# **Annual Report 2013**







Medivir is a high-growth research-based pharmaceutical company. Our research focuses on infectious diseases, but also includes other projects. 2013 saw an important milestone in the company's history, when simeprevir was approved and sales of the product began. Simeprevir is a new protease inhibitor for the treatment of hepatitis C that has been developed in collaboration with Janssen. We also have a broad product portfolio comprising prescription pharmaceuticals that are sold in the Nordic region.

# **Research & development**

Pharmaceutical research and development is a key cornerstone of Medivir's operations. Medivir works with the entire development chain, from early research to the finished pharmaceutical product on the market. Medivir's research has a strong focus on infectious diseases and has cutting edge expertise in the fields of protease and polymerase inhibition.

The R&D portfolio comprises five pharmaceutical projects, two of which are being conducted in collaboration with partners. Three of the projects focus on the development of antiviral pharmaceuticals, of which two are in the field of hepatitis C.

The company also conducts research and development in other areas, such as bone-related disorders and neuropathic pain.

Some of the company's research operations are conducted in partnership with university groups, biotechnology and pharmaceutical companies.

# **Pharmaceuticals**

Medivir supplies prescription pharmaceuticals for large patient groups.

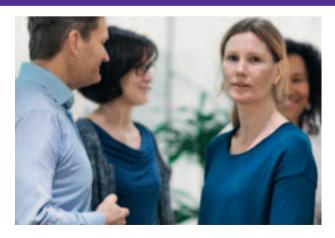
Medivir markets pharmaceuticals in the Nordic market. The product portfolio comprises sixteen prescription pharmaceuticals in a variety of different therapeutic areas. The best-known and best-established products include Citodon, Laxabon, Lithionit, Mollipect and Paraflex. Simeprevir and Adasuve will be added to the product portfolio in 2014 in conjunction with their expected launch in the Nordic region.

Simeprevir was approved in 2013 for the treatment of genotype 1 chronic hepatitis C virus in Japan, the USA and Canada.

The Group's net turnover totalled SEK 446.1 million in 2013, SEK 258.5 million of which comprised non-recurrent payments and SEK 10.5 million comprised royalty income from December for simeprevir.

Medivir has a research portfolio that is based on specific expertise. The company has a growing pharmaceutical portfolio in the Nordic market with a focus on specialty pharmaceutical products.





# Important events during the year

#### Focus on research

- > Global registration applications for simepreving were submitted by our partner, Janssen. Medivir received SEK 126.8 million in milestone payments.
- > Simeprevir achieved positive results for the treatment of hepatitis C in a number of phase III studies
- > The COSMOS study reported positive data for simeprevir in combination with sofosbuvir. Several more interferon-free combination studies with simeprevir began during the year.
- > The research portfolio was streamlined by concentrating R&D resources in the hepatitis C area exclusively on nucleotide-based polymerase inhibitors. The hepatitis C NS5A inhibitor project and the MIV-210 project for the treatment of hepatitis B, were wound up.
- > The phase I study with the cathepsin K inhibitor, MIV-711, presented positive results. Cathepsin K inhibitors may, potentially, be used for the treatment of osteoarthritis, osteoporosis and other bone-related
- > A candidate drug was selected from the cathepsin S project for the treatment of neuropathic pain. This compound, MIV-247, has now entered the preclinical development phase.

### Focus on pharmaceuticals

- > Simeprevir was approved in Japan in September (Sovriad™). Medivir received SEK 43.6 million in a milestone payment from Janssen.
- > Simeprevir was approved in Canada (Galexos™) and the USA (Olysio™) in October, triggering a payment to Medivir totalling SEK 88 million.
- > Simeprevir was launched in December when the pharmaceutical became available for patients with hepatitis C in Japan, Canada and the USA.
- > The product portfolio was expanded through agreements with the Ferrer pharmaceutical company relating to the right to sell Adasuve in the Nordic region. Adasuve has been approved for the treatment of agitation in conjunction with schizophrenia and bipolar disorder and a launch is planned for the first half of 2014.

# Focus on the company

> The Cross Pharma AB subsidiary company was divested as part of ongoing efforts to streamline the operations. Total remuneration amounted to SEK 135 million on a cash- and debt-free basis, SEK 119 million of which was paid in cash at the time of sale. The remaining purchase price will be paid by the purchaser over a threeyear period commencing on the sale date.

The Group's 402 The Group's rot turnover

Pharmaceutical projects

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In the event of any discrepancies between the Swedish and the English Annual Report, the former should have precedence.

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# One of the most important years in Medivir's history

2013 was, without doubt, one of the most eventful years in Medivir's 25-year history! The biggest single event during the year was the marketing approval of simeprevir – a pharmaceutical for the treatment of patients with chronic hepatitis C that we have helped develop.

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he approval has allowed the launch of simeprevir in Japan, Canada and the USA. Hepatitis C infected patients can now be treated using a drug that we have helped discover and develop. It is a source of great satisfaction to all Medivir employees, myself included, that we have developed a pharmaceutical all the way from a concept to a new treatment that can cure people and save lives. We expect a positive response from the European Medicines Agency (EMA) during the first six months of 2014. Simeprevir has been developed in collaboration with our partner, Janssen, as a project licensed from Medivir in 2004. The treatment regimes that have now been approved mean that simeprevir is administered together with interferon and ribavirin – two pharmaceuticals that are associated with severe adverse event profiles. One of the important goals as part of the ongoing development of simeprevir is, therefore, to develop an interferon- and ribavirin-free treatment for hepatitis C. Our partner, Janssen, is conducting a number of interferon-free clinical trials. Data were presented in November from the interferon-free COSMOS study, where the efficacy and safety of a combination treatment with simeprevir and sofosbuvir (which is marketed by Gilead) were evaluated. The study reported a high percentage of patients cured, including those with advanced liver disease. The same was also true for patients who were previous null responders. The results of the COSMOS study are extremely encouraging.

CEO's statement Medivir Annual Report 2013

Looking back on 2013, it is also clear to me that this was the year when we became a fully integrated pharmaceutical company. We now have a portfolio of sixteen pharmaceuticals within a variety of different therapeutic areas, and we established a strong Nordic marketing and sales organisation as part of our preparations for the anticipated launches of simeprevir and other specialist pharmaceuticals in the Nordic market.

### Strong innovation

Simeprevir is clear proof of Medivir's strong innovation and unique cutting edge competence. It also provides a very good illustration of the importance of collaboration and partnership with large pharmaceutical companies. Collaboration is vital if we, as a relatively small company, are to be able to play a part in the development of new pharmaceuticals with extensive clinical trials. We have long-term, in-depth experience of working in partnership with large global companies, which shows that Medivir has both considerable reputation capital and recognised scientific expertise.

We are also conducting research projects where we have not, as yet, initiated external partnerships. MIV-247, a cathepsin S inhibitor selected during the year as a candidate drug, is one example of this type of project. The compound will now enter preclinical development for the treatment of various kinds of neuropathic pain. Our cathepsin K inhibitor, MIV-711, for the potential treatment of osteoarthritis and other bone-related disorders, is another example and a project where, much to our delight, we received positive results during the course of 2013 from the recently concluded clinical phase I studies.

# An integrated pharmaceutical company

Looking back on 2013, it is also clear to me that this was the year when we became a fully integrated pharmaceutical company. We now have a portfolio of around fifteen stable, tried and trusted pharmaceuticals, and we established a strong Nordic marketing and sales organisation as part of our preparations for the anticipated launches of simeprevir and other specialist pharmaceuticals in the Nordic market.

We also made important changes to the company's structure in order to achieve an increased focus and to streamline our operations – changes that involved divesting the parallel imports operations and recruiting a number of key personnel in order to further reinforce our important R&D work.

Medivir took a number of important steps towards its goal of becoming a high-growth pharmaceutical company with sustainable profitability, in spite of the increasing demands being made on developmental pharmaceutical companies and the stiff market competition we are currently seeing. Creativity and innovation, coupled with the ability to collaborate and the courage to try new approaches, together with the attitude that we never compromise on quality and safety, are all important factors that contribute to our successes. We are also passionate about our operations and our desire to provide products that make a difference to people. We are helping to improve people's quality of life and to make their day-to-day lives healthier.

# 25th Anniversary

Medivir celebrated its 25<sup>th</sup> anniversary in 2013. The company's history has been characterised by consistent and efficient operations, good relationships with global pharmaceutical companies, and a clear focus. This has made us strong in a complex and competitive market and I am convinced that these qualities will pave the way for sustainable profitability. To date, we have successfully taken two products all the way from concept to market – one pharmaceutical for the treatment of labial herpes and another for the treatment of chronic hepatitis C.

Pharmaceutical sales of simeprevir began in December and we were delighted to receive SEK 10.5 million in royalty income from those initial sales in December. We have a stable pharmaceutical portfolio that we have expanded during the year by in-licensensing a new pharmaceutical for the treatment of agitation in conjunction with bipolar disorder and schizophrenia. Medivir is in the process of becoming a strong player in the Nordic market and will continue to focus on the development of pharmaceuticals for a global market and on the sale of pharmaceuticals in the Nordic region.

I am very proud of the dedicated work over the past 25 years that has brought us to our current position. As we move on into the next phase of the company's development, I am looking forward to an eventful period of continued growth and important steps forward in the development of new pharmaceuticals. Being involved in and contributing to improvements in people's health and quality of life is something very special.

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March 2014

Maris Hartmanis

CEO

Medivir Annual Report 2013 CEO's statement

# Focusing on longterm profitability

My goal, and that of the Board, is for Medivir to be a high-growth, researchbased pharmaceutical company with sustainable profitability.

he global economy has faced substantial challenges in 2013 and the pharmaceutical industry was naturally also affected by the financial uncertainty in the world at large. Austerity measures have resulted in, amongst other things, a reduction in the budgetary scope for health care and the increased use of generics. The costs of developing new pharmaceuticals have successively increased leading to many companies closing down or relocating large research units. The major pharmaceutical companies have also shown themselves to be inefficient when it comes to the development of new pharmaceuticals and have increasingly needed to in-license clinical development phase projects.

# **Positive performance by Medivir**

Medivir's operations have been characterised by a number of positive events during the year. I am incredibly proud of the fact that simeprevir, which we have developed in collaboration with our partner, Janssen, for the treatment of hepatitis C, has received market approval in the USA, Canada and Japan. Medivir has also strengthened its offering in the psychiatric field by in-licensing a new, specialist pharmaceutical, Adasuve, expanding our product portfolio with a prescription pharmaceutical that generates a stable revenue stream from sales in the Nordic market.

### **Focused operations**

The Board has taken a number of important decisions during the year with a view to further focusing our operations. The company's success is based on unique, cutting edge competence in proteases and polymerases and this technology platform is an important component of our future research and development strategy. Medivir will continue to work in a technology-focused way and to build on the company's core competence, rather than concentrating on therapeutic niches, because we believe that innovation and expertise are important factors that build long-term viability.

We will continue with the business model that we have previously applied and which has generated numerous successful collaborations with partners. This means that we will continue to work with partners in order to achieve income generation, cost reductions, risk reduction, and flexible capacity supply. The business model has now also been complemented with an in-house active marketing



and sales organisation in the Nordic region in response to the impending launches of simeprevir and Adasuve.

# Corporate governance

The work of the Board of Directors and its Committees complies with the Swedish Code of Corporate Governance and is characterised by a well-balanced division of responsibility between owners, the Board of Directors, and the company management. Good corporate governance is an essential component of Medivir's efforts to create value for its shareholders. We endeavour at all times to have a high level of transparency in relationships with owners, the capital market, employees, and society at large. My ambition is that everyone who contacts Medivir shall meet a company that is well run, with well-structured and orderly operations and with the right person in the right position.

#### Framework for profitability

The Board's primary focus has been on creating a good framework for Medivir's development into a successful and profitable pharmaceutical company, and this focus is also reflected in the company's strategic cornerstones – innovation-driven research and development, strong commercial operations, and sound collaborations and partnerships. Medivir's profitability over the next few years will continue to be built on strong partnerships, an expanded product portfolio and a renewed research and development strategy. We will continue to focus on hepatitis C, but we will also use our scientific core competence to engage in research and development activities that focus on the development of pharmaceuticals in other therapeutic areas.

I look forward to Medivir's future with enthusiasm and confidence!

March 2014

Göran Pettersson

Chairman of the Board

Letter from the Chairman Medivir Annual Report 2013

# Medivir from a capital markets perspective

Consistent and transparent operational reporting is a decisive and key factor in generating understanding of and confidence in Medivir's operations.

perationally speaking, 2013 was a very important year for Medivir. Significant successes for the company's research portfolio, headed by simeprevir, moved the company one step closer to sustainable profitability. Our share price also performed positively during the year, albeit with a high degree of volatility. For the year as a whole, the share gained approximately 20 per cent.

Interest in Medivir increased substantially during the year amongst both institutions and private individuals. The number of shareholders increased by just over 15 per cent and by the end of the year, we had a total of 12,696 shareholders. This has improved the trade in and liquidity of the Medivir share, but has naturally also increased the demands on us, as a company, to increase our exposure to a growing number of private shareholders.

# Increased interest in the company

A long-term perspective, consistent actions and transparency are all required in order to highlight the various aspects of our operations, whether they be early stage or more mature projects. Ethics, accuracy and relevant data are of the utmost importance in shedding light on the various projects.

Our efforts to profile and present Medivir to existing and new shareholders continue at a high level of intensity. Participation in Swedish and foreign investor seminars, meetings with individual analysts and investors, and a range of capital market activities are just some of the channels with which we are actively working. Economic reporters from various news rooms are showing increasing interest in our operations and their increased monitoring has helped boost awareness of Medivir and the company's operating conditions.

# Eventful year with the focus on Simeprevir

2013 saw simeprevir move from project to product. Simeprevir received market approval in Japan, Canada and the USA in the autumn and was launched in these markets in December. The transformation from project to a product approved for global sales, in connection with which Medivir receives global royalties from our partner, Janssen, is improving our revenue streams. It has also resulted in a partial change in the nature of the questions asked by shareholders, which have now acquired a more monetary focus.

### Transparency important in a complex market

Medivir is a research-driven pharmaceutical company with complex operations, which requires both a long-term approach and consistent action. One important component of our business model is that projects are run by partners en route to launch and sales, and this imposes certain restrictions on the information we can release to the public in relation, for example, to simeprevir. Pharmaceutical development is a global business and situations sometimes arise in which competing companies' information disclosures affect both the way in which the outside world interprets and understands Medivir and the way in which the market values the company. Pharmaceutical development in the hepatitis C area is highly competitive and it is, therefore, even more important that, wherever possible, we facilitate the monitoring of developments for our shareholders and stakeholders.

#### Focus on the future

The year ahead promises to be an extremely exciting one for Medivir. Weekly sales statistics for simeprevir from the various regional markets are generating expectations. As a listed company (with all the regulations that that entails), we report our share of the income generated by our partner's sales in different markets on a quarterly basis.

2014 will see us take a big step towards sustainable profitability. We will continue to build on and maintain our relationships and will also continue to share knowledge and explain our operations and operating conditions to a range of different stakeholder groups.

# **Analysts monitoring Medivir**

Credit Suisse

Koon Ching Ravi Mehrotra

**Danske Bank** Mattias Häggblom

**D. Carnegie AB**Carsten Lønborg Madsen
Stefan Waldenlind

Enskilda Securities Lars Hevreng

Peter Welford

Jefferies International Ltd

**Nordea Markets** Erik Hultgård

Pareto Öhman Fondkommission Yilmaz Mahshid

**Redeye** Klas Palin

**Svenska Handelsbanken** Peter Sehested

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Hevreng

Medivir Annual Report 2013 Capital market perspective

# The global pharmaceutical market

Turnover, 2012:

# SEK 4,900 bn.

Estimated growth by the end of 2018, approximately

# 4 per cent

> The USA is by far the biggest market with a share of approximately

# 40 per cent

The growth is largely driven by the developing economies in Asia and South America

**Europe's** share of the market is approximately

# 25 per cent

> The Nordic region accounts for approximately

# 7 per cent

of the European market

# **Opportunities**

- Population growth and increased life expectancy the percentage of people over the age of 65 is expected to double by 2030.
- Healthcare reforms and increased subsidies many of the larger economies are working to give uninsured people access to some degree of free health care.
- **Patient power** increased knowledge is giving patients greater influence over their treatment.
- Patent expiries a growing need on the part of the major companies to in-license new projects offers research companies greater potential to establish good revenue streams.

# Challenges

- Patent expiries reduced income due to increased competition from generics.
- Stricter regulatory requirements more stringent demands for safety and efficacy, resulting in increased costs.
- Demands for savings in public sector healthcare budgets – increased healthcare budgets are currently under discussion, e.g. in the OECD countries.

# The outside world

The pharmaceutical industry is characterised by a high degree of complexity and a rapid rate of change. Success in this market demands that we identify and understand the driving forces that have the biggest impact on both the industry as a whole and our own operations. A high degree of innovation, adjustments in line with stricter regulatory requirements, an insight into patients' needs and the behaviour of our competitors are all key factors for success. Medivir is, in these respects, well-positioned for the continued successful development of its operations.

uccessful research and development of new pharmaceuticals contribute to better health and a greater quality of life for the population at large. Access to new pharmaceuticals generates substantial value for both the healthcare sector and society as a whole, but at the same time, the development of new pharmaceuticals is becoming increasingly costly.

# Population growth and increased life expectancy

The world's population, which in 2011 was estimated at almost seven billion, is predicted to rise to almost nine billion by 2050, according to the UN. The average life expectancy worldwide is currently just over 70, corresponding to an increase of 6 years since 1990. Those who have passed the 60 year mark are expected to live for another 20 years on average, and by 2050, just over 20 per cent of the population is expected to be aged 60 or more. This doubling in the percentage of people over the age of 65 over the coming 20-year period is an important driving force in the market in that this group use, on average, between five

The outside world

Medivir Annual Report 2013

and six different types of medication simultaneously. An ageing population also entails an increase in the demand for pharmaceuticals for large disease groups.

The globalisation trend, with increased travel and increased cross-market trading, increases the risk of disease spread. This is highly significant in terms of the development of new treatments for infectious diseases – one of Medivir's focus areas. The development of resistance to anti-infective agents amongst some bacteria and viruses is a massive and rapidly growing problem and one that must be met with the development of new pharmaceuticals.

# Healthcare reforms and increased subsidies

Two of the world's biggest economies are currently in the process of introducing extensive healthcare reforms with the aim of giving all of their citizens access to health services. China is currently implementing the world's biggest healthcare reform with the ultimate goal of covering the entire population of China by 2020. The USA is implementing the so-called Affordable Care Act (Obamacare) reform which will, it is estimated, give approximately 40 million uninsured Americans access to subsidised healthcare.

#### **Patent expiries**

Many pharmaceuticals are currently approaching the expiry of their patent terms, which means that several large pharmaceutical companies risk losing up to SEK 1 billion in income over the next five years as the competition from generics increases. Ways of compensating for this trend include extending the lifespan of the pharmaceuticals and intensifying collaborations with small and medium-sized companies whose strength lies in the early research and development phases. Our partnerships with pharmaceutical companies in relation to the development in later phases have always been an important component of Medivir's business model.

# Stricter regulatory requirements

The safety and efficacy requirements imposed by authorities for the approval of a new pharmaceutical have gradually become more stringent over time. This has generally resulted in increased costs, which has, in turn, demanded increased operational quality and innovation. Researchintensive companies whose strategies entail the development of pharmaceuticals with new mechanisms of action will, in the long term, enjoy an advantage as this trend progresses.

The introduction of new pharmaceuticals on to the market has also become more complex, and additional resources must, consequently, be invested in verifying the value of a new pharmaceutical.

The rapidly growing problem of drug-resistant bacteria could result in a reduction in the authorities' requirements for the registration of new antibiotics, and hence in clinical development costs.

#### Demands for savings in public sector healthcare budgets

Many countries in the developed world have suffered economic difficulties in recent years, including substantial deficits in public sector finances and growing indebtedness. This has resulted in cut-backs in the resources available for medical and health care and the demand for more cost-effective pharmaceuticals and treatments in areas of widespread medical need will, therefore, increase.

### **Patient power**

Patients may, in future, gain a greater influence over decisions in relation to the treatment they receive. This is a natural consequence of the fact that people now know more about diseases and have the right to choose treatment alternatives. Those who do not qualify for some form of subsidy are increasingly expected to finance their own treatment. Customised treatment, known as personalised medicine, is an important element of this trend, and those companies who adapt their operations in line with this trend are expected to enjoy an advantage in the long term.

# Medivir's position

Medivir is a research-intensive pharmaceutical company that develops new pharmaceuticals for the global pharmaceutical market. We have progressed within a number of different areas during the year in order to consolidate our position as a high-growth, research-based pharmaceutical company with long-term viability. We have:

- > Established a Nordic marketing organisation;
- Made important progress in pharmaceutical research based on our core competence;
- Continued our close collaboration and strong partnerships with major pharmaceutical companies.

Medivir's research, ever since the company was founded 25 years ago, has been based on cutting edge competence in proteases and polymerases. The ability to inhibit these enzymes is an important aspect of the treatment of infectious diseases. Our unique, cutting edge competence can also be applied in other therapeutic areas, such as the treatment of bone resorption and cartilage degradation, and pain. We have, in partnership with Janssen, and taking our strong innovativeness and focused research in the areas in which we have cutting edge competence, developed simeprevir which was approved in 2013 for the treatment of chronic hepatitis C in a number of markets.

Changes in the outside world demand increased innovation, competitive expertise, and a strong focus on quality and safety. Medivir has clearly demonstrated that we have the ability to develop candidate drugs and to run clinical projects.

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Medivir Annual Report 2013 The outside world

# Business concept, goals and strategies

# **Business concept**

# Goals for 2014

# Goals 2015-2016

- To research and develop pharmaceuticals for global sales, primarily in the areas of infectious diseases, and to sell pharmaceuticals in the Nordic market
- Launch simeprevir and Adasuve on the Nordic market
- Retain good profitability in the pharmaceutical portfolio
- Implement a renewed research and development strategy
- > Expand the number of partnerships
- Further build the value of the internally-driven project portfolio
- Present the results of ongoing interferon-free studies with simeprevir for the selection of our interferon-free strategy

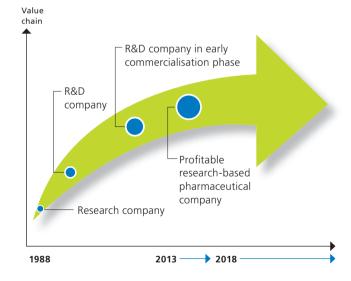
- Achieve sustainable profitability
- > Expand the Nordic pharmaceutical portfolio
- Add new projects to the research portfolio

e have continued to work in a focused way on the ongoing transformation of Medivir from a research and development company into an integrated pharmaceutical company during the year. The company is currently in an early commercialisation phase. The goal is, by focusing on our own research and development while simultaneously expanding the existing product portfolio, to achieve a lasting and sustainable level of profitability within the next couple of years.

We have taken a number of strategic decisions and implemented a range of activities designed to strengthen and develop our position in the value chain as part of our efforts to make Medivir into a profitable pharmaceutical company. These measures have included:

- In-licensing pharmaceuticals for sales by our own organisation in the Nordic region;
- Establishing a Nordic marketing and sales organisation with a presence in all of the Nordic countries;
- Strengthening our focus on early preclinical research and clinical development by recruiting personnel with key skills.

# Medivir – en route to sustainable profitability



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# Strategies for achieving our goals

# Innovative research and development:

- Continued focus on infectious diseases including hepatitis C.
- Expansion of the research operations and evaluation of new therapeutic areas based on our in-depth knowledge of proteases and polymerases.

# Establish new partnerships and collaborations:

Nurture existing collaborations and establish new ones, both within research and development and commercial operations.

# Strengthen the commercial operations:

- Prepare for a Nordic market introduction of simeprevir and Adasuve during the first half of 2014.
- Add new specialty pharmaceuticals in the growth phase to the existing portfolio in the Nordic market.

# Key achivements in 2013

- Market approval and launch of simeprevir for the treatment of chronic hepatitis C in Japan, Canada and the USA.
- > Focusing on the internal research portfolio.
- Important progress in our cathepsin S and cathepsin K programmes.
- In-licensed pharmaceutical, Adasuve, to be sold in the Nordic region by our in-house sales organisation.
- Establishment of the company's Nordic marketing and sales organisation ahead of the anticipated launches of simeprevir and Adasuve.

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• Focused operations through the divestiture of the company's parallel imports operations.

Medivir Annual Report 2013

Business concept, goals and strategies

# **Business** model

Medivir's business model is based on the development of candidate drugs until they reach what is, for the company, an optimum value, and then out-licensing them to larger global pharmaceutical companies. Medivir usually retains the rights to market and sell the pharmaceuticals in the Nordic region.

he preclinical research phase and, in some cases, the early clinical phase, form the basis for Medivir's operations. These are the phases during which candidate drugs are generated for subsequent out-licensing, primarily to major pharmaceutical companies for the expensive late development phases. The major pharmaceutical companies usually also acquire marketing and sales rights for the global market in conjunction with the out-licensing, while Medivir retains these rights in the Nordic region.

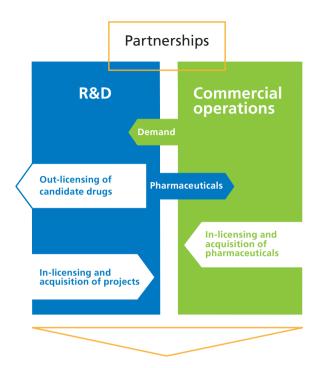
# Focus on partnerships

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Collaborations and partnerships are important elements of Medivir's current and future operations. Partnerships enable the risks to be spread while simultaneously ensuring that the research projects are conducted efficiently with access to the right skills and financial capacity. In the later development phases, partnerships are a cost-effective way of developing and value-optimising our research projects.

Partnerships also enable us to expand our pharmaceutical portfolio. Market-ready pharmaceuticals or pharmaceutical portfolios are evaluated continuously for in-licensing or acquisition purposes if they would be a good fit for Medivir's profile.

Collaboration with external partners is an important component of the business model. Our R&D organisation often conducts the projects during the early clinical phase, after which we out-license the projects to other pharmaceutical companies who assume responsibility for the subsequent development phases, market launch and sales outside the Nordic region.



#### Revenue streams:

# Ongoing pharmaceutical sales

Applies to those regions where Medivir owns marketing and sales rights. Examples include future revenues for simeprevir in the Nordic region and existing revenues from acquired and in-licensed pharmaceuticals.

# > Royalty income

Applies to the pharmaceuticals for which marketing and sales rights have been out-licensed. These currently comprise global royalty income for sales of simeprevir outside the Nordic region and of Xerclear/ZoviDuo, with the exception of sales in the USA.

### > Non-recurrent payments

Applies to out-licensing and partnership agreements concluded for out-licensed research projects, in accordance with certain agreed milestones.

Milestone payments received in 2013 comprise the revenues that Medivir has received in conjunction with the registration application and market approval of simeprevir in Japan, the USA and Canada, which totalled SEK 258.5 million (corresponding to EUR 30 million).

Business model Medivir Annual Report 2013

# From molecule to patient

Creating and developing a new pharmaceutical involves a long chain of activities from concept to market-ready pharmaceutical product.

rogressing a research concept requires biological systems and methods for the testing of new molecules that could, potentially, become a new pharmaceutical product. In the introductory phase, there might be thousands of compounds that are potential candidates for optimisation and development into a new pharmaceutical product. The important thing is to establish the molecules' ability to interact with potential target proteins and thereby successively influence the activity that triggers the disease. The goal is to identify classes of molecules that look promising for further optimisation.

#### Optimisation phase

During this phase, which demands substantial chemistry resources, the molecules' properties are optimised with regard to efficacy, safety and pharmacokinetics. Information on potential advantages over comparable pharmaceuticals is also gathered for each of these three areas. This work results in the choice of one or sometimes several candidate drugs for further development.

### **Preclinical development**

The candidate drug is first evaluated in preclinical studies, in order to establish that the compound is safe enough to enter trials on human beings. These studies form the basis for an initial application that is submitted to the relevant medicines agency. The documentation also proposes how the first clinical trials will be structured.

# Clinical trials for a new pharmaceutical product

Clinical research involves studies or trials conducted on human beings. Clinical trials follow a special process that is carefully regulated by the medicines agencies' requirements. Before a clinical trial can begin, both the medicines agency and ethical review boards must approve the design of the clinical trials. The process starts with small-scale phase I trials and ends with large-scale phase III trials, before a registration application can be submitted.

#### Phase I

Test subjects: 20 to 100 healthy volunteers, and may also, under certain circumstances, include patients with the disease in question in the latter stages of the trial. Duration: Between a few months up to one year. Purpose: To understand how the pharmaceutical is absorbed, transported round the body, and excreted, and to establish safe doses and identify side effects.

#### Phase II

*Test subjects:* Up to a few hundred patients with the disease/symptoms.

*Duration:* Between several months and two years. *Purpose:* To study the efficacy and side-effect profile and to select the dose or doses.

#### Phase III

Test subjects: Between several hundred and several thousand patients with the disease/symptoms. Duration: Depends on the disease in question, but can take up to several years.

*Purpose:* To study the efficacy and side-effect profile. Comparison studies between several types of treatment or placebos in order to evaluate the benefit/risk profile.

# Before a pharmaceutical product is approved

The next stage in the development process, once the pharmaceutical has shown itself to be safe and effective, is to apply for a licence to market the pharmaceutical. The medicines agency carries out a detailed review of the information submitted by the company. This information will typically include preclinical and clinical trial results, manufacturing and stability of the planned dosage format, e.g. tablet or infusion solution. Once all of the data has been reviewed, the authority will decide whether to approve the pharmaceutical for market introduction. This stage also involves negotiations with regard to the price.

# The entire pharmaceutical development process takes 10-15 years



Medivir Annual Report 2013 From molecule to patient 11

# Our research and development

Our research and development has taken a number of important steps forward during the past year. We have increased our focus on the company's key areas, including hepatitis C, and have also progressed the development work on our cathepsin S and cathepsin K projects and begun preparations for the new generation of projects upon which the company's future growth and development will be based.

ur expertise in the development of new pharmaceuticals is based on two approaches – the identification and optimisation of protease inhibitors and cutting edge competence in the chemistry and biochemistry of nucleoside analogues and their use as nucleotide-based polymerase inhibitors.

Our research into protease inhibitors has, amongst other things, resulted in simeprevir – a new pharmaceutical for the treatment of chronic hepatitis C.

# Our strategy for the development of new pharmaceuticals

The rapid development of effective new, direct-acting antiviral pharmaceuticals to treat hepatitis C is resulting in a stepwise reduction in the need for new hepatitis C pharmaceuticals. Medivir has, over the course of just over 10 years, built up an extensive body of biological expertise in the hepatitis C area and, at the same time, has further expanded and deepened our expertise in our core operations area with regard to the identification and optimisation of protease inhibitors and nucleotide-based polymerase inhibitors. Work on a systematic evaluation of the potential for applying our expertise in other disease areas began during the year. This strategy also takes into account the need for cost-effective R&D operations and the growing requirement to be able to demonstrate the benefits of a potential new pharmaceutical over existing forms of treatment at an early stage in the process. We anticipate completing our work on establishing our future R&D strategy in 2014.

# In-house developed pharmaceuticals and ongoing projects

		Preclini	cal phase					
Therapeutic area Project Partner	Partner	Research	Develop- ment	Phase I	Phase IIa	Phase IIb	Phase III	Market
Xerclear® (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)							
Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals							
NS5B nucleotide-based polymerase inhibitor	Janssen Pharmaceuticals							
NS5B nucleotide-based polymerase inhibitor								
Protease inhibitor	Janssen Pharmaceuticals							
tions								
Cathepsin K inhibitor								
Cathepsin S inhibitor								
	Xerclear® (Zoviduo, Zovirax Duo) Simeprevir (TMC435), NS3 protease inhibitor NS5B nucleotide-based polymerase inhibitor NS5B nucleotide-based polymerase inhibitor Protease inhibitor  tions Cathepsin K inhibitor	Xerclear® (Zoviduo, Zovirax Duo) GlaxoSmithKline (GSK) Simeprevir (TMC435), Janssen NS3 protease inhibitor Pharmaceuticals NS5B nucleotide-based polymerase inhibitor Pharmaceuticals NS5B nucleotide-based polymerase inhibitor Protease inhibitor Janssen Pharmaceuticals  tions Cathepsin K inhibitor	Project Partner Research  Xerclear® (Zoviduo, Zovirax Duo) GlaxoSmithKline (GSK) Simeprevir (TMC435), Janssen NS3 protease inhibitor Pharmaceuticals  NS5B nucleotide-based Janssen polymerase inhibitor Pharmaceuticals  NS5B nucleotide-based polymerase inhibitor  Protease inhibitor Janssen Pharmaceuticals  Cathepsin K inhibitor	Project Partner Research ment  Xerclear® (Zoviduo, Zovirax Duo) GlaxoSmithKline (GSK)  Simeprevir (TMC435), Janssen NS3 protease inhibitor Pharmaceuticals  NS5B nucleotide-based polymerase inhibitor Pharmaceuticals  NS5B nucleotide-based polymerase inhibitor  Protease inhibitor  Protease inhibitor  Cathepsin K inhibitor	Project Partner Research Development I  Xerclear® (Zoviduo, Zovirax Duo) GlaxoSmithKline (GSK)  Simeprevir (TMC435),	Project Partner Research Development I Phase IIa  Xerclear® (Zoviduo, Zovirax Duo) GlaxoSmithKline (GSK) Simeprevir (TMC435), NS3 protease inhibitor Pharmaceuticals NS5B nucleotide-based Janssen polymerase inhibitor Pharmaceuticals NS5B nucleotide-based polymerase inhibitor Protease inhibitor Janssen Pharmaceuticals  Cathepsin K inhibitor	Project Partner Research Development Phase IIa Plase IIIb  Xerclear® (Zoviduo, Zovirax Duo) GlaxoSmithKline (GSK) Simeprevir (TMC435), NS3 protease inhibitor Pharmaceuticals NS5B nucleotide-based polymerase inhibitor Pharmaceuticals NS5B nucleotide-based polymerase inhibitor Protease inhibitor Protease inhibitor  Amount of the phase Phase Phase IIIa Plase IIIa	Project Partner Research Development Phase Plase III Pla

Research and delvelopment Medivir Annual Report 2013

# Virus inhibition projects

# Hepatitis C – a rapidly changing landscape

The percentage of patients being cured in clinical trials of direct-acting antivirals has continuously increased in recent years – a trend that was also demonstrated in the results of the clinical phase III trials of simeprevir reported. More effective and safer treatments have been developed. It has also become clear that combining two or more directacting antivirals offers the potential for curing a very large percentage of patients, even without interferon. These discoveries have changed the hepatitis C field and have created a markedly complex and challenging environment for the development of new hepatitis C pharmaceuticals. The goal of most companies today, is to develop and market their own combination preparations (comprising two or more antivirals working in combination) in order to achieve a high percentage of patients cured, to maximise market shares, and to enable flexibility in pricing negotiations.

- > Hepatitis C pharmaceuticals different mechanisms Our work on the development of pharmaceuticals for the treatment of hepatitis C is based on three primary target proteins for direct-acting antivirals:
- > HCV NS3/4A protease the target for simeprevir.
- NS5B-inhibitors RNA-dependent RNA polymerases have generated two main classes of direct-acting antivirals, namely "nucleotide inhibitors" and "non-nucleoside" inhibitors of the polymerase. Nucleotide inhibitors demonstrate a superior clinical antiviral effect while simultaneously covering a broader spectrum of different hepatitis C genotypes, and have a higher barrier to resistance development during treatment.
- NS5A-inhibitors block virus replication through a mechanism that is not, as yet, fully known.

Naturally occurring variations in the amino acid sequence of the NS5A protein in different hepatitis C patients' isolates can entail resistance to the first generation of NS5A inhibitors.

New clinical data, particularly from the COSMOS study that evaluated simeprevir in combination with sofosbuvir, a nucleotide inhibitor, indicates, that very effective treatments can be achieved by combining a nucleotide inhibitor with a protease inhibitor.

### Focus on new hepatitis C pharmaceuticals

At the beginning of 2013, Medivir was running two hepatitis C projects in the optimisation phase. One of these projects involved the development of new nucleotide inhibitors, while the other focused on NS5A inhibitors with pan-genotypic coverage and improved activity against different variants of the hepatitis C virus with mutations in the NS5A gene, which are known to entail a risk of resistance development.

