PhotoCure ASA – Report 2001

From being a pure development stage pharmaceutical company, PhotoCure has in the course of 2001 become a commercial pharmaceutical company, selling and promoting its own products in addition to having an extensive research and development programme.

The most important events in 2001 are listed below.

Approval of Metvix®

PhotoCure's first pharmaceutical product, Metvix® PDT (photodynamic therapy), was in 2001 approved in Sweden for treatment of pre-cancerous skin lesions (actinic keratosis, AK) and skin cancer (basal cell carcinoma, BCC). This approval was later acknowledged in another 13 European countries, amongst these are Germany, UK, Italy and Spain. In February 2002, the product was also approved in New Zealand. Marketing authorisation applications for Metvix® have also been filed in the US, Australia and Switzerland.

In October, Metvix® PDT was launched in Sweden as the first country in the world. PhotoCure has, in accordance with its strategy, built up its own sales and marketing organisation to cover the Nordic countries. This sales organisation will market both Metvix® and the PhotoCure light sources. The company has three different light sources which all can be used separately to activate Metvix®. By the end of January 2002, PhotoCure Sweden had supplied more than 40 clinical centres with lamps and also provided them with training in the use of Metvix® PDT.

Marketing and cooperation agreement signed with Galderma S.A.

In December, PhotoCure signed a licensing agreement with Galderma S.A. for Metvix® PDT. The agreement gives Galderma exclusive global marketing rights to both the Metvix® cream and PhotoCure's activating light sources for AK and BCC outside of the Nordic region. Galderma, which is owned by Nestlé and L'Oréal, is a global company dedicated to the marketing of medical products for dermatological treatments.

Under the terms of the agreement, PhotoCure received 12 million Euros in February 2002, and is entitled to a further 18 million Euros upon approval of marketing authorisations and the launching of Metvix® in certain areas. PhotoCure will also, in addition to royalties, receive milestone payments from Galderma based on the global sales of Metvix® for sales exceeding 25 million Euros per year as well as payment for the manufacture of the light sources and the Metvix® cream. PhotoCure is guaranteed significant royalties and milestone payments during the five years following marketing approval of Metvix® in the US.

Following an initial period, Galderma will assume the responsibility for the formulation of Metvix®, while PhotoCure will continue as supplier of the active ingredient. PhotoCure will still be responsible for marketing authorisation applications in the EU, US, Australia and New Zealand. Galderma is responsible for marketing authorisation applications in other countries.

Under certain conditions, PhotoCure has also granted Galderma the rights to market Metvix® for the treatment of additional indications. For indications where PhotoCure and Galderma agree on a development plan, Galderma will fund 75% of the development costs. PhotoCure will also receive royalties and further milestone payments if Metvix® receives marketing authorisation for new indications.

The estimated number of new cases of BCC in the US, the EC and Australia is at least 2 million a year, while the corresponding estimate for AK is a minimum of 20 million.

PhotoCure is developing Metvix® for new indications and the company has recently received positive data from a clinical pilot study on the treatment of acne. The global sales of pharmaceutical products for the treatment of acne constitute approximately NOK 1.7 billion.

Hexvix® PDT – on-going clinical phase III studies

In September, PhotoCure ASA started patient enrolment in a European multi-centre phase III study, designed to document the safety and efficacy of Hexvix® fluorescence cystoscopy for detection of bladder cancer. About 300 patients will be included, across 22 university hospitals. The results from this study, together with the results from a similar study in the US, will constitute the critical clinical documentation for applications for international marketing authorisations.

The Hexvix® phase II study, which was carried out at university hospitals in Switzerland, Germany, Sweden and Norway, showed that Hexvix® fluorescence cystoscopy provided better diagnosis of bladder cancer compared to standard cystoscopy. The method was shown to give particularly good results for diagnosis of potentially dangerous pre-cancerous lesions. The diagnostic procedure with Hexvix® involves filling the patient's bladder with 50 ml of Hexvix® solution for 60 minutes, before the bladder is emptied and subsequently examined. Hexvix® accumulates in the cancerous cells and, when illuminated with blue light, the cancer cells emit a red colour that makes them clearly visible for the surgeon.

A total of 52 patients with known or suspected bladder cancer were examined with both standard cystoscopy and Hexvix® fluorescence cystoscopy. Biopsies were taken from all visible tumours and suspicious areas to confirm the findings. Results showed that among 45 patients with bladder cancer, 29% had serious pre-cancerous tumours. Among these, 92% were diagnosed with Hexvix® fluorescence cystoscopy, compared to 23% with standard cystoscopy. When assessing the results in terms of all bladder tumour types, 96% of the patients with bladder cancer were detected with Hexvix®, compared to 73% of the patients diagnosed with standard cystoscopy.

Bladder cancer is the sixth most common malignant disease worldwide. In 1990, more than 50,000 new cases were reported in the US and 66,500 new cases were reported in Europe. Market investigations show that more than 2.5 million cystoscopies (bladder inspections) are performed every year in Europe and North America to diagnose or rule out bladder cancer.

PhotoCure exploiting new important indications

Preclinical development of Benzvix® is progressing. Benzvix® is being developed for photodiagnosis and photodynamic therapy of pre-malignant and malignant lesions in the gastro-intestinal tract, including the oesophagus, stomach and colon. PhotoCure is also assessing the possibilities of developing products for the oral cavity, pharynx, brain tumours, and breast cancer as well as for gynaecology. Pilot studies on patients with pre-malignant lesions in the oesophagus and colon are about to be started.

