, first-generation protease inhibitors, both in clinical phase III trials. There is a further selection of protease inhibitors in development that are in the same, or later, phase as TMC435. One significant factor for Medivir's compound is that it is significantly more potent than telaprevir and boceprevir, meaning that it can be administered in a low dose, 150 mg or less in phase IIb trials, and only once daily, which offers a major patient benefit. Moreover, thus far in clinical trials, it has demonstrated a significantly better profile in terms of adverse events than telaprevir or boceprevir as well as other products in comparable development phases.

The two biggest pharmaceuticals currently on the market for treating hepatitis C are interferons, Pegasys and Pegintron. The third product is an immunomodulator, Rebetol.

#### Valomaciclovir – (MIV-606/EPB-348)

Indication: shingles and glandular fever.

**Medivir's compound/pharmaceutical:** valomaciclovir – MIV-606 is a polymerase inhibitor in a completed clinical phase IIb trial against shingles caused by VZV. It is also in a phase IIa trial against glandular fever caused by the Epstein-Barr virus (EBV). These studies are being conducted and funded by US pharmaceutical company Epiphany

*Progress in the year:* in the autumn, Epiphany presented positive data from a phase IIb trial. The results showed that administered in a single daily dose lower than in existing SoC, valomaciclovir (Valtrex™) achieved the primary endpoint of non-inferiority of healing of lesions. The next stage for this project is phase III trials ahead of a potential future market registration.

**Competitors:** this compound enables treatment once daily compared to thrice daily for its nearest competitor, Valtrex<sup>™</sup>. This marks a distinct dosage improvement while also probably alleviating chronic pain, both of which should provide significant patient benefits.

#### Candidate drugs MIV-710 and MIV-711 (cathepsin K)

**Indication:** bone disorders like osteoporosis, osteoarthritis and skeletal metastases.

Medivir's compound/pharmaceutical: MIV-710 and MIV-711 are being conducted in-house and are in preclinical development. **Progress in the year:** two new CDs were designated in this segment, where Medivir has been active for a number of years. In 2008, Medivir conducted phase I clinical trials on a first-generation protease inhibitor (MIV-701). The CDs designated in the year are different in profile, and are significantly superior to MIV-701 in terms of activity, which in phase Ib trials, proved the principle that inhibiting cathepsin K reduces skeletal resorption based on biomarkers, and thus works in humans, but is not being developed further. A high volume of scientific data indicate that cathepsin K inhibition can improve patient treatment in several different therapy areas. In the year, several preclinical trials have been initiated to map the possibilities of MIV-710 and MIV-711 in the courses of different diseases. The next step is to finalise the safety studies and compile new preclinical data ahead of future trials in house or in conjunction with a partner.

**Competitors:** one compound is in phase three trials (odanacatib, Merck) and another is in phase II (Ono).

#### Candidate drug HCV POL

Indication: hepatitis C.

**Medivir's compound/pharmaceutical:** HCV POL is a nucleoside polymerase inhibitor project being conducted in collaboration with Tibotec/Johnson & Johnson, who are responsible for ongoing development. The project is in preclinical safety trials.

**Progress in the year:** the CD designated in late-2008 underwent compound production and safety trials in the preclinical development phase in the year. These trials are scheduled for completion in 2010 to start clinical phase I trials in the year.

**Competitors:** there are now three nucleoside analogues in clinical phase II trials. An experimental clinical phase I trial on the combination of a protease inhibitor and polymerase inhibitor is ongoing in a research collaboration between Roche, InterMune and Pharmasset. This is the first trial of its type.

#### HIV-PI

Indication: HIV

**Medivir's compound/pharmaceutical:** HIV-PI is a protease inhibitor being developed in partnership with Tibotec/Johnson & Johnson, which is responsible for developing the project. The project is in late optimization and has demonstrated powerful antiviral activity against wild-type and multiresistant virus.

**Progress in the year:** In the year, Tibotec/Johnson & Johnson was responsible for this project which has a commercially attractive specification, because the compounds in development are highly potent and active against those mutants that are resistant to existing pharmaceuticals.

**Competitors:** there are several anti-HIV protease inhibitors on the market and there is intense competition in this segment.

#### Cathepsin S

Indication: Neuropathic pain

**Medivir's compound/pharmaceutical:** protease inhibitor project being run by Medivir. The project is in preclinical optimization.

**Progress in the year:** major advances were noted in the year, with activity demonstrated in preclinical efficacy models for chronic pain. This project is being conducted actively in preclinical optimization towards the designation of a CD as its next step.

**Competitors:** there are several products treating symptoms but no pharmaceutical on the market addressing the cause of pain.

#### BACE

Indication: Alzheimer's disease

**Medivir's compound/pharmaceutical:** BACE is a protease inhibitor project being run by Medivir. It is in preclinical optimization and targets the inhibition of BACE-1, an enzyme involved in the incidence of plaques in the brain, which is closely linked to Alzheimer's disease. Research results have demonstrated that plaque formation can be prevented by inhibiting BACE-1. This research segment is highly attractive but complex and where most of the major and pharmaceutical companies are active.

**Progress in the year:** BACE is a project that entered optimization in early-2009. One major challenge facing all companies in this segment is to develop potent and selective compounds that can readily cross the blood-brain barrier, to reach and inhibit BACE-1 activity in the brain. Medivir's project has identified important chemical starting points, and where optimization work of compound characteristics is now ongoing.

**Competitors:** many large companies are working in this segment and have projects in the research phase. BACE has the prospect of becoming the first therapy alternative that retards or prevents Alzheimer's disease developing.

#### Results of operations and financial position - group

Net sales were SEK 25.7 (97.2) m. Net sales in the period included remuneration for research collaboration on hepatitis C of SEK 8.9 m and an allocated one-off payment of SEK 15.4 m from Tibotec Pharmaceuticals Ltd. In the corresponding period of the previous year, net sales were mainly payments from Tibotec Pharmaceuticals Ltd. These consisted of an allocated one-off payment of SEK 30.8 m and a SEK 32.0 m milestone payment on hepatitis C, and SEK 29.3 m research partnership on hepatitis C and HIV protease inhibitors.

Operating costs were SEK -175.3 (-215.7) m, comprising external costs of SEK -72.3 (-101.6) m, personnel costs of SEK -92.7 (-103.8) m and depreciation and amortization of SEK -10.4 (-10.3) m. The reduced external costs are mainly due to lower research costs. The reduction of personnel costs is mainly due to staff reductions. Restructuring costs of SEK 8.3 m were charged to profit in the period. SEK 7.5 m of these costs relate to staff reductions.

The operating loss was sek -139.8 (-113.7) m. The lower figure is mainly a consequence of lower operating income because net sales fell by sek 71.5 m but was partially offset by reduced operating costs of sek 40.4 m. Profit from financial investments was sek 4.4 (13.7) m. The net loss for the period was sek -135.4 (-99.2) m.

#### Equity, share data and stock options

Share capital at the end of the period was SEK 104.2 (104.2) m and equity was SEK 153.9 (287.6) m. The number of shares was 20,843,547 (20,843,547), of which 660,000 (660,000) were class A and 20,183,547 (20,183,547) class B shares with a nominal value of SEK 5. There were 970,000 outstanding options at the beginning of the year. 210,000 options were forfeited in the 2004/2009 option plan in the period, due to their subscription period expiring. No

options were converted in the period. The number of outstanding options was 760,000 at the end of the period, corresponding to 835,600 class B shares. At the end of the period, potentially 568,000 of the outstanding options were available for conversion, which corresponds to 643,600 class B shares, and at full exercise, some 3.0% of the share capital and some 2.8% of the votes. Upon full conversion, the number of outstanding options could increase equity by SEK 56.4 m, and the total number of shares could thus amount to 21,679,147.

The equity ratio was 75.0 (77.4)%. Earnings per share, based on a weighted average number of outstanding shares, was SEK - 6.49 (-4.76) and equity per share was SEK - 7.38 (13.80).

For a review of the Medivir share, shareholder agreement and pre-emption and warrant and stock option plans, more information is provided under "the Medivir share" on pages 37-40.

For a review of Medivir's financial risks and the principles applied for financial risk control, more information is provided in Note 8 "financial risks", on pages 53–56. For a review of the progress of operations in recent years, more information is provided in Medivir's six-year summary on page 63.

### Cash flow and financial position

Cash flow from operating activities was SEK -135.1 (-34.8) m. The SEK 100.3 m deterioration is mainly due to reduced operating profit of SEK 26.1 m, worse net interest income/expense including dividends of SEK 7.8 m and a SEK 63.0 m change in working capital. In 2008, working capital was positively affected mainly by lower current receivables.

As of 1 January, cash and cash equivalents including short-term investments with a maximum maturity of three months were SEK 284.4 (329.3) m and were SEK 143.6 (284.4) m at the end of the period, a change of SEK -140.8 (-44.9) m in the period.

The company's current financial assets are judged to assure funding of operations until the end of the second quarter of 2011. In accordance with its finance policy, Medivir invests its financial assets in fixed-income securities with low risk.

# Investments, depreciation, amortization and impairment losses

Gross investments in tangible fixed assets in the period were SEK 1.4 (9.9) m; gross investments in intangible fixed assets were SEK 4.7 (0.0) m. Primarily, investments in tangible fixed assets are for research equipment. Investments in intangible fixed assets are mainly capitalized external costs and personnel costs for the completion of Xerclear<sup>TM</sup> after FDA approval of the product for marketing and sale in the US. Capitalized costs for this product will be amortized over the assessed useful life. No amortization for the product was charged to profit in the period, and amortization is scheduled to begin coincident with sales start in 2010. Sales of fixed assets were SEK 0.3 (0.4) m. Depreciation and amortization in the year of SEK -10.4 (-10.3) m was charged to profit.

### Results of operations and financial position - Medivir AB

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 38.4 (104.0) m. Operating costs were SEK -174.5 (-214.5) m, divided between external costs of SEK -71.4 (-100.4) m, personnel

costs of sek -92.7 (-103.8) m and depreciation and amortization of sek -10.4 (-10.3) m. The operating loss was sek -128.3 (-107.7) m. The loss from financial investments was sek -6.7 (8.9) m. Profit from financial investments included a cost relating to covering the losses of Medivir (UK) Ltd. of sek -11.0 (-4.8) m. The net loss for the period was sek -135.0 (-98.8) m.

Sales to Medivir UK Ltd. were sek 11.5 (4.7) m. Sales to Medivir HIV Franchise AB were sek 1.3 (2.1) m. Purchasing from Medivir HIV Franchise AB was sek 1.3 (2.1) m.

Gross investments in tangible fixed assets were SEK 1.4 (9.9) m and gross investments in intangible fixed assets were SEK 4.7 (0.0) m. Cash and cash equivalents including short-term investments with a maximum maturity of three months amounted to SEK 140.5 (283.2) m. For comments on operations, please refer to the 'Results of operations and financial position – group'.

### Financial assets held for sale

Holdings of shares in Medivir's licensing partners Epiphany Biosciences and Presidio Pharmaceuticals Inc. have been classified as financial assets held for sale. Because none of these shares are listed, and are not registered on a recognized marketplace, other non-observable data is used as the basis for valuation of the shares instead. An estimation of value consists of the companies' reported results of operations and financial position, the progress of the companies' project portfolios, share price performance on the Nasdaq biotech index, and where applicable, independent third-party valuations. If the valuation results in an estimated value change, the value change is stated in the statement of other comprehensive income for the period.

### **Royalty obligations**

A major part of Medivir's research and development projects, such as cathepsin K and lagociclovir (MIV-210), were generated entirely in-house and Medivir thus retains all milestone and royalty income from licensing out such projects. Medivir has in place an inventor compensation scheme for its employees which is compliant with Swedish and UK legislation, and trade union agreements.

Other research and development projects, such as TMC-435, HIV PI, BACE and MIV-410, have their genesis at Swedish universities. The written agreements regulating these collaborations provide Medivir with the rights to the inventions within these research areas in return for a modest sharing of milestone and royalty payments.

Some of Medivir's projects have previously been licensed to pharmaceutical partners, but resumed by Medivir under concluding agreements in which Medivir undertakes to pay a minor royalty to the former partner. This applies to HCV POL, previously outlicensed to Roche, and valomaciclovir (ABT606) previously licensed to Abbott. The cathepsin S project is subject to limited amounts of compensation, payable to Acambis plc (formerly Peptide Therapeutics plc).

Xerclear™ has its origin in a collaboration with AstraZeneca and according to the agreement with them, they are entitled a portion of the milestone and royalty payments Medivir will be receiving, as long as these payments exceed a predefined threshold. The agreement further provides that before making any payments to AstraZeneca, Medivir has got the right to recoup a predefined sum broadly corresponding to Medivir's phase III clinical trial costs.

During 2009 Medivir had no royalty obligations. During 2008 Medivir had for HCV POL a royalty obligation of sek 4.9 m.

### Transactions with related parties

No transactions occurred between Medivir and related parties that significantly affected the company's financial position and results of operations.

#### **Human resources**

Internally, Medivir has many highly skilled staff. The skills level among employees is high, with 56% of its researchers holding PhDs, with two of them being professors. Medivir employees have average professional experience in the pharmaceutical sector of approximately 16 years. Thanks to the skills and knowledge the company possesses in-house, it has been able to take one project, Xerclear<sup>TM</sup>, right the way from original idea to finished product and market launch. This demonstrates impressive breadth despite the company being perceived as relatively small in the sector.

The various disciplines in the company are well-balanced. Expert knowledge, breadth of the project portfolio, highly accomplished patent management and good collaboration skills with external partners give Medivir a very competitive foundation. Its employees have the capacity to judge and predict the value of different projects, and interact in an informal and beneficial way to drive various projects forward.

Operations are largely based on employees' creativity and innovation skills. To enhance opportunities for in the unofficial and spontaneous encounters, Medivir invested in its employees' well-being in the year through means including creating a practical, open-plan staff restaurant that is also used for staff meetings, celebrations and similar events. Spontaneous meetings reduce administration and facilitate fast decision-making. With its measures started in 2009 to further sharpen focus on the most viable projects, Medivir's already-high productivity will increase further.

The company's commitments on questions like the working environment, environment, equal opportunities and ethnic diversity in recent years have made these issues a natural and integrated part of daily work. People from ten different countries work at Medivir, in its management team of seven people there are two women, and in its Board of Directors of five people one is a woman. The company is also working to make it easier for its employees to reconcile their work with parental responsibilities, and women and men have the same opportunities for parental leave. Medivir endeavors to create a working environment that promotes health and well-being, and in 2009, sickness absence in the company was 2.4%. The company offers keep-fit activities, and funds regular health-checks.

The number of employees of the group at the end of the period was 79 (103), of which 48 (49)% were women. Accordingly, the number of employees reduced by 24 in the period, mainly as a result of restructuring operations. The average number of employees in the year was 93 (100). More information on the average number of employees, salary, other benefits and social security costs, and the latest adopted guidelines governing remuneration to senior executives is in Note 4 on pages 50–52.

### The working environment and environmental work

Medivir endeavors to comply fully with all working environment-related legislation and regulations, and conducts systematic working environment activities in order to continuously improve safety and the working environment. Medivir's Working Environment and Environmental Policies demonstrate the importance of a good working environment and of minimizing its impact on the external

environment. Documented safety procedures are in place and Medivir's staff receives ongoing training on safety issues. Formal responsibility for the working environment is delegated down the management line. A working environment team consisting of managers, safety representatives and others work on these matters on an ongoing basis and conduct regular safety inspections.

In 2009, overall working environment and incident reporting routines were updated. Incident reporting is an important tool for improving the working environment and safety, and implies all incidents and accidents being followed up. No accidents in the workplace were reported to the Swedish Work Environment Authority in 2009.

The company's research and development work involves controlled use of biological and hazardous material and waste. The greatest health risks arise when handling chemicals. Conducting risk assessments before laboratory experimentation and handling all chemicals correctly minimizes the health risks. Protective equipment and clothing are used. All work with chemicals is conducted in ventilated space. All fume cupboards and clean benches are equipped with alarms and are regularly checked.

Medivir has reported its usage of class II biological substances to the Swedish Work Environment Authority inspectorate and holds permits from the Swedish Work Environment Authority to use class III and III\* (normally not airborne infection) biological substances (reference AFS 1997:12). Additionally, Medivir has permits from the Municipality of Huddinge to process inflammable solvents and research approval from the Swedish Ministry of Agriculture. The Swedish Work Environment Authority previously inspected the operation and laboratories. Medivir pursues a far-reaching program for sorting waste at source and for the processing and destruction of hazardous waste. Medivir constantly strives to minimize the usage of environmentally hazardous materials and is not party to any environmental disputes.