It became apparent in the spring that the majority of leading pharmaceutical companies already had an NS5A inhibitor in the clinical development phase, but that only two companies had nucleotide inhibitors in clinical development. The change in the competitive situation prompted our evaluation of the future commercial potential of hepatitis C pharmaceuticals in the optimisation phase. The conclusion was that the probability of successfully out-licensing a new NS5A inhibitor was very low if it was still in the early stages of research. There was, however, an ongoing need for the development of new nucleotide inhibitors, which are expected to play a key role in future combination treatments of hepatitis C. The decision was. therefore, taken to terminate the work on NS5A inhibitors and to focus our research in the hepatitis C area on the development of new nucleotide inhibitors, in order to increase the probability of identifying a candidate drug in 2014. Very good progress was made on this project in the latter half of 2013.

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# Bone-related disorder projects

# MIV-711 – a cathepsin K inhibitor for the treatment of osteoarthritis

Osteoarthritis is the most common form of joint disease and is characterised by pain and varying degrees of inflammation in one or more joints. The patient experiences pain in conjunction with movement or load-bearing and the joints most commonly affected are in the knees, hips and hands. Typical signs of osteoarthritis include degradation of the cartilage and skeletal structures in the vicinity of the joint (the bone tissue immediately under the cartilage). The incidence of osteoarthritis is increasing, partly due to an ageing population. It was estimated in 2009 that approximately 80 million people in the USA, Europe and Japan suffer from this disease. The treatment of osteoarthritis is limited to symptomatic treatment, i.e. pain relief in combination with physiotherapy, weight loss and, in more severe cases, surgical intervention. There are currently no pharmaceuticals that can halt the progress of the disease and there is, therefore, a substantial need for treatments that can arrest the progress of both cartilage breakdown and the weakening and deformation of the bones in affected joints.

# > Focus on our cathepsin K project

Cathepsin K is a protease that is primarily produced in osteoclasts, the cells in the body that resorb bone. The enzyme plays a key role in this process by breaking down the bone matrix protein known as type I collagen. Cathepsin K is also produced in cells in cartilaginous tissue, where it can resorb type II collagen and aggrecan, the primary components of cartilage matrix, resulting in cartilage loss. Recent research suggests that both bone resorption

and cartilage degradation play an important part in the development of osteoarthritis and that any future optimal treatment for osteoarthritis should, therefore, have an arresting effect on both of these processes in order to prevent the progress of the disease. As a result of its dual function, the inhibition of cathepsin K is potential highly attractive approach for the treatment of osteoarthritis and other bone-related disorders. We have achieved positive results with our in-house developed cathepsin K inhibitor, MIV-711, during the year from both preclinical and clinical trials and which support the further development of MIV-711 for the treatment of osteoarthritis.

# > MIV-711 – completion of phase I

The company's in-house developed cathepsin K inhibitor, MIV-711, demonstrated positive results in the clinical phase I trial that ended during the year. The trial evaluated safety, tolerability, pharmacokinetics and pharmacodynamics (effect on biomarkers of bone and cartilage turnover) of different doses of MIV-711 or a placebo, administered once daily for between one and 28 days. The results showed that treatment with MIV-711 is safe and well tolerated at doses that effectively reduce the resorption of bone and degradation of cartilage. MIV-711 reduced the biomarkers for bone resorption and cartilage degradation by up to 72 per cent and 55 per cent, respectively, compared with placebo. The positive results of the first clinical trial support our belief that MIV-711 has potential as a disease-modifying treatment for bone- and cartilagerelated diseases such as osteoarthritis.





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# Neuropathic pain projects

### MIV-247 - a cathepsin S inhibitor for pain

Neuropathic pain may result from an injury to or disease of parts of the nervous system that affect sensations of pain, touch, vibration and temperature. Examples of diseases with this type of chronic, nerve damage-related pain include diabetes neuropathy, postherpetic neuralgia and herniated disks or other chronic lumbar region disorders. Approximately 30 million people in the USA, Europe and Japan suffer from neuropathic pain. The few pharmaceuticals that have been approved for the treatment of neuropathic pain have a relatively limited effect, with the pain continuing to be felt by around 75 per cent of the patients treated. There is, therefore, a substantial need for new pharmaceuticals that are more effective, are faster-acting, which lack the dose-limiting side-effects of existing pharmaceuticals, and which can be used in the treatment of larger patient groups.

# > Focus on our cathepsin S project

Medivir's cathepsin S programme originally focused on autoimmune diseases, such as rheumatoid arthritis and multiple sclerosis. In recent years, however, the focus has been on neuropathic pain in line with new research suggesting that cathepsin S has an important part to play in this condition. Cathepsin S is a protease that is released from cells in the central nervous system in conjunction with a nerve injury and that triggers a local inflammatory process which, in turn, increases sensitivity to pain. Inhibiting cathepsin S reduces the inflammation and it is also possible, in many cases, to achieve an analgesic effect – something that we have been able to demonstrate in our preclinical model systems.

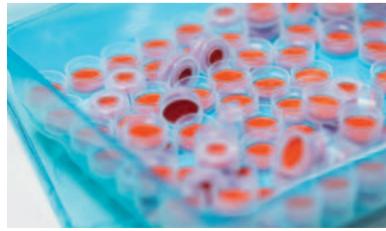
A number of molecules had been shown to have very good effects in these preclinical models by the beginning of

the year. The final aspects in need of optimisation in order to enable nomination of a candidate drug were the pharmacokinetic properties. This means, amongst other things, that the molecules must be absorbed in the gut, remain in the body for a sufficient length of time, and not break down too quickly. A number of initial safety trials were also conducted. As a result of a programme of highly purposeful work and in-depth studies of these molecules, we identified MIV-247 as an optimal candidate drug for further development for the treatment of neuropathic pain.

# > MIV-247 – exciting addition to our development

Our work on characterising the analgesic effect of MIV-247 and other selective cathepsin S inhibitors, demonstrates that the effect is not only achieved rapidly – as early as after the first dose – but that the effect in preclinical models also lasts after longer periods of administration. If this continues to be the case in a future clinical situation, it means that the patient, unlike with existing pharmaceuticals for the treatment of neuropathic pain, could obtain a good level of pain relief as early as after the first dose and, potentially, would not develop a tolerance to the treatment. Another positive new discovery was the fact that when a cathepsin S inhibitor was administered together with an existing pharmaceutical, e.g. gabapentin, a stronger analgesic effect was noted in preclinical models. This supports our belief that Medivir's cathepsin S inhibitor could, in future, be used in combination with existing pharmaceuticals in low doses in order both to maximise the treatment effect and to minimise the existing pharmaceuticals' side-effects. A great deal of work remains to be done before we can confirm these findings in clinical studies, but MIV-247 has an attractive preclinical profile and we are looking forward with great excitement to the ongoing development of MIV-247.





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# Two in-house developed pharmaceuticals

Developing a new pharmaceutical is a long process involving a number of different links in the development chain. The focus of our research is always on the patient in terms of both patient safety and patient benefit. Medivir has now developed two pharmaceutical products, all the way from concept to marketed pharmaceutical products.

#### **Xerclear**

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Xerclear was approved for the treatment of labial herpes in 2009. It is the first and only topical treatment that can both prevent the incidence of cold sores and shorten the time taken for them to heal. In Xerclear, Medivir's researchers have managed to combine the active ingredient, acyclovir, which is present in many herpes treatments, with hydrocortisone, which has an inflammation inhibitory effect. Xerclear was a completely new, patented type of treatment in which two active ingredients cooperated, resulting in both an antiviral and an anti-inflammatory effect. Clinical data from extensive clinical trials in the USA and Canada carried out by Medivir showed that Xerclear was able to prevent the incidence of cold sores in almost 50 per cent of the patients. The unique cold sore cream represented a major breakthrough for Medivir's research.

Xerclear became available in pharmacies in Sweden and Finland during the first half of 2010 and the same year, Medivir entered into two partnership agreements for the commercialisation of Xerclear. Meda became Medivir's sales and marketing partner in the USA, Canada and Mexico, while GlaxoSmithKline (GSK) became our sales and marketing partner in Europe and the rest of the world, excluding, South America, South Korea, Israel and China.

In February 2011, Xerclear was launched in the USA, Canada and Mexico by Meda. Xerclear is sold as a prescription pharmaceutical in these markets. In the summer of 2011, Medivir sold the North American marketing rights to Meda and received a substantial non-recurrent payment. GSK is responsible for OTC sales in other markets and the launch of Xerclear in major European markets will continue in 2014. The milestone payments that Medivir has received for these commercial partnership agreements have helped finance other projects within the company. Future royalties from GSK's sales will help Medivir achieve its goal of sustainable profitability.

# Simeprevir

Simeprevir is an improved second generation NS3/4A protease inhibitor that was discovered by Medivir and then developed by Janssen, Medivirs global partner of this product. Simeprevir is used in the treatment of chronic hepatitis C virus genotypes 1 and 4 patients with compensated liver disease, including liver fibrosis. Janssen is responsible for the global clinical development of simeprevir and owns the exclusive, global marketing rights, other than in the Nordic region, where Medivir holds the marketing rights.

Simeprevir, in combination with interferon and ribavirin, was approved for the treatment of hepatitis C genotype 1 patients in Japan in September 2013 and in the USA and Canada in November 2013. Sales began in December 2013.

A Marketing Authorisation Application for simeprevir in Europe was submitted to the European Medicines Agency (EMA) in April 2013. The application refers to the treatment of patients with genotype 1 and genotype 4 chronic hepatitis C infection. The development of simeprevir is described in more depth on pages 18-21

In-house developed pharmaceuticals Medivir Annual Report 2013

# What is hepatitis C?

The hepatitis C virus is a blood-borne virus. When it enters the body, the virus is carried in the blood to the liver, where it infects and damages the cells of the liver. There are six major genotypes of the hepatitis C virus: genotypes 1-6. Genotype 1, which is the most common type in Japan, western Europe and North America, is also the most difficult to treat. If the infection lasts for more than 6 months, it is known as chronic hepatitis C which can, in turn, result in chronic liver disease.



# What are the initial symptoms of hepatitis C?

The hepatitis C infection usually does not show any symptoms during the early stages of the infection. If symptoms do occur, they usually involve an influenza-like feeling of illness, with tiredness, a fever and aches throughout the body, possible pain in the area of the liver, and, in more severe cases, a jaundiced look to the skin and the whites of the eyes. These symptoms usually disappear within a few weeks but it does not necessarily mean that the infection has self-healed. The hepatitis C virus continues to relicate persistently in over 70 per cent of those infected, i. e. these people have a chronic infection. Many of them develop chronic liver disease, but many decades can pass before any symptoms of the actual liver damage from the infection become apparent.

# How is hepatitis C transmitted?

The hepatitis C virus is spread through contact with infected blood. In the developed world, HCV is now most commonly transmitted through intravenous drug abuse with dirty needles or through needle sharing. Hepatitis C can also be spread through:

- Tattooing or piercing with equipment that has not been properly cleaned, disinfected or sterilised.
- Infected blood that comes into contact with open wounds to the skin or mucous membranes of another person.
- Needle stick injuries (primarily within the health care and medical sector).
- Blood transfusions before 1992, when hepatitis C virus testing of blood transfusions was introduced.
- In rare cases, the infection can be transmitted from the mother when giving birth.
- The risk of infection during sexual contact is small and hepatitis C is not classified as a sexually transmissible infection.



# What kind of long-term damage can hepatitis C infection cause?

Around 15-20 per cent of those with chronic hepatitis C develop cirrhosis of the liver. Cirrhosis of the liver means that large parts of the liver tissue have died and been replaced by fibrous tissue, which causes severe scar formation in the liver. A severely damaged liver is unable to function as it should – so-called liver failure. The lesions caused by chronic HCV infection usually develop slowly, and it can take between 20 and 40 years before cirrhosis of the liver develops. Every year, a few per cent of those who have developed cirrhosis of the liver go on to develop liver cancer. Hepatitis C is the single most common cause of liver transplants in the west.

# How common is hepatitis C?

According to the World Health Organisation (WHO), around 170 million people worldwide are infected and it is estimated that an additional four to five million people become infected each year. In Sweden, it is estimated that around 50,000 people are infected, and that there are approximately 125,000 people with the infection in the Nordic region as a whole. Around 75 per cent of those who are infected do not know that they carry the virus. Researchers fear that cirrhosis of the liver and liver cancer resulting from hepatitis C will increase sharply between now and 2025.



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# How is hepatitis C treated?

Hepatitis C can be detected by means of a simple blood test, but few people get themselves tested. The first pharmaceutical for the treatment of hepatitis C was introduced in 1996. Later combination treatments (pegylated interferon and ribavirin) brought about a marked improvement in the results of treatment. Hepatitis C is now a therapeutic area that is the subject of intensive research and numerous clinical trials are now in progress as part of efforts to develop new treatments that are easier to administer and more effective with fewer side effects. The aim of the treatment of hepatitis C is to cure the infection and prevent the serious complications in the form of cirrhosis of the liver, liver failure and liver cancer that can occur in conjunction with chronic infection.

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# Simeprevir's history

Medivir makes progress in the wide-ranging academic collaboration with the universities of Linköping, Uppsala and Stockholm. The aim is, jointly, to identify molecules that specifically inhibit the HCV NS3/4A protease, which will be the starting point for a pharmaceutical development project.

# Simeprevir is chosen as a candidate drug for

further development. The preclinical development phase of simeprevir consequently begins in collaboration with Janssen/Tibotec. The aim is to study safety, efficacy and tolerability ahead of future clinical trials.

The first patients are treated with simeprevir

of the phase II a programme based on the good results of the phase I trials. Initially, smaller groups of patients receive simeprevir over the course of 7 days, and, in a later trial, for 28 days. The aim is to study how rapidly and to what extent simeprevir eliminates the virus in different doses.

2003

2004

2005

2006

2007

2008

Identification

Phase I

Phase II

18

Phase III

Registration and launch

The project is outlicensed to Janssen/ Tibotec for further development. The

collaboration is based on specific and highly potent HCV protease inhibitors identified by Medivir. Phase I is initiated.

All preparatory safety and toxicology trials have been completed, with good results, and simeprevir can now, for the first time, be administered to human beings. The first trial only enrols healthy volunteer subjects and the aim is to study the safety, tolerability and pharmacokinetics of simeprevir.



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### Phase IIb initiated globally.

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The study programme comprises two large-scale phase II trials – PILLAR and ASPIRE – and includes both treatmentnaïve patients and treatmentexperienced patients. The aim of these trials is to define the optimum dose and dosage period for the respective patient groups.

# A very high cure rate

is reported in all patient groups in trials of simeprevir in combination with the standard treatment of interferon and ribavirin. Even difficult-to-treat patients and those with very advanced liver disease demonstrate a very high cure rate, which is unique. Simeprevir also demonstrates a very good safety profile. The planning for phase III begins.

2012 2013 2010 2011 2009

# Phase III is initiated.

Three pivotal phase III trials are begun globally - QUEST-1, QUEST-2 and PROMISE. Four phase III trials are also launched in Japan in parallel with these trials. The first interferon-free trial of simeprevir, known as COSMOS, is initiated. The study comprises simeprevir and sofosbuvir, another directacting pharmaceutical that is currently owned by the American pharmaceutical company, Gilead.

# Very positive phase III

data is reported at the end of the year. Robust data confirms the results of the phase II trials, with high cure rates and a good safety profile. The phase III data, together with the results of a large number of smaller trials describing simeprevir's properties in specific patient populations, e.g. patients with reduced liver function or with potential interactions with other pharmaceuticals, can now begin to be compiled.

# A New Drug Application

is submitted in Japan, the USA, Canada and the EU for triple treatment with simeprevir in combination with pegylated interferon and ribavirin for patients with chronic hepatitis C.

#### Simeprevir is approved

in Japan (September) and in Canada and the USA (November) in combination with pegylated interferon and ribavirin for the treatment of chronic hepatitis C infection.

The first patients are treated with simeprevir in Japan (Sovriad™), Čanada (Galexos™) and the USA (Olysio™). The names in parentheses are the names by which simeprevir is known in the respective markets.

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# Simeprevir on the market in 2013

Simeprevir is a pharmaceutical product for the treatment of genotype 1 chronic hepatitis C. The product is approved in the USA, Japan and Canada and relates to treatment with simeprevir in combination with interferon and ribavirin.

n the autumn of 2013, simeprevir was approved in the USA, Japan and Canada under the trade names Olysio™, Sovriad™ and Galexos™, respectively. We anticipate a number of registrations in 2014, including in Europe, where a Marketing Authorisation Application for simeprevir was submitted to the European Medicines Agency (EMA) in April 2013. The application is in respect of the treatment of genotype 1 and genotype 4 chronic hepatitis C.

# The first generation of direct-acting, antiviral hepatitis C pharmaceuticals

Prior to 2011, hepatitis C treatment comprised pegylated interferon and ribavirin, which by means of, amongst other things, stimulating the body's own defences against the virus could result in the patient no longer suffering from their chronic infection, i.e. being cured. Both interferon and ribavirin are, however, associated with severe side effects and as the treatment period for this combination is 48 weeks for the genotype that is most common in the West and Japan (genotype 1) it is extremely unpleasant for the patient. In spite of the lengthy and problematic treatment, only 40-50 per cent of patients were cured. 2011 saw the introduction of the first direct-acting antivirals (DAA) on to the market, namely telaprevir and boceprevir. When these treatments are administered in addition to interferon and ribavirin, the cure rate increases to just over 70 per cent in treatment-naïve patients. Up to 25 per cent of the patients were able to halve the treatment time to 24 weeks, but the new pharmaceuticals were, unfortunately, associated with additional severe side effects. The need to develop new pharmaceuticals for the treatment of hepatitis C that were both safe and effective continued, therefore, to be substantial.

# Simeprevir – the next generation of direct-acting antiviral hepatitis C treatment

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Simeprevir is a second generation NS3/4A protease inhibitor that has been developed for the treatment of genotype 1 and genotype 4 chronic hepatitis C infection in patients with compensated liver disease, including all

stages of liver fibrosis. Simeprevir has a simple dosage profile and is administered once daily for 12 weeks. It has demonstrated stable efficacy data with a high cure rate in a broad patient population, including patients who have responded poorly or not at all to previous hepatitis C therapy. Simeprevir also has a more advantageous safety profile than the first generation of protease inhibitors. Clinical trials aimed at expanding simeprevir's usage are ongoing and the past year saw, amongst other things, the enrolment of the final patient in a large scale pivotal phase III study in China. Clinical trials were also carried out during the year on HIV patients with a hepatitis C infection and on patients infected with genotype 4 hepatitis C. Simeprevir has demonstrated very good treatment results in both of these patient groups, with a high percentage cured, even in the very difficult to treat groups. Genotype 4 hepatitis C is more common in southern Europe. North Africa and Asia and is estimated to account for up to 20 per cent of all hepatitis C in the world.

# Tomorrow's hepatitis C treatment

Many patients cannot, for medical reasons, be treated with interferon. There are also patients who, due to the severe side effects, are unwilling to commence or elect to terminate a hepatitis C treatment that includes interferon. There has been no effective form of treatment available for these large patient groups until recently. Ribavirin also has severe side effects, such as itchiness, anaemia and diarrhea. Ribavirin is also contraindicated for several patient groups. The need to develop, in particular, an interferon-free treatment for hepatitis C – but preferably also a ribavirin-free one - continues, therefore, to be substantial. There are currently a number of ongoing clinical trials clearly showing that it is possible to combine two or three direct-acting antivirals with different operating mechanisms. No such pharmaceutical combination has, however, been registered, but there are numerous ongoing phase II and phase III clinical trials of different combinations. There are currently interferon-free combinations of different direct-acting antivirals which have demonstrated a very high cure rate of over 90 per cent in early clinical trials and the first combinations are expected to reach the market in approximately one year.

# Simeprevir's development continues

A broad clinical development programme is currently in progress, studying simeprevir in various interferon-free combinations with other DAAs in order to evaluate which combination is most optimal in different patient populations. A number of phase II trials have been initiated and

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data began to be reported in 2013. Very promising interim results were reported from the COSMOS study, in which the efficacy and safety of simeprevir and sofosbuvir (a nucleotide polymerase inhibitor from Gilead) were studied. Other ongoing trials include simeprevir in combination with in-house DAAs (JNJ-56914845 and TMC647055) and in combination with DAAs from other pharmaceutical companies (daclatasvir from BMS and samatasvir from Idenix).

### COSMOS - the first interferon-free study results

The first results of the COSMOS study, which is a phase II combination study of simeprevir and sofosbuvir, were reported in 2013. These data showed that 12 weeks' treatment with simeprevir and sofosbuvir, without either interferon or ribavirin, cured a very large percentage of patients who were generally regarded as difficult to cure. In the group of patients who had previously been treated with interferon-based therapy and who had failed to respond at all, known as "null responders", 93 per cent were cured. The term, "cured", means that they had achieved SVR12 (virus-free 12 weeks after completing the treatment). In an interim analysis of a group of patients with advanced liver disease (METAVIR F3-F4), 100 per cent of treatment-naïve and 100 per cent of null responders were reported to have achieved SVR4 (virus-free 4 weeks after completing the treatment).

Simeprevir and sofosbuvir are now both registered in the US market, but the combination has not been approved as a treatment of hepatitis C in that no phase III data is currently available. In January 2014, AASLD/ IDSA/ IAS-USA announced the first new guidelines for hepatitis C treatment in the USA and these guidelines include the next generation of direct-acting antiviral hepatitis C pharmaceuticals. Treatment with a combination of simeprevir and sofosbuvir for 12 weeks, with or without ribavirin, is recommended (on the basis of the COSMOS data) for difficult-to-treat hepatitis C patients and for hepatitis C patients who cannot take interferon.

Future registrations of interferon-free simeprevir regimens will ensure that simeprevir also has a prominent part to play in tomorrow's hepatitis C therapy.

### Simeprevir in interferon-free treatments

Simeprevir is being evaluated in clinical phase II trials in combination with several DAAs with different mechanisms, with and without ribavirin, as part of new interferon-free treatments. In October 2013, Janssen Pharmaceuticals, Inc. acquired an NS5A replication complex inhibitor, GSK2336805 (now JNJ-56914845).

Ongoing interferon-free phase II trials with simeprevir:

- Simeprevir + sofosbuvir (nucleotide inhibitor, Gilead) the COSMOS study.
- Simeprevir + JNJ56914845 (NS5A inhibitor, Janssen) + TMC647055 (non-nucleoside NS5B polymerase inhibitor, Janssen)
- Simeprevir + daclatasvir (NS5A inhibitor, BMS).
- Simeprevir + samatasvir (NS5A inhibitor, Idenix) in GT1 and GT4 patients – the HELIX-1 study.
- Simeprevir + samatasvir + TMC647055 the HELIX-2 study.

# Molecular goals for hepatitis C pharmaceuticals

There are currently essentially four antiviral mechanisms/ molecular targets for new candidate drugs:

- HCV NS3/4A protease inhibitors (PI) block the enzyme activity leading, in turn, to arrest of virus propagation in the host cell. Simeprevir is a second generation protease inhibitor with a high degree of potency, high barrier to resistance, minor side effects, and better pharmacokinetics (including a once daily dosage).
- NS5A replication complex inhibitors bind to the NS5A protein, which is essential to the replication of the hepatitis C virus, hereby inhibiting virus production. The exact function of the NS5A protein is, however, not fully clear.
- Nucleotide-based NS5B polymerase inhibitors are activated in the body and thereby inhibit the hepatitis C virus' NS5B RNA polymerase. They bind to the enzyme's active site, resulting in a termination of the RNA chain's extension.
- Non-nucleoside NS5B polymerase inhibitors bind to the hepatitis C virus' NS5B RNA polymerase outside the active site, thereby resulting in a change in conformation which results in the inhibition of the polymerase's activity.

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# Our pharmaceuticals

Our aim, by selling and marketing pharmaceuticals that alleviate and cure, is to help people function in their everyday lives. Our existing pharmaceutical portfolio currently contains 16 prescription pharmaceuticals sold in the Nordic market. Our best known products are Citodon, Mollipect, Lithionit, Suscard and Laxabon.

his existing pharmaceutical portfolio enables us to offer the healthcare sector and individual patients cost-effective, tried and trusted pharmaceuticals in a number of therapeutic areas (disease groups). Our portfolio also includes new, specialist pharmaceuticals that will be launched on the Nordic market in 2014. Our primary

focus is on ensuring that the pharmaceuticals we provide give people a better quality of life by alleviating or curing a range of different diseases.

### Focus on delivery and quality

Medivir is an integrated pharmaceutical company and our organisation comprises all of the functions required to ensure a high delivery capacity and high quality of the products we deliver. Those who work with our regulatory activities track and document the changes made in relation to our pharmaceuticals, and communicate these changes to the authorities in the respective countries.

Medivir also has a pharmacovigilance department that monitors all of the news in relation to our pharmaceuticals and their active ingredients worldwide. Any aberrations, such as side effects, are reported to the authorities in accordance with a regulated monitoring system. The pharmacovigilance department also responds to medical enquiries in relation to our pharmaceuticals from patients, authorities and medical and healthcare personnel.

We have a very extensive knowledge and information base, detailing the ways in which our various pharmaceuticals work. Quality issues are always a top priority for

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Medivir and we work with quality assurance at every stage of the process. We also have a logistics department that monitors and structures transportation, to ensure that they reach the right place at the right time. The logistics department is also responsible for the choice of distribution routing and stock management, and ensures that there is an efficient product flow.

This structure is not only vital in ensuring that Medivir's existing pharmaceuticals are optimally managed, it is also a prerequisite of our ability to launch new pharmaceuticals quickly and cost-effectively.

### Increased focus on specialty pharmaceuticals

One of our primary objectives is to offer cost-effective, tried and trusted pharmaceuticals from our existing portfolio. One of our goals for the future – and one that we are getting ever closer to achieving – is also to be able to offer the medical and health care sector and patients a number of innovative specialty pharmaceuticals. There are currently a large number of diseases for which no good treatment alternatives exist. The need for new pharmaceuticals with a good efficacy profile and a minimal number of side effects is, therefore, considerable. Our ambition is to meet this demand and to improve the situation for the medical and health care sector and patients alike.

One part of this work involves developing new pharmaceuticals in collaboration with partner companies, while another comprises our ongoing evaluation of pharmaceuticals that are potential candidates for acquisition or in-licensing for the Nordic market. Our primary focus on specialist pharmaceuticals in the growth phase in these contexts is due to our profound belief in innovation and in our expertise in market launches in the specialty care field, both of which are important components of our efforts to generate long-term profitability within the company.

# Strengthening the marketing organisation

We have established a Nordic marketing and sales organisation during the year and in order to strengthen our presence and our involvement in all of the Nordic countries, we now have employees with local knowledge of the medical and health care sector and the marketing of pharmaceuticals in the respective countries. The concentrated focus on the Nordic countries is designed to ensure that our pharmaceuticals reach all of those patients who might benefit from them, not just in Sweden but in Norway, Denmark and Finland too. It is also an important part of our strategy of providing more specialty pharmaceuticals in the Nordic market. In 2014, we anticipate gaining EMA approval of simeprevir, which is developed for the treatment of chronic hepatitis C in collaboration with

our partner, Janssen. The application was submitted to the European authorities in April 2013 and, if approval is granted, Medivir will own the Nordic sales rights. We also in-licensed Adasuve during the year for the treatment of agitation in conjunction with bipolar disorder or schizophrenia. Adasuve will be launched on the Nordic market in 2014.

# Focus on the patient when introducing new pharmaceuticals

The resources available to the publicly financed medical and health care system are limited, and a number of different systems designed to evaluate the social benefit of the use of various pharmaceuticals are, therefore, being formulated on an ongoing basis in the Nordic countries.

Making new pharmaceuticals available enables us to generate increased benefit for patients and, at the same time, to generate improved commercial benefits. We have both in-house expertise and well-developed collaborations with a range of different partners that can help the authorities and medical and health care sector to evaluate the added value that our pharmaceuticals can offer in connection with various types of treatment. The pharmaceuticals that we launch shall be ready for rapid deployment by the medical and health care sector and will hence generate benefit for both individual patients and society at large.

### Our pharmaceuticals and therapeutic areas

Medivir currently markets sixteen prescription pharmaceuticals in the Nordic market. We offer pharmaceuticals in several therapeutic areas.

### Respiratory organs

The respiratory organs can be affected by a number of different diseases and symptoms, such as coughing, asthma and chronic obstructive pulmonary disease (COPD). Asthma is caused by a bronchial inflammation. COPD is a respiratory disease where the lungs have been damaged in such a way that the bronchi are narrower than normal, making oxygen absorption more difficult. Coughing, by contrast, is not a disease but a symptom and is a reflex that is triggered when the nerve endings in the bronchi are irritated.

Our pharmaceutical products in this therapeutic area are **Mollipect**, **Teovent**, and **Theo-Dur**.

#### Gout

Almost 3 per cent of the population will, according to the Swedish Rheumatism Association, suffer from gout at some point in their lives. Gout is an inflammation of the inner joint of the big toe, ankle joint, elbows, heels

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or wrists. The disease occurs when there is an imbalance in the body's uric acid levels and sodium urate crystals precipitate out from the uric acid into the joints.

Our pharmaceutical product in this therapeutic area is **Probecid**.

# The cardiovascular system

The cardiovascular system comprises the heart, blood vessels and the approximately five litres of blood transported around the body by the blood vessels. Cardiovascular diseases kill an estimated 17 million people worldwide every year, with the majority of these deaths attributable to heart attacks and strokes.

Our pharmaceutical products in this therapeutic area are **Nitroglycerin BioPhausia**, **Digoxin BioPhausia** and **Suscard**.

#### Liver disease

The liver can be impacted by a range of different diseases. Hepatitis C is a disease that occurs when the liver becomes infected with the hepatitis C virus. If the infection lasts for more than six months, it is known as chronic hepatitis C. According to the World Health Organization (WHO), around 170 million people worldwide are infected.

Our pharmaceutical product in this therapeutic area is **simeprevir** (launched in 2013 in the USA, Japan and Canada).

# The gastrointestinal system

Most people suffer from gastrointestinal problems at some point in their lives. Diarrhea and constipation are the commonest problems, and they are usually symptoms of digestive disorders, but there can also be other underlying causes. Doctors may, from time to time, need to investigate the intestines with x-rays or a colonoscopy to enable them to make the correct diagnosis, and sometimes, they may need to carry out some form of surgery on the intestines.

Our pharmaceutical products in this therapeutic area are Laxabon and Egazil.

#### Cold sores

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Most cold sores are caused by the herpes simplex virus. These viral disorders are also known as labial herpes. Herpes sores often begin with small pricking sensations and itching, followed by a reddening that develops into small blisters and sores.

Our pharmaceutical product in this therapeutic area was **Xerclear**, which is marketed by our partners, Glaxo-SmithKline and Meda.

#### **Psychiatry**

There are many different kinds of metal disorder, of which bipolar disorder, also known as manic-depressive disorder, is one example. People with bipolar disorder experience intermittent periods of unusually intense emotional states. It is estimated that approximately 5 per cent of the Swedish population suffers from bipolar disorder.

Our pharmaceutical products in this therapeutic area are **Lithionit** and **Adasuve** (launched in the spring of 2014).

# The musculoskeletal system

The musculoskeletal system is the collective name given to the skeleton, muscles, tendons and ligaments. The skeletal muscles are the active part of the musculoskeletal system and the most common cause of muscular pain is that an excessive load or strain has, in some way, been placed on the muscles. Rather than acting directly on the muscles, muscle relaxant pharmaceuticals act centrally on the brain by blocking the nerve impulses that result in the body's perception of pain.

Our pharmaceutical product in this therapeutic area is **Paraflex**.

#### Pain

When the body is injured in some way, pain receptors in the skin and the body's other tissues are activated. It is not until the pain impulse reaches the cerebral cortex that we become aware of the pain. Treating pain adequately requires a pain analysis because different types of pain require different types of treatment.

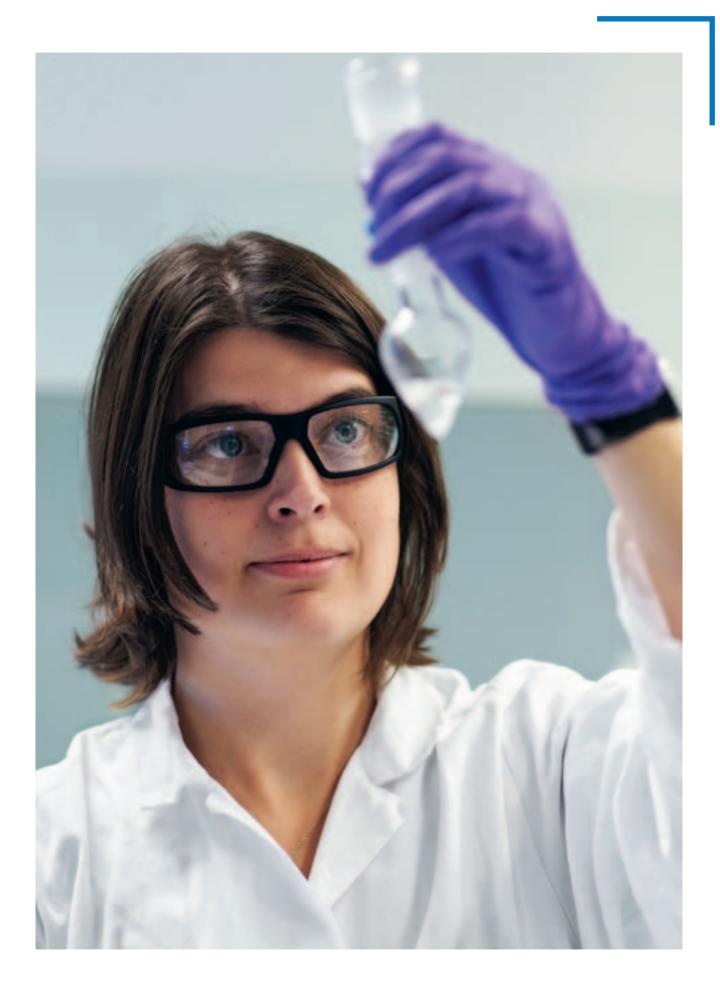
Our pharmaceutical products in this therapeutic area are **Citodon** and **Morfin Special**.

# Zinc deficiency

Vitamins and minerals fulfil many important functions in our bodies. Zinc is a mineral which, amongst other things, boosts the body's immune system, helps heal wounds, and improves vision, fertility and reproduction. The most common cause of zinc deficiency is insufficient zinc in the diet.

Our pharmaceutical product in this therapeutic area is **Solvezink**.

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# Our patents

Securing patent protection is the foundation for all new pharmaceutical projects. Patents are crucial to companies' future commercial prospects. At the same time, it is important to monitor the competition in order to avoid patent infringements.

edivir has now been granted a patent for simeprevir in 106 countries, including most of the major markets, and applications to patent offices are currently being processed in 20 further countries. The main USA patent has been extended until August 2029 and a further extension until February 2030 is expected when the clinical trials on children are com-

pleted. Everything suggests that the main EU patent



will be extended until November 2029 by means of a supplementary protection certificate (SPC) and paediatric extensions.

Medivir has been granted a patent for Xerclear in around 50 countries and in most of the major EU countries, the patent has been extended until February 2021 through an SPC.

The table below shows Medivir's key patents.

Project	Patent no.	Normal expiry	AU	BR	CA	CN	EU	IL	IN	KR	JP	MX	MY	RU	TW	US	ZA	Expiry of additional patent families
Xerclear	WO96/24355	Feb 2016					19											
	W000/29027	Dec 2019					20											
Simeprevir	WO07/014926	July 2026					36											2028
	WO05/073195	Jan 2025					35											
HCV NS5B (Janssen)	WO2010/130726	May 2030					37											2033
HCV NS5B nucleotides	Not published	Sep 2034					All											2034
HIV-PI	WO2011/070131	Dec 2030					All											
Cathepsin K	WO2010/034790	Sep 2029					33											2034
Cathepsin S	WO2011/158197	June 2031					All											2034

# **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, TW: Taiwan, US: USA, ZA: South Africa. WO is an international (PCT) patent application.

EU: A European patent can cover all of the EU member states plus a number of other European countries such as Switzerland, Iceland, Croatia, Turkey and Norway. The figure in this column shows the total number of European countries in which the patent has been validated.