PCI Biotech AS developing new transfection methods

The subsidiary PCI Biotech AS is currently working on the development of new transfection methods for both research and clinical markets. The technology platform consists of a unique method for delivering large molecules (pharmaceuticals) to intracellular targets, a problem which restrains the development of pharmaceuticals based on gene technology, antibodies and so on. The company is working actively to develop this technology.

Financially strong

PhotoCure's total operating revenues for 2001 amounted to NOK 5.4 million, compared to NOK 4.7 million in 2000. Operating revenues include sales of products and government grants.

As planned in the 2001 budget, considerable amounts were spent on research and development in connection with the products that the company is developing. The group's operating loss for 2001 amounted to NOK 127.9 million, compared to an operating loss in 2000 of NOK 66.8 million. All costs related to research and development are expensed as they incur. The increase of the operating loss is primarily caused by increased research and development activities related to Metvix® and Hexvix®. The increase in labour costs is a result of a larger number of employees in marketing and the subsidiary PCI Biotech AS. Other operating costs have primarily increased due to higher marketing costs in relation with the commercialisation of Metvix®.

Net financial income improved from NOK 16.8 million in 2000 to NOK 26.2 million in 2001. This is mainly a result of higher average liquid assets in 2001 as well as a higher interest rate.

The group's net loss for 2001 amounted to NOK 101.7 million, compared to NOK 50.0 million in 2000. PhotoCure ASA (the mother company) had a net loss of NOK 93.3 million in 2001 compared to a net loss of NOK 49.7 million in 2000. The Board of Directors of PhotoCure ASA proposes that the net loss is covered by a transfer from the company's other equity capital. Available equity capital will after this amount to NOK 206.7 million. The Board will not propose payment of any dividend in respect of the 2001 financial year.

For its liquid assets, the group has adopted a cautious investment strategy, investing in bank deposits and money market funds with maturities of up to one year. The profit from PhotoCure's liquid assets is dependant on the interest rates in the money market and may therefore vary considerably. By 31st December 2001, the group's equity capital amounted to NOK 259.4 million, while liquid assets amounted to NOK 305.2 million. The group's reduction in liquid assets in 2001 totalled to NOK 94.5 million. The Company received in February Euro 12 million (equals NOK 93 million) from Galderma.

PhotoCure's costs and revenues are in a number of different currencies. The group is therefore, to a certain extent, subject to fluctuations in the exchange rates. This risk is constantly assessed.

The financial statements have been prepared on the assumption that the company is a going concern, cf. Section 3-3 of the Accounting Act.

Since the end of the financial year of 2001, there have been no events, other than those stated in this report, that are of any material significance to an evaluation of the company's financial conditions and results.

Stronger organisation

PhotoCure is located in modern office facilities in Oslo, adjacent to the Norwegian Radium Hospital. The PhotoCure group had 31 employees at the end of 2001, 5 of which are employed at the subsidiary PCI Biotech AS. The group uses to large extent external suppliers and consultants.

The working environment in the company is considered to be good. No accidents or injuries were reported in 2001. Absence from work due to sickness totalled to 72 working days in 2001, which equals 1.1% of total working days in 2001.

The company does not pollute the external environment.

Positive future prospects

PhotoCure's main focus will now be to secure the commercial success of its first pharmaceutical product, Metvix®, exclusively developed by PhotoCure. This will be achieved in close co-operation with Galderma

S.A., PhotoCure's marketing partner for Metvix® PDT outside the Nordic countries. The Metvix® documentation is already approved by 14 European countries and New Zealand. Moreover, marketing authorisation applications for Metvix® are pending in the US, Australia and Switzerland, and in co-operation with Galderma, applications will also be filed in other countries. Before PhotoCure can expect substantial income from Metvix®, healthcare professionals must receive necessary training, lamps must be distributed, price and reimbursement needs to be negotiated and so on.

The on-going clinical phase III programme for Hexvix® PD is critical for the marketing authorisation application planned to be filed in the first half of 2003.

The research and development activities of PhotoCure are now focused on new indications for Metvix® PDT, Hexvix® PD and Benzvix®. Research and development costs related to Metvix® are expected to be lower in 2002 than in 2001, while the costs related to Hexvix® and Benzvix® are expected to increase. Future research and development activities, will to a growing extent, be focused on diagnosis and treatment of various types of internal cancer and pre-cancerous lesions. As a result of PhotoCure's significant investments in research and development, the company also expects to incur a loss in 2002.

PhotoCure is a development stage pharmaceutical company that successfully reached all of its pre-set milestones in 2001, and is now in the process of commercialising Metvix® PDT in a number of countries. The company still would like to draw attention to the inherent risks associated with the development and commercialisation of its products.

Oslo, 26 February 2002

Halvor Bjerke, Chairman	Per-Olof Mårtensson, Deputy Chairman
Tharald Brøvig, Member of the Board	Erik Engebretsen, Member of the Board
Stener Kvinnsland, Member of the Board	Lars Lindegren, Member of the Board
Åse Aulie Michelet, Member of the Board	Vidar Hansson, President and CEO