Medivir also conducts active and mainly preventative fire safety work. In 2009, overarching fire safety routines were updated for: fire safety organization, training plans, fire safety rules, fire safety reviews, operational and maintenance instructions, self-checking and documentation, and updating.

### IT security

IT security is a high priority for Medivir because it is important to safeguard the company's internal information. Medivir's IT security policy includes guidelines for its resources, responsibilities, authorization, administration of rights, virus protection, traceability, classifying information, plus operational and communications security.

All data is replicated and processed pursuant to well-defined security and back-up routines. External communication is safeguarded with encrypted data traffic. PCs and software are secured by applying local hardware encryption. Medivir also endeavors to continuously increase staff security-consciousness when handling hardware and software continually.

The focus in the year was on activities including updating Medivir's IT policy, disaster plan and upgraded the financial business system to attain a still-higher security level.

### Remuneration to senior executives

For 2010, the Board of Directors is proposing the following guidelines for remuneration to senior executives. Senior executives mean the CEO and other members of the management team. Medivir will offer overall compensation on market terms that enables skilled senior executives to be hired and retained. Remuneration to senior executives will consist of basic pay, potential performance-related pay, stock options in stock option plans approved by the AGM, pension and other benefits. Basic pay will consider individual areas of responsibility and experience. Performance-related pay may be a maximum of 50% of basic pay. No pension plan will be payable to the CEO. The pension plans of other senior executives will conform to the ITP scheme, and the relevant individual plan in the UK corresponds to legislated contributions, plus 6% of basic pay excluding bonus and benefits. The CEO and other senior executives will be subject to a mutual notice period of six months. In addition to what is stated above, severance pay or similar remuneration will not be payable, but subject to a maximum of 100% of basic pay, may be subject to agreement in instances of changes to ownership structure. The Board of Directors is entitled to diverge from the above guidelines if the Board considers that there are special circumstances in an individual case that justify this. For more detail on remuneration, see Note 4 on pages 50-52.

### Significant events after the end of the period

EUR 5 m milestone received

An advance milestone payment of 5 MEUR was received from Medivir's partner Tibotec at the end of January.

Medivir partnered with Meda for North American commercialisation of Xerese™(Lipsovir®)

In mid-February, Medivir entered an agreement with Meda for commercialisation of Medivir's cold sore product which will be marketed under the trade name Xerese<sup>TM</sup> on North American markets.

Under the terms of the agreement Meda is granted the exclusive right to market sell and distribute Xerese<sup>™</sup> in the Unibted States, Canada and Mexico for the treatment of cold sores (herpes labialis) In addition to funding the commercial development of Xerese<sup>™</sup>, Meda will pay to Medivir up-front and pre-launch milestones totalling 5 MUSD and double-digit royalties on sales.

### **Future progress summary**

The ambition is for Medivir to evolve to a profitable pharmaceutical company with proprietary products and its own marketing organization. Medivir's research project, in partnership with Tibotec/Johnson & Johnson, is progressing as planned, and if it reaches the market, will significantly change the financial profile and commercial opportunities available to the company. It will facilitate the business goal to become a profitable, medium-sized, high growth pharmaceutical company within five years. It will also provide Medivir with the opportunity for expanding the geographical sales and marketing base so the company can also extend its reach outside its Nordic home market.

Medivir is now a well-established research company and harbors world-leading knowledge in polymerases, proteases and infectious diseases. Through innovation and effective teamwork, these abilities have enabled us to create a stable and expanding preclinical and clinical portfolio of high-quality new experimental pharmaceuticals. To build on our successes, our intention is to invest in new infectious disease projects, in hepatitis C for example.

We started reviewing our project portfolio in 2009, which will result in a more focused R&D portfolio, where a number of current projects that do not fit our new strategy will be outlicensed or discontinued.

There are a number of successful projects lying outside our focus on infectious diseases, and we will continue to support them and identify suitable collaboration partners. Future research projects will be evaluated on the basis of how well they fit our strategy, and the time and cost implicit in going all the way to market launch.

Xerclear™ secured market approval in the US and Europe in 2009 and is well positioned for launch. The market for topical treatment of herpes infections in the USA and Europe are estimated to USD 230 million and USD 170 million, respectively.

The current focus is on launching Xerclear™ in the Nordic region ourselves, initially as an Rx pharmaceutical.. This means we will need to invest to be able to exploit this strong brand. The objective is to enter commercial partnerships in 2010 to launch Xerclear™ in the rest of Europe and the US.

We are also examining the type of product we can inlicense to supplement and develop our project portfolio on the Nordic market. We are enabling the achievement of our long-term goals by building a commercial organization with the task of outlicensing and inlicensing products, and acquiring products.

Developing new pharmaceuticals to approved registration and launch is a risky and capital intensive process. Medivir's business model is characterized by high risk and the majority of projects may never reach market registration. The ability to produce new CDs, to enter partnerships and successfully develop products to market launch and sale, and to secure funding of operations is decisive to Medivir's future. The progress of existing and new future partnerships will have a significant impact on Medivir's revenues and cash position, but it is not possible to accurately forecast expected revenue flows. The company's current financial assets are judged to assure funding of operations until end of the second quarter of 2011 inclusive. Proceeding from our solid starting-point, we have a vision of a future that will also create long-term shareholder value.

### Risks and uncertainty factors

Summary

Developing a new pharmaceutical to approved registration and launch is a highly capital intensive and risky process. A number of Medivir's potential products are in early stages of development. Accordingly, the risk level is high and their is no guarantee that the company's product development will be successful, that potential products will be safe and effective, that the requisite permits will be received or that the pharmaceuticals launched on the market are well received. However, the likelihood of reaching the market increases as projects move forwards in the development chain, which also affects the costs, which rise steeply in the later clinical phases. Accordingly, Medivir's business model is characterized by high risk and the majority of research projects never reach market registration. Medivir has taken a goal-oriented and strategic approach over many years to create the best possible prospects of running projects quickly and with balanced risks, but despite continued work on this, there are still factors the company cannot influence. Effective risk assessment unites Medivir's business opportunities and results with the requirements of shareholders and other observers for stable long-term value growth and control. Operations have two types of risk to manage, financial risks and operational, or project-specific risks.

#### Financial risks

The company's ability to produce new CDs cost-effectively that develop into new products in clinical trials, to enter partnerships on development projects and clinical projects resulting in the successful launch and marketing of products is decisive to Medivir's future profit growth and requirement for capital. Existing and new partnerships may have a significant impact on Medivir's future revenues and cash position, but it is not possible to schedule revenue flows. There can be no guarantee that in the future, Medivir will be able to post positive profits. For a detailed review of financial risks such as currency risk, interest risk, credit risk and liquidity risk, please refer to Note 8 on pages 53-56.

### Project-specific risks

Before the launch of any experimental pharmaceutical is initiated, Medivir or its collaboration partner must demonstrate that such pharmaceutical satisfies the stringent standards of safety and efficacy set by the authorities in those countries where marketing of the pharmaceutical is planned. Potential shortcomings or delays in the execution of preclinical or clinical trials will reduce or delay Medivir's ability to generate revenues from commercialization of its CDs and may have a significant adverse effect on its ability to retain and supplement the project portfolio. The FDA, EMEA and other regulatory authorities may delay, limit or withhold permission for several reasons, including the experimental pharmaceutical possibly not being safe or effective. Even if potential products in the project portfolio secure regulatory permits, it is not certain that the pharmaceutical obtains market acceptance among doctors, patients, client organizations and the medical community.

### Collaborations risks

Entering collaboration agreements with pharmaceutical and biotechnology companies to develop and launch the company's potential products is a component of Medivir's strategy. Success in such collaborations will be largely dependent on the work of collaboration partners, because these parties have the possibility of directing the work and resources to be allocated to projects. Conflicts or differences of opinion may arise between Medivir's collaboration partners or counterparties in terms of interpreting clinical data, achieving milestone payments, interpretation of financial remuneration for, or ownership rights to, patents and similar rights developed within the auspices of collaborations.

### Competition risks

Competition in Medivir's business segment is significant and competitors may develop and market pharmaceuticals that are more effective, safer and cheaper. Medivir's competitors include multinational pharmaceutical companies, specialist biotechnology enterprises, and universities and other research institutes. The pharmaceutical industry features rapid changes in technology, continuous improvements to industrial know-how and the emergence of new, and mutations of already known, viruses and bacteria that cause diseases. Overall, this results in the constant emergence of new products. Accordingly,

future successes will be largely dependent on the ability to diversify the project portfolio and develop new and competitively priced products that satisfy the standards of a constantly changing market, and are effective at treating new diseases.

### Intellectual property risks

Medivir's success will depend to a great extent on the company's ability to secure protection of intellectual property relating to the company's products, in Sweden and other countries. The patent situation in the biotechnology and pharmaceutical segment is generally uncertain and involves complex legal and scientific questions. Over and above patented products and technologies, Medivir also utilizes proprietary technologies, processes and knowledge not protected by patents. Medivir endeavors to protect such information, through channels including non-disclosure agreements with employees, consultants and collaboration partners.

#### Commercial risks

Medivir has started work on establishing its own marketing resources for the sale of pharmaceuticals that address specialists, on the Nordic market. However there is no guarantee that these costs are not higher than estimated or that Medivir will be able to license in products or secure product rights when entering future licensing or collaboration agreements. Nor is there any guarantee that Medivir's sales resources will be successful. For future marketing and sale of the company's other products on markets outside the Nordic region, Medivir is dependent on those partners it has entered, or will be entering, licensing or collaboration agreements with.

### Work of the Board of Directors

The Board of Directors' overall task is to manage the company's affairs as well as possible on behalf of the shareholders. The Board possesses substantial skills in pharmaceutical research, finance and strategy.

The Board judges the group's financial position and appraises its executive management on an ongoing basis. The Board decides on matters including the group's strategic orientation and organizational resources, and on significant investments and commitments. The Board of Directors has three internal preparatory committees: the Remuneration Committee, the Audit Committee and the R&D Committee.

For a more detailed review of the nomination committee, Board's and Committees' work, please refer to the Corporate Governance Report on pages 18-23. Remuneration to the Board of Directors is reviewed in Note 4 on pages 50-52.

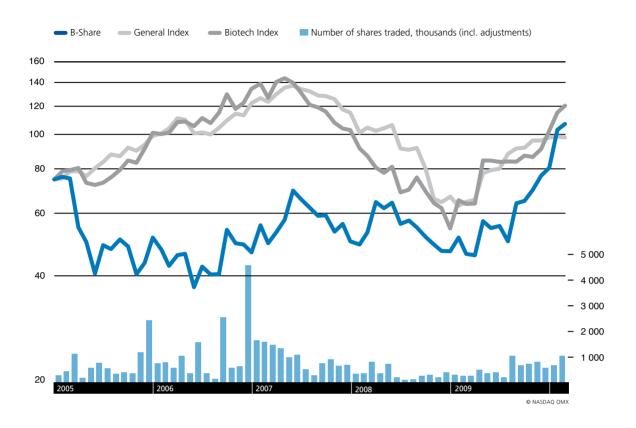
### Proposed appropriation of losses

The Board and the Chief Executive Officer propose that the accumulated deficit, SEK -779,276,631 be carried forward.

### Dividends

The Board of Directors proposes that no dividends are paid for 2009.

### THE MEDIVIR SHARE



### The Medivir share

Medivir's class B share was floated on the Nasdaq OMX Stockholm Stock Exchange on 14 November 1996; the high-vote class A share is not listed.

### **Share structure**

Medivir has 20,843,547 shares divided between 660,000 class A and 20,183,547 class B shares. All shares confer equal rights to participation in Medivir's assets and profits. Class A shares have ten votes and class B shares one vote. The share capital is SEK 104, 217,735.

### Share structure, 30 December 2009

| Share class | No. of shares |            | % of capital | % of votes | full exercise<br>of options |
|-------------|---------------|------------|--------------|------------|-----------------------------|
| A10 votes   | 660,000       | 6,600,000  | 3.0          | 25.0       | 660,000                     |
| B 1 vote    | 20,183,547    | 20,183,547 | 97.0         | 75.0       | 21,019,147                  |
| Total       | 20,843,547    | 26,783,547 | 100.0        | 100.0      | 21,679,147                  |

### Share price and turnover 2009

Medivir's share price rose 71%, from SEK 47 to SEK 80.5, in 2009. In the same period, the Stockholm Small Cap Index (OMX-SSCPI) rose 67% and the biotechnology index rose 90%. At year-end 2009, Medivir's market capitalization was SEK 1,680 m, based on the closing price for the year of SEK 80.5. There were 8,678,690 Medivir shares turned over on Nasdaq OMX Stockholm Exchange in 2009, equivalent to a turnover rate of 43% against 119% for Nasdaq OMX Stockholm Exchange overall. As of 28 February 2010, the share price was SEK 107, equivalent to a market capitalization of SEK 2,230 m.

### Beta value

Shares after

As of 31 December 2009, Medivir's class B share had a beta value of 1.09. This value is based on historical closing prices on the last trading day of each of the preceding 24 months. The same measure is applied on the Nasdaq OMX Stockholm All-share Index, and provides an indication of the extent to which a share price fluctuates against an index. If a share has the same price variation as the index, its beta value is 1.0; if it has been more volatile, its value is greater than 1.0, and vice versa.

### Outstanding option plans, 31 December 2009

| Туре      | Duration  | Number  | Rights to no. shares |       | Outstanding<br>shares today<br>and at conv. |
|-----------|-----------|---------|----------------------|-------|---|
|           |           |         |                      |       | 20,843,547                                  |
| Stock opt | 2005–2010 | 280,000 | 355,600              | 68.60 | 21,199,147                                  |
| Stock opt | 2007–2012 | 480,000 | 480,000              | 66.64 | 21,679,147                                  |
| Total     |           | 760,000 | 835,600              |       |   |

### Medivir's 15 largest shareholders, 31 December 2009\*

| Descending order of vote          | Class A<br>shares | Class B<br>shares | % of votes | % of capital |
|-----------------------------------|-------------------|-------------------|------------|--------------|
| Bo Öberg                          | 284,000           | 233,180           | 11.5       | 2.5          |
| Staffan Rasjö                     |                   | 3,074,440         | 11.5       | 14.8         |
| Nils-Gunnar Johansson             | 284,000           | 98,800            | 11.0       | 1.8          |
| Handelsbanken Funds               |                   | 1,169,856         | 4.4        | 5.6          |
| DNB Nor Bank AB                   |                   | 1,141,228         | 4.3        | 5.5          |
| Länsförsäkringar<br>Småbolagsfond |                   | 1,116,080         | 4.2        | 5.4          |
| Tredje AP-fonden                  |                   | 1,031,506         | 3.8        | 5.0          |
| Christer Sahlberg                 | 92,000            | 29,381            | 3.5        | 0.6          |
| Skandia Fonder                    |                   | 926,403           | 3.5        | 4.4          |
| Carnegie Fonder                   |                   | 809,741           | 3.0        | 3.9          |
| Skandia Liv                       |                   | 756,230           | 2.8        | 3.6          |
| Alecta Pensionsförsäkring         |                   | 660,000           | 2.5        | 3.2          |
| Unionen                           |                   | 563,360           | 2.1        | 2.7          |
| Bear Sterns & Co                  |                   | 479,727           | 1.8        | 2.3          |
| Awake Swedish Equity Fund         |                   | 460,000           | 1.7        | 2.2          |
| Others                            |                   | 7,633,615         | 28.4       | 36.5         |
| Total                             | 660,000           | 20,183,547        | 100.0      | 100.0        |
| Total A- and B-shares             |                   | 20,843,547        |            |              |

<sup>\*</sup> Source: VPC Analys, register of shareholders. The table may include composites from multiple entries in VPC's statistics. These composite entries are intended to indicate an institution or private individual's total holdings in Medivir. Such composite entries are not utilized in other tables relating to the Medivir share.