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# Our Corporate Social Responsibility

Medivir develops and sells pharmaceuticals that help improve people's health and enhance their quality of life. But it is important that we take into account other factors in the value chain that help build a healthy society.

healthy environment is an important prerequisite of good health and we accordingly endeavour to be a good and responsible member of society that focuses on sustainability and ethics. This attitude shall permeate every aspect of our operations, from the way in which we run our projects on a day-to-day basis to the way in which we interact with the world around us.

#### Focus on the environment

Much of what we do, as part of our operations, is strictly regulated and governed by the authorities' requirements when it comes to our conduct. We work actively to ensure we are up to date with and comply with applicable environmental legislation, rules and guidelines. Our primary efforts in this respect involve in-house monitoring and training designed to help build increased environmental awareness amongst all of our employees. We comply with the rules and guidelines set regarding quality, the environment and the work environment and endeavour to ensure that we comply with the regulatory requirements laid down by the Swedish Work Environment Authority.

# Responsibility in practice

MIV-150 and MIV-170 were initially developed by Medivir as potential treatments for HIV.

Medivir has, as part of our CSR work, donated information, substance stocks, and development and distribution rights for MIV-150 to the USA-based non-profit organisation, the Population Council, who have developed vaginal rings that contain MIV-150, an enzyme inhibitor that prevents HIV-infected cells from producing new virus. The rings can hence block the HIV infection and are intended for free of charge distribution to women in developing countries where HIV is prevalent. Medivir has also donated the patent and development rights and substance stocks of MIV-170 to the non-profit organisation, CONRAD, which was

# An environmental policy framework

Medivir's environmental policy creates a framework for a unified and consistent approach throughout the company that focuses on our environmental impact on both our immediate environment and the markets in which we operate. We strive, at all times, to reduce our environmental impact and place particular emphasis on energy, chemicals and transport. We are able to achieve continuous improvements in these areas by reducing our energy consumption, using less hazardous substances, and choosing eco-friendly modes of transport.

Our environmental work focuses on promoting a sustainable society. Examples of our efforts in this respect include our endeavours to reduce the use of harmful substances throughout our operations, increasing the percentage of waste that we recycle, and ensuring that hazardous waste is handled in a safe and eco-friendly way. Our environmental impact and responsibility are also taken into account when choosing partners, suppliers and transport and we place great emphasis on ensuring that our partners are certified in accordance with the ISO 9001 and ISO 14001 standards.

We monitor and follow up on our environmental work continuously. In dialogues with our employees, we review what has been done and what can be done in future to reduce our environmental impact.



the first organisation in the world to demonstrate in clinical trials that a vaginal preparation of another HIV pharmaceutical, tenofovir, can prevent the spread of HIV. We are proud that our research is able to contribute to fighting HIV/AIDS and to improving women's health in low- and medium-income countries.

Medivir has also donated the development rights to uniquely potent inhibitors of the parasitic agent that causes Chagas disease. The disease is only found in the Americas, primarily in rural areas of Latin America, where there is widespread poverty. This is a potentially life-threatening disease and we are pleased to have been able to contribute to research and development in an important disease area.

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# Our employees

The focus of Medivir's HR work is on building a good working environment in which employees feel a sense of commitment to the operations and contribute ideas that help promote the company's development. Medivir's corporate culture is an important building block in the continued development of the company.

t is of the greatest importance, in ensuring our ability to retain and attract the skills needed to achieve our strategic goals, that we are perceived as an attractive employer, both by our own employees and by the outside world. A deliberate and structured programme of HR work supports the company's growth, helps generate increased profitability, and results in quality-assured HR processes.

# Focus on a good corporate culture

We have continued, in 2013, to work with the implementation of a strong, shared set of core values across the company. The core values and our value words have been formulated through internal collaborative exercises. The aim of our core values is to create a shared corporate culture that builds pride and passion within the company, as this, too, is an important step in achieving our goal of retaining and attracting employees.

All forms of collaboration are, for us, a given in ensuring our ability to progress different types of process. It is also of the utmost importance that we are focused on quality and that we are agile in our day-to-day work. We are passionate about our endeavours to develop pharmaceuticals that can improve patients' quality of life. We are creative and have the courage to take bold decisions. We

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work uncompromisingly to achieve our goals and we do not take shortcuts that may have a deleterious effect on quality or delivery capability.

All of our employees have been trained in our Code of Conduct during the year. The training took the form of discussions by various working groups on difficult issues that we may face. The aim of this work was to further strengthen and underline the importance of all employees taking an ethical approach at all times in their daily work and in all decision-making processes.

We are a value-driven company with a strong focus on our conduct towards and responsibility in relation to our employees and the outside world. This is why we have focused during the past year on the implementation and communication of our strategy, our goals and our core values in a wide range of contexts in order to ensure that everyone is fully familiar with our important steering documents.

### A happy workplace

Medivir conducts a long-term and focused programme of HR work at all levels in the company. It is a given for us that our employees should enjoy job satisfaction, be able to take pride in their work and feel a positive sense of community with their colleagues. Medivir has a high internal job satisfaction rating, which is important for an innovative company like us. We work continuously to develop processes and regulations that support our values, in order to further support this personnel policy.

If we are to be an attractive employer, it is important that we are able to offer our employees a competitive remuneration package, and in 2013 we have, therefore, implemented a three-year share saving plan in which all employees are eligible to participate. A massive 73 per cent of employees opted to participate in the share saving plan, which is clear evidence of the employees' commitment to Medivir's operations and of their faith in our future development.

#### Nordic presence imposes new demands

Medivir has established a Nordic marketing and sales organisation in 2013. We worked intensively in the autumn of 2013 on recruiting employees in the other Nordic countries in order to ensure that we have the skillsets required to launch simeprevir and other new pharmaceuticals effectively on the Nordic market.

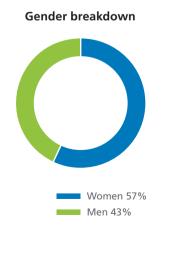
#### **Developmental and learning leadership**

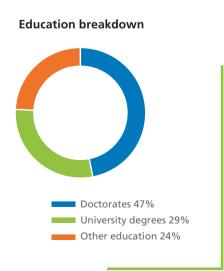
Medivir's managers shall lead not only its operations, but also its people and themselves. These three key components are the basis of our focus on competent and qualitative management, which is largely about learning to inspire and develop employees. Employees must, if they are to contribute to Medivir's development, have a good understanding of our expectations of them as individuals, and be given the right conditions and skills needed to live up to these expectations. All employees should have clear goals and receive feedback on their performance and goal fulfilment. We also measure the extent to which employees conduct themselves in accordance with our values. Good management is vital if we are to be able to manage these processes and evaluate the specific parameters that are important to each employee.

We have continued, in 2013, to implement and develop our efforts to promote good management that began in 2012. The development and training of managers and leaders is an important focal area if the company is to ensure good management, and a number of training activities have been carried out during the year. We have also encouraged a leadership collective based on internal networking. The employee survey carried out in 2013 shows that Medivir has a competitive management and leadership index.

# **Employees in figures**

- > A total of 128 employees,
- of whom 123 (70 women and 53 men) are employed in Sweden
- and of whom 5 (3 women and 2 men) are employed in the UK
- Average period of employment:7 years
- > Average age: 46
- Number of nationalities >10





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Anders Kärnell Medical Affairs Director

I have medical responsibility for Medivir's pharmaceuticals, both our current ones and those which will reach the market in future. Understanding the terms under which the medical and health care sector operates is important for us at Medivir. I am in close and regular contact with my fellow physicians in the Nordic region, telling them about our products, and hearing their points of view on diagnostics and treatment, and on what they need in their day-to-day work. This insight and know-how guide us as a company, showing us the best approach to making it easier for the individual doctor to give each patient the best possible treatment using our pharmaceuticals. I also have numerous contact interfaces within the company – from early research to marketing and sales – and these are of huge benefit to me when I meet with physicians, researchers, authorities and stakeholder organisations.

Katarina Eriksson Quality Assurance Director

The day-to-day work of the Quality Assurance department varies. We ensure that Medivir complies with the medicines agencies' requirements for the licences we hold for the manufacture and wholesale selling of pharmaceuticals. These requirements are intended to ensure that the pharmaceuticals provided to patients are safe to use. We maintain and develop the quality management system, which entails identifying, improving and enhancing the efficiency of our processes. We are responsible for ensuring that the manufacture and distribution of the company's pharmaceuticals is conducted in a quality assured way, which requires close cooperation with our contract manufacturers and wholesalers. We sometimes carry out inspections in order to ensure compliance with legislation and guidelines, both in-house and by our partners. We also take part in a variety of projects in the capacity of quality experts.





Karin Tunblad Senior Research Scientist

I work in the Drug Metabolism and Pharmacokinetics (DMPK) department. We describe the properties of new chemical compounds with the aid of "in vitro" and "in vivo" methods in order to see how the human body will handle the compound. It's all about understanding how a compound is absorbed by the body, dispersed through different tissues, broken down, and excreted from the body. Our focus is, with the help of preclinical models, on understanding the link between the concentration of a compound in the body (pharmacokinetics, PK) and the pharmacological effect of the compound (pharmacodynamics, PD). The PK-PD relationship is used to predict the concentration of a substance that will be required in order to achieve a sufficient pharmacological effect in clinical studies. Once this concentration is known, we can predict the dose and dosage interval needed to achieve a particular effect in humans.

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# Directors' Report

The Board of Directors and the President of Medivir AB (publ.), corporate ID no. 556238-4361, whose registered offices are in Huddinge, Sweden, hereby submit the Annual Report for the operations of the Group and the Parent Company, Medivir AB, (publ.) for the 2013 financial year. All figures refer to the 2013 financial year of the Group, unless otherwise indicated. Comparisons, unless otherwise indicated, are made with the 2012 financial year.

The Medivir Group comprises eight companies with sales in Sweden, Norway and Denmark. The Swedish public limited company, Medivir AB, whose shares are quoted on the Nasdaq OMX Stockholm Exchange, is the Parent Company of the Group. For additional information, please visit www.medivir.se.

### **Operations**

Medivir is a growing Nordic pharmaceutical company in which successful R&D activities in the infectious diseases area are combined with a Nordic sales organisation. The company was founded in 1988 as an offshoot of AstraZeneca's antiviral research unit. Medivir was listed on the Nasdaq OMX exchange, the Stockholm Stock Exchange's midcap list for medium-sized companies, in 1996.

Pharmaceutical research and development is an important cornerstone of Medivir's operations. There is a strong focus on infectious diseases and cutting edge competence when it comes to proteases and polymerases. Medivir has the in-house expertise to take a project from the early research stage to clinical development and sales.

Medivir has, over the years, entered into a number of successful partnerships with other pharmaceutical companies for the development of new pharmaceutical compounds and currently has a number of ongoing partnerships, in both clinical and preclinical phases, with both established pharmaceutical companies and smaller biotechnology companies.

The research portfolio comprises five pharmaceutical projects, two of which are being conducted in collaboration with partners. Three of the projects are focused on infectious diseases and two of them are in the hepatitis C area. Medivir is currently well-positioned in the hepatitis C area and in 2013, simeprevir was approved in three markets. Simeprevir has been developed by Medivir in partnership with Janssen Pharmaceuticals, and in the spring of 2013, a Marketing Authorisation Application was also submitted to the European Medicines Agency (EMA).

In 2011, Medivir acquired a commercial pharmaceutical portfolio from BioPhausia AB. This was an important stage in the company's development towards becoming a profitable, highgrowth pharmaceutical company in the Nordic region. Medivir is now a pharmaceutical company that integrates successful pharmaceutical development with a Nordic market presence. The pharmaceutical portfolio comprises 16 prescription pharmaceuticals for use in several different therapeutic areas. The best-known and most well-established pharmaceuticals include Citodon, Laxabon, Lithionit, Mollipect and Paraflex. The pharmaceutical portfolio will also, as of 2014, include simeprevir and Adasuve, which are expected to be launched in the Nordic region during the year.

The wholly owned subsidiary company, Cross Pharma, was sold during the year as part of the efforts to streamline and focus Medivir's operations.

### Significant events in 2013

# New Drug Application, approval and sales launch for Simeprevir

In the first half of 2013, Medivir's partner, Janssen, submitted New Drug Applications for simeprevir to the medicines agencies in Japan (the Ministry of Health, Labour & Welfare), the USA (FDA), and Europe (EMA). The applications were based on clinical studies of treatment with simeprevir in combination with pegylated interferon and ribavirin for genotype 1 chronic hepatitis C infection. Simeprevir was approved by the authorities in Japan, the USA and Canada during the autumn, and simeprevir is now marketed in these markets under the following brand names: Sovriad™ in Japan, Galexos™ in Canada, and Olysio™ in the USA. The treatment has been approved for adult patients with compensated liver disease (including cirrhosis) who have not been treated before (treatment-naïve) and patients who have relapsed or failed to respond to previous interferon-based treatment. Simeprevir is administered once daily for twelve weeks in combination with pegylated interferon and ribavirin. Either pegylated interferon or ribavirin is then administered in isolation for a further 12 or 36 weeks.

Medivir received milestone payments from Janssen totalling SEK 126.8 million in conjunction with the submission of the New Drug Applications.

The Japanese and American approvals jointly triggered milestone payments to Medivir of SEK 131.6 million.

# The COSMOS phase II study is evaluating Simeprevir in combination with sofosbuvir

COSMOS is an open phase IIa study that is evaluating the safety and efficacy of simeprevir in combination with sofosbuvir, with or without ribavirin, over 12 or 24 weeks. The study has enrolled patients with genotype 1 hepatitis C, divided into two cohorts. Cohort 1 comprises patients who have failed to respond to previous treatment with interferon and ribavirin (null responders) and with METAVIR scores of F0-F2. In this cohort SVR12 rates (sustained virologic response 12 weeks after end of treatment) were reported to be 96 per cent (26/27) and 93 per cent (13/14) with and without ribavirin, respectively, with 12 weeks treatment duration. Cohort 2 comprises treatment-naïve patients and null responder patients with METAVIR scores

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of F3-F4. The METAVIR score is used to quantify the degree of inflammation and fibrosis/cirrhosis in the liver on a four-grade scale where F4 corresponds to cirrhosis. In cohort 2 an interim analysis showed that the SVR4 rates were 96 per cent (26/27) and 100 per cent (14/14) with and without ribavirin, respectively, with 12 weeks treatment duration.

The COSMOS study's interim results did not show any benefit from adding ribavirin to simeprevir and sofosbuvir for these difficult-to-treat patient groups. Simeprevir and sofosbuvir, with or without ribavirin, were generally well tolerated.

# HELIX-1 and HELIX-2: two interferon-free phase II studies with Simeprevir

HELIX-1 is a 12-week randomised, double blind parallel group study that evaluates the safety, tolerability and antiviral effect of simeprevir and samatasvir (IDX719) in genotype 1b or 4 hepatitis C infected treatment-naïve non-cirrotic patients. Samatasvir is being developed by Idenix and is a pan-genotypic NS5A inhibitor that is administered once daily. The patients were randomised to receive 50, 100 or 150 mg samatasvir in combination with 150 mg simeprevir and ribavirin for 12 weeks.

HELIX-2 is the second clinical phase II study under the terms of the non-exclusive collaboration agreement between Idenix and Janssen. HELIX-2 is evaluating an all-oral, direct-acting antiviral combination treatment for hepatitis C with simeprevir, samatasvir and TMC647055, a non-nucleoside polymerase inhibitor. The study include genotype 1 hepatitis C patients who are either treatment-naïve or who have relapsed after previous treatment with interferon and ribavirin (relapsers). Patients receive 75 mg simeprevir, 50 mg samatasvir and 450 mg TMC647055 and a low dose of ritonavir as a pharmacokinetic enhancer (improves bioavailability of TMC647055), with or without ribavirin, once daily for 12 weeks.

# Phase IIa combination study with Simeprevir, TMC647055 and JNJ56914845

A clinical phase IIa study with patients who have genotype 1 chronic hepatitis C was initiated with simeprevir, TMC647055 and JNJ56914845, an NS5A replication complex inhibitor acquired by Janssen from GSK. The study is including patients who are treatment-naïve or who have relapsed after previous treatment with interferon and ribavirin (relapsers). The patients are treated once daily for 12 weeks with 75 mg simeprevir, 30 or 60 mg JNJ56914845 and 450 mg TMC647055, and a low dose of ritonavir as a pharmacokinetic enhancer. The aim is to evaluate the efficacy, safety and tolerability of 12 weeks of combination treatment.

# Phase III study, PROMISE, with Simeprevir in treatment-experienced patients with hepatitis C reported final results

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The phase III study, PROMISE, enrolled patients with genotype 1 chronic hepatitis C who had relapsed after previous interferon-based treatment. Simeprevir or placebo was administered

in addition to pegylated interferon and ribavirin for 12 weeks. Based on response-guided treatment criteria, the treatment then continued with pegylated interferon and ribavirin for either 12 or 36 weeks. The study showed that simeprevir in combination with pegylated interferon and ribavirin resulted in 79 per cent of the patients achieving SVR12, in comparison with 37 per cent in the placebo group. A majority (93 per cent) of the patients treated with simeprevir were able to conclude treatment after 24 weeks, and 83 per cent of them achieved SVR12.

# The phase III studies, QUEST-1 and QUEST-2 with Simeprevir in treatment-naïve hepatitis C patients reported final results

Two phase III studies with simeprevir, QUEST-1 and QUEST-2, evaluated simeprevir in combination with pegylated interferon and ribavirin. Data from these studies showed that SVR12 was achieved in 80 and 81 per cent, respectively, of the patients, in comparison with 50 per cent of the patients in the respective placebo groups.

# Phase III studies with Simeprevir in hepatitis C subpopulations – HCV/HIV co-infected and genotype 4

The studies were designed to evaluate simeprevir in combination with pegylated interferon and ribavirin in genotype 4 hepatitis C virus infected patients, and in genotype 1 hepatitis C virus infected patients who are co-infected with HIV-1, respectively. In the study on genotype 4 patients an interim analysis showed that SVR4 (sustained virologic response four weeks after completion of treatment) was achieved in 89 per cent of treatment-naïve patients and 91 per cent of patients who had relapsed after previous hepatitis C treatment.

The results of the study of patients with HCV/HIV co-infection showed a high cure rate, irrespective of previous hepatitis C treatment results. SVR12 was achieved in 79 per cent of the treatment-naïve patients, 87 per cent of the patients who had relapsed, 70 per cent of the patients who had partially responded to previous treatment, and 57 per cent of the patients who had failed to respond to previous treatment.

# MIV-711 for the treatment of osteoarthritis and other bone-related disorders

The company's in-house developed cathepsin K inhibitor, MIV-711, for the treatment of osteoarthritis and other bone-related disorders yielded positive results in a clinical phase I study. The study was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics (effects on biomarkers for bone and cartilage turnover) of treatment with 50 mg, 100 mg and 200 mg of MIV-711 or a placebo once daily for 7-28 days. MIV-711 reduced the biomarkers for bone resorption by up to 72 per cent and for cartilage degradation by up to 55 per cent in comparison with the placebo.

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#### MIV-247 for the treatment of neuropathic pain

MIV-247, a potent and selective cathepsin S inhibitor, was selected as a candidate drug for the treatment of neuropathic pain. MIV-247 will, therefore, now move on to preclinical development, including the safety studies required for testing on human beings in clinical trials. MIV-247 has demonstrated a good efficacy profile in experimental models for neuropathic pain with no signs of tolerance development.

### Medivir focused its research portfolio

Medivir and its partner, Daewoong Pharmaceutical Co. Ltd, agreed to terminate the development of MIV-210 for the treatment of hepatitis B. Under the terms of the partnership agreement, Daewoong was responsible for the research and development work.

Medivir also decided to focus its HCV drug discovery on nucleotide-based polymerase inhibitors and consequently ended the internally run hepatitis C virus NS5A inhibitor project.

# Nordic agreement for the marketing of a new treatment for agitation in conjunction with schizophrenia and bipolar disorder

Medivir concluded an agreement with Ferrer and thereby gained the exclusive right to market, sell and distribute Adasuve on the Nordic market, which comprises Denmark, Finland, Norway, Iceland and Sweden. Under the terms of the agreement, Medivir gained sole rights to this new treatment therapy for use with mild to moderate agitation in patients with schizophrenia or bipolar disorder. Adasuve is a hand-held inhaler that is designed to transport the pharmaceutical, loxapin, in the air inhaled into the lungs, where it has a rapid, systemic effect through a simple, non-invasive method.

Medivir paid an upfront payment to Ferrer in conjunction with the signing of the agreement. Milestone payments will then be made, based on sales performance.

#### The Group's results and financial position

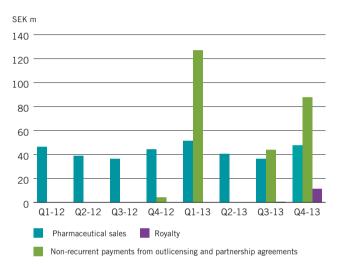
Medivir was, until 30 June 2013, organised into two operating segments. On 30 June, the wholly owned subsidiary company, Cross Pharma, which conducted parallel imports of pharmaceuticals, was sold. The Group's continuing operations consist, as of the third quarter of 2013, of one segment comprising both pharmaceutical research and development, and pharmaceutical sales. Comparisons in the Annual Report are, unless otherwise indicated, with the corresponding period in 2012.

#### **Revenues and results**

Net turnover totalled SEK 446.1 million (SEK 170.6 m), corresponding to an increase of SEK 275.5 million. Non-recurrent payments from out-licensing and partnership agreements totalled SEK 258.5 million and related both to the New Drug Application and approval for simeprevir in Japan (EUR 10 million) and the New Drug Application and approval in the USA (EUR 20 million). Royalty income from pharmaceutical sales of simeprevir and Xerclear totalled SEK 11.5 million (SEK 0.0 m), SEK 10.5 million of which comprised simeprevir. Income from

proprietary pharmaceutical sales totalled SEK 176.1 million (SEK 164.9 m), corresponding to an increase of SEK 11.2 million that resulted primarily from an increase in the number of units sold and a price increase for Mollipect. The most important products in terms of proprietary pharmaceutical sales continued to be Mollipect, Lithionit and Citodon.

Net turnover breakdown (SEK m)	2013	2012	
Out-licensing and partnership agreements Non-recurrent payments	258.5	4.4	
Pharmaceutical sales	176.1	164.9	
Royalties	11.5	_	
Other services	_	1.3	
Total	446.1	170.6	



The gross profit was SEK 374.3 million (SEK 109.3 m), corresponding to an increase of SEK 265.0 million and a gross margin of 84 per cent (64%). The increase relates primarily to the effect of non-recurrent payments and royalty income.

Operating expenses totalled SEK -349.1 million (SEK -310.7 m), corresponding to an increase of SEK 38.4 million.

Selling expenses rose by SEK 22.7 million, while administrative expenses fell by SEK 7.8 million, partly due to a SEK 17.0 million reclassification between different cost types after the divestment of the parallel imports operations, and partly due to preparations ahead of an anticipated Nordic market introduction of simeprevir. Research and development costs increased by SEK 26.0 million, largely due to an increase of SEK 13.0 million in royalty costs and to a write-down in respect of R&D assets totalling SEK 10.0 million acquired from Novadex. Other operating income/expenses increased by SEK 2.5 million, primarily as a result of exchange rate effects.

The operating profit/loss was SEK 25.2 million (SEK –201.4 m), corresponding to an increase of SEK 226.6 million. The positive change was largely due to an increase in net turnover.

Net financial items totalled SEK 2.5 million (SEK -9.4 m). A negative change in the value of shares was included in this item for the corresponding period last year.

The tax expense for the period totalled SEK –11.7 million (SEK –23.3 m). The cost comprises a reduction in the deferred tax receivable due to the utilisation of fiscal loss carry forwards.

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The profit/loss for the period from continuing operations was SEK 16.0 million (SEK –234.1 m). Basic and diluted earnings per share from the continuing operations totalled SEK 0.51 (SEK –7.49).

### Discontinued operations, parallel imports segment

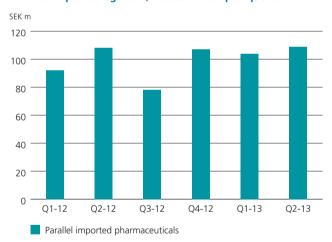
The wholly owned subsidiary company, Cross Pharma, which conducted parallel imports of pharmaceuticals, was divested on 30 June 2013. Organisationally, parallel imports had been a discrete segment prior to the sale. For details of the divestment, see Note 24 on page 79.

Parallel imports segment (SEK m)	2013	2012	
Net turnover	213.0	384.4	
EBITDA	8.2	14.4	
EBITDA %	3.8	3.7	

#### Revenues and financial results

Net turnover for the period totalled SEK 213.0 million (SEK 384.4 m). The operating profit/loss before depreciation and amortisation (EBITDA) totalled SEK 8.2 million (SEK 14.4 m), corresponding to a margin of 3.8 per cent (3.7%). The parallel imports operations were divested on 30 June and the segment consequently has no net turnover or profit/loss to report during the latter half of the year.

### Parallel imports segment, net turnover per quarter



# Cash flow and financial position

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Liquid assets, including short-term investments with a maximum term of three months, totalled SEK 296.7 million (SEK 536.3 m) at the beginning of 2013, and SEK 402.2 million (SEK 296.7 m) at the period end, corresponding to a change of SEK 105.5 million (SEK –239.6 m). Pledged assets at the period end totalled SEK 54.3 million (SEK 148.4 m). Medivir's financial assets are, in accordance with its financial policy, invested in low-risk interest-bearing securities. The company's current financial assets are, in Medivir's opinion, sufficient to ensure operational funding.

Cash flow from operating activities totalled SEK 43.0 million (SEK -139.5 m), with changes in working capital accounting for SEK -24.2 million (SEK 7.9 m) of this total. The cash flow

from investing activities was SEK 111.0 million (SEK –7.3 m) and related primarily to the divestment of the Cross Pharma subsidiary company. Other changes in investment operations related primarily to investments in research equipment and software totalling SEK 4.0 million (SEK 15.7 m).

Cash flow from financing activities amounted to SEK -48.6 million (SEK -92.8 m) and comprised primarily the amortisation of loans and current account overdrafts totalling SEK -88.6 million and the raising of loans for SEK 40.0 million.

### Investments, depreciation and amortisation

A total of SEK 3.6 million (SEK 10.6 m) was invested in tangible fixed assets during the period and related to the purchase of research equipment. Investments in intangible fixed assets totalled SEK 4.2 million (SEK 10.0 m) and related, in the main, to product rights acquired. Amortisation was charged to the profit/loss for the period in the sum of SEK –33.5 million (SEK –34.5 m), SEK –9.9 million (SEK –10.2 m) of which referred to tangible fixed assets and SEK –23.6 million (SEK –24.5 m) of which referred to intangible fixed assets. Depreciation of intangible fixed assets in the sum of SEK –10.0 million (SEK –0.0 m) was charged to the profit/loss for the period.

# **Royalty undertakings**

A significant percentage of Medivir's research and development projects work has been carried out exclusively in-house, and Medivir is consequently entitled to all revenues in respect of these inventions. A smaller percentage of Medivir's projects originate from Swedish universities. Medivir is consequently entitled to the revenues generated by these projects but obliged to pay royalties on the same.

### **Seasonal variations**

Medivir's sales and operating profit/loss are, to some extent, dependent on seasonal variations over which the company has no control. Sales of influenza- and common cold-related products during the first and fourth quarters are affected by the intensity and timing of the influenza and common cold season. This risk is, however, mitigated by the fact that Medivir has a number of other products in other therapeutic areas.

### Transactions with related parties

Transactions with related parties are on an arm's length basis. There are agreements between companies owned by senior key employees and Medivir, conferring entitlement to royalties on products that the company may develop based on patented inventions that the company has acquired from the parties in question. Payments to these parties of SEK 4.4 million (SEK 0.0 m) occurred during the period. Other services were purchased from related parties for a total of SEK 0.1 million (SEK 0.4 m). Parent company purchases from Group companies totalled SEK 0.0 (SEK 2.7 m) and sales to Group companies totalled SEK 85.3 million (SEK 36.9 m).

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#### The Parent Company in brief

Medivir AB (publ.), corporate ID no. 556238-4361, is the Parent Company of the Group. Its operations comprise research and development, marketing and sales, and administrative and company management functions.

The Parent Company's net turnover totalled SEK 327.3 million (SEK 34.3 m), corresponding to an increase of SEK 293.0 million. Non-recurrent payments for out-licensing and partnership agreements totalled SEK 258.5 million and related to both the New Drug Application and approval for simeprevir in Japan (EUR 10 million) and the New Drug Application and approval in the USA (EUR 20 million). Royalty income from pharmaceutical sales of simeprevir and Xerclear amounted to SEK 11.5 million (SEK 0.0 m), SEK 10.5 million of which related to simeprevir.

The gross profit totalled SEK 313.7 million (SEK 34.0 m), corresponding to an increase of SEK 279.7 million.

The operating costs totalled SEK –295.1 million (SEK –258.8 m), corresponding to an increase of SEK 36.3 million. Research and development costs increased by SEK 22.6 million, with the increase deriving from royalties totalling SEK 13.0 million and a write-down of SEK 10.0 million in respect of R&D assets acquired from Novadex. Selling expenses increased by SEK 17.8 million while administrative expenses increased by SEK 5.2 million attributable primarily to expanded infrastructure and to preparations ahead of the anticipated Nordic market introduction of simeprevir.

Other operating income/expenses totalled SEK 16.7 million (SEK 7.4 m), corresponding to an increase of SEK 9.3 million and primarily comprising services to Group companies.

The operating profit/loss was SEK 18.6 million (SEK –224.8 m), corresponding to an increase of SEK 243.4 million. The positive change is mainly due to a higher net turnover.

Net financial items totalled SEK 80.2 million (SEK -25.1 m), corresponding to an increase of SEK 105.3 million. Net financial items include dividends totalling SEK 120.0 million received from the BioPhausia AB subsidiary company. The net profit/loss for the period totalled SEK 98.8 million (SEK -249.9 m).

The cash flow from operating activities totalled SEK -13.0 million (SEK -229.8 m), with changes in working capital accounting for SEK -56.9 million (SEK -27.5 m).

Investments in tangible and intangible fixed assets totalled SEK 7.9 million (SEK 19.5 m) and comprised investments in research equipment and product rights.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 380.4 million (SEK 272.4 m).

#### **Employees**

Medivir's operations impose stringent demands not only on its employees, but also for an innovative and high-performing corporate culture. We work in accordance with a specific process of management by objectives and follow-up monitoring in which managers and personnel together set individual goals for the year based on the overall objectives of the company, and evaluate and appraise previous efforts. The level of commitment required demands that every employee understands both

the company's missions and objectives and the ways in which their individual performances contribute to realising them.

#### Skill development and innovation

Medivir is a knowledge-intensive company with highly educated employees. Our employees' advanced skill sets are a decisive factor in determining whether Medivir will achieve its ambitious objectives. Many employees are active participants in academic networks and consequently have access to new research findings and other know-how that contribute to the development of Medivir's operations.

#### Salaries, benefits and labour market regulations

Favourable conditions of employment are a prerequisite of Medivir's ability to recruit and retain skilled employees. Medivir endeavours to offer competitive salaries and benefits. The company conforms to the principle that salary levels should be set individually and should be differentiated, and that salaries should be set on the basis of local agreed salary criteria. Medivir complies with and respects labour market regulations and the agreements reached between labour market parties.

#### Working climate

A good working climate paves the way for job satisfaction, low sick leave levels, good relationships and low levels of staff turnover. Employee surveys are carried out on a rolling basis to ensure a positive working climate. Management and individual managers place great emphasis on the information provided by the employee surveys and work to implement changes in accordance with the results. Medivir endeavours to create a work environment that promotes health and well-being, offers its employees fitness subsidy, and pays for influenza vaccinations.

#### **Diversity and equal opportunities**

The company had a total of 117 (103) employees at the period end, 55 per cent (64%) of whom are female. Medivir's management team, including the CEO, comprised eight people (two women and six men) at the year-end, while the Board of Directors, including the Chairman, comprised eight people elected by the Annual General Meeting (two women and six men). The Board also includes two employee representatives (one woman and one man). Medivir regards it as self-evident that everyone shall be offered the same opportunities and treated in the same way, irrespective of their age, gender, religion, sexual orientation, disability or ethnic origin. Medivir has employees from more than 10 different countries. Medivir strives to be a company that offers its employees a good work-life balance.

### Occupational health & safety and environmental work

Medivir conducts an active programme of environmental work and endeavours to comply fully with all occupational health & safety-related legislation and regulations and to minimise any harmful environmental impact of our operations. Medivir's Occupational Health & Safety Policy, and our Environmental Policy, both emphasise the importance of maintaining a good

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working environment and of minimising our environmental impact. Medivir works continuously to reduce its use of environmentally hazardous substances and the company is not involved in any environmental disputes.

Our goal is to recycle everything that can be recycled. Any hazardous waste that cannot be recycled is stored, processed and disposed of in accordance with best practice. Our research facility in Huddinge generates small amounts of hazardous waste, primarily in the form of solvents and chemically contaminated materials, which are processed appropriately. We have established comprehensive routines for recycling paper, consumable plastic, glass packaging, and cardboard. All of our production of pharmaceutical products is carried out by subcontractors with whom Medivir has contractual agreements. The production facilities are located in Switzerland, Germany, Portugal, Finland, Norway and Sweden. Our manufactures are certificated in accordance with the ISO 9001 and ISO 14001 standards.

The biggest health risks arise in connection with the handling of chemicals, but by carrying out risk assessments before the laboratory experiments begin and by ensuring that all chemicals are handled correctly, the health risks are minimised. Protective equipment and clothing are used. All work with chemicals is carried out in ventilated facilities. All fume cupboards and secure benches are fitted with alarms and are inspected regularly.

Medivir conducts a systematic programme of occupational health & safety work in order to ensure continuous improvements in our employees' safety and in their work environment. The company has documented safety routines and employees receive ongoing training in safety issues. The formal occupational health & safety responsibility is delegated down the management line. An occupational health & safety group comprising managers, health & safety representatives, etc. work continuously with these issues and carry out regular health & safety inspections. Incident reporting is an important tool in improving occupational health & safety and requires all incidents and accidents to be followed up. No workplace accidents were reported to the Swedish Work Environment Authority in 2013 or 2012.

#### IT security

The importance of protecting the company's information means that IT security is a high priority concern for Medivir. The company's IT policy contains guidelines on organisation, responsibilities, authorisation, permissions administration, antivirus protection, traceability, classification of information, and operational and communications security.

All data is copied and handled in accordance with carefully defined security and backup routines. External communication is safeguarded by means of encrypted data traffic. Computers and software are secured with the aid of local hardware encryption. Medivir also works continuously to reinforce its employees' security awareness when handling both hardware and software.

#### Guidelines for remuneration to senior executives

The Board of Directors has proposed guidelines for remuneration to senior executives which broadly conform to the principles applied to the past. Senior executives in this context refers to the CEO and other members of the Group management. The guidelines apply to contracts of employment entered into after the adoption of the guidelines by the AGM or amendments to existing contracts. The guidelines essentially state that the company shall offer a competitive total compensation package that enables the recruitment and retention of qualified senior executives. Remuneration payable to the senior executives may comprise a fixed salary, performance-based pay, AGM-approved incentive schemes, pensions and other benefits. Variations to the remuneration principles are permissible if warranted by local conditions.

#### **Fixed salary**

The fixed salary should reflect the individual's areas of responsibility and experience.

#### Performance-based pay

Performance-based pay, as a cash bonus, may comprise a maximum of 50 per cent of the annual fixed salary. Performance-based pay shall be linked to predetermined and quantifiable criteria formulated in order to promote the company's long-term value creation.

#### Other benefits

The senior executives may be granted other customary benefits, such as a company car, membership of a company health care scheme, etc.

#### **Pension**

Pensions should be of the defined contribution type. The contribution payable to the CEO and other senior executives may comprise up to 35 per cent of the fixed salary. The Board of Directors shall be entitled, the above provision notwithstanding, to offer other solutions that are approximately equivalent in cost terms with the above.

#### Severance pay, etc.

A maximum mutual notice period of six months shall apply. Severance pay or similar remuneration should not, as a basic principle, be paid but may – in a lump sum payment corresponding to no more than 100 per cent of the annual fixed remuneration – be agreed in the event of a change of control.

An additional entitlement to severance pay corresponding to a maximum of 100 per cent of the annual fixed remuneration may also apply for the CEO in the event of the company terminating the employment of the CEO or of the CEO resigning due to a significant breach of contract on the part of the company.

#### Share- and share price-related incentive schemes

Share- and share price-related incentive schemes shall, where applicable, be approved by the AGM of the company's share-holders. Allocation shall be carried out in accordance with the resolution by the AGM.

