

# **CEO Presentation AGM 2011**

Dear shareholders, colleagues, ladies and gentlemen,

2010 was a year when major steps were made both in an operational and strategic perspective. I would like to guide you in what has and what will be important for Medivir, it's operations aiming for profitability and continued creation of shareholder value.

## **Operational Performance**

During the course of 2010 the core operational activity for Medivir has been to progress its R&D portfolio. The undoubted highlight for year has been the outstanding progress that has been made in the clinical development of our Hepatitis C protease inhibitor TMC435, partnered with J&J Tibotec. Efficacy and safety data for the phase 2b ASPIRE trial in treatment experienced patients and in the phase 2b PILLAR trial for treatment naive patients showed very impressive results. 83% of the naïve patients in the PILLAR trial were able to stop all therapy at week 24. At the follow up time point, 24 weeks later, potent SVR24 rates of up to 84% were also achieved. These patients are classified as cured, these data are very strong in comparison with the competitors.

Most importantly the drug which is a once daily dosing regimen had no adverse events over and above the standard of care control group. Most industry commentators following this disease area regard TMC435 as the best in class drug in clinical development today.

We have also increased the research effort into developing drugs for other targets for Hepatitis C because we believe that in the long term there will be a paradigm shift which will progressively see the existing 48 week standard of care with Interferon and Ribavarin being replaced with a combination of faster acting drugs with more benign side effects. We also believe that TMC435 will be an anchor for such new drug combinations. In this context we are also delighted that after the year end our HCV polymerase inhibitor entered phase 1 clinical trials in a partnership with Tibotec Pharmaceuticals and we are hopeful that at least two other compounds for other Hepatitis C targets will enter into pre clinical development in the near future.

All internal new preclinical projects today are now focused exclusively on our focus area of infectious disease.

Strong progress has also been made with our lead compounds for Cathepsin K for the treatment of osteoporosis, rheumatoid arthritis and metastatic bone disease and we are hopeful that this drug will enter phase 1 clinical development in Q4 2011.

All of our R&D programmes and projects are subject to bi annual multi disciplinary scrutiny to assess technical, commercial, IP and financial risk together with performance against milestones so that only the very best projects progress through pre clinical and clinical



development. Our goal is to get drugs that will meet unmet medical needs to the market in the shortest possible time. It is also our intention wherever it is judged appropriate to take drugs further in clinical development so that more of the value can be retained by Medivir in the future.

## **Commercial Development**

Medivir's commercial focus is to build a portfolio of high value speciality pharmaceutical products which together with royalty income from licensing drugs that reach the market will take Medivir to a position of sustainable long term profitability. The first steps in this direction were taken with the licensing agreements with Meda for Xerese<sup>™</sup> in the North America and for Xerclear<sup>®</sup> with GSK for OTC markets in Europe and other Geographies. We have agreements in Korea with Daewoong and in Israel with Luxembourg pharmaceuticals. Meda launched Xerese<sup>™</sup> in USA recently and we expect GSK to follow suit in some European markets later this year. We have high hopes for these products which are for the treatment of cold sores because they are the only licensed products in the world with a regulatory claim for being able to prevent the cold sores developing. Approximately 7% of the entire population suffer from recurring cold sores.

Our next challenge and opportunity is to prepare for the launch of TMC435 which it is anticipated will achieve regulatory approval towards the end of 2013. Medivir's partner J&J has the global rights to this product but Medivir has retained the marketing rights for the Nordic Region. There are 115,000 people in the Region who are chronic suffers from this illness. When these patients become critical they follow the existing standard of care treatment which takes a year and has a success rate of no better than 40-50% for patients who are able to endure the treatment. The average reimbursement level for this treatment is around SEK 175,000 in the Nordic Region which makes the market opportunity for Medivir very considerable. Because competitors are expected to launch their products at the end of this year or early in 2012 we have an urgent need to build our own commercial platform and to recruit specialists who can educate leading physicians about the clinical progress and advantages of TMC435.

We have an EGM after this meeting today seeking approval to acquire BioPhausia. This company has a commercial platform, it has a portfolio of profitable well respected speciality pharmaceutical brands and it provides Medivir with a fast cost effective means of ensuring Nordic Market entry assuming the regulatory approval for TMC435 is secured as is anticipated. BioPhausia also provides Medivir with the means to build a much larger Nordic speciality pharmaceutical business which together with existing its existing sales and expected royalties from Xerclear<sup>®</sup>/Xerese<sup>™</sup> will take Medivir the first step on its journey to achieving sustainable profitability

### Strategic Development

Progress has been made on a number of fronts in terms of Medivir's strategic development with the overall goal of transitioning the company from an R&D only Biotech Company to a research based profitable speciality pharmaceutical company.



The recent partnering deal on Dengue with J&J is a full partnership deal with equal investment from both companies in finding a drug to treat this growing disease problem. This will enable Medivir to extract greater value than it could achieve from early out licensing which has been the historic practice for the company.

Our partnership with Daewoong for the treatment of Hepatitis B enables Medivir to retain full rights to this product for all geographies outside of Asia and the Pacific Rim. Previous agreements have been based on retaining only Nordic Rights.

Drugs that look very good in preclinical development will now routinely be taken into clinical development by Medivir. An example of this policy is illustrated by our future plans for Cathepsin K which we expect to take into the clinical development by Q4 of this year.

The acquisition of BioPhausia will provide a commercial platform to exploit Medivir's own drugs and also to build on BioPhausia's own portfolio of profitable speciality pharmaceutical products through in licensing or other smaller acquisition opportunities.

Pursuit of many of these initiatives would not have been possible without the support that we received from our shareholders for the Rights Issue in June which approximately raised SEK 325m and the directed issue in December that raised SEK 280m. We believe that the directed issue was also very important for the company strategically because it introduced international high quality investors who are both knowledgeable and focused on the industry in which we operate, Fidelity is our largest shareholder today We believe that this is in both the company best interest and the best interest of all of our current shareholders many of whom have supported our company for many years.

Finally I would like to express our delight at receiving the Sweden Bio industry Award for 2010. This is in recognition for the companies achievements particularly in innovation and has been extremely motivational to all Medivir employees

### The Year Ahead

We entered 2011 with a solid financial position followed by a flying start of the year. As reported in our Q1 report today significant progress have been made in our main projects. For the remaining part of the year we are looking forward to new clinical data on both our hepatitis C projects in partnership with J&J Tibotec and the start of clinical phase 1 studies with our cathepsin K inhibitor.

We will also see progress in other internal projects like cathepsin S for Neuropathic pain, hepatitis B and C and Dengue fever, all in line with our present expectations.

In a commercial perspective we are monitoring the recent launch of Xerese<sup>™</sup> in the US and the upcoming OTC launch in Europe starting later this year. The bid on BioPhausia if approved at the EGM later today will offer many opportunities for further earnings and continued value creation.



To create long term shareholder value is of top priority. Part of that work is a continued work establishing Medivir on the international arena, reflecting the large interest for Medivir as a innovation driven company and it's projects. Creating long term shareholder value remains the top priority for the Medivir Board and Management Team. This will continuing to involve building on the work that we have done to establish Medivir in the International area which is driven by the interest that investors are showing in our innovation and our R&D projects.

I am grateful for all the support our shareholders are giving us making it possible to develop Medivir on its way to profitability. A special thanks also to my colleagues for the hard work that they are putting in making this happen.

I am looking forward to an exciting 2011, thank you.