### Shareholder categories, 31 December 2009\*

|                             | % of Votes | % of Capital | No. of<br>shareholders |
|-----------------------------|------------|--------------|------------------------|
| Swedish institutions        | 31.0       | 39.8         | 295                    |
| Foreign institutions        | 17.9       | 23.0         | 225                    |
| Swedish private individuals | 50.8       | 36.8         | 4,632                  |
| Foreign private individuals | 0.3        | 0.4          | 55                     |
| Total                       | 100.0      | 100.0        | 5,207                  |

# Shareholder statistics as of 31 December 2009, by size of holding\*

| Size of<br>holdings | No. of<br>shareholders | No. of<br>shares | % of<br>capital | % of votes |
|---------------------|------------------------|------------------|-----------------|------------|
| 1-100               | 1,636                  | 76,200           | 0.4             | 0.3        |
| 101-1000            | 2,759                  | 1,099,363        | 5.3             | 4.1        |
| 1001-5000           | 600                    | 1,395,520        | 6.7             | 5.2        |
| 5001-20000          | 129                    | 1,252,479        | 6.0             | 4.7        |
| 20001-100000        | 50                     | 2,394,889        | 11.5            | 8.9        |
| 100001-             | 33                     | 14,625,096       | 70.1            | 76.8       |
| Total               | 5,207                  | 20,843,547       | 100.0           | 100.0      |

<sup>\*</sup> Source: VPC Analys

### **Dividend policy**

A proposal on dividends will not be raised until long-term profitability can be expected through new product launches on the market.

#### Warrants and stock options

Medivir had two outstanding stock option plans at the reporting date (see table to left).

At 1 January, there were 970,000 outstanding options. In the period, 210,000 options were forfeited in the 2004–2009 stock option plan through the expiry of the subscription period. No options were converted in the period.

The total number of remaining outstanding warrants as of 31 December 2009, 760,000, entitle the holders to 835,600 new class B shares, and upon full exercise, are equivalent to some 3.9% of the share capital and some 3.0% of the votes.

Through the new share issue completed in early-2007, the staff stock option plan launched in 2005 has been restated, whereupon these staff stock options entitle the holders to 1.27 shares per option and the exercise price has been restated, see table to the left.

Upon full exercise, the number of outstanding options could increase equity by SEK 56.4 m, and thus, the total number of shares could amount to 21,679,147.

The year's Income Statement includes a provision of some SEK 3.6 (0.6) m for accrued social security costs that would arise on the taxable benefit coincident with exercise of the stock options.

The value of the issued options for the purposes of calculation of accruals is in accordance with UFR 7, IFRS 2 and social security costs, which were introduced in 2005. Information on accounting principles is in the Stock option plans section on page 47.

### The 2005 – 2010 plan

The Annual General Meeting of 21 April 2005 resolved to raise a subordinated debenture of SEK 1,000 through the issuance of debt instruments with 280,000 detachable warrants. The debenture was subject to 5% interest and has been repaid. Of the 280,000 options, 183,600 were granted to staff. The remainder were held by Medivir Personal AB to cover social security costs. Subscription for class B shares is possible from 1 July 2005 to 31 December 2010, at a price of SEK 87.

The subsidiary Medivir Personal AB controls these detachable warrants in order to fulfill undertakings relating to stock options issued within the framework of the stock option plan 2005–2010. Each staff stock option is exercisable to acquire one Medivir AB share through the agency of the subsidiary, against the payment of a redemption fee equivalent to at least 130% of the closing price of the Medivir class B share quoted on Nasdaq OMX Stockholm Exchange's Small Cap-list at the grant date (albeit subject to a minimum of SEK 87.00). These stock options have been issued to staff of the Medivir group, free of charge. The theoretical market value according to the Black & Scholes equation was SEK 11.60 per option at the grant date, and SEK 18.54 as of the reporting date, 31 December 2009

Upon full exercise of the warrants, Medivir's cash and cash equivalents and equity would increase by approximately SEK 24.4 m, whereupon the company's share capital would increase by SEK 1.78 m. The number of class B shares would increase by 355,600.

As a result of the new issue completed in 2007, the plan has been restated whereupon one option entitles the holder to 1.27 shares at an exercise price of SEK 68.60.

### **Transactions**

| Year    | Transaction   | Nominal amount, sek | Change in share capital, SEK | Total share<br>capital, seк | Total no. of<br>class A shares | Total no. of<br>class B shares | Total no. of shares |
|---------|---|---------------------|------------------------------|-----------------------------|--------------------------------|--------------------------------|---------------------|
| 1988/89 | Incorporation   | 10                  |                              | 50,000                      | 5,000                          |                                | 5,000               |
|         | New share issue 1:1   | 10                  | 50,000                       | 100,000                     | 10,000                         |                                | 10,000              |
|         | New share issue 3:1   | 10                  | 300,000                      | 400,000                     | 10,000                         | 30,000                         | 40,000              |
| 1991/92 | Bonus issue 1:1   | 10                  | 400,000                      | 800,000                     | 20,000                         | 60,000                         | 80,000              |
|         | New share issue 1:8   | 10                  | 100,000                      | 900,000                     | 22,500                         | 67,500                         | 90,000              |
| 1992/93 | Bonus issue 4:1   | 10                  | 3,600,000                    | 4,500,000                   | 112,500                        | 337,500                        | 450,000             |
| 1994/95 | Non-cash issue 1:7  | 10                  | 2,250,000                    | 6,750,000                   | 112,500                        | 562,500                        | 675,000             |
| 1996    | Bonus issue 3:1   | 10                  | 20,250,000                   | 27,000,000                  | 450,000                        | 2,250,000                      | 2,700,000           |
|         | Split 2:1   | 5                   |                              | 27,000,000                  | 900,000                        | 4,500,000                      | 5,400,000           |
|         | Reclassification to class B shares                                | 5                   |                              | 27,000,000                  | 740,000                        | 4,660,000                      | 5,400,000           |
|         | New share issue 598:2700<br>at a subscription price<br>of SEK 125 | 5                   | 5,980,000                    | 32,980,000                  | 740,000                        | 5,856,000                      | 6,596,000           |
| 1997    | Reclassification to class B shares                                | 5                   |                              | 32,980,000                  | 660,000                        | 5,936,000                      | 6,596,000           |
| 1999    | Non-cash issue  | 5                   | 295,110                      | 33,275,110                  | 660,000                        | 5,995,022                      | 6,655,022           |
| 2000    | Private placement   | 5                   | 7,025,000                    | 40,300,110                  | 660,000                        | 7,400,022                      | 8,060,022           |
|         | Non-cash issue  | 5                   | 475,000                      | 40,775,110                  | 660,000                        | 7,495,022                      | 8,155,022           |
|         | Options conversion,<br>1996–2001                                  | 5                   | 665,000                      | 41,440,110                  | 660,000                        | 7,628,022                      | 8,288,022           |
| 2001    | Options conversion,<br>1996-2001                                  | 5                   | 500                          | 41,440,610                  | 660,000                        | 7,628,122                      | 8,288,122           |
| 2002    | Private placement   | 5                   | 1,507,390                    | 42,948,000                  | 660,000                        | 7,929,600                      | 8,589,600           |
| 2004    | New share issue 2:1   | 5                   | 21,498,410                   | 64,446,410                  | 660,000                        | 12,229,282                     | 12,889,282          |
|         | Options conversion,<br>2002–2007                                  | 5                   | 66,645                       | 64,513,055                  | 660,000                        | 12,242,611                     | 12,902,611          |
| 2007    | New share issue 5:3   | 5                   | 38,707,830                   | 51,610,441                  | 660,000                        | 19,984,177                     | 20,644,177          |
|         | Options conversion,<br>2002-2007                                  | 5                   | 996,850                      | 52,607,291                  | 660,000                        | 20,183,547                     | 20,843,547          |
|         |   |                     |                              |                             |                                |                                |                     |

### The 2007 - 2012 plan

The Annual General Meeting of 24 April 2007 approved a staff stock option plan of 480,000 options. Of the 480,000 options, 360,000 were granted to staff. The remainder were held by Medivir Personal AB to cover social security costs.

Subscription for class B shares is possible from 18 June 2007 to 30 April 2012, at a price of Sek 66.64. The subsidiary Medivir Personal AB controls these detachable warrants in order to fulfill undertakings relating to stock options issued within the framework of the stock option plan 2007–2012. Each stock option is exercisable to acquire 1.0 Medivir AB share through the agency of the subsidiary, against the payment of a redemption fee equivalent to at least 115% of the closing price of the Medivir class B share quoted on Nasdaq OMX Stockholm Exchange's Small Cap-list at the grant date (albeit subject to a minimum of Sek 64.64) for each share. These stock options have been issued to staff of the Medivir group, free of charge.

The theoretical market value according to the Black & Scholes equation was SEK 11.90 per option at the grant date, and SEK 6.41 as of the reporting date 31 December 2009, SEK 29.08.

Upon full exercise of the detachable warrants, Medivir's cash and cash equivalents and equity would increase by approximately SEK 32.0 m, whereupon the company's share capital would increase by SEK 2.4 m. The number of class B shares would increase by 480,000.

### Rights to acquire shares

For the stock options issued in 2005, each holder possesses the right to exercise one third of the total number of granted stock options from a date two year after granting onwards, with another one third on the corresponding date in each of the ensuing two years, providing the stock option holder remains an employee of the Medivir group.

The plan issued in 2007 confers the right to acquire new shares at 30% of the whole number of granted options from the date occurring one year after granting onwards, another 30% on the second anniversary and 40% on the third anniversary.

A taxable benefit arises upon potential future exercise by staff, on which security costs are payable. To cover future social security costs, the subsidiary controls a number of options for subscription for new Medivir AB stock (as a hedge). The hedge functions by those options assigned to the hedge held by Medivir Personal AB being converted to shares, which are sold on the market to generate a commensurate cash flow for the group to cover the payment of social security costs. However, the personnel costs arising in the Consolidated Income Statement (social security costs) are not offset by a cost reduction (revenue), but rather the effect arises in cash flow terms exclusively. This is because the income from such share sales from a group perspective is considered as an issue from equity. More information under Accounting principles, Social security costs on stock options, on page 47.

#### Cash settlement

In November 2008, the Board of Directors introduced a cash settlement facility for all stock option plans, with the aim of making subscription for shares easier.

### The valuation of staff benefits via stock option plans

Medivir utilizes the Black & Scholes model for calculating the theoretical value of the stock options its employees receive. This model is used both at the grant date and at each quarterly financial statement.

Medivir utilizes this value, determined by the Black & Scholes model at the grant date, to account a personnel cost pursuant to IFRS 2, which is allocated over the accrual period. For a review of accounting pursuant to IFRS 2, please refer to Stock option plans in the Accounting principles section on page 47. The market value of

the option is also calculated quarterly, and utilized to determine the provision for social security costs to be reported pursuant to UFR 7.

Calculations consider share price, exercise price, the option term, expected volatility, risk-free interest and expected dividend. During the financial year, expected volatility of about 30% was applied in accordance with previous analysis conducted by Carnegie Investment Bank AB

### Shareholder agreement and pre-emption

There is an agreement between holders of class A shares in Medivir, stipulating that the parties will behave in accordance with decisions reached on relevant issues by the parties prior to annual general meetings. If, during their preparatory deliberation, the parties are unable to agree on a particular issue, the resulting decision is that opinion represented by the majority of class A share votes represented during the deliberation process. Furthermore, the agreement implies that if holders of class A shares wish to transfer their class A shares to another holder of class A shares or a third party, the shares will be converted into class B shares. The same applies if a party acquires class A shares of Medivir in any other way. If a majority of the holders of class A shares so decide, the class A shares will have the facility for transfer to a new owner without reclassification, at which point the new owner will become party to the applicable shareholders' agreement for holders of class A shares. For class A shares, preemptive rights apply pursuant to the Articles of Association.

# INCOME STATEMENT

|   |        | Med      | ivir group_ | Me       | edivir AB |
|---|--------|----------|-------------|----------|-----------|
| SEK 000   | Note   | 2009     | 2008        | 2009     | 2008      |
| Turnover, etc.                                      |        |          |             |          |           |
| Net sales   | 1      | 25,684   | 97,175      | 38,423   | 103,952   |
| Work performed by the company for its own use       |        |          | •           | ,        | ,         |
| and capitalized                                     | 13     | 4,077    | _           | 4,077    | _         |
| Other operating income                              | 20     | 5,737    | 4,800       | 3,716    | 2,838     |
| Total   | 2      | 35,498   | 101,975     | 46,216   | 106,790   |
| Operating costs                                     |        |          |             |          |           |
| Other external costs                                | 2,3,20 | -72,269  | -101,594    | -71,412  | -100,408  |
| Personnel costs                                     | 4      | -92,654  | -103,791    | -92,704  | -103,796  |
| Depreciation and amortization                       | 5      | -10,390  | -10,323     | -10,390  | -10,323   |
| Total operating costs                               | 6      | -175,313 | -215,708    | -174,506 | -214,528  |
| Operating profit/loss                               |        | -139,815 | -113,733    | -128,290 | -107,738  |
| Profit/loss from financial investments              |        |          |             |          |           |
| Profit/loss from participations in group companies  | 7      | _        | _           | -11,040  | -4,800    |
| Other interest income and similar profit/loss items | 8,9    | 4,771    | 14,327      | 4,691    | 14,291    |
| Interest costs and similar profit/loss items        | 8,10   | -344     | -616        | -344     | -586      |
| Total profit/loss from financial investments        |        | 4,427    | 13,711      | -6,694   | 8,905     |
| Profit/loss after financial items                   |        | -135,388 | -100,023    | -134,983 | -98,834   |
| Tax on profit/loss for the year                     | 11     | 13       | 820         |          | -         |
| Net profit/loss                                     |        | -135,375 | -99,203     | -134,983 | -98,834   |
| Net profit/loss attributable to                     |        |          |             |          |           |
| Equity holders of the parent                        |        | -135,375 | -99,203     |          |           |
| Basic and diluted earnings per share                | 12     | -6,49    | -4,76       |          |           |
| Average number of shares, 000                       |        | 20,844   | 20,844      |          |           |
| Number of shares at year-end, 000                   |        | 20,844   | 20,844      |          |           |
| Proposed dividend per share, SEK                    |        | 0        | 0           |          |           |
| -=not applicable                                    |        |          |             |          |           |

# STATEMENT OF COMPREHENSIVE INCOME

| r comprehensive income ange rate differences r comprehensive income for the period, net after tax comprehensive income for the period | Medivir group |         |  |  |
|---|---------------|---------|--|--|
| sek 000   | 2009          | 2008    |  |  |
| Net profit/loss   | -135,375      | -99,203 |  |  |
| Other comprehensive income  |               |         |  |  |
| Exchange rate differences   | 422           | 611     |  |  |
| Other comprehensive income for the period, net after tax  | -134,952      | -98,592 |  |  |
| Total comprehensive income for the period   | -134,952      | -98,592 |  |  |
| Total comprehensive income attributable to:   |               |         |  |  |
| Equity holders of the parent  | -134,952      | -98,592 |  |  |

# BALANCE SHEET

|   |     | Med     | ivir group | Me      | divir AB |
|---|-----|---------|------------|---------|----------|
|   |     | 2009    | 2008       | 2009    | 2008     |
| SEK 000   | Not | 31 dec  | 31 dec     | 31 dec  | 31 dec   |
| ASSETS  |     |         |            |         |          |
| Fixed assets  |     |         |            |         |          |
| Intangible fixed assets                                   |     |         |            |         |          |
| Capitalized expenditure for research and development work | 13  | 4,077   | _          | 4,077   | _        |
| Other intangible assets                                   | 13  | 555     | 482        | 555     | 482      |
| Total intangible fixed assets                             |     | 4,632   | 482        | 4,632   | 482      |
| Tangible fixed assets                                     |     |         |            |         |          |
| Buildings and land  | 14  | 2,136   | 2,349      | 2,136   | 2,349    |
| Equipment, tools, fixtures and fittings                   | 14  | 24,805  | 33,415     | 24,805  | 33,415   |
| Total tangible fixed assets                               |     | 26,941  | 35,764     | 26,941  | 35,764   |
| Financial fixed assets                                    |     |         |            |         |          |
| Participations in group companies                         | 15  | _       | _          | 200     | 200      |
| Receivables from group companies                          |     | _       | _          | _       | 2        |
| Financial assets held for sale                            | 16  | 18,793  | 18,793     | 18,793  | 18,793   |
| Total financial fixed assets                              |     | 18,793  | 18,793     | 18,993  | 18,995   |
| Total fixed assets  |     | 50,366  | 55,038     | 50,566  | 55,240   |
| Current assets  |     |         |            |         |          |
| Inventories, etc.   |     |         |            |         |          |
| Finished goods and goods for resale                       |     | 619     | _          | 619     | _        |
| Total inventories, etc.                                   |     | 619     | -          | 619     | _        |
| Current receivables                                       |     |         |            |         |          |
| Accounts receivable                                       |     | 0       | 11,877     | 0       | 9,897    |
| Other receivables   |     | 2,245   | 11,167     | 2,245   | 11,167   |
| Prepaid costs and accrued income                          | 17  | 8,391   | 8,946      | 6,998   | 7,590    |
| Total current receivables                                 |     | 10,635  | 31,990     | 9,243   | 28,653   |
| Investments in securities, etc.                           |     |         |            |         |          |
| Other investments in securities, etc.                     | 18  | 130,402 | 227,842    | 130,402 | 227,842  |
| Cash and bank balances                                    | 18  | 13,178  | 56,644     | 10,133  | 55,429   |
| Total current assets                                      |     | 154,834 | 316,476    | 150,397 | 311,924  |
| TOTAL ASSETS  |     | 205,200 | 371,515    | 200,963 | 367,165  |