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#### Non-compliance

The Board of Directors shall be entitled to deviate from the above guidelines if, in the opinion of the Board, there are specific circumstances justifying this in any individual case.

#### Previously agreed remuneration packages

There are no previously agreed remuneration packages that have not matured. For additional information, see Note 5 on page 69.

#### Remuneration paid in 2013

For details of remuneration disbursed to senior executives, please see Note 5 on page 69.

#### Details of deviations from the 2013 guidelines

The Board of Directors has not departed from the guidelines for remuneration to senior executives approved by the 2013 AGM of the company's shareholders.

#### Events after the end of the financial year Interim results from Helix-1 presented

The interim results (SVR4) from the phase II combination study, Helix-1, were presented and demonstrated that the combination treatment was well tolerated. Treatment-naïve hepatitis C patients without cirrhosis and who were infected with genotype 1b or genotype 4 HCV received 150 mg simeprevir and 50 mg samatasvir plus ribavirin for 12 weeks. 85 per cent of the patients achieved SVR4 (sustained virologic response four weeks after the treatment ended).

#### Decision to initiate the process of finding a new CEO

The Board of Directors decided to initiate the process of finding a new CEO, with a profile that has a stronger focus on business development and commercialisation. Maris Hartmanis will remain as the CEO of Medivir until a successor has been appointed.

#### SVR 12 data reported from phase IIa combination study

The results of a phase IIa study evaluating simeprevir and Daclatasvir, with and without ribavirin, were presented at the annual CROI conference (Conference on Retroviruses and Opportunistic Infections). The study was conducted by Bristol-Myers Squibb and enrolled patients with genotype 1b hepatitis C infection. The study showed that sustained virologic response 12 weeks after the treatment ended (SVR12) was achieved in between 75 and 85 per cent of treatment-naïve patients and in between 65 and 95 per cent of the patient group who had failed to respond to previous treatment after 12 or 24 weeks' treatment.

### The Nomination Committee's proposal for a new Board of Directors

The composition of the 2013-2014 Nomination Committee was as follows:

- Anders Algotsson, Chairman of the Nomination Committee, representing AFA Försäkring
- Annelie Enquist, representing Skandia Fonder
- · Göran Pettersson, Chairman of the Board of Medivir AB
- Bo Öberg, representing the class A shareholders

The Nomination Committee has agreed to propose, with reference to the upcoming 2014 Annual General Meeting, that a new Board of Directors be appointed by means of the re-election of the Board's existing Members, namely Björn C Andersson, Anna Malm Bernsten, Anders Hallberg and Birgitta Stymne Göransson, and the new election of three Members, namely Anders Ekblom, Niklas Prager and Bertil Samuelsson. Birgitta Stymne Göransson is proposed to be elected Chairman of the Board.

#### Positive data from phase III study with Simeprevir

New phase III data for simeprevir have been presented at the Conference of the Asian Pacific Association for the Study of the Liver (APASL) in Brisbane, Australia.

- In the ATTAIN study, including treatment-experienced adult patients with chronic hepatitis C virus and compensated liver disease, achieved its primary efficacy endpoint by demonstrating non-inferiority of simeprevir compared to telaprevir when both are given in combination with PegIFN/RBV. Simeprevir demonstrated superior safety profile including fewer adverse events, fewer serious adverse events and less anemia versus telaprevir.
- Pooled analysis of data from the phase III QUEST-1 and QUEST-2 studies confirmed efficacy in treatment-naïve genotype 1b HCV patients.
- In the PROMISE study, including prior relapse patients, a subgroup analysis of genotype 1b patients demonstrated that 86 percent (ITT analysis) of these patients achieved SVR12 when treated with simeprevir in combination with PeqIFN/RBV.

#### Summary of future development work

Medivir is a research-based pharmaceutical company whose focus is on infectious diseases. Its goal is to become a high-growth pharmaceutical company with sustainable profitability. Medivir is working resolutely and strategically to generate the best possible prospects for developing the company quickly while also balancing risks. The company has a solid financial position.

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New Drug Applications were filed for simeprevir in Japan and the USA in the first quarter and in Europe in the second quarter of 2013. Marketing approval was received in Japan in September 2013 and in the USA and Canada in November, while European approval is expected during the first half of 2014. Medivir has several attractive projects in the development phase, such as its in-house cathepsin K inhibitor project for bone-related disorders, the cathepsin S inhibitor project for neuropathic pain. At Janssen, a number of different combination studies with simeprevir are being conducted with the aim of developing interferon-free therapies for hepatitis C. These projects, together with research projects aimed at generating the next wave of development projects, and Medivir's intensive search for new business opportunities in the Nordic region, form the basis of our ongoing efforts to develop Medivir towards sustainable profitability.

#### **Corporate Governance**

Medivir has applied the Swedish Code of Corporate Governance since 1 July 2008. See the Corporate Governance Report on page 43.

#### **Annual General Meeting**

The Annual General Meeting will be held on 8 May 2014 at the "7A Odenplan" conference centre at Norrtullsgatan 6, Stockholm. Shareholders wishing to participate shall both be registered in the register of shareholders maintained by Euroclear Sweden AB no later than Friday, 2 May, and shall notify the company of their intention to attend using the following address: Medivir AB, Blasieholmsgatan 2, 111 48 Stockholm, Sweden, or telephone on +46 (0)8 407 64 30. The company must receive the application no later than Friday, 2 May. Updated information on the AGM is available from the company's website: www.medivir.se.

#### Proposed treatment of the unappropriated earnings

The Board of Directors proposes that the accumulated deficit be treated as follows:

Total	SEK -839,219	shall be carried forward
Profit for the year	SEK 98,798,535	
Accumulated loss	SEK -1,201,602,530	
Share premium reserve	SEK 1,101,964,776	

#### **Dividend**

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The Board of Directors proposes that no dividends be paid for the 2013 financial year.

#### Significant risks and uncertainty factors

An effective risk assessment reconciles Medivir's business opportunities and financial results with the requirements of shareholders and other stakeholders for stable, long-term value growth and control. If competing products take market shares or competing research projects achieve better efficacy and reach the market more quickly, the future value of Medivir's product and project portfolio may be lower than originally

expected. The process of research and pharmaceutical development, all the way up to approved registration, is both highly risky and capital-intensive. The majority of the projects begun never achieve market registration. Medivir's ability to produce new candidate drugs, to enter into partnerships for its projects, and to successfully develop its projects to market launch and sales, are decisive in terms of the company's future.

#### Competition

The competition within Medivir's business sector is intense and Medivir's competitors may develop, market and sell pharmaceuticals that are more effective, safer and cheaper than Medivir's. The pharmaceutical industry is a highly competitive one and there is a risk that the company will be unable to maintain its current profit margins. A number of Medivir's most significant competitors develop and market pharmaceuticals addressing the same diseases as those upon which Medivir is focusing. Competitors may also have both greater manufacturing and distribution capacity and superior pharmaceutical sales and marketing prospects than Medivir.

#### Commercial success and market acceptance

There is no guarantee, even if Medivir's project and product portfolio receives regulatory approval, that the pharmaceuticals will achieve commercial acceptance amongst physicians, patients or drug purchasing organisations. The degree of market acceptance depends on a number of different factors, including the incidence and degree of any side effects, the availability of alternative therapies, price and cost effectiveness, and sales and marketing strategies.

#### **Seasonal variations**

Medivir's sales and operating profit/loss are, to some extent, dependent on seasonal variations over which the company has no control. Sales of influenza and common cold medications are affected by the influenza and common cold season and the quarter in which it occurs. This risk is, however, mitigated by the fact that Medivir has a number of other products in other therapeutic areas.

#### **Regulatory approval**

Medivir is exposed to regulatory decisions such as the permits required to commercialise pharmaceuticals and regulatory changes with regard to pricing and discounting of pharmaceuticals, or altered conditions for prescribing a particular pharmaceutical product.

#### Product liability and insurance cover

Medivir's operations entail product liability – something that is unavoidable in conjunction with research and development, preclinical trials and clinical trials, and the production, marketing and sale of pharmaceuticals. Even if Medivir considers its existing insurance cover to be sufficient, the extent and amount of indemnity provided by the insurance cover is limited and there is, therefore, no guarantee that Medivir will receive full recompense for any damage incurred under its existing

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insurance cover. There is, equally, no guarantee that suitable insurance cover can be obtained at an acceptable cost, that such insurance cover can actually be arranged, or that product liability claims or other claims will not have a significantly negative effect on Medivir's operations and financial position.

#### **Production**

Medivir has no proprietary production and the company is consequently dependent on subcontractors for pharmaceutical production and for production for preclinical and clinical development. The relevant compound must be produced in a sufficient quantity and with sufficient quality. The risk exists that Medivir will not have the ability to satisfy its production needs at a reasonable cost at the appropriate time.

#### **Patent protection**

Medivir's future success is largely dependent on the company's ability to secure and retain protection for the intellectual property rights attributable to Medivir's products. Assessing the potential for achieving patent protection for inventions within the pharmaceutical and biotechnology areas is generally difficult and entails addressing complex legal and scientific issues. There is no guarantee that Medivir will be able to secure and retain patents for either its products or its technologies. Even if patents are issued, they may be contested, invalidated or circumvented, which will limit Medivir's ability to prevent competitors from marketing similar products and reducing the time for which Medivir has patent protection for its products.

#### Collaboration risks

Entering into collaboration agreements with pharmaceutical and biotechnology companies for the development and sales of the company's potential products is a significant component of Medivir's strategy. The success of such partnerships may vary. Conflicts or differences of opinion may arise between Medivir's partners or counterparties with regard to the interpretation of clinical data, achieving milestone payments, and interpretation of financial remuneration for or title to patents and similar rights developed within the frameworks of these partnerships. A few partnership collaborations are presently responsible for

a large percentage of Medivir's current and future potential revenues and these partners are, in many cases, significantly larger than Medivir.

#### Safety and efficacy criteria in clinical trials

Medivir and/or its partner must, before launching any of Medivir's pharmaceutical compounds, demonstrate that the pharmaceutical complies with the stringent safety and efficacy norms set by the regulatory authorities in the countries in which Medivir plans to market the pharmaceutical. The process for obtaining regulatory authorisation usually demands extensive preclinical and clinical trials, which are extremely costly and take a very long time. The FDA, EMA and other regulatory authorities may delay, restrict or refuse authorisation for a number of reasons, including the possibility that a pharmaceutical is unsafe or ineffective. If Medivir is unable to obtain authorisation for its existing or future candidate drugs, it will be unable to market or sell them. Any deficiencies or delays in the implementation of preclinical or clinical trials will reduce or delay Medivir's ability to generate revenues from the commercialisation of these candidate drugs and may have a significant negative effect on Medivir's ability to retain and complement its project portfolio.

#### Reliance on key employees

Medivir is very reliant on certain key employees. The ability to recruit and retain qualified employees is of the utmost importance in ensuring the requisite level of expertise within the company.

#### **Financial risks**

Medivir has, historically, posted losses and there is no guarantee that Medivir will, in future, be able to report a profit, nor is there any guarantee that it will be possible for Medivir to obtain the capital it requires on terms that are acceptable to Medivir. New partnerships and those already entered into may have a significant impact on Medivir's future revenues and cash position. For a detailed presentation of financial risks, such as currency risk, interest rate risk, credit risk and liquidity risk, see Note 8 on page 71.

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# The Medivir share

Medivir's class B share has been listed on the Nasdaq OMX Stockholm Exchange since 1996, with all trade taking place on the Mid Cap list. The class A share, which carries enhanced voting rights, is not listed.

#### Share structure, earnings per share, and equity

There were a total of 31,260,027 (31,260,027) shares in Medivir AB at the year-end, 660,000 (660,000) of which were class A shares and 30,600,027 (30,600,027) class B shares with a nominal value of SEK 5. The average number of shares during the year was 31,260,027 (31,256,927). All shares are equally entitled to participation in Medivir's assets and profits. Class A shares carry 10 voting rights while class B shares carry 1 voting right. The share capital at the year-end was SEK 156.3 million (SEK 156.3 m) and the equity totalled SEK 852.6 million (SEK 874.9 m). Basic and diluted earnings per share, based on a weighted average number of outstanding shares, were SEK 0.51 (SEK -7.49). Equity per share was SEK 27.27 (SEK 27.99). The equity/assets ratio was 85.7 per cent (81.3%). For a presentation of Medivir's financial risks and principles applied for financial risk management, see Note 8, "Financial risks", on page 71.

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#### **SHARE STRUCTURE 31 DECEMBER 2013**

Share class	Number of shares	Number of votes	% of capital	% of votes	Shares after full exercise of options
A, 10 votes	660,000	6,600,000	2.1	17.7	660,000
B, 1 vote	30,600,027	30,600,027	97.9	82.3	31,004,401
Total	31,260,027	37,200,027	100.0	100.0	31,664,401

#### **Shareholders**

There were a total of 12,696 (11,004) shareholders at the yearend, 11,026 (9,672) of whom held 1,000 or fewer shares. The ten biggest shareholders accounted for 34.0 per cent (34.0%) of the total number of shares and 45.0 per cent (45.6%) of the total number of votes. Bo Öberg was the largest shareholder by votes, followed by Nils-Gunnar Johansson and Staffan Rasjö. Foreign owners accounted for 19.9 per cent (27.9%) of the total equity. For additional information on the ownership structure, see page 42.



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#### Share price performance and turnover, 2013

Medivir's share price rose by 22,5 per cent from SEK 69 to SEK 84.5 in 2013. The Nasdaq OMX Stockholm Stock Exchange's Mid Cap index (OMX-SMCPI) rose by 44.7 per cent during the same period. Medivir's market capitalisation at the end of 2013 was SEK 2.64 billion, based on the closing price paid at the year-end of SEK 84.5. A total of 28, 466, 238 Medivir shares were traded on the Nasdaq OMX Stockholm Stock Exchange in 2013, corresponding to a turnover rate of 99 per cent in comparison with one of 67 per cent for the Nasdaq OMX Stockholm Stock Exchange. The share price on 28 February 2014 was SEK 114.5, corresponding to a market capitalisation of SEK 3.58 billion.

#### Beta value

On 31 December 2013, Medivir's class B share had a weighted beta value in comparison with the exchange's general index of 0.87. The beta value is based on historic values for the share's closing price paid on the final day of trading in each of the last 24 months. The same measurement is applied to the Nasdaq OMX Stockholm Stock Exchange's 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, the share's beta value is 1.0. If the share has been more volatile than the index, the value is higher than 1.0, and vice versa.

#### **Dividend policy**

A proposal for a dividend policy will not be raised until such time as long-term profitability can be predicted as a result of the launch of new pharmaceuticals on the market.

#### Share-related incentive plans

The intention of share-related incentive plans is to promote the company's long-term interests by motivating and rewarding the company's senior executives and other members of staff. Medivir currently has one active share-related incentive plan.

#### Share saving plan 2013 (LTI 2013)

The Share saving plan 2013 (LTI 2013) is a three year, performance- based share-related incentive programme that was approved at the Annual General Meeting held on 6 May 2013. The Share saving plan has been offered to all permanent employees of Medivir AB, on equal terms for the CEO, other senior executives, and other employees. Participation in LTI 2013 is contingent upon the employee making a personal investment by buying shares in Medivir at the market rate - so-called savings shares. The participant may, within the framework of LTI 2013 and over the course of one year, invest a sum corresponding to no more than one twelfth of their fixed annual basic salary before tax. Provided that the participant stays with the company for three years, the participant will receive one matching share warrant and up to three performance-based share warrants for every savings share in which they invest. The performance-based share warrants are based on the strategic

development of Medivir's research and product portfolios and earnings per share during the period from 2013 to 2015. 73 per cent of all permanent employees have opted to participate in the plan, including the CEO, who has invested SEK 0.3 million (4,341 shares), and other senior executives, who have invested SEK 0.6 million (9,544 shares).

LTI 2013 will be reported in accordance with "IFRS 2 – Sharebased payment". The maximum number of class B shares in Medivir that may be disbursed in accordance with the plan, including those additional shares that may be obtained through the exercise of warrants, is 249,110 class B shares corresponding to approximately 0,79 per cent of the total number of shares and approximately 0.67 per cent of the total number of votes in Medivir.

The maximum amount by which the share capital can increase is SEK 1.2 million. SEK 2.0 million in costs in connection with LTI 2013, including the cost of social security contributions, has, in accordance with certain assumptions such as share price performance, participation, and staff turnover, been charged to the profit/loss.

The right of disposal must exist with regard to the warrants and the shares that will be disbursed through the exercise of the warrants in order to enable the shares to be disbursed to the participants at the end of the programme. The warrants are also issued in order to hedge the cash flow costs of the programme for the Group, such as social security costs, that arise in connection with LTI 2013.

#### Stock option plan, 2010-2013

The staff stock option plan 2010-2013 was adopted at the 2010 Annual General Meeting. The plan extended to all permanent employees of Medivir AB. The term of the plan was from 30 April 2010 to 31 May 2013. The plan was forfeited during the second quarter of 2013 without any options having been exercised during its term. Detailed information on the stock option plan 2010-2013 is presented in Medivir's 2012 Annual Report.

#### Shareholder agreement and pre-emption

There is an agreement between the holders of Medivir's class A shares whereby the parties undertake to abide by the decisions on current issues mutually agreed before the Annual General Meeting. If, during their preparatory decisions, the parties are unable to agree on a particular issue, the decision shall accord with the opinion held by the majority of the class A share votes represented during the deliberations. The agreement also reguires any holder of class A shares wishing to transfer his or her class A shares to another holder of class A shares or to a third party to have the shares reclassified as class B shares. The same applies if a party acquires class A shares in Medivir in any other way. If so decided by a majority of the holders of class A shares, the class A shares may be transferred to a new owner without reclassification, at which time the new owner shall become a signatory to the current shareholders' agreement for holders of class A shares. Pre-emptive rights, as specified in the company's Articles of Association, shall apply to class A shares.

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#### MEDIVIR'S 15 LARGEST SHAREHOLDERS 31 DEC. 2013<sup>1)</sup>

Name	Class A shares	Class B shares	% of votes %	of capital
Bo Öberg	284,000	262,475	8.3	1.8
Nils Gunnar Johansson	284,000	66,575	7.8	1.1
Staffan Rasjö	0	2,049,428	5.5	6.6
AFA Försäkring	0	1,629,229	4.4	5.2
Skandia Fonder	0	1,545,618	4.2	4.9
Gladiator	0	1,482,732	4.0	4.7
UNIONEN	0	1,204,200	3.2	3.9
Christer Sahlberg	92,000	29,881	2.6	0.4
DnB Carlsson Fonder	0	939,540	2.5	3.0
Avanza Pension	0	804,255	2.2	2.6
Tredje AP-Fonden	0	742,713	2.0	2.4
Alecta Pensionsförsäkring	0	710,000	1.9	2.3
Swedbank Robur Fonder	0	687,421	1.9	2.2
Catella Fondförvaltning	0	684,570	1.8	2.2
JPM Chase NA	0	531,730	1.4	1.7
Total, 15 largest shareholders	660,000	13,370,367	53.7	44.9
Total, other shareholders		17,229,660	46.3	55.1
TOTALT	660,000	30,600,027	100.0	100.0

<sup>1)</sup> Source: Euroclear Sweden. Ownership data in the table may comprise composite data from multiple entries in Euroclear's statistics. These composite entries are designed to show an institution's or private person's total holdings

# SHAREHOLDER BREAKDOWN BY SIZE OF HOLDING, 31 DECEMBER 2013

	No. of shareholders	No. class A shares	No. class B shares	% of capital	% of votes
1–100	5,251		224,035	0.72	0.60
101-1,000	5,775		2,441,408	7.81	6.56
1,001-5,000	1,280		2,837,024	9.08	7.63
5,001–20,000	257		2,366,256	7.57	6.36
20,001-100,000	84		3,992,129	12.77	10.73
100,001-	49	660,000	18,739,175	62.06	68.12
Total	12,696	660,000	30,600,027	100.0	100.0

#### SHAREHOLDER CATEGORIES 31 DECEMBER 2013

	% of votes	% of capital	No. of shareholders
Swedish institutions	39.98	47.57	670
Foreign institutions	16.29	19.39	430
Swedish private investors	43.48	32.75	11,492
Foreign private investors	0.25	0.29	104
Total	100.0	100.0	12,696

#### SHARE AND SHAREHOLDER STRUCTURE

Year	Transaction	Nominal amount, SEK	Change in share capital, SEK	Total share capital, SEK	Total no. of class A shares	Total no. of 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	450,000	1,350,000
	Reclassification of class B shares	5		27,000,000	740,000	4,660,000	5,400,000
	New share issue 598:2700	5	5,980,000	32,980,000	740,000	5,856,000	6,596,000
1997	Reclassification of 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
	Exercise of options 1996-2001	5	665,000	41,440,110	660,000	7,628,022	8,288,022
2001	Exercise of options 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
	Exercise of options 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	103,220,885	660,000	19,984,177	20,644,177
	Exercise of options 2002-2007	5	996,850	104,217,735	660,000	20,183,547	20,843,547
2010	New share issue	5	26,219,390	130,437,125	660,000	25,427,425	26,087,425
	Private placement	5	11,250,000	141,687,125	660,000	27,677,425	28,337,425
	Exercise of options 2005-2010	5	921,650	142,608,775	660,000	27,861,755	28,521,755
	Exercise of options 2007-2012	5	357,370	142,966,145	660,000	27,933,229	28,593,229
2011	Exercise of options 2007-2012	5	496,705	143,462,850	660,000	28,032,570	28,692,570
	Non-cash issue	5	12,806,285	156,269,135	660,000	30,593,827	31,253,827
2012	Exercise of options 2007-2012	5	31,000	156,300,135	660,000	30,600,027	31,260,027

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# Corporate Governance Report



The chart above reflects the current situation on 31 December 2013.

The Medivir Group comprises eight companies with sales in three countries. The Parent Company of the Group is the Swedish public limited company, Medivir AB, whose shares are guoted on the Nasdaq OMX Stockholm Stock Exchange.

Good corporate governance is an essential component of Medivir's efforts to create value for its shareholders and to this end, we endeavour at all times to:

- Generate optimum conditions for active and responsible corporate governance.
- Achieve a well-balanced division of responsibility between owners, the Board of Directors, and the company management.
- Maintain a high level of transparency in relationships with owners, the capital market, employees and society at large.

The figure above illustrates Medivir's corporate governance model and the way in which the central bodies operate.

#### **External regulations**

As a Swedish public limited company with securities quoted on the Nasdaq OMX Stockholm Stock Exchange, Medivir is obliged to comply with a variety of different regulations that impact on the company's governance. The most important external regulations include:

- The Swedish Companies Act
- Accounting regulations
- The Nasdaq OMX Stockholm Stock Exchange's Rules for Issuers
- The Swedish Code of Corporate Governance

#### Regulatory compliance

In December 2013, the Nasdaq OMX Stockholm Stock Exchange's Disciplinary Committee imposed disciplinary sanctions on Medivir in the form of a fine. The Committee held that Medivir had neglected its obligations in accordance with the Exchange's Rulebook for Issuers in two ways: firstly, by not publishing information from a research conference sufficiently quickly, despite the information having leaked in advance in a way that could, according to the Committee, have impacted the share price, and secondly, by having failed from time to time to comply with applicable regulations regarding certain information that shall, under certain circumstances, be provided in Medivir's press releases.

### Compliance with the Swedish Code of Corporate Governance

Medivir has applied the Swedish Code of Corporate Governance since 1 July 2008 and has undertaken to follow best practice, wherever possible, with regard to corporate governance. Medivir has not deviated from any of the regulations specified in the Code. The Code can be viewed on the website of the Swedish Corporate Governance Board, which is responsible for the administration of the Code (www.bolagsstyrning.se).

#### Internal regulations

Medivir has also established internal regulations in order to comply with legislative and regulatory provisions and with the high ethical standards that we have set for ourselves. These regulations include:

- The Articles of Association
- The Board of Directors' Rules of Procedure and the CEO Instructions

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- The Board Committees' Rules of Procedure
- Guidelines for remuneration to senior executives
- The Financial Policy
- The IT Policy
- The Accounting and HR Manual
- The Code of Conduct

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#### Significant events in 2013

A new Board of Directors was appointed at the 2013 Annual General Meeting of the company's shareholders through the re-election of Björn C Andersson, Rolf Classon, Ingemar Kihlström, Anders Hallberg, Anna Malm Bernsten and Göran Pettersson (Chairman) and the new election of Birgitta Stymne Göransson and Bo Öberg.

Richard Bethell joined the Group's management group in April in the capacity of Executive Vice President for Discovery Research, while Charlotte Edenius, formerly Executive Vice President for R&D, took over the position as Executive Vice President for Development. In August, Henrik Krook joined the Group's Management as Executive Vice President for Commercial.

#### Decision-making at shareholders' meetings

Medivir's shareholders exercise their right of decision at the Annual General Meeting and any Extraordinary General Meetings. Most of the decisions at the shareholders' meetings are taken with a simple majority. In some cases, however, the Swedish Companies Act prescribes that decisions shall be taken by a qualified majority.

#### **Annual General Meeting**

Shareholders exercise their control over the company at the Annual General Meeting or, if called, at Extraordinary General Meetings, which constitute Medivir's supreme decision-making body. The Annual General Meeting shall be held within six months of the end of the financial year. The items on the agenda of the Annual General Meeting for resolution shall include the election of the Board of Directors and the Chairman of the Board, the appointment of auditors, the adoption of Income Statements and Balance Sheets, the appropriation of the company's unappropriated earnings, and the discharge from liability for the Members of the Board and the CEO, the Nomination Committee and its work, and guidelines on remuneration for senior executives. Details of the company's previous Annual General Meetings can be found on Medivir's website, which also includes information on shareholders' entitlement to raise matters for consideration at the Annual General Meeting, and on when such requests for consideration should be received by Medivir.

#### 2013 Annual General Meeting

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The 2013 Annual General Meeting was held on 6 May 2013. 72 (78) shareholders attended the Meeting, either in person or through proxies, representing approximately 40.86 per cent (42.4%) of the votes. Attorney-at-Law, Erik Sjöman, was elected Chairman of the Meeting. All Members of the Board elected by the Meeting, with the exception of Anna Malm Bernsten, were present. The Minutes of the Meeting are available on Medivir's website. The matters resolved by the Meeting included:

 The re-election of Board Members Göran Pettersson, Björn C Andersson, Anna Malm Bernsten, Rolf Classon, Anders Hallberg and Ingemar Kihlström. The new election of two Board Members, Birgitta Stymne Göransson and Bo Öberg. The reelection of the Chairman of the Board, Göran Pettersson.  The Directors' fees for the period until the next Annual General Meeting were maximised at SEK 2,605,000, divided between them as follows:

Total	2,605,000
R&D Committee (convening: SEK 80,000; three members: SEK 65,000 each)	275,000
Remuneration Committee (convening: SEK 65,000; one member: SEK 50,000)	115,000
Audit Committee (convening: SEK 80,000); three members (SEK 65,000 each)	275,000
Seven members (SEK 210,000 each)	1,470,000
Chairman	470,000

- SEK 20,000 shall, over and above their ordinary fee, be payable to Board Members resident outside Europe for every physical Board Meeting attended, up to an annual cap of SEK 100 000 per Member.
- The Auditor's fee for the period until the next Annual General Meeting shall, as before, be payable upon account.
- · Guidelines for remuneration to senior executives.
- Procedures for the appointment of the Nomination Committee and its work.
- Authorisation of the Board of Directors on one or more occasions before the next Annual General Meeting, with or without deviation from the shareholders' preferential rights, to approve the new issue of class B shares in a number that shall not, collectively, exceed 10 per cent of the total number of class B shares outstanding after utilisation of the authorisation<sup>1)</sup>.
- The adoption of a long-term incentive programme for the employees of Medivir and the authorisation of the Board to issue warrants as a hedging measure for the long-term incentive programme.
- 1) The authorisation was not utilised in 2013.

#### 2014 Annual General Meeting

Medivir's 2014 Annual General Meeting will be held on 8 May 2014 at the "7A Odenplan" conference centre at Norrtullsgatan 6 in Stockholm. Shareholders wishing to raise a matter for consideration by the Annual General Meeting must submit a written request to the Board of Directors in good time prior to the Meeting. See Medivir's website for further information.

#### **Nomination Committee**

The Nomination Committee procedure adopted at the 2013 Annual General Meeting entails the following:

- That the Chairman of the Board shall contact the three biggest shareholders in terms of the number of votes at the end of the third quarter of the year and offer them the opportunity to each appoint a representative to the Nomination Committee.
- That if any of these shareholders waive their right to appoint a representative, the right shall pass to the shareholder with the next largest shareholding after these shareholders.
- That the Chairman of the Board shall, in accordance with the procedure, also be a member of the Nomination Committee.
   The Nomination Committee members shall jointly elect a Chairman to lead the work of the Committee.

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• That the Nomination Committee shall draw up proposals for the nomination and remuneration of the Board of Directors, the Chairman of the Board and, where relevant, auditors. It shall, furthermore, develop methods of appointing the Nomination Committee and its Chairman. The findings of the Nomination Committee shall be submitted to the Annual General Meeting for adoption. Shareholders may submit proposals to the Nomination Committee by means including emails to valberedning@medivir.se. The names of the shareholder representatives who make up the Nomination Committee shall be published no later than six months before the Annual General Meeting.

#### **Members of the Nomination Committee**

The current Nomination Committee comprises the Chairman of the Board and three members appointed by the three shareholders with the largest shareholdings on 30 September 2013:

- Anders Algotsson, Chairman and representative of AFA Försäkring
- Annelie Enquist, representative of Skandia Fonder
- Bo Öberg, founder and representative of the class A shareholders
- and Göran Pettersson, Chairman of the Board of Medivir

#### Nomination Committee ahead of the 2014 AGM

Name	Representing	Proportion of votes, %, on 30 Sept. 2013
Bo Öberg	Class A shareholders	18.73
Anders Algotsson	AFA Försäkring	4.35
Annelie Enquist	Skandia Fonder	4.11
Göran Pettersson	Medivir's Board of Directors	0.06
Total		27.25

#### **Nomination Committee duties**

The duties of the Nomination Committee have changed over the years in order to comply with the requirements of the Swedish Code of Corporate Governance. The primary duty of the Nomination Committee continues, however, to be to propose candidates for election to the Board of Directors. The Nomination Committee must, in order to ensure its ability to evaluate the expertise and experience required of the Board Members, keep itself informed of the Group's strategy and the challenges it will face in the years ahead.

The Nomination Committee must also take into consideration all applicable rules governing the independence of the Members of the Board. The Nomination Committee shall also draw up proposals for resolution by the Annual General Meeting regarding the remuneration and fees payable to:

- Members of the Board who are not employed by the company and who are elected by the Annual General Meeting
- The Auditor
- The members of the Nomination Committee

The Nomination Committee has not, to date, proposed the payment of any remuneration to its members. The Nomination Committee proposes candidate auditors in consultation with the Board's Audit Committee. The Nomination Committee is also tasked with proposing a candidate for election as Chairman of the Annual General Meeting.

# The work of the Nomination Committee ahead of the 2014 Annual General Meeting

The work of the Nomination Committee begins with a review of a checklist detailing all of the duties of the Nomination Committee as prescribed by the Swedish Code of Corporate Governance and by the Nomination Committee's Rules of Procedure as adopted by the Annual General Meeting. A timetable is also set for the work to be carried out. A good understanding of Medivir's operations is vital in enabling the members of the Nomination Committee to carry out their duties.

The Chairman of the Board is responsible for the annual appraisal of the work of the Board of Directors, including the efforts of the individual Members of the Board. The Nomination Committee has been informed of the results of these appraisals, including the appraisal of the Chairman of the

Audit Committee

R&D Committee

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#### Attendance by the Members of the Board at meetings held in 2013<sup>1)</sup>

Name	Elected	Born	Function	Attendance/total number of Board	mittee, Attendance/ total number of Committee meetings	Attendance/total number of Commit- tee meetings	Attendance/total number of Commit- tee meetings
Björn C Andersson	2008	1946	Member	12 of 12		3 of 3	
Rolf Classon	2012	1945	Member	11 of 12		3 of 3	
Anders Hallberg 4)	2012	1945	Member	12 of 12			3 of 3
Ingemar Kihlström	2008	1952	Member	12 of 12	3 of 3		3 of 3
Anna Malm Bernsten	2006	1961	Member	11 of 12	3 of 3	3 of 3	
Göran Pettersson	2008	1945	Chairman	12 of 12			3 of 3
Birgitta Stymne Göransson	2013	1957	Member	9 of 9		2 of 2	
Bo Öberg <sup>2,5)</sup>	2013	1939	Member	9 of 9			2 of 2
Susana Ayesa Alvarez 3)	2013	1970	Employee representative	2 of 3			
Christian Sund 3)	2013	1958	Employee representative	2 of 3			
Stina Lundgren <sup>3)</sup>	2013	1979 Er	nployee representative, deputy	2 of 3			
Veronica Werlinder 3)	2013	1966 Er	mployee representative, deputy	2 of 3			

Board Meetings. Remuneration Com-

- 1) Members prevented from attending a Board Meeting have been afforded the opportunity to submit their views to the Chairman before the Meeting.
- 2) Appointed at the 2013 AGM.
- 3) Appointed 20 November 2013
- 4) Independent in relation to the company's major shareholders but not independent in relation to the company and the company management.
- 5) Not independent in relation either to the company and the company management or to the company's major shareholders.

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Board. The Nomination Committee is able, on the basis of this information, to adjudge the expertise and experience required on the part of the Members of the Board.

The Nomination Committee has also studied the Group's and Audit Committee's appraisals of the quality and efficiency of the Auditor's work, including recommendations for auditors and audit fees.

The Nomination Committee has held five meetings, at which all members were present, by 13 March 2014. The Nomination Committee's full proposal for the 2014 Annual General Meeting was published in conjunction with the issue of the notice convening the Annual General Meeting.

#### **Duties and work of the Board of Directors**

The primary duty of the Board of Directors is to manage the Group's operations on behalf of the owners in such a way that the owners' interests, in terms of a long-term healthy return on capital invested, are optimally protected. The work of the Board is regulated by means of, amongst other things, the Swedish Companies Act, the Swedish Code of Corporate Governance, the Articles of Association, and the Rules of Procedure adopted by the Board for its work. Medivir's Articles of Association are available on the company's website.

The Board of Directors manages and decides on Group-wide issues such as:

- Strategic orientation and significant objectives
- Significant issues in relation to financing, investment, acquisitions and divestments
- Following up and monitoring of operations, information provision and organisational issues, including appraisals of the Group's executive management
- Appointment and, when required, dismissal of the company's CEO
- Overall responsibility for setting up efficient systems for internal monitoring and risk management
- Significant policies

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#### The composition of the Board of Directors

The Board of Directors shall, in accordance with the Articles of Association, comprise a minimum of three and a maximum of ten Members and a maximum of two Deputy Members. The Members shall serve from the end of the Annual General Meeting at which they were elected until the end of the next Annual General Meeting. There is no limit on the number of consecutive periods during which a person may be a Member of the Board. The CEO may be elected to the Board but under the provisions of the Swedish Companies Act, a CEO of a public limited company may not be appointed Chairman of the Board.

The Board of Directors elected by the shareholders at the 2013 Annual General Meeting for the period until the end of the 2014 Annual General Meeting comprised eight Members and no Deputy Members, including the Chairman of the Board. The Board also includes two employee representatives, each with their own Deputy Members.

Neither the CEO, the CFO or the Secretary to the Board are Members of the Board, but do, however, attend the Board

Meetings with the exception of agenda items where a conflict of interest may arise or when it is otherwise inappropriate for them to be present, e.g. in conjunction with the appraisal of the work of the CEO.

See pages 50-51 for a description of the Members of the Board.

#### Independence

Several different types of independence requirement apply to the Board of Directors and its Committees. Medivir applies independence requirements taken from applicable Swedish legislation, the Swedish Code of Corporate Governance, and Nasdaq OMX's stock exchange rules.

The Nomination Committee evaluates the Board's independence ahead of the Annual General Meeting. The Board has been adjudged to fulfil the applicable requirements for independence. The evaluation of each Member of the Board's independence is presented in the table above. Anders Hallberg has been adjudged to be independent in relation to the company's major shareholders, but not independent in relation to the company and the company's management. Anders Hallberg is part of a consortium of people who, under the terms of an agreement with Medivir, are entitled to receive certain royalty payments on products that the company may develop, based on patented inventions previously acquired from the consortium. Bo Öberg is not independent in relation to the company and the company management, nor is he independent in relation to the company's major shareholders. Bo Öberg is the founder of the company and representative of the company's class A shareholders.

#### **Rules of Procedure and Board Meetings**

The Board of Directors adopts written Rules of Procedure every year in accordance with the provisions of the Swedish Companies Act, clarifying the duties of the Board and regulating the division of labour of the Board and its Committees, including the role of the Chairman, the decision-making process within the Board, the Board's schedule of meetings, notices convening Board meetings, agendas and minutes. The Rules of Procedure also regulate the ways in which the Board shall receive information and documentation in order to ensure its ability to take well-founded decisions. The Board of Directors also adopts written instructions for the Chief Executive Officer each year, clarifying the CEO's responsibility for the ongoing administration, methods of reporting to the Board, the requirement for internal control instruments, and other matters requiring a decision by the Board or which must be reported to the Board.

The Rules of Procedure require an inaugural Board Meeting to be held immediately after the Annual General Meeting. The Board normally also holds a minimum of six further Meetings each year. Four of these Meetings are held in conjunction with the publication of the Group's annual and interim financial reports. At least one of the Meetings deals with the research portfolio and at least one deals with specific strategic issues. The budget and economic outlook are addressed during the final Meeting of each calendar year. Additional Meetings, including telephone conferences, are held as required.

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#### The duties of the Chairman of the Board

The Chairman of the Board is responsible for ensuring that the work of the Board is well-organised, conducted efficiently, and that the Board fulfils its obligations. The Chairman monitors company operations in dialogue with the CEO and is also responsible for ensuring that other Board Members receive the information and documentation required to enable a high standard of discussion and decision-making, and for monitoring the implementation of the Board's decisions. The Chairman is, furthermore, responsible for conducting an annual appraisal of the Board's work and for ensuring that the Nomination Committee is provided with the results of the appraisals. The Chairman represents Medivir on ownership issues.

#### The work of the Board of Directors in 2013

The Board of Directors has held 12 minuted Meetings in 2013. The attendance of the individual Members of the Board at these Meetings is shown in the table on page 45. All of the Meetings during the year have followed an approved agenda which, together with the documentation for every item on the agenda, was supplied to the Members before the relevant Board Meeting. An ordinary Board Meeting usually lasts for half a day in order to ensure sufficient time for presentations and discussions. An appointed Attorney-at-Law has acted as Secretary at all Board Meetings. The CEO and CFO participate in the majority of Board Meetings. Reviews of the current business position, the Group's results and financial position, and the outlook for the rest of the year are conducted at every ordinary Board Meeting. A member of the Group's management group will usually also review a relevant strategic issue. Reports on the work of the Committees are usually also presented at each Board Meeting by the Chairmen of the respective Committees. The work of the Board during the year has largely focused on:

- Interim Reports, the full-year financial statement, and the annual accounts
- Financial performance, financing issues and the Group's capital structure
- Announcements of clinical results and regulatory approvals for simeprevir
- Development of the project portfolio
- Transaction issues
- Partnerships and collaborations
- Strategic orientation

#### **Board Committees**

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

#### The Remuneration Committee

The Remuneration Committee is appointed by the Board of Directors and shall comprise a maximum of four members. The 2013 Remuneration Committee has comprised Ingemar Kihlström and Anna Malm Bernsten (Chairman). The Committee is an advisory one and has no independent right of decision.

The primary duty of the Remuneration Committee is to represent the Board of Directors on issues relating to remuneration and employment terms for the CEO and senior executives who report directly to the CEO, based on remuneration and employment terms for the CEO and other senior executives adopted by the Annual General Meeting. The Committee reports continuously on its work to the Board of Directors.

The Remuneration Committee has held three minuted meetings in 2013. The attendance of individual Board Members is shown in the table on page 45. The Committee has also held a number of consultations by telephone and email. The Committee has largely focused on:

- Reviews of proposals regarding salaries and remuneration for the CEO and other senior executives
- Reviews of proposals for a programme for short-term performance-related pay
- Reviews of proposals for a programme for long-term performance-related pay.

#### **The Audit Committee**

The Audit Committee is appointed by the Board of Directors and shall comprise a maximum of four members. The 2013 Audit Committee has comprised Björn C Andersson (Chairman), Rolf Classon, Anna Malm Bernsten and Birgitta Stymne. The members are independent and have audit competence. The Committee advises the Board of Directors and has no independent right of decision.

The primary duty of the Audit Committee is to support the Board of Directors in its work with Medivir's risk management, governance and internal control, and to quality assure the financial reporting. The Committee considers significant auditing issues that affect the Group and meets on an ongoing basis with Medivir's auditors and evaluates the audit process. The Committee also assists the Nomination Committee in the production of proposals for auditors and the fees payable to auditors, and approves the supplementary services that the company may purchase from its external auditors. The Chairman of the Audit Committee is responsible for ensuring that the entire Board of Directors is kept continuously informed of the work of the Committee and, when necessary, submits matters to the Board for decision.

The Audit Committee has held three minuted meetings in 2013. The attendance of the respective Board Members is shown in the table on page 45. The CEO and CFO have attended all meetings. The Committee has largely focused on:

- The scope and accuracy of the year-end financial statement
- Reviews of the company's risk management, governance and internal controls
- Significant audit issues
- Reviews of reports from the company's Auditor elected by the Annual General Meeting, including the Auditor's audit plan

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#### The R&D Committee

The R&D Committee is appointed by the Board of Directors and shall comprise a maximum of five members. The 2013 R&D Committee has comprised Anders Hallberg, Ingemar Kihlström (Chairman), Göran Pettersson and Bo Öberg. Professor Bertil Samuelsson, Medivir's "Chief Scientific Advisor", was also a member of the R&D Committee. The Committee is an advisory one and has no independent right of decision.

The primary duties of the R&D Committee are to review and evaluate the R&D portfolio and to provide the Board with supporting data ahead of decisions on the strategic orientation of the R&D portfolio. The R&D Committee also has an advisory role in relation to the company management with regard to specific scientific matters.

The R&D Committee has held three minuted meetings in 2013. A number of physical, non-minuted working meetings and telephone conferences have also been held during the year. The attendance of the respective Board Members is shown in the table on page 45. The Committee has largely focused on 6-monthly reviews and evaluations of the R&D portfolio.

#### The Group management

The Board appoints the CEO and, where necessary, the Deputy CEO. The CEO leads the work of the Group management and is, together with the Group management, responsible for ensuring that the operating activities are conducted in accordance with the provisions of the Swedish Companies Act, other legislation and regulations, applicable regulations for listed companies, the Articles of Association, and the CEO's Instructions. At the beginning of 2013, the Group management comprised seven people (two women and five men) and at the end of the year, it comprised eight people (two women and six men). The Group management has a broad composition of individuals with in-depth and extensive experience of research and development, the marketing and sale of pharmaceuticals, and the requisite expertise in accounting, finance and communication. For a presentation of the Group management, see page 52.

The role of the Group management is to:

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- Set goals, allocate resources, and follow up on the operating units' results.
- Produce information and documentation as support data that enables the Board to take well-founded decisions.

Goals are updated for the year ahead on the basis of the annual strategic work. Goals are communicated throughout the organisation. The goals are a management tool used to adapt the goals of the operating units and employees in line with the company's goals and to monitor goal fulfilment and identified risks.

#### **Election of Auditors**

The duties of the Nomination Committee include proposing an auditor to the Annual General Meeting.

PricewaterhouseCoopers AB (PwC) was appointed as the company's external auditors for a one-year period up to and including the 2014 Annual General Meeting. Authorised Public Accountant, Hans Jönsson, is the Auditor-in-Charge for Medivir.

- The auditors work to an audit plan and report their observations on a rolling basis to the Audit Committee and the Board, both during the course of the audit and in conjunction with the preparation of the annual accounts.
- The auditors review one interim report and the annual financial statement in order to assess their accuracy, completeness and the correspondence of the accounts with generally accepted accounting practice and relevant accounting principles.
- The Auditor-in-Change attends the Annual General Meeting at which he or she presents details of the audit work and observations made.

When additional services are requested from PwC over and above the audit engagement, such as consultancy on tax issues and on a range of different accounting and financial issues, such services are provided only to the extent that is compatible with the provisions of the Swedish Audit Act and the professional ethics guidelines issued by FAR (Sweden's professional institute for authorised public accountants) with regard to the impartiality and independence of auditors.

# Remuneration to the Board of Directors and senior executives

#### **Remuneration principles**

Remuneration principles for senior executives of Medivir are determined by the Annual General Meeting. The term, senior executives, refers to the CEO and other members of the management group. The Nomination Committee's proposed guide-

#### Remuneration to senior executives (SEK 000) 1,2)

Function	Year	Fixed salary	Performance- related pay	Severance pay	Benefits	Total	Pension	Total incl. pension
CEO	2013	3,462	1,321		98	4,881	1,218	6,099
	2012	3,344	990	_	85	4,419	1,184	5,603
Other senior executives	2013	9,133	1,982	1,104	433	12,653	2,053	14,706
	2012	9,080	1,257	1,860	530	12,727	2,313	15,040
Total	2013	12,595	3,303	1,104	531	17,534	3,271	20,805
	2012	12,424	2,247	1,860	615	17,146	3,497	20,643

1) At the beginning of 2013, the management group, including the CEO, comprised 7 people. At the end of the year, it comprised 8 people.

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<sup>2)</sup> At the beginning of 2012, the management group, including the CEO, comprised 8 people. At the end of the year, it comprised 7 people.

#### Directors' fees (SEK 000) 1), 5)

		Director's	s fees	Audit Com	mittee	Remuner Commit		R&D Com	nittee	Tota	al
Name	Function	2013	2012	2013	2012	2013	2012	2013	2012	2013	2012
Björn C Andersson	Member	210	210	80	80	-	-	-	-	290	290
Rolf Classon	Member	210	210	65	65	-	-	-	-	275	275
Anders Hallberg 2)	Member	210	210	-	-	-	-	65	65	275	275
Ingemar Kihlström	Member	210	210	_	_	50	50	80	80	340	340
Anna Malm Bernsten 3)	Member	210	210	65	65	65	65	-	-	340	340
Göran Pettersson	Chairman	470	470	-	-	-	_	65	65	535	535
Birgitta Stymne	Member	210	-	65	-	-	-	-	-	275	-
Bo Öberg <sup>4)</sup>	Member	175	-	-	-	-	_	65	-	240	-
Total		1,905	1,520	275	210	115	115	275	210	2,570	2,055

- 1) Remuneration to the Board of Directors for the period from May 2013 to April 2014 and for the period from May 2012 to April 2013, SEK thousands. The fee payable to Members of the Board elected by the Annual General Meeting is determined by the Annual General Meeting in line with proposals by the Nomination Committee. Remuneration has been paid as shown in the above table in 2013 and 2012. The remuneration does not include travel expenses.
- 2) Pursuant to an earlier agreement, royalties have, in addition to Directors' fees, been paid to Uppsala Hallbechem AB in the sum of SEK 1,903,000 (-).
- 3) Consultancy fees, approved by the Board of Directors, have, in addition to Directors' fees, been paid to Bernsten Konsult AB in the sum of SEK 72,000 (SEK 414,000).
- 4) Reduction in the Directors' fees by 2/12 parts due to employment with a salary of SEK 108,000 for the period from May to June 2013.
- 5) No Directors' fees have been paid to the Board's employee representatives.

lines for remuneration to senior executives were adopted at the 2013 Annual General Meeting. These guidelines are essentially consistent with the principles previously applied. The guidelines mean, in effect, that the company shall offer a competitive total remuneration package that enables the recruitment and retention of qualified senior executives. Remuneration for senior executives may comprise a fixed salary, performance-related pay, share incentive programmes approved by the Annual General Meeting, pensions and other benefits. The fixed salary shall take into account the individual's areas of responsibility and experience. Performance-related pay paid in cash may total a maximum of 50 per cent of the annual fixed salary. Performance-related pay shall be linked to predetermined and quantifiable criteria, structured with the aim of promoting the company's long-term value creation.

For additional information on remuneration, see Note 5 on page 69.

The Board's proposal for remuneration guidelines to be submitted to the 2014 Annual General Meeting is essentially consistent with the principles applied previously. See page 36 for the Board's full proposal to the 2014 Annual General Meeting.

#### Long-term incentive programmes

The purpose of long-term incentive programmes is to generate the conditions for retaining and recruiting competent personnel to the Group and promote employee shareholding in the company, so as to encourage continued company loyalty by combining the interests of the shareholders and the employees. A three-year share saving plan, LTI 2013, was accordingly approved at the 2013 Annual General Meeting. Medivir believes that the plan will have a positive effect on the Group's further development and that LTI 2013 is, therefore, to the benefit of both the shareholders and the company. The Board intends to conduct an evaluation of LTI 2013 that focuses on the abovementioned objectives and which systematically analyses the results achieved. The goal of the evaluation will be to determine whether the plan has fulfilled its stated objectives, and will also include a review of the results and costs of the plan.

#### Remuneration to senior executives

The term, senior executives, refers to the CEO and other members of the management group. Medivir gathers and evaluates information on competitive remuneration levels for relevant sectors and markets on a rolling basis. Remuneration payments in 2013 and 2012 are shown in the table on page 48.

#### **Remuneration to the Board of Directors**

The Director's fee payable to the Members of the Board of Medivir is determined by the Annual General Meeting in line with proposals by the Nomination Committee. Remuneration payments in 2013 and 2012 are shown in the table above.

#### **Auditors' fees**

Fees for auditing Medivir's accounts are determined by the Annual General Meeting in line with proposals by the Nomination Committee. Remuneration payments in 2013 and 2012 are shown in the table below.

#### Auditors' fees (SEK 000)

	2013	2012
PwC		
Audit engagement	1,047	1,003
Auditing services over and above the audit		
engagement	259	116
Tax advice	845	196
Other services	912	1,087
Subtotal	3,063	2,402
EY		
Audit engagement	36	129
Auditing services over and above the audit		
engagement		
Other services	-	88
Subtotal	36	217
Total	3,099	2,619

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# The Board of Directors



Rolf Classon

Birgitta Stymne Göransson

Björn C Andersson

#### Göran Pettersson

Chairman of the Board. Born 1945. Elected to the Board of Medivir in 2008. Göran is a graduate pharmacist and market economist (IHM) and has extensive experience of the Swedish pharmaceutical industry, both in Sweden and other countries. Göran has run his own life sciences consultancy firm since 2000 and has previously held senior executive positions in the Astra corporate group, KabiVitrum, Pharmacia/PharmaciaUpJohn and Meda. Göran holds a number of directorships in other companies and is the Chairman of the Board of Axelar AB and the Vice Chairman of the Board of Mobidiag Oy, and a Member of the Boards of Pergamum AB, Pfizer Sweden Pensions-stiftelse I and Recipharm AB.

Shares in Medivir, including holdings by family members: 20,550 class B shares.

#### Björn C Andersson

Born 1946. Member of the Board since 2008 and Chairman of Medivir's Audit Committee. He has a Licentiate in Economics and was previously employed by Handelsbanken, where he was the Deputy CEO and the Director of Handelsbanken Markets and, subsequently, Director of Handelsbanken Asset Management. Björn is a Member of the Boards of Bliwa Livförsäkring and SPP Fonder AB.

Shares in Medivir: 3,000 class B shares.

#### Anna Malm Bernsten

Born 1961. Member of the Board since 2006, and also a member of Medivir's Audit Committee and Chairman of the Remuneration Committee. Anna holds a B.Sc. in Engineering, has extensive knowledge of the life sciences sector, and runs her own management and business development firm. Anna is the CEO of Carmeda AB, and has held senior executive positions in GE Healthcare Life Sciences, Pharmacia, Assa Abloy, Medivir, and Baxter Medical. Anna is a Member of the Boards of Birdsteep ASA, CEBA/Oatly AB, Cellavision AB, Fagerhult AB, Matrisen AB, Neurovive AB and Nolato AB, and was formerly a Member of the Board of BioPhausia AB.

Shares in Medivir, including holdings via companies: 3,406 class B shares.



Bo Öberg

Anna Malm Bernsten

#### Rolf Classon

Born 1945. Member of the Board since 2012. Rolf holds a Master's degree in Political Science from the University of Gothenburg. He has extensive experience of senior executive positions in the pharmaceutical and medical technology industry with such companies as Pharmacia and Bayer Diagnostics, and as Global CEO for Bayer Healthcare. He was also a Divisional Manager at Swedish Match. Rolf's current directorships include membership of the Boards of Hill-Rom Corporation (USA), Auxilium Pharmaceuticals (USA), Tecan Group (Switzerland), Fresenius Medical Care (Germany) and Aerocrine AB (Sweden). Shares in Medivir: 0

#### Anders Hallberg

Born 1945. Member of the Board since 2012. Anders has held a professorship in Medicinal Chemistry at Uppsala University's Faculty of Pharmacy since 1990 and has also held a number of positions as scientific advisor at AstraZeneca and smaller pharmaceutical companies between 1990 and 2006. Prior to this, he was the Head of the Medicinal Chemistry Department at Astra in Lund. Between 2006 and 2011, he was the Vice Chancellor of Uppsala University. He has published over 260 scientific articles, a large number of which are on the subject of pharmaceuticals for the treatment of infectious diseases. Anders Hallberg is a member of the Royal Swedish Academy of Sciences, and the Royal Swedish Academy of Engineering Sciences. He has also been awarded honorary doctorates in Sweden and other countries.

Shares in Medivir, including holdings by family members: 1,600 class B shares.

#### Ingemar Kihlström

Born 1952. Member of the Board since 2008, Chairman of Medivir's R&D Committee and a member of the Remuneration Committee. Ingemar is an Associate Professor at Uppsala University and a life sciences advisor, via his own consultancy firm. Ingemar has extensive experience of the pharmaceutical sector and business development from both the pharmaceutical industry and the finance sector. Ingemar has previously held senior executive positions within Pharmacia, Aros Securities and ABG Sundal Collier. He currently holds directorships in

The Board of Directors Medivir Annual Report 2013



Ingemar Kihlström

Göran Pettersson

Anders Hallberg

a number of companies, including as Chairman of the Boards of BoMill Holding, Gasporox AB, Recopharma AB, and Spectracure AB, and is a Member of the Boards of Health Invest Partners AB, Miris AB and Respiratorius AB.

Shares in Medivir, including holdings by family members: 9,350 class B shares.

#### Birgitta Stymne Göransson

Born 1957. Member of the Board since 2013 and a member of the Audit Committee. Birgitta holds a B.Sc. in Engineering, specialising in biotechnology, from the Royal Institute of Technology in Stockholm and a Master of Business Administration degree from Harvard Business School. Birgitta has extensive experience of working as a CEO and senior executive in trade and industry. Her previous positions include CEO of Memira, CEO of Semantix, and Deputy CEO of Telefosgruppen, and senior executive at Åhléns, McKinsey and Gambro. Birgitta currently serves on the Boards of Elekta AB, HL Display, Sophiahemmet, Rhenman & Partners Asset Management AB and the Stockholm Chamber of Commerce.

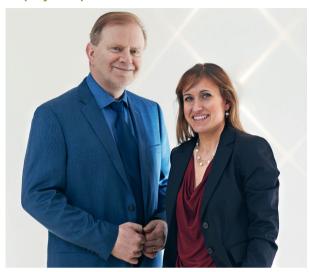
Shares in Medivir: 0.

#### Bo Öberg

Born 1939. Associate Professor at Uppsala University and Visiting Professor in Virology at the Karolinska Institute, has published 180 papers and holds a number of patents and patent applications in the field of antiviral pharmaceuticals. Bo, who is a former head of Astra's viral research department, is one of Medivir's founders and has been actively involved with Medivir since 1988. He has extensive experience from the Boards of biotechnology companies and has worked with the Swedish Research Council and a number of international organisations active in the area of infectious diseases. In 2010, Bo received The Elion Award for outstanding work with the development of pharmaceuticals to treat viral infections. He is currently also a Member of the Board of Beactica AB and is a member of the Royal Society of Sciences, Uppsala. Shares in Medivir:

284,000 class A shares and 262,475 class B shares.

#### **Employee representatives**



**Christian Sund** 

Susana Ayesa Alvarez

#### Susana Ayesa Alvarez

Ph.D., Senior Research Scientist, Lead Discovery Chemistry

Born1970. Employed since 2000 and Member of the Board since 2013.

Shares in Medivir, including holdings by family members: 2,023 class B shares.

#### **Christian Sund**

Ph.D., Senior Research Scientist, Medicinal Chemistry Born 1958. Employed since 1997 and Member of the Board since 2013.

Shares in Medivir: 42 class B shares.

#### **Deputy Members of the Board**

#### Stina Lundgren

Ph.D., Senior Research Scientist, Lead Discovery Chemistry

Born 1979. Employed since 2008 and Deputy Member of the Board since 2013.

Shares in Medivir: 337 class B shares.

#### Veronica Werlinder

Ph. Lic., Senior Research Scientist, DMPK & Bioanalysis Born 1966. Employed since 2008 and Deputy Member of the Board since 2013.

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Shares in Medivir: 287 class B shares.

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# Management







Håkan Wallin Paul Wallace



Henrik Krook Christina Kassberg Rein Piir

#### **Maris Hartmanis**

Born 1953. Ph.D. and Associate Professor of Biochemistry at the Royal Institute of Technology in Stockholm. President and CEO of Medivir and CEO of BioPhausia. Employed since 2011.

Over 25 years' experience of the Life Sciences industry in a range of different senior executive and R&D management positions, including at BioPhausia, Gambro, Amersham and Pharmacia.

Shares in Medivir: 35,000 class B shares.

#### **Richard Bethell**

Born 1963. Doctor of Philosophy (D. Phil.) in Chemistry, Oxford University.

EVP Discovery Research. Employed since 2013.

Formerly Head of Biological Sciences at Boehringer Ingelheim (Canada), Head of Therapeutic Research at Shire and a variety of different positions at Pfizer and GlaxoSmithKline in the field of pharmaceutical R&D.

Shares in Medivir: 2,281 class B shares.

#### **Charlotte Edenius**

Born 1958. MD and Ph.D., Karolinska Institute. EVP Development. Employed since 2010. Formerly Senior Vice President Preclinical and Clinical R&D at Orexo, Chief Scientific Officer at Biolipox, and various positions within AstraZeneca's clinical R&D operations.

Shares in Medivir, including holdings by family members: 10,840 class B shares.

#### Christina Kassberg

Born 1968. B.Sc. Economics. EVP Finance & Administration. Employed since 2000. Previous positions include Controller at Medivir AB, Accounting Manager at Skandia Link Multifond, and Auditor at Öhrling PricewaterhouseCoopers.

Shares in Medivir, including holdings by family members: 21,427 class B shares.

#### Henrik Krook

Born 1973. Executive MBA, Stockholm School of Economics. Graduate Pharmacist and Ph.D. in Immunology from Uppsala University. EVP Commercial. Employed since 2013. Formerly Country Manager/ Commercial Director for Novartis Norway and over ten years' experience of various senior executive positions in clinical studies, sales and marketing at Roche and Novartis, in addition to the position of Research Project Manager at Uppsala University Hospital. Shares in Medivir: 639 class B shares.

#### Rein Piir

Born 1958. B.Sc. Business Economics and Management. EVP Corporate Affairs & IR. Employed since 2000. Previous senior executive positions include Health Care and Research at D. Carnegie AB, and Analysis & Strategy at SPP.

Shares in Medivir: 1,292 class B shares.

#### Paul Wallace

Born 1962. Ph.D. in Biochemistry, University of Cambridge. EVP Business Development.

Employed since 2000. Formerly senior position in business development at Peptide Therapeutics plc. and Director of Research at Eclagen, both in the UK.

Shares in Medivir: 7,690 class B shares.

#### Håkan Wallin

Born 1962. B.Sc. Business Economics and Management, Stockholm University, and CEFA from the Stockholm School of Economics. EVP Corporate Development. Employed since 2010. Previous senior executive positions include ABG Sundal Collier AB's Corporate Finance department, Libertas Capital Nordic AB and Ernst & Young's Corporate Finance.

Shares in Medivir: 4,380 class B shares.

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# Board of Directors' internal controls report

The Board of Directors' responsibility for internal controls is regulated in the Swedish Companies Act and the Swedish Code of Corporate Governance. Internal controls with regard to the financial reporting are one component of the total internal controls system within Medivir and are a central component of Medivir's corporate governance.

#### Internal control of the financial reporting

The following presentation comprises the Board of Directors' report on Internal Controls in respect of the financial reporting. It has been reviewed by the company's auditors. The purpose of the internal control of the financial reporting is to provide reasonable assurance that the external financial reporting in the form of interim reports, annual accounts and full-year financial statements is reliable and has been prepared in accordance with legislative requirements, applicable accounting standards, and other requirements of listed companies. The overall purpose of the internal control is to provide reasonable assurance that the company's strategies and goals are monitored and that the owners' investments are protected. According to the COSO framework, the internal control shall include, amongst other things, a control environment, risk assessment, control activities, information and communication, and monitoring.

#### Control environment

Medivir's internal control structure is based on the division of labour between the Board of Directors and its Committees, and the CEO and President. The control environment also includes the culture that the Board of Directors and company management communicate and on the basis of which they operate. Medivir's control environment is based on:

- Steering documents, such as the Board's Rules of Procedure and the CEO's Instructions, policies and guidelines.
- Medivir's Core values and the Code of Conduct.
- The company's organisation and the way in which it conducts its operations, with clearly defined roles and areas of responsibility, and delegation of authority.
- Group-wide planning processes, such as the process for appraisal of the R&D portfolio, the budget process, and performance reviews.

Medivir's financial reporting complies with the laws and regulations applicable to companies listed on the main market of the Nasdaq OMX Stockholm Stock Exchange. The internal control environment includes, in addition to external laws and regulations, a code of conduct, important policies and guidelines for the financial reporting, such as the finance policy, endorsement and authorisation instructions, and the purchasing and investment policy. The internal steering documents are updated regularly in line with changes in legislation. Checklists have also been drawn up for important routines and processes. Internal

instructions and routines are developed on a rolling basis. Operational and financial reports are drawn up on a monthly and quarterly basis for the Group, the Parent company, the subsidiary companies, operating units and projects. The process includes specific controls that shall be carried out in order to ensure that the reports are of a high quality.

#### Risk assessment

An effective risk assessment reconciles Medivir's business opportunities and results with the requirements of shareholders and other stakeholders for stable, long-term value growth and control. Medivir continuously updates its risk analysis with regard to the assessment of risks, which can result in errors in the financial reporting. The risk work is reported annually to the management group, the Audit Committee and the Board of Directors. Medivir is exposed to the following main risk categories:

- External risks such as regulatory approval, competition, price changes, external seasonal variations, and patent protection.
- Operating risks such as integration risk, production risk, and reliance on key persons and partnerships.
- Financial risks such as liquidity, interest, currency and credit risks.

Medivir's risk assessment with regard to the financial reporting is intended to identify and evaluate the most significant risks that affect the internal controls with regard to the financial reporting. Policies and guidelines for accounting and financial reporting comprise the areas of particular importance in promoting correct and complete accounting, reporting, and information provision at the right time. Risks identified are handled through well-documented processes, through a clear division of responsibility and labour, and an appropriate decision-making process. Important transactions consequently require special approval in order to ensure that assets are managed correctly. The risk of material misstatements in financial reporting may arise in conjunction with the bookkeeping and valuation of assets, liabilities, income and expenses, or deviations from disclosure requirements. Other risks in conjunction with the financial reporting include fraud, losses or embezzlement of assets, or improper preference of another party at the company's expense. For a more detailed presentation of risk exposure and the way in which Medivir handles it, see pages 38-39.

#### **Control activities**

The primary purpose of the control activities is to prevent, identify and rectify errors in the financial reporting. Routines and activities during the full-year financial statement and reporting process, and which are critical to the reliability of the financial reporting, have been structured to handle and action

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significant risks. The activities include analytical monitoring and comparison of profit performance or items, reconciliation of accounts and balance specifications, and approval of all business transactions and partnership agreements, powers of attorney and authorisation instructions, and accounting and valuation principles. Access to ERP systems is largely restricted in line with authorisation, responsibilities and roles.

There is an established Controller function that carries out control activities at all levels within the company. The function analyses and follows up on deviations from budget, draws up forecasts, follows up on significant fluctuations over time, and reports within the company, thereby minimising the risk of misstatements in the financial reporting.

#### Information and communication

Medivir has information and communication pathways that are designed to promote the completeness and accuracy of the financial reporting. The Board of Directors approves the consolidated annual accounts and the year-end financial statement, and tasks the CEO with presenting quarterly reports in accordance with the Board's Rules of Procedure. All financial reports are published in accordance with applicable regulations. External information is communicated by means of, amongst other things, Medivir's website (www.medivir.se), where quarterly reports, year-end financial statements, annual reports, press releases and news are published in chronological order. The website is also complemented with information from press conferences and analysts' meetings.

The Board of Directors receives regular financial reports on the Group's position and profit performance. Meetings are held within the company at management group level, and then at the level deemed appropriate by the respective units. There are processes during which all relevant employees certify in writing their knowledge of and compliance with significant internal steering documents. Important communications channels within the company include the intranet, where policies, guidelines and information are published, and regular information meetings for all members of staff.

#### Monitoring

The Board of Directors reviews all of the Group's quarterly reports, year-end financial statements, and annual reports before publication. The Board receives monthly financial reports on the Group's position and profit performance, and the Group's financial position is discussed at every Board Meeting.

The Board's monitoring of the internal controls in respect of the financial reporting is primarily conducted through the Audit Committee. Medivir's auditors carry out reviews of the operations in accordance with a set audit plan and follow up on selected aspects of the internal controls annually within the framework of the statutory audit. Once an audit is completed, observations are reported back to the Audit Committee on a rolling basis. The auditors also attend one Board Meeting per year and report their observations made during the audit for the year and the operational routines. The practice on these occasions is to set time aside for specific discussions not attended by the CEO or other employees.

The company has a Board with an Audit Committee, a simple legal and operational structure and well-developed steering and internal control systems. The Board of Directors has, therefore, opted not to institute a special internal audit process. The Board and the Audit Committee evaluate and monitor the situation continuously with regard to the possible establishment of an internal audit function.

# **Income Statements**

		The G	Group	Parent Co	mpany
SEK k	Note	2013	2012	2013	2012
Net sales	1	446,146	170,647	327,271	34,327
Cost of goods sold		-71,771	-61,315	-13,590	-269
Gross profit		374,375	109,331	313,681	34,058
Selling expenses		-70,486	-47,727	-21,618	-3,793
Administrative expenses		-51,867	-59,690	-61,320	-56,113
Research and development costs		-229,430	-203,352	-228,882	-206,264
Other operating income		6,347	4,607	27,864	10,747
Other operating expenses		-3,775	-4,501	-11,193	-3,469
Operating profit/loss	2,3,4,5,6	25,164	-201,331	18,531	-224,834
Profit/loss from participations in Group companies	7	405	_	76,043	-27,492
Profit/loss from other securities and receivables	8,10	_	-9,659	_	-9,659
Other interest income and similar profit/loss items	8,9	4,199	5,599	4,304	12,114
Interest expenses and similar profit/loss items	8,10	-2,134	-5,381	-80	-56
Profit/loss after financial items		27,633	-210,772	98,799	-249,927
Tax	11	-11,619	-23,325	_	-
Net profit/loss for the year from continuing operations		16,014	-234,098	-	-
Net profit/loss from discontinued operations	24	-37,350	15,018	_	_
Net profit/loss for the year		-21,336	-219,080	98,799	-249,927
Net profit/loss attributable to:					
Parent company shareholders		-21,336	-219,080	98,799	-249,927
Basic and diluted earnings per share	12				
Continuing operations, SEK		0.51	-7.49	_	_
Discontinued operations, SEK		-1.19	0.48	_	-
Total operations, SEK		-0.68	-7.01	-	_
Average number of shares, '000		31,260	31,257	-	-
Number of shares at year-end, '000		31,260	31,260	-	-
Proposed dividend per share, SEK		0	0	_	_

<sup>-=</sup> not applicable

# Statement of comprehensive income

	The G	iroup	Parent C	ompany
SEK k	2013	2012	2013	2012
Net profit/loss for the year	-21,336	-219,080	98,799	-249,927
Other comprehensive income – items to be recycled to the				
profit/loss				
Exchange rate differences	-2,165	-2,244	_	_
Other comprehensive income for the period, net after tax	-23,501	-221,324	98,799	-249,927
Total comprehensive income for the period	-23,501	-221,324	98,799	-249,927
Total comprehensive income attributable to:				
Continuing operations	14,949	-236,042	_	_
Discontinued operations	-38,450	14,718	_	_

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# **Balance Sheets**

	_	The G	roup	Parent Cor	npany
SEK k	Note	2013 31 Dec.	2012 31 Dec.	2013 31 Dec.	2012 31 Dec.
ASSETS					
Fixed assets					
Intangible fixed assets					
Capitalised expenditure for research and development work		2,739	13,102	2,739	13,102
Trademarks and brands		_	16,189	_	-
Product rights		278,516	296,843	3,798	-
Goodwill		150,420	188,092	_	_
Other intangible assets		404	163	404	163
Total intangible fixed assets	13	432,080	514,389	6,942	13,265
Tangible fixed assets					
Buildings and land		1,287	1,499	1,287	1,499
Equipment, tools, fixtures and fittings		26,671	34,571	26,006	31,500
Total tangible fixed assets	14	27,958	36,070	27,292	32,999
Financial fixed assets					
Participations in Group companies	15	_	_	604,212	604,312
Financial assets held for sale	16	_	_	_	_
Deferred tax receivable	11	43,187	49,238	_	_
Other non-current receivables	17	10,001	_	_	_
Total financial fixed assets		53,188	49,238	604,212	604,312
Total fixed assets		513,226	599,697	638,447	650,576
Current assets					
Inventories	18	23,982	87,321	_	16
Current receivables					
Accounts receivable		21,474	70,203	13,241	247
Receivables from Group companies		_	_	44,472	7,396
Tax receivables		3,084	1,516	2,311	_
Other receivables		9,338	3,889	4,018	3,676
Prepaid expenses and accrued income	19	22,146	16,842	19,995	13,505
Total current receivables		56,042	92,450	84,037	24,824
Short-term investments					
Other short-term investments	20	370,588	257,514	370,588	257,514
Cash and bank balances	20	31,632	39,213	9,805	14,932
Total short-term investments		402,220	296,727	380,393	272,446
Total current assets		482,244	476,498	464,430	297,286
TOTAL ASSETS		995,470	1,076,195	1,102,877	947,862

<sup>-</sup> = not applicable

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Balance Sheets Medivir Annual Report 2013

# **Balance Sheets**

		The G	iroup	Parent Co	mpany
SEK k	Note	2013	2012 31 Dec.	2013	2012 31 Dec.
SEK K	Note	31 Dec.	31 Dec.	31 Dec.	31 Dec.
EQUITY AND LIABILITIES					
Equity, the Group					
Share capital		156,300	156,300	_	_
Other capital contributed		1,759,059	1,757,852	_	_
Exchange rate difference		1,363	3,522	_	_
Accumulated loss		-1,064,135	-1,042,794	_	_
Total equity, the Group		852,587	874,880	-	-
Equity, Parent Company					
Restricted equity					
Share capital		-	_	156,300	156,300
Statutory reserve		_		827,971	827,971
Total restricted equity		-	-	984,271	984,271
Non-restricted equity					
Share premium reserve		-	_	1,101,965	1,100,758
Accumulated loss		-	_	-1,201,603	-951,676
Net profit/loss for the year		-		98,799	-249,927
Total non-restricted equity		-	-	-839	-100,845
Total equity, Parent Company		-	-	983,432	883,426
Non-current liabilities					
Liabilities to credit institutions	21	40,000	40,000	40,000	_
Other liabilities		_	448	_	_
Total non-current liabilities		40,000	40,448	40,000	-
Current liabilities					
Liabilities to credit institutions	21	_	48,657	_	41
Accounts payable		28,676	37,636	18,621	17,226
Liabilities to Group companies		_	_	61	1,016
Other liabilities		12,711	16,631	10,700	8,137
Accrued expenses and deferred income	22	61,497	57,943	50,062	38,016
Total current liabilities		102,883	160,867	79,445	64,436
Total equity and liabilities		995,470	1,076,195	1,102,877	947,862
Pledged assets	23	54,250	148,355	_	_

<sup>-</sup> = not applicable

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# Change in equity

The Group, SEK k	Share capital	Other capital contributed	Exchange rate difference	Accumulated loss	Total equity	Number of shares
Opening balance, 1 January 2012	156,269	1,757,255	5,766	-823,714	1,095,576	31,253,827¹)
Net profit/loss for the year	_	_	_	-219,080	-219,080	
Exchange rate differences		_	-2,244	_	-2,244	
Total comprehensive income for the period	-	_	-2,244	-219,080	-221,324	
Conversion of options	31	348	_	_	379	6,200
Staff stock option programmes: value of						
employees' service	-	249	_	_	249	
Closing balance, 31 December 2012	156,300	1,757,852	3,522	-1,042,794	874,880	31,260,0272)
Opening balance, 1 January 2013	156,300	1,757,852	3,522	-1,042,794	874,880	31,260,027³)
Net profit/loss for the year	_	_	-	-21,336	-21,336	
Exchange rate differences	_	_	-2,165	_	-2,165	
Total comprehensive income for the period	-	_	-2,165	-21,335	-23,500	
Conversion of options	_	_	_	_	_	
Share saving plan: value of employees'						
service	_	1,207		_	1,207	
Closing balance, 31 December 2013	156,300	1,759,059	1,357	-1,064,129	852,587	31,260,0274)

<sup>1)</sup> Opening number of shares in 2012: 660,000 class A shares and 30,593,827 class B shares, nominal value: SEK 5

The nominal value has been calculated as the share capital divided by the total number of shares. Proposed dividend payment for 2013: SEK 0 per share.