<sup>-=</sup>not applicable

|                                   |      | Med      | livir group | Medivir AB |          |  |
|-----------------------------------|------|----------|-------------|------------|----------|--|
|                                   |      | 2009     | 2008        | 2009       | 2008     |  |
| SEK 000                           | Note | 31 dec   | 31 dec      | 31 dec     | 31 dec   |  |
| EQUITY AND LIABILITIES            |      |          |             |            |          |  |
| Equity, Medivir group             |      |          |             |            |          |  |
| Share capital                     |      | 104,218  | 104,218     | _          | _        |  |
| Other contributed capital         |      | 848,231  | 847,030     | _          | _        |  |
| Exchange rate difference          |      | 4,758    | 4,335       | _          | _        |  |
| Accumulated deficit               |      | -803,351 | -667,976    | _          | _        |  |
| Total equity, Medivir group       |      | 153,855  | 287,606     |            |          |  |
| Equity, Medivir AB                |      |          |             |            |          |  |
| Restricted equity                 |      |          |             |            |          |  |
| Share capital                     |      | _        | _           | 104,218    | 104,218  |  |
| Statutory reserve                 |      | _        | _           | 827,971    | 827,971  |  |
| Total restricted equity           |      |          |             | 932,189    | 932,189  |  |
| Non-restricted equity             |      |          |             |            |          |  |
| Share premium reserve             |      | _        | _           | 191,138    | 189,939  |  |
| Accumulated deficit               |      | _        | _           | -834,556   | -735,722 |  |
| Net profit/loss                   |      | _        | _           | -134,983   | -98,834  |  |
| Total non-restricted equity       |      |          |             | -778,401   | -644,617 |  |
| Total equity, Medivir AB          |      |          |             | 153,788    | 287,572  |  |
| Long-term liabilities             |      |          |             |            |          |  |
| Liabilities to group companies    |      | _        | _           | 1,634      | 1,696    |  |
| Other liabilities                 |      | 191      | _           | 191        | _        |  |
| Total long-term liabilities       |      | 191      | -           | 1,825      | 1,696    |  |
| Current liabilities               |      |          |             |            |          |  |
| Accounts payable                  |      | 11,809   | 10,588      | 11,809     | 10,588   |  |
| Other liabilities                 |      | 2,794    | 2,406       | 2,720      | 2,341    |  |
| Accrued costs and deferred income | 19   | 36,551   | 70,914      | 30,820     | 64,967   |  |
| Total current liabilities         |      | 51,154   | 83,908      | 45,350     | 77,897   |  |
| TOTAL EQUITY AND LIABILITIES      |      | 205,200  | 371,515     | 200,963    | 367,165  |  |
| Assets pledged                    |      | -        | -           | _          | -        |  |

<sup>-=</sup>not applicable

# CHANGES IN EQUITY

| Group, sek 000                             | Share<br>capital | Other con-<br>tributed<br>capital | Exchange<br>rate<br>difference | Accumul-<br>ated deficit | Total<br>equity | Number of shares |
|--|------------------|-----------------------------------|--------------------------------|--------------------------|-----------------|------------------|
| Opening balance, 1 January 2008            | 104,218          | 844,810                           | 3,724                          | -568,773                 | 383,978         | 20,843,5471      |
| Total comprehensive income for the period  |                  |                                   | 611                            | -99,203                  | -98,592         |                  |
| Stock option plans: value of staff service |                  | 2,221                             |                                |                          | 2,221           |                  |
| Closing balance, 31 December 2008          | 104,218          | 847,030                           | 4,335                          | -667,976                 | 287,606         | 20,843,5471      |
| Opening balance, 1 January 2009            | 104,218          | 847,030                           | 4,335                          | -667,976                 | 287,606         | 20,843,5472      |
| Total comprehensive income for the period  |                  |                                   | 422                            | -135,375                 | -134,952        |                  |
| Stock option plans: value of staff service |                  | 1,201                             |                                |                          | 1,201           |                  |
| Closing balance, 31 December 2009          | 104,218          | 848,231                           | 4,758                          | -803,351                 | 153,855         | 20,843,5472      |

¹ Opening and closing number of shares in 2008: 660,000 class A shares and 20,183,547 class B shares, quotient value: SEK 5

Proposed dividend for 2009: SEK 0 per share.

| Parent company, SEK 000                                | Share<br>capital | Statutory reserve | Share<br>premium<br>reserve | Accumul-<br>ated deficit | Net<br>profit/loss | Total<br>equity | Number of shares |
|--|------------------|-------------------|-----------------------------|--------------------------|--------------------|-----------------|------------------|
| Opening balance, 1 January 2008                        | 104,218          | 827,971           | 187,717                     | -708,512                 | -27,210            | 384,185         | 20,843,547¹      |
| Appropriation of profit/loss, AGM 2008:                |                  |                   |                             |                          |                    |                 |                  |
| Previous year's profit/loss brought forward            |                  |                   |                             | -27,210                  | 27,210             | 0               |                  |
| Net profit/loss 2008                                   |                  |                   |                             |                          | -98,834            | -98,834         |                  |
| Total reported income and costs                        | 0                | 0                 | 0                           | -27,210                  | -71,624            | -98,834         |                  |
| Stock option plans: value of staff service, Medivir AB |                  |                   | 2,221                       |                          |                    | 2,221           |                  |
| Closing balance, 31 December 2008                      | 104,218          | 827,971           | 189,938                     | -735,722                 | -98,834            | 287,572         | 20,843,5471      |
| Opening balance, 1 January 2009                        | 104,218          | 827,971           | 189,938                     | -735,722                 | -98,834            | 287,572         | 20,843,5472      |
| Appropriation of profit/loss, AGM 2009:                |                  |                   |                             |                          |                    |                 |                  |
| Previous year's profit/loss brought forward            |                  |                   |                             | -98,834                  | 98,834             | 0               |                  |
| Net profit/loss 2009                                   |                  |                   |                             |                          | -134,983           | -134,983        |                  |
| Total reported income and costs                        | 0                | 0                 | 0                           | -98,834                  | -36,149            | -134,983        |                  |
| Stock option plans: value of staff service, Medivir AE | 3                |                   | 1,200                       |                          |                    | 1,200           |                  |
| Closing balance, 31 December 2009                      | 104 218          | 827 971           | 191 138                     | -834 556                 | -134 983           | 153 788         | 20 843 5472      |

<sup>&</sup>lt;sup>1</sup> Opening and closing number of shares in 2008: 660,000 class A shares and 20,183,547 class B shares, quotient value: SEK 5

<sup>&</sup>lt;sup>2</sup> Opening and closing number of shares in 2009: 660,000 class A shares and 20,183,547 class B shares, quotient value: sεκ 5 Quotient value is calculated as share capital divided by total number of shares.

<sup>&</sup>lt;sup>2</sup> Opening and closing number of shares in 2009: 660,000 class A shares and 20,183,547 class B shares, quotient value: SEK 5 Quotient value is calculated as share capital divided by total number of shares.

# CASH FLOW STATEMENT

|   |      | Medi     | vir group | vir group Medivir AB |          |
|---|------|----------|-----------|----------------------|----------|
| SEK 000   | Note | 2009     | 2008      | 2009                 | 2008     |
| Operating activities                                |      |          |           |                      |          |
| Operating profit/loss                               |      | -139,815 | -113,733  | -128,290             | -107,738 |
| Reversal of non-cash items                          |      |          |           |                      |          |
| Depreciation and amortization                       |      | 10,390   | 10,323    | 10,390               | 10,323   |
| Other reversals <sup>1</sup>                        |      | -434     | 7,331     | -887                 | 6,478    |
|   |      | -129,859 | -96,079   | -118,787             | -90,937  |
| Interest received                                   |      | 277      | 8,630     | 197                  | 8,593    |
| Dividend received                                   | 9    | 6,518    | 902       | 6,518                | 902      |
| Interest paid                                       |      | -17      | -83       | -17                  | -79      |
| Tax received  | 11   | 13       | 820       | 0                    | 0        |
| Cash flow from operating activities before          |      |          |           |                      |          |
| changes in working capital                          |      | -123,068 | -85,810   | -112,089             | -81,521  |
| Increase(-)/decrease(+) in inventories              |      | -619     | 0         | -619                 | 0        |
| Increase(-)/ decrease(+) in current receivables     |      | 21,355   | 41,948    | 19,410               | 40,910   |
| Increase(+)/ decrease(-) in current liabilities     |      | -32,754  | 9,011     | -32,547              | 11,358   |
| Cash flow from operating activities                 |      | -135,086 | -34,851   | -125,845             | -29,253  |
| Investing activities                                |      |          |           |                      |          |
| Acquisitions of intangible fixed assets             |      | -4,663   | 0         | -4,663               | 0        |
| Acquisitions of tangible fixed assets               |      | -1,417   | -9,915    | -1,417               | -9,915   |
| Sales of tangible fixed assets                      |      | 290      | 199       | 290                  | 199      |
| Cash flow from investing activities                 |      | -5,790   | -9,716    | -5,790               | -9,716   |
| Financing activities                                |      |          |           |                      |          |
| Financial inter-company transactions                |      | _        | _         | -11,102              | -3,725   |
| Cash flow from financing activities                 |      | -        | -         | -11,102              | -3,725   |
| Cash flow for the year                              |      |          |           |                      |          |
| Cash and cash equivalents at beginning of year      |      | 284,486  | 329,330   | 283,271              | 325,964  |
| Change in cash and cash equivalents                 |      | -140,876 | -44,567   | -142,736             | -42,694  |
| Exchange rate difference, cash and cash equivalents |      | -30      | -277      | 0                    | 0        |
| Cash and cash equivalents at end of year            |      | 143,580  | 284,486   | 140,535              | 283,271  |

 $<sup>^{\</sup>rm 1}$  Reversals mainly consist of the valuation of financial instruments.

### ACCOUNTING PRINCIPLES

#### Group

Medivir has prepared its Consolidated Accounts pursuant to IFRS, International Financial Reporting Standards, as endorsed by the EU. The same principles were applied to the Annual Report for 2008. In addition to IFRS, the group also observes RFR's (Rådet för finansiell rapportering, the Swedish Financial Reporting Board) recommendation RFR 1.2 Supplementary Accounting Rules for Groups) and applicable statements from the Swedish Financial Reporting Board.

The Medivir group presents its Income Statement by cost class, implying that operating costs are divided between other external costs, personnel costs as well as depreciation, amortization and impairment losses.

The essential significance of IFRS is stated in the following headings, where the principles of the Annual Report are reviewed in more detail.

### Parent company

Medivir AB continues to apply those accounting principles relevant to legal entities that prepare Consolidated Accounts and are listed on a stock exchange. Medivir AB observes RFR 2.2, Accounting for Legal Entities.

Pursuant to RFR 2.2, the parent company will structure its reports pursuant to all applicable IFRS unless the standards allow an exception from their application. Accordingly the parent company's principles are consistent with the group's unless otherwise stated below

### **Basis for valuation**

The group uses historical costs for balance sheet items unless otherwise stated.

### **Consolidated Accounts**

The Consolidated Accounts have been prepared using acquisition accounting, implying that subsidiary equity at the time of acquisition is eliminated. Subsidiaries are all companies where Medivir is entitled to formulate financial and operational strategies in a manner usually following from a shareholding amounting to more than half of the votes. Subsidiaries are consolidated from the day when the controlling influence is transferred to the group onwards. They are deconsolidated from the date the controlling influences ceases onwards. Moreover, the preparation of Medivir's Consolidated Accounts conforms to the stipulations of IAS 27 and IFRS 3 such as elimination of intra-group receivables and liabilities as well as intragroup income and costs, implying that the Consolidated Income Statement and Consolidated Balance Sheet are reported without intra-group transactions.

### Translation of foreign currency

Functional currency and reporting currency

Medivir has a foreign subsidiary, Medivir UK Ltd. Items stated in the financial statements for this entity within the group are valued in GBP, as this is the subsidiary's functional currency. Swedish krona, the parent company's functional currency and reporting currency, is utilized in the Consolidated Accounts.

### Transactions and balance sheet items

Foreign currency transactions are translated to the functional currency at the rates of exchange ruling on the transaction date. The exchange rate gains and losses arising when paying such transactions, and upon translating foreign currency monetary assets and liabilities at the rate of exchange ruling on the reporting date, are reported in the Income Statement. Profits and losses on trading receivables and liabilities are reported net under other operating income or other operating costs.

### Group companies

Profits and the financial position of all group companies with a functional currency that differs from the reporting currency, are translated to the group's reporting currency as follows:

(i) assets and liabilities for each balance sheet are translated at the rate of exchange ruling on the reporting date; (ii) income and costs for each of the Income Statements are translated at average rates of exchange. If average rates of exchange are not a reasonable estimate of total exchange rate effects for the year from each transaction date, income and costs are translated instead at the transaction date, and (iii) all exchange rate differences arising are reported as a separate portion of equity.

# **Financial instruments, reporting, disclosure and classification** For information on financial risks and investments, see Note 8, financial risks.

Financial assets reported at fair value in the Income Statement Medivir's investments in securities, etc. are managed as a group of financial assets and the profit/loss is evaluated based on fair value, in accordance with the documented risk management and investment strategy. Accordingly, Medivir has chosen to report the changes in fair value of its investments in securities, etc. in the Income Statement.

#### Financial assets held for sale

Holdings of shares in Medivir's licensing partners Epiphany Biosciences and Presidio Pharmaceuticals Inc. have been classified as financial assets held for sale.

Because none of these shares are listed, and are not registered on a recognized marketplace, other non-observable data is used as the basis for valuation of the shares instead. An estimation of value consists of the companies' reported results of operations and financial position, the progress of the companies' project portfolios, share price performance on the Nasdaq biotech index, and where applicable, independent third-party valuations. If the valuation results in an estimated value change, the value change is reported in the statement of other comprehensive income for the period.

### Accounts receivable and other receivables

Accounts receivable are non-derivative financial assets, with measured or measurable payments that are not listed on an active market. Their distinguishing feature is that they arise when the group supplies money, goods or services direct to a customer without any intention to trade in the arising receivable. They are included in current assets, apart from items with maturities more than 12 months from the reporting date, which are classified as fixed assets. Initially, accounts receivable are reported at fair value, and subsequently, at accrued historical cost, by applying the effective interest method, less potential provisioning for impairment. Other receivables, and where applicable interim receivables, are reported according to the same principles.

Provisioning for the impairment of accounts receivable is effected when there is objective evidence that the group will not be able to receive all the amounts due according to the original terms of such receivables. The provisioning amount is the difference between asset carrying amounts and the present value of estimated future cash flows, discounted by effective interest. The provision amount is reported in the Income Statement. Other receivables are reported in the same manner.

### Purchases and sales of financial instruments

Purchases and sales of financial instruments are reported on the transaction date – the date Medivir undertakes to buy or sell the asset. Financial instruments are removed from the Balance Sheet

when the right to receive cash flows from the instrument has expired or been transferred and the group has transferred basically all risks and benefits associated with rights of ownership.

#### Accounts payable

Accounts payable are initially reported at fair value, and subsequently at amortized cost by applying the effective interest method.