Parent Company, SEK k	Share capital	Statutory reserve	Share premium reserve	Accumula- ted deficit	Net profit/ loss for the year	Total equity	Number of shares
Opening balance, 1 January 2012	156,269	827,971	1,100,161	-1,105,269	153,593	1,132,725	31,253,8271)
Appropriation of profits: Profit/loss for the							
previous year brought forward	-	-	_	153,593	-153,593	_	
Net profit/loss for the year	-	-	-	_	-249,927	-249,927	
Conversion of options	31	_	348	_	_	379	6,200
Staff stock option programmes: value of							
employees' service, Medivir AB	-	-	249	_	_	249	
Closing balance, 31 December 2012	156,300	827,971	1,100,758	-951,676	-249,927	883,426	31,260,0272)
Opening balance, 1 January 2013	156,300	827,971	1,100,758	-951,676	-249,927	883,426	31,260,0273)
Appropriation of profits: Profit/loss for the							
previous year brought forward	_	_	_	-249,927	249,927	_	
Net profit/loss for the year	-	_	_	_	98,799	98,799	
Share saving plan: value of employees'							
service, Medivir AB	_	_	1,207	_	-	1,207	
Closing balance, 31 December 2013	156,300	827,971	1,101,965	-1,201,603	98,799	983,432	31,260,0274)

<sup>1)</sup> Opening number of shares in 2012: 660,000 class A shares and 30,593,827 class B shares, nominal value: SEK 5

The nominal value has been calculated as the share capital divided by the total number of shares. Proposed dividend payment for 2013: SEK 0 per share

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<sup>2)</sup> Closing number of shares in 2012: 660,000 class A shares and 30,600,027 class B shares, nominal value: SEK 5

<sup>3)</sup> Opening number of shares in 2013: 660,000 class A shares and 30,600,027 class B shares, nominal value: SEK 5

<sup>4)</sup> Closing number of shares in 2013: 660,000 class A shares and 30,600,027 class B shares, nominal value: SEK 5

<sup>2)</sup> Closing number of shares in 2012: 660,000 class A shares and 30,600,027 class B shares, nominal value: SEK 5

<sup>3)</sup> Opening number of shares in 2013: 660,000 class A shares and 30,600,027 class B shares, nominal value: SEK 5

<sup>4)</sup> Closing number of shares in 2013: 660,000 class A shares and 30,600,027 class B shares, nominal value: SEK 5

# Statements of cash flows

		The C	Group	Parent Co	ompany
SEK k	Not	2013	2012	2013	2012
Operating activities					
Operating profit/loss¹)		34,286	-185,792	18,531	-224,834
Reversal of non-cash items					
Depreciation and amortisation		33,477	34,817	9,863	10,205
Write-downs		10,045	_	10,045	_
Other reversals		-7,524	7,585	4,776	8,230
		70,283	-143,390	43,215	-206,399
Interest received		3,885	3,893	-97	807
Dividends received		832	3,309	832	3,309
Interest paid		-6,750	-10,892	-80	-43
Tax paid		-1,024	-354	_	
Cash flow from operating activities		67,226	-147,434	43,870	-202,326
before changes in working capital		07,220	,	15,070	202,520
Increase(-)/decrease(+)in inventories		-19,255	-13,331	_	245
Increase(–)/decrease(+)in current receivables		-25,266	-7,029	-59,287	-38,507
Increase(+)/decrease(–)in current liabilities		20,335	28,230	2,367	10,854
Cash flow from operating activities	24	43,041	-139,564	-13,051	-229,734
Investing activities					
Purchase of intangible fixed assets		-461	-5,023	-461	-5,023
Purchase of tangible fixed assets		-3,594	-10,630	-3,583	-9,473
Sale of operations	24	115,025	8,421	-13	_
Sale of tangible fixed assets		-	83	-	_
Loans to subsidiary companies		-	_	-35,000	_
Dividends received from subsidiaries				120,000	
Cash used in investing activities	24	110,971	-7,149	80,943	-14,496
Financing activities					
Conversion of options		_	379	_	379
Borrowings		40,000	_	40,000	_
Amortisation of loans		-88,616	_93,174	-	
Cash flow from financing activities	24	-48,616	-92,795	40,000	379
Cash flow for the year		105,396	-239,508	107,892	-243,851
Cash and cash equivalents at the beginning of the year		296,727	536,279	272,446	516,297
Cash flow for the year		105,396	-239,508	107,892	-243,851
Exchange rate differences, cash and cash equivalents		97	-44	_	
Cash and cash equivalents at the end of the year	20	402,220	296,727	380,338	272,446

<sup>1)</sup> Of which, discontinued operations, SEK 9,222 thousand (SEK 15,538 k).

Medivir Annual Report 2013 Statements of cash flows

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<sup>-</sup> = not applicable

# Accounting principles

#### The Group

Medivir prepares its Consolidated Accounts in accordance with IFRS, International Financial Reporting Standards, as endorsed by the EU. In addition to the stated IFRS, the Group also observes the Swedish Financial Reporting Board's recommendation, RFR 1 Supplementary Accounting Rules for Groups, and applicable pronouncements from the Swedish Financial Reporting Board.

The Medivir Group presents an Income Statement classified by function, which means that the operations' expenses are broken down into cost of goods sold, selling expenses, research costs and administrative expenses. The Group utilises the acquisition value for Balance Sheet items, unless otherwise indicated.

IFRS are under constant development. A number of standards and interpretations were published during the preparation of the consolidated accounts as of 31 December 2013, only some of which have come into effect. An assessment of the impact that the introduction of these standards and statements has had, and may have, on Medivir's financial statements follows. Comments are restricted to those changes that have had, or could have, a significant effect on Medivir's accounting.

# New and revised standards applied by the Group from 1 January 2013

IAS 1 Presentation of financial reports. The revision requires the division of items under other comprehensive income into two categories, based on whether the items may be reversed to the net profit/loss for the year. The Group's comprehensive income statement has been amended in line with the revision.

IFRS 13 Fair value measurement. The standard provides an exact definition and a joint source in IFRS for valuation at fair value and associated information. The standard does not entail any extension of the requirements that state when fair value shall be applied but does contain guidelines on the way in which it shall be applied when other IFRS already require or permit valuation at fair value. The new standard has had no significant impact on the reported values for Medivir, but does entail additional disclosures.

The revisions to IAS 19 do not affect Medivir as the company has no defined benefit pension plans.

# New and revised standards that have not come into force and not applied proactively by the Group

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IFRS 9 is the first standard issued as part of the large-scale project to replace IAS 39. IFRS 9 retains but simplifies the model of several bases on valuation and establishes two primary measurement categories: the accrued acquisition value and fair value. Classification is on the basis of the company's

business model and the characteristic qualities of the contracted cash flows. The guidance contained in IAS 39 regarding impairment testing of financial assets and hedge accounting continue to apply. Previous periods do not need to be restated when a company applies the standard. The standard is not yet endorsed by the EU. The IASB's stated enactment date is from 1 January 2015 onwards. Medivir will evaluate the effect of the remaining phases of IFRS 9 once work on these phases has been completed by IASB.

IFRS 10 Consolidated Financial Statements. This standard replaces IAS 27 Consolidated and Separate Financial Statements regarding the rules for consolidated financial statements. The standard contains no changes relative to the current IAS 27 on when consolidated financial statements should be prepared and the rules for consolidation on acquisition and divestment, but offers further guidance on determining control when this is hard to judge. The standard has been adopted by the EU and shall be applied to financial years beginning on or after 1 January 2014. Medivir does not anticipate that the standard will have any significant impact on its reported values.

IFRS 12 Disclosure of interests in other entities. The standard covers disclosure requirements for subsidiaries, joint arrangements, associated companies and non-consolidated structured entities. The standard has been adopted by the EU and shall be applied to financial years beginning on or after 1 January 2014. Proactive application is allowed. Medivir does not anticipate that the standard will have any significant impact on its reported values.

Medivir does not intend to proactively apply the three new standards, IFRS 9, 10 and 12.

#### The Parent Company

Medivir AB continues, as in previous years, to apply those accounting principles relevant to legal entities that prepare Consolidated Accounts and which are listed on a stock exchange. Medivir AB complies with the Swedish Financial Reporting Board's recommendation, RFR 2 Accounting principles for legal entities.

The Parent Company shall, in accordance with RFR 2, structure its reports in accordance with all applicable IFRS unless the recommendation permits an exemption from application. The Parent Company's principles are consequently consistent with those of the Group, unless otherwise indicated below.

#### **Consolidated Accounts**

The Consolidated Accounts have been prepared using acquisition accounting, whereby the subsidiary company's equity at the time of acquisition is eliminated. The equity of the acquired subsidiary is measured on the acquisition date on the basis of the fair value of identifiable assets and liabilities taken over. The acquisition value consists of the fair value of assets sub-

Accounting principles Medivir Annual Report 2013

mitted as payment, issued equity instruments, and liabilities arising or taken over as of the transfer date.

In cases where the acquisition value of shares in the subsidiary exceeds the fair value of the assets and liabilities acquired, the difference is recognised as goodwill.

Costs directly attributable to the acquisition are reported in the Group under other operating expenses in the Income Statement as they arise. In the Parent Company, transaction costs are included in the acquisition value of equity in subsidiary companies.

Subsidiary companies comprise all companies in which Medivir is entitled to formulate financial and operational strategies in a manner usually ensuing from a shareholding comprising more than half of the votes. Subsidiaries are consolidated from the day when controlling influence is transferred to the Group. They are deconsolidated from the date when the controlling influence ceases. For each acquisition, the Group determines whether potential non-controlling interests in the acquired company are recognised at fair value or at the holding's proportional share of the carrying amount of the acquired company's identifiable net assets.

The preparation of Medivir's Consolidated Accounts also complies with the instructions stipulated in IAS 27 and IFRS 3, such as eliminations of intragroup receivables and liabilities and of intragroup income and expenses between Group companies, and the Consolidated Income Statement and the Consolidated Balance Sheet are consequently reported without intragroup transactions.

# Translation of foreign currencies Functional currency and reporting currency

Items included in the financial statements for the various entities within the Group are valued in the currency used in the economic environment in which the respective company is primarily active (functional currency).

The Swedish krona, which is the Parent Company's functional currency and reporting currency, is the currency utilised in the Consolidated Accounts.

#### **Transactions and Balance Sheet items**

Transactions in foreign currencies are translated to the functional currency at exchange rates applicable on the transaction date or the date when the item is translated. Exchange rate profits and losses arising when paying for such transactions and when translating monetary assets and liabilities in foreign currencies at the closing day rate are reported in the Income Statement. Profits and losses on trading receivables and liabilities are reported net under other operating income or other operating expenses.

#### **Group companies**

The profit/loss and financial position of all Group companies whose functional currency differs from the reporting currency are translated to the Group's reporting currency as follows:

- Assets and liabilities for each Balance Sheet item are translated at the closing day rate.
- Income and expenses for each Income Statement are translated at the average exchange rate. If the average exchange rate is not a reasonable estimate of the total exchange rate effects for the year from each transaction date, income and expenses are translated at the closing day rate instead.
- All exchange rate differences arising are reported under other comprehensive income and accumulated as a separate portion of the equity.

#### The Income Statement

Medivir applies a classification by function approach to the presentation of the Income Statement in accordance with the description in IAS 1 Presentation of Financial Statements. Medivir's operations are broken down into Cost of goods sold, Marketing & Sales, Administration, and Research and development:

#### Cost of goods sold

Cost of goods sold comprises purchasing and manufacturing costs for goods sold during the period.

#### **Marketing & Sales**

This function is responsible for the commercialisation of research projects, product launches, and sales of pharmaceuticals on a proprietary basis and via partners.

#### Administration

This function comprises the company's administrative functions, such as company management, business development, IR, and the finance department.

#### Research and development

This function comprises Medivir's research and pharmaceutical development in preclinical and clinical trials, and regulatory activities.

### Financial instruments, reporting, disclosure and classification

For information on financial risks and investments, see Note 8, Financial Risks, on page 71.

# Financial assets reported at fair value in the Income Statement

Medivir's short-term investments are managed as a group of financial assets and the profit or loss is evaluated on the basis

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of fair value in accordance with the documented risk management and investment strategy. Medivir has, therefore, chosen to report changes in the fair value of its short-term investments in the Income Statement.

#### Financial assets held for sale

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

None of these shares are listed and are hence not registered on an active marketplace, and other non-observable data is consequently used as a valuation basis for the shares. An estimation of the value is carried out based on the companies' posted financial results and position, the development of the companies' project portfolios, the share price performance of the Nasdaq OMX biotech index and, where relevant, independent valuations by third parties. If the valuation results in an estimated change in value, this change in value is reported in the statement of other comprehensive income for the period.

If a negative change in value is adjudged to be significant, or to have occurred over an extended period of time, the accumulated loss is reported in the profit or loss for the period. A subsequent positive revaluation of any such impairment is reported under other comprehensive income and not in the Income Statement.

#### Accounts receivable and other receivables

Accounts receivable comprise non-derivative financial assets with measured or measurable payments not listed on an active marketplace. They are distinguished by the fact that they arise when the Group supplies money, goods or services directly to a customer without any intention to trade in the receivable arising. They are included in current assets, with the exception of items with due dates that fall more than 12 months after the reporting date, which are classified as fixed assets. Accounts receivable are initially reported at fair value and then at amortised cost by applying the effective interest method, less potential provisioning for impairment. Other receivables and, where applicable, interim receivables, are reported in the same manner.

Provisioning for the impairment of accounts receivable is effected when there is objective evidence that the Group will not be able to collect all amounts due in accordance with the original terms of such receivables. The amount of the provision comprises the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted by effective interest. The provisioned amount is reported in the Income Statement. Other receivables are reported in the same way.

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#### Purchases and sales of financial instruments

Purchases and sales of financial instruments are reported on the transaction date – the date when Medivir undertakes to buy or sell the asset. Financial instruments are derecognised from the Balance Sheet when the right to receive cash flows from the instrument has expired or been transferred and the Group has transferred essentially all risks and benefits associated with title to the asset.

#### Accounts payable and loan liabilities

Accounts payable and loan liabilities are classified in the other financial liabilities category and are reported initially at fair value and subsequently at amortised cost, applying the effective interest method.

#### Share-related incentive plans

#### **Share saving plan**

The Share saving plan 2013 (LTI 2013) has been offered to all permanent employees of the Parent Company, including senior executives. IFRS requires a company to report payroll expenses in relation to share-related incentive plans based on a metric of the value to the company of the services rendered by the employees during the term of the plans. This value is based on the fair value of, for example, free shares on the vesting date, valued at the share price in conjunction with every investment. The value on the vesting date is carried as an expense in the Income Statement in the same way as all other salary earned during the vesting period. Example: the value on the vesting date is SEK 90. Given the normal vesting period of three years within the Group, SEK 30 is charged to the Income Statement per year during the vesting period. The amount carried as an expense in the Income Statement is reversed in shareholders' equity every time an item is carried as an expense in the Income Statement. The reason for this accounting principle under IFRS is that these payroll costs have no direct effect on the cash flow. The objective, in reporting share-related payments in accordance with IFRS (IFRS 2) is to present the effect of share-related payments, which are a component of the payroll costs, in the Income Statement.

When remuneration costs for shares received through performance-based share saving plans are calculated, the Parent Company assesses, on every reporting date, the probability that the performance goals will be achieved. The costs are calculated on the basis of the number of shares which it is estimated will be matched by the end of the vesting period. When share matching occurs, social security contributions shall be paid for the value of the employee's benefit. This value is, in general, based on the market value on the matching date. Provision for these estimated social security contributions is made during the vesting period in accordance with the Swedish Financial Reporting Board's statement UFR 7.

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#### Intangible fixed assets

#### Goodwill

Goodwill arises in conjunction with the acquisition of subsidiary companies and comprises the amount by which the acquisition value exceeds the fair value of the Group's share of the acquired company's net assets upon acquisition. Goodwill is subject to annual impairment testing and is reported at acquisition value less accumulated impairment losses. Impairment of goodwill is not reversed. Goodwill is allocated to the cash-generating units expected to benefit in conjunction with the business acquisition that gave rise to the goodwill item.

#### Trademarks and brands, product rights

Trademarks and brands, and product rights acquired separately are recognised at cost in the Group. Trademarks and brands, and product rights acquired through a business combination are recognised at fair value on the acquisition date. Trademarks and brands, and product rights have a defined useful life and are recognised at cost less accumulated impairment. Amortisation is effected linearly over the estimated useful life of 10-15 years.

#### Research & Development costs - in-house development

Pharmaceutical development expenses are capitalised in accordance with IAS 38 Intangible assets, when the following criteria are fulfilled:

- It is technically possible to complete the pharmaceutical.
- The company's management intends to complete the pharmaceutical and the conditions for sale are in place.
- The asset is expected to provide future economic benefits.
- Medivir adjudges that the resources required to complete the development of the asset are available.
- Developmental expenses can be reliably calculated.

Medivir's judgement of this principle with regard to ongoing development projects is presented on page 67 (Research & Development costs).

Development costs for the product are reported, as of the date when the criteria are fulfilled, as intangible fixed assets at historical cost. Expenses arising before this date will continue to be reported as costs. Historical costs include direct costs for the completion of the pharmaceutical, including patents, registration application costs, and product tests including remuneration to employees. Amortisation is conducted linearly in order to distribute the development costs on the basis of the estimated useful life. Amortisation begins when the pharmaceutical begins to generate income. Useful life is based on the underlying patent term.

The amortisation term for capitalised development costs for Xerclear is 10 years and consequently exceeds the 5 years which, under the provisions of the Swedish Annual Accounts Act, should be the Parent Company's amortisation period under normal circumstances. The longer amortisation is due to the fact that Xerclear is expected to generate income throughout its patent term.

Medivir's other research and development costs are reported as they arise as costs for patent and technology rights, and other similar assets, developed in-house. Against the background of the contents of the "Research and development costs" section on page 67, other research work performed by Medivir is judged to be associated with such uncertainty that IAS 38's capitalisation criteria cannot be considered satisfied, primarily because of the difficulties in judging whether it is technically possible to complete the pharmaceutical.

#### **Development projects acquired**

Amortisation of intangible assets acquired, e.g. customer relationships or trademarks and brands, is effected linearly over the useful life. Amortisation of other intangible assets acquired, such as development projects, is effected linearly over the useful life – linked to the term of patents obtained.

#### Other intangible fixed assets

Expenses incurred in connection with the development of Medivir's ERP systems such that the software's performance is improved or its useful life extended, are reported at historical cost. These expenses are amortised over the estimated useful life. The useful life is estimated at 5 years, whereupon the reported asset will be amortised linearly in accordance with this estimate.

#### Tangible fixed assets

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

Depreciation according to plan has, in accordance with IAS 16, been calculated for tangible fixed assets on the basis of the original historical costs with depreciation rates based on the estimates of the assets' economic useful lives.

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

#### **Impairment**

Goodwill, which has an indefinite useful life, is subject to annual impairment testing. Tangible and intangible fixed assets are subject to impairment testing and impairment losses are recognised whenever internal or external indications of potential impairment are identified, in accordance with IAS 36. An impairment is effected in the amount by which the asset's carrying value exceeds the recoverable amount. The recoverable amount is whichever is the higher of the asset's fair value

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less selling expenses and its value in use. The term, value in use, refers to the sum of the present value of expected future cash flows and the estimated residual value at the end of the useful life. When calculating the value in use, future cash flows are discounted at an interest rate that takes into account the market's assessment of risk-free interest and risk. In the Group, the calculation is based on results achieved, forecasts and business plans. When conducting impairment testing, assets are grouped together at the lowest levels at which there are separate, identifiable cash flows (cash-generating units).

Intangible assets that are not in use are not amortised, but are subject to annual impairment testing. If the recoverable amount is less than the carrying amount, an impairment loss is recognised. The recoverable amount comprises whichever is the higher of the fair value and the value in use. The value in use is calculated on the basis of the estimated future cash flows, based on the competitive situation and estimated market shares.

Investments in subsidiary companies are valued in the Parent Company at historical cost and impairment testing is carried out at each year-end. The subsidiary company's equity forms a key criterion for assessment in this context. Supplementary investments may be made in the form of new share issues or shareholders' contributions.

#### **Inventories**

Inventories are reported at whichever is the lower of the historical cost and the net realisable value. The historical cost is determined using the first in, first out (FIFO) method. The historical cost includes purchasing costs, customs duties and transportation costs, and other direct costs associated with goods purchases. The net realisable value is the expected sale price in operating activities less selling costs. Obsolescence risk and confirmed obsolescence are taken into account in the valuation. As goods in inventory are sold, their carrying amount is carried as an expense in the period in which the corresponding revenue is recognised. Losses on goods in inventory are recognised in the Income Statement in the period to which the loss relates.

#### Equity

Transaction costs directly attributable to the issuance of new shares or options are reported in equity as a deduction from issue proceeds in the capital component of Other capital contributed.

#### Revenues

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Revenues include the fair value of what is received or will be received for goods or services sold. Revenues are recognised excluding VAT, returns and discounts, and after eliminating intragroup sales. Revenues are recognised when the amounts can be measured reliably and it is likely that future economic benefits will flow to the Group.

#### Sales of pharmaceuticals

To recognise revenues from the sale of pharmaceuticals, the following criteria of IAS 18:14 must be satisfied:

- The company has transferred to the buyer the significant risks and rewards of ownership of the goods.
- The company retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold.
- The revenue amount can be measured reliably.
- It is probable that the economic benefits associated with the transaction will flow to the company.
- The costs incurred or which can be expected to be incurred in respect of the transaction can be measured reliably.

For Medivir, the applied principle means that revenues from sales of pharmaceuticals are recognised at the time of delivery to the customer in that the customer takes over the economic risks and rewards at that time. This presupposes that the other above-mentioned criteria are also adjudged to have been satisfied at that time.

#### **Royalty income**

Income in the form of royalty is reported when there is a likelihood of the financial benefits associated with the transaction accruing to Medivir, and when the income can be reliably calculated.

#### Out-licensing and collaboration agreements

Revenues from agreements made with Medivir's partners on research projects are recognised on the basis of their economic substance. Remuneration can, under the terms of these agreements, be payable in the form of upfront fees when the agreement is entered into, milestone payments, remunerations paid during the term of the agreement for a set number of full-time equivalent research positions (FTEs), and/or royalties. Medivir may also be entitled, under the terms of the agreements, to receive remuneration for costs incurred. The remuneration is recognised as revenue for invoiced costs in the same period as the cost.

Revenue recognition is initially conducted on the basis of a judgement of whether the agreement with the counterparty in relation to one of Medivir's intangible assets (one or more research projects) means that: i) the collaboration shall take the form of a research project with the partner, or ii) the licence that the counterparty is granted under the terms of the agreement means that the intangible asset has, from an accounting perspective, been divested (i.e. a sold licence to dispose over the asset).

The judgement is made on the basis of the criteria laid down in IAS 18 for sales of goods (see above under Sales of pharmaceuticals). If these criteria are satisfied, the judgement is that

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the economic substance of the agreement entails a divestment of the underlying asset. If the criteria are not satisfied, no divestment of the asset has occurred.

# Reporting in cases where the economic substance of an agreement is that a sale of a research project has occurred

Payments received when a licensing agreement is entered into (upfront fees) are recognised as revenues when the agreement is entered into if there is no restriction in the agreement with the counterparty. If any criterion in accordance with IAS 18:14 (see above) is not satisfied, the revenue recognition is post-poned until such time as all criteria are satisfied. Any additional remuneration in the form of milestone payments is recognised as revenue when it can be reliably measured, i.e. when the criteria in the relevant out-licensing agreement regarding remuneration to Medivir have been satisfied and verified with the counterparty. Revenues are regarded as remuneration for a sold licence that entitles the counterparty to utilise Medivir's intangible asset. Royalties are recognised in the period in which they accrued under the terms of the agreement.

# Reporting in cases when the economic substance of an agreement is that a collaboration shall occur

Medivir retains undertakings in the agreement in these cases, often for future development work that will be conducted either separately or jointly with the counterparty. A reporting method is chosen to determine when and at what value revenue is recognised on the basis of the contents of the specific agreement. Factors affecting revenue recognition in collaboration agreements include:

- Whether the remuneration is only received once goals have been achieved.
- Whether remuneration is payable for work done directly (e.g. for a number of FTEs).
- Whether remuneration is received in advance or in arrears in relation to services rendered under the agreement.

Remuneration received in the form of upfront fees, and which refers to undertakings in the agreement not yet rendered by Medivir, is allocated over the term of the agreement during which Medivir fulfils its undertakings. If the remuneration refers to research services (such as FTEs), revenue is recognised as the work is carried out. Remuneration received when development goals are achieved (often in the form of milestone payments) in a collaboration agreement is recognised when it is clear, under the terms of the agreement, that Medivir shall receive the remuneration. This is then considered as a remuneration for services rendered during the period up to and including that date. This revenue recognition model is often referred to

as the milestone method in that successive revenue recognition cannot be applied to those research projects that have potential future milestones from a collaboration partner as it is not possible to measure a degree of completion in a sufficiently reliable manner as stipulated by IAS 18 as a requirement for successive revenue recognition of a project, nor is it possible to measure with sufficient accuracy the precise expenses that will be incurred in order to receive the corresponding milestone (the number of researchers and other direct expenses may vary over time), nor is any remuneration payable if the criteria agreed with the collaboration partner are not satisfied.

### Central government support (EU grants and other subsidies)

Central government support is reported in accordance with IAS 20 under other income. Support received is recognised 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 prepaid income and is recognised as revenue as the terms for receiving the funds are satisfied. Medivir receives central government support mainly in the form of research grants from the EU. An insignificant percentage of Medivir's projects are financed with central government support.

#### **Operating segments**

IFRS 8 requires segment information to be presented from the management's perspective, which means that it is presented in the way used in internal reporting. The basis for identifying reportable segments is internal reporting as it is reported to and followed up on by the chief operating decision maker. The company has, in this context, identified the Group President/ CEO as the chief operating decision maker. The President/CEO evaluates the operating segments' results on the basis of the EBITDA metric, which comprises the operating profit/loss before depreciation and amortisation. Since 1 July 2013, Medivir's business operations are organised into a single segment comprising research and development work on the Group's research portfolio and the marketing and sale of proprietary and acquired pharmaceuticals. Up until 30 June 2013, Medivir had an additional operating segment for parallel imports through the Cross Pharma subsidiary company. Cross Pharma imported original pharmaceuticals from EU countries where the price level was lower than in Sweden and sold these pharmaceutical products to the pharmacy market at a price below that charged by the original producer. The parallel imports segment was wound up on 30 June, when the Cross Pharma subsidiary company was sold to an external party and the segment is consequently reported as discontinued operations.

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#### Leasing

Leasing agreements are classified either as operational or financial leasing agreements.

Leasing agreements for fixed assets under which the Group has, in every significant way, assumed the economic risks and benefits associated with ownership, are classified as financial leasing. The leased object is reported as a fixed asset in the Balance Sheet and the obligation to pay leasing charges is reported as a liability. Financial leasing is reported in the Balance Sheet at the beginning of the lease term at whichever is the lower of the lease object's fair value and the present value of the minimum leasing charges. Leasing charges paid are allocated between amortisation and interest. The leased fixed asset is depreciated over the asset's useful life.

Leasing agreements where Medivir incurs no significant risk or benefit from an object are reported as operational leasing agreements. Payments made during the lease term are booked as expenses in the Income Statement linearly over the lease period. See also Note 21 on page 79.

#### Pension liability and pension costs

Medivir's ITP (supplementary pensions for salaried employees) scheme is insured with Alecta and should be regarded as a defined benefit pension scheme in accordance with the UFR 3 statement from the Swedish Financial Reporting Board.

In accordance with UFR 3, the company shall report its proportional share of the defined benefit undertakings and the plan assets and costs associated with the scheme. Alecta is unable to provide sufficient information and the scheme is consequently reported, until further notice, as if it were a defined contribution plan.

Alecta's surplus can be distributed among the policyholders and/or the beneficiaries. At the end of 2013, Alecta's surplus in the form of the collective consolidation ratio was preliminarily calculated by Alecta at 148 per cent (130%). The Group is of the opinion that the current premiums should cover existing undertakings. Other pension schemes within the Group are defined contribution schemes. The premiums paid are reported as personnel costs when they fall due for payment.

#### Severance pay

Severance pay is booked as an expense when the obligation to pay the remuneration arises.

#### Income tax

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The tax expense for the period consists of current tax and deferred tax. Tax is recognised in the Income Statement apart from when tax relates to items recognised in other comprehensive income or directly in equity. In such cases, tax is also recognised in other comprehensive income and equity, respectively.

Current tax is tax to be paid or received for the current year and restatements of current tax relating to previous years.

Deferred tax is recognised in accordance with the balance sheet method on all temporary differences that arise between the taxable values of assets and liabilities and their carrying amounts in the consolidated accounts.

Deferred tax receivables are recognised to the extent it is likely that future taxable profits will be available.

Note 11 lists items that include the estimated deductible deficits accumulated in the Group. The Group's taxable deficits have no expiry date.

The treatment of deferred tax on temporary differences is reported and explained in Note 11 on page 75. The various components of consolidated total tax are also explained in this Note.

#### **Discontinued operations**

Discontinued operations are reported in accordance with IFRS 5. A discontinued operation is that part of a company that has either been divested or which is classified as being held for sale and which comprises an independent, significant operating segment or a significant operation that is conducted within a geographical area, is part of a single, coordinated plan for the divestment of an independent operating segment or a significant operation that is conducted within a geographical area, or is a subsidiary company that has been acquired exclusively for the purposes of resale. The sum of the profit/loss after tax of discontinued operations is reported as a single item in the Income Statement. The disclosures are also provided for previous periods.

The disclosures in the Notes comprise the Group's total operations unless otherwise indicated. See also Note 24.

#### **Statement of Cash Flows**

The Statement of Cash Flows has been reported by applying the indirect method. Reported cash flow only includes transactions involving payments made or received. Cash and bank balances, and short-term investments such as commercial papers and fixed income and bond funds with a maximum term of three months, are reported as cash and cash equivalents in the Statement of Cash Flows.

#### Significant estimates and judgements

The company management and the Board of Directors must, in order to be able to prepare the accounts in accordance with generally accepted accounting practices and in compliance with IFRS, make estimates and assumptions regarding the future. These estimates and assumptions affect both recognised revenue and cost items and asset and liability items, as well as other disclosures. Estimates and judgements are evalu-

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ated continuously and are based on historical experience and other factors, including expectations of future events regarded as reasonable under the prevailing circumstances. Segments that include such estimates and assumptions that may have a material impact on the Group's operating results and financial position are presented below.

#### Revenues

Medivir does not apply successive revenue recognition for impending potential milestone payments within the research projects due to the constant uncertainty regarding the extent of the progress made by the project and the likelihood that the next goal/milestone will be achieved. The income side consequently only shows confirmed and non-refundable income that can be considered to have accrued.

Allocation to particular periods could show how Medivir successively receives revenues from the counterparty's utilisation of incorporeal rights, but if successive revenue recognition were to be applied, there is a risk that income would be reported that is uncertain in terms of whether Medivir would ever receive any payment. An announcement by the counterparty that the project was to be discontinued, for example, could, under such circumstances, mean that Medivir had reported its profit or loss inaccurately.

#### Research and development costs

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

Product development costs shall be capitalised when it is likely that the project will succeed. Every research project is unique and must be judged individually on the basis of its own preconditions. The earliest date for capitalisation to occur is adjudged to be upon completion of the phase III trials, but a number of uncertainty factors may still remain, even after completion of phase III trials, such that the criteria for capitalisation cannot be considered to be satisfied. Where this is the case, capitalisation does not occur until the pharmaceutical is approved by the relevant regulatory authority.

Premature capitalisation entails a risk of a project failing and of it being impossible to justify offset costs which must, instead, be carried directly as an expense. This would, in turn, mean that the previous year's results, and those for the year in question, would be misleading due to overly optimistic probability assessments.

#### **Intangible fixed assets**

The Group conducts impairment testing every year with regard to goodwill, other intangible assets with an unidentified useful life, and as yet uncompleted development projects. Other intangible assets are subject to impairment testing when events or changes indicate that the carrying amounts are not recoverable. When calculating the value in use, future cash flows are discounted at an interest rate that takes into account the market's assessment of risk-free interest and risk (WACC). In the Group, the calculation is based on results achieved, forecasts and business plans. When conducting impairment testing, assets are grouped together at the lowest level at which there are separate, identifiable cash flows (cash-generating units). The estimations and assumptions made by the management in conjunction with impairment testing can have a significant impact on the Group's reported profit or loss. Impairment is effected if the estimated value in use is less than the carrying amount and is charged to the profit or loss for the year. See also Note 13 for significant assumptions and a description of the effect of reasonable possible changes in the assumptions that form the basis for the calculations.

#### Tax

The deferred tax receivable has been calculated on the basis of the management's and Board of Directors' judgement of the future utilisation of the consolidated accumulated deficits within the foreseeable future. A revised judgement of the way in which the deductible loss carry forward can be recovered through future taxable surpluses may affect reported tax in the results of the operations and the balance in forthcoming periods. See also Note 11.

#### Other information

The financial reports are presented in thousands of kronor (SEK k) unless otherwise indicated. Rounding off may mean that certain tables in the Notes do not add up.

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# **Notes**

### Note 01 Segment reporting (SEK k)

Operating segments are reported in a manner that is consistent with internal reporting presented to the chief operating decision maker. The chief operating decision maker is the function responsible for allocating resources and judging the results of operating segments.

In the Group, this function has been identified as the CEO.

Medivir was, until 30 June 2013, organised into two operating segments: pharmaceuticals and parallel imports. On 30 June, the wholly owned subsidiary company, Cross Pharma, which had conducted parallel imports of pharmaceuticals, was divested. The Group's continuing operations have subsequently comprised one segment that comprises research and development and pharmaceutical sales.

The pharmaceuticals segment includes the Group's research portfolio, the in-house developed pharmaceuticals, simeprevir and Xerclear, and the original pharmaceuticals owned by the wholly owned subsidiary company, BioPhausia. The other operating segment comprised parallel imports of pharmaceuticals, which were conducted via BioPhausia's subsidiary, Cross Pharma, until the divestment on 30 June 2013.

The Group management assesses the operating segments on the basis of the EBITDA metric, which comprises the operating profit/loss before depreciation and amortisation.

		2013				2012		
	Pharma- ceuticals	Parallel imports	Elimination	Total	Pharma- ceuticals	Parallel imports	Elimination	Total
Net sales	446,146	213,006	=	659,153	170,647	384,379	=	555,026
EBITDA	76,389	8,222	-6,825	77,786	-165,254	14,279	_	-150,975
EBITDA, %	17	4	-	12	-97	4	=	-27
Depreciation and amortisation				-43,500				-34,817
Net financial items				-44,447				-7,120
Profit/loss after net financial items				-10,161				-192 912
-of which continuing operations				27,633				-210,772
-of which discontinued operations				-37,795				17,860

Information has not been provided for assets and liabilities per operating segment as the Group management does not use this information in its control work. All of the Group's fixed assets are located in Sweden.

	The G	roup	Parent Co	ompany	
Breakdown of net sales	2013	2012	2013	2012	
Out-licensing and collaboration agreements					
Non-recurrent payments	258,495	4,353	258,495	4,353	
Research collaborations	-	-	44,485	26,916	
Pharmaceutical sales	176,140	164,994	60	300	
Parallel imports	213,006	384,379	_	_	
Royalties	11,512	_	11,512	_	
Other services	-	1,300	12,719	2,758	
Total	659,153	555,026	327,271	34,327	

The G	iroup	Parent Co	ompany	
2013	2012	2013	2012	
368,985	517,548	13,630	1,837	
16,168	17,132	_	-	
4,971	20,346	44,612	32,490	
269,029	_	269,029	_	
-	_	_	-	
659,153	555,026	327,271	34,327	
	2013 368,985 16,168 4,971 269,029	368,985 517,548 16,168 17,132 4,971 20,346 269,029 – –	2013         2012         2013           368,985         517,548         13,630           16,168         17,132         -           4,971         20,346         44,612           269,029         -         269,029           -         -         -	

#### Large customers

The Group's three largest customers collectively account for 85 per cent of the Group's total net sales. The three largest customers within the parallel imports segment account for 88 per cent of net sales, while in the pharmaceuticals segment, the three largest customers account for 97 per cent of net sales.

### Note 02 Costs by type of cost (SEK k)

	The Group		Parent Co	ompany
_	2013	2012	2013	2012
Cost of raw materials and consumables	251,991	402,671	825	269
Other external costs	182,722	179,376	169,221	142,645
Personnel costs	148,728	136,982	141,068	112,857
Amortisation of intangible fixed assets	33,648	24,589	10,045	541
Depreciation of tangible fixed assets	9,853	10,228	9,863	9,664
Total	626,942	753,846	331,021	265,976

### Note 03 Intra-group transactions

#### **The Parent Company**

Intra-group sales totalled SEK 85,276 thousand (SEK 36,404 k). Intra-group purchases totalled SEK 0 thousand (SEK 2,673 k).

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# Note 04 Audit costs and audit consulting fees (SEK k)<sup>1)</sup>

	The G	iroup	Parent C	ompany
	2013	2012	2013	2012
PwC				
Audit engagement	1,047	1,003	795	871
Auditing activities over and above audit				
engagement	259	116	259	116
Tax advice	845	196	645	196
Other services	912	1,087	912	980
Total, PwC	3,063	2,402	2,621	2,193
EY				
Audit engagement	36	129	-	-
Other services	-	88	_	_
Total, EY	36	217	_	_
Total	3,099	2,619	2,620	2,163

<sup>1)</sup> The Group's auditors are PricewaterhouseCoopers AB.

The term, audit engagement, refers to fees payable for the statutory audit, i.e. work that was needed to submit the audit report, and so-called audit advisory services provided in conjunction with the audit engagement.

# Note 05 Average number of employees, salaries, other remuneration, social security contributions, and pension costs

Average number of employees	The Group 2013		The Group 2012		Parent Company 2013		Parent Company 2012	
	Women	Men	Women	Men	Women	Men	Women	Men
Sweden	73	53	68	52	68	49	53	44
Poland	20	7	31	13	-	-	-	_
Total	93	60	99	65	68	49	53	44

	The Group		Parent Company		
Salaries, remuneration, social security contributions, and pension costs, SEK k	2013	2012	2013	2012	
Salaries and remuneration					
Maris Hartmanis	4,782	4,334	4,782	4,375	
Anna Malm Bernsten (Member of the Board)	340	340	340	340	
Björn C Andersson (Member of the Board)	290	290	290	290	
Ingemar Kihlström (Member of the Board)	340	340	340	340	
Rolf Classon (Member of the Board from 10 May 2012)	275	275	275	275	
Anders Hallberg (Member of the Board from 10 May 2012)	275	275	275	275	
Göran Pettersson (Chairman of the Board)	535	535	535	535	
Birgitta Stymne Göransson (Member of the Board from 6 May 2013)	183	_	183	_	
Bo Öberg (Member of the Board from 6 May 2013)	257	_	257	-	
Total, Board of Directors and CEO	7,376	6 389	7,376	6,430	
Other senior executives	12,219	12,197	12,219	12,304	
Other employees	75,954	73,125	70,208	57,510	
Salaries and remuneration, total	95,450	91,711	89,704	76,244	
Statutory and contractual social security contributions	30,741	27,286	29,609	22,493	
<b>Pension costs</b> (of which SEK 1,218 thousand (SEK 1,184 k) for the CEO	16,531	14,548	15,823	11,790	
Total salaries, remuneration, social security contributions, and pension costs	142,721	133,545	135,136	110,527	

#### Remuneration during the financial year The Board of Directors

Fees are payable to the Members of the Board in accordance with the resolution by the Annual General Meeting, as proposed by the Nomination Committee. Members of the Board not elected by the Annual General Meeting receive no fee. No fees are payable for the work of the Nomination Committee. SEK 2,495 thousand (SEK 2,055 k) was paid in director's fees to the Board of Directors of Medivir AB during the financial year, SEK 535 thousand (SEK 535 k) of which was paid to the Chairman of the Board, Members of the Board are also reimbursed for travel expenses in connection with Board Meetings, etc. SEK 20 thousand per physical Board Meeting is paid to Members of the Board resident outside Europe, over and above the normal fee and up to a maximum of SEK 100 thousand per year. There is no pension plan for the Board of Directors. Consultancy fees of SEK 72 thousand (SEK 414 k), approved by the Board of Directors, have been paid to Bernsten Konsult AB (Anna Malm Bernsten), as have royalties totalling SEK 1,903 k (SEK 0), which have been paid to Uppsala Hallbechem AB (Anders Hallberg)in accordance with an earlier agreement.

#### Guidelines for remuneration to senior executives

It is apparent from the remuneration policy adopted by the 2013 Annual General Meeting, that Medivir should offer a competitive total remuneration package that enables the recruitment and retention of qualified senior executives. Remuneration payable to the senior executives may comprise a fixed salary, any performance-related pay, incentive programmes approved by the AGM, pensions and other benefits. The fixed salary shall take into account the extent of the individual's responsibilities and their experience. Performance-related pay paid in cash shall

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# Note 05 Continued

total a maximum of 50 per cent of the annual fixed salary. Performance-related pay shall be linked to predetermined and quantifiable criteria formulated in order to promote the company's long-term value creation. The Directors' Report on pages 36-37 presents the proposed guidelines for 2014 in their entirety.

#### **Pensions**

Pensions shall be premium-based. The premium can, for the CEO, and other senior executives, comprise up to 35 per cent of the fixed salary. The Board of Directors shall be entitled, the above provisions notwithstanding, to offer other alternative solutions which, from a costs point of view, are approximately equivalent to the above.

#### Severance pay, etc.

A maximum mutual notice period of six months shall apply. No severance pay or similar remuneration shall, as a basic principle, be payable but may – up to an one-off amount corresponding to a maximum of 100 per cent of the annual remuneration – be agreed with reference to any change of control. An additional entitlement to severance pay corresponding to a maximum of 100 per cent of the annual remuneration may also apply for the CEO in the event of the company terminating the employment of the CEO or of the CEO resigning due to a significant breach of contract on the part of the company.

#### Remuneration for the Chief Executive Officer

Maris Hartmanis was appointed President and CEO of Medivir on 26 September 2011. A review of the CEO's salary is conducted on 1 January every year by the Board of Director's Remuneration Committee and the salary is then set by the Board of Directors. Salaries and remuneration paid to Maris Hartmanis during the year comprised SEK 3,462 thousand (SEK 3,344 k) in salary, SEK 1,320 thousand (SEK 990 k) in bonuses, and SEK 98 thousand (SEK 85 k) in other benefits. The pension plan for the CEO conforms to the individual pension plan of 35 per cent of the annual gross salary, excluding bonuses and benefits. Pension provision made during the year totalled SEK 1,218 thousand (SEK 1,184 k).

Any bonuses are maximised to a value of 50 per cent of the fixed salary. A mutual notice period of six months applies for Maris Hartmanis. Maris Hartmanis is entitled to severance pay corresponding to twelve times the value of the fixed monthly salary at the time when notice is given plus the average of any bonuses paid in the last three full financial years if notice of the termination of Maris Hartmanis' employment is given by the company or if Maris Hartmanis gives notice due to significant breach of contract on the part of the company.

#### Other senior executives

The term, other senior executives, refers, in addition to the CEO, to the people who, together with the CEO, have comprised the management group during the year. At the beginning of 2013, the management group, incl. the CEO, comprised seven persons (two women and five men), while at the end of the year, it comprised eight persons (two women and six men). Salaries totalling SEK 9,133 thousand (SEK 9,080 k) have been paid to other senior executives, together with SEK 1,982 thousand (SEK 1,257 k) in performance-related pay, SEK 1,104 thousand (SEK 1,860 k) in severance pay, and SEK 433 thousand (SEK 530 k) in benefits, comprising a total of SEK 12,653 thousand (SEK 12,727 k) in total remuneration paid. Pension provisions have been made in the sum of SEK 2,053 thousand (SEK 2,313 k).

#### Fixed salaries and performance-related pay

The CEO and Group management, managers and a number of key individuals receive performance-related pay in addition to their fixed salaries. The performance-related pay follows a system adopted by the Board of Directors, based on financial goals, company-wide goals, functional goals and, where relevant, individual goals.

The level of the performance-related pay per individual is maximised to between 10 and 50 per cent of the basic salary received and is disbursed every year in cash for the previous year. For the CEO, 30 per cent of the performance-related pay is based on financial goals, 10 per cent on company-wide goals, and 10 per cent on individual goals. For other senior executives, 10 per cent of the performance-related pay is based on financial goals, 10 per cent on company-wide goals and 10 per cent on functional goals. 5 per cent of the performance-related pay for a number of key individuals is based on financial goals, 5 per cent on company-wide goals, and 10 per cent on functional goals, or alternatively, 2.5 per cent on financial goals, 2.5 per cent on company-wide goals, and 5 per cent on functional goals.

The performance-related pay does not constitute pensionable income. The anticipated result is reconciled continuously throughout the year and reserves are adjusted monthly. An evaluation of the performance-related pay results is conducted on each reporting date.

#### Share-related incentive plans

The intention of share-related incentive plans is to promote the company's long-term interests by motivating and rewarding the company's senior executives and other members of staff. Medivir currently has one active share-related incentive plan.

#### Staff stock option plan, 2010-2013

The staff stock option plan 2010-2013 was adopted at the 2010 Annual General Meeting and comprised both share warrants and staff stock options. The plan covered all permanent employees of Medivir AB. The term of the plan was from 30 April 2010 to 31 May 2013. The plan was forfeited during the second quarter of 2013 without any options having been exercised during the term of the plan. Detailed information on the staff stock option plan 2010-2013 is presented in Note 5 of Medivir's 2012 Annual Report.

#### Share saving plan 2013 (LTI 2013)

The Share saving plan 2013 (LTI 2013) is a long-term, performance-based share-related incentive programme that was approved at the Annual General Meeting held on 6 May 2013. The Share saving plan has been offered to all permanent employees of Medivir AB, on equal terms for the CEO, other senior executives, and other employees.

Participation in LTI 2013 is contingent upon the employee making a personal investment and buying class B shares in Medivir at the market rate on the Nasdaq OMX Stockholm Stock Exchange – so-called savings shares. Employees participating in the programme may save up to an amount corresponding to one month's fixed salary before tax. The minimum possible investment is SEK 6,000. Employees may either make a (i) one-off investment, or (ii) save monthly, in order to purchase shares.

One-off saving occurred in June 2013. Participants who save monthly, save for the first time from their June 2013 salary, while those saving quarterly make their investments in August, November, February and May.

Participants receive one matching share warrant and three performance-based share warrants for every Savings share in which they invest. The performance-based share warrants are based on the strategic development of Medivir's research and product portfolios and earnings per share during the period from 2013 to 2015. 73 per cent of all permanent employees have opted to participate in the plan, including the CEO, who has invested SEK 285 thousand (4,341 shares), and other senior executives, who have invested SEK 636 thousand (9,534 shares).

LTI 2013 is reported in accordance with IFRS 2 - Share-based payment. The maximum total number of class B shares that Medivir may issue in accordance with the plan, including the shares that may be acquired through the exercise of warrants, is estimated to be 249,110 class B shares, corresponding to approximately 0.79 per cent of the total number of shares and approximately 0.67 per cent of the total number of votes in Medivir on 31 December 2013. The maximum amount by which the share capital can increase is SEK 1.2 million. SEK 2.0 million in costs in connection with LTI 2013, including the cost of social security contributions, has, in accordance with certain assumptions such as share price performance, participation, and staff turnover, been charged to the profit/loss. The right of disposal must exist with regard to the warrants and the shares that will be disbursed through the exercise of the warrants in order to enable the shares to be disbursed to the participants at the end of the programme. The warrants are also issued in order to hedge the cash flow-related costs of the programme for the Group, such as social security costs, that arise in connection with LTI 2013.

#### Transactions with related parties

Transactions with related parties are conducted on market terms. There are agreements between companies owned by senior executives and Medivir conferring entitlement to royalties on products that the company may develop based on patented inventions that the company has acquired from the relevant parties. Remuneration totalling SEK 4,391 thousand (SEK -) has been disbursed during the period. Other services purchased from related parties total SEK 72 thousand (SEK 414 k).

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# Note 06 Leasing agreements including Property rent (SEK k)

	The Group		Parent Co	ompany
	2013	2012	2013	2012
Cost of the year 1)	18,117	15,392	11,139	9,166
Nominal value of future minimum lease payments for irrevocable leasing agreements including property rent				
Within one year <sup>2)</sup>	15,077	14,947	8,890	8,765
Between one and five years <sup>3)</sup>	40,269	60,517	11,591	30,222
Total	55,346	75,464	20,481	38,987

- 1) The costs refer mainly to premises rent for Medivir UK, Medivir AB and BioPhausia AB. Rent costs within the Group total SEK 15,888 thousand (SEK 14,080 k) of which rent costs in Medivir AB total SEK 9,230 thousand (SEK 8,062 k), and SEK 5,722 thousand (SEK 6,018 k) in Medivir UK. SEK 6,366 thousand (SEK 7,014 k) of the rent costs for the year are recognised as revenue due to the subletting of research facilities in Chesterford Park. The net profit/loss for the subletting of SEK 644 thousand (SEK –996 k) has been reported under other revenue in the Income Statement. The lease agreements for Medivir AB expire between 2013 and 2016, while the lease agreement for Medivir UK in Chesterford Park expires in 2025. Medivir UK's lease agreement is index-linked every five years. The research facilities in Chesterford Park have been sublet up to and including 2015 after which the contract may be extended. No provision has been made for rent costs after 2015 as the company calculates that the costs will continue to be covered by rental income for the remaining period.
- 2) Of which SEK 6,366 thousand will be recognised as revenue due to the subletting of the research facilities in Chesterford Park.
- 3) Of which SEK 25,470 thousand will be recognised as revenue due to the subletting of the research facilities in Chesterford Park.

# Note **07** Profit/loss from participations in Group companies (SEK k)

	The Group		Parent C	ompany
	2013	2012	2013	2012
Capital gain/loss from the sale of Cross Pharma AB, included in discon- tinued operations, see Note 24	-46,389	_		-
Capital gain/loss from the liquidation of Lefarm sp.	446	_	_	_
Capital gain/loss from the winding up of dormant companies	-41	_	-27	_
Dividend from Biophausia AB	_	_	120,000	_
Impairment losses on shares in the Medivir UK Ltd. subsidiary (see also Note 15, Participations in Group companies)	_	_	-43,930	-27,492
Total	-45,984	_	76,043	-27,492

## Note 08 Financial risks (SEK k)

Medivir is, by virtue of its operations, exposed to a variety of different types of risks. The operations are affected by a number of factors that can impact the company's profit or loss and its financial position. The strategy entails the ongoing identification and management of risks, as far as possible. The risks can be divided into operational risks and financial risks and the section below describes the financial risk factors that are adjudged to be of the greatest significance in terms of Medivir's development, together with the way in which Medivir manages them in order to minimise the risk level. The main financial risks that arise as a result of the management of financial instruments comprise market risks (interest risk, currency risk and share price risk), credit risk, and liquidity and cash flow risk. Operational risks are described in a separate section of the Directors' Report – see page 38.

#### Financial policy

Medivir has established a Group policy for its financial operations. The policy defines the financial risks and describes the way in which the company shall manage these risks. The policy states that the company must, at all times, maintain a liquidity that corresponds to at least twelve months' known future net cash disbursements.

Medivir has an agreement with SHB regarding the discretionary management of the company's funds. The investment regulations associated with the agreement specify how the funds may be invested. Investments of liquid assets shall be made in such a way that the capital invested provides a reliable and secure return. Investments are made in interest-bearing instruments, fixed income funds, and cash or cash equivalent instruments. Underlying instruments shall have a low risk level and a risk spread shall be sought when investing cash and cash equivalents. Investments may only be made in specified securities, which are low risk securities (such as Swedish bonds and papers issued by the Swedish State and A1-rated commercial papers).

#### Capital risk

An effective risk assessment reconciles Medivir's business opportunities and results with the requirements of shareholders and other stakeholders for sustainable profitability, stable long-term value growth, and control. The process of research and pharmaceutical development, all the way up to approved registration, is both highly risky and capital-intensive.

The Group's objective with regard to its capital structure is to secure the Group's ability to continue its operations such that it can continue to generate a return for its shareholders and benefits for other stakeholders, and to maintain an optimal capital structure in order to keep capital costs down.

The goal is, within a few years' time, to be a stable, profitable and highgrowth Nordic pharmaceutical company. Growth – both organic and through acquisitions – requires that Medivir has a strong capital base. Medivir works purposefully and strategically to generate the best possible conditions for developing the company rapidly and in a way that ensures risks are balanced. The company has a solid financial position. The consolidated equity totals SEK 852,587 thousand (SEK 874,880 k). The cash and cash equivalent position and short-term investments total SEK 402,220 thousand (SEK 296,727 k). The equity/assets ratio is 85.7 per cent (81.3%). Medivir will continue to maintain a low debt/equity ratio and a high equity/assets ratio as long as the company has no long-term, independent earnings ability.

No proposals for the payment of dividends to shareholders will be made until long-term profitability can be foreseen, via the market launch of new pharmaceuticals.

## Note 08 Continued (SEK k)

#### The connection between IAS 39 categories and Medivir's Balance Sheet items

The Group, 31 Dec. 2013	Financial assets recognised at fair value in the Income Statement	Cash and cash equivalents	Accounts receivable and loan receivables	Financial assets held for sale	Loans and accounts payable	Total
Financial assets held for sale		-	-	=	-	-
Other non-current receivables	=	=	10,001	-	-	10,001
Accounts receivable	=	-	21,474	-	-	21,474
Other receivables	-	-	5,000	-	-	5,000
Other short-term investments	370,588	_	-	_	_	370,588
Cash and bank balances	-	31,632	-	-	-	31,632
Accounts payable	-	-	-	-	28,676	28,676
Borrowings		_	_	_	40,000	40,000
Financial leasing liabilities	_	_	-	_	_	_
Total	370,588	31,632	36,475	_	68,676	507,371
The Group, 31 Dec. 2012	Financial assets recognised at fair value in the Income Statement	Cash and cash equivalents	Accounts receivable and loan receivables	Financial assets held for sale	Loans and accounts payable	Total
Financial assets held for sale	=	-	_	_	_	-
Accounts receivable	_	_	70,203	-	-	70,203
Other short-term investments	257,514	_	_	_	_	257,514
Cash and bank balances	=	39,213	_	_	_	39,213
Accounts payable	-	_	-	-	37,636	37,636
Borrowings	-	_	-	-	88,616	88,616
Financial leasing liabilities	-	_	-	-	41	41
Total	257.514	39,213	70,203	_	126,293	493,223

#### Financial assets recognised at fair value

The table below shows financial instruments valued at fair value, based on the way in which they have been classified in the value hierarchy. The different levels are defined as follows:

Level 1 fair value is determined on the basis of listed prices on an active market for identical financial assets and liabilities.

Level 2 fair value is determined on the basis of observable information other than listed prices included in level 1.

Level 3 fair value is determined on the basis of valuation models where material input data is based on non-observable data.

The Group has level 1 short-term investments. The short-term investments in the form of fixed income funds are managed as a single group of fixed assets and are recognised at fair value in the Income Statement. The Group has financial assets that can be sold at level 3 and which are not adjudged to have any value. Fair value for other level 3 assets and liabilities is determined by discounted cash flows.

#### Financial assets recognised at fair value

	Carrying amount	Recognition at fair value at the end of the period based on:			
The Group, 31 Dec. 2013		Level 1	Level 2	Level 3	
Financial assets recognised at fair value in the Income Statement		_	-	-	
Other short-term investments	370,588	370,588	-	_	
Other non-current receivables	10,000	-	-	10,000	
Other receivables	5,000	-	-	5,000	
Financial assets held for sale	-	-	-	-	
Total	385,588	370,588	-	15,000	
Borrowing	40,000	-	-	40,000	
Total liabilities	40,000	_	_	40,000	

	Carrying amount	Recognition at fair value at the end of the period based on:			
The Group, 31 Dec. 2012		Level 1	Level 2	Level 3	
Financial assets recognised at fair value in the Income Statement		=	=	-	
Other short-term investments	257,514	257,514	-	_	
Financial assets held for sale	_	-	-	_	
Total	257,514	257,514	_	_	

# Note 08 Continued (SEK k)

The following table shows the changes for level 3 instruments

	2013	2012
Opening balance	-	9,659
Losses recognised in the		
Income Statement	-	-9,659
Closing balance	-	_

#### Other financial assets and liabilities

The fair value of financial instruments such as accounts receivable, loan receivables, accounts payable and other non-interest-bearing financial assets and liabilities which are recognised at the accrued historical value less any amortisation is deemed to correspond to the reported value due to the short anticipated term.

#### Market risks

#### Interest risk

Interest risk is the risk of a negative impact on cash flow or financial assets and liabilities resulting from changes in market rates of interest. Interest risk arises in two ways; the Group's investments in interest-bearing assets whose value changes when interest rates change and the cost of the Group's borrowings when interest rates change.

Medivir's cash and cash equivalents are invested in instruments such as bank and corporate commercial papers, fixed income and bond funds, fixed bank investments and special deposits. Changes in market rates of interest consequently affect Medivir's profit/loss by reducing or increasing returns on financial assets.

The Group's cash and cash equivalents, including short-term investments with a maximum term of three months, totalled SEK 402,220 thousand (SEK 296,727 k) on 31 December 2013. SEK 370,588 thousand (SEK 257,514 k) of this sum was invested in fixed income funds with discretionary management. An average return on cash and cash equivalents of 1.6 per cent (3.0%) was achieved in 2013. The year's return has fluctuated between –1.8 and 3.0 per cent (0.5 and 5.6%). Assuming an average of existing short-term investments during the year, if the average return had been 1 percentage point higher or lower, the annualised positive or negative effect on the profit/loss would have been approximately SEK 2,770 thousand on a full-year basis. Falling interest rates result in a reduction in the return on the Group's cash or cash equivalents. If the return falls to 0 per cent in 2014, the effect on the profit/loss would be SEK –5,900 thousand, given unchanged holdings of cash and cash equivalents.

The Group's credit facilities on 31 December 2013 comprised bank loans and an overdraft facility with an interest rate calculated on the basis of the STIBOR 3-month interest rate. The Group's interest risk is attributable to the change in market interest rates and their effect on the debt portfolio. The Group does not make use of interest hedging instruments. The choice of fixed interest term is based on a cost-benefit analysis on a case-by-case basis when raising loans. The Group's estimated cash flow is taken into account when assessing the fixed interest period.

Borrowing	31 Dec. 2013	Interest expense, 2014, given unchanged interest levels	Average interest rate level, %	Average fixed interest term, months	Change in interest expense, 2014, given a +1% change in interest rates, SEK k
Bank loans	40,000	1,519	3.80%	3	400

#### 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.

- The profit/loss 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 a foreign currency are translated into Swedish kronor (translation risk).

In accordance with Medivir's financial policy, the Group has not made use of currency hedging in 2013. Income and expenses have consequently been affected by fluctuations in foreign currency exchange rates. The company's operating profit/loss was affected during the financial year by a net of SEK –1,802 thousand (SEK –5,711 k) in exchange rate profits/losses and the

exchange rate items component of net financial items total SEK -64 thousand (SEK -455 k).

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, and accounts payable and accounts receivable consequently have currency exposure.

The Group's transactions in foreign currency consist of revenues from partners on research projects, pharmaceutical sales, purchases of goods and other operating costs.

The Group's transactions in its most common currencies and the theoretical effect on profit or loss arising if the average rates of exchange for each currency change by 5 per cent are shown below.

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2013	Net sales	Costs	Operating profit/loss	Change +/- 5%
EUR	264,501	-148,803	115,698	+/- 5,785
USD	559	-26,855	-26,296	+/- 1,345
GBP	8,721	-67,479	-58,758	+/- 2,938
DKK	1,260	-2,050	-790	+/- 39
NOK	14,731	-6,869	7,862	+/- 393
PLN	3,613	-52,027	-48,414	+/- 2,421
Total	293.385	-304.083	-10,698	+/- 535

2012	Net sales	Costs	Operating profit/loss	Change +/- 5%
EUR	4,642	-218,248	-213,606	+/- 10,680
USD	0	-29,878	-29,878	+/- 1,494
GBP	653	-162,022	-161,369	+/- 8,069
DKK	1,167	-2,946	-1,780	+/- 89
NOK	15,906	-7,956	7,950	+/- 397
PLN	5,568	-45,172	-39,604	+/- 1,980
Total	27,936	-466,224	-438,288	+/- 21,914

The table shows the currency exposed operating income and operating expenses as net amounts per currency in SEK k.

A sensitivity analysis shows that a strengthening of the Swedish krona by 5 per cent against the above currencies' annualised average exchange rates would have entailed an improvement in the Group's net profit/loss of SEK 535 thousand (SEK 21,914 k). A corresponding weakening of the Swedish krona would have yielded a deterioration in the net profit/loss of SEK 535 thousand (SEK 21,914 k).

## Note 08 Continued (SEK k)

#### Share price risk of unlisted shares

Medivir received 2,007 shares in conjunction with the new share issue conducted by Epiphany Biosciences, Medivir's licensing partner for the MIV-606 (EPB-348) shingles project and shares in conjunction with the new share issue conducted by Presidio Pharmaceuticals, Inc., Medivir's licensing partner for the MIV-410 (PTI-801) compound. The value of the shares held, which totalled SEK 9,659 thousand at the beginning of 2012, were impaired to SEK 0 in the previous year. Medivir has classified the shares as financial assets held for sale in accordance with IAS 39 and has reported the shares in the Balance Sheet under the "Financial fixed assets" item.

#### Credit risk (counterparty risk)

Credit risk is the risk that a counterparty is unable to fulfil 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. No credit risks are deemed to exist in relation to the above investments.

Medivir may also be exposed to credit risk in accounts receivable. Medivir's partnership agreements are with established pharmaceutical companies and historically, Medivir has never needed to impair accounts receivable. Pharmaceutical sales are made to large, established distributors which, in turn, sell the pharmaceuticals on to the pharmacies. The distributors bear no credit risk for deficient solvency on the part of the pharmacies and the Group consequently risks credit losses if the pharmacies suspend payments to the distributor. Medivir had SEK 21,474 thousand (SEK 70,203 k) in outstanding accounts receivable on the reporting date.

	The Group		Parent Company	
Age analysis, accounts receivable	2013	2012	2013	2012
Not due	21,075	64,436	4,074	107
Due, 1-90 days	160	5,895	9,075	140
Due, 91 + days	239	-128	92	-
Total	21,474	70,203	13,241	247

Other receivables total SEK 12,423 thousand (SEK 5,405 k) of which SEK 0 thousand (SEK 0 k) was due on the reporting date.

#### Liquidity and cash flow risk

Liquidity risk is the risk of Medivir experiencing difficulties, in future, in fulfilling their 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.

In accordance with Medivir's financial policy, Medivir invests its cash and cash equivalents with Swedish fund managers with high credit ratings, low risk and a liquid market. Medivir's management and Board of Directors have continuous access to information on the company's equity and cash and cash equivalents. Liquidity and cash flow forecasts are prepared continuously on the basis of anticipated cash flows in order to monitor liquidity capacity.

Medivir had a negative debt/equity ratio at the period end, i.e. the available cash and bank balances and short-term investments exceed the Group's interest-bearing liabilities. Medivir's research operations in 2013 and 2012 have been financed internally. The steady sale of pharmaceutical products since the acquisition of Biophausia in 2011 provides a continuous positive cash flow. As portions of the Group's interest-bearing liabilities become due for repayment, there is a refinancing risk in tandem with the extension of existing borrowing in terms both of the long-term loan requirement and to Medivir's day-to-day payment to its lenders and suppliers. Current liabilities are covered by Medivir's cash position and short-term investments. The Group also disposes over unutilised credit facilities.

The following table shows the contractual undiscounted cash flows from the Group's financial liabilities, broken down by the time which, on the closing day, remains until the contractual due date.

31 Dec. 2013	The Group			Parent Company		
	Less than 1 year	Between 1 and 2 years	Between 2 and 3 years	Less than 1 year	Between 1 and 2 years	Between 2 and 3 years
Accounts payable	28,676		-	18,621	-	
Bank loans	-	40,000	-	-	40,000	_
Overdraft facility	-	_	-	_	-	

31 Dec. 2012	The Group			Parent Company		
	Less than 1 year	Between 1 and 2 years	Between 2 and 3 years	Less than 1 year	Between 1 and 2 years	Between 2 and 3 years
Accounts payable	37,636	-	-	17,226	-	
Bank loans	30,000	-	40,000	-	-	_
Overdraft facility	18,616	-	-	-	-	_

The amounts maturing within 12 months are consistent with the reported amounts, because the discount effect is insignificant. Other liabilities total SEK 12,711 thousand (SEK 16,631 k) and mature within 12 months. The Group's bank loans correspond to the recognised fair value.

# Note 09 Other interest income and similar profit/loss items (SEK k) 1)

	The Group		Parent Co	mpany
	2013	2012	2013	2012
Interest income, bank	-	1,035	-	807
Exchange rate difference, other	3,789	2,745	35	_
Dividends from fixed income fund	832	3,309	832	3,309
Change in fair value of fixed income fund, unrealised	3,569	7,998	3,569	7,998
Other financial income	96	550	-132	_
Total	8,286	15,637	4,304	12,114

<sup>1)</sup> Other interest income and similar profit/loss items are an effect of short-term investments recognised at fair value in the Income Statement and cash and bank balances.

# Note 10 Interest expenses and similar profit/loss items (SEK k)

	The G	roup	Parent Compan		
	2013	2012	2013	2012	
Interest expenses	-2,893	-7,705	-77	-56	
Exchange rate difference, intragroup transactions	_	-3,200	-	-	
Exchange rate difference, other	-3,854	_	-	_	
Issue cost, subordinated loan	-	-1,411	-	-	
Other financial expenses	-3	-782	-3	-9,659	
Total	-6,750	-13,098	-80	-9,715	

## Note 11 Tax (SEK k)

	The G	iroup	Parent Company	
Tax on the profit/loss for the year	2013	2012	2013	2012
Current tax <sup>1)</sup>	-1,766	-345	_	_
Change in deferred tax <sup>2)</sup>	-9,407	-25,823	_	_
Tax on profit/loss for the year	-11,173	-26,168	_	-

1) Of which SEK –1,766 thousand (SEK 0) is reported as discontinued operations. 2) Of which SEK 2,212 thousand (SEK 2,842 k) is reported as discontinued operations.

Applicable tax rate for the Parent				
Company	22.0%	26.3%	22.0%	26.3%

## Difference between the Group's tax reported in the Income Statement and tax based on applicable tax rate

in the Income Statement and $\overset{\cdot}{tax}$	based on	applicabl	e tax rate	
Profit/loss before tax	-10,162	-192,912	98,799	-249,927
Tax at applicable tax rate				
for the Parent Company	2,236	50,736	-21,736	65,731
Tax effect of change in tax rate	_	-9,624		
Tax effect of non-deductible costs	-11,165	-4,398	-9,994	-10,173
Tax effect of non-taxable income	30	2,111	26,427	2,104
Effect of foreign tax rates	838	-393	-	-
Adjustment of tax in respect of previous years	1,962	-	_	_
Utilisation of loss carry-forwards not previously capitalised	5,326	_	5,303	-
Tax effect of deficits for which tax receivables are not recognised	-10,400	-64,600	_	-57,662
Reported tax	-11,173	-26,168	_	_

### Note Continued

Deferred tax recognised in the Balance Sheet refers to the following:								
Deferred tax	Receivable	Liability	Net					
Deferred tax receivable								
Capitalised loss carry-forward	45,687	-	45,687					
Intangible fixed assets	-	2,500	-2,500					
Closing balance	45,687	2,500	43,187					

#### Changes in deferred taxes for the period

Deferred tax receivable	As of 31 Dec. 2012	Operation acquired	Operation sold	Recogni- sed in profit/loss	As of 31 Dec. 2013
Capitalised loss carry-forward	55,588	-	-	-9,901	45,687
Total deferred tax receivable	55,588	_	_	-9,901	45,687
Deferred tax liability					
Temporary differences relating to:					
Intangible assets	6,350	_	-3,350	-500	2,500
Total deferred tax liability	6,350	_	-3,350	-500	2,500
Net deferred tax receivable	49,238	_	3,350	-9,401	43,187

At the year-end, the total accumulated taxable loss of the Group was SEK 1,534 million (SEK 1,340 m), of which SEK 208 million (SEK 253 m) has been capitalised. The remaining loss of SEK 1,326 million (SEK 1,088 m) comprises primarily tax losses in the Parent Company and in Medivir UK and have not been capitalised due to the difficulty in assessing the point in time when it will be possible to offset loss carry-forwards against future taxable profits. There is no time restriction on the utilisation of capitalised loss carry-forwards.

## Note 12 Earnings per share

	The Group	
	2013	2012
Continuing operations		
Basic and diluted earnings per share, SEK <sup>1)</sup>	0,51	-7,49
Net profit/loss for the year, SEK k	16 014	-234 098
Discontinued operations	-	
Basic and diluted earnings per share, SEK <sup>1)</sup>	-1,19	0,48
Net profit/loss for the year, SEK k	-37 350	15 018
Total operations		
Basic and diluted earnings per share, SEK <sup>1)</sup>	-0,68	-7,01
Net profit/loss for the year, SEK k	-21 336	-219 080
Average number of shares, '000	31 260	31 257

Earnings per share have been calculated as the net profit/loss for the year divided by the average number of shares during the year.

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<sup>1)</sup> Basic earnings per share – the profit/loss after financial items less the tax expense for the period divided by the average number of shares. Diluted earnings per share – the profit/loss after financial items less the tax expense for the period divided by the average number of shares and outstanding share warrants, adjusted for any dilution effect.

## Note 13 Intangible fixed assets (SEK k)

			The Group			P	arent Company	
2013	Trademarks and brands	Product rights	Goodwill	Capitalised R&D expenditure	Other	Product rights	Capitalised R&D expenditure	Other
Cost at beginning of the year	19,234	331,874	188,092	14,364	2,742	-	14,364	2,742
Additions	-	3,798	-	115	350	3,798	115	350
Sales and disposals	-19,234	-109	-37,672		_	-	-	_
Exchange rate differences	-	-1	-	-	_	-	-	_
Accumulated cost at year-end	0	335,562	150,420	14,479	3,092	3,798	14,479	3,092
Amortisation at beginning of the year	-3,045	-35,031		-1,262	-2,579		-1,262	-2,579
Amortisation for the year	-962	-22,100	-	-432	-109	-	-432	-109
Sales and disposals	4,007	85	_	-	_	-	-	_
Accumulated amortisation at year-end	0	-57,046		-1,694	-2,688	-	-1,694	-2,688
Depreciation for the year				-10,045			-10,045	
Book value at year-end	0	278,517	150,420	2,739	404	3,798	2,739	404

	The Group					Parent Company		
2012	Trademarks and brands	Product rights	Goodwill	Capitalised R&D expenditure	Other	Product rights	Capitalised R&D expenditure	Other
Cost at beginning of the year	19,234	331,874	188,153	4,319	2,742	-	4,319	2,742
Additions	=	=	-	10,045	-	-	10,045	-
Exchange rate differences	-	-	-61	-	_	-		_
Accumulated cost at year-end	19,234	331,874	188,092	14,364	2,742	_	14,364	2,742
Amortisation at beginning of the year	-1,122	-12,906		-830	-2,470		-830	-2,470
Amortisation for the year	-1,923	-22,125	-	-432	-109	_	-432	-109
Accumulated amortisation at year-end	-3,045	-35,031	-	-1,262	-2,579	_	-1,262	-2,579
Book value at year-end	16,189	296,843	188,092	13,102	163	-	13,102	163

#### Trademarks and brands

Trademarks and brands relate to the Cross Pharma trademark, which was sold on 31 June 2013. Amortisation has been effected linearly up to and including the divestment over the estimated useful life of 10 years.