#### Stock option plans

As of the reporting date, Medivir has two outstanding stock option plans. Upon conversion/exercise, cash and cash equivalents would increase by the exercise/conversion price and the share capital by a nominal SEK 5 per share, with the remaining deposited amount increasing equity.

For more details on the various effects of each plan and the number of outstanding stock options, please refer to pages 38-40, 'warrants and stock options'.

Medivir reports its stock option plans in accordance with IFRS 2 and IFRIC 11. Medivir values current plans at the grant date at fair value and then allocates the value over the vesting period as a personnel cost. This remuneration to personnel implies that Medivir issues equity instruments (warrants that personnel are entitled to in the plans' agreements) and thus, for the cost associated with each period, achieves the corresponding increase in other contributed capital (share premium reserve in the parent company). The stock options that are attributable to personnel in the subsidiary Medivir UK Ltd. are reported in accordance with IFRIC 11. Here, Medivir's issue of equity instruments is defined as a shareholder contribution to the subsidiary from the parent company, implying that it is reported as investment in a subsidiary. Like other contributions, the investment is then tested for impairment. If there is value impairment in a subsidiary, the effect is that a financial cost is reported in Medivir AB's Income Statement.

### Social security costs on stock option plans

For each outstanding plan, Medivir makes provisions for social security costs at the end of each accounting year. The provision for social security costs is calculated according to UFR 7 with the application of the same valuation model used when the options were written. The provision is revalued on each reporting date on the basis of a calculation of the charges that may be payable when exercise takes place.

Medivir uses the Black & Scholes model for valuation, which takes into account factors including the share price, remaining time until exercise, volatility and risk-free interest rate, see pages 38-40.

Payments of social security expenses in connection with employees exercising options is offset against the provision made according to the above.

The social security cost on the taxable benefit (the difference between the redemption/exercise price and market value of shares) that arises when stock options are exercised can be covered in terms of cash flow in the group. This is achieved by Medivir exercising a portion of options the group retains to shares and selling them. However, the personnel cost arising in the Income Statement, which is provisioned on a continuous basis pursuant to UFR 7, will not be offset by a cost reduction (income), but the effect arises in cash flow terms only.

### Intangible fixed assets

Research and development costs

Research expenditure is expensed on an ongoing basis.

Pursuant to IAS 38 Intangible assets, costs for researching and developing pharmaceuticals should be capitalized when the following criteria are satisfied:

- it is technically possible to complete the pharmaceutical,
- management intends to complete the pharmaceutical and the conditions for sale are in place,
- the asset is expected to provide future economic benefits,
- Medivir judges that the resources necessary to complete development of the asset are available,
- expenditure for development can be measured reliably.

In 2009, Medivir demonstrated that the above criteria are satisfied for Xerclear<sup>TM</sup>, as approval from registration authorities in the US and Europe was secured. Development costs for the product are reported as intangible fixed assets at historical cost.

Historical cost includes direct expenses for completion of the pharmaceutical including patents, costs for registration applications, product testing, including remuneration for employees.

Amortization is on a straight-line basis to allocate development costs on the basis of estimated useful life pursuant to IAS 38, and begins when the pharmaceutical starts generating income.

Medivir's other costs for research and development are reported as they arise, as are costs for patent and technology rights developed itself and other similar assets. Against the background of the contents of the 'significant estimates and forecasts' section on page 49, other research work performed by Medivir is judged to be associated with such uncertainty that IAS 38's capitalization criteria cannot be considered satisfied, primarily because of difficulties in judging whether it is technically possible to complete the pharmaceutical.

### Other intangible fixed assets

Development costs for Medivir's ERP systems that enhance the performance or extend the useful life of software are reported at historical cost. These costs are amortized over the estimated useful life. The estimated useful life is five years, whereupon the reported asset will be amortized over this term on a straight-line basis in accordance with this estimate.

### Tangible fixed assets

Tangible fixed assets are reported at historical cost less depreciation. Historical cost includes expenditure that can be directly attributed to acquisition of the asset.

Pursuant to IAS 16, Property, Plant and Equipment, plan depreciation is estimated on the original historical cost with depreciation rates based on estimates of the assets' economic useful lives.

The group applies the following depreciation terms: buildings 20 years, equipment, tools, fixtures and fittings 5-10 years and IT hardware 3 years.

### **Impairment**

Tangible and intangible fixed assets are subject to impairment testing, and impairment losses are taken at any time internal or external indications of potential impairment arise pursuant to IAS 36.

Intangible assets that are not in use are not amortized, but subject to impairment testing yearly. If the recoverable amount is less than the carrying amount, an impairment loss is taken.

Recoverable amount is calculated on the basis of estimated future cash flows based on the competitive situation and estimated market shares.

An unconditional shareholders' contribution was made to Medivir UK Ltd. in order to strengthen this subsidiary's shareholders' equity. This additional investment is reported as an increase in shares in subsidiaries. Investments in subsidiaries are subject to impairment tests at each year-end. The subsidiary's equity forms a key criterion for this assessment, see Note 15.

#### Inventories

Inventories are reported at the lower of cost or net realizable value. Cost is determined using the first in, first out (FIFO) method. Cost includes purchasing cost, customs and transportation costs and other direct costs associated with goods purchases. The net realizable value is the expected sales price in operating activities less cost of sales. Risk of obsolescence and established obsolescence are considered in the valuation.

#### Revenues

### Upfront payments

According to Medivir's interpretation of IAS 18, the payment received in connection with an upfront payment, and where there is an outstanding undertaking to provide services from the licensor's side, is considered as an advance payment. Thus the licensor has not completed the earning of revenue until the estimated or appointed collaboration period expires. In cases where an agreement implies that Medivir has outstanding commitments and/or is to provide services for the counterparty, the remuneration received at the beginning of agreements is allocated over the estimated or determined collaboration period.

Down-payment revenue is recognized when the agreement is reached, providing there is no reservation or other impediment to receiving the remuneration and this is not related to future performance on Medivir's part.

### Milestone payments

Contracted milestone payments from a counterparty are reported when the remuneration criteria of the relevant outlicensing agreement have been satisfied and verified with the counterparty.

Medivir does not apply the percentage of completion method on those research projects that have potential future milestone payments from a collaboration partner. This is because:

- it is impossible to measure the degree of completion with sufficient accuracy as IAS 18 stipulates as a requirement for the percentage of completion method;
- it is impossible to measure the expenditure that will be due to secure the corresponding milestone revenue with sufficient accuracy, the number of researchers and other direct expenditure may vary over time;
- no remuneration is due if the criteria contracted with the collaboration partner are not achieved.

### Research services

Research services that Medivir renders pursuant to collaboration agreements and that generate remuneration from counterparties are recognized on an ongoing basis as Medivir provides such services.

### Co-promotion

Recognition of revenue from co-promotion agreements is recognized when the economic outcome of work completed can be reliably measured and the economic benefits accrue for the group.

Central government support (EU and other subsidies)
Central government support is reported pursuant to IAS 20 under other income. Support received is recognized as revenue when the company satisfies the conditions associated with the support, and it can be reliably determined that the support will be received. Support received is reported in the Balance Sheet under deferred income with revenue recognized as the terms for securing the funds are satisfied. Medivir receives central government support mainly in

the form of research subsidies from the EU. An insignificant portion of Medivir's projects are financed with central government support.

### **Operating segments**

IFRS 8 requires segment information to be presented from management's perspective, which means it is presented in the way used in internal reporting. The basis for identifying reportable segments is internal reporting such as that reported and monitored by the chief operating decision maker.

In this context, the group has identified the group President as the chief operating decision maker. The adoption of IFRS 8 has not meant the group identifying new operating segments compared to previously. Because Medivir's business activities consist of one integrated operation, the President monitors operations at an aggregate level. Accordingly, operations are reported as one segment.

#### Leases

Medivir's lease arrangements are classified as either operating or finance leases.

Lease arrangements of fixed assets were the group essentially has the economic risks and benefits associated with ownership are classified as finance leases. The leased item is reported as a fixed asset in the Balance Sheet, and the obligation to pay the leasing charges is reported as a liability. At the beginning of the lease term, finance leasing is reported in the Balance Sheet at the lower of the leased item's fair value and the present value of minimum leasing charges

Lease payments made are reported allocated between amortization and interest. The leased fixed asset is depreciated over the asset's useful life.

Lease arrangements where Medivir does not have any significant risk or benefits from an item are reported as operating leases. Payments made over the lease term are expensed in the Income Statement on a straight-line basis over the lease term, see Note 20.

### Pension liability and pension cost

Medivir AB's ITP (supplementary pensions for salaried employees) scheme is insured with Alecta and should be considered as a defined-benefit pension scheme pursuant to statement UFR 3 from

Pursuant to UFR 3, the company should account its proportional share of defined-benefit commitments, plan assets and costs associated with the scheme. Because Alecta is unable to provide sufficient information, for the present, this scheme is reported as defined contribution.

Alecta's surplus can be distributed to policyholders and/or beneficiaries. At year-end 2009, Alecta's surplus in the form of its collective consolidation ratio was 141 (112)%, according to Alecta's computations. The group judges that current premiums should cover the current commitments. The group's other pension schemes are defined contribution. The charges are reported as personnel costs when they become due for payment.

### Remuneration on dismissal

Remuneration on dismissal is expensed when the obligation to pay remuneration arises.

### Income tax

Pursuant to IAS 12, deferred tax assets should only be reported to the extent that it is likely that deductions will be utilized. Note 11 states items including the estimated deductible deficits accumulated in the group, and the explanation for no income taxes recoverable being reported for the group. The taxable deficits of Medivir AB and Medivir UK Ltd. have no expiry.

The treatment of potential deferred tax on temporary differences is reported and explained in Note 11. The various components of consolidated total tax are also explained.

The positive tax amount relates to the tax credit for Medivir UK Ltd., as a result of UK legislated research support. The UK tax authority, HM Revenue & Customs, pays claims after a customary review.

This amount is reported as revenue since HM Revenue & Customs' decision to waive the taxation is definitive. Loss carry-forwards in Medivir UK Ltd. are reduced because of the tax credit. More information is in Note 11, Tax on profit for the year.

#### **Cash Flow Statement**

The Cash Flow Statement has been reported by applying the indirect method.

Reported cash flow only encompasses those transactions involving payments made or received.

Cash and bank balances, plus investments in securities, etc. such as commercial paper, fixed-income and bond funds with maximum maturities of three months are reported as cash and cash equivalents in the Cash Flow Statement.

### Significant estimates and forecasts

The reporting of income and research & development costs are two important parts of Medivir's accounting.

Medivir does not utilize the percentage of completion method for forthcoming potential milestone payments, because there is constant uncertainty regarding how far the project has progressed, and the likelihood of it achieving the next goal/milestone. Thus, the income side only states determined and non-repayable income that can be considered to have accrued.

Allocation to periods could demonstrate how Medivir progressively receives income from the counterparty's utilization of intellectual property. But if the percentage of completion method was applied, there would be a risk of income being reported as uncertain in terms of whether Medivir would ever receive any payment. In such circumstances, an announcement from a counterparty that a project was being discontinued, for example, would imply that Medivir had reported inaccurate profits/losses.

Development costs including registration costs are reported on an ongoing basis as long as the future economic benefits from these costs are uncertain. Pharmaceutical development is generally a complex and risky activity, and the majority of research projects never result in a pharmaceutical on the market.

Development costs should be capitalized when projects are likely to succeed. Each research project is unique and must be judged individually on its own conditions. The earliest assessed timing for capitalization is after phase III trials have been conducted, but even after the completion of phase III trials, the majority of uncertainty factors could remain so that the criteria for capitalization cannot be considered satisfied. In such cases, capitalization does not occur before the pharmaceutical is approved by the relevant regulatory authority.

Given premature capitalization, there is a risk that a project would fail and that the costs offset could not be justified, but would have to be expensed directly. In turn, this would imply that previous and current year profits/losses would be misleading because of an overly optimistic assessment of the likelihood of success.

### Introduction of new accounting principles

At the time of the preparation of the Consolidated Accounts as of 31 December 2009, a number of standards and interpretations had been published that have yet to take effect. A preliminary assessment of the impact the introduction of these standards and statements

have had, and could have, on Medivir's financial reporting follows. Comments are only provided on those changes that could have an impact on Medivir's accounting.

### New and revised standards that the group has adopted from 1 January 2009

IAS 1 (Amendment) Presentation of Financial Statements: This amendment came into effect on 1 January 2009 and has stipulations on the presentation and content of financial statements to ensure comparability between the company's previous reports, but also between the company and other companies. The standard has been amended to include more detailed information on items including changes in the company's equity resulting from transactions with owners, in respect of owners, as opposed to all "non-owner changes" to equity. This does not affect the scale of Medivir's reported results of operations and financial position but required changes to the presentation of the company's financial statements.

IFRS 7 (Amendment) Financial Instruments—Disclosures
This standard applies from 1 January 2009. The standard stipulates
extended disclosures on measurement and fair value, disclosures
should be made on measurement and fair value by level in the valuation hierarchy, and disclosures on liquidity risk. The amendments
do not affect the group's results of operations and financial position,
and only require extended disclosures.

### IFRS 8 Operating Segments:

This standard came into effect on 1 January 2009 and applies to financial years that begin from this date onwards. The standard relates to the breakdown of a company's operations into different segments. According to this standard, the company should proceed from the structure of internal reporting, and designate its reportable segments according to this structure. Pursuant to IAS 14, in 2008, Medivir reported a single segment. The introduction of IFRS 8 did not affect Medivir's accounts or the structure of its financial reports, because Medivir's operations also only consist of a single segment in terms of internal reporting, but has implied increased disclosures.

### New and revised standards that have not come into effect and have not been adopted in advance by the group

IFRS 3 (Amendment) Business Combinations:

This amendment applies from financial years that begin after 1 July 2009. The amendment applies in advance to business combinations after the time it comes into effect. Application will imply changes to how future business combinations are reported in terms of factors including reporting transaction costs, potential conditional purchase prices and gradual acquisitions. The amendment will not have any effect on previous business combinations but will affect the reporting of potential future transactions.

In addition to the above standards, a number of interpretation statements and amendments have been issued that are not relevant to the group, and accordingly, no comment has been provided.

### NOTES

-= Not applicable

### Note 1 Division of net sales (SEK 000)

|                         | G      | roup   |
|-------------------------|--------|--------|
|                         | 2009   | 2008   |
| Upfronts                | 15,415 | 30,830 |
| Milestones              | _      | 32,046 |
| Research collaborations | 9,035  | 34,099 |
| CRO services            | 211    | 200    |
| Co-promotion services   | 1,008  | _      |
| Other services          | 15     | _      |
| Total                   | 25,684 | 97,175 |

The company has is registered office in Sweden. Income from customers in Sweden amounts to 1,234 (200) and total income from external customers in other countries is 24,450 (96,974). Income of 24,450 (96,936) is from a single external partner. This income is

sourced from outlicensing and research income divided between the partner's operations in the US 15,414 (62,876), Ireland 165 (16,467) and Belgium 8,870 (17,593).

### Note 2 Intra-group transactions (SEK 000)

### Parent company

Purchases from Medivir UK Ltd. amounted to 0 (0). Sales to Medivir UK Ltd. amounted to 11,478 (4,693). Purchases from Medivir HIV Franchise AB amounted to 1,265 (2,090). Sales to Medivir HIV Franchise AB amounted to 1,261 (2,084).

### Note 3 Costs for auditing and audit consulting (SEK 000)

|                           | C    | Group |      | Parent company |  |
|---------------------------|------|-------|------|----------------|--|
|                           | 2009 | 2008  | 2009 | 2008           |  |
| Audit costs <sup>1</sup>  | 527  | 454   | 490  | 260            |  |
| Consulting cost, auditors | 324  | 440   | 256  | 205            |  |
| Total                     | 851  | 894   | 746  | 465            |  |

 $<sup>^{\</sup>mathrm{1}}$  The group's auditing firm is Pricewaterhouse Coopers.