#### **Product rights**

The product rights relate to the acquisition of the product portfolio of proprietary products from the acquisition of BioPhausia AB. The addition for 2013 refers to the acquisition of the rights to Adasuve. Amortisation of the product portfolio is effected linearly over the estimated useful life of 15 years. Amortisation of pharmaceuticals acquired begins when the product goes into use in conjunction with its market launch.

#### Goodwill

Goodwill relates to the acquisition of BioPhausia AB. Goodwill has an indefinite useful life and is subject to annual impairment testing. The sale for 2013 refers to goodwill for the parallel imports operations which were wound up in conjunction with the sale of Cross Pharma AB.

#### Capitalised research and development expenditure

Capitalised expenditure for research and development work relates both to capitalised development expenditure for Xerclear and to antiviral research programmes acquired. The useful life for Xerclear is based on the lifetime of the underlying patent and is 10 years. Amortisation is effected linearly in order to distribute the development costs in line with the estimated useful life. Amortisation of other intangible assets acquired, such as development projects, is effected linearly over the useful life and is linked to the lifetime of patents obtained. Antiviral research programmes acquired have been amortised in 2013 to the tune of SEK 10,045 thousand as they are not adjudged to have any remaining value and no additional resources are being invested in the further development of the research programme acquired.

#### Other

Other intangible assets relates to capitalised development expenditure on ERP systems. The useful life is estimated at 5 years, during which time the booked asset is amortised in line with this assessment.

#### Impairment testing

Intangible assets with an indefinite useful life are subject to impairment testing at least once every year. Assets depreciated or amortised according to plan are subject to impairment testing whenever events or changes in circumstances indicate that their carrying amount is not recoverable.

The table below illustrates the carrying amount for goodwill, allocated by cash-generating unit:

	2013	2012
Pharmaceuticals	150 420	150 420
Parallel imports	=	37 672
Total	150 420	188 092

Goodwill assigned to the parallel imports operations has been divested during the year.

The present value of anticipated future cash flows is calculated for every cash-generating unit in conjunction with impairment testing. Future cash flows are based both on the budget adopted by the Board of Directors and current trends. The budget adopted is based on a large number of detailed assumptions regarding growth in volume, exchange rates, expense development, etc. The budget is also based on the expertise of the management and other key individuals within the organisation, and on historic trends and projections. The forecast for the period pursuant to the yearly budget and onwards is based on the management's long-term projections, which cover five years. It is based on several overall assumptions regarding the development of the economy,

## Note 13 Continued

volume growth, competition, exchange rates, expense development, etc. The calculations and forecasts are based both on supporting data drawn from external sales statistics and from internal trend analyses. This input, together with the management's experience, estimated forecasts, business plans and existing supplier agreements, has formed the basis for the estimates. The cash flow after the budget period is expected to show a growth rate of 0 (0) per cent.

#### WACC

The discount rate applied has been calculated as the WACC (weighted average cost of capital) and totals 9 per cent (9%) before tax. The discount interest rate is based on a market assessment of the average capital cost, taking into account the estimated prevailing risk level. The return on equity requirement is based on assumptions with regard to the risk-free interest rate, market risk premium, and beta value.

#### Sensitivity analysis

Sensitivity analyses are carried out in order to analyse the way in which changes in WACC and estimated growth rates affect the estimated value in use of the cash-generating units. The sensitivity analysis shows that even if the significant parameters change, a significant surplus value still exists.

## Note 14 Tangible fixed assets (SEK k)

	The Group		Parent Company		
Buildings and land 1)	2013	2012	2013	2012	
Cost at beginning of the year	17,719	17,719	4,232	4,232	
Capital expenditure	-	_	_	_	
Accumulated cost at year-end	17,719	17,719	4,232	4,232	
Depreciation at beginning of the year	-16,220	-16,007	-2,733	-2,520	
Depreciation for the year	-212	-213	-212	-213	
Accumulated depreciation at year-end	-16,432	-16,220	-2,945	-2,733	
Book value at year-end	1,287	1,499	1,287	1,499	

<sup>1)</sup> The value of the Group's buildings corresponds to the incurred cost of improvements to rental properties.

	The Group		Parent C	ompany
Equipment, tools, fixtures and fittings	2013	2012	2013	2012
Cost at beginning of the year	159,817	149,390	143,531	134,058
Capital expenditure	3,619	10,642	3,619	9,474
Sales and disposals	-4,636	-215	-7	_
Exchange rate differences	-26	_	_	_
Accumulated cost at year-end	158,774	159,817	147,142	143,532
Depreciation at beginning of the year	-125,246	-115,481	-112,035	-102,581
Depreciation for the year	-9,640	-10,015	-9,109	-9,451
Sales and disposals for the year	2,783	206	7	-
Exchange rate differences	_	44	_	-
Accumulated depreciation at year-end	-132,103	-125,246	-121,137	-112,032
Book value at year-end	26,671	34,571	26,006	31,500

## Note 14 Continued

#### Financial leasing

Tangible fixed assets include leasing objects held through financial leases as shown below:

	The Gr	oup	Parent Co	mpany
Equipment, tools, fixtures and fittings	2013	2012	2013	2012
Cost	266	266	266	266
Accumulated depreciation	-191	-138	-191	-138
Book value at year-end	75	128	75	128
Future minimum lease payments have the following due dates:				
Within 1 year	-	_	_	_
Between 1 and 5 years	-	_	_	_
Total	-	_	_	-

Depreciation totalling SEK 53 thousand (SEK 53 k) has been charged to the profit/loss.

# Note 15 Participations in Group companies (SEK k)

	Parent Company		
	2013	2012	
Opening balance	604,312	604,312	
Divestments	-100	-	
Shareholders' contributions made	43,930	_	
Impairment loss	-43,930	-	
Closing balance	604,212	604,312	

## Note 15 Continued

Subsidiary company:	Corporate ID no.	Registered office	Number of shares	Share of capital	Book value, 2013	Book value, 2012
BioPhausia AB <sup>1)</sup>	556485-0153	Stockholm	342,564,194	100%	604,112	604,112
Medivir UK Ltd,	3496162	Essex, England	2,000,007	100%	0	0
Medivir Personal AB	556598-2823	Huddinge	1,000	100%	100	100
Medivir HIV Franchise AB	556690-7118	Huddinge	1,000	100%	_	100
Total					604,212	604,312

1) Holdings in BioPhausia AB:				
Cross Pharma AB 2)	556660-4541	Stockholm	1,000	100%
Oy Cross Pharma AB	1896628-4	Finland	1,000	100%
Glycovisc BioTech AB	556535-0005	Stockholm	5,000	100%
Medivir A/S	30587014	Denmark	5,000	100%
Medivir OY	2012608-1	Finland	1,000	100%

2)Divested in 2013

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

	The Group		Parent Company	
	2013	2012	2013	2012
Epiphany Biosciences				
Opening book value	-	6,329	_	6,329
Impairment loss	-	-6,329	-	-6,329
Closing book value	-	_	_	-
Presidio Pharmaceuticals Inc.				
Opening book value		3,330		3,330
Impairment loss	-	-3,330	_	-3,330
Closing book value	-	_	_	-
Total	_	_	_	_

In 2012, valuations carried out by independent parties have shown that the market value was significantly lower than the carrying amount. The value impairment was adjudged to be significant and lasting and the holdings in Epiphany and Presidio were accordingly impaired to SEK 0.

## Note 17 Other non-current receivables (SEK k)

	The Group		<b>Parent Company</b>	
	2013	2012	2013	2012
Opening book value	-	_	_	-
Acquisitions for the year	15,001	_	_	-
Reclassification to current receivables	-5,000	_		_
Closing book value	10,001	_	_	_

## Note 18 Inventories (SEK k)

	The Group		Parent Company	
	2013	2012	2013	2012
Finished goods	23,982	54,297	_	16
Raw material inventories	-	29,060	_	_
Goods in repackaging	-	3,964	_	_
Total	23,982	87,321	_	16

Impairment of inventories totals SEK 2,717 thousand (SEK 240 k). The impairment has been charged to Cost of goods sold. Cost of goods sold includes cost of goods of SEK 244,071 thousand (SEK 392,892 k).

# Note 19 Prepaid costs and accrued income (SEK k)

	The Group		Parent Company	
	2013	2012	2013	2012
Prepaid rent	3,912	3,733	2,278	2,155
Licensing fees	2,283	2,244	2,283	2,244
Accrued milestone payments	-	4,353	_	4,353
Accrued royalties	10,944	_	10,944	1,985
Service agreements	1,077	1,985	1,060	1,300
Connection to external databases	775	1,300	775	1,469
Other items	3,156	3,228	2,655	-
Total	22,146	16,842	19,995	13,505

## Note 20 Cash and cash equivalents (SEK k)

	The Group		Parent Company	
	2013	2012	2013	2012
Fixed income and bond funds	370,588	257,514	370,588	257,514
Cash and bank balances	31,632	39,213	9,805	14,932
Total	402,220	296,727	380,393	272,446

## Note 21 Interest-bearing liabilities (SEK k)

	The Group		Parent Company	
	2013	2012	2013	2012
Non-current interest-bearing Bank loans	40,000	40,000	40,000	-
Financial leasing liability	_	_	_	_
Total non-current interest-bearing liabilities	40,000	40,000	40,000	-
Current interest-bearing liabilities Liabilities to credit institutions		48,616		
Financial leasing liability	_	41	_	41
Total current interest-bearing liabilities	_	48,657	_	41
Unutilised credit facilities Overdraft facility		81,384		

# Note 22 Accrued costs and deferred income (SEK k)

	The Group		Parent Company	
	2013	2012	2013	2012
Accrued holiday pay	17,670	17,115	17,456	14,752
Accrued performance-related pay and severance pay	12,104	9,616	12,104	9,458
Accrued research costs	3,260	3,547	3,260	3,547
Accrued production costs	1,100	-	-	-
Accrued rent costs	4,266	4,447	-	_
Accrued social security contributions	2,843	3,612	2,821	2,293
Deferred royalty payments	5,425	2,462	5,425	2,462
Deferred product costs	4,710	_	_	_
Deferred licensing costs	2,062	-	2,062	-
Other items	8,056	17,145	6,935	5,505
Total	61,497	57,943	50,062	38,016

## Note 23 Pledged assets (SEK k)

	The G	The Group		<b>Parent Company</b>		
	2013	2012	2013	2012		
Floating charges	54,250	104,250	_	-		
Shares in subsidiaries	-	44,105	_	_		
Total	54,250	148,355	_	-		

## Note **24** Discontinued operations

On 25 June, Medivir announced the sale of its parallel imports operations conducted through the Cross Pharma AB subsidiary, including the Polish company, Prodlekpol. The transaction of 30 June resulted in a capital loss of SEK 46.4 million. The consolidated value of Cross Pharma AB was SEK 57.3 million, which referred primarily to goodwill and trademarks and brands. The capital loss also includes transaction costs and an exchange rate profit/loss of SEK 10.1 million. Payment for the shares totalled SEK 19.7 million, SEK 4.7 million of which was paid in cash, leaving a remaining balance due from the purchaser of SEK 15 million. In Q3 2013, receivables totalling SEK 115.0 million were paid by the purchaser, Unimedic. Cash and cash equivalents in Cross Pharma AB totalled SEK 4.8 million. The total cash flow from the sale of Cross Pharma amounts to SEK 114.9 million.

The divestment has been reported separately as discontinued operations in the Income Statement in accordance with IFRS 5. Discontinued operations are reported separately from continuing operations in the Income Statement with retroactive effect for previous periods. Parallel imports are reported as discontinued operations below.

Profit/loss for the period for the discontinued		
operations, parallel imports	2013	2012
Operating income	213,006	384,379
Operating expenses	-203,784	-368,841
Operating profit/loss	9,222	15,538
Profit/loss from divestment of operations	-46,389	-
Financial items	-628	2,321
Profit/loss before tax	-37,796	17,860
Tax	446	-2,842
Profit/loss after tax	-37,350	15,018
Cash flow attributable to discontinued operations	2013	2012
Cash flow from operating activities	26,896	14,813
Cash flow from investing activities	-	-917
Cash flow from financial activities	-9,260	347

The discontinued operations' assets on the transaction date	
Trademarks and brands	15,227
Goodwill	37,672
Tangible fixed assets	1,854
Inventories	82,954
Other current assets	72,983
Total	210,690

17,636

14,243

Cash flow for the period

The discontinued operations' liabilities on the transaction date	he
Deferred tax liability	3,350
Non-current liabilities	342
Current liabilities	150,934
Total	154,626

## Note 25 Events after the end of the financial year

#### Interim results from Helix-1 presented

The interim results (SVR4) from the phase II combination study, Helix-1, were presented and demonstrated that the combination treatment was well tolerated. Treatment-naïve hepatitis C patients without cirrhosis and who were infected with genotype 1b or genotype 4 HCV received 150 mg Simeprevir and 50 mg samatasvir plus ribavirin for 12 weeks. 85 per cent of the patients achieved SVR4 (sustained virologic response four weeks after the treatment ended).

#### Decision to initiate the process of finding a new CEO

The Board of Directors decided to initiate the process of finding a new CEO, with a profile that has a stronger focus on business development and commercialisation. Maris Hartmanis will remain as the CEO of Medivir until a successor has been appointed.

## SVR 12 data reported from phase IIa combination study, with and without ribavirin

The results of a phase IIa study evaluating simeprevir and Daclatasvir, with and without ribavirin, were presented at the annual CROI conference (Conference on Retroviruses and Opportunistic Infections). The study was conducted by Bristol-Myers Squibb and enrolled patients with genotype 1b hepatitis C infection. The study showed that sustained virologic response 12 weeks after the treatment ended (SVR12) was achieved in between 75 and 85 per cent of treatment-naïve patients and in between 65 and 95 per cent of the patient group who had failed to respond to previous treatment after 12 or 24 weeks' treatment.

#### The Nomination Committee's proposal for a new Board of Directors

The composition of the 2013-2014 Nomination Committee was as follows:

- Anders Algotsson, Chairman of the Nomination Committee, representing AFA Försäkring
- Annelie Enquist, representing Skandia Fonder
- Göran Pettersson, Chairman of the Board of Medivir AB
- Bo Öberg, representing the class A shareholders

The Nomination Committee has agreed to propose, with reference to the upcoming 2014 Annual General Meeting, that a new Board of Directors be appointed by means of the re-election of the Board's existing Members, namely Björn C Andersson, Anna Malm Bernsten, Anders Hallberg and Birgitta Stymne Göransson, and the new election of three Members, namely Anders Ekblom, Niklas Prager and Bertil Samuelsson. Birgitta Stymne Göransson is proposed to be elected Chairman of the Board.

#### New positive data from phase III study with Simeprevir

New phase III data for simeprevir have been presented at the Conference of the Asian Pacific Association for the Study of the Liver (APASL) in Brisbane, Australia

- In the ATTAIN study, including treatment-experienced adult patients with chronic hepatitis C virus and compensated liver disease, achieved its primary efficacy endpoint by demonstrating non-inferiority of simeprevir compared to telaprevir when both are given in combination with PegIFN/RBV. Simeprevir demonstrated superior safety profile including fewer adverse events, fewer serious adverse events and less anemia versus telaprevir.
- Pooled analysis of data from the phase III QUEST-1 and QUEST-2 studies confirmed efficacy in treatment-naïve genotype 1b HCV patients.
- In the PROMISE study, including prior relapse patients, a subgroup analysis
  of genotype 1b patients demonstrated that 86 percent (ITT analysis) of these
  patients achieved SVR12 when treated with simeprevir in combination with
  PeoIFN/RBV.

# **Attestation**

The Board of Directors and the Chief Executive Officer hereby attest that the Consolidated Accounts have been prepared in accordance with the IFRS international financial reporting standards, as adopted by the EU, and that they present a true and fair view of the Group's financial position and results of operations. The Annual Accounts have been prepared in accordance with generally accepted accounting principles and provide a true and fair view of the Parent Company's financial position and results of operations. The Directors' Report for the Group and the Parent Company provides a true and fair view of the development of the Group's and the Parent Company's operations, financial positions and results of operations and describe significant risks and uncertainty factors facing the companies included in the Consolidated Accounts.

Huddinge, 24 March 2014

Björn C. Andersson Member of the Board

Susana Ayesa Alvarez Member of the Board Employee Representative Anna Malm Bernsten Member of the Board

Rolflen

Rolf A Classon Member of the Board Anders Hallberg Member of the Board Ingemar Kihlström Member of the Board

Göran Pettersson Chairman of the Board

Birgitta Stymne Göransson Member of the Board Christian Sund Member of the Board Employee Representative

Bo Öberg Member of the Board

Our Audit Report was submitted on 2 April 2014

PricewaterhouseCoopers AB

Hans Jönsson

Authorised Public Accountant

# **Auditor's Report**

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

#### Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of Medivir AB for the year 2013, except for the corporate governance statement on pages 43-54. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 31-80.

Responsibilities of the Board of Directors and the Managing Director for the annual accounts and consolidated accounts. The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions.

#### **Opinions**

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In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of 31 December 2013 and of its financial performance and its cash flows for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2013 and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 43-54. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the group.

#### Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Medivir AB for the year 2013. We have also conducted a statutory examination of the corporate governance statement.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act and that the corporate governance statement on pages 43-54 has been prepared in accordance with the Annual Accounts Act.

#### Auditor's responsibility

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss, we examined whether the proposal is in accordance with the Companies Act.

As a basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Furthermore, we have read the corporate governance statement and based on that reading and our knowledge of the company and the group we believe that we have a sufficient basis for our opinions. This means that our statutory examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden.

#### **Opinions**

We recommend to the annual meeting of shareholders that the loss be dealt with in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

A corporate governance statement has been prepared, and its statutory content is consistent with the other parts of the annual accounts and consolidated accounts.

Stockholm, 2 April 2014 PricewaterhouseCoopers AB

Hans Jönsson

Authorised Public Accountant

Auditor's Report Medivir Annual Report 2013

# **Key ratios**

The Group	2013	2012	2011	2010	2009	2008
EBITDA, SEK k	76,389	-165,254	134,151	-128,851	-129,425	-103,410
EBIT, SEK k	25,164	-201,331	112,051	-136,726	-139,815	-113,733
Operating margin, %	5.6	-118.0	21.9	-222.2	-544.4	-117.0
Profit margin, %	6.2	-123.5	21.9	-218.1	-527.1	-102.9
Debt/equity ratio, multiple	0.0	0.1	0.2	0.0	0.1	0.0
Return on:						
Shareholders' equity, %	3.2	-21.4	13.8	-35.3	-61.3	-29.5
capital employed, %	3.3	-17.6	14.0	-35.2	-61.2	-29.6
total capital, %	3.3	-16.6	12.3	-28.8	-46.8	-23.9
Equity/assets ratio, %	85.7	81.3	80.7	83.7	75.0	77.4
Average number of shares, '000	31,260	31,257	29,924	24,718	20,844	20,844
Number of shares at year-end, '000	31,260	31,260	31,254	28,593	20,844	20,844
Basic and diluted earnings per share, SEK <sup>1)</sup>	0.51	-7.49	3.75	-5.43	-6.49	-4.76
Equity per share before and after dilution, SEK1)	27.27	27.99	35.05	21.24	7.38	13.80
Net worth per share before and after dilution, SEK1)	27.27	27.99	35.05	21.24	7.38	13.80
Cash flow per share from operating activities, SEK	1.38	-4.47	1.91	-3.11	-6.48	-1.67
Cash flow per share after investments, SEK	4.93	-4.69	-4.26	-3.34	-6.76	-2.14
Cash flow per share after financing activities, SEK	3.37	-7.66	-3.71	20.39	-6.76	-2.14
Dividend per share, SEK	0	0	0	0	0	0
Number of outstanding share warrants	249,110	394,400	712,507	803,647	760,000	970,000
Capital employed	955,470	963,537	1,095,576	607,254	153,855	287,606

<sup>1)</sup> IAS 33 states that potential ordinary shares do not give rise to any dilution effect when their conversion to ordinary shares entails an improvement in earnings per share, which would be the case in conjunction with an exercise of the outstanding share warrants in Medivir.

# **Definitions**

#### Average number of shares

The unweighted average number of shares during the year.

#### Capital employed

Balance Sheet total less noninterest-bearing liabilities including deferred tax liabilities.

#### Cash flow per share

Cash flow divided by the average number of shares.

#### Debt/equity ratio

Interest-bearing liabilities divided by shareholders' equity.

## Earnings per share after dilution

Earnings per share after financial items less full tax divided by the average number of shares and outstanding share warrants adjusted for any dilution effect.

## Earnings per share before dilution

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

#### EBIT

Profit/loss before financial items and tax.

#### **EBITDA**

Operating profit/loss before depreciation and amortisation, financial items and tax.

#### **Equity/assets ratio**

Shareholders' equity in relation to the Balance Sheet total.

#### Net worth per share

Shareholders' equity plus hidden assets in listed shares divided by the number of shares at the period-end.

#### **Operating margin**

Operating profit/loss as a percentage of net sales.

#### **Profit margin**

Profit/loss after financial items as a percentage of net sales.

#### Return on equity

Profit/loss after financial items less full tax as a percentage of average equity.

#### Return on capital employed

Profit/loss after financial items plus financial expenses as a percentage of average capital employed.

#### Return on total capital

Profit/loss after financial items plus financial expenses as a percentage of the average Balance Sheet total.

#### Shareholders' equity

The sum of non-restricted and restricted equity at the year-end. Average shareholders' equity has been calculated as the sum of the opening and closing shareholders' equity balances, divided by two.

## Shareholders' equity per share

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

#### Tax cost for the year

The sum of current and deferred tax, taking into account changes in temporary differences and loss carry-forwards.

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Medivir Annual Report 2013 Key ratios and Definitions

# Six-year summary

446,146					
446,146					
	170,647	512,626	54,912	25,684	97,175
-71,771	-61,315	-70,636	-770	_	_
	_		_	4,077	_
	_		_	5,737	4,800
-70,486	-47,727	-84,749	-9,517	-	-
-51,867	-59,690	-38,105	-29,533	_	_
-229,430	-203,352	-184,064	-153,398	_	_
6,347	4,607	14,658	7,852	_	_
-3,775	-4,501	-34,791	-6,273	_	_
_	_	_	_	-175,313	-215,708
25,164	-201,331	114,938	-136,727	-139,815	-113,733
2,470	-9,441	25	2,499	4,427	13,711
27,633	-210,772	114,963	-134,228	-135,388	-100,023
-11,619	-23,325	4,910	0	13	820
16,014	-234,098	119,873	-134,228	<b>–</b> 135,375	-99,203
31 Dec. 2013	31 Dec. 2012	31 Dec. 2011	31 Dec. 2010	31 Dec. 2009	31 Dec. 2008
432,080	514,389	528,994	4,348	4,632	482
27,958	36,070	35,621	24,811	26,941	35,764
10,001	_	9,659	18,793	18,793	18,793
43,187	49,238	78,385	_	_	_
80,025	179,771	167,833	30,299	11,254	31,990
402,220	296,727	536,279	647,240	143,580	284,486
852,587	874,880	1,095,576	607,254	153,855	287,606
_	_	_	-	-	_
40,000	40,000	70,041	116	191	_
_	448	610	-	_	_
	-71,771  -70,486 -51,867 -229,430 6,347 -3,775 - 25,164 2,470 27,633 -11,619 16,014  31 Dec. 2013  432,080 27,958 10,001 43,187 80,025 402,220 852,587	-71,771	-71,771	-71,771	-71,771         -61,315         -70,636         -770         -           -70,486         -47,727         -84,749         -9,517         -           -51,867         -59,690         -38,105         -29,533         -           -229,430         -203,352         -184,064         -153,398         -           6,347         4,607         14,658         7,852         -           -3,775         -4,501         -34,791         -6,273         -           7         - 4,501         -34,791         -6,273         -           - 7         - 4,501         -34,791         -6,273         -           - 1,75,313         25,164         -201,331         114,938         -136,727         -139,815           2,470         -9,441         25         2,499         4,427           27,633         -210,772         114,963         -134,228         -135,388           -11,619         -23,325         4,910         0         13           16,014         -234,098         119,873         -134,228         -135,375           31 Dec. 2013         31 Dec. 2012         31 Dec. 2011         31 Dec. 2010         31 Dec. 2009           432,080         514,389

<sup>1)</sup> The Income Statements for 2010 to 2012 are classified by function, while the Income Statements for 2008 to 2009 are classified by cost type. For details of the cost type breakdown, see Note 2.

102,883

995,470

160,867

1,076,195

190,545

1,356,722

118,121

725,491

51,154

205,200

83,908

371,515

Current liabilities

Balance Sheet total

Six-year summary Medivir Annual Report 2013

<sup>2)</sup> Revenues from pharmaceutical sales via the BioPhausia operations acquired are included from 1 June 2011.

# Glossary

#### Aggrecan

A protein found in vertebrates, primarily in articular cartilage.

#### Agitation

Serious and debilitating complication that can affect patients suffering from schizophrenia or bipolar disorder. Patients who experience agitation describe the condition as an internal feeling of stress that escalates to a dysfunctional condition.

#### **Antiviral**

Effective against viruses.

#### **Biomarker**

A biological or chemical effect which suggests that a substance may have an effect on a disease.

#### Candidate drug

See CD (Candidate Drug).

#### Cathepsin K

A protease that can break down collagen in bones and cartilage.

#### Cathepsin S

A protease that plays a role in chronic pain and autoimmune diseases.

#### CD (Candidate Drug)

Substance selected for further development to clinical trials. The requirement specifications used by Medivir conform to those used by major pharmaceutical companies.

#### Cirrhosis of the liver

Atrophy of the liver that results in the liver tissue gradually being destroyed and replaced by fibrous scar tissue.

#### Clinical studies

Trials of pharmaceutical substances on human subjects.

#### Colonoscopy

Examination of the large intestine (the colon) with a soft, flexible instrument.

#### Enzyme

A protein molecule responsible for chemical reactions in animal and plant cells. It happens quickly and very precisely and the actual enzyme is not consumed. Polymerases and proteases are both enzymes.

#### Fibrosis of the liver

Increased quantities of fibrous tissue in the liver.

#### Genotype

An individual's precise genetic properties (its genome), usually in the form of DNA. For HCV, genotype 1a is the most common in North America while 1b is the most common in Europe.

#### HCV

See hepatitis C.

#### **Hepatitis C**

Jaundice caused by the human hepatitis C virus (HCV).

## HIV (Human Immunodeficiency Virus)

Virus which damages the immune system leading to AIDS.

## IAS (International Accounting Standards)

See under IFRS.

## IFRS (International Financial Reporting Standards)

New accounting rules adopted by the EU. The rules are designed to facilitate comparability between annual accounts in Europe. Listed companies have been obliged, since 1 January 2005, to comply with these rules.

#### Interferon

An endogenous protein with an antiviral effect.

#### Issue

Issuance of new shares in order to obtain new capital.

#### Janssen

The collective name given in this report to those companies within the Johnson & Johnson corporate group with which Medivir has agreements, such as Tibotec Pharmaceuticals Ltd, Ortho Biotech Products LP, Centocor Ortho Biotech Products LP and Janssen Pharmaceuticals.

#### Milestone payments

Payments as contractual goals are achieved.

#### Multiple sclerosis

Multiple sclerosis (MS) is a chronic disease in which inflammation causes damage to the central nervous system. It is a so-called autoimmune disease that affects the brain and spinal cord.

#### Neuropathic pain

Nerve pain that occurs as a direct consequence of a lesion or disease that affects the somatosensory system. It is important to distinguish between peripheral and central neuropathic pain.

#### NS5A/B inhibitor

Inhibitor of one of the two polymerase proteins which, together, replicate the HCV genome.

#### Nucleoside analogue

Chemical variants of the nucleosides that build up genetic material.

#### Nucleotide

A nucleoside with one or more phosphate groups.

#### Option

Right to buy shares in the future.

#### Osteoarthritis

Degradation of the cartilage in the body's joints.

#### Osteoporosis

Brittle bones

#### Pegylated interferon

Interferon treated with polyethylene glycol in order to extend its half-life.

#### Pharmacokinetics

The study of the metabolism of pharmaceuticals by the human body.

#### Pharmacovigilance

The science of and activities in relation to the identification, evaluation, understanding and counteracting of side effects or other pharmaceutical-related problems.

#### Pivotal studies

The most important studies in conjunction with the registration of a new pharmaceutical.

#### **Polymerase**

A type of enzyme that copies the genetic material (genes) in, for example, a virus.

#### **Preclinical research**

All research into a pharmaceutical substance up to the first trials on humans, after which the research is known as clinical trials.

#### Pre-emption

If a holder of a class A share wishes to sell those shares, they shall be offered to other holders of class A shares first.

#### Protease

An enzyme that can cleave proteins into smaller units.

#### RBV

See Ribavirin.

#### Replication complex inhibitor

A substance which, by either inhibiting NS5A or NS5B, prevents the replication of the HCV genome.

#### Resistance

A genetic change in a virus or bacterium which results in a reduction in the inhibiting effect of a substance.

#### Ribavirin

A nucleoside analogue which, via cellular mechanisms, has an antiviral effect.

#### Royalty

Remuneration, often a percentage, for sales of a product (pharmaceutical).

#### SEK k

Swedish kronor in multiples of 1,000

#### SEK n

Swedish kronor in multiples of 1,000,000.

#### SVR

Sustained Virological Response.

#### Volatility

Variability

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# Medivir – 25 years of successful research

In 1988, the pharmaceutical company, Astra, decided to sell its HIV/AIDS-focused antiviral projects. Swedish researchers, journalists and even the Swedish government reacted strongly when it became known that an American company was interested in buying the project, and Astra's newly appointed CEO, Håkan Mogren, accordingly decided to transfer the majority of the antiviral projects for a token fee to a group of researchers headed by Bo Öberg, who wanted to found a new company. The purchase also included equipment, chemicals, research data and patent applications, and the token price was one krona. The researchers decided to name their newly launched company "Medivir" – an amalgam of "medicine" and "virus".

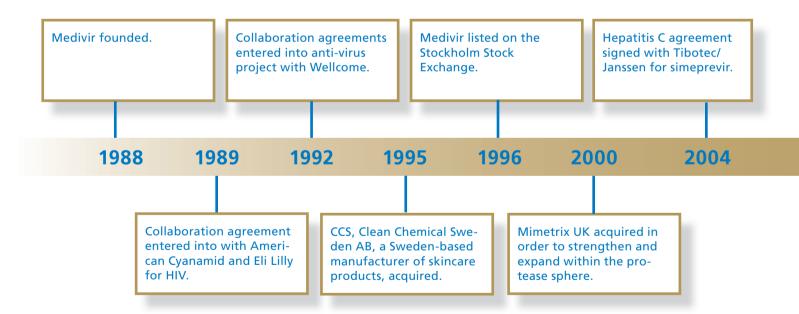
Medivir initially employed five researchers who worked in collaboration with Swedish university-based researchers in such areas as virology, chemistry and enzymology. Collectively, these university-based researchers were the equivalent of 35 full-time positions. The experienced and retired businessman, Kurt Rydé, formerly the CEO of Pripps, was employed as a part-time CEO, and completed

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a number of successful out-licensing processes that provided the financial basis for expansion and continued operations.

The researchers initially rented low-cost chemistry and virology laboratories until such time as the company was able to build its own laboratory facilities. A loan of SEK 3 million from STU (the National Board for Technical Development) and a further SEK 25 million from Industrifonden were raised to finance the operations. Drawing down on the latter loan ultimately proved unnecessary, however, because as the money from the STU (Board for Technical Development) loan ran out, a two-week period saw licensing and partnership agreements with Lilly and Lederle yield SEK 90 million in revenues for the company.

Right from the start, Medivir focused on two types of mechanism – polymerase inhibitors and protease inhibitors – which are the target of pharmaceuticals designed to treat a number of different diseases. There were a number of factors that influenced the choice of research platform and disease areas, one of which was that the development of pharmaceuticals to treat infectious diseases has a lower



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# and pharmaceutical development

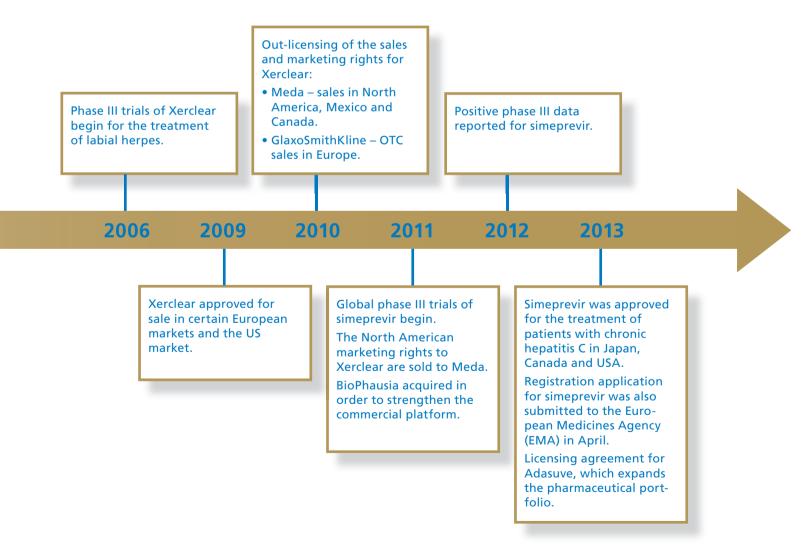
failure rate than is the case with many other types of disease – a fact that made this disease area even more interesting for the researchers at Medivir. Another important factor was the existence of large libraries of polymerase and protease inhibitors that could be used in the research.

The new company's business concept focused on the development of pharmaceutical substances to treat HIV/ AIDS, but was also open to other possibilities. Herpes was part of the picture from day one and this resulted, in 2009, in Medivir being able to celebrate regulatory approval of the company's first in-house developed pharmaceutical, Xerclear, for the treatment of labial herpes.

Research into the treatment of hepatitis C quickly became one of the more important focal areas within

the overall context of infectious diseases, and in 2013, 25 years after the company was founded, Medivir's partner, Janssen, was able to submit global new drug applications for Medivir's second pharmaceutical, Simeprevir. In the autumn of 2013, Simeprevir was approved for the treatment of hepatitis C in Japan. Canada and the USA.

Medivir has also, in addition to its in-house developed products, acquired an established pharmaceutical portfolio and in-licensed a product from another company, and consequently now has sixteen prescription pharmaceuticals that are marketed in the Nordic area. The company is also simultaneously continuing with its research into and development of new pharmaceuticals at the company's own research unit in Huddinge.



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# Shareholder information

#### Forthcoming financial information, 2014

- Q1 Interim Report, published 8 May 2014.
- Q2 Interim Report, published 21 August 2014.

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

Medivir sends its reports to all shareholders with the exception of those who, in conjunction with the registration of their securities accounts, declined all information.

For additional information on Medivir, please contact Rein Piir, EVP Corporate Affairs & IR.



#### **REIN PIIR**

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# 2014 Annual General Meeting

#### The Annual General Meeting will be held at

the 7a Odenplan conference centre at Norrtullsgatan 6, Stockholm, Sweden.

# Shareholders wishing to attend the Annual General Meeting shall:

- be entered in the register of shareholders maintained by Euroclear Sweden AB no later than 2 May 2014, and
- notify the company of their intention to attend, no later than 2 May 2014, stating their name, address and telephone number, either by letters in the post to: Medivir AB, Blasieholmsgatan 2, SE-111 48 Stockholm, Sweden or by telephone: +46 (0)8 407 64 30

or by fax: +46 (0)8 407 64 39 or by email: enter@medivir.se.

#### **PLEASE NOTE:**

# Important information regarding nominee-registered shares

Shareholders whose shares are nominee-registered must, in order to be entitled to attend the Annual General Meeting, temporarily re-register their shares in their own names with Euroclear Sweden AB. Shareholders wishing to effect such re-registration must inform their nominee thereof in good time before 2 May 2014.

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