### ${\color{red}Note~4}~~\text{Average number of employees, salaries, other remuneration and social security costs (SEK~000)}$

| Average number of employees |      | Group |      |      |
|-----------------------------|------|-------|------|------|
|                             | 2009 | 2008  | 2009 | 2008 |
| Women                       | 46   | 46    | 46   | 46   |
| Men                         | 47   | 54    | 47   | 54   |
| Total                       | 93   | 100   | 93   | 100  |

### Total sickness absence by group 2009 (2008)

| Parent company            | Women     | Men       | Age < 29   | Age 30-49 | Age >50  | Total       |
|---------------------------|-----------|-----------|------------|-----------|----------|-------------|
| Total sickness absence, % | 3.9 (1.8) | 1.1 (3.3) | 2.7 (12.9) | 2.7 (1.8) | 1.7(1.0) | 2.4 (2.6)   |
| %, of which > 60 days     | 44.9 (0)  | 0 (23.6)  | 0 (35.1)   | 44.0 (0)  | 6.6(0)   | 34.0 (15.9) |

|  | G      | roup    | Parent o |         |
|--|--------|---------|----------|---------|
| Salaries, benefits, social security costs and pension costs, (SEK 000) | 2009   | 2008    | 2009     | 2008    |
| Salaries and benefits  |        |         |          |         |
| Ron Long (CEO from 1 February 2009 onwards)                            | 3,337  | _       | 3,337    | _       |
| Lars Adlersson (CEO until 31 January 2009 inclusive)                   | 1,354  | 7,050   | 1,354    | 7,050   |
| Anders Vedin (Chairman) <sup>1</sup>                                   | 178    | 535     | 178      | 535     |
| Lars-Göran Andrén (Board member) <sup>1</sup>                          | 83     | 250     | 83       | 250     |
| Anna Malm Bernsten (Board member)                                      | 250    | 250     | 250      | 250     |
| Magnus Falk (Board member) <sup>1</sup>                                | 88     | 265     | 88       | 265     |
| Donna Janson (Board member) <sup>1</sup>                               | 100    | 300     | 100      | 300     |
| Ron Long (Board member)  | 4      | 300     | 4        | 300     |
| Björn C Andersson (Board member)                                       | 260    | 167     | 260      | 167     |
| Ingemar Kihlström (Board member)                                       | 262    | 157     | 262      | 157     |
| Göran Pettersson (Chairman) <sup>2</sup>                               | 402    | 157     | 402      | 157     |
| Total, Board of Directors and Chief Executive Officer                  | 6,319  | 9,430   | 6,319    | 9,430   |
| Senior executives  | 9,895  | 11,112  | 9,895    | 11,112  |
| Other employees  | 44,810 | 47,244  | 44,810   | 47,244  |
| Total  | 61,023 | 67,786  | 61,023   | 67,786  |
| Statutory and contracted social security costs                         | 21,833 | 24,474  | 21,833   | 24,474  |
| Pension costs  |        |         |          |         |
| (of which for the CEO of the group 2 (706) and parent company 2 (706). | 8,043  | 8,844   | 8,043    | 8,844   |
| Total salaries, benefits, social security costs and pension costs      | 90,900 | 101,104 | 90,900   | 101,104 |

<sup>&</sup>lt;sup>1</sup> Resigned 23 April 2009

### Remuneration in the financial year

### **Board of Directors**

Fees pursuant to resolution by the AGM are payable to the Chairman of the Board and Board members elected by the AGM. During the financial year, fees to the Board of Directors of Medivir were 1,628 (2,270), of which 402 (535) to the Chairman of the Board. In addition, reimbursement of travel expenses to Board meetings, etc. was paid to Board members. Remuneration of 25 (0) was paid for specific consulting assignments to Anna Bernsten. There is no pension scheme for Board members.

### Remuneration guidelines for senior executives

The AGM 2009 resolved that the company would offer total compensation on market terms that would enable the hiring and retention of skilled senior executives. Remuneration to senior executives will consist of basic salary, potential performance-related pay, stock options pursuant to the 2007/2012 stock option plan resolved by the AGM, pensions and other benefits.

Basic salary will consider the individual's areas of responsibility and experience.

Performance-related pay – which at present, and where applicable, is payable as a discretionary individual bonus – will be a maximum of 50% of basic salary. The Board of Directors is entitled to diverge from the above guidelines if the Board judges that there are special circumstances in individual cases justifying this.

### **Chief Executive Officer**

Salary and benefits of 3,337 (0) was paid to Ron Long in the year. The CEO is subject to a mutual notice period of 6 months. The CEO's remuneration consists of basic salary that is subject to annual review by the Board of Directors. There is no pension plan for the CEO. No fees in addition to basic salary are payable for the position as a Board member after becoming CEO. For the period until 31 January 2009 inclusive, Ron Long received 4 of Directors' fees. Ron Long has not been granted any stock options. Salary and benefits to Lars Adlersson, who resigned as CEO on 31 January 2009 were 208 (2,394) in the year, with a bonus of 0 (2,168), other benefits of 12 (123) and provisions for severance pay of 1,133 (2,365). Total remuneration was 1,354 (7,050). The pension provision in the year was 2 (706).

Pursuant to a resolution by the AGM 2007, the CEO was granted 46,000 stock options from the 2007/2012 option plan. The theoretical market value of these options, calculated according to the Black & Scholes model, was SEK 14.4 per option at the grant date, corresponding to a value of 662. For other holdings, see page 38.

### Other senior executives

Other senior executives means the 6 people apart from the CEO that make up the management team. The management team consists of two women and five men.

<sup>&</sup>lt;sup>2</sup> Became Chairman 23 April 2009

Salary of 9,657 (6,803), bonuses of 0 (3,965) and other benefits of 238 (344) was paid to other senior executives, thus total remuneration was 9,895 (11,112).

The management team included one person employed on a consultancy basis until April 2009 inclusive. The pension plans of other senior executives conform to the ITP scheme, and the relevant individual plan in the UK corresponds to legislated contributions, plus 6% of basic salary excluding bonus and benefits. Pension provisions of 2,076 (2,194) were made in the year.

Other senior executives are subject to a mutual notice period of six months. Severance pay or similar remuneration is not payable, but in instances of changes to ownership structure, may be agreed at a maximum amount of 100% of basic salary. Pursuant to a resolution by the AGM 2007, this group was granted 104,000 stock options from the 2007/2012 option plan. The theoretical market value of these options, calculated according to the Black & Scholes model, was SEK 14.4 per option at the grant date, corresponding to a value of 1,498. For other holdings, see page 38.

#### Other staff

Current stock option plans are reviewed on pages 38-40. Pursuant to a resolution by the AGM 2007, this group was granted 21,000 stock options from the 2007/2012 option plan. The theoretical market value of these options, calculated according to the Black & Scholes model, was SEK 14.4 per option at the grant date, corresponding to a value of 302.

In addition, a small number of individuals received bonuses in accordance with a fixed bonus program. The group has defined-benefit pension schemes via Alecta and defined-contribution schemes through alternative solutions.

### Closely related parties

Among other senior executives there are agreements with Medivir, as well as agreements between companies owned by senior executives and Medivir, which confer rights to royalties on products Medivir may develop based on patented inventions that Medivir has acquired from these senior executives before and during their time as researchers with Medivir. No such benefits became due in 2008 and 2009.

### Note 5 Depreciation and amortization (SEK 000)

|   | Group  |        | Parent company |        |
|---|--------|--------|----------------|--------|
|   | 2009   | 2008   | 2009           | 2008   |
| Amortization of intangible fixed assets | 513    | 454    | 513            | 454    |
| Depreciation of tangible fixed assets   | 9,877  | 9,869  | 9,877          | 9,869  |
| Total                                   | 10.390 | 10,323 | 10,390         | 10,323 |

### Note 6 Research costs (SEK m)

The cost of research work including plan amortization but less administrative costs for the group, was approximately SEK 123.5 (190.6) m. Research costs in the parent company amounted to

approximately SEK 123.3 (190.1) m. The operating profit/loss for the research segment of the group was SEK -95.1 (-83.4) m.

### Note 7 Profit/loss from participations in group companies (SEK 000)

|   | Group |      | Parent company |        |
|---|-------|------|----------------|--------|
|   | 2009  | 2008 | 2009           | 2008   |
| Impairment losses on shares in subsidiary Medivir UK Ltd. |       |      |                |        |
| (see also note 15, Participations in group companies)     | _     | _    | -11,040        | -4,800 |
| Total   |       |      | -11.040        | -4.800 |

### Note 8 Financial risks

The main financial risks that arise as a consequence of managing financial instruments consist of market risk (interest risk, currency risk and share price risk) credit risk, liquidity and cash flow risk. The financial risks are managed pursuant to a policy adopted by the Board. This policy means that investments of cash and cash equivalents will be conducted in such a manner that the invested

assets generate secure and stable returns. The objective is to achieve the best possible return for the lowest possible risk level. Underlying instruments will have low risk, and the aim when investing cash and cash equivalents will be to diversify risk. The company will invest its cash and cash equivalents with recognized bodies, such as banks

### The link between IAS 39 categories and Medivir's balance sheet items in the Balance Sheet

| Group, 31 Dec 2009 (sek 000)          | Financial assets<br>recognized<br>at fair value<br>in the Income<br>Statement | Cash and cash<br>equivalents | Accounts<br>receivable | Borrowings<br>and accounts<br>payable | Financial<br>assets held<br>for sale | Total   |
|---------------------------------------|---|------------------------------|------------------------|---------------------------------------|--------------------------------------|---------|
| Financial assets held for sale        |   |                              |                        |                                       | 18,793                               | 18,793  |
| Other investments in securities, etc. | 130,402   |                              |                        |                                       |                                      | 130,402 |
| Cash and bank balances                |   | 13,178                       |                        |                                       |                                      | 13,178  |
| Accounts payable                      |   |                              |                        | 11,809                                |                                      | 11,809  |
| Finance lease liabilities             |   |                              |                        | 266                                   |                                      | 266     |
| Total                                 | 130,402   | 13,178                       | _                      | 12,075                                | 18,793                               | 174,447 |

| Group, 31 Dec 2009 (seк 000)          | recognized<br>at fair value<br>in the Income<br>Statement | Cash and cash<br>equivalents | Accounts<br>receivable | Borrowings<br>and accounts<br>payable | Financial<br>assets held<br>for sale | Total   |
|---------------------------------------|---|------------------------------|------------------------|---------------------------------------|--------------------------------------|---------|
| Financial assets held for sale        |   |                              |                        |                                       | 18,793                               | 18,793  |
| Accounts receivable                   |   |                              | 11,877                 |                                       |                                      | 11,877  |
| Other investments in securities, etc. | 227,842   |                              |                        |                                       |                                      | 227,842 |
| Cash and bank balances                |   | 56,644                       |                        |                                       |                                      | 56,644  |
| Accounts payable                      |   |                              |                        | -10,588                               |                                      | -10,588 |
| Total                                 | 227,842   | 56,644                       | 11,877                 | -10,588                               | 18,793                               | 304,568 |

### Financial assets recognized at fair value

|  |                 | Measurement at fair value<br>at end of period based on: |        |        |
|--|-----------------|---|--------|--------|
| Group, 31 Dec 2009 (SEK 000)                                       | Carrying amount | Tier 1  | Tier 2 | Tier 3 |
| Financial assets recognized at fair value in the Income Statement: |                 |   |        |        |
| Other investments in securities, etc.                              | 130,402         | 130,402   | _      | -      |
| Financial assets held for sale:                                    | 18,793          | _   | _      | 18,793 |
| Total  | 149,195         | 130,402   | _      | 18,793 |

### Financial assets recognized at fair value

|  |                 | at end of period based on: |        |        |  |
|--|-----------------|----------------------------|--------|--------|--|
| Group, 31 Dec 2008 (seк 000)                                       | Carrying amount | Tier 1                     | Tier 2 | Tier 3 |  |
| Financial assets recognized at fair value in the Income Statement: |                 |                            |        |        |  |
| Other investments in securities, etc.                              | 227,842         | 227,842                    | _      | -      |  |
| Financial assets held for sale:                                    | 18,793          | _                          | _      | 18,793 |  |
| Total  | 246,635         | 227,842                    | _      | 18,793 |  |

No purchases or sales of financial assets recognized at fair value based on tier 3 occurred in 2008 or 2009. No gains or losses were reported in the Income Statement or other comprehensive income in 2009 or 2008.

### Market risks

#### Interest risk

Interest risk is the risk of a negative impact on cash flow or financial assets or liabilities resulting from changes in market rates of interest. Medivir's investment policy implies that the company invests its cash and cash equivalents in instruments such as bank and corporate commercial paper, fixed-income and bond funds, fixed bank investments and special deposits. Thus changes in market rates of interest affect Medivir's profit/loss through reduced or increased returns on financial assets.

As of 31 December 2009, the group's cash and cash equivalents including investments in securities, etc. with maximum maturities of three months were 143,580 (284,486). 130,402 (227,842) of this total was invested in fixed-income funds with discretionary management.

In 2009, Medivir received an average yield on cash and cash equivalents of approximately 2.1%. Yields in the year varied between 1 and 6%. Based on an average of existing investments in securities, etc. in the year, and if yields had been 1 percentage point higher or lower, this would have had an annualized positive or negative profit impact of some 2,100. Falling interest rates in 2010 would result in reduced yields on the group's cash and cash equivalents. If yields fall to 0% in 2010, this would exert a profit/loss effect of sek -4,696 given unchanged holdings of cash and cash equivalents. At year-end 2009, the company had no interest-bearing liabilities, and accordingly, no other interest risks apply.

### Currency risk

Currency risk is the risk that the fair value or future cash flows associated with financial instruments vary due to changes in foreign exchange rates. Profit is affected when costs and revenues in foreign currencies are translated into Swedish kronor (transaction risk). The Balance Sheet is affected when assets and liabilities in foreign currencies are translated into Swedish kronor (translation risk).

Measurement at fair value

Medivir did not use currency hedging in 2009; future income and costs will be exposed to foreign currency fluctuations. The company's operating profit had a -356 (-549) net effect in exchange rate gains/losses in the financial year, with the exchange rate gains/losses in the net financial position amounting to -327 (-507).

Sterling fluctuated between SEK 11.0 and SEK 13.1 in the year, with an average of SEK 11.9 for the year. In the year, the dollar exchange rate fluctuated between SEK 6.8 and SEK 9.2, with an average of SEK 7.6.

In the same period, the euro exchange rate fluctuated between SEK 10.1 and SEK 11.6 with an average rate of SEK 10.6. All trading in foreign currency was conducted at the best rate of exchange attainable at the point of exchange. Many of Medivir's contracts involve payments in EUR and USD, implying that accounts payable and accounts receivable have exposure.

The table illustrates the currency-exposed operating income and operating costs as net amounts per currency in SEK 000

|       |        | Group Parent con |          |        | ent company | ompany.  |  |
|-------|--------|------------------|----------|--------|-------------|----------|--|
| 2009  | Income | Costs            | Net      | Income | Costs       | Net      |  |
| EUR   | 3,706  | -12,973          | -9,267   | 3,706  | -12,973     | -9,267   |  |
| GBP   | _      | -5,663           | -5,663   | _      | -5,663      | -5,663   |  |
| USD   | _      | -19,383          | -19,383  | _      | -19,383     | -19,383  |  |
| Total | 3 706  | -38 010          | -3/1 313 | 3 706  | -38 010     | -3/1 313 |  |

|       |         | Group   |         | Parent company |         |         |
|-------|---------|---------|---------|----------------|---------|---------|
| 2008  | Income  | Costs   | Net     | Income         | Costs   | Net     |
| EUR   | 48,774  | -12,309 | 36,465  | 48,774         | -12,309 | 36,465  |
| GBP   | _       | -11,298 | -11,298 | _              | -11,298 | -11,298 |
| USD   | 78,291  | -31,962 | 46,329  | 78,291         | -31,962 | 46,329  |
| Total | 127,065 | -55,569 | 71,496  | 127,065        | -55,569 | 71,496  |

A sensitivity analysis indicates that 5% appreciation of the Swedish krona against the above currencies' average rates of exchange would have resulted in a 1,723 (1,028) profit improvement for the group and parent company. The corresponding depreciation of the Swedish krona would have reduced profits by -1,723 (-1,028).

### Share price risk of unlisted shares

In 2007, Medivir received shares from a new issue conducted by Epiphany Biosciences, Medivir's licensing partner on the shingles project MIV-606 (EPB-348) and shares from a new issue conducted by Presidio Pharmaceuticals Inc., Medivir's licensing partner on the compound MIV-410 (PTI-801). The total value of the shares amounted to 18,793 (18,793).

No net gains or net losses arose as a result of these investments in 2009. Medivir classifies the shares as financial assets held for sale pursuant to IAS 39, and the shares are reported in the Balance Sheet under the "financial fixed assets" item.

Because none of these shares are listed, and are not registered on a recognized marketplace, other non-observable data is used as the basis for valuation of the shares instead. An estimation of value consists of the companies' reported results of operations and financial position, the progress of the companies' project portfolios, share price performance on the Nasdaq biotech index, and where applicable, independent third-party valuations. If the valuation results in

an estimated value change, the value change is reported in the statement of other comprehensive income for the period. Medivir does not have any investments in listed shares, hence there is no share price risk.

### Credit risk (Counterparty risk)

Credit risk is the risk that a counterparty is unable to fulfill its contracted obligations to Medivir, thus causing a financial loss for the company. Medivir invests its cash and cash equivalents with Swedish fund managers with high credit ratings, P-1 from Moody's. In the year, these investments did not experience any value changes resulting from changes to asset managers' credit risk.

Medivir may also be exposed to credit risk in accounts receivable. As of the reporting date, Medivir has no outstanding accounts receivable, and accordingly, no such credit risk exists. Historically, Medivir has never needed to impair accounts receivable. Medivir has several partnerships with established pharmaceutical companies and smaller biotechnology enterprises, which diversify risks.

| Age analysis of accounts receivable (SEK 000) |      | Group  |      |       |
|---|------|--------|------|-------|
|   | 2009 | 2008   | 2009 | 2008  |
| Accounts receivable                           |      |        |      |       |
| Not due                                       | 0    | 11,877 | 0    | 9,897 |
| Total   | 0    | 11,877 | 0    | 9,897 |

Other receivables amount to 2,245 (11,157) of which 0 (0) was due on the reporting date.

The group's cash and cash equivalents are invested in liquid assets with low credit risk such as certificates of deposit, fixed income and bond funds subject to low risk levels (P-1, Moody's) through discretionary management. No credit risks are considered to apply to the above investments.

### Liquidity and cash flow risk

Liquidity risk is the risk of future difficulties for Medivir to fulfill its obligations associated with financial liabilities. A financial liability is each liability in the form of a contracted obligation to pay cash or other financial assets to another company, or to exchange a financial asset or financial liability with another company subject to terms that may be disadvantageous for the company.

| Maturity analysis, accounts payable (SEK 000) | G      | Group Pa |        |        |
|---|--------|----------|--------|--------|
|   | 2009   | 2008     | 2009   | 2008   |
| Amounts becoming due within 1 year            | 11,809 | 10,588   | 11,809 | 10,588 |
| Amounts becoming due after more than 1 year   | 0      | 0        | 0      | 0      |
| Total   | 11,809 | 10,588   | 11,809 | 10,588 |

Other liabilities amounted to 2,794 (2,406) and become due for payment within 12 months.

The amounts due for payment within 12 months are consistent with book values, because the discounting effect is insignificant.

Current liabilities are covered by Medivir's cash position and investments in securities, etc. on the reporting date, and accordingly, there is no liquidity risk for financial liabilities.

Liquidity risk is managed by Medivir investing cash and cash equivalents in fixed-income funds with low risk and a liquid market. Medivir's management and Board of Directors maintain continuous access to information regarding the company's equity and cash and cash equivalents. Liquidity and cash flow forecasts are prepared on an ongoing basis based on expected cash flow, to monitor liquidity capacity.

### Capital

Consolidated equity is 153,855 (287,606) and is the company's secure base for financing operating activities. A detailed specification of shareholders' equity is on page 44. While Medivir does not have any independent long-term earnings capacity with sustainable profitability, the company will retain low debt gearing and a high

equity ratio. Proposals regarding dividends will not be made until long-term profitability can be predicted. Accordingly, no dividends will be considered for the forthcoming years.

Medivir's objective is to attain profitability by receiving income from licensing agreements with partners on its own research, receiving income on sales of specialist pharmaceuticals, and to bring proprietary compounds to market registration. Medivir's research partners are responsible for funding outlicensed projects, and Medivir receives income in the form of upfront and milestone payments as projects progress towards the market. These revenues contribute to funding other parts of operations.

The ability to develop new candidate drugs, enter into partnerships on projects and successfully develop its projects to market launch and sale, as well as securing funding of its operations, are crucial to Medivir's future. The progress of existing partnerships, and the addition of new partnerships, will exert a significant influence on Medivir's revenue and cash balance. However it is not possible to schedule expected revenue flows.

Medivir's current financial assets are judged to secure funding of operations until the end of the second quarter of 2011 inclusive.

### Note 9 Interest income and similar profit/loss items (SEK 000)<sup>1</sup>

|  | Group  |        | Parent company |        |
|--|--------|--------|----------------|--------|
|  | 2009   | 2008   | 2009           | 2008   |
| Interest income, bank                              | 196    | 2,165  | 191            | 2,129  |
| Interest income on current receivables             | 75     | _      | _              | _      |
| Interest income from fixed-income investments      | 6      | 6,464  | 6              | 6,464  |
| Dividends from fixed-income fund                   | 6,518  | 902    | 6,518          | 902    |
| Fair value change on fixed-income fund, unrealized | -2,024 | 4,796  | -2,024         | 4,796  |
| Total  | 4,771  | 14,327 | 4,691          | 14,291 |

<sup>&</sup>lt;sup>1</sup> Interest income and similar profit/loss items are an effect of investments in securities, etc., recognized at fair value in the Income Statement and cash and bank balances.

### Note 10 Interest costs and similar profit/loss items (SEK 000)

|  | Group |      | Parent company |      |
|--|-------|------|----------------|------|
|  | 2009  | 2008 | 2009           | 2008 |
| Interest costs                                       | -17   | -83  | -17            | -79  |
| Exchange rate difference, inter-company transactions | -205  | -263 | -205           | -236 |
| Exchange rate difference, other                      | -122  | -270 | -122           | -270 |
| Total  | -344  | -616 | -344           | -586 |

### Note 11 Tax on profit/loss for the year (SEK 000)

|  | C        | iroup    | Paren    | nt company |  |
|--|----------|----------|----------|------------|--|
|  | 2009     | 2008     | 2009     | 2008       |  |
| Tax credit <sup>1</sup>  | 13       | 820      | _        | _          |  |
| Tax on profit/loss for the year, according to Income Statement               | 13       | 820      | -        | _          |  |
| Applicable tax rates   |          |          |          |            |  |
| Sweden   | 26%      | 28%      | 26%      | 28%        |  |
| UK   | 30%      | 30%      | =        | -          |  |
| Difference between consolidated tax cost reported in the Income              |          |          |          |            |  |
| Statement and tax cost based on applicable tax rate                          |          |          |          |            |  |
| Profit/loss before tax   | -135,388 | -100,023 | -134,983 | -98,834    |  |
| Tax at applicable tax rates  | 35,607   | 28,006   | 35,501   | 27,673     |  |
| Tax effect of non-deductible impairment losses                               | 0        | 0        | -2,904   | -1,344     |  |
| Tax effect of other non-deductible items                                     | -1,343   | -163     | -1,343   | -163       |  |
| Tax effect of non-taxable income   | _        | 1,343    | _        | 1,343      |  |
| Effect of foreign tax rates  | 423      | 119      | -        | _          |  |
| Tax credit received, Medivir UK Ltd., for the previous year's deficit        | 13       | 820      | _        | _          |  |
| Tax effect of deficits for which income taxes recoverable are not considered | -34,700  | -29,305  | -31,254  | -27,509    |  |
| Tax on profit/loss for the year  | 13       | 820      | -        | -          |  |

<sup>&</sup>lt;sup>1</sup> The tax credits apply to Medivir UK Ltd., ensuing from UK legislated research support, implying the definitive relinquishment of income taxes recoverable on Medivir's part. The tax credit for the year relates to the tax credit for 2008.

The group has estimated accumulated deductible deficits amounting to some SEK 1,027 m until 2009 inclusive. No related income tax receivables are reported because it is not considered likely that the group will account taxable income exceeding costs within the foreseeable future. The deductible deficits of Medivir AB and Medivir UK Ltd. have no expiry.

The temporary differences that arise from non-deductible impairment losses (due to impairment losses on Medivir AB's shares in

Medivir UK Ltd. and non-recurring impairment losses of fixed assets in the group) do not give rise to any deferred tax asset in the Balance Sheet because Medivir does not capitalize the total deductible deficits, as indicated above. There are no other temporary differences in the group. There are no temporary differences in the parent company. The tax rate in Sweden was reduced from 28% to 26.3% from 1 January 2009 onwards.

### Note 12 Earnings per share

|  | G        | roup    |
|--|----------|---------|
|  | 2009     | 2008    |
| Basic and diluted earnings per share, sek <sup>1</sup> | -6,49    | -4,76   |
| Net profit/loss  | -135,375 | -99,203 |
| Average number of shares, 000                          | 20,844   | 20,844  |

The calculation of earnings per share is based on net profit/loss divided by the average number of shares for the year.

<sup>&</sup>lt;sup>1</sup> Pursuant to IAS 33, potential ordinary shares do not cause any dilution effect if their conversion to ordinary shares results in increased earnings per share. This would be the case upon the conversion of Medivir's outstanding options.

### Note 13 Intangible fixed assets (SEK 000)

|   | Gr    | Group |       | Parent company |  |
|---|-------|-------|-------|----------------|--|
| Capitalized expenditure for research and development work <sup>1</sup> Opening acquisition cost Capitalization Closing accumulated amortization | 2009  | 2008  | 2009  | 2008           |  |
| Opening acquisition cost  | _     | _     | _     | _              |  |
| Capitalization  | 4,077 | _     | 4,077 | _              |  |
| Closing accumulated amortization  | 4,077 | _     | 4,077 | -              |  |
| Book value at year-end  | 4,077 | _     | 4,077 |                |  |

¹ Capitalized development expenditure for Xerclear™. Amortization is based on estimated useful life and is expected to start when the pharmaceutical is ready for sale in 2010. Impairment testing is conducted through recoverable amount being measured on the basis of estimated future cash flow. if the recoverable amount is less than carrying amount, an impairment loss is taken. No indication of impairment has arisen.

|                                  | Group  |        | Parent company |        |
|----------------------------------|--------|--------|----------------|--------|
| Other intangible assets 1        | 2009   | 2008   | 2009           | 2008   |
| Opening acquisition cost         | 2,270  | 2,270  | 2,270          | 2,270  |
| Capitalization                   | 586    | 0      | 586            | 0      |
| Closing accumulated amortization | 2,856  | 2,270  | 2,856          | 2,270  |
| Opening amortization             | -1,788 | -1,334 | -1,788         | -1,334 |
| Amortization for the year        | -513   | -454   | -513           | -454   |
| Closing accumulated amortization | -2,300 | -1,788 | -2,300         | -1,788 |
| Book value at year-end           | 555    | 482    | 555            | 482    |

<sup>&</sup>lt;sup>1</sup> Other intangible assets relate to capitalized development expenditure for ERP systems. The useful life is estimated at 5 years, whereby the reported asset is amortized in accordance with this estimate.

### Note 14 Fixed assets (SEK 000)

|                                      | Group   |         | Parent company |        |
|--------------------------------------|---------|---------|----------------|--------|
| Buildings and land <sup>1</sup>      | 2009    | 2008    | 2009           | 2008   |
| Opening acquisition cost             | 17,719  | 17,719  | 4,232          | 4,232  |
| Closing accumulated acquisition cost | 17,719  | 17,719  | 4,232          | 4,232  |
| Opening depreciation                 | -15,370 | -15,158 | -1,883         | -1,671 |
| Depreciation for the year            | -213    | -212    | -213           | -212   |
| Closing accumulated depreciation     | -15,583 | -15,370 | -2,096         | -1,883 |
| Book value at year-end               | 2,136   | 2,349   | 2,136          | 2,349  |

<sup>&</sup>lt;sup>1</sup> The value of buildings in the group corresponds to incurred costs of improvement in rental properties.

|   | C        | Group    |         | Parent company |  |
|---|----------|----------|---------|----------------|--|
| Equipment, tools, fixtures and fittings | 2009     | 2008     | 2009    | 2008           |  |
| Opening acquisition cost                | 137,011  | 127,800  | 122,291 | 113,080        |  |
| Purchases                               | 1,417    | 9,915    | 1,417   | 9,915          |  |
| Sales and disposals                     | -7,502   | -704     | -7,502  | -704           |  |
| Closing accumulated acquisition cost    | 130,925  | 137,011  | 116,206 | 122,291        |  |
| Opening depreciation                    | -103,596 | -94,483  | -88,876 | -79,763        |  |
| Depreciation for the year               | -9,665   | -9,657   | -9,665  | -9,657         |  |
| Sales and disposals for the year        | 7,140    | 544      | 7,140   | 544            |  |
| Closing accumulated depreciation        | -106,121 | -103,596 | -91,401 | -88,876        |  |
| Book value at year-end                  | 24,805   | 33,415   | 24,805  | 33,415         |  |

### **Finance leases**

Tangible fixed assets include leased items held through finance lease arrangements as follows:

|  | Gre  | Parent company |      |      |
|--|------|----------------|------|------|
| Equipment, tools, fixtures and fittings                      | 2009 | 2008           | 2009 | 2008 |
| Acquisition for the year                                     | 266  | _              | 266  | _    |
| Depreciation for the year                                    | -4   | _              | -4   | _    |
| Book value at year-end                                       | 262  | _              | 262  | _    |
| Future minimum lease payments have the following maturities: |      |                |      |      |
| Within one year  | 75   | _              | 75   | _    |
| Between one and five years                                   | 191  | _              | 191  | _    |
|  | 266  |                | 266  |      |

Depreciation of 4 (0) was charged to profit/loss.

### Note 15 Participations in group companies (SEK 000)

|  | Group |      | Parent company |        |
|--|-------|------|----------------|--------|
|  | 2009  | 2008 | 2009           | 2008   |
| Subsidiary:  |       |      |                |        |
| Medivir UK Ltd,  |       |      |                |        |
| Company no: 3496162, reg. office: Essex, UK                            |       |      |                |        |
| 2,000,007 shares with a nom. value of £1, participating interest 100%  | _     | _    | 0              | 0      |
| Shareholders' contribution paid to subsidiary                          | _     | _    | 11,040         | 4,800  |
| Impairment loss on participations in subsidiary                        | _     | _    | -11,040        | -4,800 |
| 2,000,007 shares with a nom. value of £1, participating interest 100%  |       |      | 0              | 0      |
| Subsidiary:  |       |      |                |        |
| Medivir Personal AB  |       |      |                |        |
| Corp. ID no.: 556598-2823, reg. office: Huddinge, Sweden               | _     | _    | 100            | 100    |
| 1,000 shares with a nom. value of SEK 100, participating interest 100% |       |      |                |        |
| Subsidiary:  |       |      |                |        |
| Medivir HIV Franchise AB   |       |      |                |        |
| Corp. ID no.: 556690-7118, reg. office: Huddinge, Sweden               |       |      |                |        |
| 1,000 shares with a nom. value of SEK 100, participating interest 100% | _     | _    | 100            | 100    |
| Total  |       |      | 200            | 200    |

### Note 16 Financial assets held for sale (SEK 000)

|                               | Gi     | Group  |        | Parent company |  |
|-------------------------------|--------|--------|--------|----------------|--|
|                               | 2009   | 2008   | 2009   | 2008           |  |
| Epiphany Biosciences          | 14,165 | 14,165 | 14,165 | 14,165         |  |
| Presidio Pharmaceuticals Inc. | 4,628  | 4,628  | 4,628  | 4,628          |  |
| Total                         | 18,793 | 18,793 | 18,793 | 18,793         |  |

## Note 17 Prepaid costs and accrued income (SEK 000)

|                                  | Group |       | Parent company |       |
|----------------------------------|-------|-------|----------------|-------|
|                                  | 2009  | 2008  | 2009           | 2008  |
| Pre-paid rent                    | 2,334 | 2,329 | 941            | 973   |
| Licensing fees                   | 1,179 | 1,696 | 1,179          | 1,696 |
| Servicing agreements             | 1,838 | 0     | 1,838          | 0     |
| Connecting to external databases | 1,359 | 3,473 | 1,359          | 3,473 |
| Other items                      | 1,681 | 1,448 | 1,681          | 1,448 |
| Total                            | 8,391 | 8,946 | 6,998          | 7,590 |

### Note 18 Other investments in securities, etc. and cash and bank balances (SEK 000)

|                               | Group   |         | Parent company |         |  |
|-------------------------------|---------|---------|----------------|---------|--|
|                               | 2009    | 2008    | 2009           | 2008    |  |
| Fixed-income and bond funds 1 | 130,402 | 227,842 | 130,402        | 227,842 |  |
| Cash and bank balances        | 13,178  | 56,644  | 10,133         | 55,429  |  |
| Total                         | 143,580 | 284,486 | 140,535        | 283,271 |  |

<sup>&</sup>lt;sup>1</sup> Book value is equal to market value.

### Note 19 Accrued costs and deferred income (SEK 000)

|  | Group  |        | Parent compar |        |
|--|--------|--------|---------------|--------|
|  | 2009   | 2008   | 2009          | 2008   |
| Accrued holiday pay                            | 10,925 | 12,209 | 10,925        | 12,209 |
| Accrued bonuses and severance pay              | 3,997  | 11,832 | 3,997         | 11,832 |
| Accrued research costs                         | 1,371  | 5,335  | 1,371         | 5,335  |
| Accrued rent                                   | 3,783  | 3,952  | 0             | 0      |
| Accrued social security costs on stock options | 3,637  | 510    | 3,637         | 510    |
| Accrued salaries                               | 3,737  | 350    | 3,737         | 350    |
| Deferred income                                | 2,928  | 23,043 | 1,136         | 21,320 |
| Other items                                    | 6,174  | 13,683 | 6,018         | 13,411 |
| Total  | 36,551 | 70,914 | 30,820        | 64,967 |

### Note 20 Operating lease arrangements incl. property rent (SEK 000)

|  | Group  |        | Parent company |       |
|--|--------|--------|----------------|-------|
|  | 2009   | 2008   | 2009           | 2008  |
| Costs for the year 1   | 10,522 | 10,859 | 4,899          | 5,098 |
| The nominal value of future minimum lease payments on irrevocable leasing contracts including property rents |        |        |                |       |
| Within one year <sup>2</sup>   | 9,214  | 10,035 | 3,798          | 4,281 |
| Between one and five years <sup>3</sup>  | 33,786 | 26,331 | 12,122         | 3,317 |
| Total  | 43,000 | 36,366 | 15,920         | 7,598 |

Primarily, costs comprise rents on property in Medivir UK Ltd. and Medivir AB. The total rental cost for the group amounts to 9,523 (9,390), of which rental costs in Medivir AB are 3,899 (3,825) and rental costs in Medivir UK Ltd. are 5,624 (5,565). Of rental costs for the year, 7,645 (7,527) has been recognized due to subletting of the research facility at Chesterford Park. Net profit from subletting of 2,021 (1,962) is reported under other income in the Income Statement. Medivir AB's rental contracts expire between 2011 and 2013, Medivir UK Ltd.'s rental contract at Chesterford Park expires in 2025. Medivir UK Ltd. is subject to indexation every fifth year. The research facility at Chesterford Park has been sublet until 2015 inclusive. The contract may be extended subsequently, and as a result, no provisioning for the period beyond 2015 has been conducted, because the judgment is that these costs will also be covered by rental income for the remaining term.

<sup>&</sup>lt;sup>2</sup> Of which 7,362 will be recognized as revenue due to subletting of the research facility at Chesterford Park.

<sup>&</sup>lt;sup>3</sup> Of which 29,449 will be recognized as revenue due to subletting of the research facility at Chesterford Park.

### Note 21 Subsequent events

### EUR 5 m milestone payment received

In late-January, Medivir received an advance milestone payment of EUR 5 m from its partner, Tibotec.

# Medivir enters agreement with Meda AB for the launch and sale of Xerese™ (Lipsovir®) in North America

In mid-January, Medivir entered an agreement for the launch and sale of Medivir's cold sore product, which will be marketed under

the brand Xerese<sup>™</sup> in North America. According to this agreement, Meda will receive exclusive rights to market, sell and distribute Xerese<sup>™</sup> in the US, Canada and Mexico for treating cold sores (labial herpes). Meda will be funding the commercial development of Xerese<sup>™</sup> and will be paying USD 5 m to Medivir in one-off payments until product launch and double-digit royalties on sales.

#### Certification

The Board of Directors and Chief Executive Officer hereby certify that the Consolidated Accounts have been prepared pursuant to IFRS (International Financial Reporting Standards) as endorsed by the EU and give a true and fair view of the group's financial position and results of operations. The Annual Accounts have been prepared pursuant to generally accepted accounting principles and give a true

and fair view of the parent company's financial position and results of operations. The Report of the Directors of the group and parent company give a true and fair view of the group's and parent company's operations, financial position and results of operations, and describe the significant risks and uncertainty factors facing the parent company and group companies.

Huddinge, Sweden, 19 February 2010

Björn C. Andersson

Board member

Ingemar Kihlström Board member Ron Long
Board member/CEO

Anna Malm Bernsten

Board member

Göran Pettersson

The Report of the Auditors was presented on 10 March 2010 PricewaterhouseCoopers AB

Claes Dahlén
Authorized Public Accountant

### AUDIT REPORT

To the Annual General Meeting of the shareholders of Medivir AB (publ) Corporate identity number 556238-4361

We have audited the Annual Accounts, the Consolidated Accounts, accounting records and the administration of the Board of Directors and the Chief Executive Officer of Medivir AB (publ) for the year 2009. The annual accounts and consolidated accounts of the company are included in this document on pages 29-61. These accounts and the administration of the company, and the application of the Swedish Annual Accounts Act when preparing the Annual Accounts, and the application of IFRS (International Financial Reporting Standards) as endorsed by the EU and the Swedish Annual Accounts Act when preparing the Consolidated Accounts, are the responsibility of the Board of Directors and the Chief Executive Officer. Our responsibility is to express an opinion on the Annual Accounts, the Consolidated Accounts and the administration based on our audit.

We conducted our audit in accordance with generally accepted accounting principles in Sweden. Those standards require that we plan and perform the audit to obtain reasonable assurance that the Annual Accounts and Consolidated Accounts are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the accounts. An audit also includes assessing the accounting principles used and their application by the Board of Directors and the Chief Executive Officer and significant estimates made by the Board of Directors and the Chief Executive Officer when preparing the Annual Accounts and Consolidated Accounts as well as evaluating the overall presentation of information in the Annual Accounts and Consolidated Accounts.

As a basis for our opinion concerning discharge from liability, we examined significant decisions, actions taken and circumstances of the company in order to be able to determine the liability, if any, to the company of any Board member or the Chief Executive Officer.

We also examined whether any Board member or the Chief Executive Officer has, in any other way, acted in contravention of the Swedish Companies Act, the Swedish Annual Accounts Act or the Articles of Association. We believe that our audit provides a easonable basis for our opinion set out below.

The Annual Accounts have been prepared in accordance with the Swedish Annual Accounts Act and give a true and fair view of the company's results of operations and financial position in accordance with generally accepted accounting principles in Sweden. The Consolidated

Accounts have been prepared in accordance with IFRS as endorsed by the EU and the Swedish Annual Accounts Act and give a true and fair view of the group's results of operations and financial position. The statutory administration report is consistent with the other parts of the Annual Accounts and Consolidated Accounts.

We recommend to the Annual General Meeting that the Income Statement and Balance Sheet for the parent company and for the group be adopted, that the loss of the parent company be dealt with in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Chief Executive Officer be discharged from liability for the financial year.

Stockholm, Sweden, 10 March 2010 PricewaterhouseCoopers AB

> Claes Dahlén Authorized Public Accountant

# SIX-YEAR SUMMARY

| Medivir group, seк 000                        | 2009        | 2008        | 2007        | 2006        | 2005        | 2004        |
|---|-------------|-------------|-------------|-------------|-------------|-------------|
|   |             |             |             |             |             |             |
| INCOME STATEMENT                              |             |             |             |             |             |             |
| Net sales <sup>1</sup>                        | 25,684      | 97,175      | 249,623     | 126,048     | 102,646     | 82,602      |
| Work performed by the company for its own use |             |             |             |             |             |             |
| and capitalized                               | 4,077       | 0           | 0           | 0           | 0           | 0           |
| Other operating income                        | 5,737       | 4,800       | 3,840       | 3,287       | 2,211       | 2,505       |
| Operating costs                               | -175,313    | -215,708    | -290,783    | -330,931    | -220,996    | -211,442    |
| Operating profit/loss                         | -139,815    | -113,733    | -37,320     | -201,596    | -116,139    | -126,335    |
| Profit/loss from financial investments        | 4,427       | 13,711      | 8,489       | 1,140       | 8,335       | 12,330      |
| Profit/loss after financial items             | -135,388    | -100,023    | -28,832     | -200,455    | -107,805    | -114,005    |
| Full tax                                      | 13          | 820         | -487        | 4,876       | 3,229       | 2,490       |
| Profit/loss after full tax                    | -135,375    | -99,203     | -29,318     | -195,580    | -104,576    | -111,515    |
|   | 31 Dec. '09 | 31 Dec. '08 | 31 Dec. '07 | 31 Dec. '06 | 31 Dec. '05 | 31 Dec. '04 |
|   |             |             |             |             |             |             |
| BALANCE SHEET                                 |             |             |             |             |             |             |
| Intangible fixed assets                       | 4,632       | 482         | 936         | 1,390       | 9,052       | 10,927      |
| Tangible fixed assets                         | 26,941      | 35,764      | 35,878      | 33,361      | 81,708      | 80,732      |
| Financial fixed assets                        | 18,793      | 18,793      | 18,793      | 0           | 47          | 47          |
| Inventories and current receivables           | 11,254      | 31,990      | 73,928      | 56,942      | 63,304      | 24,323      |
| Cash and cash equivalents and investments     |             |             |             |             |             |             |
| in securities, etc. <sup>2</sup>              | 143,580     | 284,486     | 329,330     | 195,066     | 301,875     | 440,569     |
| Equity  | 153,855     | 287,606     | 383,979     | 186,306     | 377,964     | 475,694     |
| Deferred tax liability/provisions             | 0           | 0           | 0           | 0           | 2,039       | 2,519       |
| Long-term interest-bearing liabilities        | 191         | 0           | 0           | 0           | 11,194      | 21,200      |
| Current liabilities                           | 51,154      | 83,908      | 74,887      | 100,452     | 66,827      | 59,702      |
| Total assets                                  | 205,200     | 371,515     | 458,866     | 286,758     | 455,985     | 556,597     |
| Capital employed                              | 153,855     | 287,606     | 383,979     | 193,181     | 398,325     | 506,061     |
|   |             | •           | •           | •           | •           | •           |

<sup>&</sup>lt;sup>1</sup> Net sales in 2007 mainly comprised three milestone payments totaling SEK 182.3 m for HCV protease inhibitors from Tibotec Pharmaceuticals Ltd.

<sup>&</sup>lt;sup>2</sup> The increase in cash and cash equivalents in 2007 and 2004 are due to factors including the new share issues conducted by Medivir AB in the first quarter of 2007 and the second quarter of 2004.

### KEY FIGURES

| Medivir group <sup>1</sup>                                      | 2009    | 2008    | 2007    | 2006    | 2005    | 2004    |
|---|---------|---------|---------|---------|---------|---------|
| Operating margin, %   | -544.4  | -117.0  | -15.0   | -159.9  | -113.1  | -152.9  |
| Profit margin, %  | -527.1  | -102.9  | -11.6   | -159.0  | -105.0  | -138.0  |
| Debt gearing, multiple  | 0.1     | 0.0     | 0.00    | 0.04    | 0.05    | 0.06    |
| Return on:  |         |         |         |         |         |         |
| equity, %   | -61.3   | -29.5   | -10.3   | -69.3   | -24.5   | -29.7   |
| capital employed, %   | -61.2   | -29.6   | -9.9    | -66.6   | -23.7   | -28.9   |
| total capital, %  | -46.8   | -23.9   | -7.6    | -52.8   | -21.0   | -26.2   |
| Equity ratio, %   | 75.0    | 77.4    | 83.7    | 65.0    | 82.9    | 85.5    |
| Average number of shares, 000                                   | 20,844  | 20,844  | 16,873  | 12,903  | 12,903  | 10,746  |
| Number of shares at year-end, 000                               | 20,844  | 20,844  | 20,844  | 12,903  | 12,903  | 12,903  |
| Basic and diluted earnings per share, SEK <sup>2</sup>          | -6.49   | -4.76   | -1.74   | -15.16  | -8.10   | -10.38  |
| Equity per share before and after dilution, SEK <sup>2</sup>    | 7.38    | 13.80   | 18.42   | 14.44   | 29.29   | 36.87   |
| Net worth per share before and after dilution, SEK <sup>2</sup> | 7.38    | 13.80   | 18.42   | 14.44   | 29.29   | 36.87   |
| Cash flow per share after investments, SEK                      | -6.76   | -2.14   | -4.91   | -7.39   | -2.17   | -22.12  |
| Cash flow per share after financing activities, SEK             | -6.76   | -2.14   | 7.95    | -8.28   | -10.75  | 18.74   |
| Dividend per share, SEK   | 0       | 0       | 0       | 0       | 0       | 0       |
| Number of outstanding warrants                                  | 760,000 | 970,000 | 970,000 | 676,995 | 886,995 | 646,895 |

<sup>&</sup>lt;sup>1</sup> International Financial Reporting Standards (IFRS) apply for the financial years 2004–2009. For estimated earnings per share for 2010, please refer to the heading 'Furure progress summary' on page 35 in the Report of the Directors.

### **DEFINITIONS**

### Average number of shares

The unweighted average number of shares during the year.

### **Capital employed**

Total assets less non interestbearing liabilities including deferred tax liabilities.

### Cash flow per share

Cash flow divided by the average number of shares.

### **Debt gearing**

Interest-bearing liabilities divided by shareholders' equity.

### Earnings per share

Profit after financial items less full tax divided by the average number of shares.

### **Equity ratio**

Shareholders' equity in relation to total assets.

### Full tax

Tax on profit after financial items and deferred tax on change in untaxed reserves.

### Net worth per share

Shareholders' equity plus, until 31 Dec 2004, hidden assets in listed equities less deferred tax, i.e. assets not included in ordinary operations, divided by the number of shares at the end of the period. Net worth does not include the value of research projects, patents, real estate, etc.

### Operating margin

Operating profit as a percentage of net sales.

### Profit margin

Profit after financial items as a percentage of net sales.

### Return on equity

Profit after financial items less full tax as a percentage of average shareholders' equity.

### Return on capital employed

Profit after financial items plus financial costs as a percentage of average capital employed.

### Return on total capital

Profit net of financial items plus financial costs as a percentage of average total assets.

### Shareholders' equity

Taxed shareholders' equity plus 72% of untaxed reserves.

### Shareholders' equity per share

Shareholders' equity divided by the number of shares at the end of the period.

<sup>&</sup>lt;sup>2</sup> Pursuant to IAS 35, potential ordinary shares do not give rise to any dilution effects when their conversion to ordinary shares implies an improvement to earnings per share, as would be the case coincident with the conversion of Medivir's outstanding options.

### Forthcoming financial information

- The Three-month Interim Report will be published on 29 April 2010.
- The Six-month Interim Report will be published on 8 July 2010.
- The Nine-month Interim Report will be published on 22 October 2010.

These reports will be available at Medivir's website, www.medivir.se under the heading Investor Relations, as of these dates.

Medivir sends its reports to all shareholders, except those who declined all information when registering their VP accounts.

For more information on Medivir, please contact Rein Piir, CFO and VP, Investor Relations.



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### **Annual General Meeting**

Medivir's AGM will be held in Polstjärnan Conference Center, Sveavägen 77, Stockholm, Sweden on Thursday 29 April 2010 at 3 p.m.

Shareholders intending to participate in the Annual General Meeting should

- firstly, be recorded in the shareholders' register maintained by Euroclear Sweden AB by no later than 23 April 2010 and
- secondly, notify the company of their name, address and telephone number by mail to Medivir AB, Box 1086, SE-141 22 Huddinge, Sweden or by telephone: +46 (0)8 546 83100 or fax: +46 (0)8 546 83195 or e-mail: enter@medivir.se by no later than 23 April 2010.

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# LEASE NOTE

### Important notice for nominee-registered shareholders

For entitlement to participate in the Annual General Meeting, shareholders with nominee-registered holdings should temporarily re-register their shares in their own name with Euroclear Sweden AB. Shareholders desiring such re-registration must inform their nominee thereof in good time before 23 April 2010.

